

US EPA ARCHIVE DOCUMENT

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UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY

PESTICIDE PROGRAM DIALOGUE
COMMITTEE MEETING

June 5, 2014

Conference Center - Lobby Level

2777 Crystal Drive

One Potomac Yard South

Arlington, VA 22202

1 P R O C E E D I N G S

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

22 Session six, Bob McNally and BPPD is going to

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 Pesticides.

2 MR. TAYLOR: Donnie Taylor representing
3 Agricultural Retailers Association.

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

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

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

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

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

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

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

1 representing the American Association of Pest Control
2 Officials.

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

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

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

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

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

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

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

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

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

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

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

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

12 MR. WHITTINGTON: Andy Whittington, Farm Bureau
13 Federation.

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

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

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

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

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

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

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

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

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

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

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

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

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

21 The \$7.2 billion is the AA's office and other.
22 This is other portions of OCSP that support the work

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

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

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

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

6 So, they took the 2012 level, which is \$128.3
7 million, or .277 according to this chart, and that is now
8 the required amount. So, you'll see that was what was
9 passed in 2012. That's the threshold. And then, for
10 2013, the president's budget put us a little bit above
11 that threshold. Congress appropriated a significant
12 amount below that threshold.

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

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

1 appropriation requirement. We could still collect fees.

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

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

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

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

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

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

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

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

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

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

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

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

19 So, the amount was increased from PRIA 2 from
20 22 million to 27 million initially. We believe that the
21 additional five million a year was really critical to
22 help us with the completion of the registration review

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

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

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

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

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

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

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

8 Then, the next two slides, the first one shows
9 the PRIA collections, \$15.6 million in '12, \$15.4 in '13,
10 \$12 million thus far in '14, and we're anticipating \$11
11 million in '15. We always anticipate less than we think
12 we might collect because you just never know. We don't
13 want people to assume we're going to collect any more
14 millions than we really feel we can because we're apt to
15 be cut on the other end if we go that route. So, we do
16 lowball our anticipation. Certainly, in light of the
17 last three years, it looks like it's a lower estimate.

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

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

6 Any questions? Beth?

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

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

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

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

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

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

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

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

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

19 MS. MONELL: Thank you, Beth.

20 Others? Ray?

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

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

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

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

22 (Whereupon, there was an

1 interruption.)

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

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

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

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

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

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

1 work processes.

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

7 Others?

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

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

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

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

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

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

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

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

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

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

1 a pathogen arise that needed our immediate review and
2 attention.

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

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

13 UNIDENTIFIED MALE: Just to add another voice
14 to the federal perspective of the decreases we faced.
15 I'm not at all surprised to see that you lost 10 percent
16 of your workforce. Over a two year period, our agency
17 lost 10 percent of our entire workforce. We've got about
18 9,000 people in the Fish and Wildlife Service across the
19 country, down from 10,000 just two years ago. So, the
20 sequester obviously has affected all of the federal
21 agencies greatly.

22 I clearly know it's affected other

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

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

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

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

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

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

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

7 DR. GRAGG: There's one more.

8 MR. HOUSENGER: Okay.

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

11 MR. HOUSENGER: Okay, thanks.

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

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

1 recommendation we received from the PPDC last year in
2 2013 for some OPP metrics.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 specific goals.

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

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

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

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

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

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

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

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

3 So, one of my hats that I wear right now is I
4 am one of two co-chairs of ICCVAM. If you're not
5 familiar with that acronym, it stands for the Interagency
6 Coordinating Committee on the Validation of Alternative
7 Methods, which is very much of a mouthful. We're
8 essentially a committee established by congress back in
9 2000 comprised of 15 federal agencies that require, use,
10 generate, or disseminate tox data. So, it's a
11 combination of EPA, FDA, CPSC, OSHA, several parts of
12 NIH, but also, for example, the National Library of
13 Medicine has a representative, as does USGS and a number
14 of other agencies.

