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ENVIRONMENTAL PROTECTION AGENCY

PESTICIDE PROGRAM DIALOGUE

COMMITTEE MEETING

DAY TWO - OCTOBER 22, 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: Why don't we get started, if everyone will have their seat. I warned you yesterday or I told you that Jim was coming today. In fact, he's here. I assume that most people in this room know who Jim Jones is. He's been in the program for a number of years and now is our assistant administrator for the program. So, Jim.

MR. JONES: Thanks, Jack. It's good to see you all, a lot of familiar faces. I'm not sure that I have met all of you. I'm sorry that I was not able to join you yesterday, but I'm able to be here for a few minutes this morning. I really just want to give my usual thank you to all of you for your service. That's what it is that you're providing to your country, to the EPA, to the office of pesticide programs, is your service. We greatly appreciate that.

This program, I think, has been a leader in the government in being very aggressive of seeking feedback from the stakeholder community, the work that we're doing, which is fundamentally what the pesticide program

dialogue committee is about. It's about seeking feedback on the direction that we're going as an organization from a wide array of stakeholders.

I think we started this federal advisory committee act group over 20 years ago. It must be closer to 25, actually. I think we have been served well by the input that we've gotten from this committee over many, many years. I recognize that it is not without cost to you, even though there is no remuneration from the government for your participation.

Being actively participating in the areas that we're looking for feedback on is no small matter. It isn't cheap to do. It isn't easy. There's nothing simple about it. The simple stuff we sort of gear out on our own and execute on it, but really challenging stuff we come and ask you for your input, along with other various standardized processes that the government uses, like notice and comment. To be informed about how to give us advice is not easy because the issues are so dense.

I'll just talk about a couple of the issues that are high priorities for us. Many, if not most, are

reflected on the agenda here today, and it's because they're high priorities for us, starting with the (inaudible) as a priority because we have executed on one of our top priorities, and that is the worker protection standards, which I'm extraordinarily proud of that regulation that was signed by the administrator, though I think it was the last day of the fiscal year, the last day of September.

Now, the priority is about implementing it. Implementation has been a very high priority for the Administrator across the board. She's made it perfectly clear to me that we have to work very hard to ensure that the standard that we've put in place, which we think is a very good standard, is effectively implemented. That's going to mean working with a lot of parties, many of them around the table here, not the least of which, probably most importantly, our state-lead agencies who have the key enforcement role for pesticide use issues, which the worker protection standard falls within. Not only state-lead agencies but other entities who have the ability to get information to the regulated community, that being the producers, the farmers, as well as the worker

community.

The more routes we use to get information to those who are provided protections or have requirements, the more likely we are to see better compliance. So, we'll be working across the government and with multiple stakeholders in the months to come to see that that rule is effectively implemented.

Following hot on its heel, so not within weeks but months, many months, but within a year, is the certification training rule, which I know you guys all spent some time on yesterday, another very important rule for us. We have a long history of having a certification program for the use of restricted use pesticides. It is how we have justified the use of some of the more challenging pesticides, whether it be for human health, worker, environmental issues.

The importance of having a robust certification and training program is key to the availability of the products that are restricted use pesticides. So, that proposal went out last summer. The comment period is still open, I believe. Isn't that right, Jack?

MR. HOUSENGER: Yes.

MR. JONES: We'll be looking to finalize next summer. Another really high priority activity for the Administrator, for myself, and for the program.

A couple of issues that have been long on the PPDC agenda, one very long, endangered species, which I know you are spending some time on. I don't think you have yet today. Oh that was yesterday. Endangered species continues to be really important to our ability to protect endangered species and to function as a program.

I think that most people who are paying attention in this space, which I would expect includes everybody in this room, has noticed that there's been somewhat of a shift in the litigation from existing chemicals to new chemicals, which creates a particularly challenging issue for us. We're just going to need to wrestle with it. We're going to need to figure it out. This Committee has been active on endangered species issues for many years.

The issue being pollinators, which, as you know, has been a priority for us. I think it was my immediate predecessor who stood up the pollinator workgroup, Debbie Edwards. We are at least seven years

into our efforts to get our arms around the issues that confront pollinators in the United States. They're incredibly challenging issues. I find them to be the most difficult issues as it relates to pesticide regulation that I've experienced in my time, working on pesticide issues, which is over 25 years. The science is challenging. The sociology is somewhat unique in my experience.

The importance of the relationships within that space are incredibly difficult. But I am confident that working together, we will collectively -- and by the collectively, I don't just mean the people in this room but a broader universe of stakeholders as well. My colleagues from the Department of Agriculture are here. I think the path forward the Administration set in our action plan I think will serve us well.

We even broadened the universe of federal entities well beyond EPA and USDA to include colleagues, most importantly being in Interior, but also other parts of the government that you might not necessarily think have a role in pollinator health like the Department of Transportation and other agencies.

I have a general sort of observation. It could be wrong, but it's an observation of mine. When pesticides are involved, at the end of the day, we will be held accountable. Even though we've been very clear as a government that pesticides play a role in pollinator health issues, it is one factor. But I'm confident, until the issues are resolved -- what I mean by the issues being resolved, I mean the stabilization of pollinator health in the United States -- pesticides will be held accountable. So, with that kind of a mindset, it may set the bar kind of high, but it allows you to own an issue.

I think that that's what we've been trying to do, is own the issue, even though there are other elements that need to be addressed beyond the ones that we here have control over. But it is sort of keeping us in the game in a very meaningful and active way. We are going to do what we always do, which is let science inform our decision-making. That's what we have done, and that's what we are going to keep doing, at least while I'm here.

Lastly, I just wanted to point an issue out

that I think you've spent a little bit of time on. I'm going to frame it a little bit differently. It's kind of interesting that when we finished up re-registration in 2008, it created a much needed a lull in regulation from I'm sure everybody's perspective because we had just finished evaluating every single pesticide in the United States. We were beginning to stand up the reevaluation program, called reg review.

So, the first several years involved putting in place the necessary structure, calling in the necessary data, doing the necessary problem formulation. That would ultimately lead to assessments and then a second round of evaluation, re-evaluation, called reg review.

We are now past that sort of planning and data gathering and problem formulation stage, and we are moving aggressively into the assessment regulation phase. I am noting that people haven't totally picked up on that, but I assume that that will happen soon. A number of assessments have rolled out of the Agency, like several dozen over the last several years. But the pace is going to be picking up. The nature of the chemicals are going to be of greater interest to stakeholders. We

released seven organophosphates risk assessments, which I know you talked about yesterday, just about a month ago.

A number of high profile chemicals are going to start rolling out. So, hopefully, folks weren't lulled into this sense that oh, I guess we're sort of done kind of a mode. Things are going to begin picking up, and it's going to feel a little bit more like it did in the heat of the re-registration era, which probably went from 1998 to 2008.

There are a lot of pesticides that we need to get through, and they will all follow the process that we have articulated. You guys got a little bit of a flavor for that when you talked about the organophosphates. There will be a number. Just looking at the work plan that's on the web, you'll be able to see it. That's a high priority for us as well.

So, there's a lot of things left to talk about. I again thank you for your service. I know that it's not easy. I hope you know that it is deeply appreciated by the leadership of the Agency, as well as the leadership of this organization as well. Thanks.

MR. HOUSENGER: Thanks, Jim. Well, today's

schedule is a little bit lighter than yesterday. We only have half a day. We're going to continue hearing from the workgroups. There's three more to report on. They'll give us an update of where they are. We get into endocrine a little. I know yesterday Tox 21 came up in this context, so David Dix will be over to talk to us about that. Then a discussion of topics for next time, and dates, and logistics, and things like that.

But for now, let's get into integrated pest Management in schools. Bob McNally and Frank Ellis will lead that discussion.

MR. McNALLY: Thank you, Jack. So, what I wanted to start out doing first is give you a sense of how the workgroup started. As you can see, we started about four years ago, and there were three sort of areas we wanted advice in. The first is metrics, the second is ways to assess the benefits quantitatively of school IPM, in particular in any of those sectors, and then third, other issues relating to the promotion and use of IPM that we wanted to bring to the workgroup.

So, let me cover each of these in terms of what we've done to date. The first one is metrics. So, what

we mean by metrics is how do you measure whether the program is working. So, it would be things like the number of pest complaints, the amount of pesticides used, the cost of your program, and maybe even ultimately days of school attendance. If kids missed school because of pest related problems, that's something we want to measure.

We also wanted to have this group give us advice on what are good components of an IPM program. So, under components, things like do you have a sense of what pests you have in this school, do you have an idea of how to inspect and monitor for pests in your school. Then, if you have a problem, what can you do to address it in terms of exclusion or sanitation. That's what we mean by that.

So, the last area was some sense of what's the baseline out there in terms of surveys of people practicing IPM in schools currently. We had input from those various groups. So, that's the first area, the metrics to measure school IPM.

The next area, is how about benefits, that school IPM works. We started on advice and recommendations on

the benefits of IPM. These are areas that we've worked in. I want to draw your attention to the last two. We have efforts on the way for the economics of school IPM with a cooperative agreement to look at sort of the cost benefit. Does it work? How long does it take to pay back any initial investment?

Then, lastly, the health case for school IPM. We also have an effort on the way currently to look at that to see if there's a way to assess the benefits of IPM in terms of reduction of pest-borne ailments that school children might confront, things like asthma and those sorts of things.

So, we had feedback and suggestions on all those areas. The last two we have efforts on the way currently to have those things pulled together in a cooperative agreement for the economics. And for the health case, we have a contract where we should have a result in terms of materials to disseminate sometime this winter.

The last area where we sought feedback and advice was, okay, those two first areas very specific, metrics and benefits. Are there other things that we

should be looking at? In particular, the sense of the workgroup was we should focus initially on schools. We've done that.

I think you've heard at previous sessions of the PPDC, feedback on our Washington State pilot program in region 10. What they set up was a program out there to try to take good programs that are working and have a mentor/mentee relationship with school systems that may not have a program at all, to try to improve their efforts.

Jim Jones was just out there for one of the events in Seattle. We hope to have webinars, at least one webinar, on this pilot sometime this winter for Washington State to share their information with their colleagues in other states about what worked and what didn't.

There's an IPM roundtable we had this spring where EPA was convening a group of interested parties from school entities, like school administrators, to groups like school nurses, groups like the PTA and other groups who are interested in healthy, safe school environment to participate.

The effort there, quite frankly, is to share with them some information and hopefully have them disseminate that information throughout their networks across the country, so school administrators, school business officials, school facility managers.

Lastly, we shared with the workgroup our school IPM strategic plan. Now, simply put, the plan has three basic components. We want to increase demand for school IPM. Well, how do you do that? I think I've covered two areas. If you can show from an economic standpoint that it pays to do school IPM, we think people will want to do it at the school level.

If you show that the health of your student population is better if you do school IPM, we think that will drive demand as well for school IPM. An additional benefit to that is that many school systems actually get more revenue from each day their children are in school. So, if your kid isn't at home sick with asthma and he or she is in school, that's another benefit to the school system. So, that's demand.

So, the school might way, well, great, we get the message, but now what do we do. EPA has worked very

hard over the last four or five years to develop what we're calling sort of a school backpack of technical assistance materials to help schools. So, for example, Dawn Gouge has put together for us under a cooperative agreement a series of training programs for everybody in the school who might need to know about school IPM.

That would be people like the custodial and maintenance staff who generally want to have a pristine school environment. If they do, that will reduce pest pressures. It's also for school facility managers and business officials and the principal. All the affected parties need to be involved in school IPM to be successful. So, we're developing that.

