UNITED STATES

ENVIRONMENTAL PROTECTION AGENCY

PESTICIDE PROGRAM DIALOGUE COMMITTEE MEETING

DAY ONE - OCTOBER 21, 2015

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, and welcome to PPDC. I'm Jack Housenger. I'm the director of the Office of Pesticide Programs. As you look around, you'll see that membership has declined by five. We have brand new PPDC membership, including 15 new members, 12 representative members and 3 regular government employees. So, it's a little different. We'll hopefully get some different perspectives than we have in the past.

I appreciate everybody coming today, taking the time. I know it's not an easy thing to take off a couple days to attend these, but I think it's important for us to hear different views on what we're doing. It's probably important for you to hear what we're doing.

Along those lines, we try to give enough notice that people can plan around these meetings. We had a lot of members or nominations for these seats. So, for those of you who are new, please take that seriously and try to be present for these meetings. We're going to announce upcoming meetings for 2016 that will occur in May and November. So, we give enough notice, and we just ask

that you hold those dates and attend in person for these.

I just wanted to go over the agenda a little bit before we get started. It reflects what we heard at the end of last May's meeting with respect to some of the topics. Some of the topics we've added that we think you should be hearing. It also includes more time for discussion. Last time, we heard that members thought that we maybe rushed through some topics, and there wasn't an opportunity to discuss. So, today's agenda allows for enough time.

Because we have a lot of new members, we're going to go over the rules of the Advisory Committee Act. Jim McCleary from ODACMO, which stands for something, I have no idea what it stands for, I'm sure he'll tell you, is here to give us some important information. We were going to do this in a webinar, but there was trouble getting everybody at the same time. We thought it would be good for existing members to hear the rules once more.

Then we're going to talk a little bit about the workgroups. We've broken it up into two chunks, one today and one tomorrow, about these workgroups, the original charge, what they've accomplished, and then we

want to hear about if there's a continuing need for these same workgroups or have they accomplished what they've set out to do.

The first group up is the pollinator workgroup. Pollinators are always a big topic. It's led by Rick Keigwin, followed by the comparative safety statements that is led by Marty Monell, and then 21st century tox led by Jennifer McLain. Then that gets us to lunch, believe it or not.

Following lunch, we're going to talk about the WPS. That was a big rule that we've been working on for a number of years, a 20-year-old rule that was signed off by the administrator on September 28th. We're going to need a lot of assistance in getting the word out, the outreach, the implementation as we go through the next year and ramp up for when it finally kicks in in about a year. So, we're going to hear about assistance and collaboration that you people may help us in implementing this rule.

So, after that, we're going to talk about certification and training rule. So, it's kind of a worker safety afternoon. Kevin Keaney is going to talk

about that and Michelle Arling. This rule is currently out as a proposal, but it gives the rules/training for people handling the most restricted pesticides that we have registered. We'd like to hear your thoughts on it.

After a short break, no PPDC would be complete unless we talked about ESA. So, we're going to talk a little bit about biological opinions and biological evaluations and the work that's being done. Gina Shultz from Fish and Wildlife is here, and Anita Pease of our office will be talking about that.

Then, for the last topic of the day, Dana Vogel will talk about OPP's risk assessments, human health risk assessments for the organophosphates. At the end of the day, we'll have an opportunity for public comment. So, if you want to make a public comment, anybody in the audience, please sign up at the registration desk at the outside of this room.

Then, when we reconvene in the morning tomorrow, Jim Jones, who couldn't be with us today, will be here. Jim is the assistant administrator for our office. I'm sure he'll give some inspiring words that will resonate anyway.

Following Jim, we're going to go back to the workgroups. We'll have school IPM led by Bob McNally, public health led by Susan Lewis, and then Jackie Mosby will give you a quick update on our newest workgroup, pesticide incidents. Certainly, this is something that's been in the news lately with methyl bromide and sulfuryl flouride incidents that have happened. So, I'm sure there will be a lot of interest in that workgroup.

Then, our final topic will be endocrine disruption screening program that David Dix will come over and talk about, what progress we've made in terms of that program. Like I said, we're going to talk about the dates for the next year, 2016. PPDC is currently scheduled for May 11th and 12th for our spring session and then November 2nd and 3rd for our fall session, and also the topics for the next PPDC.

I look forward to a productive meeting. Welcome. It would be good to go around the room and introduce ourselves. So, please, Gina, why don't you start. These are new microphones. I think you have to turn them on and then after you're done, turn them back

off.

MS. MONELL: Slide the button towards you to turn it on, and push it away from you to turn it off.

MR. HOUSENGER: Marty used to be a stewardess.

MS. SCHULTZ: Good morning, everybody. I'm Gina Shultz. I'm deputy assistant director for Ecological Services at US Fish and Wildlife Service.

DR. CALVERT: I'm Geoff Calvert, and I'm with the Centers for Disease Control and Prevention.

MS. CODE: I'm Aimee Code with the Xerces Society for Invertebrate Conservation. I'm the pesticide program director.

MS. SELVAGGIO: Hi, I'm Sharon Selvaggio with the Northwest Center for Alternatives to Pesticides. I'm the healthy wildlife and water program director.

MR. KUNKEL: Good morning. I'm Dan Kunkel with the IR4 Program.

MR. JAKAI: Louis Jakai, North Carolina A&T State University, one of the few ag schools in North Carolina which addresses mostly small farmer problems.

MS. GILDEN: Good morning, Robyn Gilden, University of Maryland School of Nursing.

MS. LUDWIG: Good morning, Gabriele Ludwig, Almond Board of California, and I'm also on the Minor Crops Farmer Alliance.

MR. COY: I'm Steve Coy. I'm a commercial beekeeper and queen breeder. I represent the American Honey Producers Association.

MR. GUPTON: I'm Richard Gupton for the Agricultural Retailers Association sitting in for Donald Taylor.

MS. LAW: Good morning, I'm Beth Law with the Consumer Specialty Product Association.

MR. JAIN: Good morning, Komal Jain, Assistant General Counsel for American Chemistry Council. I serve as counsel for the biocides panel.

MR. FORTH: Good morning, Chris Forth representing the National Association of Landscape Professionals. I'm here subbing for Tom Delaney.

MR. HANKS: I'm Douglas Hanks, National Potato Council.

MS. CLEVELAND: Cheryl Cleveland, BASF. I'm in the global consumer safety portion.

MR. McALLISTER: Ray McAllister of CropLife

America. Thank you for the new name tag.

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

MS. RAY: Liz Ray with SIPCAM, representing BPIA, sitting in for Nina Wilson.

MR. BAREFOOT: Al Barefoot, DuPont Crop Protection. I'm a scientist in the environmental fate and modeling area. I'm sitting in for Jake Vukich today.

MS. MONELL: When you get close to the microphone, make sure you push it on and push it off after you're done. Thank you.

MS. LIEBMAN: Good morning, my name is Amy Liebman. I'm the director of Environmental and Occupational Health for the Migrant Clinicians Network.

MR. LAME: Hello, I'm Marc Lame with Indiana University's School of Public and Environmental Affairs. I'm representing the National Environmental Health Association.

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

MS. BISHOP: Good morning, I'm Pat Bishop. I'm

with the Regulatory Testing Division of People for the Ethical Treatment of Animals.

MS. HARRIOTT: Good morning, I'm Nichelle Harriott with Beyond Pesticides.

MR. WHITE: Mike White, Council of Producers and Distributors of Agrotechnology.

MR. PECKHAM: John Peckham, Minnesota Department of Ag. I'm representing AAPCO.

MS. PALMER: I'm Cynthia Palmer. I'm Director of Pesticides Science and Regulation for the American Bird Conservancy.

MR. BUHLER: I'm Wayne Buhler, enthusiastic entomologist from the eastern US, representing North Carolina State University and the American Association of Pesticide Safety Educators.

MS. GOUGE: Dawn Gouge, overly enthusiastic entomologist from the western US. I'm here today representing the National Environmental Health Association.

MR. STELL: I'm Fred Stell from the Armed Forces Pest Management Board.

MS. KUNICKIS: I'm Sheryl Kunickis. I'm the

director in the USDA Office of Pest Management Policy, and I'm married to an entomologist.

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

MS. VOGEL: Hi, I'm Dana Vogel. I'm the Director of the Health Effects Division in OPP.

MR. KEIGWIN: I'm Rick Keigwin. I'm the Director of the Pesticide Reevaluation Division in OPP.

STEVE: Steve Knizner. I'm the Director of the Antimicrobials Division in OPP.

MS. MOSBY: Hi, I'm Jackie Mosby, the Director of the Field and External Affairs Division in OPP.

MR. HOUSENGER: All right. It's kind of disappointing that none of our people are enthusiastic. Let's go to the first presentation which is by James McCleary, attorney, Office of Diversity Advisory Committee, Management and Outreach. That's the ODACMO.

MS. ZIMMERMAN: I'm hoping Jim is here. Jim doesn't appear to be here.

MR. HOUSENGER: Jim missed my talk about showing up, I guess.

MS. MONELL: At least the on time part.

RICHARD: Can Mr. Gragg introduce himself?

MR. HOUSENGER: He was here and he left.

RICHARD: Hello, good morning.

MS. MONELL: Wait a minute, somebody is on the phone.

MR. HOUSENGER: Jim?

RICHARD: No, Richard Gragg, the enthusiastic Professor of Environmental Science and Policy, representing Florida A&M University School of the Environment.

MR. HOUSENGER: That's right, we have people on the phone. I forgot the phone. Thank you. It takes an enthusiastic entomologist again to --

RICHARD: No, toxicology, toxicology.

MR. HOUSENGER: Oh, all right.

MS. ZIMMERMAN: There may be a couple of other PPDC members on the phone. If you're a PPDC member and you're on the line, can you hit pound 6 to unmute your phone. Please introduce yourself.

(No response.)

MS. ZIMMERMAN: Okay, we've globally unmuted a line for a moment. So, if there are other PPDC members

who are on the phone, can you please introduce yourself?

(No response.)

MR. HOUSENGER: Is there anybody else on the phone?

(No response.)

MS. ZIMMERMAN: I will put the global mute back on.

MR. HOUSENGER: All right, well, we can go to the pollinator workgroup. Rick Keigwin is going to lead this discussion.

MR. KEIGWIN: So, unfortunately, Mary Clock-Rust was here, and she is enthusiastic. She was here earlier.

So, what we wanted to do today, Don Brady is the co-chair of this workgroup. He's on vacation this week. We wanted to provide you all with an overview of what the pollinator workgroup's initial mission was and what the group has accomplished to date. Then, I think this will fit in with the discussion that Jack will be leading later on about where you all would like to take each of these workgroups. So, we'll kick things off there.

Mary Clock-Rust has really been our leader and coraller and making sure that we get everything done. So, I'm going to turn things over to Mary to lead us through the presentation.

MARY: Good morning. The pollinator protection workgroup was begun in 2011. This group of full PPDC decided to start a workgroup to focus on pollinator protection. On the board here, you can see that these are the initial 2011 objectives for the workgroup. At that time, if you all recall, we were developing the science, we are still working very hard to improve our science. We wanted a workgroup to focus on so-called low hanging fruit and things that could be changed immediately and quicker.

So, back in 2011, these are the objectives that the group identified, exploring initial science-based risk management approaches, including appropriate label restrictions and training; develop information on State approaches and different authorities; transfer lessons learned by various stakeholders in order to improve existing management practices; continue international communication; and any other issues that came up.

So, as I said, this was five years ago now, four years ago, four-and-a-half years ago. The group met frequently. The group was huge. I mean, it is huge. At one point it had almost 80 people, a lot of people on the phone. It made it really cumbersome and difficult for anything to get done, actually. We had a lot of diverse people on the phone. We have beekeepers, we have growers, we have registrants, we have academics, anybody who was interested. The most important, probably, is the agriculture extension agents and the people that actually meet with people on the ground.

As we go through here, I'll identify each of these objectives and how we put them into action, and the things that the group worked on. The first one is the workgroup recommended, somewhat confusingly, that we should replace visiting and actively visiting on pesticide labels with the word foraging, not actively foraging, just foraging. So, this has been implemented somewhat on a case-by-case basis. As you probably know, it's difficult to change pesticide labels after they've already gone out and they're already on products and things.

So, this is being implemented now. I'm pretty sure our registration division here is working hard to get rid of the visiting and actively visiting. The only opportunity to do that kind of thing is when there's a label amendment or new use proposed for that pesticide. So, it's going slowly, but this is a change that's being implemented.

Next, the workgroup recommended that labels be harmonized and protective language should be made clearer. This topic was so difficult. We got a lot of people chiming in and talking about all of their opinions and experiences on the phone. It was, for sure, a difficult topic for the workgroup to handle. As you're probably aware, the president's initiative has kind of usurped this and the media and everything that's happening with pollinators in the last four or five years has really taken a life of its own.

As you can see, EPA has been responding to that with a number of national level actions that have to do with this. Nonetheless, we allowed the group to discuss and talk about the neonicotinoid language that was proposed back in June 2014 and then again in the fall of

2014. Then, this year we've had some changes. As you know, there's proposals for mitigation. They were out there for comment, extended three times our comment period. I think we have over 100,000 comments. So, this topic has been taking on a life of its own. I'm not sure the workgroup itself is very effective in working on it.

Next, the workgroup recommended that the RT25 data would be a useful tool to make available for pesticides. So, this information is on our website now. Also, some labels have RT25 on them. Response to this workgroup advice, the EPA just put all of the RT25 data that we have, made it available pretty much just instantly as soon as it was something that needed to get done. So, that was something that took place. I have a link to it if you wanted to get that.

Next, the workgroup recommended that more research on BMPs, best management practices, be done and have them posted in a centralized location. For this, I really have to look at Wayne Buhler and say thank you to him because he made his website available, pesticidestewardship.org. If you go to that website and click on the pollinator protection link, you will find so

much information, including the best management practices for beekeepers, best management practices for applicators, and a whole bunch of other information.

So, EPA's website links to Wayne's website, as well as the IPM Center's website also links to his website on this. So, there's a number of ways that people that want this information can get it now. So, we made that available.

Also, the next topic is the workgroup identified many kinds of pesticide applicator training information around the country that has included pollinator awareness information. Again, Wayne's website links to ours for this information. Also, a lot of this information has been compiled and is easily accessible now on our website, as well as the pesticidestewardship.org website.

Finally, the workgroup recommended that there be more uniform and transparent bee kill investigations. Responding to this, Region 5 developed enforcement guidance for state inspectors and inspectors that go to bee kill investigations. We found that there was a real knowledge gap there, and that they could really use this

information. So, we made that available. It's been done and it's finished now. So, that guidance is available.

MR. KEIGWIN: So, that's a quick overview of where the workgroup has been and what the workgroup has accomplished. I think from EPA's standpoint, the group has really accomplished the initial mission that it had been charged with. We'd like to, I think at this point, get feedback from you all. And then, if there are areas where you all think that the workgroup should go next, we'd like to hear that.

MR. HOUSENGER: Mark.

MARK: Yes. It's a good report and was an important topic. I think the workgroup has really made great strides and has accomplished a lot. As with a lot of things, we're kind of just at the beginning of things. Of course, it was mentioned that the president has an initiative. While the administration might have a workgroup, or whatever, task force, I don't know what they're calling themselves, I'm sure they're a group of (inaudible) people but not as enthusiastic entomologists like us.

But I think it behooves the agency to maintain

a presence of advisors and workgroup members to basically look and see how this beginning gets going, whether it really gets on its feet and is moving in a measured direction of improvement. That would be my concern.

MR. HOUSENGER: Nichelle.

NICHELLE: Thank you for the report. So, a lot of work on pollinator protection these days has now shifted to states and their development of their state plans for pollinator protection. Do you think that this workgroup would have any type of role to play in sort of helping to guide these states since EPA ultimately has that responsibility as well to guide states into developing robust pollinator plans?

MR. KEIGWIN: I think that's one of the things that we'd like to hear from this wider group, is what other areas that you all as advisors to us think that we should be taking on. So, we have been working with states as they develop guidance for how these state and tribal pollinator plans should be developed.

We've identified some common criteria that we think are important in the development of those plans, specifically focused on that there's a mechanism for

communication, that there's a mechanism for monitoring the effectiveness of the plan that's developed, and that the plan is developed in an open and transparent way so that all stakeholders can participate.

But each state and each tribe are approaching these plans in different ways. SFIREG, the state FIFRA issues, research, and evaluation group, which is largely the state regulators responsible for pesticides has developed a very detailed guidance document that is being used.

Now, I think there are approximately 40 states that are in the process of developing these plans. I think there are only about five, though, that are all the way completed. So, that could possibly -- Nichelle, getting back to your suggestion -- be one of the areas that this group could play.

MR. HOUSENGER: One of the things that you're going to hear as we go through the workgroups is we're not interested in just having workgroups for the sake of having workgroups. We want to get meaningful input into critical issues that we need advice on. So, any workgroup that is done, we would like to close it up and

move on. We can give updates about topics here at the PPDC, but we're looking for issues to receive advice on.

UNIDENTIFIED FEMALE: One area that the pollinator workgroup discussed was looking into our native bees, because while there's a lot of overlap with managed bees and native bees, they aren't exactly the same beast. There are issues that need to be faced. That's really only just started to talk about. That would be an area I'd love to see more focus on.

One other area is I feel like it's so much easier to respond to incidents and look at that short term immediate concern. It makes sense that we need to address those immediate concerns first. But, with the increasing use of systemic long lived neonicotinoids, we are trying to think of how do we respond to the effects over time.

Just very quickly looking at trees, we're seeing -- and woody plants, we're looking at exposure or at least residues in pollen years after applications. So, how do we better understand what that concern may or may not be, and then respond to it.

MR. HOUSENGER: Ray?

RAY: A couple of questions. I sympathize with the task that the agency has of responding to more than 100,000 comments.

MS. MONELL: We can't really hear you too well, Ray. Get closer and speak up.

RAY: I sympathize with the agency's task of responding to more than 100,000 comments on the recent proposal regarding the compounds that are toxic to bees. What's the time line for responding? We're still waiting to see the comments that have posted on the website. What's your time line for getting those posted, for formulating a response, for announcing next steps?

MR. KEIGWIN: So, as many of you may know, that website regulations.gov is not an EPA website. So, we don't have much control on how quickly the comments that are submitted actually get posted for public viewing. I think to date there are only about 500 comments that have been made available to the public. I will say there's only about 500 comments that have been made available to EPA staff to begin to be able to do the evaluation.

What we are told is that the vast majority of the comments were a single comment that was replicated

multiple times as part of a petition type of campaign. So, we're reasonably confident that the 500 or so that are publicly available are the most substantive of the comments. Not that people voting with their e-mail isn't important, because it is, but we think from a substantive directional standpoint, we have the vast majority of them. So, you all have those as well.

We're trying to build that time line now. I will say from the preliminary review that we've done, there have been some very robust and thoughtful and substantive ideas that have been brought forward. So, I think over the next couple of months, once we've digested those a little bit more, we'll be in a better position to be able to provide a time line for moving forward on that action.

RAY: A couple of follow-up questions. You mentioned earlier the incident investigation guidance which is provided. Does the agency have any feedback from states on how useful that has been in practice and to what extent it has been used?

MR. PECKHAM: The states in Region 5 have adopted it, and I think it's been very, very useful.

Each state has its own authorities and abilities to do things certain ways. I know in Minnesota we've adopted it. Actually, it's kind of prompted us to do additional training for both colony health as well as pesticide incidents. So, all of our staff are trained, and they're all trained in the guidance. We have a couple little different things that we do that other states maybe are not doing because we have entomologists on staff that can actually go out on our bee kills.

RAY: And I'm sure those entomologists are enthusiastic.

MR. PECKHAM: You know what, they're kind of laid back.

RAY: Well, the guidance itself and its use has a direct impact on how the agency should handle the comments, because there was a significant emphasis in that proposal regarding reports of incidents had been received. We're very interested in the extent to which those incidents listed by the agency as a justification for their proposal have been investigated or investigations will continue. It's important that these reports of incidents be verified, validated, and their

true significance with respect to regulatory decisions is determined and made public.

One last question. In the present strategy on pollinator protection, they rolled in the monarch butterfly issue into the same document. The agency, a few months ago, put out its own proposal regarding some strategy regarding the monarch protection.

Is this an appropriate topic for the pollinator protection workgroup to handle, or will you bring it up in another different PPDC workgroup?

MR. KEIGWIN: So, thanks, Ray. On the risk management framework that we put out for public comment, for that one we received about 46,000 comments. I think, though, about 30,000 of them were really a letter writing campaign through one organization. About another 10,000 or so were a letter writing campaign sponsored through another organization.

But similar to the acute risk mitigation proposal that we put forward in May, a number of very thoughtful comments on what types of information, what types of data the agency should be taking into account when we’re looking at making regulatory decisions for

pesticides and what impacts, if any, those regulatory decisions might have, particularly on milkweed habitat for monarch butterflies.

I think that one from a time line standpoint, we're in a very similar time line situation to be able to digest the comments and formulate a response. I don't know at this point that we've decided how we would specifically roll that out, but it is an important part of EPA's contribution to the national strategy.

MR. HOUSENGER: Okay.

CYNTHIA: Can I just clarify real quick? The guidance you asked about, Ray, it wasn't the MP3; it was the incident reporting guidance. I just got confused there.

MR. HOUSENGER: Okay, Richard?

RICHARD: Thank you. One, I want to thank the PPDC's working group. It's an important thing to pollinators, so it's a priority trying to get consensus on how to address this issue.

We're actively involved in the honeybee health coalition. EPA and USDA is involved in that. We think that has a broad diverse group of participants that can

hopefully have some programs in place and recommendations. I think it's in alignment with the president's task force for the most part. So, we look forward to working with you.

I did have some questions as far as the workgroup and things that are of concern. From the applicator's standpoint, and this goes back, I guess, to Monday, the USDA had given a report as far as bee kills, bee deaths. Part of that was pesticides, but a big portion of that were the pesticides related to verroa mites for home brews. So, maybe misuse or not following the labels of some of the products or off use of label of products.

So, when you talk about training and enforcement on pesticide product use, is that just the applicator you're focusing on or others that are using it that are impacting bee kills as well?

The other thing, from an applicator's standpoint, if you don't know where the bee hives are and you're not part of the contract between the farmer and the beekeeper, it may be a farm adjacent to it, it makes it very difficult. So, I was just wondering what EPA is

doing to encourage -- and this is really a state and local issue to resolve these issues.

What is EPA doing to encourage some of these state plans for reporting of where these bee locations are from the applicator's standpoint? Again, if they don't know where the hives are, it makes it very challenging for the applicator if they're not aware of them.

MR. KEIGWIN: Thanks, Richard. On the training piece, the website that Wayne developed through NC State not only has best management practices for applicators, but it also has best management practices for beekeepers. I think the honeybee health coalition, one of their subgroups has substantive discussions on hive management, which again I think is developing best management practices for beekeepers on the appropriate use of pesticides and training opportunities there. EPA is contributing to that group separate. We think that's an important piece of work that the honeybee health coalition is doing.

In terms of the concern that applicators might have about where beehives might be located, what we have

been encouraging as part of the development of the state and tribal managed pollinator protection plan is that applicators and growers and beekeepers at a local level reach agreement on what is the best way to facilitate that identification and communication of where hives might be located in relationship to agricultural fields.

How states and tribes and stakeholders within those communities reach agreement on how to do that, we have said to this point that that's a state and tribal decision, but there has to be agreement amongst all of the parties in the development of the plan or how they best want to do that.

Some states are taking advantage of some commercial software that's available through Field Watch. Other states either have or are considering the establishment of apiary registration programs. But at this point, EPA has not said which way is the best way to do it. We've just been encouraging that there be communication channels established that all the interested parties agree to.

MR. HOUSENGER: Cynthia?

CYNTHIA: So, in terms of new directions or

priorities for us, two things. The elephant in the room seems to be the use of coated seeds and impact on water quality and biodiversity. Maybe there could be some guidance from the workgroup in terms of whether use of coated seeds is out of sync with integrated pest management.

Secondly, we would like to suggest looking at pollinators beyond managed bee populations echoing what Aimee mentioned earlier, looking at native invertebrate species and also, of course, at birds, bats, butterflies, and other wildlife. Thank you.

MR. HOUSENGER: Gabriele?

GABRIELE: A couple of thoughts and also response to what I've just heard, a suggestion. I think the main one, what I'm seeing, is that EPA is in the midst of registration review. That's your process for trying to get additional information to help you make good assessments of where are the potential impacts and where they're not.

Again, I'm not the risk assessor here, but I don't think there's a lot of clarity about what data is needed, what the methods are for those data. I mean,

just yesterday, I had someone call me up, I'm not a risk assessor, for advice on what studies they needed for bees because the kinds of questions they'd been getting from the agency just weren't making sense.

I know that registrants for post-harvest fumigants have been asked for bee studies. You're kind of going, it's a post-harvest fumigant, why are you asking for a bee study.