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

22 The committee was established in 2000. Rear

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

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

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

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

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

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

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

14 Plans to improve communications with
15 stakeholders and the public, previously and prior to
16 2013, there had been a lot of comments from the public
17 that ICCVAM and NICEATM weren't as transparent as people
18 would have liked them to be. It's not open to public
19 input. So, we've been working very hard on that front to
20 change that. Being here today I think is a statement of
21 that.

22 Lastly, very briefly, the document covers an

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

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

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

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

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

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

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

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

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

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

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

22 So, just a minute to give you some contacts for

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

9 Once we feel like it's compiled and everything
10 is QA'd, we'll be sending that dataset to NICEATM, and
11 that's hopefully within the next couple of weeks.

12 NICEATM will be conducting the statistical analysis on
13 our behalf.

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

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

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

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

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

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

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

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

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

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

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

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

1 developing assays.

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

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

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

17 Cheryl?

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

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

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

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

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

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

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

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

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

19 MR. JONES: Mae?

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

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

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

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

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

22 But there is some optimism that some data

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

9 MR. JONES: One last question from Matt.

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

14 DR. LOWIT: No.

15 MATT: It's not?

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

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

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

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

10 MATT: Right.

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

16 MATT: Right. Thank you.

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

19 (Whereupon, a brief recess was
20 taken.)

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

1 Take it away.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

4 So, one of the things that we thought was
5 important was that all of our members in our conversation
6 acknowledged the importance and agreement on the ultimate
7 goal of encouraging research on pesticide biomarkers.

8 So, given the concerns that folks had on the list, but
9 the agreement on the goal of advancing research, the
10 workgroup decided to use the draft list as a working
11 tool.

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

22 In the past, our workgroup has talked to DARPA

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

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

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

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

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

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

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

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

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

1 to make the decision.

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

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

12 MR. JONES: Thank you.

13 Mark?

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

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

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

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

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

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

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

1 on the committee.

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

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

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

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

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

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

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

22 So, the medical profession still has ways to go

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

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

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

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

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

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

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

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

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

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

14 MS. ACONOMIS: Okay, sorry about that.

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

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

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

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

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

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

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

4 Using the draft list as a working tool, it
5 specifically talks about those next steps I outlined.

6 So, what the workgroup is doing right now, using the
7 draft list to have some discussions about what we think
8 are the best candidates for having the initial
9 discussions with the researchers.

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

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

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

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

11 MR. JONES: Ray.

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

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

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

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

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

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

22 So, the focus of this project has been on the

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

4 MR. JONES: Cheryl, bring it home.

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

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

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

1 difficult than maybe some things.

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

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

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

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

1 stage and have some discussions along those lines.

2 That's, I think, where everybody wants to go. We get
3 hung up on some of these other pieces.

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

7 DR. MCLAIN: Thanks, Cheryl.

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

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

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

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

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

22 So, we received a lot of comments from all of

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

22 The other issue that we would like to discuss

1 with them is joint reviews. I was really surprised when
2 folks on the staff mentioned that in our joint reviews
3 that we've done with other countries, it resulted in 82
4 percent harmonization of pesticides. Another 18 percent
5 is somewhat negligible, the difference somewhere between
6 0 and .5 parts per million.

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

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

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

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

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

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

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

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

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

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

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

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

9 Any questions whatsoever?

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

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

19 MR. JONES: Jerry, you want to go?

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

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

10 MS. TAVEAU: They can't, right.

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

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

22 So, can we put our heads together and figure

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

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

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

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

1 sensitivities right now.