We also have worked on model contract specifications. If you want to hire somebody in the private sector, what do you look for to make sure you're getting good school IPM in making that hire.

Lastly, we've had a series of technical assistance materials developed. Janet Hurley at Texas A&M is developing a full set of information on the web to answer just about any question a school might have about how do you do school IPM. We partnered with our region 9

office in the state of California to do a series of videos that we think are very informative in four or five minute segments which describe, we think, succinctly what school IPM is and how you address certain problems in the school environment. That's a little bit on what we've done on supplying what schools need.

The last point is reward success. You'll recognize someone in that picture who is here this morning. Yes, that's Jim Jones, actually, presenting a plaque to a gentleman in Indiana who has had a very successful school IPM program.

We want to recognize success, though. We're not looking for the gold medal, necessarily, right off the bat. So, we're recognizing success at various levels. You know, if you get started, there's a recognition for that. Maybe it's the bronze medal. If you start to refine your program, we want to recognize that. You get a silver medal. And if you're really excelling, there's kind of a gold medal. So, we want to build those different levels into it to really encourage people throughout the process to have continuous improvement.

That effort should be launched by EPA sometime later this fiscal year, fiscal year '16. So, that's what we've done in terms of our strategy. The workgroup has bought off on that strategy and supports that strategy. So, where do we go from here? I think there's a sense to continue to focus on school IPM as we implement these programs over the next year.

So, the involvement of the workgroup has been helpful, although I don't see it necessarily as a mandate of the PPDC to give us sort of QA/QC or constructive feedback. It's more advice and recommendations, I think. We had found this a useful forum to get valuable feedback from the people in the field about how our program is working. So, we'd like to continue that.

Then, as I said, the third area -- the first area was metrics, then it was benefits. The third area is what are some other issues. I think, as I indicated earlier, the workgroup wanted to focus on schools initially. We've done that.

The next question is, where do we go from here? What we thought about is we could spend some time, if the workgroup continued on over the next year, looking at

where the next opportunity might present itself. These are just suggestions. I think yesterday's meeting wasn't so much to hone in on one or two, but to say these are the kind of things we should talk about as a workgroup over the next year to figure out perhaps where do we go from here.

So, that's sort of a summation in terms of how we started, what we've done, and what we might do if we continue on into the future. Let me stop there and see if there's any questions that people have or perhaps people on the workgroup, if they needed to, add something to my presentation. Thank you.

MR. HOUSENGER: Mark?

MARK: Good presentation, Bob. It's been a long time. I do want to remind the committee here that the agency has been invested in school IPM since the late 90s and has done lots of things. So, in advocating for a continued workgroup presence, I would say that this is a matter of efficiency in government, which we all would like to see more of. So, over this long period of time, the agency has developed certain skills. Some of it has taken a really long time, strategic planning, this kind

of stuff. But the fact is that they've done it. It's done now.

So, what they can do now into moving into different views. So, from schools to hospitals or from schools to daycare. They can virtually use the infrastructure that has taken many years to develop with a lot of money and a lot of skills and everything else. They can take all of that infrastructure and now drop it into something to where there's an incredible efficiency. I think this is good government and it's also a good thing to do for our children.

MR. HOUSENGER: Robyn?

ROBYN: Thank you for that wonderful presentation. I unfortunately had to get off the call yesterday to try to get on the incidents call.

I'd just like to second what Mark had said. I really hope this workgroup continues. I think we all are collectively very interested in helping advise EPA. I look forward to seeing it move into other areas and be successful as we were in the school IPM. I would particularly like to see it move into health care and child care.

There are already good examples out there. The Children's Environmental Health Network has the eco-healthy child care program, which is a national program, but they don't have very specific examples of IPM. Also, the Maryland Pesticide Network has been doing this already in hospitals. We could use that as a model, in addition to the school IPM Center of Excellence.

MR. HOUSENGER: Nichelle?

NICHELLE: Great presentation. Thank you for that. I think I would be interested in knowing how many schools you guys are working with, how many have been successful. I don't know if you mentioned it. How many have been successful and how many still need work?

MR. ELLIS: We haven't been actively measuring the numbers of schools that we touch, because a lot of the work, especially with our regional coordinators, their efforts are at the school district level, but they do kind of track the work that they do there.

What we've not been able to do, what we don't have currently the authority or the funding to do is to go out and assess each school in the country to see where

they are with IPM implementation. So, what we have done is to rely on the work of other organization groups like the National School IPM Working Group that the IPM Institute of North America helps bring together.

They have conducted surveys with experts in the community, including folks like Mark and Dawn and others to assess where they believe schools are, because they're folks that often spend time working in schools directly. We also get it a bit through the CDC SHPPS Report has elements of IPM in it. So, I think with the most recent estimates, we feel that about half of the schools in the country have some element of an IPM program in place doing some of the things. But to be more specific than that, we are not able to do that right at this time.

MR. MCNALLY: Just to follow up, I think, correct me if I'm wrong, I think in the early part of this century, it might have been 5, 10, or 15 percent. Maybe around the time the workgroup was formed, estimates might have been around a quarter of the schools had some form of it. I'll look to you guys.

So, we think, just to answer your question, over the four years -- and again, these are not hard and

fast numbers because we don't want to get in the business of government having reporting requirements for schools on this, but from other sources, we think it's perhaps as much as doubled from 25 to 50. But you guys want to --

NICHELLE: So, when it comes to rewarding success, like you mentioned in one of your slides, that will be focused at the local level to gauge success?

MR. ELLIS: Yes. The plan there is that school districts could apply to our program for recognition. Then there are criteria for each of the reward categories. We would reward them at that level. It's based on the same model that the Tools for Schools program used successfully for about 10 years in rewarding schools for their programs.

MR. HOUSENGER: Dawn?

DAWN: Thank you. I just want to put Mark on the hot seat because he has some of the statistics regarding the state numbers. Each of those within their own states tend to track our numbers a little bit differently. I can say that for my own state, we're at about 58 percent of students. I tend to focus in on the

number of students attending public schools.

If you count school districts, you can have one school district that represents 400 students and you can have one school district that has tens of thousands. So, for each of us, it's a little different. Washington State, they've seen some dramatic expansion in the last two years. They're now way into the 60/70 percent of their students enrolled in schools that are practicing integrated pest management, somewhere along that continuum.

Then, across the US, I'm going to ask Mark to give that stat because he quoted it just this morning.

MARK: I don't remember any of that. I assume I have permission. So, when we started, actually when EPA started this in the 90s and then we got involved, it was about three percent of the states were involved. Well, at the beginning of this year, it was 84 percent of the states are involved, which is a tremendous success as far as diffusion of the IPM innovation in schools.

That's the good news. The not so good news is a little bit of what Dawn was talking about. We have not reached what we call in the study of diffusion the

adoption of innovations. The individual state, if they've reached a carrying capacity or a plan in which it's going to sustain itself, that's really in the works right now. I suspect that that is occurring right now.

But most states are less than -- are more in the 25 to 40 percent range of implementation of reaching children. Of course, we would like to see that go much higher than that. So, when you reach critical mass, that will have happened. I suspect that that will, unless we pull back at this point, I suspect that will happen and then it will be easier, again efficiency, to roll over into different venues.

MR. HOUSENGER: All right, not seeing any more cards, I guess we'll move on to public health. Thanks, Bob and Frank.

Susan Lewis and Susan Jennings is on the phone. Susan Lewis is here, Susan Jennings is on the phone. Susan Jennings, do you hear us?

MS. JENNINGS: Yes, I can. Can you hear me?

MR. HOUSENGER: Yes.

MS. LEWIS: Good morning. I'm Susan Lewis, the Director for Registration Division. We have Susan

Jennings on the phone, so Susan Jennings is our public health coordinator or liaison. We changed the title, but it's pretty close. She's actually located in Georgia, which is close to CDC. A lot of her interaction is with CDC, so we are practicing green conferencing for her participation today.

She's going to run through sort of the purpose of the public health PPDC subcommittee, some of the accomplishments that have happened, and then some future topics. So, Susan.

MR. HOUSENGER: Before you get started, you weren't here yesterday, this is a workgroup, it's not a subcommittee, as we learned yesterday. A subcommittee has to be more than 50 percent of the members here. This is just a workgroup.

MS. LEWIS: It's a workgroup, and I believe it's been going on for about five years.

Susan Jennings.

MS. JENNINGS: So, I'm going to just talk a little bit about the workgroup, as Susan said. We were created about five years ago, over five years ago, to address issues involving pesticides that vector diseases

or control pests that vector diseases with a public health component to them. I'll get into a little bit as to the difference. For some of you, I apologize if this is redundant, but I want to make sure we're all on the same page for the discussion portion.

The issues that we cover is really anything covering these types of pesticides, the regulatory policy, any programmatic issues, environmental, technical, economic, or science policy decisions. It's not intended to be anything other than a very broad focus on a small population of pesticides that are regulated by OPP. Unlike other workgroups, it's an ongoing workgroup that's intended to address issues involving pesticides with public health uses as they arise. In a second, I'll just tell you why that is.

We've identified three critical roles. We, being the workgroup, has identified three critical roles for the interactions with EPA. This was done right at the very beginning of the creation of the workgroup. It's an advisory panel for EPA to seek FACA advice or input on public health pesticides, in particular. It's also a portal for people to bring issues to us of concern

to EPA, unlike many of the agricultural or other types of pesticides.

The public health pesticides don't have a lot of associations and stuff. You'll have public health associations, and you'll have disease associations, but there aren't a lot of pest-specific associations, other than the American Mosquito Control Association. What happens in these situations is it kind of falls through the cracks a lot of these public health issues with these pests. So, part of the purpose of this group is for us to just have a dialogue with a part of the public that is very, very concerned about this and to have it be quality, efficient and effective.

The last purpose, critical role, was to have a forum for discussing items of common interest. So, basically, at each meeting we kind of try to address these three things. For the last item, the forum item, frequently that will be someone from the workgroup that will actually talk to the workgroup about something that they have ongoing that is a new and different thing that might benefit everyone's knowledge.

This workgroup does allow us to get a broader

stakeholder engagement on public health issues than we can get without the FACA umbrella. By going through the FACA umbrella of the PPDC, we're able to actually reach out to much broader stakeholder's base for input on our policies and stuff early on than we would be able to do so without that umbrella.

The issues that we've addressed in the past are repellency graphic, the efficacy guidelines. We've talked about this fairly regularly over the last five years. We've gotten very technical on these. We've also gone broader, what the guidelines actually are. We've had discussions on that. We've also talked a bit on the different process for requiring efficacy, whether there are improvements that can be made on that.

We've talked about communication materials. Most recently, the bed bug strategy went out. It was finalized in February, I believe, of this year. It's when it was released as final. We brought that in, I think, twice during the draft phase just to get people's input on where it was going and how it was going. That is a federal government product, not just an EPA product.

Lastly, we talked a bit about regulatory

issues. We talk about tick IPM, bed bug control IPM, availability of the products, labeling. It's a smorgasbord of public health issues on these pesticides.

Where we see this workgroup going in the future, vector control diseases are growing in this country. This is documented by CDC. I know when I first started doing this job, West Nile is what the trip was. Since then, we've had numerous numbers of diseases that have been of concern coming into the country. So, the interest and the need for this workgroup or the work that the workgroup does, the public health aspects are critical to our ongoing mission.

In the future, some immediate future opportunities we have, one is communicating the risk for products, packages, concentrates. I think we discussed it at the last workgroup and got some very valuable information from the workgroup on that at the last meeting.

