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UNITED STATES

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

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

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

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

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

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

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

1 community.

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

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

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

22 MR. HOUSENGER: Yes.

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

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

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

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

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

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

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

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

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

22 Lastly, I just wanted to point an issue out

1 that I think you've spent a little bit of time on. I'm
2 going to frame it a little bit differently. It's kind of
3 interesting that when we finished up re-registration in
4 2008, it created a much needed a lull in regulation
5 from I'm sure everybody's perspective because we had just
6 finished evaluating every single pesticide in the United
7 States. We were beginning to stand up the reevaluation
8 program, called reg review.

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

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

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

3 A number of high profile chemicals are going to
4 start rolling out. So, hopefully, folks weren't lulled
5 into this sense that oh, I guess we're sort of done kind
6 of a mode. Things are going to begin picking up, and
7 it's going to feel a little bit more like it did in the
8 heat of the re-registration era, which probably went from
9 1998 to 2008.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

13 MR. HOUSENGER: Mark?

14 MARK: Good presentation, Bob. It's been a
15 long time. I do want to remind the committee here that
16 the agency has been invested in school IPM since the late
17 90s and has done lots of things. So, in advocating for a
18 continued workgroup presence, I would say that this is a
19 matter of efficiency in government, which we all would
20 like to see more of. So, over this long period of time,
21 the agency has developed certain skills. Some of it has
22 taken a really long time, strategic planning, this kind

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

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

12 MR. HOUSENGER: Robyn?

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

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

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

8 MR. HOUSENGER: Nichelle?

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

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

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

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

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

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

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

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

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

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

16 MR. HOUSENGER: Dawn?

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

1 number of students attending public schools.

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

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

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

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

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

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

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

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

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

20 MR. HOUSENGER: Yes.

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

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

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

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

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

18 Susan Jennings.

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

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

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

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

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

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

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

22 This workgroup does allow us to get a broader

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

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

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

22 Lastly, we talked a bit about regulatory

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

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

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

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

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

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

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

1 call, if there's an issue that has some urgency to it.

2 So, it's a little different than some of the other
3 workgroups.

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

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

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

17 MR. HOUSENGER: Wayne.

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

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

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

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

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

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

1 offline. I can't provide it right now.

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

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

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

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

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

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

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

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

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

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

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

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

11 WAYNE: Thank you.

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

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

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

22 MR. HOUSENGER: But I think that list is pretty

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

6 Aimee?

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

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

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

4 MR. HOUSENGER: Amy?

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

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

22 MR. HOUSENGER: Mark.

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

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

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

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

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

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

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

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

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

5 MS. JENNINGS: Yes. Thank you.

6 MR. HOUSENGER: John.

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

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

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

3 MR. HOUSENGER: Ray.

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

7 MR. HOUSENGER: Are you volunteering, Ray?
8 Cynthia?

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

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

21 MR. HOUSENGER: Dawn.

22 DAWN: Thank you. I have just one

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

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

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

1 whether Susan has any kind of additional update on that.

2 MS. JENNINGS: No, I do not. You're correct.

3 I realize that is part of the plan. I think their effort
4 right now is trying to get the digital thing complete. I
5 can't speak for CDC on what their plans are.

6 MR. HOUSENGER: Amy?

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

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

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

22 MR. HOUSENGER: Yes.

1 MS. JENNINGS: Okay.

2 MR. HOUSENGER: Anyone else?

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

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

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

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

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

21 MS. JENNINGS: For resistance?

22 MR. GRAGG: Yes.

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

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

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

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

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

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

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

16 MR. GRAGG: Okay, thank you.

17 MR. HOUSENGER: Sure.

18 Robyn?

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

22 MS. JENNINGS: Yes.

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

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

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

8 MS. JENNINGS: Thank you.

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

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

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

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

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

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

1 We have a broad membership. We have a broad
2 interest and representation on the workgroup. We have
3 NGOs, registrants, user groups, state government
4 agencies, regional, state, federal agencies, academia, and
5 even pollinator groups. That's the 23 members. We
6 actually got an additional member yesterday, so we have
7 24 members on the workgroup.