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

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

13 MR. JONES: Okay. Susan, last comment.

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

22 So, at what level are these discussions going

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

5 The IR-4 in the US and the PMC, the Pesticide
6 Management Council, in Canada has a partnership. We've
7 been working together for many years, probably since
8 1997, actually, on joint reviews of new active
9 ingredients, use expansions, and minor uses. It's become
10 a routine way of doing business.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

17 So, OECD, global initiatives, OECD has been a
18 major, major form for us over the years, starting back in
19 1990, where countries could come together and work on
20 building the foundation and the blocks that will
21 ultimately lead to harmonization and work sharing. We
22 have expanded the global joint review process over the

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

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

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

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

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

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

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

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

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

15 Then, we plan for these new active ingredient
16 joint reviews well in advance, so we're in presubmission
17 stages on 11 of them that will come in from now until
18 2017. What we do at the OECD meeting also is we do
19 actually present at each meeting an analysis of the MRL
20 harmonization on the active ingredients that have been
21 jointly reviewed. The results are presented on this
22 slide and the next. This is where Daniella got her 82

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

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

10 But on this slide, or on your paper, you can
11 see in March of 2014, we evaluated or jointly established
12 278 MRLs and we harmonized only 82 percent. That's where
13 she got that. You can see that, you know, back in
14 September of 2011, it was more like 57 percent. It goes
15 to 80 percent. It went down to 67 percent, but that was
16 a smaller sample size.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 reduce risks associated with biocide use.

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

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

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

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

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

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

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

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

22 This year, Codex is certainly way behind on

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

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

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

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

1 be harmonized.

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

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

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

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

1 visitor from the Food Safety Commission in early
2 September.

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

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

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

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

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

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

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

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

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

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

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

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

1 building blocks that are in place.

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

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

9 MR. JONES: Thanks, Lois.

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

19 (Whereupon, a luncheon recess
20 was taken.)

21

22

1 AFTERNOON SESSION

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

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

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

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

21 MR. JONES: Beth?

22 BETH: This is sort of a related question,

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

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

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

17 MR. JONES: Mark?

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

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

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

12 MR. JONES: Doug.

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

18 MR. JONES: Gabrielle.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

4 MR. JONES: Dave?

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

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

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

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

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

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

11 MR. JONES: Virginia?

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

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

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

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

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

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

21 MR. JONES: Ray?

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

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

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

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

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

1 10 to 12 years to get a Codex MRL. We literally did sit
2 through a couple of meetings there where you were
3 watching paint dry. There were all these MRLs coming
4 through and they were just staying there. They were
5 never elaborated to the point of becoming adopted. They
6 were on a lot of older materials in some cases and some
7 cases not.

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

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

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

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

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

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

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

1 ideas. They want to move forward.

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

7 MR. JONES: Mike?

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

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

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

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

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

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

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

9 MR. JONES: Mae.

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

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

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

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

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

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

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

1 though, and see if they were coming out.

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

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

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

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

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

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

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

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

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

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

22 MR. JONES: Okay, thank you, Lois.

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

7 UNIDENTIFIED MALE: Okay, thanks, everybody.

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

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

1 to the committee.

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

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

22 At first, it was noted in the new labeling

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

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

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

22 The labeling subgroup, and there's a carryover

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

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

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

1 broadly.

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

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

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

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

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

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

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

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

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

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

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

1 So, that's it for the labeling subgroup.

2 UNIDENTIFIED MALE: Thanks, Marylou.

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

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

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

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

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

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

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

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

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

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

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

1 labels.

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

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

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

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

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

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

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

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

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

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

1 Gabrielle is here.

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

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

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

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

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

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

22 So, I just provide that as background to

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

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

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

1 there's a hesitancy there.

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

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

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

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

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

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

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

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

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

1 So, with that, that's our report.

2 MR. JONES: Mark.

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

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

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

18 MR. JONES: Dawn.

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

1 certification processes or continuing education units?

2 UNIDENTIFIED MALE: I can address that by
3 saying yes and no. I think we're addressing it as one of
4 174 competency areas that applicators need to know for
5 core knowledge. Recertification is really dependent upon
6 the state. In North Carolina, we will be having that for
7 our private applicator program using this particular
8 package that the pollinator protection group has put
9 together. Other states may have that developed to a
10 point where they have programs through their state
11 apiarists.

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

16 MR. JONES: Dave.

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

1 triggering unnecessary or enforcement.