IPM activities for tick control and residential pests, that continues to be an item that we're working on. One thing we will be doing in the next year or so is going to be potentially updating and clarifying the role

of the pest list and discussing the content of the pest list with our sister agencies of CDC and USDA. We'll be trying to figure out, trying to make sure that it still meets our needs according to the standards for today. That will be a good thing for us to get some input from the group on.

Then, lastly, resistance issues and communication, particularly for mosquito control. The toolbox for these is just insufficient right at this moment to handle resistance, particularly on a worldwide basis. As we all know, these things start on a worldwide basis and find their way in here. So, we're going to be doing some work on that that it would be good to get workgroup input on.

Again, it's just a good time for people to come in and talk to us about what their concerns are as well. We try to be very efficient and effective with our meetings. Like, this time we did not hold a face-to-face meeting. We try to have the meetings when we want to have the meetings, when we think that there's sufficient topics and sufficient interest to hold one. Sometimes we'll hold conference calls, just an hour long conference

call, if there's an issue that has some urgency to it. So, it's a little different than some of the other workgroups.

So, in summary, we basically focus only on public health initiatives. The workgroup can engage more efficiently and effectively in this manner than if we were to try to bring these issues to the full PPDC as a whole. As I said, I think it's a valuable resource for OPP. It really helps us out to make more higher quality decisions on our public health issues and more knowledgeable decisions.

That's really all I have to talk about the workgroup. I don't know, Susan, if you want to take it from there.

MS. LEWIS: Thanks, Susan. I thought we'd open it up for questions.

MR. HOUSENGER: Wayne.

WAYNE: Thank you, Susan. I'm just curious about where the body of information resides. There's a reference to web page revisions, IPM, actually everything that's covered in the presentation, all interesting information. But do you have all of this at a place

somewhere in the Internet, or where can we find or read about public health?

MS. JENNINGS: Yes, it's on the web page. But, like public health pesticides, it's in different areas. It's not all in one public health spot on our web page. The web revisions, a lot of that was bed bug things that we did. We have a pretty extensive bed bug web page that we've developed with a lot of input from various sources. The documents that I reference there are all on there.

There is a tick specific page on our web page. Much of that work was actually done by Candy Brassard in the group that I'm working with a little bit more closely now that she's gone. Then there's also a mosquito resistence. There's mosquito pages and things like that. So, it's throughout our web page.

WAYNE: Maybe I missed the URL. Can you provide that for us?

MS. JENNINGS: Well, I can provide a list of URLs. So, if you into like the biggest one, www.EPA.gov/bedbugs. I can provide a list of URLs where all the public health things lie. But, as I said, they're on varying pages. I can provide that to you

offline. I can't provide it right now.

WAYNE: So, if we went into the EPA.gov web site and did a search for these things, we should be able to find them?

MS. JENNINGS: Yes. If you have any problems, feel free to give me an e-mail, give me a call, or send me an e-mail at jennings.susan@epa.gov. I can help you find whatever it is you're looking for.

WAYNE: The other thing is on the slide that has the future indicated on it, right before your summary slide, you mentioned the pest list, which I think I'm familiar with, but what is the current relevance of the pest list? Is there any regulatory significance to that?

MS. JENNINGS: Yes, actually, there's quite a bit. That's the list that we use as a guideline for deciding what needs efficacy data, what does not need efficacy data. That's the nuts and bolts of it. But then there are lots of other ways that it is used and incorporated. Anything that's on there kind of gets --

FIFRA does its best to pull out public health uses separately from ag uses where it can and tries to encourage the Agency to look at the benefits. Before we

take regulatory actions, we've got certain regulatory obligations as far as consulting with CDC on public health pesticides before we take regulatory action. That's all driven by that list.

It also facilitates greatly our interactions with CDC because things that are on that list we're not supposed to have a lot of discussion about it as to whether or not there's a public health impact for them.

WAYNE: And how or who makes the decisions or how is that list updated?

MS. JENNINGS: That list has never been updated, really. It was required by FIFRA when it was amended by FQPA. It was required by FIFRA, and it's a joint product from USDA, CDC, and EPA. That's what was mandated by FIFRA. That's what we're intending on doing now.

We're hoping not to make a lot of changes to it, but it's been a very long time and it really needs just to have a current blessing, if only that, or changes to accommodate the world of pests as we see it. But it's a joint product from the three agencies, and that's what it will be. Revisiting it could be as little as a

statement saying we think it's great as is, but we want to make sure everybody knows we think that in 2015 instead of 2002. Or it could be slightly more comprehensive than that.

We're right now putting together the group of people that will be working on that. It just would be really helpful to get -- we really need to know how the public uses that list or if the public uses that list. We use it extensively, but we're real interested in how other people might view it and see it.

WAYNE: Thank you.

MS. LEWIS: Wayne, just for some of the newer members, typically, the agency does not look at efficacy data for agricultural pests. We only look and review efficacy data for public health pests, and for things such as termites, because of the financial damage. So, that is what can drive the efficacy requirements.

WAYNE: So, is efficacy required just for those pests that are on that list?

MS. JENNINGS: If you are asking for a public health pest claim, yes. Efficacy would be required.

MR. HOUSENGER: But I think that list is pretty

extensive. It includes bears and alligators. I don't think we ask for efficacy for those things. That's kind of why the revisit of the list, to narrow it down to those that we're really interested in looking at efficacy data for.

Aimee?

AIMEE: I guess this is a question for the workgroup and for EPA. Maybe it's going a little bit far out. I'm looking at the IPM workgroup that just presented and now the public health workgroup. I see the IPM workgroup created this great backpack for IPM, for schools specifically. It feels like it's very different than what you have done, but to capture all that same sort of information in a mosquito net instead of a backpack, to provide information to our communities about mosquito management, there's so much fear, there's so many new potential vectors coming in.

People don't understand the difference between nuisance and pest mosquitos. There's just so much out there. There's so much information about IPM and mosquito management. It seems like that would be a wonderful tool if that was something that this workgroup

would want to move to. I got a thumbs up, but not from a workgroup member. So, I'm curious if people have input on that idea.

MR. HOUSENGER: Amy?

AMY: So, thank you for the presentation. Obviously, this topic is incredibly important. I had a suggestion along the lines of our discussions for transparency and what the workgroups do. I'm a little bit troubled by the title of this workgroup, a public health workgroup. While you're arguing that vector-borne disease is a public health issue, the public health issues regarding pesticides are so much broader than vector-borne diseases.

I feel like it's a little bit confusing to call this a public health workgroup because when you drill down and you see what your mission is, you get it, but I think we should think about a public health workgroup for vector-borne diseases or just really clarify that in the title, because public health can involve surveillance, reporting, all these other really important issues that this workgroup is not charged with.

MR. HOUSENGER: Mark.

MARC: Hi, Susan, this is Marc Lame. Nice presentation. I'm saying hi to Susan down in Atlanta since I can wave at that Susan over there.

I know that you work a lot with the CDC folks. One of their big concerns with regard to public health and pests and pesticides has to do with the drastic decrease which, to my knowledge, is still continuing with environmental health specialists in vector control and getting the knowledge that they need and also the personnel that they need to deal with these issues, one of which, for instance, would be resistance. If you don't have educated people there and if they're overusing pesticides, resistance is going to just increase.

I know this is mostly the CDC working through the National Environmental Health Association to educate those folks, but where do you see the Agency, EPA, with regard to assisting in that effort as far as a workgroup challenge?

MS. JENNINGS: As far as a workgroup challenge, I'm not sure where I would see the workgroup in there. As far as what EPA is doing, we had in the middle of September we held an upper management meeting in Atlanta.

We actually had three of our division directors and Jack Housenger fly down from D.C. to meet with the director of the National Center for Environmental Health and a bunch of CDC people. We all got together in a room for a day and talked about all these types of issues.

I think one of the things you're probably getting at is the training program that was conducted by CDC to educate the environmental health professionals. I know CDC is in the process of converting that into a digital format so it will be available online. EPA is going to be working with them in all the pesticide modules to provide our input and our support for that.

Money is always a problem, but expertise and knowledge should not be. So, we're always willing to help however they see fit. But, as you said, that is very much in their lead on that. Does that answer the question?

MARC: Yes. I certainly want you guys to be able to take some credit for that. I think it's a good thing, but certainly, we've talked about certification here and other things, not that I'm implying that needs to take place. Programs that EPA is involved in with assisting in

other sectors of pest management. Of course, the pest management in this situation would be vector management. I just wanted to see if there was a consistent and equitable effort.

MS. JENNINGS: Yes. Thank you.

MR. HOUSENGER: John.

JOHN: Thanks. This is John Peckham representing AAPCO. One of the things that states are encountering more frequently is the illegal use of pesticides indoors for bed bugs, as well as ants and other pests, especially with immigrant communities. I'm kind of asking that this workgroup or the IPM workgroup or however, whichever group it is, that there be some additional focus on this issue.

These clean ups are extremely expensive. We had one in Minnesota three or four years ago, an illegal use of an off shore product containing malathion, and diazinon that ended up costing the housing agency more than $10,000 to clean up the apartment. Products had to be removed, furniture, drywall, kitchen sinks, and cabinets. It is a pretty serious issue both in immigrant communities and economically disadvantaged communities.

I would just ask that that be raised up a little bit higher. Thank you.

MR. HOUSENGER: Ray.

RAY: Just a brief comment. If you were going to register a bear repellant, I really, really want to know that it works.

MR. HOUSENGER: Are you volunteering, Ray?

Cynthia?

CYNTHIA: So, I've used several of your public health and residential pest materials, and I found many of them to be very useful. I just want to echo the thought. Whatever you can do to get the word out, there's so much institutional secrecy.

I've become an informal advisor to the elder care industry and have found that when pest problems strike, when bed bugs infest or other pest problems, there is -- I mean, they clamp down and the immediate reaction is just spray like hell. Whatever we can do to get the word out to these institutions before the pests actually become an issue is very, very helpful.

MR. HOUSENGER: Dawn.

DAWN: Thank you. I have just one

clarification, and I also wanted to give a strong back up to John and his concerns. I want to focus on that first. As a person who does whole building analysis in public housing, I can back his concerns up very, very strongly. I was showing photographs last night under the influence of two glasses of wine.

Just dramatic, dramatic pesticide use. Residents purchasing restricted use pesticides online from a variety of places. It's a really significant issue. I'm new to the public health workgroup, but I can say that it definitely is one of the top things that I'm concerned with.

Also, just a quick clarification about the National Environmental Health Association education programs. Susan very eloquently described it. These modules were based on in-class teaching materials that a number of people in this room were involved in deploying around the country. Those have been turned into online modules and will be available shortly. The hope was, however, that we would be developing some in-class training materials for more rigorous practitioner based training at some point in the future. I'm not sure

whether Susan has any kind of additional update on that.

MS. JENNINGS: No, I do not. You're correct. I realize that is part of the plan. I think their effort right now is trying to get the digital thing complete. I can't speak for CDC on what their plans are.

MR. HOUSENGER: Amy?

AMY: I think some of the comments being raised about the vulnerable populations and the immigrant communities use of pesticides to control some of these vector-borne issues is really, I think, an important comment that's being made. I'm not sure if you want more people on there or how we can help, but it is -- I mean, I really welcome that topic being addressed. It is a huge issue.

MR. HOUSENGER: So maybe, Susan, it would be good if you could list the URL sites. We can get them out to the group just so people can see what information we do have on our web site. It's not that easy to find stuff there.

MS. JENNINGS: No, it's not. Can I send that to Dea?