Then, if I looked at what was in the proposal for acute toxicity and the state plans, there was discussion about needs for additional tests, whether it was for insect growth regulators and so forth. So, there's a lot of questions about what data is needed for EPA to make good questions.

I will also say, looking around this room, you have people in the room that want every bit of data. That's unrealistic. So, the other balancing act here is what data is realistic to get, what data is not realistic to get. We have others in the room that would prefer not to have any data because it's all additional money. So, this is the balancing act. I don't think we've had a good discussion about what are all the questions that are

coming up and so forth.

I am going to be editorial here. I will say that the acute pesticide risk assessment showed that lack of asking questions. That is one of the least thought out proposals I've seen come out of EPA. Sorry, guys. I think the comment flow that you've gotten reflects part of that. It's like, wait a minute, you've not had the dialogue, so it's not as well thought out as it could have been.

So, I think that's one thing I would say. I will say that I'm not interested in having the workgroup start dealing with the state plans. There's enough other groups and feedback going on in that arena. I don't think it's something that's needed right now. Maybe if we get further down the line, yes.

It's partly also because for those of us who are engaged on bee issues, there's only so many meetings we can handle. We're on a number of other groups. So, I'm just trying to figure out how to make it effective. So, to me, one thing that's really unique here is of the whole range of things that could be asked, what makes sense to really be asking, what are the criteria for when

something should be asked or not be asked on the risk assessment side.

MR. HOUSENGER: The last PPDC meeting where we went over the framework for conducting bee assessments, which outline tier one data, tier two data, tier three data. So, I'm a little confused.

GABRIELE: Yeah, but then there's questions coming up about secondary effects. There's a question of if you're looking at a developmental potential effect in the honeybee hive, what exactly should you be looking at. So, the big broad outline, sure.

But it's now getting into EPA and the registrants are sitting down and negotiating what are the data call-ins. That means you have to have a good idea of what kind of data is relevant when. So, I'm asking for a level deeper than the big broad -- you know, here are the various tiers, because there are a lot of questions coming up in that arena from a lot of different voices in this room, is my sense. Again, it's a difficult area because some people want every bit possible.

MR. HOUSENGER: Right.

GABRIELE: That's not realistic. Some would like as little as possible, and that's probably not realistic either. So, just trying to find that balance.

MR. HOUSENGER: Yeah, I'm struggling with trying to figure out if you're saying that the data that we're requiring aren't adequate.

GABRIELE: I think in some cases that's a question that's on the table. I think the flip side of it is that questions are being asked that seem utterly unreasonable. It's both. So, why for certain best biopesticides do you suddenly need bee health effects? There's just some questions. I'm just saying there doesn't seem to be a balance there. Again, I'm not the person sitting in those meetings; I'm just reflecting what has come to me in the form of questions or comments.

I'm just saying, hey, there's a lot of confusion at the moment when you are in the midst of trying to move this process forward. Would having this committee have some more feedback -- or may it's not this committee and you do one of your day long meeting where you really go through the risk assessments in some of these questions. It's not an SAP level, not that deep.

I mean, I've gone to some of those and that's over my head.

MR. HOUSENGER: I think when we issue our first risk assessments for bees, which will be in December of this year, for the neonics, or imidichloprid, we'll see how the data that we require will fit in with our assessment of bee health. Maybe that would be a good place to start to see how the data that's required actually allows us to do an assessment.

Steven.

STEVEN: Looks like these new microphones revert to old technology.

MR. HOUSENGER: They are.

STEVEN: Just an observation. So, I was one of the members of the workgroups that kept things interesting at times. I do not want to go back through all that again. It was a lot of head banging on my part. Before I forget it, I do think that a better risk assessment is needed for many of these products. You all just discussed that, and a lot of that was over my head.

I'd like to go back and talk a little bit about the Region 5 development and the workgroup

recommendations for bee kill investigations. I think it's important to remember that bee kills is not a violation of the label. It's a symptom of a label violation. The beekeepers believe that the label is the law.

Personally, I have some concerns that the goal line is being moved as we approach it. So, I don't want the label changed to meet what's currently happening out there in the fields. I'm a little concerns that the MP3 programs are usurping the federal label with a less restrictive label by the state. It may not be written that way, but that's the way it's going to be happening. That's what's going to happen on the ground.

Many of these plans put most, if not all, of the risk mitigation on the backs of the beekeepers. I don't know that any of those things are suitable for a workgroup discussion, but those are all things that we discussed in various aspects of our discussions over the last several years. Those haven't been adequately addressed.

MR. HOUSENGER: Cheryl?

CHERYL: So, I'm listening more to the broader

question that's been raised about all the workgroups. I know we're going to speak about all of them. Have they achieved their goals? Do they need to continue? I'm seeing a lot of levels here. You have a lot of different resources to get stakeholder input. You have the docket. You have this broad PPDC forum.

Then you have the workgroups. The workgroups are supposed to exist for a deeper drill. The best outcome of a workgroup is if you can have that diverse conversation and reach consensus. It's not always possible.

The second outcome of a workgroup is that you raise issues that then get discussed and discussed and kind of brought back here. I was hoping that in this presentation that we skipped on roles and responsibilities, we might get a little bit more clarity about what you want out of workgroups, not just what you want out of the PPDC membership.

At times, we hear, okay, this was discussed at PPDC. It was vetted at PPDC. You don't get consensus, and yet you move forward. So, PPDC is kind of used as a place to go. So, those are my questions. I'd like to

get a little bit more from you as we go through the whole process of reevaluating all the workgroups. What do you want from them?

Then, if I look at this particular workgroup and I look at the top page and they say, what was the charge in 2011, what was achieved, you did a good job of explaining what had happened. I think you can check, a lot of low hanging fruit kind of came out of here. It's easier -- I'm not trying to say, Wayne, it was super easy, but it's probably easier to gather best management practices than it is to agree on some of these other things. Yet, you have a group that's very large and very interested.

So, I think I would be a little bit reticent to just see this let go, but it should be refocused to say where can you take advantage of the fact that there are some things that are going to have diversity. You're not going to reach consensus, but what can you do in that workgroup to gather and still take advantage of this broad forum? Thank you, Jack.

MR. HOUSENGER: Thank you, Cheryl. You know, this is one thing that we've struggled with, too, is what

are the workgroups. Certainly, the workgroups have served as an update for people, which is good. But what we're looking for are the things that we aren't thinking about. Like one of the workgroups, I guess one of the things that was recommended that we made available was the RT25. I think it's coming at it from a different way. We're probably close enough to it that maybe sometimes we just miss the finer points or really what's on the minds of a diverse group like this. That's kind of what we're looking for here.

I agree, I think the management plans, I think we've got a good public process going. I'm not sure that the workgroup, if the members haven't already commented through the regular means, that it's a good use of the time of the workgroup. But that's kind of what I'd like to see out of the workgroups, advice on things that may not be as evident to us sitting here.

Dan?

DAN: Thanks, Jack. I'd echo, I think the workgroup has done a great job. I'd echo some of the comments that were made here. But I still have one comment that I'd like to add. That is, has there been

any retrospective analysis of the indications of how these plans have actually helped in resolving the issue with regard to bee health? If there has, then maybe that could be communicated to the public in a broader sense. Or, if it hasn't, then maybe that can be a further charge of this working group.

MR. KEIGWIN: I think that's something we were envisioning once more plans got developed. Many of the plans that have been developed to date have really only been in place for maybe one use season. So, I think it's hard to say one way or the other, but that was one of the reasons why when we did layouts and criteria for the states and tribes, we said it would be important to have a process in place to revisit those plans to see how well they're working. So, if improvements are needed, they can be made. So, that's a good point, thanks.

MR. HOUSENGER: I remember back when Jim Gray brought the plan forward and talked about how much he thought it helped in his state. We said, well, what if that's expanded across the United States. So, I think it's still an outstanding question about how these plans are implemented by each state, whether they make a

difference or not.

Doug?

DOUG: I just have to echo. In the beginning, you said that you had accomplished your purpose. I just want to say that as you look at this, that all metrics needs to be followed up on. The studies for bee pollination and pollinators have begun, so we need to monitor those still as a workgroup but not as a full group, just a follow up group. Like you say, are you monitoring that training at state and tribal levels to follow up how well that's being done. That's all I have.

MR. HOUSENGER: Ray again.

RAY: Your mention of depending on PPDC for bringing up topics that the EPA staff may not have thought of brings to mind that we individually as members of the PPDC represent larger constituencies also. This particular workgroup on pollinators was a very large group, well beyond the folks around this table. I'd suggest you put the same questions to that larger group and give a short but reasonable time for them to feedback on what they see the value of the group is before you make hard and fast decisions on its future.

MR. KEIGWIN: I think that's something that we can explore, Ray. I will say I think we've tried that at least once, but maybe since the national strategy has come out, this would be a good time to revisit that question with the workgroup.

MR. HOUSENGER: All right, seeing no cards except Ray, who just put it down, I think we'll move on to -- let's do the next workgroup and then think about a break.

MS. MONELL: I guess that's me. So, the title of our committee is a bit misleading. Comparative safety statements is actually prohibited on a pesticide product label.

But about five years ago, this group, or the PPDC at that time, requested of the agency that we form a workgroup to look at the issue of allowing some sort of distinction on pesticide labels with respect to a product's greenness. We can't say safety because we address that in our regulatory process.

But consumers at the time, and actually to this day, really are very interested in information about the relative greenness of products across the board, and that

includes pesticide products. So, this group was formed to look into that issue. We did a lot of research. We interviewed several organizations that did sort of a screening of components in both pesticide and non-pesticide chemical products.

We decided upon partnering with our sister organization, the Office of Pollution Prevention and Toxics. At the time, they were running their DFE, Design for the Environment program, which involves a screen of all ingredients in a product by a third party screener. If the product passes that screen, then it is eligible for allowing that logo on a pesticide product label if it meets certain criteria within the pesticide program.

So, we essentially focused on antimicrobial products because those are the ones that lent themselves to the ability to pass the DFE screen. Then, we gradually included biopesticides. Although we don’t have any biopesticide active ingredients yet that have actually pursued the screening process, we do have 7 antimicrobial active ingredients and 10 products that have been approved to have the DFE logo on them.

Obviously, the registrant’s interests are to

provide consumers with the marketing information that they desire. It's the agency's position that our job is to make sure that whatever is on that label is not false or misleading. So, there's sort of a three-legged stool approach to this process. While we do have the 7 AIs approved and 10 products, I don't believe any states have permitted the registrations.

The states are very concerned about this, about the issue of allowing this logo. They believe that it could be false or misleading. We have two opinions from Office of General Counsel in this regard. The basic underlying principles are that A, we are utilizing a program that is run by a federal agency so there's a bit of credence given to the rigor with which these chemicals are reviewed. There is a third party certifier so there is no vested interest in the process.

Of equal importance, when the DFE logo is allowed on a pesticide product, there is a reference to the website so that it is very clear that what the DFE for pesticide products is intended to convey, there is educational material on the website. It's actually different than that message which the industrial chemical

DFE logo had historically conveyed.

As you know or may not know, but I will tell you, the DFE program for industrial chemicals has now evolved into a program called Safer Choice. This decision followed a lot of market research, an extensive amount of market research, and a desire by the agency to encourage green purchasing across the board. This was a way of enabling consumers to make choices in terms of the products that they buy.

We, in the pesticide world, cannot, both by statute and regulation, allow the use of the words safe or safer on a pesticide label. So, that’s a non-starter for us. The workgroup agreed to extend the pilot for the DFE logo use for another year, so we’re still aggressively pursuing with the states sort of clearing up any misunderstandings or apprehensions that they have about the use of the logo. I think that we’re in a good place there. They seem to be very interested in pursuing better understanding and ultimately approving the use of the logo on state labels, which is critical to achieving any kind of success. So, that was one piece of our work.

The other piece was allowing certain factual

statements on pesticide labels. We started with the two that are sort of the most straightforward, and that is making statements about dye free or fragrance free. A lot of consumers really need that information for allergy reasons or just their desire to stay away from dyes and fragrances.

So, we had a history in this program of sort of allowing it. We memorialized that in terms of it being a part of the factual statement pilot program. We also allowed statements which essentially are a reference to a website that a pesticide company might want to put on a product label that references the website and their corporate commitment to the environment, to public health, recognizing that a reference to the website does become part of the label. So, we have actually had a fairly good amount of interest in that and have about 30 product labels that have been approved through this pilot for the corporate commitment.

This is all over a period of five years, mind you. So, we also allowed biodegradability, the status of a product's biodegradability. So, we decided that there were two situations where you could have this statement

on a label. One is if all of the ingredients in the pesticide products are biodegradable, then you could put that statement on your label.

If the surfactants in the product formulation is biodegradable, we would allow that statement. Thus far, we have no products that have been pursued to have the complete biodegradability statement, but we did have two products with surfactants that are biodegradable come forward. They're allowed to put that on their label.

Then, the last and most recent was our sister organization, USDA, has a program wherein a product can achieve a bio-based mark. This is an effort to promote sustainability in various product sectors. So, we agreed that we would allow a bio-based mark once the product had been certified by USDA through its program. We would allow that mark to be on our label with a disclaimer that it is in no way a statement as to the safety of the product. So, we still don't have any products that have been put forth for that particular mark.

All of these efforts are again designed to provide consumers with information that we believe they want. I think that's more true today probably than it

was five years ago. I think people want to know what's in the products they're using, whether they're pesticides, cleaning products, or anything like that.

In the past year, we had a request to revisit our position on allowing statements on labels as to the safety of a product for use on a particular surface. So, this is a very specific claim. Apparently, years ago, we used to allow statements that said safe for use on porcelain, like toilets, or safe for use on counter tops, formica, et cetera, et cetera.

There was a determination made that while it's true that consumers probably would be interested in having that information, that the opportunity for consumers to be mislead by the use of the term safety overweighed the utility of it to consumers.

So, a group of companies came forward and they believed that consumers really would take advantage of this information. In fact, if you knew that something was specifically safe for use on a formica table top, that you would only buy one product rather than six or seven and keep trying them all until something worked.

Anyway, they constructed a survey, a consumer

survey which was really very, very rigorous in the diversity of the consumers to whom it was made available. It was a large number, over 2,500, I believe, respondents. Usually, I guess, the norm is about 400 or 500, so this was above and beyond.

The agency had the opportunity to review the survey. We couldn't tell them what to put in the survey because that runs afoul of information collection rules. But we did say, if you're trying to elicit X, Y, Z information, you might want to ask questions about this.

So, the survey results came back. They were presented to the workgroup on a couple of occasions, most recently summarized again yesterday. The feeling is that consumers, and the results support it, are not confused by statements about the safety of a product for the surface. They don't feel it's in any way confusing that I can drink this or I can pour this on my child or anything like that. There was absolutely no confusion whatsoever.

So, the workgroup talked a lot about it. We came down on the side of yes, let's allow the use again of this statement as to the safety for the surface for

which it was planned to be applied and under the construct of the factual statement pilot, so that we can get a little bit of experience under our belts. The companies obviously will be continuing with their market surveys to assess whether or not this is helpful information and whether consumers are confused by it.

So, that's the most recent discussion we've had there. As you can see, there are various angles to this whole desire to provide consumers with information. It seems every year we get another proposal to look at. To that end, we have brand new business that was brought before our workgroup meeting yesterday. Actually, it was a result of last May's PPDC meeting which had to do with comparative efficacy statements.

So, my product is 10 percent more effective than the leading brand, those kinds of statements. We see it on advertising on television all the time. So, clearly, this is something that's before us. It's in our life. The issue is does the pesticide program, with our scarce resources, do we become embroiled in the business of approving these claims for pesticide product labels. There's legal arguments why we may have to. There are

realistic constraints, policy issues as to why we need to really be thoughtful about this.

So, that was the new business presented to our workgroup yesterday. I think there is a lot of interest in pursuing that, as you could imagine, pursuing the discussion if not the implementation of such statements. In any event, the workgroup feels we should continue on. We started with about 40 non-EPA participants. We're down to now about 15 regular participants. Twenty-three are officially on the workgroup.

So, our recommendation back to this group is that we continue on but that we open up membership that we get some new members. I am particularly interested in having consumers or NGO involvement in these discussions, because if you have just trade associations and companies, clearly, you're hearing one perspective on an issue. The whole purpose of having the workgroups and this meeting and this committee is to get a diverse interest represented in all of our discussions.

So, any questions? Gabriele?

GABRIELE: Just to clarify, because I know nothing about this. What is the concern about not on the

label, per se, but in the advertising part, which is what I'm hearing became a new item?

MS. MONELL: Maybe I wasn't clear. The reality is in the advertising world, there are comparative statements made all of the time. What we're being asked to do is take those comparative statements and put them on pesticide product labels, allow them on pesticide product labels. That's where the distinction is.

UNIDENTIFIED FEMALE: So, my question is back to again trying to understand workgroups versus EPA actions. You described a whole lot of things that wouldn't have been in the workgroup. You kept using we. So, sometimes it was we as the workgroup, sometimes it was we as EPA. Can you articulate for us what the best use of this workgroup is in this space? How are you using this workgroup to move this program forward to meet the needs that you just described?

MS. MONELL: Well, think somebody described it earlier as a deeper dive into issues. This particular diving has been around issues of information that we allow on pesticide product labels to assist consumers in understanding or selecting or whatever they're interested

in.

So, unlike this committee, which recommended that this was an issue that was worthy of a deeper dive -- that's what the workgroup is doing, is a deeper dive. The results of our initial diving resulted in the agency -- and we brought it back here, the recommendation back here, but then the agency proceeded to develop the criteria and allow the DFE logo on pesticide product labels, factual statements, biobase, biodegradability.

So, it was just sort of evolving through the discussions to recommendations to this group and then carrying them forth. So, when I say we, I guess it's in two different contexts, my workgroup context as well as the EPA context, sorry.

UNIDENTIFIED FEMALE: I just think that "we" is an important distinction as we go through trying to understand if we cue up all these workgroups, what are they doing? Do they need to refocus? The "we" is important.

MS. MONELL: Got it.

Pat?

PAT: Marty, I think it was a year or so ago we

had talked about somehow if there was a way to include animal testing information on these labels, particularly in the light of EPA's new thrust into trying to replace a lot of these toxicity tests with non-animal alternatives. I'm wondering if that ever went anywhere or is that something that might be able to be reopened for discussion.

MS. MONELL: Absolutely. As you may or may not recall, Kristie Sullivan, who used to be a member of the PPDC and was an active member of this workgroup, did a lot of work on that very issue and came up with various options. I will have to say there was some concern raised about emphasizing the fact that animal testing occurred in the first place. So, to have statements about well, animals were not tested in the development of this product, could perhaps have an adverse impact.

So, the workgroup had some serious concerns about proceeding without wrestling with that issue. Then, Kristie left the PPDC and left the workgroup, so it's just been languishing. We did talk about it yesterday, though, and there is a desire by the workgroup to work closer with OPP to talk about where we're at with

the reduction in the use of animal testing and any encouragement that we could give through statements, factual statements, to that effort.

So, we agreed we would have Jennifer McLain and Anna Lowit come to our next workgroup meeting to talk about where we're at with those efforts to reduce, if not preclude, the need for animal testing in the pesticide registration process. So, it languished for a bit, but it's very much back on our agenda.

PAT: (Inaudible)

MS. MONELL: Thanks, Pat.

Aimee.

AIMEE: You actually touched on it. I was curious to have access -- I don't know if there is access to see the criteria you used for the DFE and these statements of safety on different surfaces.

MS. MONELL: There is a website, PPDC comparative safety statement website.

AIMEE: But is the comparative safety the correct one for DFE?

MS. MONELL: Yes, yes. It's under this umbrella.

Dawn?

DAWN: So, as an academic who has an extension component to her job, I talk about efficacy of products and approaches all the time. Terribly important stuff. But given the dynamic reality to efficacy in both time and space, I'm wondering how that could possibly be constantly updated if it was placed on a label?

MS. MONELL: That is clearly one of the big issues that we have to wrestle with.

Sharon?

SHARON: Just two questions. The first one, to clarify, when you said that safe and safer are not words that can be used on pesticide labels, did I understand that correctly, so that the safer choice label is only going to be for the non-pesticidal products?

MS. MONELL: At this point, yes. We have regulations that specifically preclude comparative safety statements. In those same regulations, there is an example given of comparative language that is prohibitive. Safe and safer are specifically enunciated. We're looking, as an AAship towards the possibility of amending our regulations because they are out of step,

some think, with the times.

SHARON: So, a follow up on that is that the other aspects, it looked like they are going to be included on pesticide labels, including the biodegradability, fragrance types of information?

MS. MONELL: Yes, yes, that's correct. We recommended that as a workgroup. We recommended that to this group. The agency took the recommendation and is moving forward.

Wayne?

WAYNE: This is an issue that may be outside of what you discussed, Marty, so I'm sorry for targeting you with this. What is the difference in the websites -- and maybe this is an item for further discussion later. The WW2 seems to be the new EPA website prefix, but I've noticed that there are still some WWWs. Are the WW2s going to revert to WWW or is the whole new complex of the EPA's website remaining with this WW2 prefix? The reason I ask that is that you have information on comparative safety statements without the 2 in the prefix; whereas, the others seem to have the 2. I guess I'd like to know that in regards to changing links within my own program.

MS. MONELL: I cannot specifically answer that question. Actually, Claire Gessalman, I believe, made a big presentation on the changes to our website at the last meeting. I didn't commit it to memory, so I'm not the person to answer that question.

(Inaudible), Dea can you?

DEA: I didn't quite get the question, Wayne.

WAYNE: I was just asking, in terms of the new EPA website, it's a prefix of WW2. But I still see a number of sites, like the one that Marty has listed here within comparative safety, for the WWW. I'm wondering if we made changes to our own home pages and websites, what's going to stick? Is it the WW2 or the WWW?

DEA: I'll get with Claire. I'll send her an e-mail and see if she can help us answer that question.

WAYNE: Okay.

MS. MONELL: Yeah, we'll have that information for you before we leave tomorrow.

MS. MONELL: Cheryl?

CHERYL: On the possibility of comparative

either safety or efficacy, the criteria by which you make that claim and that comparison, depending on how deep it goes and what criteria you use, those comparisons could change. To Dawn's point, there's also going to be market and dynamics that change.

So, I guess I'm wondering, in the current label approval process, which is very laborious and legally binding, is that really the place for some of this information, or could you take a page from the pollinator group where they pulled off the RT25 and they posted it on the website? So, it's easier to update and have more information than a label.

MS. MONELL: That's definitely something that we will be talking about as we go forward. As I say, this whole issue really -- it was directed to our workgroup. Yesterday was the first time that we actually had a conversation about it and decided that yes, this is an area that we should further discuss. But the parameters and a framework for it, all of that is yet to come. But that's good advice.

Beth?

BETH: I guess one thing, you sent an e-mail,

but there was an announcement I think about a week or week and a half ago that EPA sent out regarding the change of the new URL for the pesticides website. It did say that you would need to change a lot of your links if they didn't actually carry over. So, I just offer that.

I guess what we were talking about earlier, and Cheryl, you might have raised the point initially, what is the scope or the mission of these workgroups and what do you want them to do. From having just compared what the pollinator workgroup has done with what this comparative statements workgroup has done, I would urge us to not to try to come up with a monolistic solution. I think what you want from those workgroups really does depend on what subjects they are addressing.

With this comparative safety statements workgroup, clearly what they're dealing with is a much more defined universe of issues. My understanding of the pollinator workgroup is that it has so many moving parts and there's so many separate issues, I would think what you'd need from that would be more like policy and ranking. Whereas, compared to the safety workgroup, you're dealing with should biodegradability be a label

statement. So, that would be my contribution to that discussion.

MS. MONELL: Thank you, Beth.

Okay, thank you very much. I appreciate it.

MR. HOUSENGER: All right. Well, we're about on time. Let's take a 15-minute break. When we come back, we have one more workgroup. Jim McCleary is on his way. So, 15-minute break, back here at 10 of.

(A brief recess was taken.)

MR. HOUSENGER: We're going to get started now. Jim McCleary is here. He's going to talk about the FACA rules. Jim?

MR. McCLEARY: Good morning, everyone. Thank you, Jack. My name is Jim McCleary. I'm with the Office of Diversity, Advisory Committee Management and Outreach, an office within EPA. Our primary function and the roles that involves you is that we manage the federal advisory committees that provide advice and guidance to the agency.

First of all, let me say welcome. Thank you very much for serving. We do appreciate your efforts and the time and attention it takes to be here today and to

work on this committee.

FACA, the Federal Advisory Committee Act, was passed by congress in 1972, and it governs all aspects of your work. One of the things that the government has to be careful of is not invoking FACA unintentionally. So, if we grabbed a group of people from the outside together to provide consensus or group advice, FACA is usually invoked. So, we have to go through the formal membership process and chartering process to bring everyone on board to make sure that we're doing it right and that we're not in violation of FACA.

At EPA and elsewhere throughout the government, members of the committee serve at the administrator's discretion, at her pleasure, we call it. We try to balance the committee to make sure it's balanced in reference to the points of view to be represented and in the functions to be performed.