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

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

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

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

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

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

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

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

11 MR. JONES: Thank you. Sheryl?

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

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

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

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

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

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

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

8 MR. JONES: Tom?

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

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

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

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

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

22 Then, during the public comment period, we will

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

4 UNIDENTIFIED MALE: I'm hoping that enforcement
5 will be involved that can evaluate it beforehand, because
6 we found out after it was -- the last one was introduced
7 I enforcement, had different comments of what the
8 language actually meant beforehand. So, if we're going
9 back to issuing the same language or changing something,
10 I hope the Enforcement Division plays a better role in
11 making everybody understand what the results may be,
12 because that's always been a problem in my experience for
13 30 years; enforcement gets in on the end or after and not
14 beforehand.

15 MR. JONES: Okay, Cynthia.

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

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

1 frustration about the thresholds. For example, for
2 flocking species of birds, the reporting threshold is
3 200, flocking species for raptors is 5 raptors, for
4 mammals it's 50 or more of a herding species, for fish,
5 it's 1000 or more of a schooling species, and so on.

6 These are the sort of reporting thresholds required of
7 registrants. For pollinators, they are just grouped
8 under other non-target organisms.

9 I'm wondering as EPA thinks about revamping the
10 682 reporting rules, what would be the ideal for
11 pollinators? Could the pollinator workgroup maybe assist
12 in making recommendations for that rulemaking?

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

15 Steve?

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

1 being utilized like it's intended to?

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

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

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

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

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

15 That's my comments.

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

22 STEVE: Yes.

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

9 MR. JONES: Okay, Mike.

10 MR. WILLETT: Mike Willett, Northwest
11 Horticultural Council.

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

22 Has there been any thought given to how that's

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

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

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

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

20 MR. WILLETT: Okay, perfect. Thank you.

21 MR. JONES: Ray?

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

1 wanted to make. We discussed briefly yesterday in the
2 workgroup meeting a number of the state efforts which are
3 underway to develop BMPs. On one point, I disagree with
4 a minor point that Steve Coy made. There are
5 circumstances where those BMPs do need to be less
6 restrictive. That's one of the reasons we have section
7 18 exemptions, because they have the ability to control a
8 very focused situation.

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

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

1 from reporting the incident so that they can be
2 investigated.

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

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

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

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

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

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

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

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

3 So, thank you.

4 MR. JONES: Mae?

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

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

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

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

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

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

17 MR. JONES: Ray, are you a rerun?

18 RAY: No.

19 MR. JONES: Good, good. Tom?

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

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

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

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

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

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

21 MR. JONES: Yes.

22 MR. SANCHEZ: I was going to say that going

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

8 MR. JONES: Yes.

9 MR. SANCHEZ: That's some background music.

10 MR. JONES: We figured that.

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

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

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

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

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

17 MR. JONES: Okay, thanks.

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

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

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

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

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

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

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

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

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

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

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

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

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

22 They are also working on developing

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

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

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

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

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

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

16 It was originally identified as a need at a
17 2011 product chemistry workshop. That it would be very
18 useful for the Canadian and US regulators to get together
19 to come up with a form that really helps us get quality
20 information through the door. So, again, there were lots
21 of errors being seen with these submissions. It was
22 actually developed as an action item under the RCC, which

1 was also mentioned earlier, related to our NAFTA
2 agreement.

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

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

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

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

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

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

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

22 It also has the ability to link directly to the

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

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

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

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

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

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

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

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

3 The last one is the conditional registration
4 tracking system. So, again, right now, this takes
5 advantage of what technology we have available to us. It
6 was quite a bit of work for us to consolidate a table of
7 existing conditional registrations for our AIs since
8 1999.

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

14 We'll be using this to monitor the timely
15 submission of data, making sure that we're actually
16 getting the additional information that we've required as
17 part of that conditional registration. A potential phase
18 2 implementation is under consideration.