MR. HOUSENGER: Yes.

MS. JENNINGS: Okay.

MR. HOUSENGER: Anyone else?

MR. GRAGG: Richard Gragg. My question is, is this workgroup having discussions around insecticide resistance for these vectors?

MS. JENNINGS: That was one of the topics we said we would cover on potential future topics. So, it will be brought up probably at the next meeting as to how we want to look at it and how we want to adjust it.

MR. GRAGG: So, you've never addressed it, the agency? Nobody is working on it?

MS. JENNINGS: Well, I mean, the agency has addressed it, but right now, particularly for mosquito control, there's increasing concerns because resistance is increasing in mosquito control. So, that's probably where we would start. I don't think it's necessarily a workgroup product, per se, but more workgroup input into EPA products.

MR. GRAGG: Is there any information on your outreach and education?

MS. JENNINGS: For resistance?

MR. GRAGG: Yes.

MS. JENNINGS: Not a lot right now, no. I mean, I'd have to look for that as well. Whatever I can find on the web, I'll include that on the URL list as well.

MR. GRAGG: I do have one other thing to say. I mean, I understand the perspective, the public health perspective, but just in listening to the presentation and then the other presentations we had yesterday, I don't know, in my head I feel like there's a disconnect. I thought it was all public health. I mean, when we talk about the impact of pesticides on human health, I thought it was all public health.

So, I'm sort of concerned if there is -- I don't know. It seems to me there needs to be a holistic message about pesticides and their human health impact and then if we want to talk about specific issues. But to me, just in hearing it and thinking about it, to put this public health over here, it's sort of not addressing the whole picture when you get out into the public education and educating people.

MR. HOUSENGER: I think for the last two PPDC meetings we've had, the comment that the name needs to be

a little more directed at what this workgroup is and isn't. So, I think that should happen before the next one.

In terms of resistance, the agency has done some things on resistance. I think most of it has been so far with weeds and labeling to indicate what the mode of action is for different products and what active ingredients are contained in that product so that you can rotate and avoid resistance. But I think it's one of the issues that we're tackling on three fronts, the weeds, the insects, and fungicides. We haven't made a lot of progress yet.

MS. JENNINGS: And those initiatives are kind of what spawned the public health discussion, other than mosquito control which has been around for a long time.

MR. GRAGG: Okay, thank you.

MR. HOUSENGER: Sure.

Robyn?

ROBYN: Just real quick. If you don't mind, could you also send a link to the members of the public health subgroup too so other people can see who is on it?

MS. JENNINGS: Yes.

ROBYN: And if anybody else wants to join, we'd be happy to have you.

MS. JENNINGS: Okay, I will do that, because that's actually on the web site as well, so I can just send a link to that.

MR. HOUSENGER: All right, thank you, Susan and Susan.

MS. JENNINGS: Thank you.

MR. HOUSENGER: And our last workgroup is a new one. Jackie Mosby is going to report on that one. It's incidents.

MS. MOSBY: Good morning. What I'd like to do is go over one of the newest PPDC workgroups, the incident workgroup. This is just a few slides. What I'd like to do is just pretty much go through the objective of the workgroup, the importance of the workgroup, discuss the membership makeup, and also upcoming meetings. I'm the chair of that workgroup, the EPA chair, and Rich Dumas and also Melissa Panger are the technical co-chairs for the workgroup.

So, the objective of the workgroup is for the workgroup to provide recommendations and feedback to EPA

on one of its long-term goals, which is to develop an electronic incident data system which will be publicly available and also useful to a broad range of stakeholders. That's our long-term goal. Our short-term or near-term goal is to actually get recommendation on developing the data elements. So, that's what we're working on now.

So, the importance of this workgroup, well, OPP relies on this incident data, one, for our risk assessment or risk management decision or individual chemicals or groups by use patterns or chemistry. We also use it for rulemaking such as the WPS or C & T -- incident data was used in that rulemaking -- and also for priority areas such as associated with a label use or label misuse.

The PPDC feedback is really important in OPP's effort to improve the data quality and the data management. Creating an incident data system that is easy to use as standard data elements that is useful and accessible will increase the likelihood that it will be used. We also believe that it could also increase the number of voluntary incidents that we receive.

We have a broad membership. We have a broad interest and representation on the workgroup. We have NGOs, registrants, user groups, state government agencies, regional, state, federal agencies, academia, and even pollinator groups. That's the 23 members. We actually got an additional member yesterday, so we have 24 members on the workgroup.

As I mentioned, this is just starting, so we had our first kickoff meeting on the 6th of October, and that was a teleconference call. It was to introduce ourselves and to also identify the organization, how we would function as a workgroup. We also had a meeting this week on the 20th where we actually started to roll our sleeves up, and we started looking at the near-term goal, the data elements.

So, we started looking at human incident data elements. So, at that meeting, we did an overview sort of how OPP would use the incident data. We had good participation. As I mentioned, we started looking at the human data elements.

In terms of the upcoming meetings, we did not complete our review of the human data elements, so we

will complete that at an upcoming meeting. After we have completed identifying what would be good data, human data elements, looking at a list that we had proposed, any additional ones or ones that we think will be good to use for an incident report, we'll do that. Then we'll start to rank them by critical needs.

The work that remains for us to do -- as I mentioned, we looked at the human data elements. We still have to go through the same process for the wildlife, plants, pet and domestic animals, and insect pollinators. The goal for the workgroup is to provide recommendations on the data elements that we would use to the full PPDC workgroup spring of 2016.

That really is all that we've done so far. It is a new workgroup. We've had two meetings. We've had good participation. I'm looking forward to diving in and working with the workgroup to identify data elements for this incident data system that we hope to develop.

Did you have anything, Rich, that you would like to add?

MR. DUMAS: The only thing (inaudible) grief about being a workgroup or whatever. We are a workgroup,

but looking around this table, we have more than 50 percent of our membership sitting at this table right now. We're not looking to change our status.

MS. MOSBY: Thanks for that. Now, if there are any questions for me or Rich or any of the workgroup members, please.

MR. HOUSENGER: Robyn?

ROBYN: Thank you. I am on the workgroup, so I thank you for the presentation. I was not able to join the teleconference yesterday because of some issues, but I would like to point out that not only do you have academia, but you also have public health people. So, thank you. I look forward to working with you guys, too.

MS. MOSBY: Thanks.

MR. HOUSENGER: Steven?

STEVEN: I'd like to be the 25th member, if I could. I do have a question. One of your slides here you talk about increasing the number of voluntary incidents. I'm assuming that's incidents reports. What is a voluntary incident and what is an involuntary incident report?

MS. MOSBY: Well, the involuntary would be 6A2,

the required reporting. So, voluntary would be sort of like if there's an incident, folks would -- you would take the status -- they would have information. It would be easy for them to report that, so the general public could report.

STEVEN: Okay, and the 6A2 is?

MS. MOSBY: Registrants reporting.

STEVEN: Okay, okay.

MR. HOUSENGER: Amy?

AMY: Thank you for your tackle of this topic. I have a couple of questions and also thinking about sort of like a long-term home for some of this. First of all, echoing what was just raised about voluntary and involuntary, there are, I think, 30 states that now require clinicians to report suspected or confirmed cases of pesticide exposure. Each of those states, some of their reporting goes to the poison control, others go to the state health department. It just varies depending on the state.

My first question is, how will this incident data process impact what the states are already collecting, and how will it be coordinated with that?

MS. MOSBY: Well, one of the things that we want to do is to create a data system that will allow us to cross walk. So, we're trying to identify data elements that may be used in other systems so that there is some sort of cross coordination or cross walking between them.

AMY: So, when you think about it in terms of like a home for this, like thinking of some place where anyone could go in and input this data, right, it doesn't have to be anyone with any expertise, it could be the general public. So, what will happen in terms of you get a report from the clinician, maybe you get a 6A2 report, and then also this report. Are you thinking about coordination or is that something to think about? I'm just kind of wondering what it will look like at the end of the day.

MS. MOSBY: I think we are thinking about it, and I welcome input on what a system might look like that would facilitate all of these different scenarios.

AMY: Well, I think it's great what you're starting at. I just want to at the very beginning be thinking about the coordination aspect. I know there's

like 12 states that have an active surveillance system. Maybe helping out some of the states where there isn't an active surveillance system, and there's lots of questions. Who do I report to? Where does this data even go? It might be a place to start in the 18 states that kind of have a regulation, but there's nothing going on.

MS. MOSBY: We'll look into that.

MR. DUMAS: The diagram that was in this slide, this sort of represents our broad effort to get input. The data elements are the first little piece. But ultimately, in building whatever this system is, many of the problems you raised we recognize them. We know there's a lot of good quality data out there that we don't usually see. So, we are looking for help in every step of the way. That's why we have this group. We envision this is going to be a fairly long term longstanding group.

MR. HOUSENGER: Cheryl?

CHERYL: So, as a new member of this group, I really appreciated the way they were really organized, because that graphic right there. We kept trying to talk

about some of the things that Amy was talking about, how are you going to get source it, how you're going to tie it in, how you're going to autopopulate it. They kept coming back we're at the top of this schematic. We're talking about data elements today. So, they were very focused, and they kept refocusing the group.

But I think these are questions that all of us have. You're asking for seven pages of data elements. How are people going to fill this out, et cetera, et cetera? So, that was something that's going to be answered over the course of the project.

The thing that we did not get to, we didn't get done with the data elements. But the thing that I did need to mention here is I think the use of the data is also important for the regulatory process and making sure that there's some data elements that go into the strength of the correlation between the proposed exposure and the adverse effect.

We didn't get into anything about validating there was a label or if the symptomology matched to the alleged effect. You're going to have to have a way of capturing or ranking the strengths of the report with their

biological plausibility, correlation. Just like we heard in bees, pesticides are not the only cause of incidents in bees. There can be illness. There can be other things, confounding factors. At the end of the day, what we heard is this incident reporting goes into regulatory decision making and having an understanding of that strength and making sure it's fit for purpose.

There was a lot of attention talked to not double counting, not getting three reports from the same incident, which is great. There also needs to be some attention on the strength of the report.

MR. HOUSENGER: Cynthia?

CYNTHIA: I would like to commend EPA for this first effort. It was clear that there was a tremendous amount of work behind the scenes that led to these initial meetings. I thought that this workgroup exemplifies what a useful role an EPA PPDC workgroup can have.

As EPA moves toward greater use of computational toxicology, decreased use of animal testing, more protections for endangered species, I think this is a really important way to truth test whether

and validate whether our protections are really working. As Amy mentioned, there is a huge opportunity to bring together databases from the states, databases within EPA and across the government with the new Fish and Wildlife Service database as well. My hope is that ultimately some of these efforts also will lead to the revision of the 6A2 rules, thresholds for wildlife, so that there will be required reporting when there are fewer than 50 of a hurting species of mammals that are killed or 50 song birds, and so forth.

Also, with regard to what Cheryl was just mentioning, I hope that these efforts go hand in hand with the development of biomarkers for neonicotinoids and other compounds so that we will have more confidence in the associations between the exposures and the outcomes.

So, thank you very much. I think this is a really good start.

MR. HOUSENGER: Dawn?

DAWN: Thank you. What Cynthia said, I back that up 100 percent.

I'm here representing the National Environmental Health Association. I just want to say

that I have strong support for this workgroup and your mission. It's very important.

I do have a logistical question. I wonder how this is going to mesh with Sensor (phonetic) or whether -- that's a Geoff question. Is there any comment or is that question premature at this point?

MS. MOSBY: Well, I'm not sure.