FACA requires several things, including openness and transparency. This is an open meeting today. We have a visitor's gallery. We have noticed this meeting in the Federal Register and in other places. Opportunities are provided for the public to provide

comments.

We appoint members depending on whether the member is being asked to represent a point of view of the group, which is what you are, you are representative members, or if you're representing your own expertise, and that would be an SGE member. This committee has no SGE members. Every single one of you here are asked to provide the point of view of the group that you're representing.

We also keep detailed meeting minutes, and committee documents are available to the public. Our minutes will be certified by your committee chair, Jack, and the requirement applies to all of the meetings, including teleconferences. If you invoke a forum, we have to maintain these records.

You have a designated federal officer representing the agency here today. That's Dea Zimmerman. Dea is one of our best and finest DFOs. You're very lucky to have her. The DFO manages the daily operations of the committee, and the DFO has to be present for every single committee meeting. If you're having a meeting, whether in person or remotely, the DFO

has to be here. In the event Dea can't make it, the agency can appoint someone else to be DFO, acting DFO, for the purposes of running that meeting.

A couple of things we ask of you, to participate. This is a dialogue committee, and it doesn't work if you're not here to talk with each other and express your points of view. We ask that you come prepared to the meetings. Like we send our children to school, you're supposed to send them to school prepared to learn. We ask you to come here prepared to participate. That means reviewing the materials in advance. We ask that you engage in a cordial, polite, and professional manner with each other.

We ask that you represent your interest group. So, while your own personal views might be very important and interesting, you're really here representing an organization. We want to hear the points of view of that organization or group.

We ask that you work towards consensus where possible and where appropriate, and that you provide feedback through your chair. The chair is the person that provides the leadership for this committee. If you

have any issues or concern, please bring them to Jack's attention.

We ask that you collaborate with each other to achieve the committee's charge, and that you serve your appointed term. Now, sometimes things come up. Life gets in the way. For whatever reason you can't serve your term, we ask that you please notify Jack as soon as possible, because it may throw off the balance of the committee. If the balance of the committee is not appropriate, then we have to bring someone else on board before the group can meet again.

We ask that you stay in close communication with your DFO, Dea. Dea is really the point of contact through the agency for this group.

There are travel and ethic considerations to talk about. As invitational travelers, the government pays for your travel here. Later on, I'm going to throw it to Dea so she can introduce the person who manages your travel. You're also entitled to a per diem for every day that you're on government travel.

The next item is our plays well with other item. We ask that you refrain from any language that may

be offensive to other members of the committee. We don't expect that to be a problem with this committee, but unfortunately, in the past, with one of our committees, it has been a problem.

The next issue is that members may not lobby congress in their capacity as advisory committee members. This is something that has been an issue with some of our committees in the past. As US citizens, you are fully entitled to lobby your governments on issues that are personal to you, but we ask that you not represent this group. Jack is our chair, and he represents the group. If there are any issues that have to be brought up to congress, he'll work with EPA's office that's involved in that to make sure that happens.

In the event that you do go up to congress, we ask that you do it on your own dime and on your own time. So, while the government has brought you here, you shouldn't leave this meeting for a couple hours to run up to Capitol Hill to talk to your member of congress. You shouldn't put in a travel voucher for the taxicab that takes you there and back. Any questions on that, I'd be happy to field those.

This is the same prohibition also that EPA employees, myself, and Dea are subject to as well. We can't go up to congress and lobby them to do things that we think they should be doing on behalf of the agency either.

There's some limitations here. You're asked to provide advice and recommendations directly to the EPA. Sometimes some of our committees provide advice also to congress or to the president. This is a dialogue committee that their advice comes through the discussion that takes place here and it goes directly to the agency administrator.

With our approval, you can form subcommittees and workgroups to accomplish the goals of the committee. That's something you would have to work through Jack and Dea to set up. Subcommittees must report their findings directly through the parent committee for full deliberation.

So, if there is a workgroup or a subcommittee that's doing some part of your work here, they don't have authority to present that material directly to the administrator themselves. It has to be brought up to

this whole committee as a group before it can be passed forward.

At EPA, we make our subcommittees go through the same membership requirements that you do here for the parent committee. That's not the case for other federal departments and agencies. So, if you do set up a subcommittee, we have to go through the full membership process for that subcommittee.

Workgroups and subcommittees, generally what they do is they'll do research into specific activities that you're performing as a committee. If this committee doesn't generate a written report for the committees that do often, there will be a writing subcommittee or a research workgroup that will look into those aspects of it.

Workgroups are not subject to FACA. That's the good thing about workgroups at EPA or elsewhere throughout the agency. We don't have to go through membership requirements. We don't have to go through chartering requirements for them. We can set them up. The only thing that you have to be careful of, and Jack and Dea know this already, is that you can't invoke a

forum.

So, if you have a subcommittee that has more than half -- at EPA, we consider a quorum to be 50 percent plus 1. So, if we have a subcommittee or workgroup of more than half the committee, you invoke the quorum and then it's a full meeting and we have to go through all of our meeting requirements.

Additional resources, there's the Federal Advisory Committee Act that you can look up. Our EPA website is full of information. Like, the ODACMO website is where most of this is kept. ODACMO stands for, as I said earlier, Diversity Advisory Committee Management and Outreach. That's the office that I work in. Really, the best source, if you have any questions, is to go through Jack or Dea. If they need additional resources, they'll contact me or other appropriate partners in the agency.

Again, I'd like to thank you all for serving. This is a great thing that you do, and the agency appreciates it. I'm available for any questions now or else I'll hang around a little bit, too, if you have any later. Any questions now?

Cynthia?

CYNTHIA: What's the difference between a subcommittee and a workgroup?

MR. McCLEARY: At EPA, a subcommittee has to go through the full membership cycle. So, we have to balance it and everything like that. A workgroup doesn't have to do that.

CYNTHIA: I see that, but how do you determine -- so, all of our small groups are workgroups?

MR. McCLEARY: Well, it depends. It depends largely on the DFO and how the DFO wants to manage that. Workgroups are usually for a limited purpose and a limited duration. So, you have a specific purpose. We need you to research this issue for the group to present at the next meeting. A subcommittee can be ongoing. So, if you wanted a subcommittee that dealt with a specific portion of what you do and it's going to continue on into the future, that's when you would invoke a subcommittee.

Other questions?

MR. HOUSENGER: Cheryl?

CHERYL: So, thank you for that. I'm really interested in understanding some of these definitions, as Cynthia was as well. I've served for five years now, so

I'm in my third term. I found this to be an excellent forum for broad discussion and different viewpoints. But I haven't found it to be a forum for a lot of consensus or full recommendations. We've had recommendations out of subcommittees that have sometimes been adopted. But this idea of consensus -- so, one of your slides said you should work towards consensus as much as possible.

At one point, Steve raised his hand and said you don't vote. This committee doesn't vote. So, how else do you reach consensus if we don't vote? What are the expectations and processes? Along those lines, if you're watching a whole lot of other FACA groups, are there some best practices from those groups that maybe we haven't used here?

MR. McCLEARY: Thank you to that question. This is a dialogue committee. This is EPA's only dialogue committee, so this is a little bit unique here. So, working towards consensus probably isn't as important in this group. What we're looking for from a dialogue committee like this is your discussion and this open exchange of ideas that occurs during the course of your meeting. So, that slide is part of my regular

presentation, but this group is a little bit unique as EPA's only dialogue committee.

Consensus is usually very important when you're working on a written report because a written report is providing advice to the administrator. We want to give her some very concise recommendation. That's hard to do if you don't reach consensus. But since you don't produce a written report here, it's through dialogue and consensus. As a result, it's not as important.

Dawn?

DAWN: Thank you. So, if a workgroup felt that they may want to transition into a subcommittee to continue or felt that they could have an ongoing extent beyond three years, what would be the process and limitations and benefits?

MR. McCLEARY: The process would be going through Jack and Dea and saying that we think this workgroup has a role far beyond this immediate cycle. We should consider turning it into a subcommittee. The benefit is that subcommittees are open to all the transparency requirements and openness requirements that the general committee is subject to.

The downside is it's a lot of work. You didn't see it necessarily, but when putting this group together, what Dea had to go through to get you all on board was impressive. It's a lot of work to make sure it's balanced, to make sure you have the top people on board. So, that's the downside of it.

MR. HOUSENGER: Ray?

RAY: Does FACA, as a law and its associated regulations, recognize a difference between an advisory committee and a dialogue committee?

MR. McCLEARY: No, it's not mentioned in FACA.

RAY: What is the difference?

MR. McCLEARY: Well, a dialogue committee is specifically for that, to dialogue for this exchange of ideas that's discussed.

RAY: If it's not recognized in FACA, there's not a difference. That's my contention. If you're going to ask us for advice, we give advice, whether it's a dialogue or an advisory committee, if we're operating under FACA.

MR. McCLEARY: Can you say that last part again?

RAY: If you're operating under FACA and it's associated regulations, and there's no difference recognized there, how can EPA create a difference between an advisory committee and a dialogue committee?

MR. McCLEARY: Well, we don't make that distinction. A dialogue committee is an advisory committee.

RAY: You have made that distinction here.

MR. McCLEARY: Well, perhaps I misstated it, then. But a dialogue committee is a Federal Advisory Committee. You are a charted Federal Advisory Committee of the EPA. Your charter is filed with congress. You are a Federal Advisory Committee. What we're asking you to do is dialogue as opposed to writing a report.

RAY: If EPA is going to represent the actions and activities of this committee as having done an issue by the Federal Advisory Committee, having run an issue past the pesticide program dialogue committee, unless it's been asked for a report or a formal recommendation of the committee, it cannot represent running it passed the committee either as agreement by the committee or lack of disagreement by the committee. If there's no

formal report, then just simply running it by the committee doesn’t imply any agreement or disagreement.

MR. McCLEARY: I would agree that there’s no implied agreement or disagreement. We’re asking for your dialogue.

RAY: Another question. You mentioned specifically that subcommittees must pass their recommendations through the full committee and cannot pass those on directly to the agency.

MR. McCLEARY: That’s correct, yes.

RAY: Is there any difference in how a workgroup handles recommendations or results that it comes up with?

MR. McCLEARY: No, it’s exactly the same. They would also have to pass any recommendations or advice that comes from them through the parent committee.

MR. HOUSENGER: Steven?

RICHARD: Me?

MR. HOUSENGER: Yes.

RICHARD: It’s Richard with the Ag Retail Association. I just had a question, and this is maybe for new members or current members. This goes back way

before my time or Jim Thrift from ARA. There was a spray drift working group, if you all recall that, going back a ways. They actually did issue a report. So, there was consensus with that workgroup. I believe it's part of the EPA archive.

So, if those reports are put together, there's a lot of time and effort put on that, what happens with those? Those are actually written reports that are put together. What happens with those recommendations or reports?

MR. McCLEARY: Would you like me to answer that?

RICHARD: Sure.

MR. McCLEARY: Okay. Several things happen with reports that are generated by Federal Advisory Committees here at EPA. Copies are sent to the Library of Congress. They require eight hard copies, even in this day and age of electronic submission. They require eight hard copies to be sent there. EPA's library also maintains these reports. Usually, the program office would have them printed and disseminated and sent out to their channels. So, they're maintained, they're kept,

they're archived. Those are written reports of this Federal Advisory Committee.

Now, I'll make a distinction that these are not work products of the EPA. You are not EPA employees, for the most part. Your reports are the work product of this committee. So, federal archiving and records requirements are usually not applied to those reports.

RICHARD: A follow up. So, it's not necessarily like the PPDC is approving those reports; those are just like part of the dialogue that you may review? Is that what part of that is?

MR. McCLEARY: That's absolutely right. The committee will approve it, but the program office will not approve it at all. This is advice that you're providing to EPA. EPA is not allowed to have undue influence by saying you've got to retract this or you have to add this or anything like that. If you're going to generate a report, it would be your work product.

RICHARD: Did you just say the PPDC would need to approve the work product?

MR. McCLEARY: That's right, yes. If it was a report generated by a workgroup of the PPDC, it would

have to be presented to the full board of the PPDC for approval before it could go any further.

RICHARD: So, there are some reports, then, that are approved by the PPDC for review by EPA?

MR. McCLEARY: If you generated them, then, correct, yes.

MR. HOUSENGER: We tend not to ask for them. But if the workgroups want to generate a report, then yes, it would be before the committee.

Dawn?

DAWN: If you don't mind, are those reports citable in any particular format?

MR. McCLEARY: Yes. They do get cited on occasion, especially the reports from our scientific committees who will be approving levels of chemicals and things like that. They often get cited in scientific journals. News agencies will often cite to them. I don't know that there's any specific format for doing that, but they can say, you know, according to this report by the PPDC, this is what they concluded. So, yes, they are cited. You will see citations to Federal Advisory Committee reports of EPA in many media.

MR. HOUSENGER: All right, if that's it, thank you, Jim. Thanks for the warning on the foul language. I'll refrain.

MS. MONELL: Thank you very much.

MR. HOUSENGER: Before we start with our next presentation, I think included in your packets is the new organizational chart. Since the last PPDC, we've named two new directors. One is Dana Vogel, who is the Health Effects Director. Do you want to stand up, Dana, so they can see you behind me? The other is Steve Knizner, who is the Antimicrobials Division Director.

So, I just wanted to introduce those to the committee.

MS. MONELL: While we're at it, I have another piece of information for you. This concerns the web address information. Either WWW or WWW2 will work for your searching purposes. If you enter WWW, the browser will show up as WWW2. The servers are being merged. There will be no impact on your ability to search, however. So, you can use either one, it will work fine.

MR. HOUSENGER: That's in theory. I use Google to get my things.

So, our next workgroup presentation is going to

be made by Jennifer McLain, and she's reporting on the 21st Century Toxicology Effort.

MS. McLAIN: Good morning. So, I'm going to talk about the toxicology for the 21st century new integrated testing strategies workgroup. I'm the chair of the workgroup. This workgroup has been around for quite some time. It was established in 2008.

So, I'm not going to go through the whole presentation you have in your packet. That's really so you can understand the details of the accomplishments of the workgroup over the years if you're interested in those details.

Mainly, it also goes on the slide which is the charter of the workgroup and give you some highlights of those accomplishments so that you can understand what the workgroup has done to meet this charter. Then, I'll talk a little bit about the recommendation of the workgroup as far as continuing on.

We had a discussion yesterday, and I think there are some folks here that are a part of our workgroup and also part of the PPDC committee. They might want to share some perspectives on that afterwards.

So, we have a very engaged and interested group of core members, probably about a dozen members who regularly come to our meetings, our teleconferences, or our face-to-face meetings. We have many more than that that are officially signed up for the workgroup, but there really has this dedicated core, and it's been great working with them.

The charter of the workgroup is to focus on communication and transition issues as EPA phases in new molecular and computational tools. We identified key transition activities being identifying other internal and external applications of this new science and providing process recommendations to transition to the new testing paradigm.

An important perspective to note is that this workgroup was set up right at the time of the National Academy of Sciences report on 21st century toxicology. EPA, in particular the pesticides program, was very interested in how we're going to be using this new science and how we can change the way we do things to improve the quality of our risk assessments and make our risk assessments and our testing program more efficient

and beneficial.

We set up this workgroup because it was a big change that we were contemplating, and we wanted to make sure that we were going through that change thoughtfully with the consideration of a multitude of perspectives that are represented in the workgroup.

So, as I said, I'm not going to go through each slide, but some of the things that the workgroup have done over the years, we started as a workgroup learning the aspects of the science that we were contemplating transitioning to. So, we had a lot of folks come in, EPA scientists from both Office of Pesticide Programs and Office of Research and Development, and sometimes from other agencies and groups to come and talk to the group about some aspect of emerging science.

The group itself put identified issues that either their group had or others had that they had heard in other contexts about primarily concerns with moving to new science. What would this mean? Where were the places of discomfort? Why were they there?

Using that, we hosted three different workshops on various aspects of 21st century science and the

transition that the pesticide program was making into its regulatory application. Two of those were broad on tools and their application of pesticide programs. One of them was specific to biomarker tools.

These perspectives that the workgroup has been discussing and that were brought forward in even greater detail in the workshops that we put together have been very helpful as EPA has, over the course of these years, been developing guidance and policies on how we're going to be incorporating specific tools into our program.

We've taken those perspectives into consideration as we've been putting together the policies, developing the documents, and making sure that we are touching upon those issues that we know are out there in the stakeholder community so that our program is fully explained.

We have two ongoing projects right now that the workgroup is still looking at. One of them is primarily now in OPP's hands. OPP is following up on a recommendation that came from our workgroup to this PPDC group, and then the PPDC group recommended to OPP, which is the establishment of metrics by the program for

advancing alternative approaches. That recommendation from the workgroup and the discussion in the workgroup I think has given our program a lot of energy and moving forward with that.

For example, we put out a guidance document for public comment last year on the process for evaluating alternative approaches. As someone mentioned earlier in one of the discussions, we're looking now at the acute testing and mapping out our goals for significantly advancing alternative approaches with respect to the acute testing.

The second project that's ongoing is on the biomonitoring tools that I mentioned or the focus of one of the workshops that the group did. This has been ongoing discussion in subgroup within our workgroup. Right now, the subgroup is developing a paper that is going to be outlining the need for more research in this area.

So, beyond those two pieces that we're working on, where are we now in 2015? Obviously, as a program, we feel there's never an end to communication. The objective of this workgroup was quite broad to begin

with. We always want to be engaging stakeholders and being transparent with changes and new ideas that our program is thinking about.

We're definitely as a program not in the same place now that we were in 2008. Science is definitely not in the same place. The science has been rapidly developing, and the acceptance of that science has been rapidly changing over the years since this workgroup was established. We've really transitioned to more of an implementation phase than we were when the workgroup was established.

I think we had pretty general agreement yesterday that the workgroup has accomplished its charter that it was initially set out to do. It would be a good time to sunset the workgroup. There were a number of different perspectives in the workgroup about whether there is a need for a new group to focus on the implementation of 21st century tools in the program. That is to carry on the communications with the stakeholders maybe to work on some specific aspect of the implementation.

There was also some discussion about the fact

that a lot of the work that we are doing in implementation we are doing in coordination with various stakeholders. It's happening through other venues. So, there's some perspectives that those other venues are serving that purpose right now, and that perhaps we don't need a workgroup under this PPDC to carry on that work or to provide additional input.

As I mentioned, from a program perspective, the communication is always paramount and will be regardless of whether there is a workgroup. We will certainly be coming to this PPDC group to be talking about where we're going, what advancements we've made. For example, if we're developing a new policy or guidance, we'll be coming to this group at some point to talk about what we've done, and why, and to hear your comments on those.

So, that's all I had for this summary. I know that a few folks from the workgroup wanted to share their ideas on the future. So, I think I'll hand it over to anyone who wants to speak on that point.

PAT: I guess I'll jump right in here. Pat Bishop with PITA. I think a lot of what Jennifer said, you know, there was agreement on. I don't think people

were completely ready to give up the workgroup, maybe just have it in a different forum or have a different charge.

We think because the implementation of tox 21 methods is kind of really building now, that there still may be a role for us. It may not be all of the same people that were originally on the group. There are, like Jennifer said, sort of a core group, but there's a lot of people listed that get the notices that never seem to participate. But I think there's people out there that we can draw upon if we maybe get some more of the right people in.

But I guess, from my perspective, we're interested in helping EPA in any way that we can for implementation of the alternative methods. Jack, I don't know if you want to talk about this later, but we had a stakeholder meeting a couple weeks ago to talk about some of the acute tox methods and eventual adoption of them or approval of them by EPA.

We talked about a few barriers that might come up to that adoption. So, I think there's some areas there that maybe we can help you with and figure out how

to try to get by some of these barriers or working on the international scale with Europe and some other countries that have already adopted some of these methods, how did they do it. The issues get into classification and labeling, things like that, which may be kind of sticking points. There may be some way we can help you guys with that.

But I think what a lot of people were saying is we need to hear from you as an agency too as to where you think we can help you the best, where can we provide input or advice or whatever to try to get by some of these issues.

I don't know if, Cheryl, you want to kick in there, too.

CHERYL: So, I had to exit for another meeting, but when I left the first meeting to go to the incidents meeting, I was hearing that we definitely had not let go of the workgroup, but wanted to refocus for sure. I just want to make sure one more time, Jennifer, to clarify, when you say the biomonitoring subgroup is working on a publication, we just had a big discussion about what's a PPDC workgroup product and what's not. That publication

can come from members, but it's not a PPDC workgroup product.

JENNIFER: Right. Yes, Cheryl, that is correct. I can't remember if you were in the room or not when we had that specific conversation, but that question was asked. It might have been you that asked it, I can't remember.

CHERYL: I think that's very important.

JENNIFER: Yes, it is.

CHERYL: I think the workgroup broke off into these different pieces and tackled a bunch of different things. Then, that biomonitoring piece took a couple of different twists and turns. You've got a lot of information, and there's some people that really want to put together a publication. But that publication can't come out of the workgroup; it needs to come from those authors.

JENNIFER: Right, right, yes. That was an accurate description of the conversation we had yesterday. Thanks for that clarification.

Aimee?

AMY: Hi. So, I have a couple questions

about this workgroup because I've been involved in various stages of it. I guess I'm concerned. One of the pieces that the migrant clinicians network has been very concerned about since the inception of this workgroup is that front line clinicians lack the clinical diagnostic tools to be able to determine with a test whether or not one of their patients is exposed to pesticides in helping with their diagnosis.

So, I guess I feel like that was actually looking back to the original objective of this workgroup. That was one of the very reasons we proposed this, because we still feel like there is this need. So, I know the science has changed, and we've come a long a way, but somehow this workgroup really got more into a lot of different things which, in part, still address that.

But the reason I think that there was folks working on a publication is that there's still this very important need that when pesticides are put on the market and people are exposed to them in their work or in their day-to-day lives, that clinicians still do not have a good way to understand those exposures.

So, it's sort of circling back, but I'm not

quite sure where the agency is going with this at this point in time. From 2008 to 2015, clinicians still don't have tools at their disposal to be able to help with the diagnosis. I think the publications are important because -- Jack, you can speak to that because I know that you're a part of it. The publication is coming out because there's still this need.

JENNIFER: Thanks, Amy. I think that's exactly where this subgroup who is working on the paper landed a way to get out the communication of the need for research on biomonitoring tools more broadly and in the science community.

MR. HOUSENGER: Sharon.

SHARON: Hi. I have not been involved with this working group. Just learning a little bit since this is my second PPDC meeting about the work. So, just kind of a question. In risk assessment, there's usually an evaluation of multiple lines of evidence at different levels of biological organization.

So, my question is about the transition which appears to be in place for some of the new traditional studies to move to new kinds of studies. I'm just

wondering what effect that might have or if the discussion has taken into account those multiple lines of evidence for the robustness of risk assessment through looking at interacting systems at the organismal level and at the ecosystem level.

JENNIFER: That's a pretty big question, but I guess I'll just basically say yes. The way OPP is doing this implementation basically is on an action-by-action basis. We're delving down deep into those questions as we make specific changes.

MR. HOUSENGER: Are you concerned that we would just use the non-animal tests and the results of that without considering all the other information out there?

SHARON: Well, sort of. Again, not fully understanding what the neutrals are, it's hard to know if that's really totally my concern. I'm looking at the concept of looking at different levels of biological organization and understanding the effects of pesticides at the molecular level, at a tissue level, at an organismal level, and at an ecosystem level, and wondering if the thrust of this workgroup, which is not new, is going to be able to adequately account for those

different levels with these new tools.

JENNIFER: The workgroup itself has been focused on identifying perspectives of concerns, such as the one you're raising. Are you going to be using a full set of information in your decision-making? So, EPA, when developing policies or determining to allow new tests to be used and the information that we're receiving that we're using in our risk assessments, we can ensure that we're taking those perspectives into consideration and understanding.

For this example, there's a concern that we wouldn't be using a full range of information as we integrate this new test or as we use this new method, and making sure that we're fully discussing that in our policy document that we're laying out.

MR. HOUSENGER: Ray.

RAY: I recognize that the biomonitoring question and the research question has been before the workgroup for several years. If a subgroup prepares a paper on the topic with the intent on providing advice to EPA on how it's conducted, mentions this workgroup as the source of its concern or efforts, if EPA has provided support

through the workgroup or any portion of that paper, it should come back to PPDC for review before publication and promulgation.

JENNIFER: Okay. We'll take that into consideration.

MR. HOUSENGER: I guess you listened to Jim.

Amy?

AMY: (Not on mic)

MR. HOUSENGER: Right. One of the things I've struggled with as we've talked about biomonitoring over the years is what is the specific need, what do the clinicians need, what are available to you now, are you using those tools, how effective are they, are you looking for something different. All those things is number one.

Number two, we're going to talk about two rules that are coming out, one that has already been passed that will help address this issue, but still recognizing that there is this need. I think the paper will hopefully answer those questions a little better than they've been answered in this group in the past. I'm still struggling with what is it specifically that you're

asking for. Getting that out and having some research done on it I think is a good job, but I think people need to know what they're shooting for.