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

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

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

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

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

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

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

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

20 I'm happy to take any questions.

21 MR. JONES: Sheryl?

22 SHERYL: A couple of questions and a couple of

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

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

8 SHERYL: Yes.

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

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

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

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

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

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

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

22 There is always some concern because the label

1 is legally binding. Then the registrants are always
2 concerned that you're going to add yet another step to
3 the laborious process of checking the labels. This is
4 going to add resources instead of actually making it
5 better. So, I just wanted to throw that out there.

6 Continue to keep the stakeholders and all those people
7 that are going to use the system well involved so that it
8 actually gets (inaudible) for everybody.

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

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

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

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

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

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

16 Did I hit all your questions? Okay.

17 MR. JONES: Ray.

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

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

1 a time line for phase 2?

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

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

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

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

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

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

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

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

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

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

15 RAY: Thanks.

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

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

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

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

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

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

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

1 to you.

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

6 MR. JONES: Cynthia?

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

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

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

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

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

10 So, one of the tasks that the workgroup has
11 taken on is to look not only at that database but other
12 data that all the agencies sold and think about the best
13 ways to be efficient in the use of our IT resources as
14 well as our information of that species.

15 We have presented on that database probably two
16 years ago to this group. So, anyway, it's part of the
17 ongoing discussion between the agencies.

18 MR. JONES: Jerry?

19 JERRY: Phil, I've got a bunch of nuts and
20 bolts questions, but I won't bog this group down. I'll
21 speak offline with you. But I have one question, and
22 that is, with your pilot, would you want to include a

1 tenth group, a publicly sector group, that submits an
2 awful lot of data to EPA?

3 MR. VILLANEUVA: I think that's a little bit
4 different from our label submission, but I'd be happy to
5 talk with you about some of the work that we've done so
6 far.

7 MR. JONES: Okay. If there's no more
8 questions, we'll move on to IPM. So, Bob McNally, the
9 Director of the Biopesticides and Pollution Prevention
10 Division, will chair this session.

11 MR. McNALLY: Jack, are you sending me a
12 message? I don't have a name card.

13 MR. JONES: I think everybody knows you.

14 MR. McNALLY: Thank you. I want to do three
15 things. The first thing we want to have is Thomas Cooke
16 (phonetic) who heads up our Center of Expertise give you
17 an overview of the activities of the Center of Expertise.
18 Then we'll turn to the state pilot. That's the second
19 part of the presentation. So, let me have Thomas give
20 you an overview.

21 MR. COOKE: Thank you. Good afternoon. What I
22 wanted to do is pretty much give everybody here a quick

1 glimpse of our past year and activities we've been able
2 to accomplish with the Center of Expertise. Let me
3 figure out how to work this.

4 So, over the past year, we've been working hard
5 to help create a demand for school IPM. With that
6 demand, we're also working to empower schools. We've
7 been able to enhance the involvement in coordinating with
8 some of the national and regional school IPM working
9 groups.

10 We worked diligently to formalize a lot of
11 existing networks, as well as form some new networks that
12 we can pursue. Also, recently we've been able to align
13 some of the agency-wide school-related programs to make
14 sure we're all sort of thinking from the same page and
15 working together internally.

16 So, how are we creating that demand? Over the
17 past year or so, we've been able to partner up with some
18 of the large national organizations. For example, we
19 worked with the National Parent Teachers Association.
20 We've been able to create some articles and blog
21 materials and disseminate that information through these
22 organizations. We've had an opportunity to partner up

1 with the School Nurses Association. So, we're pretty
2 excited to work and build on these large national groups.

3 We're also working to create a mass outreach.
4 I'll go into it a little further a couple slides later on
5 how we're actually performing our outreach efforts.

6 We've also been able to create a series of webinars that
7 we're going to roll out in the future to really work hand
8 in hand with both state and local officials and really
9 pushing the school IPM message.

10 Also, as far as continued efforts as far as
11 creating demand, as I just mentioned, we have
12 publications we've been able to create within the Center.
13 We've created a business case to be able to aid and
14 assist school officials in showing the great examples of
15 how school IPM can affect their overall programs.