MR. DUMAS: That's very similar to Amy's question. Ultimate goal is to try to have all the databases talking to one another or ultimately have something at a national level where anyone can look at it. So, that's sort of our gold standard, what we want to aim towards. We're very aware of Sensor, and we use it already.

MR. HOUSENGER: Beth?

BETH: I just wanted to underscore what a couple people have already said. That is I think we're off to a really -- I'm new to this workgroup. We're off to a really good start, but it is just a start. I think as we sort of work our way through the data elements and through the various phases there in that graphic, many of the suggestions and concerns that have been raised by all

of you who have spoken, hopefully it will be addressed.

But yes, I think it will be a very taxing effort, but clearly one of the worthwhile. I think the whole community, everyone in the community will benefit from it. So, thank you.

MR. HOUSENGER: Ray?

RAY: I'd just like to follow up on Cheryl's comment. I haven't had a chance yet to go through the proposed criteria or proposed reporting documents. But it would be important for the Agency to seek up front from a reporting party or individual what alternative explanations for the observations have been considered or pursued. Allow opportunity for narrative input.

We're all aware that pesticide exposure can be mimicked by disease and vice versa. There are multiple alternate explanations for some of the observations. I think it's important for everybody to understand this possibility and to start with seeking all possible explanations for an observed incident. Thank you.

MR. HOUSENGER: Amy?

RAY: I forgot one thing, sorry. It's a bit troubling to consider having general public input into

this, not that we should exclude it, but consider how to use that appropriately. The American Association of Poison Control Centers receives hundreds of thousands of responses and inquiries and reports on an annual basis. They do a very good job of filtering general inquiries for information from actual reports of exposure and injury. We need to take into account the information that EPA collects and how to appropriately filter that if there's a broad opportunity for input from the public.

AMY: I just want to follow up on some points that Ray made that I think are really important coming out of this discussion. Just in case you didn't hear me yesterday, there really is an ongoing need for clinicians to be able to diagnose and understand pesticide exposure. They practice medicine without that ability to have a test, a clinical diagnostic tool to see what's going on. That ultimately would help drastically with incident reporting.

MR. HOUSENGER: Anyone on the phone who is a member of the PPDC?

(No response.)

MR. HOUSENGER: All right, thank you, Jackie,

Rich.

Let’s reconvene at a quarter of. We’ll hear about endocrine, and, hopefully, David will show up.

(A brief recess was taken.)

MR. HOUSENGER: Can everybody please sit down? We’re ready to get started here.

MS. MONELL: One very quick piece of information sort of left over from yesterday’s discussion. Anita?

ANITA: Hi, everyone. I know there was a lot of interest in the ESA discussion yesterday on the tools. I just wanted to alert everyone of a public meeting that’s happening on Monday, the 26th. It’s our EMPM meeting. It’s Ecological Modeling Public Meeting. There will be a presentation at 2:30 p.m. Eastern Standard Time on our terrestrial tools, the whole presentation on that. There will be some other presentations that you all might be interested in from different consulting groups and various academia. So, what we’ll do is I will send the agenda to Dea and have her send it out to the group so that you can phone in. There’s a webinar available if people would like to sign in. Thanks.

MR. HOUSENGER: All right, so the last presentation is by David Dix, Director of the Office of Science Coordination and Policy on the endocrine disruption screening program.

David?

MR. DIX: Thanks, Jack. It's a pleasure to join the group and discuss the endocrine disruptor screening program. I've got a relatively small number of slides that we'll go over rather quickly, and then leave a lot of time for questions and also for discussion.

For those of you who have been active in the PPDC for more than a couple years, I think you're pretty familiar with the background of the endocrine disruptor screening program. So, I haven't spent any time in terms of slides on that.

So, first off, I wanted to recap where we're at with the list one chemicals, the tier one test orders that were issued a number of years back and the data that came in around those. I'll just remind you that the original list one chemicals, there were 67 chemicals on list one. Those generated 762 tier one test orders.

In response to that, 50 of the pesticide

actives generated data in response to those tier one test orders. Eight of the pesticide actives cancelled. In terms of the inerts, two of the inerts generated data and seven of the inerts opted out of the pesticide market. So, 52 chemicals went forward for tier one testing or screening, and then data packages were submitted, and weight of evidence reviews/screening level reviews were conducted by the agency.

The results for those 52 chemicals are captured in this slide where 20 of the compounds, actives and inerts, there was no potential for interaction with the estrogen, androgen, or thyroid pathways, as indicated by all of the data relevant, not just the tier one screening data but all of the other scientifically relevant information.

For 32 of the compounds, there was an indication of some potential for interaction or activity in endocrine, estrogen, androgen, and/or thyroid pathways. In many cases, there was a little bit of a can’t-be-ruled-out type of situation, particularly some of the in vivo studies in the tier one. They certainly are indicative of endocrine mediated effects, but there’s oftentimes a

very fine line separating endocrine mediated and what might be a response to a general or systemic toxicity.

So, for those 32 potential actives, if you will, 18 were recommended for additional testing, primarily related to tier two type tests, and 14 it was determined no additional need for testing. The table lays out those 18 different chemicals and the types of testing going forward.

Before I go into this table, I'll just say quickly that in the cases where there was some potential for activity in the endocrine pathway but no need for additional testing, this was based on that complete data package. Most of these were pesticide actives. I think maybe all of them were pesticide actives that had a large amount of part 158 data.

So, the potential endocrine activity that was indicated in the screening package was either -- in those cases, it was already trumped by the existing data. It was occurring at much higher concentrations or doses, so it wouldn't be relevant to the risk assessment in most cases. In other cases, it was already accounted for in the existing data and the existing risk assessment.

So, going to this table, it lays out the 18 compounds from list one where either human health or wildlife testing is called for. You see that for human health related, there was actually no true blue tier two type tests lined up in terms of either a RAT (phonetic) multigen reproductive test or an extended one gen test in RAT.

What lined up for human health related testing are special studies looking at androgen related effects impacting male reproductive health, or thyroid related tests, the comparative thyroid assay or other protocols that could be considered.

On the wildlife side, it’s much more directly linked to the tier two test guidelines that have been developed for ecological species. These were just finalized in the past year for fish and for frogs for the Medaka Extended One Gen Reproductive Test, the MEOGRT, that’s indicated here. The (inaudible), LAGDA, the frog assay, the Larval Amphibian Growth and Development Assay, which has a lot of endocrine specific endpoints.

So, you can see for the different compounds, the weight of evidence screening level determination

indicated potential activity in a pathway and in a taxa and species that would be relevant to meeting definitive testing in either the fish or the frog tier two assay. In one case, the case of linuron, there's an indication and need for data from both the fish and the frog assay.

So, in this slide, I think it captures a lot of the points I was making earlier in terms of the human health testing relating to thyroid activity and male reproduction, and in wildlife the 13 chemicals that are lined up for fish for the Medaka assay and the 5 chemicals that are lined up for the frog test, the LAGDA.

Moving forward quickly, and then we can come back and discuss and address questions, I wanted to talk a little bit about the status of high throughput assays and computational models, or predictive models, being applied to the program. We referred to this over the past year as a pivot in the program from the current approach to screening, which is relatively low throughput.

As you sort of saw implicitly in the review of the list one tier one screening, a lot of work, a lot of

resources go into issuing those test orders, generating all of that data, reviewing all of that data, and moving forward, something along the lines of five years and millions and millions of dollars, both by stakeholders external as well as internally for all of the activities that we have to do to conduct this screening.

So, we need a higher throughput approach to endocrine screening. There's too many chemicals that are relevant to the program. We can't just continue to do this a drop at a time as we have with list one and with the existing list two. We need an approach that can address thousands of chemicals and prioritize them and rapidly screen them for endocrine activity.

This has been the plan all along. It's just been some challenges to the implementation. If you look back at the 1998 EDSTAC (phonetic) report, you'll see that there was a prioritization, screening, and testing step that incorporated computational and high throughput methodologies.

Over the past 10 years, the agency has invested quite a bit of resources in our research and development arm into computational toxicology. The fruits of that

investment are coming to bare, particularly from our ToxCast/Tox 21 program for high throughput screening, as well as our ExpoCast program for high throughput exposure modeling. So, we're going to be able to incorporate the ToxCast data at the screening level for the endocrine disruptor screening program to identify estrogen, androgen, and thyroid activity.

The first example of that is the 18 different high throughput screening assays from ToxCast/Tox 21 and are relevant to the estrogen receptor pathway, which is a very significant portion of the estrogen related activity you need to screen for in the endocrine disruptor screening program.

So, we take data from these 18 different high throughput screening assays and we incorporate them into a pathway model. So, we're using what we know about the biology to interpret the results in a biological/toxicological context.

The point of this slide here -- and I think I can do this without zapping anyone -- if you take all of the data -- they're very inclusive -- you take all of the data, concentration response data, from these 18

different high throughput screening assays and you integrate it into a biological predictive model of the pathway. You end up saying that for this particular compound, it's bisphenol-a, which is a well-known estrogen receptor agonist, or positive, you see a clear signal, agonist signal from the pathway-based model as the R1 signal. That's the agonist signal.

You can integrate all of the results from these 18 different assays into defining clearly and quantitatively the agonist or, for other compounds, antagonist signal relative to estrogen receptor signaling and the estrogen receptor signaling pathway. We're doing something very similar to the androgen receptor signaling pathway and somewhat similar for the thyroid pathway, though most of the activity there is coming from nonreceptor mediated effects. So, we're having to take a slightly different tact there.

We spent a lot of time this past year validating this high throughput and predictive modeling approach. We took these data to the FIFRA SAP in December of 2014, and we followed that up with a series of publications and characterizations of the results of

this high throughput method versus the existing tier one battery. The estrogen receptor model really did perform as well or better than these existing methods for detecting estrogen receptor agonists and antagonist activity.

We used a lot of compounds, reference chemicals, to validate this method, 45 different reference chemicals for the in vivo method portion of the validation, a total of 68. So, the results of an additional 40 compounds for the in vitro validation. This compares very favorably to the number of reference chemicals used to validate the tier one methods, whether we're talking about the ER binding, the ER transactivational, or the uterotrophic assays.

In our current validation, we limited ourselves to the comparison of this high throughput method to those three tier one estrogen receptor screening methods, the two in vitro assays for binding and transactivation and the uterotrophic in vivo assay.

So, the estrogen receptor model, the ToxCast based estrogen receptor model result was in 100 percent agreement with the tier one results for those three

assays for the list one chemicals. It's actually a fairly astonishing result given the noise within these assays.

Each one of these assays has its own strengths and weaknesses. So, we're not comparing an imperfect method to a perfect method; we're comparing a series of imperfect methods/imperfect models that are all being used to predict results to each other. So, that type of consistency is really astonishing but very helpful to taking the first step forward.

One of the reasons I say that is because, for example, the uterotrophic result itself, and that's what's indicated in this portion of this slide, is not always consistent. So, in the course of pulling this together, we curated with partners from the NIH hundreds of different uterotrophic studies, in the end about 100 different chemicals.

What we found is that for many of these chemicals, we had multiple uterotrophic studies that have been run. Depending on how they were run, where they were run, when they were run, they sometimes showed very different results in terms of whether there was estrogen

receptor agonist activity or inactivity indicated for the same chemical, using essentially the same guideline protocol, at least the same within the context of the scope of the guideline.

So, you can infer from that a real challenge to comparing the results of these high throughput alternative methods to the individual results of the tier one screening battery. It also speaks back to the strength of the tier one battery approach.