UNIDENTIFIED FEMALE: (Not on mic).

MR. HOUSENGER: I guess one of the things I struggle with is if you have a test to say I've been exposed to a certain pesticide and if I've been out in the field, I might be exposed to a number of pesticides. Are you looking for a test that tells me that you've got enough exposure to cause an illness or that I've just been exposed? How does that influence your treatment?

UNIDENTIFIED FEMALE: (Not on mic)

GOEFF: I would agree that there are not a whole lot of tests available for clinicians to determine if a person is exposed. So, if such tests were available, you could compare the results of that test with the baseline, what you would expect in the normal population.

So, for example, the CDC, through the NHANES study, they measure pesticide metabolites or the parent compounds. So, if a clinician has a result on a patient, they could compare the results on that patient

with the population norms. So, if the result of the patient is elevated, that would be indication that the pesticide exposed patient was exposed to the pesticide acutely.

The issue is that a lot of these pesticides don't produce unique health effects, so they produce health effects that are common for other diseases. So, if you want to distinguish between like a flu or gastroenteritis versus a pesticide toxicity, it would be helpful to have that information to prove that the patient was overexposed to the pesticide.

I think that's especially important when you have a worker's compensation case. You're trying to prove to the worker's compensation insurance company that this person was made ill by the pesticide. If you can show that there's pesticide exposure information, biological information to prove that case, then that's going to make it more likely that the patient will get the worker's comp benefits, which is important since a lot of workers don't have health insurance and a lot of times just can't afford the healthcare associated with some of these exposures.

MR. HOUSENGER: Pat?

PAT: I just wanted to go back to Sharon's question a little bit. We were talking about the different levels of impact that are tested for. I saw that David Dix is going to be on later. The endocrine disruptor program is one of the areas where EPA has made a lot of progress in using some of these alternative methods, not only in vitro or molecular tests but computational, toxicology, and predictive models for both hazard effects and exposure. So, I'm hoping maybe he'll cover some of this stuff.

The way this whole tox 21 stuff is working is we're trying to develop what they call adverse outcome pathways where you can figure out what happens from exposure to effect at the molecular level, the cellular level, tissue level, population level, organ level, whatever.

So, there are ways to do this. I think that's one of the challenges of the transition between those kinds of methods and what we have now of testing specifically animals, getting some sort of black box result and trying to figure out what does that mean in

terms of the impact on an individual versus a population.

So, I'm hoping when David gives his talk, that will become a little bit more apparent as to how we might do this. The stuff we were talking about earlier with the Q tox testing where you're just looking at a lethal dose or an acute affect on an animal or if you put something on your skin, what is it going to do, we have ways to do that now, where we've done side by side comparisons of in vitro and in vivo data and showing that method works quite well for many classes of chemicals.

MR. HOUSENGER: We can get David to do that.

Cheryl, you're the last one, and you're between us and lunch. So, it better be good.

CHERYL: I want to come back to Amy's call for kits and tests. I've been part of this biomonitorng piece though I'm not on this paper, but I have been part of the biomonitoring subgroup at some point. I think some of this also comes back to scope, though, because this whole biomonitoring question took a number of twists and turns where we talked about in order to get a test or a kit at the clinician's office, you still have to go back through what's an appropriate biomarker, what's the toxicokinetics

what's the (inaudible) profile, is there a common metabolite, is it specific? So, when you made this broad call for pesticides, it gets really difficult and it's kind of a research area for any given pesticide or class of pesticide.

So, the PPDC workgroup really struggled with a couple of these aspects. How do you advance this? We went through the exercise of looking at basically some decision documents on the ADME that comes out of the registration process. Does that get you further?

We talked about the fact that Europe has these biomonitoring requirements for acutely toxic pesticides in blood and urine and could clinicians make use of that. It's not a kit, but there are methods out there. All of this went on and we went through the process of criteria for what you want to your point. There was not agreement. Do you want a criteria for like an epi biomarker long term, do you want it for an acute poisoning? All of these things swirled within the effort.

I think it kind of comes down to scope because there's scope for OPP of where they can regulate and

what's in their purview to ask for. There's also scope of what a workgroup of just a few people can do and discuss and tackle. So, I think that's why, after going through all of that, coming out with a paper from a certain perspective is probably a really good outcome. It's not reflective of the entire PPDC workgroup, but it's a good outcome, call for research. How do you address that further? I'm not sure.

MR. HOUSENGER: Did someone have something else to say?

RICHARD: Yes, Richard Gragg, if I could. I would just like to know first off, with the new toxicology paradigm, is there some strategy or objective to focus on specific pesticides as it relates to certain populations or certain health outcomes? Also, what is the time line that this transition and implementation is going to occur in where there will be some results that people can look at?

I'm not clear either on how this activity will tie into clinical research or clinical practice. It seems to me as it's outlined here, it's mostly basic science research that will link into regulatory decision

making, but I don't see it clearly linking into clinical practice.

JENNIFER: This is Jennifer. There are a number of different aspects to your question, so let me know if I don't capture them all. The time line has really been ongoing since the inception of this workgroup. It started basically before the workgroup was even established.

So, this change in science that has been happening globally and the workgroup's purpose was to help EPA adopt new science in a thoughtful way and ensure that as we integrate new science into our guidance and policies and methods of doing risk assessment that we are doing that with an understanding of the various perspectives of our stakeholders as well as staying true to the science.

The specific question about how is it appearing in a clinician's office I think is specific to the biomonitoring tools. So, as we've been discussing, the group has talked a lot about biomonitoring tools, in particular, the need for biomonitoring tools in a clinician's hands. The paper that the subgroups members

are currently working on, the intent of that paper is to outline that need case someone was talking about and basically put out to the science community the need for more research in this area to develop tools for clinicians.

So, the hope would be that with that paper, there would be interest to do that research. That ultimately would result in the development of tools that clinicians could use.

RICHARD: Is there a strategy or priority to focus when and how on vulnerable populations in terms of pesticide exposure and health outcomes with this in the context of this new research paradigm or toxicology paradigm?

JENNIFER: The basic tenets of our risk assessment in terms of looking at vulnerable subpopulations aren’t changed by integrating new science, new ways of getting information into those assessments. So, we will still be looking at vulnerable populations in our risk assessment.

RICHARD: Okay, thank you.

MR. HOUSENGER: All right, so it’s lunch time.

We have until 1:15. There's a restaurant across the street at the Renaissance. There's a little tiny place right up the road here on the right. There's a place to eat across from the Hyatt. If you want to walk, there's places down the road. So, just be back at 1:15, and we'll get started with worker protection standards. Thank you.

(A luncheon recess was taken.)

AFTERNOON SESSION

MR. HOUSENGER: Let's get started with our next session. You can tell it's the afternoon. People aren't as obedient as they were this morning. So, the next session is on the worker protection standard. I know that this is a long time coming. It was 20 years in the making, assuming that we started right when we issued the other one, which it seems like for some, I'm sure. It's a big rule. It's a complicated rule. It's a rule that there was not all consensus by all parties, as I'm sure we'll hear as we go on with this. But it's the rule that we have. So, now we're looking for ideas of outreach and implementation and how we can effectively get this rule out and implemented so it starts protecting workers that haven't necessarily been protected to this extent in the past.

So, I'm going to turn it over to Kevin Keaney and Nancy Fitz.

MR. KEANEY: I guess you are going to enthusiastically turn it over us. The agricultural worker protection regulation covers farms, forests, nurseries, and greenhouses where they have workers and

pesticide handlers. It places an obligation on the agricultural employer to be in compliance with the regulation.

As I said, it covers a great number of people. They're usually a challenge to reach and to train. There are a lot of challenges that we face. It's nothing, if not bureaucratic arrogance, to think that writing a regulation in this building is going to make it real in the field where it will matter. So, we look forward to engaging you as a group and engaging you as individuals to help us in communication, outreach communication, and implementation activities.

We do have a fairly extensive network in the state regulatory agencies and the state extension services and a number of grants that will help us with that. I think engaging with you, as I said, as a group and individually will benefit us and benefit the population.

MS. MONELL: We can't hear you.

MR. KEANEY: Anyway, engagement with us is going to be productive and ensure that we try to get the benefits to where it's appropriate and work with the

agricultural community to allow them to understand the regulation and to be in compliance with the regulation.

Nancy is going to give you an overview, and then we can discuss implementation strategies and methods.

MS. MONELL: Just before we do that, can the folks on the phone hear? Is anyone on the phone?

RICHARD: Richard Gragg.

MS. MONELL: Can you hear all right?

RICHARD: Yes, I can.

MS. MONELL: Great. Anyone else?

SUSAN: Marty, it’s Susan. I can hear fine.

MS. MONELL: It’s Susan who?

SUSAN: Susan Studlien, and I can hear fine.

MS. MONELL: Oh, good, Susan, thank you. Glad you could join us.

UNIDENTIFIED MALE: This is Valentin Sanchez. Can you guys hear me?

MS. MONELL: Yes, thank you.

MS. FITZ: I’m going to give a real quick overview of the WPS and highlight some of the key provisions in the final rule, and then talk about the

outline of our implementation and outreach program, and then leave a lot of time for discussion. So, I'm going to breeze through the slides. You've got the details. They'll be posted on the website. We can answer questions as they come up. So, that's the general plan here.

Kevin actually covered a lot of the overview, but just to make sure we're all on the same page, the worker protection standard, the responsibilities lie on the agricultural employers of crop-producing establishments. It's farms, forests, nurseries, and greenhouses, and commercial pesticide handling establishment employers.

The protections are provided for farmworkers, those who work in the field to harvest, cultivate, irrigate, actually doing the hand labor, pesticide handlers who are the applicators, mixers, and loaders of the pesticides, and there are protections for other persons during pesticide applications. So, the pesticides have to be applied in a manner so as not to contact workers or other persons. This is true for the current rule, and it's true for the revision. There's

nothing changed about that.

During the comment period, we received a lot of comments kind of questioning why we need WPS when all the protections are on the label. In a nutshell, the WPS is a way that some of those label protections are implemented.

So, for example, the restricted entry interval is the time that workers have to stay out of a treated area for the residues to decline to a safer level, but the workers don't actually have access to the labels. They're not the ones with the labels, so WPS provides a way for that information to get to the workers. Similarly, the labels identify what personal protective equipment has to be worn, but it doesn't say the employer has to provide that.

So, that's the function of WPS. So, that's sort of the relationship, the symbiotic relationship. Then, there's also a number of things like training and some of the requirements that apply to all pesticides. It's just more efficient to have it in one place. That's why we need both.

This slide lists the goals of the revised

worker protection standards. One of the key ones is to improve occupational protections for workers and handlers to provide comparable protections to those covered by workers and other industries by OSHA.

The second one is even though we think the current WPS has provided a lot of protections and improvements and the number of incidents have decreased from the estimates when the 92 rule was produced, there's still too many in our opinion, and we think many of those are preventable. So, we're still trying to reduce those acute exposures that cause workers and handlers to become ill and miss work.

The rule is reorganized and streamlined, so it's easier. We think this is going to make it easier to comply with. Just the way things are grouped and phrased, we think that's going to help people understand what's actually in the current rule as well as the new requirements.

And then to address areas of concern that have been raised through many years of discussions with stakeholders, including a PPDC group, the National Assessment, meetings with regulatory partners, and also

in comments. We received over 2,400 comments from all different types of commentors. We looked at them carefully. I know some people think we didn't address all of their concerns, all their comments. We probably didn't accept all of any single individual commentor's concerns, but looked at them all, tried to find what made sense. We did tweak a lot of things based on those comments.

A couple of the key points that are in the revised rules, we did keep and actually expanded the exemption for farm owners and their immediate families, family members, which there's about 500,000 farms that fit under this that are exempt from many of the WPS provisions. They still have to comply with some, so you can't say WPS exempts family farms. That's not the case. But farm owners and their immediate families do not have to comply with many of the protections in WPS.

We also delayed compliance dates to give Farmers, states and everybody a chance to get their heads around what the new requirements are. I'll talk about that in a little bit more detail, but most of the requirements will kick in 14 months from when the rule is

published, which should be any day now. Then there are a couple that kick in a year after that.

This is going to be the five minute version of some of the key requirements. Again, the details are there, but we want to focus on outreach and implementation. I'm going to just hit the highlights here.

So, pesticide safety training was an important component of the final rule. Probably the biggest changes there are changing it so workers and handlers have to be trained every year instead of every five years, just to reinforce the important information, how to protect themselves.

We expanded the training content to cover take home exposure and ways to reduce the exposure to farm workers and handlers at home and their families. We got rid of the grace period, so workers and handlers have to be trained before they go into work in an area that has been treated with pesticides or before handlers work with pesticides. That's kind of the quick version of training. We think it's important for people to know how to protect themselves and what they're dealing with.

Notification is how workers find out about the restricted entry intervals and when they can and cannot enter areas that have been treated. Currently, unless the label requires both, a notification can be given to workers orally. One of the things we changed was if the restricted entry interval is greater than 48 hours, the field has to be posted. If it's 48 hours or less, there's still that option to post or provide the information orally.

Another thing we tightened up a little bit was to make sure the people who are going into a treated area before that restricted entry interval is up, which we call early entry workers, make sure they have the proper personal protective equipment and all the information they need to protect themselves and to understand what their tasks are and how long they're allowed to be in that area.

For hazard communication, we did retain the requirement to post pesticide application records at a central location. We also added the requirement that the safety data sheets for those pesticides also have to be available at that central location so workers and

handlers have access to the information about what has been applied and then what the hazards are associated with those pesticides.

In addition to the requirement to keep those displayed at a central location for 30 days after the restricted entry interval has expired, which is what's in the current rule, the revisions also require that ag employers keep that information for an additional two years, so the application records and the safety data sheets.

Those are available from the display period for that whole time in certain ways. First, the worker and handler can request access to it or request copies of it either orally or through a written request. Treating medical personnel and people working under those treating medical personnel can also request it orally or written.

Then, lastly, the rule allows workers or handlers to have a designated representative to provide a written request to obtain copies of or access of that information. The designated representative has to be identified in writing by the worker or handler. There's

certain information that has to be provided, including when that person worked there and the specific information that's requested.

The final rule establishes a minimum age of 18 for handlers. Again, those are people who are mixing, loading, and applying the pesticides, and for early entry workers. So, people going in while the restricted entry interval -- before it has expired. So, there's no minimum age for workers who are going in to harvest or do work after that restricted entry interval has passed.

As it's listed on the slide, members of the owner's immediate family would not have to comply with this minimum age requirement. We also expanded the definition of immediate family to go beyond basically parent-child relationships. It also covered grandparents, grandchildren, in-laws, aunts, uncles, nephews, nieces, and first cousins. So, we have an expanded definition of immediate family.

Only a couple more and then we can get into the meat of this. For respirators, the final rule requires if respirators are required on labels, the handler employer has to ensure that the handlers comply with the

fit test requirements, medical evaluations, and training requirements that are in the OSHA regulations. Make sure that the respirators actually fit and do the job that they're supposed to be doing.

Lastly, there's a number of provisions in the WPS that try to prevent exposure to people during pesticide applications. The approach in the final rule was to define what we call an application exclusion zone, which is essentially a bubble around the application equipment, whether it's an airplane, a tractor, or a sprayer, whatever it is. What it comes down to is the agricultural employer has to keep people from not being near that application equipment. If somebody does happen to be near that application equipment, the applicator has to temporarily suspend application until that person moves.

So, there are a lot of details. It's 100 feet for some, and it's 25 feet for others. But what it comes down to, the approach we propose was that the entry restricted area would be all the way around the outside of the treated area. This is actually just around the application equipment because that's where the pesticide

is most likely to land. So, ag employers need to keep people out of that area, and handlers have to stop and temporarily suspend application if someone is in it.

So, I'll talk a little bit about the outreach and implementation. The rule was announced on September 28th. I think your handout says August 28th. That's my mistake. It just seems like it was that long ago. It will be published at some point, we think this month. So, the clock actually starts once it's actually published in the Federal Register.

For the sake of argument, let's say it's going to be October 25th. Then, there's a 60-day period. It's essentially a holding period before the rule becomes effective. So, that would take us to late December of this year. Most of the new requirements, compliances required with them, kick in a year after that. So, that would be December 2016. Up until December 2016, the current WPS requirements will be in place and will be enforced.

There are three requirements that we needed a little bit more extra time, and that's the display of some of the pesticide safety information, training on the

new contents, because it’s going to take us a while to get the training materials available and get everybody up to speed on that. And then, the requirement for handlers to suspend application if somebody is in that application exclusion zone, we needed to make sure that there was a whole training cycle for handlers before that one kicked in. So, that’s the reason for those being extended a little bit.

We know there’s a long list of materials. We started some. Some are available and others we need to develop. We have fact sheets and a standard presentation. There’s a number of different comparison tables. There’s a short one, if you call five pages short, on the website.

We have a longer version that includes the current requirement, the proposed requirement, and the final requirement. Even this only focuses on the key requirements. So, we’re working on one that is completely comprehensive and covers everything.

We know there are areas where we’re going to have to provide more detail, like things on the respirator requirements. That’s a new area for a lot of

people, so that's something we need to provide information so growers know how to comply. How do I do this medical evaluation? How do I do a fit test? Who can I contact? The information is out there. We just need to provide it for them.

The application exclusion zone, that's a new idea. Those types of areas we know we're going to have to have separate individual fact sheets or presentations and ways to get that information out. We do plan to revise the How to Comply Manual. That was a big comment from states and industry. It's probably not going to be a 100 page paper document again. We're going to try to figure out how to make it more useable. We're open for ideas on that. Then, hopefully at the end here we'd love to get your ideas about what educational materials you see a need for as we move forward.

In addition to the educational materials, there's a lot of work being done to get us set for compliance and enforcement, including some of the internal implementation guidance for inspectors, questions and answers. If you've been involved with WPS for a while, you know there's a long list of interpretive

questions and answers. We need to update that for the new rule, as well as I'm sure there will be new questions that we'll add to that list.

The last time, in 92, we had issued inspector pocket guidance. That's probably going to be inspector smartphone guidance now, but we need to figure out what that is, what that looks like, and what people are going to need to have access to while they're out in the field.

We mentioned the need to update the training materials for both workers and handlers to make sure we incorporate the new content. Some of that we'll be doing ourselves. Outside groups can also develop that, but it does have to go through an EPA approval process. That's something else we'll be working on.

In terms of training, our focus at the beginning here has been to try to focus on the regions, EPA regions, and the states. We have a three-day training course in two weeks for the regions. Then there's a state PREP course the first week in December.

We're trying to develop a pretty large body of people who have a good understanding of the rules so when there are requests for presentations -- there's only a

handful of us. So, we can't be in all 50 states all the time. So, we're trying to make sure that there's a lot of people who understand the rule.

The other group that we're going to hit soon, and Wayne, I guess this is a heads up for you, are the pesticide safety educators, because we know we're going into the big training season. You guys need to know what's going on. Like I said, we're almost done with that standard Power Point presentation with talking points. So, if you kind of heard the overview, you should be able to go ahead and give that presentation.

So, this is an area where we'd love to get your input. We need help reaching growers, commercial handler employers, and other people who actually have to comply. So, we're reaching out through the channels we have, again, states, regions. Hopefully, we'll get a lot of ideas here.

We do think the best way to explain this rule to somebody is face to face so they have somebody they feel like they can call if they have questions. So, we need a mechanism to find out about good meetings to attend, opportunities to spread the word on this.

Hopefully, you guys can help on that with all of your networks.

We also plan to do a number of webinars, both overview and sort of specific topics in detail. Those aren't quite as good as the face to face, but it will do in a pinch. Again, we're open to ideas about how best to do that. Should we do them every couple weeks, do one and put it on the web in a recorded version? If you have ideas on that, we'd love to hear them.

I just want to give an example of working with the regulated community. We talked with the Ag Retailers Association on Friday about combining/coordinating on a tri-fold brochure that they would get to their members to distribute to their customers, and also maybe having some sort of ongoing conversation about what outreach materials are useful and is there a way to sort of consolidate meeting opportunities. So, just throwing that out there as a starting point for some ideas.

So, these are some questions that I posed throughout. So, what outreach materials are there? How can you help us reach growers? Any ideas on how to run the webinars? What opportunities do you see for us to

partner with you to help get the word out?

So, that's what I've got. Questions? Comments?

VALENTIN: If I could speak.

MS. MONELL: Did someone on the phone try to make a comment?

VALENTIN: Yes. This is Valentin Sanchez.

MS. MONELL: I'm sorry, it's very difficult to hear you. Can you speak closer to your microphone?

VALENTIN: Yes, this is Valentin Sanchez with the Oregon Law Center. Can you hear me now?

MS. MONELL: Yes, that's better.

VALENTIN: Okay, sounds good. First of all, I want to thank EPA. I recently had a meeting with a group of farmworkers who say thank you, thank you. In the span of 20 years of the current WPS existence, we still have some farmworkers who are still unfamiliar with WPS. Also, enforcement is another big issue.

But one thing I wanted to mention is that it may be a great idea, and this is just a thought I'm putting on the table, to perhaps have a workgroup looking to WPS implementation and outreach, because I don't think in 15

or 20 minutes we'll be able to talk extensively about how it needs to be done.

There's another thing that I'd like you to have in mind. We have a lot of minority farmers and also farmworker contractors and most of the contractors assuming they speak Spanish. So, those are some of the things that we should in mind.

One question I have is, I just want to know more about how much money has been allocated for outreach and implementation.

MS. MONELL: Actually, a significant amount. In addition to the PRIA set aside for worker protection activities that are being used -- and Kevin and his folks can give you more particulars. But, as you probably are aware, though, those monies have been used to fund specific activities around worker protection and now obviously the focus will be adjusted to include implementation of the new standard, or revised standard.

In addition to that, though, the agency, the AA-ship is committed to the implementation of this rule making. It's one of the more important rule makings that this administration has undertaken. So, we have

allocated thus far almost $3 million in appropriated funds to help support the implementation activities, one of which I should note is geared towards Spanish translation of materials.

MR. KEANEY: I can put together a list of all of the things that are being funded and what the intent would be of them and send it through the network here.

MS. MONELL: That would be great.

MR. KEANEY: Did we hear you wanted to establish a workgroup out of PPDC?

MS. MONELL: That's what Valentin was suggesting, I think.

MR. HOUSENGER: Andy?

ANDY: Since this is a final rule, I won't point out all of the things. I think what's more important from EPA's standpoint with the training materials, don't focus so much on what as how. In other words, whoever normally writes guidance for EPA, don't let them do it.

Write it in a way that is easily distributed and transmitted to the people who are going to use it. Know your audience when you write this because it is

going to be extremely -- it's a huge deviation from what we have done in the past, and it's going to be a transition for these people to understand that. Work with the state lead agencies a lot. However many webinars you have planned, double it. They are going to need a lot of help.

I've talked to several lead agencies. Just write it where it's very clear, it's very plain, everybody understands exactly what they're supposed to do and what their obligations are. We'll transition much more smoothly. Write it, take it out in the street, pull some guy off the street and let him read it. If he doesn't understand it, you probably need to work on it some more. I think that is one of the biggest problems that we have, being able to translate things out of this office to our membership. Thank you.

MR. HOUSENGER: Thanks. I'm surprised our guidance isn't always clear.

Cynthia?

CYNTHIA: You mentioned translation of some of the materials into Spanish, and it's great. I'm just wondering what are the requirements for languages for

worker notifications. For example, when there's a restricted entry interval, are there certain requirements?

MS. FITZ: The notification has to be provided in a manner that the worker can understand. So, that generally means there's somebody there that can translate for them. Similarly, the training has to be provided in a manner that the workers and handlers can understand. Currently, we have the worker training information in probably 15 to 20 languages. That's not going to happen in 12 months, but we'll get a couple out and then keep working to add the relevant languages.

MR. HOUSENGER: Richard?

RICHARD: Thank you. As Nancy said, we look forward to trying to work with you all on clear and plain language to make it easier for our members to understand and their farmer customers. That's going to be kind of critical, as was mentioned. I mean, the rule is final.

We still have some angst with some of the cost estimates and things, but it is what it is at this point. We want to make sure our members are aware of it, the farmer customers are aware of the regulations, and make

sure they're complying with those regulations. So, again, having the industry involved and just folks that aren't necessarily lawyers. I am a lawyer, but clear and simple terms will be kind of critical.

I did want to get some clarification, and maybe some of that was in the slides that Nancy had about potential problem areas implementing the regulations and then a question on the training schedule. One is maybe a little bit better explanation about the designated representative, exactly how that's going to work with the regulations, and also the criteria qualifications for the fit test of respirators. Those are two things that maybe will be flushed out by EPA for explanations.

On the training side of things, I was just asking if that training is for EPA officials for outreach compliance or on enforcement side. Are those combined trainings or how is that actually internally with the EPA and the training sessions you're looking for externally with industry? Since they're kind of in alignment and on the same page, are those going to be similar training sessions?