16 I think I just mentioned, as far as the blog
17 material, we're working with some of the great partners
18 we have here within the PPDC on creating a lot of the
19 blogging and pushing that mass messaging out.

20 Outreach efforts, we've been pretty excited as
21 well to have our AA Jim Jones. He's had an opportunity
22 to actually go out and visit a couple schools throughout

1 the country and see how the implementation is going on
2 the ground. So, Jim has been able to visit a school in
3 New Orleans, as well as participate in a couple big check
4 events, most recently in the University of Arizona. So,
5 these outreach efforts are really helping to create that
6 excitement on the ground.

7 So, now, how are we empowering schools and
8 (inaudible) change agents and IPM champions on the
9 ground? As I mentioned, we've been able to create a
10 model policy, pesticide policy, for school districts to
11 actually use and help them on a lot of the
12 implementation.

13 We've created a series of stock power points
14 that are readily available for both internal partners, as
15 well as external stakeholders. We've created a national
16 school IPM expert list, as well as our most recent action
17 we're working on, updating the Rat Book. So, we're
18 excited to continue that effort.

19 Providing additional information, what we've
20 found is that we've heard a lot of feedback from the
21 community, and a lot of it seems like individuals would
22 like to have that on hand in person training. So, we had

1 an opportunity to pilot an actual school IPM effort in
2 region 10 with the Environment of Health Officers. It
3 was well received, and we're looking to disseminate the
4 information across the entire country to the other
5 regions as well.

6 As I mentioned, providing additional
7 information. We've scheduled a series of webinars that
8 we're going to roll out over the next year or so reaching
9 the on-the-ground stakeholders. Of course, we're working
10 within our strategic plan or coordinating and
11 collaborating our efforts with both our regions as well
12 as our team members within the PPDC. I mentioned already
13 that we're aligning our school related programs together.

14 MR. McNALLY: Let me just stop there. Are
15 there any questions about the program in terms of the
16 Center of Expertise? It's been up and running I think
17 about a year now, so we wanted to give you a flavor of
18 what we've done the first year and what the plans are
19 coming up to get the message out to help change agents at
20 the state and local level, the school level, take the
21 information we've developed, and use it to try to instill
22 the school IPM philosophy within the school community.

1 So, that's sort of the goal of what Thomas and his group
2 are up to.

3 With that, the second part is Julienne Barta
4 (phonetic) from region 10 is going to talk about the
5 state pilot. This is the pilot for school IPM tat the
6 PPDC commissioned about a year ago. So, we wanted to
7 give you an update on the status of that. So, Juliann.

8 MS. BARTA: Thank you. I'm Juliann Barta from
9 region 10. I'm from the other Washington. I work with a
10 lot of different state partners in my region. One of
11 them is Carrie Foss from Washington State University
12 Extension. She's not going to be here today, but she was
13 at the IPM workgroup yesterday and helped present with me
14 on this topic.

15 But the goal of this whole pilot project in
16 Washington State is we really want to create a model that
17 other states can use and try to diffuse a school IPM
18 statewide model for school districts within the state.
19 Our objectives include increasing our school IPM
20 partnerships.

21 We have a number of great partnerships
22 currently in Washington State, including the state

1 agencies, the Indian Health Service in the Portland area,
2 our extension, and, of course, the school districts
3 themselves. So, we want to keep the program sustainable
4 by continuing to strengthen those partnerships and also
5 trying to find new partnerships in our state.

6 We want to definitely document what works and
7 what doesn't work over the next 18 months of this project
8 so that it will be a successful model for other states to
9 use. Of course, our ultimate goal is to increase IPM
10 implementation in K through 12 public schools.

11 Some of the resources that we will have is a
12 staff, including the expertise from the Center of
13 Expertise. We also have a group called the UPEST, Urban
14 Pesticide Education Strategy Team. There's
15 representatives from different Washington state agencies.
16 We have an information clearinghouse on line. If you
17 Google UPEST, it should come up. It's talking about
18 urban pesticide safety and IPM.