You'll recall that the 11 assays for that part of the tier one screening battery were meant to be interpreted alone. Each one of them has their strengths and weaknesses. It's when they're put all together that they are able to be used and then provide the greatest strength in decision-making.

So, I mentioned some publications. A couple that I point you to that might, if you're interested, to follow up, one is in Environmental Science and Technology. It really pulls together this validation of the high throughput alternative models and methods versus the three tier one screening battery assays. That was published by scientists from my office, Patience Browne,

as well as scientists from our Office of Research and Development, and our partners at the NIH.

I mentioned the FIFRA Scientific Advisory Panel meetings that were held, one in July, where we looked at sort of early on developing high throughput exposure models that we think will be useful to the endocrine disruptor screening program in the future, as well as eventually to other chemical programs.

Then, in December is where we really brought the estrogen and androgen receptor models and data to start to compare those to the tier one screening battery results and to validate them as alternatives to some of the tier one screening batteries.

We laid this policy out based on that science in a June Federal Register notice on the use of high throughput assays and computational tools in the endocrine disruptor screening program. This proposed use of the estrogen receptor model as an alternative for the two in vitro assays, the binding and transactivation assays, as well as the uterotrophic assay.

What we published in that Federal Register notice and this table are slightly different formats but

the same information. We're not planning to stop with those first 3 of the 11 assays; we're planning to move forward and, as much as the science supports, develop alternatives based on the high throughput predictive models for androgen receptor, the androgen receptor pathway, for steroidogenesis, and thyroid pathway. We think combinations of these tools, these alternatives may well substitute for some, if not all, of the current tier one battery of assays. So, we'll see how that develops over the coming year or years.

We have a lot of data in hand for literally thousands of chemicals for the estrogen receptor, androgen receptor, steroidogenesis, and thyroid pathways. So, we think we'll be able to make progress, make use of these existing data and establish new alternative methods for rapidly and efficiently screening chemicals for potential endocrine activity as part of the endocrine disruptor screening program, and doing it in a way that uses a lot fewer animals, a lot more time and dollar efficient, and provides at least as a robust screening as the existing tier one battery. Because it's so rapid and it will address so many more chemicals in such a shorter

period of time, that in itself will be a more robust and protective approach to identifying potential endocrine disruption.

So, with that, I think I'll stop. We did start a little late, so maybe we have at least five minutes or so for questions and discussion.

MR. HOUSENGER: Cheryl.

CHERYL: So, thank you for that. As always, registrants are really interested in knowing when the next round of test orders are coming. So, what I didn't hear was when is the test orders coming, the tier two for this one and this two tier one. And then I have one more comment.

MR. DIX: Sure. I can comment on that. If anyone else wants to, Jack or others, they could add in.

The ICR, the information collection request, for this one tier two test orders is with OMB now. I think we've provided all of the information. It's gone through the multiple steps of public comment, response to public comment, another public comment, and so now it's in its final stage of waiting for OMB review and a decision on giving us the green light to move forward

with the tier two test orders.

CHERYL: And the other one, which is this two tier one, are you going to wait until you've had some of the science advance?

MR. DIX: So, what happened with list one tier one test orders, which were issued in 2009 and 2010, by the time those data came in and worked their way through to analysis review and publication of the weight of evidence screening level determinations just this past June, science over the course of five or six years moved forward.

We found ourselves in this position of having the answer in hand from some of these alternative methods that we had acquired in the course of that long process of list one tier one. We don't want that to happen again with list two or with other chemicals. So, we want to push the science and the science policy forward as quickly as possible to allow for the most efficient path forward with any future screening.

I say that with any future screening without referring explicitly to list two for the reason that if you look at the results in hand from the high throughput

methods for at least the estrogen receptor and androgen receptor, the most potentially active compounds in those pathways are not in list two.

So, we want to carefully consider that in terms of prioritization of chemicals for the screening program. We want to make use of these alternative methods as possible and develop them, and we want to make use of the existing data to point us towards the highest priority chemicals in terms of who should go next into the screening phase of the program.

CHERYL: So, I mean, that all makes perfect sense, I guess. The question always is, through the process and the postings and lists, how does the regulatory process catch up with this really practical thing that you just expressed?

MR. DIX: So, we need to develop an approach to the information collection request process. We need to develop an ICR that is flexible to the priorities indicated from these alternative methods and compatible with these alternative methods. So, we're developing and working within our program, across the partners, as well as with OMB to develop that type of approach, an ICR that

would be amenable to allowing us to chase the high priority chemicals efficiently.

CHERYL: I mean, that sounds perfectly reasonable. We just always want to be updated on the process part.

I have a question, too, though. I know that you've had some communication -- as registrants, we get asked for the results from these tests that are conducted here by other global agencies, specifically with Europe. They have their hazard criteria. They have their endocrine concerns. I believe you've had some communications within the European community. I guess I would just like to hear a little bit more about that.

I would also encourage that to go on consistently while packaging screening versus finalized tasks, packaging lists as what they are versus maybe some black list. All of that information continues to be very important that it can't be communicated properly. I'd like to hear about what activities continue in that space, especially in the discussions with Europe.

MR. DIX: Well, there's kind of two things there. One is what the European Commission is doing and

various member states. There there's been, as you know, it's been publicly discussed. There was a meeting between the US and the EU a couple weeks ago, you know, here in October. EPA, FDA, NIH participated in that discussion from our side and the full breadth of European Commission, directorate generals and ECA and EPSA (phonetic), as well as the Joint Research Center. So, it was a full panel of relevant parties from the European side. There they shared information that's going on both in ECA, in EPSA, and in the JRC related to this.

I think one of the more impactful things going on right now is this impact assessment that JRC is conducting some analysis to support. So, the JRC is kind of the European Commission NIH, the Joint Research Center. They're using a variety of different information to characterize chemicals using their different optional approaches that they laid out in that road map with public comment.

They've had several public meetings. I think the next one is coming up November 6th where they've described the methodology that they're applying for this impact assessment to say be sure to use criteria one,

option one, two, three, or four. This would be the potential impact on this number of compounds.

I think they started with something like in the order of 700 compounds, most of them pesticidal or plant protection products, pesticides basically, and then also some biocides, and then also some industrial chemicals. They're using a methodology that they've described a couple of times that incorporates a lot of existing data from (inaudible) other sources.

They are looking at some of the high throughput data as well. I think that's a good thing. I think it would be useful for them to look at the data sort of assay by assay, but to incorporate it into a pathway type of model in terms of interpreting the results. But it depends on the purpose.

The challenge here will be to keep people's perspective on what they can do and what they eventually publish on this impact assessment work in the context of a case study and not a definitive assessment of potential endocrine disruption or endocrine disrupting chemicals, which is a phrase I don't like to use. But that will almost surely happen in the broader context.

We've had examples of that in the past where people take lists of chemicals that were generated, cumulations of data, reviews of data that were done for a specific purpose. Over time, it's kind of forgotten, the limitations of that analysis, and it becomes in some people's minds, perhaps, a de facto list of endocrine disrupting chemicals. That, to me, would be a great shame. So, I think they're very well aware of that.

From what I've seen, they're doing a very good job in this impact assessment. I think that's one of the more important activities that are going on there right now. There's a couple of other activities going on that I think are very good venues for international discussion, communication, collaboration. One, of course, is the OECD, the Organization of Economic Cooperation and Development. There's a very active endocrine disruption testing and assessment program as part of the test methods guide development program.

Also, UNEP (phonetic), the environmental program, has recently established an endocrine disruption advisor group or expert group. That's another very good venue for discussion and, collaboration. I think EPA is

participating in that, as well as other parts of the US government, along with a pretty full range of stakeholders.

MR. HOUSENGER: Pat.

PAT: Thanks, David, for that update. As one who has followed this program for many years, I can attest to the amount of work that did go into the first round of chemicals, not only looking at all of the relevant scientific information that was available by both the registrants and EPA doing the testing, reading through all the weight of evidence reports, it was a huge effort just to basically get through about 50-odd chemicals.

I also want to point out that the cost to animals for this first round of testing was somewhere in the range of 25,000 to 30,000 rats and fish and amphibians. So, we are very excited about the new direction the EDSP is taking for the high throughput assays and the computational tox.

I do have a couple of questions. As far as you moving forward, as you say, to the next round of chemicals, I think there’s 8,000 or 10,000 chemicals that

are supposed to be screened at some point. What do you see as the next step? After the chemicals you've looked at that already have come out and there's ones that are showing some potential for at least this point in direction with estrogen pathway, what do you see as the next round of testing for those? Obviously, we're kind of trying to phase out the tier one screening. Would there kind of be something in the middle? Would they go directly to tier two? How do you see that?

MR. DIX: If you take a look at the science policy that we've presented in June, we're presenting these as alternatives to the tier one screening program. The tier one screening is linked to the tier two testing as needed. So, the future application really depends on whether you're talking about application to pesticidal chemicals under that legislative mandate or to non-pesticidal chemicals.

So, how that moves forward will vary significantly depending on what we're talking about. But for pesticidal chemicals, actives and inerts, we have to screen them all. That's somewhere on the order of 3,000 compounds, just actives and inerts, somewhere in that

ballpark (inaudible) antimicrobials.

So, we think that this alternative approach will provide at least a partial solution to the throughput of the tier one battery, perhaps even a complete solution to the throughput of a tier one battery. But these are alternatives to the tier one battery, and then, compounds where there's activity, they'd be analyzed similar to the first round and a determination made if additional data was needed for either human health or ecological assessment.

I think we can probably take some lessons from the list one result and the weight of evidence result. It's certainly maybe not going to hold true for that full set of thousands of compounds, by any means. But, for the ones that did indicate some activity, some will need additional testing, tier two type testing, and some won't because there will already be more than enough information, including, in some cases, the same test.

PAT: So, you're envisioning a weight of evidence evaluation like we just did with list one, with the high throughput data and any other relevant data

that’s available?

MR. DIX: For pesticidal chemicals, absolutely.

PAT: Yes, and then the decision to go on either to more testing or no.

MR. DIX: Right. For non-pesticidal, it’s a different story, because there the exposure component is a big piece of the screening.

PAT: And then what about some mixtures or formulations and stuff, are they going to be tested too or are we just looking at, at least for pesticides, the active ingredients at this point?

MR. DIX: I’m just thinking. How long is it going to take us to get through those 2,000 or 3,000 chemicals? I don’t know how many of us will be around the table at that point in time. So, we can say whatever we want.

MR. HOUSENGER: Yes, definitely.

MR. DIX: Don’t take this the wrong way, but it’s kind of the same response when people say, well, what about other pathways. Other pathways beyond estrogen, androgen, and thyroid are really important. I think we need to have a lot of research and development

around those other pathways. But when you talk about the regulatory program, in this case the EDSP, let's get through E, A, and T before we start implementing and really even seriously planning for other pathways.

That's kind of how I would respond to what about formulations, what about mixtures. There might be alot that can be done computationally in that area once you have the data on all of the individual compounds. Then there's ways, I think, to validate that approach.

PAT: Thank you.

MR. HOUSENGER: Nichelle.

NICHELLE: So, thank you very much for your presentation. I guess I just have some questions for clarification. So, earlier in your presentation, you mentioned that when we were talking about the 32 who had the potential for interaction risk or potential endocrine interaction, 18 recommended for additional testing and 14 for no additional testing. You mentioned that for some of these 14, you saw interaction at higher concentrations. This was not relevant to risk assessment. Then you also mentioned that for many of these chemicals not moving forward for additional

testing, that some of the impacts were accounted for in existing risk assessment. I was just wondering what does that mean?