One is a little different because you're on

enforcement, but the basic premise of what you're trying to comply with are the same. So, making sure there's apples to apples understanding from the enforcement arm and the industry side of things we think will be very critical because that has not always occurred in other regulations in the past.

MS. FITZ: We realize the designated representative and respirators are areas where we're going to have to -- those are on our list for needing some clearer explanation and guidance.

In terms of the training, right now we're focusing on trying to make sure everybody understands the rule. For example, the regional training, there's a program and an enforcement person from each region. The first course with the states is, again, focusing on content with some discussion about outreach education and compliance and enforcement.

Then, in the late spring there will be a more detailed inspector training, again focusing on covering the content but also how are the inspections going to be done, what are the tricky parts with some of these new requirements, what are they going to look for for the

respirator requirements, things like that.

I agree with you that I think the same information that we go over with the states and regions should be gone over with industry to make sure everybody is on the same page. With the container containment rule, we shared the check lists with anybody who wanted them. So, I think the best thing for people who have to comply is to know what they have to do and what's going to be looked for. So, we'll push for that.

RICHARD: I'll just say, that model, because you helped drive that, the container containment rules helped a lot with the implementation of it. So, if you follow closely to that model, I think you'll be in good steps.

MR. KEANEY: So, in effect, you're saying Nancy is suffering now for her past performances.

MR. HOUSENGER: Louis?

LOUIS: Thank you. I think that's a wonderful report. I like the direction and where it's going. I had some questions on enforcement, which Richard has actually covered. I think that's an important aspect of everything you're setting in place, because if you don't

enforce it or it cannot be enforced, it’s almost an exercise in futility).

There’s one more thing I was wondering about. On one of your slides, you showed that training is going to be now every year from every five years. I wonder what instructed that, because I think it’s really -- well, I’ll let you tell me because every year for training it looks like too much, in my opinion, especially if there’s no guarantee there’s going to be something new to learn every year. Why don’t you tell us what instructed you to do that. Then, is there a fee associated with that training? That’s the other thing that I’d like to find out.

MR. KEANEY: Well, the training primarily is basic safety principles. We know that there’s a heavy turnover in the work force. We also worked on the basic premise that if you’re hiring someone to work in areas that might present hazards, they should know the nature of the hazards and how to protect themselves. So, I mean, all of those things drove us away from a multi-year cycle to you hire someone, you bring him in, you put him through some sort of your hired process. Part of that is

a fairly short insight into what you might be facing on the job and how you can better protect yourself.

LOUIS: Is there any fee for that?

MR. KEANEY: Any what?

LOUIS: Any fee? Is there any charge for the training?

MS. FITZ: So, this can be done on the farm, so you can do it -- the people who can do the training are certified applicators, people designated as trainers by the state, EPA or the tribe, or people who have gone through a train the trainer program. So, if you have a certified applicator on your establishment, you used EPA approved training material, which could be a video that’s developed, you can do that in house, essentially. So, there’s a cost in terms of the time spent, but it shouldn’t be $50 per worker.

MR. KEANEY: One of our grants that I’ll be telling you about is the Association of Farmer Opportunity Programs. It’s a national network. They are a network of safety trainers that are providing free safety training to comply with this regulation.

MR. HOUSENGER: Wayne?

WAYNE: Thank you, Nancy and Kevin, for being here, and congratulations for getting this close to the finish line. One thing that I would suggest is if Kevin can give you the afternoon free to video tape or perhaps put this onto a webinar format, it would be great. The information that could be submitted or sent out to extension typically doesn't get read. But every agent eats lunch in his office. So, this would be a great lunch and learn kind of thing. So, I would suggest just saying it the way you just said it and having it available that we could send out.

MS. FITZ: If we're going to record it, that's going to be Richard. He's knows it way better, but that's a good idea.

MR. HOUSENGER: Eric?

ERIC: On the enforcement side of things, we all use these things more and more, so I agree with the smartphone end of things. But don't not print the pocket guides because if you're out in the bright sunlight, you can't see these things, if you have battery problems. There's a whole host of things.

MS. FITZ: Good information and very consistent

with what we're hearing from other people. There's still a need for paper, which actually makes me feel better. I'm not that much of a dinosaur.

MR. HOUSENGER: Dawn?

DAWN: I think Wayne's reading my notes. I just want to put that on the record. I obviously rely heavily on your current network of CE providers. Consider having a session at the IPM symposium in 2018. There is a new initiative there to engage practitioners. They may end up being more your training of the trainers rather than your (inaudible).

Engage with the tribal pesticide program committee as well as IHS. Video, video, video, video, video, not just for your train the trainers and your lunch and learn, which I love that idea, but also gets around the whole literacy challenges. So, I would really encourage you to invest in that. Special training initiatives for territories and migrant worker teams.

I also had suggested webinars, mobile web pages rather than apps, which are platform specific, and definitely want a pocket guide.

MR. HOUSENGER: Gabriele?

GABRIELE: My comment about outreach is about a much bigger concept of outreach. Looking at the press release that came out announcing this rule -- and Gina McCarthy was out in California yesterday and did another press conference out in the field. We got a call at 7 p.m. East Coast time Tuesday could we send someone to be a back drop.

I have to admit, and I'm going to be very blunt here, I'm not politic-ish. I can't figure out how you are letting your boss say what she's saying about worker protection, because it makes it sound like OPP has been doing nothing for the last 20 years. That is not fair to all the work you guys have been doing, whether it's on the education side, the enforcement side, in individual pesticide registration and registration reviews, the number of decisions you've made where you've either said, look, we cannot make a safety finding or we need additional protective equipment.

So, I just want to say from my perspective, we have absolutely this whole outreach aspect. I think in California we may have somewhat easier systems in place to make that more viable. So, I'm less worried about it

for us in California. I also want to say the outreach in terms of the media and the way your bosses are talking about this I don't think is fair to what OPP's work has been.

MR. HOUSENGER: I'm not going to touch that one. I know when I took this job, I claimed a lot of stuff, too. But thank you.

Ray?

RAY: Several questions, minor and major. In the proposed rule, there is a lot of controversy about what we claimed were low estimates of the cost to the agricultural community. In the final rule, those estimates have changed. How and when will the analysis that change those estimates be made available so that they can be independently verified?

I mean, there was a great deal of effort gone into challenging the original estimates. I assume you've gone through a very rigorous process in revising those. Are you going to make available your background analyses?

MS. FITZ: The economic analysis and everything will be available in the docket as soon as it's published in the Federal Register. So, that's in the next few

weeks.

RAY: Okay. You mentioned changes to the definition of immediate family for specific purposes within the rule. Do those definitions now correspond to other definitions of immediate family used in other regulatory programs, even outside of EPA?

MS. FITZ: Actually, the definition of immediate family in WPS is broader than other definitions of immediate family in other regulations. It doesn't match up exactly with how USDA defines family farm, but family farm is a little different than owner of a farm in the immediate family. So, I think the revised definition is a little closer, but it's not exactly the same.

RAY: The training materials that have yet to be developed, there's a lot of relevant expertise among various stakeholder groups, including NASDA, state lead agencies, our industry, the crop protection industry. How will the agency involve those stakeholders in developing the materials?

MR. KEANEY: We intend to form workgroups from the variety of stakeholders to work with us on those. It's not going to be done independent of those people

that already have good experience.

RAY: Is that going to be done through some extension of PPDC?

MR. KEANEY: It could be done through extension of PPDC, or one of our cooperative agreements could manage that activity.

RAY: Okay, getting closer. You mentioned $3 million for the training for budget. Over what period of time is that? Is that one year or five years?

MS. MONELL: It’s over a five-year period. Most of these cooperative agreements are for five years.

RAY: That’s still a relative pittance regarding --

MS. MONELL: Well, it’s a three-year up front commitment for the first year of funding. And then, depending upon funds availability -- as you know, our appropriation has swung widely in the last couple of years. So, it depends upon -- all cooperative agreements and grants are funded for the first year at a set amount. Thereafter, the hope is that it will be the same amount, but it depends upon available funding.

RAY: There’s been a group from the crop

protection industry which is putting a significant amount into the training efforts. I assume you're coordinating with that group on how this is accomplished?

MS. MONELL: On how what is accomplished? On how the training is accomplished?

RAY: Yes, developing the training materials and proceeding with the training.

MS. MONELL: Well, I think, as Kevin indicated, the intention is to have stakeholder involvement in some sort of a workgroup to help with the development of those relevant materials.

RAY: And the last question, the final rule hasn't been published yet. On the website, there's, I guess, sort of a disclaimer about this isn't yet final until it actually appears in the Federal Register. There's a bit of confusion there about whether any wording change might happen?

MS. FITZ: Not intentionally. I mean, it's a 300 page document and it has to go through some process. So, the point of that is that that's what we sent forward to be published. There might be some spaces and numbering fixes and things like that, but that's the

content of the final rule. I think that's just a CYA. It's not official until it's published in the Federal Register.

RAY: Okay, thanks.

MR. HOUSENGER: Amy?

AMY: So, first of all, I just want to say thank you to the EPA for getting this out and that the process was long, but you did indeed engage stakeholders. My first stakeholder meeting I went to was 14-1/2 years ago, but who's counting. Anyway, we're really pleased that it's out there and it's really an important step in the right direction for the protection of farmworkers and their families.

It feels like a lot of your initial focus right now is getting the word out to the folks that are going to be responsible for doing much of the protecting in terms of who is going to provide the training, who is going to provide the PPE, who is going to do the record keeping. So, I think you're asking the right questions in terms of how do we get it out there, who are the stakeholders. So, I would encourage you to carry on in that direction.

I am not seeing much up there in your questioning about sort of the worker piece of this and how the information is going -- what kind of guarantees we're going to have in terms of the type of information, the literacy level, the content, the different types of populations from Spanish speakers to people who speak indigenous languages, and how all of that would work.

I encourage you to seek a broad spectrum of stakeholders in conversations about the materials that will be needed for workers. I do think that goes to some of what Valentin was saying and what's being proposed in terms of the enormity of this particular standard.

It's not at all over. We are turning our attention to implementation and enforcement. I encourage you to really maintain some kind of workgroup that you can bounce ideas off of and get input specific to this regulation because of its importance.

MR. HOUSENGER: Virginia?

VIRGINIA: Thanks. I also wanted to congratulate you on getting a final rule out. As someone who has been engaged on getting this rule out for many years, I'm looking forward to the next phase.

I wanted to echo some of what has already been proposed. Valentin had mentioned reaching out to minority farmers, farm labor contractors. That's very important. Groups who interact with many of the workers first hand should be providing the training.

It's important to remember some of the minority communities among the farmworker population as well, indigenous language speakers, Haitians, to name a few. Working closely with community based organizations that work with farmworkers would be key to making sure that that information is disseminated in a manner that workers will understand.

In addition to the training that you will be developing under the cooperative agreement, I think it's also important to have resources available to approve training materials from other organizations, institutions, perhaps to address some of these other languages that are needed.

I wanted to also remind you to remember workers who are coming to the United States on foreign work visas who also should be receiving the training. They come from a variety of different countries. Don't forget use

of technology to disseminate information. Many farmworkers do have access to smartphone technology, text messaging. That's very important.

Finally, I just wanted to agree that I think it would be a good idea to establish a workgroup within the PPDC to address the implementation, outreach, and enforcement issues. Thank you.

MR. HOUSENGER: Steven?

STEVEN: I kind of have an out in left field question. I need a very short history lesson on why this is a federal thing instead of letting the individual states write their own worker protection standards?

MR. KEANEY: Well, there is the Fair Labor Standards Act, which has omitted coverage of farmworkers and service industries. There is a need for consistency establishing a particular bar of protection that is a national need. It's good public policy, it's good health policy. Ultimately, it's good agricultural policy to protect workers and to protect pesticide handlers at a national level. Of course, that was the standard, to protect the workers.

STEVEN: Jack, I have a follow up question.

I'm not trying to make equal weight here, but I see similarities between pollinator protection, workers protections. So, would the reasons for a worker protection standard nationwide not be valid for a pollinator protection standard nationwide? Do you see any validity to that argument?

MR. HOUSENGER: That we protect the bees as much as we protect the people?

STEVEN: No, that we have a federal policy to protect bees.

MR. HOUSENGER: Well, I think on pollinators, we're moving in a direction to get a policy in place that will deal with the situation. Whether we need something like a worker protection standard for pollinators, I would hope that we don't have to get there. I would hope that some of the measures that we're putting in place make that happen, recognizing that the pollinator situation is caused by a number of stressors not just pesticides.

Louis?

LOUIS: I have what's really a general sort of question, and anybody in the group can answer it. I was

just wondering, what was in the imagination when you started talking about farmworker or pesticide applicator or producer, because that obviously guided you as you went along?

The reason I ask this is because most of the time when this process is taking place, the image that a lot of folks have is the image of a commercial farm, a commercial producer. So, the point I'm getting at is, did the image of a small producer, a small grower, factor into these decisions?

This is important because as I go around visiting farmers, I find a lot of small growers who are in complete violation of worker protections, of NPBs (phonetic) for themselves. So, this is a group that needs attention. Maybe it's a little different in the northwest where I think there's a lot more close interaction with small growers, but that's a group of producers that need to be put on the table. They need to be brought into the picture when you're developing these processes.

So, what was that image that went through your minds as you were going through this?

MR. KEANEY: Well, the image we had was the

full range of stakeholders, the full range of agricultural employment that exists. We did consider small farms. We did realize that the larger operations are much more capable in having safety trainers and safety programs.

Frankly, I think over the span from the 92 regulation to now, we've probably been not as aggressive in trying to reach down to those farms that you're speaking about and those farmers. It's something we'd certainly like to correct. It's not something that's a one-time exercise, obviously. We'll go through this process that brings things into full implementation and compliance in the field, but there's an ongoing need for pretty aggressive communication through the whole range of agricultural employers.

I agree with you that the small farms are likely to be left out of the basic meetings and venues in which this information can be shared.

MR. HOUSENGER: Okay, Nichelle, you're the last one.

NICHELLE: I just have one quick comment I didn't hear raised in the discussion today. That is to

one of the questions in the slide that's asking for what other outreach materials are needed. Just my suggestion, some type of educational material for the farmer to educate them on minimizing tracking pesticide residues from the field into the home. I think that would be very useful because, as you see, inside the home is also a considerable source of pesticide exposure, not only for them but for their families as well.

MR. HOUSENGER: Okay.

RICHARD: This is Richard Gragg. I have one question or statement. I didn't hear anything in the presentation as far as -- I saw the zones, protection zones, but I didn't hear anything mentioned about pesticide drift.

MS. FITZ: The application exclusion zones, there are a number of requirements already in the WPS, particularly the statement on labels and the requirement for handlers to apply the pesticides in a manner that will not contact any worker or other person either directly or through drift. So, that's actually already covered.

RICHARD: Okay.

MS. FITZ: So, the requirement for handlers or the applicators to suspend the application if somebody is near the application equipment is sort of built to strengthen that and give them something very specific that they can do to accomplish the do not contact requirement.

RICHARD: Okay, and just one other thing as it relates to our previous conversation in toxicology. It seems to me that this stakeholder group could be a good group for testing in terms of exposure effects which would help with the toxicology testing paradigm but also in evaluating the strategy and effectiveness of the worker training and outreach.

MS. MONELL: Is this Richard Gragg speaking?

RICHARD: Yes.

MS. MONELL: Thank you.

MR. HOUSENGER: So, I've neglected the members on the phone. Are there any other comments from members on the phone?

JEANNIE: Yes, this is Jeannie from the Farmworker Association of Florida. Can you hear me?

MR. HOUSENGER: Barely.

JEANNIE: Oh, okay. This is Jeannie from the Farmworker Association of Florida in Apopca. I just want to say a couple of things. In Florida, we have both large producers and small producers.

MR. HOUSENGER: Excuse me, Jeannie who?

JEANNIE: Jeannie from the Farmworker Association of Florida.

MS. MONELL: Are you a PPDC member, Jeannie?

JEANNIE: No.

MS. MONELL: Well, then, you will have an opportunity to make comments during the public comment period. This particular time is restricted to PPDC members only. So, those are part of the official rules.

JEANNIE: Okay, thank you.

MR. HOUSENGER: Okay. It’s time for part two, which is certification and training. Kevin is remaining. Michelle Arling is replacing Nancy.

MR. KEANEY: There’s the certification regulation for pesticide applicators of restricted use that’s out for public comment. The comment period ends the 23rd of next month. This is a regulation that is the same vintage as EPA.

This regulation came into effect when EPA, USDA retook the pesticide program to oversee it. It deals with establishing competency standards for the applicators of restricted use pesticides, more toxic pesticides. It establishes competency standards and then certification of these applicators who are required to have that in order to purchase and use restricted use pesticides.

So, it's something of a companion with the worker regulation, because under this regulation, certified applicators can supervise others to apply pesticides. Very often, in the agricultural setting, those being supervised are the handlers that are covered by the agricultural worker protection. There's a certain degree of overlap in the labor segment relative to this regulation.

So, as I said, it's out for comment. We'd give you an overview and again engage in discussions of implementation and some guidance as to how productively to comment. Michelle Arling and my staff will do that.

MS. ARLING: Let me know if you can't hear me because I have a gentler voice than Nancy, I think.

So, I'm going to do a brief overview of the current certification rule and then go over the proposed changes and then the guidance we're giving for commenting.

So, the certification rule, as Kevin mentioned, has been in place since the 1970s. It establishes requirements for determining competency of applicators of restricted use pesticides, and it also sets standards for states, tribes, and federal agencies to administer their own certification programs for applicators in their jurisdiction.

It covers private applicators who are those applying RUPs on their own land in agricultural production, commercial applicators who are applying RUPs for hire, and then those using restricted use pesticides under the supervision of a certified applicator who don't themselves have to be certified.

There's about a million certified applicators currently across the US and an unknown number of uncertified applicators. I just talked a little bit about applicator classification. Again, here are the numbers and a better description of the types of

applications they conduct.

The program is administered by states, tribes, and territories. FIFRA, which is our enabling statute, authorizes states, tribes, and territories to certify applicators under a certification plan that has to be submitted to and approved by EPA. These certification plans have to meet or exceed the federal standards. Since we haven't revised our regulation since the 70s, a lot of states have gone forward to strengthen their requirements for certification well beyond our federal standards.

Every state, as well as three territories, four tribes, and four federal agencies, have certification plans in place for applicators in their jurisdiction. Because of a number of factors, a lot of states have programs that are stronger than ours, but all the state programs aren't comparable. So, it's not like they're all stronger in the same areas or the same ways.

Some examples of state variance include additional categories of certification and subcategories, certification periods, and what's required to recertify, and then requirements for those using pesticides under

the supervision of a certified applicator.

So, with all of this in mind, we are moving forward with proposing changes to the rule. Two big reasons for this are, as Nancy mentioned, there are avoidable incidents that continue to occur, and they occur in the applicator community as well as to agricultural workers. Then there's the negative environmental impact of RUPs that aren't applied properly and can cause very severe harm.

So, these three primary goals we talk about in the proposal for these revisions. The first is to reduce adverse effects from avoidable pesticide exposure, to ensure that applicators are meeting the level of competency that we're assuming when we register a pesticide as an RUP, and then to encourage reciprocity between states to reduce the burden on applicators and state certification programs. As I mentioned, each state can administer its own certification program, but applicators may be certified in more than one state and be subject to more than one state's requirements.

So, the first area of change is private applicator initial certification. This is an area where

states are much more stringent. So, our current federal rule has a requirement for private applicators to attend the training, pass a written exam, or demonstrate competency through some mechanism that the state determines as adequate. It also has a mechanism to allow nonreaders to be certified.

The current standard federal rules cover five points, recognizing common pests to be controlled, reading and understanding the labeling, applying pesticides in accordance to the labeling, recognizing local environmental concerns to avoid contamination, and recognizing pesticide poisonings and symptoms and procedures in case of an accident. That’s all that you need to know under the federal rule to be certified to use an RUP.

So, we’re proposing to strengthen those requirements to be more detailed and to incorporate more agricultural pest management information and to provide more information on regulations relevant to these applicators, such as the worker protection standard.

We’re also proposing to strengthen the ways

that private applicators can be certified to require either that they have to pass a written exam or take a training that covers these detailed competency standards. The last thing we were talking about is eliminating the mechanism that allows nonreaders to be certified. So, we'd like to require that those who are using RUPs can read the labeling of the products that they're using.

The next area that we're talking about is adding something we're calling application method specific categories. So, there's no standard in the current rule that we're updating. This would be a new area of the rule.

For high risk application methods, such as aerial application, soil fumigation, and non-soil fumigation, we're proposing that applicators be certified specifically to use these application methods to ensure that these applications are performed properly because they have a higher risk of harming applicator by-standards in the environment.

The next area that we're talking about changing is the administration of certification exams and training for initial and recertification. The current rule has

limited information about this. It just requires that commercial applicator certification be based on a written exam.

In 2006, EPA issued a policy requiring that certification exams be closed book and proctored, but that hasn't been incorporated in the current regulation. So, we're proposing to require that exams for certification or recertification, if offered, are written and closed book and proctored, and to require that candidates present identification for initial and recertification courses to ensure that the person who is registered and will obtain the license is the person that they say they are.

We've gotten a lot of questions about what closed book means. It doesn't mean you can't use any resources; use only resources provided by the test administrator. So, if they wanted to provide a pest identification guide, that would be acceptable. But people taking the exam couldn't bring in their own study materials or notepaper or things that they could leave with a copy of the exam.

A big area where reporting changes is related

to recertification, the current rule has a very limited section on recertification, and it's under the state plan administration portion of the rule. It just requires that states have a process in place to assure continued competency of applicators. There's no time frame, there's no requirements for what would qualify as recertification.

So, looking across state programs and looking across other types of recertification programs, we developed a proposal to establish a three-year certification period to allow recertification either by taking an exam or by earning continuing education credits and when laying out the kinds and the amount of continuing education that each type of applicator would have to earn.

So, commercial applicators would need to earn six hours of training for core, which is the basic pesticide safety principles that apply across all certification categories, and six hours of training for each category in which they're certified.

Private applicators would have to recertify by taking an exam or by taking six hours of training for their general private applicator certification and three

hours of training for each additional category of certification they have.

The last bit of our proposal really is trying to make sure that people are getting continuing education throughout the certification period. The proposal would require applicators to earn at least half of their required hours within 18 months of the expiration date of their certification.

The next area of change is related to minimum age. The current rule has no minimum age requirement for people using RUPs. We're proposing to require that those using RUPs as private applicators, commercial applicators, and noncertified applicators working under the supervision of a certified applicator be at least 18 years old. This is an area where some states have taken action and established varying minimum ages from 16 to 18 for various categories of applicators.

We are also proposing changes to two areas related to noncertified applicators using RUPs under the supervision of certified applicators. For the noncertified applicators themselves, the rule has very basic information and just requires that the RUP is

applied by a competent person acting under the instruction and control of a certified applicator. I think that actually comes right out of FIFRA. So, there's no required demonstration of competency, and there's no explanation of the kind of information that a noncertified applicator should be provided with in order to use an RUP safely.

So, we're proposing to make sure that people using RUPs can do so safely by outlining annual training, outlining training requirements in the rule that would be provided annually. That covers pesticide safety, application equipment, safe application techniques, personal protective equipment, pesticide labeling, and avoiding pesticide take-home exposure.

Then, recognizing that a lot of people using RUPs under the supervision in agriculture could also be handlers under the worker protection standard, we propose to allow qualification of the handler under the WPS to also satisfy the training requirement in the certification rule.

We're also proposing to allow passing of the core exam, which is just basic pesticide safety

information and application information, to satisfy the training requirement. We're looking to offer flexibility in meeting it, but want to make sure that people using RUPs are equipped to do so safely in a way that protects themselves and others.

We're also proposing changes for those people who are supervising noncertified applicators. These are certified applicators. Currently, there aren't really any additional requirements to supervise a noncertified applicator. So, we're just doing a little bit of tightening by requiring that these supervisors be certified in the category of the application they're supervising. So, if you are doing a right of way application, you have to be supervised by somebody who is certified to do a right of way application. You couldn't be supervised by somebody doing an aquatic application.

We're also proposing to make the supervising applicator responsible for insuring that those under his supervision have met the necessary training requirements. For commercial applicators, to maintain records of that training or however the qualification was obtained. This record keeping requirement is only for commercial

applicators because FIFRA prevents EPA from requiring private applicators to maintain records.

Then, finally, to ensure adequate communication between the supervisor and supervisee, we're proposing that the supervisor ensure that there's a mechanism for communication, not just instructions to call this number with a quarter to use the nearby payphone, but to make sure there's equipment available so the supervisee can contact the supervisor immediately if necessary.

In this section, we're also requesting comments on a lot of other limitations that were suggested to us by stakeholders, such as the distance between the supervisor and the noncertified applicant and the number of people that can be under the supervision at one time.

Other areas where we're proposing changes that I won't get into in as much detail are updates to the state plan requirements to match the revised regulations. So, once the rule is finalized, states would have to update their state certification plans to ensure they meet or exceed the new requirements.