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

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

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

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

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

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

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

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

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

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

7 MR. HOUSENGER: Robyn?

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

14 MS. MOSBY: Thanks.

15 MR. HOUSENGER: Steven?

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

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

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

6 STEVEN: Okay, and the 6A2 is?

7 MS. MOSBY: Registrants reporting.

8 STEVEN: Okay, okay.

9 MR. HOUSENGER: Amy?

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

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

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

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

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

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

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

8 MS. MOSBY: We'll look into that.

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

19 MR. HOUSENGER: Cheryl?

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

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

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

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

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

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

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

12 MR. HOUSENGER: Cynthia?

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

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

1 and validate whether our protections are really working.
2 As Amy mentioned, there is a huge opportunity to bring
3 together databases from the states, databases within EPA
4 and across the government with the new Fish and Wildlife
5 Service database as well. My hope is that ultimately
6 some of these efforts also will lead to the revision of the
7 6A2 rules, thresholds for wildlife, so that
8 there will be required reporting when there are fewer
9 than 50 of a hurting species of mammals that are killed
10 or 50 song birds, and so forth.

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

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

18 MR. HOUSENGER: Dawn?

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

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

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

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

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

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

15 MR. HOUSENGER: Beth?

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

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

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

6 MR. HOUSENGER: Ray?

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

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

20 MR. HOUSENGER: Amy?

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

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

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

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

21 (No response.)

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

1 Rich.

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

4 (A brief recess was taken.)

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

7 MS. MONELL: One very quick piece of
8 information sort of left over from yesterday's
9 discussion. Anita?

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

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

5 David?

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

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

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

22 In response to that, 50 of the pesticide

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

8 You can integrate all of the results from these
9 18 different assays into defining clearly and
10 quantitatively the agonist or, for other compounds,
11 antagonist signal relative to estrogen receptor signaling
12 and the estrogen receptor signaling pathway. We're doing
13 something very similar to the androgen receptor signaling
14 pathway and somewhat similar for the thyroid pathway,
15 though most of the activity there is coming from
16 nonreceptor mediated effects. So, we're having to take a
17 slightly different tact there.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

7 MR. HOUSENGER: Cheryl.

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

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

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

1 with the tier two test orders.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

4 MR. HOUSENGER: Pat.

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

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

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

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

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

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

1 ballpark (inaudible) antimicrobials.

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

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

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

1 that's available?

2 MR. DIX: For pesticidal chemicals, absolutely.

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

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

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

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

17 MR. HOUSENGER: Yes, definitely.

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

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

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

10 PAT: Thank you.

11 MR. HOUSENGER: Nichelle.

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

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

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

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

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

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

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

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

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

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

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

12 NICHELLE: Okay.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

16 Sharon.

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

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

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

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

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

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

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

5 MR. HOUSENGER: And Ray?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 He should have just said thank you.

2 MR. BRAGG: Richard Bragg has a question.

3 MR. HOUSENGER: Hold on, Richard.

4 UNIDENTIFIED FEMALE: (Inaudible).

5 MR. HOUSENGER: David is never here.

6 Richard?

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

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

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

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

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

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

1 basic science result?

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

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

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

22 MR. BRAGG: Okay, thank you.

1 MR. HOUSENGER: All right. Thanks, David.

2 So, next topic is what to discuss next time and
3 the times of the next meeting. This room isn't available
4 whenever we want it, so we have to put in for it
5 relatively early to get it. It's also good for planning
6 purposes if you know far out what the next dates are.
7 Tentatively, we have this room scheduled for May 11th and
8 12th and again November 2nd and 3rd.

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

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

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

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

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

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

22 Mark?

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

10 MR. HOUSENGER: Ray.

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

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

16 RAY: Congratulations.

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

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

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

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

12 MR. HOUSENGER: Cheryl?

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

19 MR. HOUSENGER: Sharon?

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

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

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

10 MR. HOUSENGER: Beth?

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

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

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

3 BETH: Good.

4 MR. HOUSENGER: Hopefully.
5 Steven?

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

13 MR. HOUSENGER: Amy?

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

20 MR. HOUSENGER: Okay.

21 Cynthia?

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

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

7 MR. HOUSENGER: Dan?

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

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

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

21 MR. HOUSENGER: Any others? Dawn?

22 DAWN: Thank you. I'm excited about the

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

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

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

15 RICHARD: I've got one.

16 MR. HOUSENGER: Oh, sorry, Richard.

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

19 MR. HOUSENGER: Pesticides in?

20 RICHARD: Health disparities.

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

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

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

15 (Applause)

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

18 RAY: Public comment requests.

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

21 RAY: Right here.

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

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

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

12 The third issue is a bit more serious.

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

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

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

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

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

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

4 Thank you.

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

8 All right, hearing no other issues/comments --

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

11 MR. HOUSENGER: I'm sorry, who?

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

14 MR. HOUSENGER: Okay.

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

21 MR. HOUSENGER: They'll be up today.

22 CARL: Thank you. The second comment, there

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

8 MR. HOUSENGER: Okay.

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

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

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

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

10 CARL: Understood. Thank you.

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

14 (The meeting was concluded.)
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