Also, and this is probably related to your answer for my first question. A lot of them already have information from the data for part 158. So, what data are you using to help inform these decisions as to why these chemicals did not move forward for additional testing?

MR. DIX: So, I don't know off the top of my head exactly which of those compounds, those 14 are. You'd have to really dig into the weight of evidence document. I think what you would find is that these compounds either had existing data that provided the information that you would gain from tier two type tests. So, they already had information either from mammalian or non-mammalian tests that addressed the potential endocrine activity that was seen in the screening.

They maybe addressed it in a couple of different ways. They may have addressed it by having adverse effects and therefore regulatory points of departure occurring at much lower concentrations than

where you saw the endocrine activity. Or, I think there might be cases in there where there may well have been probably reproductive or developmental effects that were already characterized in terms of adversity and dose response in the existing data sets.

It may be that they were endocrine mediated; it may be that the screening data helped strengthen the case for that mode of action. But they were already characterized in the existing data sets, so no additional testing was necessary. I think you'd find that these were mostly food-use pesticide actives that had a huge portfolio of data already in hand.

NICHELLE: So, in terms of the risk assessment, say, for example, I look at chemical X risk assessment and I get to the endocrine section. I would see information on data that you would have already had as part of 158 sort of characterizing the endocrine potential. That's this new set of data. It's not like you're saying these chemicals don't have the potential for endocrine disruption or that we shouldn't be concerned. But they just already have data from other parts of the program.

MR. DIX: Yes. I just want to go back to this

because embedded underneath that center 32 potential interaction for E, A, or T, that’s the summary of the weight of evidence screening level determination. So, for 32 of the 52 chemicals, the program’s determination was that there was potential for activity in one or more of those pathways.

Then it was put into the context of the existing data set and whether additional information was needed as these chemicals moved further into the risk assessment process incorporating that screening level information on endocrine activity.

NICHELLE: Okay.

MR. DIX: So, no, it’s not saying those 14 compounds didn’t show endocrine activity. All 32 of those chemicals, the determination was that they had a potential for showing that endocrine interaction.

NICHELLE: So, the 14, just for clarification, the 14 it’s yes, but we already have existing data?

MR. DIX: We already have the data necessary and/or the activity was occurring at concentrations that were not relevant to the overall risk assessment. So, I think there’s an example or two in there where our

compound was neurotoxic at much lower concentrations than where you were seeing some activity, potential endocrine activity in vitro and in vivo in the screening assays. That neurotoxicity and lethality associated with it was occurring at much lower concentrations.

So, in terms of thinking about real world situations and the risk assessment and risk management, it's just not relevant. Compounds are killing organisms, whether it's the target organism in terms of pesticidal use or a potential toxicity, an adverse effect. It's happening at a much lower concentration. So, that's, in some cases, the driver there.

NICHELLE: So, I'm glad you brought up the low dose Low concentration aspect of this work. Many scientists that do independent endocrine disruption work do believe that we should be looking at those low doses. You are saying that you don't believe that we should in terms of the risk assessment?

MR. DIX: I absolutely think we should be looking at those low doses, and we should be looking for activity, measurable activity, and we should be developing assays that are as sensitive as possible to

detect that low dose activity. But if there's no activity shown at low doses, we shouldn't infer it without data to support that.

This gets to a really fundamental issue that is an unsettled scientific issue. So, we continue to work with panels and ask the National Academy of Science to pull together panels to give us the best advice possible on this issue of low dose endocrine mediated effects. Is there a concern and would it be better to address endocrine issues similar to the way we address cancer right now, with a low dose linear extrapolation? The whole issue of how we handle cancer assessments in that manner is also an open scientific question.

I understand the concept of low dose endocrine mediated effects. I understand the significance of low dose effects, particularly during developmental phases, sensitive phases of development, fetal development and otherwise.

I don't understand a concept where just because we're talking about an estrogen receptor, it operates somehow different than the dozens of other types of nuclear receptors in that superfamily. There's a

different biophysical law that somehow applies to an estrogen receptor versus a pregnanex (phonetic) receptor or a FXR (phonetic) receptor or the dozens of other receptors in that superfamily.

I think the biology is consistent here. We measure it low doses, particularly with these alternative methods. We think these are very sensitive methods. We follow those low dose effects, but to infer activity when we don’t see it from in vitro or in vivo studies is difficult.

I also understand and I appreciate that there’s potential to develop more sensitive in vivo test methods to try and address this low dose issue. That’s something we’re looking to the National Academy for some good advice on. We’re also looking for some case studies where low dose endocrine mediated effects would have an impact on chemical risk assessments.

MR. HOUSENGER: We still have two more comments to get through and we’re over.

NICHELLE: Just one last comment. You are confident right now that you guys can capture chemicals that are active at those low dose changes?

MR. DIX: In terms of the 52 weight of evidence, I'm confident that we've gone through an extremely robust, I would argue the most robust, endocrine screening of any compounds. In combination with all of the other information around those compounds, I think those 52 weight of evidence determinations are very solid, very defensible. We have the ability in those assays, the screening assays and all of the other information, to detect low dose endocrine mediated effects, yes.

MR. HOUSENGER: So, he said yes. You know, this gets at the issue of do you use the science today that you have or do you wait until it's perfect? If you do the latter, you never do anything. So, I think that relates to a lot of things just beyond endocrine as well.

Sharon.

SHARON: My question kind of relates to what you just said, which is can you just clarify the regulatory processes and decision points that will fall out of this work and how it relates to screening for other health effects whether environmental or public health?

MR. DIX: So, I think collectively there's been

a number of us from our system administrators to various office directors, et cetera, who have talked about this application of the computational toxicology methods in the endocrine program as the first step or the first application of what might be broader applications beyond the endocrine program and beyond endocrine pathways.

I think that's true. I think it's going to take some time to develop the science, the science policy to validate those methods and those alternative approaches, and then implement them into the other chemical programs. I think that's where we're headed. We're not doing this alone. I think this is the broader path internationally from the full range of stakeholders and government and regulatory bodies.

If you look at what's going on around adverse outcome pathways and their development in the context of the OECD, this program was essentially built around adverse outcome pathways. This program, this endocrine disruptor screening program, scientists and the science was a precursor for adverse outcome pathways.

It's built around pathways, mechanisms, modes of action, connecting bioactivity to adversity, starting

with the far left side of tier one and moving forward to the far right side of tier two. So, I think it is a precursor that will move beyond endocrine and beyond the EDSP.

MR. HOUSENGER: And Ray?

RAY: When I was waiting in line this morning to get in through the security, somebody suggested I should wear my helmet when I want to launch in a series of questions for extra protection. I've got basically one question and then a comment, which I hope you will find welcomed.

With respect to tier one testing, how did the results compare to the OSSRI, other significant scientifically relevant information? It's more of a rhetorical question in that did we learn enough to make the expense and effort of that tier one testing worthwhile? It's something that you kind of need to approach on a chemical by chemical basis. Is this something you're looking at?

MR. DIX: I'll answer it. I think that's a helpful question. I think that the answer to that question is demonstrated in how we went about validating

the alternatives using the estrogen receptor pathway model and the way we think we'll continue. Something that will come out of the validation steps for the alternative methods will be meta-analysis, if you will, across all of the chemicals that we have uterotrophic studies for, or Hershberger (phonetic), or Pubertal (phonetic).

Then, as we connect it across the tier one assays and across the tier one assay alternatives, there will be a meta-analysis, a joining of different results, I think in the end a very transparent, more quantitative and reproducible or computational method, if it works.

It's worked pretty well with the estrogen receptor pathway. It looks like it works very well with the androgen receptor pathway model. So, now you get to the point where you have a data set, you have the input, you have code, computational code, you run the data through the code, you get a set of numbers. It's very transparent. It's very reproducible.

Now, it gets more difficult when you want to add, combine, and use those numbers in combination with two, or three, or four other models to make a

determination, a screening level determination, a weight of evidence type call. It may not be possible in the next few years to get to the point where it's not more expert intensive and qualitative. But I think eventually we can get to an approach that's extremely quantitative and transparent, and it's based on the ability to predict with accuracy the outcomes that we're trying to predict.

Remember, end of the day, we're not looking to predict uterotrophic results or Hershberger results; we're looking to predict the risk for human populations and ecological populations via endocrine disruption. That's the difficulty, because what's the truth behind that. So, we're kind of building ourselves a trail of bread crumbs forward, across the pathways, across the tier one and tier two screening batteries, but we can use the accumulation of information on these dozens or hundreds of chemicals, or even thousands of chemicals, to test the accuracy at which we can predict our path along the way. It's kind of a convoluted answer.

RAY: Thanks. I would like to commend the agency on the scientific rigor they have demonstrated in the EDSP and the review of data, also on the pursuit of

improvements in testing and in the evenhandedness in handling the communications on the endocrine issues.

You mentioned, David, the United Nations advisory group on endocrines that's recently convened. They met about a month ago in Geneva. To follow up, the report that I heard from that session is that you were conspicuous by your absence as the voice of reason in that forum. I would like to encourage the agency to make certain that you're able to participate actively in these international forums because you do have the expertise, more than any other regulatory agency in the world.

MR. DIX: I appreciate that. I wish I could have gone, but back to back trips to Europe -- I'm trying to broaden our capacity to participate in those types of activities. Though I missed the face to face meeting that you referred to, the UNEP meeting (phonetic), believe me, we're actively engaged with that group, and we intend to move forward with UNEP, our WHO partners, the OECD, and with our European Commission/European Union partners. There's only so much time and air miles in a day.

MR. HOUSENGER: All right, thank you, David.

He should have just said thank you.

MR. BRAGG: Richard Bragg has a question.

MR. HOUSENGER: Hold on, Richard.

UNIDENTIFIED FEMALE: (Inaudible).

MR. HOUSENGER: David is never here.

Richard?

MR. BRAGG: Hi, David. My question is around the translation of this great work that your group is doing and that you're presenting. Can you share how this gets translated into policy and decision making? For example, how would this work that you're presenting here get integrated into EPA when they're talking about integrating environmental justice in the EJ 2020 or 2014 in making decisions around that? How does this kind of work get into those processes and decisions?

MR. DIX: So, that's one of the challenges that my office and our partner offices, particularly the pesticide office, are really committed to moving forward. There's a number of activities going on that I think are related to that, including the UNEP advisory group, endocrine disruption advisory group, which has a real potential to address issues relating to global

environmental justice. It's something we're actively working on. I think there's a two-fold aspect to it.

One is to communicate more effectively on the issue of endocrine disruption. I think our new web site is a step in the right direction. I think there's other activities again that we can take up in partnership with some of these international organizations to achieve that.

Then is the more difficult hard science issues, how can you make something like a high throughput screening or an endocrine screening program address issues of environmental justice. We're open to input on that.

MR. BRAGG: Okay, well, thank you for answering that. I guess it leads to my second question. In some of the previous presentations, I recall that they talked about in the 21st century toxicology about , biomonitoring. I mean, maybe it's not just for you, but how is all this going to weave together, really? The same question I asked, how does this get translated in EPA policy and decision making? Is there some time line or projected time line, or do we have to wait until all the results come in? What is the objective, other than getting a

basic science result?

MR. DIX: I'll refer to a couple activities that are supporting that. One is another NRC, National Research Council, National Academy of Science panel that was convened earlier this year that's looking at implementing toxicity testing, 21st century toxicity testing data, into regulatory decision making. So, we're looking to that panel and working with that committee to get advice from them in terms of how to move this forward.