We're proposing revisions to the options for tribal certification to reflect EPA's Indian policy and

to allow tribes the flexibility to administer certification programs in a way that works for them.

Then, codifying a policy for federal agency certification plans and removing the option for a single federal government-wide certification plan for all federal employees using RUPs.

So, the next part is where we are looking for some feedback. It's definitely an area where we're encouraging public comment from all the stakeholders. This is the implementation on what we're proposing for implementing the rule.

So, we plan to provide resources for implementation. We currently have a database called the certification plan and reporting database that states can use to keep track of their certification plans, to submit them and update them, and to report on the number of people certified annually. We will update that when the final rule is updated.

EPA has worked with states and other stakeholders to develop certification exams and manuals for applicators in different categories, and we plan to continue doing that as necessary after the final rule is

issued, and to work with all stakeholders to develop other resources as requested.

The time frame we're proposing for implementing these rules once the final rule is issued and effective is to have two years after the final rule publishes for states to update their certification programs. They would make any necessary changes to their recertification period or what categories they require or anything else required under the rule and to submit that to EPA for approval. EPA would have two years.

So, after four years of the rule's publication date, we would require that certification be done according to the new plans as long as they've been approved by EPA. But we did include a provision in the proposal that if EPA hadn't approved a plan within that four year period, the existing plan would stay in effect until such time as a final plan can be approved. We do want to make sure that the timing for implementation works for states and applicators and other affected groups.

So, this is just a general rundown of the costs included in the proposed rule. The annual cost is about

$47 million. We calculated per applicator cost by state for private applicators, commercial applicators, and state and government applicators, as well as the cost to state government agencies. This is another area where if there are costs we didn't incorporate or we weren't aware of, we're hoping for public comment on how we could better capture the cost of the regulation.

Here's just a little bit of what we think the benefits from reducing the incidents are. We think it will reduce the effects of RUP exposure to certified and noncertified applicators and also to other people who happen to be around RUP applications. We also think that the quantified benefits would be $80 million, and then there would be unquantified benefits because we didn't calculate environmental impacts.

So, for public comment, as Kevin mentioned, we issued the rule in August. It published in the Federal Register in late August of this year. There was a 90-day comment period. The comment period is currently scheduled to close on November 23rd. So, we encourage you to read the proposal and put in any kind of comment you want. I'll talk more about the kinds of comments

that would be most helpful in a minute.

Actually, this slide is out of date since we sent it in. We have received two formal comments to extend the comment period, so we're considering those now. Of course, we'll publicize any extension to the comment period.

So, here's some information on how to submit comments. The docket number you need to use, and you do it electronically through regulations.gov. We also have a document we like to reference to provide a resource for developing effective comments.

So, we're encouraging all public comments. We really appreciate effective public comments. So, as Nancy said, we got 2,400 comments on the WPS, and we took them all into consideration, and it impacted a lot of what we ended up with in the final rule. So, we take into consideration everything you say.

Things that help us more are things that tell us what works or doesn't work and why. If there's an alternative that would be better, explain what the alternative is and why it would be better for your state or your applicator group or the organization that you

represent. So, hearing that you don't like a three-year recertification period is good for us to know, but telling us that a five-year recertification is easier for a state to administer is more useful information for us to develop and justify the final requirements in the rule.

In doing this proposal, we're trying to raise the bar nationally. We're not trying to hamper states or applicators or organizations that are already doing above and beyond or are already doing the spirit of what we're trying to achieve.

So, that's all I had in terms of a presentation. So, if there are any questions or comments?

MR. HOUSENGER: Andy?

ANDY: Thank you. I appreciate you referencing the extension of the comment period. I do think that is going to be necessary for us.

MS. MONELL: Could you get a little closer to the microphone?

ANDY: I'm sorry. I do appreciate you mentioning the extension of the comment period, and I

look forward to that. I hope that you will take that under serious consideration.

I was also curious if there were any lawyers in the room and if they could tell me how many CLEs they are required to have in a year.

UNIDENTIFIED MALE: I'm a lawyer. It's usually 12 hours worth of CLEs annually, unless you get a waiver by not practicing law or living out of state.

ANDY: I think the requirement of six hours or three hours for each category that an applicator is certified in is excessive. You can only tell them read the label, don't drink it, and wear your PPE so many times. I just don't know that there's that much that somebody could learn. I have some applicators that are certified in 10 categories. We're talking 60 hours of CEUs for them. They mentioned that that may be excessive.

I look forward to an extension because it is pretty in depth. We're going through this with our extension agency. I'm curious as to why the importance of a written exam versus an online exam.

MS. ARLING: So, a written exam could be given

online. A requirement for it to be written just means it can't be oral. But delivering it electronically would be acceptable.

ANDY: I would clarify that in the proposed rule and say written or online. Some people take it literally to mean written.

MS. MONELL: These are excellent comments. Be sure that you place them in the docket as well.

ANDY: Yes, ma'am.

MS. MONELL: Okay, thanks.

MR. HOUSENGER: I wasn't sure if there was a lawyer joke in there about them needing more hours.

MS. MONELL: Be careful.

MR. HOUSENGER: Okay. Let's see, Robyn?

ROBYN: Hi thank you. I just have a couple questions. On your slide about the costs, was that new costs or increased costs over what is currently required from the existing protection plan or whatever?

MS. ARLING: The cost for state and for applicator are based on what states currently require and what it would cost to come into compliance with what we proposed.

ROBYN: Okay. What was your justification for minimum age of 18 for required age?

MS. ARLING: So I can give you a snapshot and then I encourage you to read the proposal for more information. We looked at --

ROBYN: Because that was also the same thing we heard as minimum age for the worker protection. Yet, I would think you would want to be a little bit more protective of the applicators versus the workers. It’s a bigger requirement being applicators, in my opinion. I’m sorry, I’m a nurse.

MS. ARLING: So, we looked at the development of judgment and maturity in adolescents. We looked at a lot of scholarly literature on brain development and decision-making skills. While all of those might point to a higher minimum age, what we felt comfortable going forward with was a minimum age of 18.

ROBYN: And then, lastly, I’m just curious how many -- under the existing applicator certifications on your slide about private applicator’s initial certification, the current rule, how many nonreaders were certified?

MS. ARLING: Really a few. In talking with states about that, a lot of states have outlawed it entirely. Then, states that still had it on the books, we talked to many of them and it hasn't been used in 20 or 15 years or they might have one or two over the last 10 years. We didn't hear of any rush for nonreaders to be certified.

MR. HOUSENGER: Louis?

LOUIS: Thanks. This may just be a nuance or semantics, but on slide number 7, nonreaders, I have a problem with that. What do you mean by a nonreader? My understanding is that you are actually saying somebody who is a non-English reader? What is a nonreader?

MS. ARLING: The current rule talks about people who can't read the label.

LOUIS: Yes, absolutely, in English or any language?

MS. ARLING: In the language that labeling is available in.

LOUIS: Okay, it needs to be clarified. I think it's somewhat vague and I'm coming from the university, but when we pick on stuff like that -- and

this is a document that's going to go a lot of places. I think it's important to be more specific than what it reads. Again, it might just be semantics or a nuance. It's not a big deal.

But the more important point I'd like to raise is that in the previous presentation, I had a question about how they got from five to recommend one year of certification. Now, in this one, you have three years and both this and the previous WPS presentation, there are a lot of things in common. There's a lot of overlap. That was the reason I was asking.

I thought that gap from five to one was a little too much. Actually, you strike a good balance. I like it. Three years makes me feel a little more comfortable. I just throw these out because the same things, the same argument that was made for WPS you could actually make it for this as well, you know, hiring new folks and sort of need to be retrained. You can say the same exact thing about this. So, do you think three years is best or are you considering one year like they did?

MS. ARLING: We're accepting public comments on

the range of recertification period. So, I hope you provide that.

MR. HOUSENGER: Gabriele?

GABRIELE: Two questions. One is just making sure I'm understanding the proposed time frame for implementation correctly. The four year one, because it was phrased in terms of when the states need to do it, if you're an applicator, does that mean, then, four years after the rule is final, that's the date that you need to be certified under the new standards? I'm just trying to understand for the applicators what's the time frame for them.

MS. ARLING: That's what the proposal is. So, four years after the final rule is effective, new state plans would be in effect that have new requirements. I don't think it means that at the four year mark you have to rush and take all new tests.

GABRIELE: That's the part that I think I need to clarify, because it's one thing for the states to have everything in place and educating in the right way. It's another thing for the applicators to know by when do they need to have met all the new requirements.

Then, the other question, this is really more for the high risk compounds. I mean, a number of those are in the middle of registration review. So, my question is, really, how is this proposal tying in with some of the work going on, whether it's any of the fumigants or some of the other compounds? There's overlap there and I don't know how the timing of this rule and working through it and the comments will tie in with the time frames that you're working on registration review. I'm seeing questioning eyes.

MS. ARLING: So, I can talk from soil fumigation perspective. When we did the decisions for the soil fumigants, there was either (inaudible) by the labeling that would be registrant provided or states could adopt a soil fumigation certification category that would allow applicators to get certified in that category and apply any of the soil fumigants covered by the decision. So, we took that requirement, what was laid out in the registration decision, and incorporated that into the rule.

GABRIELE: But then the flip side of it is like for post-harvest fumigations, you're still in the middle

of registration review and you may have exposure concerns in those. How does something like this tie in with that process? You talked about it going from the reregistration into the standard, and I'm also asking about the other way around.

MR. HOUSENGER: So, we'll look at individual chemicals on a case by case basis and put specific restrictions, protective equipment, warnings on those as needed. But this is a separate effort from that that will just complement it.

GABRIELE: But I guess I could envision -- I'm not sure, I don't know the details. I could envision that something that's in this rule might mitigate something that you're worried about in the risk assessment process. So, that's what I'm trying to understand.

MR. HOUSENGER: John?

JOHN: Just a few questions from a state standpoint. Of the roughly one million noncertified applicators, do we know how many states do not allow or essentially allow application under the supervision, how many states that is?

MS. ARLING: So, when we talk about noncertified applicators, we estimated that there's about a million, but we don't actually know the number. We know that four states don't allow use of RUPs under the supervision of a commercial applicator, and I think three states don't allow it under private applicators. But otherwise, it's permitted in other states.

JOHN: So, would a survey by AAPCO be helpful to inform any kind of decisions? Numbers of noncertified applicators or --

MS. ARLING: Sure. Any information we can get about the number of people that would be affected would help us better estimate the impact.

JOHN: Then, here's the money question, because obviously this is going to be very expensive. Typically, states have cooperative agreements, as you well know. States are given money to do training for folks like we're talking about.

But the big issue, we know that extension is really hurting. I'm not here advocating for extension. I'm just saying that the dollars that might be needed are pretty significant, at least they appear to be. So, what

is the dollar impact? Marty, you talked about $3 million for WPS. It's got to be $6 million for this, right?

MS. MONELL: We have not yet identified a number. I will say that the cooperative agreements that the states receive every year under our STAG appropriation, that the total amount has remained pretty flat. But we have some discretion along with OECA in it through the NPM guidance in assisting with the focus of how that money is spent. I know that worker protection is going to be updated as a priority in 16's guidance as well as 17. I'm sure that the C & T implementation activities will likewise be there.

In terms of the extension services, if you recall, we used to have an interagency agreement with USDA thru which money was given to the extension services to reimburse them for the training in this area. That effort has since been disbanded by USDA just because of the processing overhead costs.

But we have still, through PRIA set aside and our own appropriated funds, maintained a program whereby by and large it is the extension services that receive the funding to do this training, notwithstanding we don't

go through USDA any longer.

So, we have existing mechanisms for funding, and we certainly plan to increase the importance of this effort through the NPM guidance. Then, any funding that we have available through the vehicles that Kevin is talking about, or similar, will be made available.

MR. KEANEY: We are entering into a five year grant with a recipient that's going to be distributing these monies. The PRIA monies were $500,000 and we're adding $500,000 to that, so it's a five year for a million a year to extension.

JOHN: So, it's about a $1 million outlay then?

MS. MONELL: Well, that's just for the specific training.

MR. KEANEY: Right. We have other grants that would help extension with training materials or training --

JOHN: Also, from the SLA point, we get two pots of money. We get the OECA and the OPP. Do you see a switch in terms of percentages?

MS. MONELL: I'm assuming the OECA percentage is higher.

JOHN: Really? It is, you're right.

MS. MONELL: Well, the activities that they fund are in the compliance and enforcement arena, which are done through the states for our programs. So, it would naturally follow that that would receive the larger portion of monies.

JOHN: You don't see that changing, then?

MS. MONELL: Not right now, no.

JOHN: Okay, good, thanks.

MR. HOUSENGER: Wayne?

WAYNE: Hi, Michelle. Thank you for your presentation. I imagine you're getting tired of giving this over and over again.

I was just looking at a couple of issues. I saw on slide 12 you talk about noncertified applicators and the proposal there would be -- well, there's three options that are bulleted. The first one sounds a lot like the WPS training that we talked about. Is that something that you had conceptualized here, that being the annual training on safety application, personal protection, and pesticide labeling? Would it be very much along the lines, if not exact, to what WPS would

look like?

MS. ARLING: So, the requirement and the proposal for training have a lot of elements similar to the WPS training, but it doesn't include things like REIs or other WPS specific requirements.

WAYNE: So, it would be similar with the exception of --

MS. ARLING: It's substantially similar, yes.

WAYNE: Okay. Then, also, I would agree with Andy that it's obviously going to be a huge challenge for us in extension, not a burden, to provide the extra hours of training. We already are hurting, as John was indicating, with expertise and personnel to do that.

But I'm just wondering with the funds that would be administered through EPA, would there be a process similar to WPS where things are preapproved? In other words, there might be more training manuals or training material. In that case, would they be vetted or approved by EPA and then made available or distributed widely?

MS. ARLING: We are hoping to do something similar as we've done under our cooperative agreement

with the National Association of State Departments of Agriculture and Research Foundation where we developed the soil fumigation manual and exam and made it available to states and extension, and did the same for aerial applications and the core manual. So, as we get information on what's needed, we're happy to help with developing national resources.

WAYNE: Those are well done and very much appreciated. I was just curious, from the standpoint of looking at it in a different direction, within North Carolina, as in other states, commercial applicators are certified in various categories. Turf and ornamentals come to mind. There aren't many restricted use pesticides in use in turf and ornamentals, outside of golf courses and sod farms.

But is it possible that states could establish a separate certification and training plan that would deviate from this, but it would just apply toward those groups that are not using restricted use pesticides? In other words, could they develop a three year certification period that is less than the number of hours required here for RUP users? It's an interesting

wrinkle, isn’t it?

MS. ARLING: I don’t know if I understand your question.

WAYNE: So, this is a proposed change for recertification of restricted use pesticide applicators. But for many categories, there are no -- well, a number of categories there’s a very few restricted use pesticide users. Turf and ornamentals is a good example of that. Many of the products that our folks use are general use pesticides, but they are certified because they’re applying pesticides to a property of another. So, in the business, they are certified.

Could it be that our state or other states could actually develop a different certification plan that is not as stringent as this plan for groups that do not use restricted use pesticides?

MS. ARLING: I think it would be great to get that as a public comment.

WAYNE: Okay.

MR. HOUSENGER: And Richard?

RICHARD: Maybe I should know this, but I was just curious about more information on that part of the

noncertified applicators for at least as it relates to commercial applicators. Where is this the most prevalent where they're using noncertified applicators? Is it certain areas of the country, certain industries? Where is the prevalence for that? We're having a discussion actually about maybe a clarification of where it says insure that immediate communication is possible. What do you mean by immediate communication? Texting, cell phone, or I guess a clarification for that as well.

MS. ARLING: So, we, as I mentioned, don't have a lot of data on noncertified applicators. So, our economic analysis does have some estimates of where noncertified applicators are state by state. But they're really rough estimates. So, if there's more information that you can provide or any organization can provide, we'd welcome that. But we're not aware of specific areas where it's more or less prevalent.

RICHARD: At least for commercial applicators, as I remember, I think most of them are licensed and certified. So, I was just curious of the data, if it's mainly outside of ag or what. So, any information you all have additionally would be beneficial.

MS. ARLING: And then, for immediate communication, it's basically any way you can get in touch with somebody immediately. So, texting would be fine. Making sure that both parties have cell phones that are turned on would be fine. Having two way radios in areas where cell phone communication isn't always possible would also be okay.

MR. HOUSENGER: Okay, we're going a little late, so the names that are up are the last ones I'm taking. Then I'm going to the phone.

Mark?

MARK: Thanks, Jack. Mine, you'll be happy to know, is not a question, but it's a comment and a recommendation. As an older but still enthusiastic entomologist that watches the farm reports, what has gone on with both the air rule and the water rules (WOTUS) and the resistence that you are going to get on this kind of thing, your work on the cost benefit analysis is powerful.

I don't know what you are allowed to do about that from a communications and PR aspect, but I would use the hell out of it in anticipation of what's going to

happen. I'm very supportive. I think you've done great work, but you need to have this case out there. I think you've done a good job but have somebody who is good at PR working on it.

MR. HOUSENGER: Sharon?

SHARON: Just a follow up with what Wayne was saying. I just want to clarify. This proposal is actually broader than just restricted use pesticides now, but the additional application methods are part of the proposal, is that correct? So, it would include nonrestricted use pesticides if they're applied by these three application methods?

MS. ARLING: No. They're limited to restricted use pesticides at the federal level.

MR. HOUSENGER: On the phone, the members of the PPDC, any comments/questions?

VALENTIN: Yes, just one comment and one small question. First of all, I want to just say that you guys are heading towards the right directions to protecting some of the most vulnerable farmworker population because most incidents here in Oregon, I think, could have been prevented.

The question I have is, I just want to know if it's possible to try to obtain demographic information about the applicators that are certified?

MR. HOUSENGER: Are you saying where the most restricted use pesticides are applied?

VALENTIN: No. I was just saying that you guys are heading towards the right direction in protecting farmworkers just because some of the incidents here in Oregon could have been prevented. My question is in regards to slide 3 about the private applicators and commercial applicators. I just want to know if there's a way in which we could try to obtain demographic information about the applicators?

MS. ARLING: We can tell you the number of certified applicators by state in each category, but that's all the demographic information we have right now.

VALENTIN: Okay, thank you.

MR. HOUSENGER: It's 3:08, depending on what clock you look at. Let's come back in 15 minutes, so 20 after, let's say.

(A brief recess was taken.)

MS. MONELL: If everyone would please take

their seat, we're ready to resume. By anyone's clock, it's time. For those on the phone, we're about to restart the session.

MR. HOUSENGER: Our next session is on endangered species. Anita Pease of the EFED here -- I'm not going to go into that acronym -- and Gina Shultz of Fish and Wildlife Service are going to run through the presentation. Then we'll have a discussion.

MS. PEASE: Thanks, everyone. So, I'm from the Environmental Fate and Effects Division. I'm the associate director. I'm happy to be here with Gina Shultz, who is the deputy assistant director of the Ecological Services Program at the Fish and Wildlife Service. We're going to be copresenting today to the new PPDC members, so welcome.

So, I will be covering the first bullet. I'll be talking about the status of our ESA related activities and providing updates to our biological evaluation schedule for our first nationwide consultations that we've been working on with the services. Then, Gina will pick up the next two items on stakeholder engagement and the next steps on the step 3 biological opinions.

So, just by way of introduction, I'm sure most of you have seen this slide, but this really outlines the three step process that was recommended by the National Academy of Science in their 2013 report. This is the process that we are following, the interagency group is following to conduct the pesticide consultations. I'll just walk you through this very quickly.

Basically, in step one, we determine whether the use of the pesticide, according to the product label, will result in either no effect or may effect to listed species as well as designated critical habitat. If we determine there's no effect, we basically don't consult with services. We're done at that point in time and we would move forward with the action.

If we determine there's a may effect call, we would move into step two. At that point, we would determine whether the pesticide is likely to adversely affect, which we call LAA, or not likely to adversely affect, NLAA, the species in the designated critical habitat.

If we determine the pesticide is not likely to adversely affect, we would seek concurrence on that

determination with the services in what we call informal consultation. If we determine likely to adversely affect, we then move on to step 3, which is the jeopardy opinion, the adverse mod opinion. That's the biological opinion of the services.

All three steps incorporate the existing ecological risk assessment framework. This includes a problem formulation, an exposure characterization, an effects characterization, and then the integration of those two pieces and the risk characterization.

The first two steps are largely EPA's responsibility, so that's the biological evaluation, or BE. Sometimes we refer to this as our effects determination. Then the third step, the biological opinion, is the responsibility of the Services. So, that's basically the three step process.

So, in terms of progress on our ESA related activities, it's been about two and a half years. Time flies when you're having fun -- since the report came out. The NAS report came out in April of 2013. Since that point in time, we've had three interagency workshops, we've had technical staff in the Services, as

well as management, participating in workshops where we've gotten together for a week long period to work out interim methods to address the NAS report recommendations. We've also been refining those interim methods over time.

Our next workshop we're planning is for January of 2016. In that workshop, we hope to start tackling the step three biological opinion methods, as well as discussing lessons learned on some of the work we've been doing thus far in steps one and two, and looking for ways to streamline and come up with a more efficient process for steps one and two.

In addition to that, we've had four stakeholder workshops. I did check the web links on these. I heard the discussion this morning about the change to WW2, so if you click on those links, they will take you to the presentations for those workshops. In those workshops, we heard feedback from stakeholders on the interim methods that we had developed. We also provided status reports on the status of our efforts as we move through this process.

Gina is going to talk a little bit more when

she gets to her slides on the next stakeholder workshop that we have planned for January of 2016.

In addition to the interagency and stakeholder workshops, we've also been pretty active at various technical/professional meetings. We've had a number of our technical staff present on the updates to these methods at SETAC, (phonetic)at the American Chemical Society meetings, as well as the CropLife RISE meeting in the spring. We have two sessions, I believe, planned for the upcoming SETAC meeting in Salt Lake City, and that's in November.

Finally, we've obviously had some settlement agreements that have focused this work. Most recently, what we refer to as the grand bargain, was a settlement agreement that all three agencies came to on existing ESA litigation. It really allowed us to align our resources to work on the first ever nationwide consultations for five pesticides. Those include chlorpyrifos, diazinon, and malathion, and then carbaryl and methomyl. That grand bargain set schedules for final biological opinions to be delivered for the first three organophosphates -- that's chlorpyrifos, diazinon, and malathion -- by 2017 and then carbaryl and methomyl by 2018.

In addition to that, EPA has also, this past summer, come to a recent agreement with the Center for Biological Diversity on an existing ESA litigation related to the San Francisco Bay. So, for that particular litigation, EPA was on the hook for providing effects determinations for 75 different chemicals, pesticides, for 11 species in the San Francisco Bay area. We completed 59 of those determinations. We have 16 left to do.

So, the result of this new settlement agreement basically allows us to swap out those remaining 16 pesticides and do the next four nationwide consultations for four different chemicals. So, it sets the schedule beyond the first five for the next four. Those chemicals include atrazine, glyphosate, propazine, and simazine We've agreed to provide biological evaluations, or BEs, for those four chemicals by 2020.

So, in terms of the status of the ongoing work, really we've been mostly focused on the three OPs, right now in completing the steps one and two analysis for those first three chemicals, chlorpyrifos, diazinon, and malathion. These will be the first ever nationwide

pesticide consultations for listed species.

The work the teams have been doing has been very collaborative. There have been weekly meetings. We even have a staff person from National Marine Fisheries sitting up in EFED daily interacting with our staff. So, a lot of coordination on this work.

The work on these BEs is really consistent with the NAS report recommendations and the interim approaches that we've developed. Right now, in terms of the draft biological evaluations, we're going to be releasing them in two phases, which I'll discuss in the next slide. We're still on track for the final biological opinions for these three chemicals in December of 2017.

So, in terms of the revised schedule, basically the interagency teams have experienced a delay in completing the draft BEs for chlorpyrifos, diazinon, and malathion. In previous communications, we've said that these draft BEs would be out late summer/early fall of 2015. Right now, that's not going to happen. We're not going to be releasing those documents right now.

What we're going to do is release them in two

phases, the first of which will be a couple months from now, in December 2015. So, we'll be providing the draft problem formulations, the exposure characterizations, the effects characterizations, and all the related appendices for the three chemicals.

So, you'll be getting three different sections and a lot of information. Basically, what you'll be getting is all the analysis plans for the three chemicals, as well as all of the underlying data that we'll be using to make the effects determinations.

The next piece of it will come in April, in the spring of 2016. We'll be coming out with the rest of the document, which will include the effects determinations, the no effect, LAA. NLAA calls for 1,850 species, as well as 800 designated critical habitats. So, calls for all those species. That will also include the weight of evidence analysis for all those species.

So, although we're a little disappointed we couldn't get them out earlier, this really is a lot of work. It did take longer than we had originally anticipated. The teams have really completed an enormous substantial amount of work in the time since they've been

working together. So, I want to highlight some of the tasks that they've completed, things that they're working on, and what we need to do to get to the finish line.