I think what you're talking about in terms of a new approach to safety assessment, chemical risk assessment, it's something that's recognized across the agency. Not only our assistant administrator spoke to this but also Tom Burke (phonetic) from the Office of Research and Development.

It's not something that we have to take on in a vacuum. Our partners and other program offices, Office of Water, Office of Air, Office of Research and Development working on this, as well as across the US government, particularly NIH, are helping us with this.

MR. BRAGG: Okay, thank you.

MR. HOUSENGER: All right. Thanks, David.

So, next topic is what to discuss next time and the times of the next meeting. This room isn't available whenever we want it, so we have to put in for it relatively early to get it. It's also good for planning purposes if you know far out what the next dates are. Tentatively, we have this room scheduled for May 11th and 12th and again November 2nd and 3rd.

So, I guess if people don't know of any major conflicts -- or, if you do, let us know and we can adjust to that. I know there's always meetings going on, and there's always -- it's hard to find a time that works for everybody, but those are the times that work for this room, which is a big factor that goes into setting those dates. So, just let us know.

One of the things that we discussed quite a bit this time were the workgroups. We always get updates by them. If you listened to Jim McCleary, he said the workgroups were relatively short lives. If you look at the times frames that our workgroups have operated under, they've been five or more years. Now, they've tackled different issues in the workgroups, but I think we need

to go back and talk to our senior leaders about what it is these workgroups are providing, what can they provide, which ones should go on.

I heard some reference to sunsetting the tox 21. At the same time, we're starting an incident workgroup. I heard something about implementation of the WPS workgroup. So, we need to talk internally about it and see where we come out. We'll talk about that next time, if not before.

Are there any topics -- well, I guess before we get to the topics to discuss next time, one of the things we heard last time that we tried to do this time was provide more discussion time. I guess do people think we had adequate discussion time, except maybe for the OPs? No? Generally? Yes? So, we'll keep kind of with that format for the next go round.

Are there discussion topics that people want to hear about? We always make a call, but then it's kind of like people singly giving us topics. It would be good to agree on some topics for next time that everybody could agree upon?

Mark?

MARK: This is with the assumption that the roundtable for school IPM occurs. It's planned to happen next spring, but I know things do happen to where it might not happen. But assuming it does, and it's probably a game changer for the national implementation of IPM at schools and then eventually other things certainly having to do with children. I would like to get a report on how that went from the branch if that's possible.

MR. HOUSENGER: Ray.

RAY: There's a significant subset of the group, not everybody, which has a strong interest in challenges in meeting PRIA deadlines.

MR. HOUSENGER: I just signed one that we actually met the date without renegotiation.

RAY: Congratulations.

MR. HOUSENGER: So, we're making progress in that. That's been a major focus of mine since I've taken this job, recognizing that some of the PRIA actions that we have before us were accepted without all the data, which we're trying not to do in the future. But that can impact meeting the PRIA dates.

RAY: Understanding those challenges can help us both in preparing packages and assisting the agency with their work.

MR. HOUSENGER: We can certainly report out on progress that we've made and things that we're doing to ensure that the deadlines are made.

MS. MONELL: We might also, Ray, want to think about raising that as a topic for the quarterly PRIA meetings that we have. It seems to me that that's a defined enough topic that it probably should be taken up there.

MR. HOUSENGER: Cheryl?

CHERYL: I made the call before but something around the MRL internationally. I know Lois has come in a couple times. She's now gone. We have IR4 that sits on this panel. It would be nice to talk about, and several grower groups, a kind of update about the international aspect of MRLs.

MR. HOUSENGER: Sharon?

SHARON: I'm not sure if this is outside the purview, but I think it would be nice to hear about any legislative initiatives that are in front of congress

with regard to EPA's programs, whether there's a new initiative, modifications to existing programs, regulations, that kind of thing.

MS. MONELL: Just so you'll know, the agency does not initiate legislation. That would be considered lobbying. So, anything that's being discussed in congress that impacts the pesticide program we're certainly able to discuss for what we know. But we don't initiate legislation.

MR. HOUSENGER: Beth?

BETH: I would sort of endorse Cheryl's suggestion of international, but I would ask that it be maybe even broader than MRLs. What's the status of EPA's international activities with your sister organizations, particularly with Canada?

I guess, will there be a NAFTA meeting next month where maybe there will be some things to talk about as a result of the NAFTA meeting? Then, also, I would suggest that we have a follow up on the ESA discussion, because I think if I recall correctly there's a stakeholder meeting In January, I believe. So, there will probably be more to share about that.

MR. HOUSENGER: Yes, and we'll have the first three biological evaluations out.

BETH: Good.

MR. HOUSENGER: Hopefully.

Steven?

STEVEN: The pollinator workgroup has not met since about the time that the White House published their program. So, I'm just kind of wondering -- I know some of that stuff kind of overlaps what we were talking about, supercedes what we were doing. An update on the progress of that, what EPA is doing, all the stuff I don't know to ask.

MR. HOUSENGER: Amy?

AMY: I would like to continue along some of the initial discussions we had regarding worker protection standards. I know that you're going to think about the workgroup, but given the importance that the agency is placing on this, it would be great to have regular updates of that.

MR. HOUSENGER: Okay.

Cynthia?

CYNTHIA: I'm sure you can understand, the American

Bird Conservancy is particularly concerned about seeds. I would like to have a discussion about seed coatings as a pesticide delivery mechanism, specifically focused on use of coated seeds under the treated article exemption and also the compatibility or incompatibility of seed coatings in integrated pest management. Thanks.

MR. HOUSENGER: Dan?

DAN: I think this follows in line with some of the other comments that were made. Maybe just a segment of a snapshot of other activities that are going on with the agency. We talked about the international MRLs that's been brought up. Maybe some short updates about some of the other SAPs that aren't really part of some of the workgroups that are here and the legislative updates was mentioned as well. So, maybe just a short segment about other activities and updates.

MR. HOUSENGER: Sure. No one mentioned marijuana. Surprising.

UNIDENTIFIED MALE: We talked about that in the (inaudible) meeting.

MR. HOUSENGER: Any others? Dawn?

DAWN: Thank you. I'm excited about the

pesticide incident group. This could be premature, but I'd be very interested in hearing about incidents related to bed bug infestations. I would love to have been able to collar our FDA representative. I'm hoping that he participates next time. It's outside the purview of this group. Perhaps it would be worthwhile hearing from him about head lice and the pediculicide issue, because it does affect a lot of our pest management professionals.

Then, also I would be very interested in hearing about worker protection training and how that deployment is actually happening on the ground. Thank you.

MR. HOUSENGER: All right, that's a good list.

RICHARD: I've got one.

MR. HOUSENGER: Oh, sorry, Richard.

RICHARD: Okay, thanks. Can we hear something about pesticides in health disparities?

MR. HOUSENGER: Pesticides in?

RICHARD: Health disparities.

MR. HOUSENGER: I'm not sure I understand what that topic would entail.

RICHARD: Okay. Well, what is the research that is being done around this topic?

MR. HOUSENGER: Okay. Not hearing any more Suggestions. This is the last meeting, PPDC meeting, for Bill Jordan, who is retiring at the end of the year, he says. Bill has been with the program forever. He's got so much stuff in his head about this program that replacing him is not going to be possible. I was in a meeting with him the other day and someone asked him a question. He cited a 1972 court case and exactly what the ruling was. I'm sitting there wondering what we're going to do without him. I just wanted to acknowledge all his efforts in the agency. He's going to be very missed. So, congratulations.

(Applause)

MR. HOUSENGER: So, be safe and we'll see you -- no, Ray? How fitting.

RAY: Public comment requests.

MR. HOUSENGER: Oh, public comment, we had no public comments, unless there's someone on the phone.

RAY: Right here.

MR. HOUSENGER: Oh, you're a public comment?

RAY: A couple of quick issues and one a little bit longer. We haven't heard the PRIA work plan or the work plan for PRIA actions on the web site. It hasn't been updated since April or so. I'd like to see that updated as soon as possible and kept up to date.

The second issue is we may have come up with a resolution for your marijuana concerns. The new prime minister of Canada campaigned on a platform of legalizing recreational use of marijuana. If they can handle the testing there, you could handle it here as international joint reviews.

The third issue is a bit more serious.

MR. HOUSENGER: I'm not used to Ray making jokes. I don't think he should.

RAY: In our discussion yesterday, it was very evident there's a great deal of interest in the policy on use of EPI data (phonetic). Open literature is the basis of retaining the 10X uncertainty factor. It has highly significant science and policy implications. That policy change deserves prominent public notice and comment independent of the risk assessments for individual active ingredients.

We heard yesterday that the policy will effect compounds beyond the OP's that were discussed. The significant new public policies or changes should not be buried within the dockets for individual compounds and decisions, as this is less than fully transparent either in the letter or the spirit of the law.

The situation with the 10X and EPI data policy is not unique. The policy should be appropriately vetted according to statutory requirements well ahead of their use in practice and regulatory decisions. From past experience, we can predict that use of a new or novel or revised policy in one specific regulatory decision, which may be based solely on the feedback and input of a single registrant, will subsequently be cited as the precedent for applying that policy in future decisions on other chemicals.

Pesticide users and registrants focus on regulatory activity affecting their particular crop or crops or individual products. There is an understandable reluctance to comment on other crops that I don't grow or on my competitor's products. I may not realize there's a policy change involved that will affect me in the future.

We ask that the agency promptly publish a separate notice seeking public comment on the new 10X policy as was stated in the presentations from yesterday. Thank you.

MR. HOUSENGER: Unfortunately, you didn't sign up as a public commentor so we can't accept those. I'm just kidding, Ray.

All right, hearing no other issues/comments --

CARL: Can you hear me? This is Carl Malimadrome (phonetic) from IR4 on the phone.

MR. HOUSENGER: I'm sorry, who?

CARL: This is Carl Malimadrome. I'm the public health pesticide manager at IR4.

MR. HOUSENGER: Okay.

CARL: I just have two very brief comments and a question. On your web site, some of the presentations were available, which I thank you very much for. Two of those speakers this morning, their presentations are not available, the IPM and the incidents. If it's possible to post those, that would be appreciated.

MR. HOUSENGER: They'll be up today.

CARL: Thank you. The second comment, there

was some discussion about the public health group. At times, informally, my program is the public health pesticides program at IR4. I think that's a convenient shorthand. I suggest you may use that for this workgroup. As well, I think it eliminates some of the confusion about whether we're talking public health broadly or pesticides used as public health tools.

MR. HOUSENGER: Okay.

CARL: The question on the endocrine, a fascinating discussion. One thing I noted was that at least 15 materials, I believe 15 including AIs and inerts, did not provide data. Is the implication of that that they were cancelled as ingredients because of this data call in? If so, was there an evaluation of whether there would be any significant impacts on minor uses from those cancellations?

I know at least one mosquitocide, resmethrin (phonetic), was on the list. I'm not going to question right now whether we have adequate replacements. I think we probably do. But it was significant when a minor use pesticide disappears soon after a data request. Did any of the other materials that did not provide data, are

they being cancelled? If so, was there an evaluation of impact on minor uses?

MR. HOUSENGER: I think a lot of the cancellations were for inerts. I'm not sure how many were for active ingredients. But if a registrant wants to cancel a pesticide, we can't make them retain it. We go through a six-step process. We ask for comments. So, it's vetted in the public, but we can't tell chemical company X that they're going to retain their chemical.

CARL: Understood. Thank you.

MR. HOUSENGER: Okay. Is that it? Thank you very much for everybody's attention and time. Safe travels home.

(The meeting was concluded.)

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