There's been a lot of back and forth. A lot of these sections have gone through multiple rounds of comments between the agencies. We've really taken the time to make sure that we have agreement before we move forward.

It's difficult, as I'm sure most of you know, to work not only within your staff, but then when you expand it to different agencies with different regulatory statutes, it makes it even more difficult. But the people working on this project have been extremely professional, and they've really come up with a good approach. I think this will serve us well moving forward.

So, in terms of the accomplishments, they have come to agreement on methodologies for a weight of evidence approach that will be used to be making the effects determinations.

The interagency teams have completed the reviews of all the registrant submitted studies,

as well as information in the open literature for all the fate and toxicity data that you'll see in the documents that will come out in December. Even that was a large, large undertaking, especially with the open literature data, to review and come to agreement on those data reviews, and also select the thresholds that will be used to make the effects determinations.

Along with that, you'll also be getting data arrays, which I'll describe a little bit more as I describe the tools. All this information will be displayed graphically in the documentation that will be provided in December.

Another large, large effort is obtaining species range maps. So, we, in collaboration and with the help of the industry task force FESTF, which is the Federal Endangered Species Task Force, we were able to reach out to the species experts within the services, the Fish and Wildlife Services field offices. We've obtained species range maps for almost all the species that are currently listed.

So, we have all the species for the 48 contiguous states. I think we have almost all the

Hawaiian species and those in the Pacific Islands as well. So, that's something that we never had before that we actually have geographic shape files for all those species in house now to help make these effects determinations.

We also have been gathering all the biological information for each of these species. So, this is a life history data on body weight, growth, diet, habitats, things that are inputs into our models. We've compiled all that information in endangered species knowledge base. The teams have been working on that. It's also an extremely large effort and a lot of work. We've identified all the model inputs based on that life history information that you'll see in these December drafts going out.

Finally, there's been a lot of work on the tool development. It became pretty obvious when we started doing these effects determinations that you just really can't brute force this analysis for almost 2,000 species. It's just really not possible. So, we recognize the need to have to automate the tools that we have.

So, basically, a lot of work has gone into tool

development as we're developing the methods to make these effects determinations. We have a number of newer tools that are upgrades to existing tools for aquatic exposure, including the surface water concentration calculator, batch runs, and also post processors, and downstream dilution.

Basically, all this automation makes it really possible to automate thousands of aquatic modeling runs that would have otherwise had to have been done for each use pattern. So, this is a huge tool upgrade, and it will help us moving forward in all of our work.

In addition to that, we have a new tool called the TED tool. This has gone through a couple renames, but we like TED. It makes us think of a little fuzzy teddy bear, so we like that. This is the terrestrial effects determination tool. Basically, what this is is an aggregation of existing models that we have in house. So, this aggregates TREX, Terra Plant, THERPS.

It also includes ag drifts, so it calculates buffer distances, off field transport. It also incorporates a new tool we're developing called BREX, which will estimate exposure to bees and other

terrestrial invertebrates, as well as an earthworm (inaudible) model. So, this tool allows us to make effects determinations and provide all the exposure and effects data to allow us to make effects determinations for mammals, birds, reptiles, amphibians, terrestrial invertebrates, and terrestrial plants. So, this is a huge upgrade to our current models.

In addition to that, we also have TIM and Mcnest. TIM is the terrestrial investigation model. These are complementary models that allow probabilistic assessment of risk to birds. So, these tools will also be incorporated into our analysis.

Finally, we have a couple of new tools to help us characterize the effects. So, one of these is called a data array builder. So, basically, what this does is take all the registrants submitted and open literature data and it displays it graphically in a way that you can filter things not only by endpoints but also by taxonomic groups. So, a very effective way of looking at a lot of information in a concise way.

The last tool we've been working on, and it's currently built, is called the species sensitivity

distribution, or SSD toolbox. This is a tool we built in collaboration with our Office of Research and Development, ORD. This allows us to portray species sensitivity distributions for acute mortality data so that we can derive a hazard of HD5, which is basically our threshold for acute mortality. So, this has also been a huge upgrade. This is completely automated to allow that data analysis.

So, with that, I'm going to turn it over to Gina.

MS. SHULTZ: Thank you, Anita. So, I'll elaborate a little bit more on the stakeholder engagement. Several years ago, the four agencies, EPA, USDA, National Marine Fisheries Services, and Fish and Wildlife Service made a commitment to enhance stakeholder input in the pesticide registration and ESA consultation process.

A component of that has been workshops. As Anita mentioned, we've held four workshops to date. The agencies, as well as many stakeholders, believe that these workshops have not allowed for the type of information exchange and dialogue that we had hoped for. So, we plan to modify the format to improve the

effectiveness of these workshops.

One thing we are thinking about is perhaps having some smaller group discussions or breakout sessions on given topics. To ensure that we have a better process for the stakeholder workshop, we also will engage the stakeholders in advance of the January 25th workshop to seek input on how we can better structure the workshops.

As Anita mentioned, we will have released in December a great deal of information. So, we're thinking that one thing might be to, as we said, have some specific smaller discussions/breakout sessions around some of those key points. Again, we're going to seek input on that. That will be noticed, the workshops, and the agenda will be noticed as the prior ones were.

So, transitioning from step 2, which Anita talked about, that's the process where EPA is going to make a determination of likely to adversely affect or not likely to adversely affect. Actually, a third possibility, some of the things that made it into step 2, it's possible that after doing further analysis, there could be a no effect determination. In that case, as

with the step 1, if EPA makes a no effect, that terminates consultation on that species or critical habitat.

The not likely to adversely affect call, as Anita said, that would require concurrence by the service. Then consultation will be concluded for that species or critical habitat. For those that end up being likely to adversely affect, those would be moved into what we call the step 3 analysis or biological opinion.

So, for those likely to adversely affect determinations, the service will conduct jeopardy analysis for the listed species and adverse modification analysis for critical habitat. The jeopardy analysis considers the types of effects to individuals of a listed species that’s described in the biological evaluation that EPA is preparing for step 2. But it expands the analysis to populations, and ultimately, the species determines if it’s a jeopardy or not.

It considers the effects in the context of the environmental baseline status of the species and any interrelated and interdependent activities, if there are any, and then also the cumulative effects of future

nonfederal actions.

The jeopardy analysis will result in either a no jeopardy conclusion -- and if there's incidental take of a listed species, reasonable and prudent measures to offset that take could be included, or a jeopardy conclusion along with reasonable and prudent alternatives, if there are any, that are developed in consultation with EPA and the registrants.

The adverse modification analysis considers the effects of the primary constituent elements and essential biological futures of the critical habitat from the pesticides. It expands the analysis to the whole critical habitat designation as a whole. The result of the adverse mod analysis would be either no adverse mod conclusion or an adverse mod conclusion along with some RPAs if there are reasonable and prudent alternatives that are developed in consultation with EPA and the registrants.

In step 3, the service will review the analysis and other information provided in the biological evaluations and gather additional information related to the species and critical habitat and their status in the action area. This is actually something that we have in

progress now. We know the species that are in step 2, so we're already doing that part of it.

It will also include the environmental baseline and activities related to anticipated cumulative effects in the action area. We'll conduct a population level analysis using any tools and methods available or appropriate. Through step 3, we will continue to work with the interagency team to address information gaps and any uncertainties that arise in step 3.

We plan to use the interagency workshops that Anita mentioned to work through, as was done with step 2, the interagency teams, the staff from all the agencies, and work closely together to agree on the methods used in step 2. We will use that same process in step 3 to ensure that the step 3 process is also transparent and there are no surprises in the biological opinion. We plan to kick this off at our January workshop that Anita mentioned.

MR. HOUSENGER: I guess you're done.

Aimee?

AIMEE: This is a question about step 1. Recognizing that it's in EPA process to determine no

effect or may effect, but also knowing kind of the history of the difference between FIFRA and ESA and some of the original no effects that came out, there was concern from the Services that maybe they weren't using ESA screen on those, going back a decade. I'm just curious, today, looking at what we have, how much engagement did the Services have in looking at the process EPA used to evaluate for no effects/may effects?

MS. PEASE: Historically, I think those determinations, those no effect calls we made decades ago, I mean, there was very little collaboration at that point in time. I think if you look at those same use patterns and the same pesticides and the same species now, we probably would have come to a different determination, because the step 1 analysis that we're working on now is based on a co-occurrence of use with range maps, with where species are in space and time.

So, depending on the use patterns, some of these pesticides are used all over the country. We probably would have come to a may effect. Now, we might have come to a not likely to adversely effect based on further analysis, but yes, they probably would have been

different.

MR. HOUSENGER: Sharon?

SHARON: I have a couple of questions about process and a question about tools. So, my first question on processes, with the December release and the April release, is this information only or is it going to be posted for comment at the docket?

MS. PEASE: So, good question. What we're thinking right now is that the release of the documents in December would be just for your knowledge only, not for public comment at that point in time. We'd be releasing all these documents to be viewable. The official public comment period would start in April. We hope that by providing these documents early on, three months or however many months it is, in advance of the actual effects determinations, it will give people time to really digest the information. It's going to be very large documents, so we wanted to give people advance notice. Hopefully, that will mitigate the need for an extended comment period, by providing them in phases this way.

SHARON: Okay. I have a couple others. So,

with regard to the concurrence process, which normally follows the likely to adversely affect, since there's been such close collaboration between the Services and the EPA, I'm kind of wondering if that is sort of a done deal, so to speak. I mean, since the agencies are working so closely together, is it a reasonable assumption that concurrence is essentially just going to be a very quick process afterwards?

MS. PEASE: Yes, I think you're right. I think since we've been working so closely together, I think that we're concurring along the way. We're talking to each other daily.

SHARON: Will the final biological opinions also include the incidental take authorization with RPMs?

MS. SHULTZ: Yes. If there's incidental take anticipated, then it will include the incidental take statement with reasonable and prudent measures to minimize the take.

SHARON: Then, for the tools, since you're developing and have merged together a number of different existing tools, and these are complex tools, what's the status of posting of those at the website?

MS. PEASE: So, we're hoping to post those tolls in December at their current state. Right now,

we're hoping to hang all this material on our website rather than putting it in a docket, just because of size limitations. So, we're probably going to use our existing ESPP web page to put all these documents on a separate website or a separate web page within that site.

There would be a separate page for provisional tools or provisional models as they exist now. Some of these, like I said, we're kind of building the plane while we're flying it a little bit. So, the full QA/QC documentation of some of these tools is still ongoing. So, when they get complete, they'll go on our models web page. As they're being built and we're using them, they'll be on this provisional models site. That's our intention right now.

MR. HOUSENGER: Gabriele.

GABRIELE: Just two questions. The workshop in January, is that going to be held here? I missed where it was.

MS. SHULTZ: Sorry. It will be at the U.S. Fish and Wildlife Services office in Falls Church, Virginia.

GABRIELE: Okay. Following up on the question,

I just want to say I'm not someone who has been following ESA in detail, but this tool development is pretty amazing in terms of the complexity of what you're being asked to do in developing these tools.

The one thing I would ask that you do as part of maybe the December setup, and I'm sure you have all the time in the world to do this, but I semi made the mistake of attending one of your more detailed environmental risk assessment meetings here in April. I found myself very quickly off the deep end of the pool.

But one thing I took out of it is each little component of the tool has a certain amount of uncertainties in it. You're now combining all these different models together into a single model, essentially, if I'm understanding it. So, I think it's really critical to make clear where the assumptions are, I think more from the human health risk assessment perspective where you have your no effects level versus your effects level. There's already a safety margin built in there. Then, you have your 10x and then potentially additional safety factors. Is there something that helps someone understand all these

factors?

I will say what I did take out of that meeting was there is a lot of safety margins built in to each of these submodels. Then, there's also uncertainties on the other side. So, I really think it's going to be critical to understand that part of it in a way that someone like me or maybe even less than a Ph.D. can understand who doesn't have a tox background.

MR. HOUSENGER: Cheryl?

CHERYL: So, I was thinking a lot along the lines of what Gabriele just said. We know that when we string model after model after model and we string them all together, we're also stringing together precaution after precaution after precaution. Sometimes that quickly builds up to be something that maybe we didn't want. Maybe it pushes out reality. So, what effort is there to validate the models? What effort is there being made to use existing exposure information and monitoring information as you go through and string these together?

That's question one. I have one more.

MS. PEASE: Okay. I can translate that first one. So, let me just reiterate. These models that we're stringing together, it's not like we're adding a lot of

uncertainties, compounding uncertainties on top of uncertainties. They're just taking tools that are separate right now and putting them all in one spreadsheet. You put the inputs in once, and you get the output. So, it's essentially doing the same thing that all these separate models did but doing it all in one model. So, there's no compounding of uncertainties in relation to these models.

In terms of what you were talking about for using monitoring data and ground truthing, we are trying to do that with our surface water concentration calculator. Right now, we are having trouble modeling some of these aquatic bins with flowing water bodies. So, we are trying to look at existing data sets.

Atrazine comes to mind as a robust monitoring data set. Looking at that and ground truthing the information we're getting out of the surface water calculator against monitoring data to see if we're in the general ballpark. It has been a struggle to try and come up with those particular exposure values.

CHERYL: The better you can articulate the assumptions and validate the models, the better it's

going to be.

The other question I have, you're spending a lot of time in tool development, and correct me if I'm wrong, but I believe that ESA consultations are not unique to pesticides; they just presented some late challenges. So, at what point do some of the tools that you're developing for these pesticides translate outside into other types of consultations that are required under ESA?

MS. PEASE: I'm sure there's some utility for these tools elsewhere. I mean, right now they're focused on our existing tools to calculate pesticide exposure and effects for pesticides. It doesn't mean that they can't be used elsewhere. I know some of the models we're looking at to calculate surface water concentrations go beyond these models like SWAT and Basins and there's some other (inaudible) tools that are out there. So, there is utility beyond just pesticide consultation. But right now, the focus is on that.

MR. HOUSENGER: Al?

AL: Thank you. I did want to tell you I appreciated a little bit of lead time on the next

stakeholder workshop so we have a chance to get prepared. So, thanks for giving us some time lines there.

I did want to respond to your comment about not stringing together uncertainties. I would suggest that you look a lot at the various uncertainties and the various conservatism that's built into a lot of the surface water modeling, because that is worthwhile to think about in terms of what you eventually decide in your effects determination, effects meaning this may effect or no effect or likely to adversely effect, not likely to adversely effect. You also have in here a reference to looking at the weight of evidence of effects that could apply in a couple of places in the entire process.

So, I think one of the things that I was wondering was whether there had been a lot of developments in that weight of evidence agreement since what we heard in the ACS meeting, I'm not sure what we'll here at the SETAC meeting, where a lot of the focus was on the toxicological effects, the actual basic data. Can we draw a conclusion on those versus what's the potential effect, no effect, may effect, on the individuals or the

species ultimately? So, is that developed or --

MS. PEASE: The weight of evidence approach? I mean, the matrix still remains the same. It's still the same lines of evidence. I think we'll be able to provide more detail on that at the next stakeholder workshop as we start to really work through the examples that we're doing in the next phase of the work. Right now we are trying to get all the data in place for the December release. I think at that point in time we can give you an update on the weight of evidence analysis.

AL: Okay. If I could ask one more and then we can move on. Gina, you went by this rather quickly, but I thought you made the comment that when you got to step 2, you were sometimes finding that you could make a no effect determination.

Is that something that you're finding is common, because there is a difference between looking at a range map and then looking at, I think as you were pointing out in step 3, where those species are within that range and what the primary elements are that you would need to be looking at. So, there is a difference in concept of space between those two steps, as I

understand what you're doing now.

MS. PEASE: So, I think you did mention in step 2 were making no effect calls. But that actually is step 1. So, we are making some no effect calls in step 1 for some of these chemicals. That is something that would happen at step 1, not in step 2. It's kind of semantics.

MS. SHULTZ: I probably confused things by saying that it's possible -- I was talking process. It's EPA that makes the calls not Fish and Wildlife Service. I was just trying to say processwise, it's possible in a step 2 analysis that an agency could, after further analysis, find that there is a no effect in theory. Sorry for the confusion.

MR. HOUSENGER: Cynthia?

CYNTHIA: So, I'm very interested in your surface water concentration calculator and what exactly it entails and whether it's publicly available or when it will be. The reason I ask is because the American Bird Conservancy is currently engaged in a mapping exercise looking at acute and reproductive risk to birds by watershed across the United States. We are finding that doing these surface water concentration calculations is

very, very challenging. So, I'd love to hear more about how you're going about it.

MS. PEASE: Okay, I'm probably not the right person to ask about all the details of that, but I do know that what I've heard from our staff is that that particular model will be final by December. So, it will be available in December on our website. Really, it's just an upgrade to our existing prison exams model. So, it incorporates some new scenarios specific for endangered species assessments. It also incorporates the ability to drive exposure estimates not only in static water bodies but also flowing water bodies.

These post processing tools provide not only point estimates of exposure but also magnitude and duration over a period of time. So, you can get any different probability distribution of output that you would like from these particular models.

CYNTHIA: Fantastic. Can you tell me who would be the best contact at EPA?

MS. PEASE: Probably Dirk Young (phonetic), but I can give you that information offline.

MR. HOUSENGER: Aimee?

AIMEE: First, I just quickly want to thank you guys for taking the time -- every time I've looked at the biological opinions and throughout the different processes, how very transparent you are, how you note all of the uncertainties and make it clear to us as people from the outside what you're questioning still. I really appreciate that, and I really appreciate the caution that you take that endangered species warrants. So, just thank you for that, recognizing it's challenging, but --

My one question is a little bit separate from this. I'm curious how much during this back and forth there had been discussions around what label changes can we make? Are there changes that we can shift in a way so that we don't have to undergo a full process? Is that something that's still ongoing, because that seemed like a really valuable step?

MS. PEASE: Yes, that's ongoing. It's a good comment, and it's something that we're looking at more closely. I mean, we would all save ourselves a lot of time and resources if we could clean up some of the labels to make sure they are clear. So, we're trying to do that with these chemicals. I think we have done it

for a couple of these. We've had some label clean up that's helped a lot. Any mitigation that we can get up in front of the BE or in front of the biop will help us in the long run. So, we are pursuing that.

MR. HOUSENGER: Al, do you have another comment?

AL: Yes, I do. I was looking at the last page and thinking about it. I was thinking a little bit more about this difference between the range that you're using in step 1 and step 2 and your comment here on the status in the action area, which is in progress. But are you finding that there would be a difference in the outcome of the assessment if you were to look at their status in that action area in an earlier step?

MS. SHULTZ: So, that is an important consideration in the step 3 and the jeopardy analysis. The status of the species currently along with the anticipated affect of the registration of the pesticide is what's going to be factored into what does that mean for the species as a whole in determining jeopardy or not.

AL: But it's not been thought of in terms of

looking at a likely to adversely affect or not likely adversely affect?

MS. SHULTZ: No, because that question in the step 2 is at the individual level, so it’s not looking at what does it mean for the species as a whole or a population of the species. Will it adversely affect individuals or an individual? So, the status of the species as a whole then -- so, if the answer is yes, there’s an individual, then we look at what’s going on with the species in the affected area to determine whether jeopardy or not. It’s just a different trigger.

MS. PEASE: Just something to add on to that. One thing we’ll be doing as part of the April release is for species where there is an overlap of the pesticide use with their range map, we are going to be providing the extent of that overlap. So, some species may be a very small overlap with where the species range, overlaps with where pesticides are used or could be exposed. Whereas, others may be a complete overlap. We’ll be providing a percent overlap for each use, pattern for each species, as part of the analysis. I don’t know if that helps to answer your question.

AL: Yes, it does, but it brings up others.

MS. PEASE: I'm sorry I said it then.

AL: We can follow that up perhaps in January, but if your percentage is small so that the probability of an interaction is low, why wouldn't you be trying to think of that at an earlier stage? Is this likely or not likely?

MS. PEASE: Well, I think that's something that will inform the jeopardy opinion. We could consider it in step 2 also.

MS. SHULTZ: That would go into the question of, so, if it's not likely to adversely affect, is the affect insignificant or discountable. That's where it might play into determining if it's insignificant or maybe discountable. EPA makes it not likely to adversely affect.

MR. HOUSENGER: Number 3?

UNIDENTIFIED FEMALE: I spent a lot of years thinking about this. Last quick question, and if you need to direct me to the NAS report or somewhere else, you can feel free. I'm curious, in step 1, when you're doing that overlay, all of a sudden I realized which use

maps are you looking at. There's a lot of ways of determining use.

MS. PEASE: Yes. So, if you were at past PPDC meetings, you missed the talk about how we described the pesticide footprint. So, we're using crop land data layers for 11 different categories. I can talk to you more about this offline. We have presentations, actually, on our website, whole presentations of how we're determining pesticide footprints.

MR. HOUSENGER: Okay, anybody on the phone who is a member of the PPDC? You have any questions/comments?

RICHARD: One question, if I may.

MR. HOUSENGER: And you are?

RICHARD: Richard Gragg, Florida A&M University. Did you mention in your talk and in these methods, are you all looking at mixtures?

MS. PEASE: Good question. Yes, we are looking at mixtures. So, in steps 1 and 2, we have a qualitative analysis of mixtures that will be included, I think, as part of the release in December. That analysis will be included.

RICHARD: Okay. And that could also go over to the actual -- if you get to step 3, it can go over to your biop in your evaluation as well, right?

MS. PEASE: Yes, that's correct.

RICHARD: Okay, thank you.

MR. HOUSENGER: All right, thank you very much.

Next up, organophosphates. Dana Vogel is going to walk us through the presentation, and Anna Lowit is providing moral support.

MS. VOGEL: She's here for really technical questions.

MR. HOUSENGER: If it gets too deep, we go to Anna.

MS. VOGEL: Good afternoon, I'm Dana Vogel. I'm the director of the Health Effects Division. I'm going to give you a quick update. I don't have too many slides on the human health risk assessment approach we are using for the organophosphates.

So, just a brief outline of what we're going to go through. We're going to talk a little bit about the strategy we use to do the hazard assessment. Part of that will be -- and we'll get a little bit more in depth

on the safety factors and how we determine those. I'll go over a little bit of the exposure summary, risk summary, talk a little bit about PBPK because that was part of at least one of our major OP assessments and how we'd like to move forward with PBPK, and then tell you what's coming up in FY 16 and 17 for the OPs.

So, for our hazard assessment for the OPs, as we have done in the past, we're relying upon cholinesterase inhibition. We evaluated cholinesterase data for both the parent and the oxon (phonetic). We updated and generated benchmark dose for both red blood cell and brain cholinesterase across different routes of exposure, whether that's oral, dermal, or inhalation.

So, what we did for the single chemical assessments for the OPs, and it could be different for different OPs, is we're going to rely upon most sensitive compartment, whether that be RBC or brain.

We also did life stage comparison for gestational and postnatal comparative cholinesterase assay studies. So, that really helps us get to if there's any sensitivities or differences between adults and young, pregnant females, and/or in utero.

So, the endpoints we selected for the OP assessments, we did an acute assessment, which is a single day assessment. We have a specific point of departure for females. We also did chronic, but it's not really a chronic as we normally do.

It's a steady state assessment and point of departure that we chose, because what we saw by looking across the data that we have is that inhibition reaches a plateau after two to three weeks. So, the points of departure for cholinesterase that we're using are based on that two to three week period.

So, it's a steady state point of departure. So, keeping that in mind and knowing that about the OPs and the time to affect and what we're concerned about from the tox side, we matched that with the exposure that we expect for the organophosphates.

So, safety factors. As you may be aware, right now we have out for comment our OP 10X position paper. I think that went out early September. What we did is it's based on laboratory animal data that we have, mechanistic studies, and epi data, human epi data as well.

We did a scientific literature review of all

the data that we had and kind of pulled it all together looking at all the data and what it shows us in totality to figure out the appropriate safety factor for the OP.

So, if we're discussing right now the FQPA factor, when we looked at all of that data and we pulled it all together, there are some uncertainties regarding potential neurodevelopmental outcomes as we see in some of the epidemiological studies that are available. Most of the epi studies that we have on the OPs is hard to distinguish between different OPs because they're measuring a common biomarker of the DAP.

So, what the position paper says that we have out for comment is it's for at least for the ones we have out and potentially for all the OPs right now as a draft position. We're applying a 10X FQPA factor to the OPs for the potential uncertainty around the neurodevelopmental facts that we see in the epidemiological data.

So, using and expanding our use of PBPK models. As science advances, we're following science and decisions, NAS report. We're trying to use the best available science to inform our risk assessments. Specifically in this case, we're going to be talking

about the hazard assessment and then how that impacts the overall risk assessment.

So, what we've done for one OP and what we're encouraging the use of for other OPs is the recent advances and how we extrapolate from in vitro to in vivo and using comp tox models to get a better handle on data derived inter and intra species factors instead of relying upon the standard default assumptions that we currently use, the ten and the ten.

We're trying to keep pace with it as much as we can with emerging science. We do have out for comment, as is listed right here, a framework for developing PBPK models and using these new technologies in our risk assessments. One thing I might mention is as you probably are aware, in December of 2014, we put out the chlorpyrifos risk assessment, and it does rely upon PBPK. So, that's one example of where we've used it already.

One other thing I wanted to mention on this, when we use PBPK models, it helps us get a better understanding of the inter and intra species factor. They could go up or they could go down. So, it's not always going down. It could go up or down, depending

upon the science that you have.

For the OPs exposure, for dietary exposure, we use the DEEM model. What we did was similar to what we've done in different cumulative assessments. It provides like more of a longitudinal, more of a 365 day exposure estimate. This enabled us to better fit the exposure, that steady state point of departure that we're concerned about, that hazard with the appropriate exposure. So, by using DEEM in this way and incorporating the drinking water directly into our dietary assessment, it's a better fit for doing the food and drinking water assessment.

We also did occupational and residential assessments, relying upon just our standard methodologies and SOPs. We did our spray drift assessment and also applied the volatilization screen. Spray drift, as you know, was out for comment. We're hoping to make some progress on that policy, making it final in the not so distant future. Then, volatilization as well, was out for comment for a while.

For the preliminary draft risk assessments, these are the chemicals that have recently gone out.

They're preliminary in their draft. They're out for public comment. These are the OPs. If you looked at any of them, you will see that there are risks of concern identified for a lot of those, if not all of them, for different pathways.

What's coming up is we're working on now is addressing the comment that we get back on the 10X FQPA OP decision paper that we put out for comment. We're also accepting comments on those draft risk assessments, so we'll be taking those and incorporating those as soon as we can.

Then, you see the PRAs that are scheduled to come out for public comment in FY 16. Those, I will mention, are scheduled, and that's what we expect to happen right now. But, of course, things can always change. That's TCVP, acephate, malathion, coumaphos, chlorethoxyfos, bensulide, phosmet, phostebupirin, and diazinon. Then, for FY 17, the schedule right now is DDVP, naled and trichlorfon. They're grouped together because they're similar.

I think that's it.

MR. HOUSENGER: Cheryl?

CHERYL: I know that this whole thing is couched in terms of OPs. It's posted as OPs, but there's a big huge change in policy here where you're taking 10X from FQPA and putting it over on the worker side. So, is this only viewed as OPs or is this a whole change in policy for all worker assessments to come? I have several questions.

MS. VOGEL: Okay. So, I just want to make sure I answer your question right. So, it's your concern that we're applying a factor to workers that we don't normally apply.

CHERYL: My question is, is that the future policy?

MS. VOGEL: Well, right now what we would do if we have uncertainty for workers, we might not call it an FQPA factor, but we would still apply uncertainty factors. So, for instance, if there was a piece of data missing, if there was a developmental neurotox study that we thought -- that's a bad example. But if we did, we might call that in as an FQPA factor, but we would also apply an uncertainty factor to workers because of pregnant female workers. We would call it a database uncertainty

factor.

CHERYL: That's a shift in policy.

MR. HOUSENGER: That was a shift a long time ago.

MS. VOGEL: We've been doing that for a while. It's not considered an FQPA factor, but it's a database uncertainty factor that applies to workers because you want to protect pregnant --

CHERYL: Okay, then, I stand clarified. The bigger thing is I think this took several registrants by surprise because we're taking 10X uncertainty from basically epi data based on chlorpyrifos and diazinon out of a Columbia study. We're translating it to an entire group of OPs. At the same time, we're saying we don't know exactly what the mode of action of these effects are that we've seen in the Columbia study, but we're going to still translate it to the group where we classify them through this mode of action. So, we're translating, but we're not clear, and we're going to put the 10X on everything. It seems a little off kilter. At the same time, you had a reduction in one of the factors through the PBPK modeling for chlorpyrifos, but you

didn’t apply that to all the OPs.

MS. VOGEL: We don’t have PBPK models for all of the others.

CHERYL: Right. So, we’re going to take the adverse effects from the Columbia study that hasn’t been completely vetted, and we’re going to transfer those to all the OPs. But the specific information that we have as the PBPK modeling, we’re not going to translate that. So, again, it’s a little bit -- registrants are kind of scratching their heads a little bit about this.

MS. VOGEL: I mean, I’ll give you my perspective. I’m not sure if it will fully answer your question, but if we’re talking about the epi 10X, what we did is we didn’t just look at the Columbia study. There’s a variety of epidemiological data available. It’s the three cohorts and there’s a lot of other uncertainty. It’s probably some of the best epidemiological data that I think is kind of considered the gold standard as far as epi data is.

We also looked at where we have animal data and it doesn’t match up perfectly. We don’t know the mode of action or the AOP. We don’t know what the critical

windows are. However, we are seeing neurotoxicity in the animal studies as well.

So, when we look at all these different lines of evidence and we line them all up, it's hard to say when you see the data and the information that comes out of those three cohorts and how they all line up, that there is an uncertainty surrounding neurodevelopmental effects. So, we are trying to look at multiple lines of evidence. We're not just solely -- it may be the main thing that we're looking at, but we're looking at how all the data kind of fits together.

As far as use of the PBPK model goes, I think we're willing to discuss with registrants how a PBPK model could be used for other OPs. There is something very specific about the chlorpyrifos PBPK model, but it may be a starting point for other OPs.

MS. LOWIT: I'll just add a little bit. Beyond the Columbia study, there are two other children's cohorts that are partially funded by NIH and, to some degree, by EPA, but also private funding. There's the cohort run out of Berkeley, often called Chumakis (phonetic), and there's also another pollen cohort run

out of Mount Sinai.

We know Sinai and the Chumakis cohorts are focused on the dialkyl phosphates, which are more generic markers for all of OPs, not just chlorpyrifos and diazinon. In fact, Chumakis has actually found associations with the DAPs that are not associated with chlorpyrifos, so not the ethyl metabolites. It's actually the methyl metabolites.

So, if you look closely at the way we've reviewed these over the last -- around 2008, we have kept the three cohorts together because we think they belong together. Columbia alone does not stand alone. The three cohorts were started around the same time, so they cover the same time period, but yet they're three different sets of investigators, three different physical locations, three different sets of individuals, different sets of exposure pathways. They're using a similar set of outcome metrics in the children, so there's a lot of commonalities to those cohorts. So, they stand together as a group. So, Columbia does not hold up by itself. It's the three cohorts together.

Also, in our new paper, we did an update to our

2012 literature review. That 2012 literature review is reviewed by the SAP with a lot of positive feedback. We've updated that with new papers since 2012, which brings in another new cohort from Mexico, but also some other studies we haven't considered. The newer studies are not as strong as the three perspective cohorts. They do provide additional evidence. This is not just a chlorpyrifos issue. When you look at it from the DAPs point of view, there's a common pattern of outcomes.

With respect to the PBPK modeling, the physiologically based pharmacokinetic model, which is basically a big word to say. You can take a lot of mathematic equations that characterize the physiology and metabolism in the human body and do an outstanding job of predicting what happens from the point of exposure to the point of excretion across different life stages. So, these are very powerful models built on years of understanding of human physiology across the ages from birth until the elderly.

In the last few years, there's been a rapid development in ability to collect the information that underlies those models. So, there's a belief that you

can take the chlorpyrifos PBPK model and its core and with a fairly rapid amount of in vitro data and some targeted in vivo testing, turn that chlorpyrifos model into other OPs, because the foundation of the code is built. It's publicly available. It's already been peer reviewed. So, we'd like to have dialogues with stakeholders who are interested in proving the science that underlies our extrapolation and those risk assessments.

MR. HOUSENGER: Al?

AL: For some time, there's been a lot of question about the drinking water assessment that you've now incorporated. I'm not sure exactly how you've done that directly as you commented. But I wonder whether you've been looking at different -- if you could talk about how you did that and how you've been looking at ways to get a more realistic picture of what the exposure in drinking water might be in whatever the time frame is that you are concerned about.

MS. VOGEL: All right, so, our drinking water assessments are done in coordination with our Environmental Fate and Effects Division. They use their

drinking water models. They model surface and ground water. We take the outputs and we put it into our dietary assessment model. In this case, because we're worried about the two to three week window, we did rolling averages, 21 day rolling averages, and put those averages into DEEM, which is a very complex probabilistic model that I definitely cannot explain to you. That's how we did the assessments.

Now, we start when we do our dietary assessments. When we do the drinking water assessments, there's different levels of refinement. So, I think what we're trying to as we refine more and more is get down closer to the watershed level as opposed to more a national level. So, we start with a national assessment and we slowly go down to a more refinement with getting down to the watershed level. I'm not sure that fully answers your question, but it may be the best I can do.

AL: Well, partly what I was getting at was actually the comment that I made to Anita that in looking at a watershed level with those kinds of methods, you are adding on some conservatism as you go through it. I just wondered if you had been looking at other ways to model

that exposure that might have given you something that fit maybe what we would expect to see if went out and actually looked, did some monitoring data.

MS. VOGEL: I know also for chlorpyrifos as well and what we try to do to some extent to where the exposure patterns match up is see where/how the monitoring compares to the modeling.

MR. HOUSENGER: Robyn?

ROBYN: Thank you. Just two quick questions. I take it that the neurodevelopmental was the most sensitive endpoint compared to reproductive or other endpoints?

MS. VOGEL: The assessment is based on the cholinesterase inhibition, the neurotoxicity effect. What we're getting from the epidemiological data, we're not using it for points of departure. We're using it for the safety factor at this point because of the uncertainty with the neurodevelopmental. Is your question, from those studies, was that the most sensitive thing they saw in the epi studies?

ROBYN: I guess I misunderstood the safety factor. You said based on the relationship with the

neurodevelopmental effect because of its cholinesterase inhibitor. On the slide above that, you're still looking at single chemical assessments.

MS. LOWIT: That's where we are right now.

MR. HOUSENGER: Ray?

RAY: I'm not a toxicologist, and I share that blissful state with a number of folks around the table. I understand it's difficult to make these concepts understandable to those who aren't toxicologists, but that's your job in front of a federal advisory committee.

We understand that EPA has requested the raw data for these epi studies that are the basis for the 10X decisions. What's the status of that request?

MS. VOGEL: We've received some additional information from Columbia. We don't have all of the raw data, but we do have additional information that we requested to do some additional analysis. If you want to add anything to that --

MS. LOWIT: Only a little bit. It's true we have, on a couple of occasions, gone directly to Columbia and talked to them about our desire to have the individual data. So far, they have not provided that,

but they have recently provided some additional summary information that allows us to characterize the distribution in a way that the publications do not.

We've also had some offline conversations with Dana Barr (phonetic), who used to be at CDC. We ran a lot of those data. We've had some conversation with her about what she may be able to provide on top of the other cohorts, Mount Sinai and Chumakis in particular. So far, that's really just a conversation that we're having.

RAY: Are those data forthcoming?

MS. VOGEL: I don't know the answer to that.

RAY: But you made your conclusions without having those data?

MS. VOGEL: One other thing I did want to add was that we had some scientists when Vicki Dellarco (phonetic) was here and a couple people go up to Columbia and sit with Columbia investigators and query the data there in person to answer the questions that we have. They were somewhat satisfied after that with how that meeting went. You're right, we don't have all the raw data. I mean, that's for sure.

RAY: Well, being somewhat satisfied doesn't

sound like it’s a satisfactory level of proof and level of demonstration to the folks around this table as a basis for the decision.

MS. VOGEL: So, I mean, we did go up there. They did analysis that we wanted done in front of us while we were there. Subsequent to that --

RAY: Can we see that analysis?

MS. VOGEL: I don’t know that we have anything. Do we have anything written down from that? I’m not sure. I’d have to go back and check.

RAY: This is a really big deal.

MS. VOGEL: I would say, since then, when we had additional questions, we went back to them for another data request that we’ve recently gotten and are looking at that data now. We’re working, like Anna said, with Dana Barr to see what additional information we can get.

RAY: Are you going to make those data available?

MS. LOWIT: I think we’ll have to when we go out with chlorpyrifos.

RAY: But you made your decisions without

making those data available.

MS. VOGEL: Well, it's a draft risk assessment.

MS. LOWIT: Everything at the time in December 2014, everything we had at that moment in time went out in the docket. As we have more information, we'll provide it publicly.

RAY: You've explained that you've done your risk assessment based on cholinesterase inhibition. You know an awful lot about cholinesterase inhibition, a huge amount of research done on the OPs in the almost 20 years since FPQA required that work. It seems like the story is pretty well worked out for cholinesterase inhibition, but is the epi data pointing to a different endpoint?

MS. VOGEL: I'll let you follow up on me again. We've taken issue of a couple different SAPs. I think the concern is is there a potential for neurodevelopmental effects to occur below where we're regulating for cholinesterase inhibition. They're somewhat disconnected, but we need to make sure we're being protective of those effects. So, with some of the analysis we've done with the PBPK model, we're trying to figure out what was seen in the epi data, is that a

result of the cholinesterase inhibition or is there some other additional uncertainty, i.e., the neurodevelopmental, the potential for ADHD, autism, all different kinds of attentional issues to result from exposure to OPs, chlorpyrifos, and others.

RAY: Wasn't most of the neurodevelopmental testing concluded about at least 10 years ago?

MS. LOWIT: We'll do random development on neurotoxicity studies for approximately 20 OPs, plus or minus. I don't know the exact number. If we maybe take a step back, the statute requires an extra 10X factor is in place unless there is sufficient data to change the factor. So, if that's the starting point, one of the action items that the SAP recommended to the agency at the 2012 SAP was to conduct what is often called a dose reconstruction analysis. It's a big word for using the PBPK model as a tool, taking an exposure scenario, something like would be done (inaudible).

Using that exposure information, including it into the PBPK model, and asking yourselves the question, is there expectation of the exposures for -- in Columbia specifically around the 1999-1998 time period, is there

reasonable expectation you would have seen cholinesterase inhibition in the women living in the apartments at that time? We follow through on that recommendation in our 2014 risk assessment.

That analysis shows that the residential uses of chlorpyrifos that would have been available in the late 90s, we really would not expect cholinesterase inhibition in the women in that cohort. So, given that piece of powerful information on top of a growing body of information on the mechanistic understanding on a biological activity of various OPs on in vitro, along with animal studies and the three epidemiology cohorts, that there begins -- if we think about weight of evidence, you were asking about this question earlier, how you take information across different levels of biological information and bring them together, there begins to be a picture that FQPA safety factor that’s statutorily there becomes -- we’re unable to remove that factor because we have uncertainty in the dose response in the human around the neurodevelopmental.

RAY: But in multiple occasions, you have removed that factor. You’ve come to the conclusion --

MR. HOUSENGER: We've removed that factor in the absence of data causing some uncertainty like we have with the OPs, right.

RAY: Well, you've removed the factor for the OP. You've lowered that factor for the OP.

MR. HOUSENGER: Yes, that was before we analyzed these data, went to the SAP with this. The SAP basically said retain the 10.

RAY: There's a bit of confusion regarding this September 2nd publication of the position paper. I've asked a couple of my colleagues, and we don't know what that is.

MS. VOGEL: So, I think that we're talking about the 10X paper, the OP/10X paper. So, that is the paper that explains our assessment, why we're proposing to put an additional safety factor on all of the OPs for the epi, looking at how it all compares to all the different lines of evidence.

MR. KEIGWIN: Ray, that paper is included in each of the dockets for the seven OPs that went out for comment a little bit later in September. I think the date of the assessment might be September 2nd, but the

docket is actually opened around, I want to say, September -- the week of September 20th. So, Dana was referring to the dockets that opened in that time frame.

RAY: That clarifies it, thanks.

MR. HOUSENGER: Nichelle?

NICHELLE: So, this is a lot of hard work, and I want to thank the agency for doing it for this class of pesticides. I also want to thank and encourage the agency to apply the 10X safety factor approach, this class of pesticides, that we know to be highly neurotoxic. That's established in the scientific literature, so I don't think that's a lot of debate on that. Again, I'm urging the agency to retain that 10X safety factor.

I also have a question. This is the human health assessment for organophosphates, but is there any work similar for other classes of pesticides in the pipeline out of this work?

MS. VOGEL: Right now, these came up. We'll following the registration review schedule. As we go through, there will be other class of chemicals to go through. Does that answer your question? Are you

asking, are we going to apply an additional factor to other classes of chemicals?

NICHELLE: So, you're doing this work as a class of pesticides. You're doing all of them at the same time.

MS. VOGEL: So, they're coming up first in registration review, the OPs.

NICHELLE: Oh, it's just the schedule.

MS. VOGEL: So, that's why we're coming to these first.

NICHELLE: Okay.

MR. HOUSENGER: Gabriele?

GABRIELE: Just reflecting on the conversation as I'm hearing it, I have to say this is one of the harder things. This is at 4 p.m. one of the most complicated risk assessments you've come out. You're talking about in 20 minutes. This needs a lot more conversation would be my assessment.

I realize you guys are understaffed and overworked and anything like this is more work, but I come back to my training wheels and learning about pesticides with the whole FPQA implementation where EPA

had to sit down and explain how they did their risk assessments. That made a humongous difference in the quality of the risk assessments and how people understood them and understood how they could participate in the process.

The chlorpyrifos one, you may have made these decisions three or four years ago. People may not have understood you made decisions. But it's clear that in that assessment were a lot of different decisions that are suddenly cumulatively showing up.

I really encourage you to find a way to sit down and go through this with a little bit more time than 20 minutes at the end of a long day, because I don't know what you mean with a steady state due to equilibrium for enzyme inhibition. I just don't have a feel for it. I don't feel like you should be taking five minutes to explain that right now. Yet, those are important components into how you made your decision.

Using the epidemiological studies, you may have taken it to the SAP, but my question is, how do we determine which epi studies are worth using. What are the criteria for an epi study to be usable in the EPA

world? I think it's a really good one because you have a lot of epi studies out there, and it's really hard to assess the quality of them and what are the factors and so forth.

So, again, it's not saying it's necessarily all wrong or all right, but here there's a lot going on. When you have some of the experts in the room going, I didn't understand you, that makes me worried. So, just food for thought or a reflection on what I'm hearing here.

MR. HOUSENGER: Right. I think there's actually a number of venues that you can get involved in this, including the SAP and others. It is, but I think the question is, is it you that wants to hear this, is it the whole group. We can make this into an expanded presentation for the next time. I mean, there's always the next time. We've got another one of these in May.

But it's difficult to figure out, especially with the input from this group, what to put on the agenda and how much time to allow for it. As you see, there's a lot of things that we're working on. What's interesting to you may not be interesting to someone else. What's

interesting to someone else may not be interesting to you. So, it's a balance. But when we discuss topics, we can get into it. But it's not easy to explain either. I've been in this program for 40 years. It's getting to the point where I need to get out before I don't understand it any more.

UNIDENTIFIED FEMALE: (Not near mic)

MR. HOUSENGER: We can go back and do technical briefings again if that's what people want. It is a lot of work. Our resources continue to go down and our work continues to go up. We used to spend a lot of time in preparation for those, traveling for those, getting the rooms for those. I'm not willing to do it if there's only going to be five people attend it. But we can discuss that at the end of the meeting, too.

UNIDENTIFIED MALE: What you're talking about, and I'm not sure that I want to, it sounds like Ray thinks that you've changed the rules in the middle of the game.

MR. HOUSENGER: I would argue that we haven't. We haven't had epi studies before that we thought were good enough to use. But when we do have them and they

create uncertainties, I think our law is clear that we'll retain the 10X until we can prove that it's not needed. That's what's kind of happened here.

Did the same effect happen to workers who are exposed? Definitely. If you're a worker, you don't know the difference if you're a nonworker or a worker if you're exposed to chlorpyrifos. If it's an effect that you're going to see, you're going to see it regardless. So, we think that it's prudent to apply that factor regardless.

UNIDENTIFIED FEMALE: Just one comment. If anyone is interested in hearing more about some of these studies, I would suggest perhaps maybe running it through one of the communities of practice webinars that EPA holds every month or so on some of the work. You know what I'm talking about?

MS. VOGEL: I know Anna does, but it's typically some kind of research that's going on. You can dial in. There's slides that you can see. Somebody goes through for about an hour and talks about the work they're doing and the results and stuff like that. I find them to be very informative.

MR. HOUSENGER: There is a lot of information on our website as well.

Cheryl?

CHERYL: I do get the precautionary need. I'm really glad that we have precaution built into the system. I'm not against that, but I think since I'm supposed to have the mic for the registrant community, I just need to make one more point here.

What Ray was getting at is if you're going to make regulatory decisions and you still don't have the raw data in your hand, there are some in the registrant community that are going, okay, we've got peer review publications that don't agree with the weight of evidence that was articulated by EPA. We don't have the data in hand, we can't validate it, and yet, you're going to make regulatory decisions on it. It feels disconnected from the way that you would treat registrants. You would demand to be able to audit the data.

So, it's uncomfortable from the registrant community to hear that you're going to weight these epi studies so hard when all of this data has gone in under the regulatory process with data call ins, with guideline

studies. Then, we can't even get to see the data that's the trump card for the rest of the regulatory process.

MR. HOUSENGER: I understand. It's hard to measure the IQ of a rat, though. So, some of these effects you're not going to see in our animal studies. It does shed some uncertainties on the literature that's out there. That's what's preventing us from removing the 10X.

Let's go to the phones before someone else puts up their card. Oh, we've got another card. Wait, hold on. We've gone one more here and then we'll go to the phones.

AMY: I understand the complexity is something that all of us in this room may or may not understand. I do want to commend the agency for taking a look at these robust studies that frankly had been rare when we were looking at the types of pesticides being used and thinking about what the effects might be on workers and taking it to this level.

I echo what was said earlier in terms of can this be applied to other pesticides that are out there.

It just happens that we have these cohort studies that are showing these uncertainties. I think it's really important that you're taking these steps.

MR. HOUSENGER: I'm not sure how many other studies are out there like this that would be in the same situation where we would apply a 10 or couldn't remove the 10, in other words.

All right, on the phone, the members?

RICHARD: Yes, Richard Gragg, thank you. My question, first question, has to do with how this organophosphate will fit into the 21st century toxicology scheme. Is it a priority based on the results and decisions you're making now to integrate that into the scheme?

MS. LOWIT: The analysis that we've done for the OPs is part of the support to retain the 10X for the class of OPs. We have, as part of the 2012 FIFRA SAP, done a thorough review of the literature around in vitro studies and adverse outcome pathways leading to brain development in children. We have continued to monitor that literature, but the adverse outcome pathway is just many years away. It's just a reality of where we

are.

But I think at the higher level I think the analysis shows how we're thinking about putting different lines of evidence together. We do have a draft framework that was reviewed by the SAP in 2010 or 2011, I think, where we put together an analysis framework based on the concepts of problem formulation and the Bradford Hill (phonetic) criteria to think about how we would put together lines of evidence from the point of exposure, including QSAR and SAR (phonetic) and read across up through molecular initiating events, things happening at the tissue, to the organism level but also ultimately to the population level either measured through biomonitoring studies but also epidemiology studies.

So, the OP situation, I think, provides a context for how we've applied that framework in the context of how the NAS is supporting the agency of needing a check mark kind of thinking about (inaudible) effects from animal studies to using all the available information across multiple lines of evidence.

RICHARD: Okay. So, with that information, are

you planning also to look at information as regard to mixtures in inclusive organophosphates?

MS. LOWIT: So, we have already, as part of registration review, developed what we call a cumulative risk assessment for the OPs, which is really a mixtures risk assessment of OPs using the cholinesterase endpoint. That was last updated, I think, in 2006 or 2007 as part of reg review.

There are existing mixture studies in both juvenile rats and adults, looking at mixtures of OPs that support that cumulative risk assessment. But I think it's also important to remember that the epidemiology studies, that's the women and the cohorts, were themselves exposed to all the chemicals that are just in their everyday environment.

So, epidemiology studies are sort of inherently thinking about mixtures. That's one of the reasons that epi studies are so difficult to interpret, because there is -- well, exposure situation in epi say it can be very complex.

RICHARD: Okay, I'll stop there.

MR. HOUSENGER: Okay, one final comment before

we do public comments. If you haven't read our risk assessments, that, I think, is the first step to do, because I know that a lot of people say, well, I don't understand it. Have you read it? No, we haven't. But I would go through, and it's not a great document to get through.

It's heavy reading, but I think if you start there and read them, that's the best way to understand what we're doing. I think a lot of the things that we discussed today are explained fairly well in that risk assessment, especially the 10X paper for the OPs.

Public comments? Let's hear what the public has to say. Jeannie, Florida, farmworkers, are you with us?

MS. MONELL: She was on the phone. Jeannie, if you're still with us, you represented some Florida farmworker organization. Apparently, she gave up.

MR. HOUSENGER: Anyone else? Going.

(No response.)

MR. HOUSENGER: All right, we start at 9:00 tomorrow. Jim Jones will be here. Everybody get a good

night’s sleep. Thank you very much for today.

(The meeting was adjourned.)

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