19 Of course, the PPM IPM workgroup is a great
20 resource. There also is going to be some funding for
21 this project from EPA headquarters. The money is going
22 towards our cooperative agreement with the Washington

1 State Department of Agriculture. It's going to fund a
2 number of coalition events and walkthroughs over the next
3 year. WSDA is going to contract with WSU for this work,
4 Washington State University.

5 So, some of the outputs or the mechanisms we're
6 going to use for this pilot project, we're going to put
7 together some school district focus groups. We want to
8 organize a core of champions. So, this would be between
9 6 and 10 school districts who already have a pretty
10 robust school IPM program.

11 It would be bringing them together, having them
12 provide peer-to-peer mentoring to other school districts,
13 also providing us with input and what are the needed
14 resources and incentives for schools to implement IPMs,
15 and also to possibly pilot different tools that are
16 created throughout the year.

17 We also want to hold a focus group at the
18 Washington Association of Maintenance and Operation
19 Administrators Conference this fall. Again, at that
20 conference, we hope to get district input on needed
21 resources and incentives.

22 We want to start looking into a recognition

1 program and starting to answer the question how can we
2 best recognize school districts. This recognition
3 program still needs to be developed. We're working hard
4 on figuring out how it would best be designed. And then,
5 like I said earlier, having partnerships. One idea we
6 had was to create a letter of support from multiple state
7 agencies to send out to administrators and the school
8 board to support these efforts.

9 That's a quick summary of this. I'll turn the
10 tables, I think, to Dawn Gouge to talk about
11 sustainability in school IPMs.

12 MR. McNALLY: Any basic questions from folks
13 before we turn it over to Dawn in terms of what the pilot
14 is about, what it's seeking to do in terms of its mission
15 and mandate?

16 MS. GOUGE: I'm going to stand up because I
17 don't think I can talk when I'm sitting down. But if you
18 can't hear me, let me know.

19 So, the rest of the time our workgroup spent
20 trying to figure out how we're going to make this
21 sustainable, how are we going to embed school IPM into
22 the very infrastructure of our public schools. But I

1 wanted, before I move on, everybody in the workgroup who
2 is here right now to just raise their hands so that those
3 people who are sitting around you know exactly who you
4 are. Thank you.

5 So, if you have any questions and we don't have
6 time to address them today, those are the folks you can
7 ask. I want to say thank you to Janet Hurley, Mark Lame
8 and Carrie Foss for sending slides and contents that
9 you'll get to see now. We have about 96 slides, I think.
10 Only kidding.

11 I want to start by referencing Mr. Dave Tamayo
12 He is right there. He quoted some physicist and I
13 couldn't remember which one, chose I chose one of my
14 favorite ones and that was Newton. Is this the correct
15 one you referenced?

16 Yesterday, I swear he referenced a law of
17 physics in support of this idea of sustaining school IPM
18 in schools. What stuck in my brain is the second law of
19 motion being the idea that you have to give something a
20 shove. Depending on how much energy is required to keep
21 it going in a particular direction depends on how much
22 resistance comes back in the opposite direction.

1 This fits directly with the notion of
2 behavioral momentum. If you're not familiar with that
3 term, it is just that. If you are trying to cause a
4 change in people's behavior or an adoption of an
5 innovation by a society or community, then it takes
6 energy input into the system in order to get things going
7 in a different direction. You need to keep the pressure
8 on depending on how much resistance you get.

9 I want to say that having been doing this for
10 15 years, 15 years ago I felt like I was running uphill.
11 Maybe about eight or nine years ago I felt like I was
12 running on the flats. At this point, I feel like I'm
13 hurdling downhill at great speed. Something phenomenal
14 has changed. We have school districts requesting more of
15 our time than we have available. They want us to
16 facilitate the implementation of school IPM.

17 So, the magic S word for us is sustainability.
18 So, I'm going to give you some of the ideas that we came
19 up with as a group on how best to build sustainability
20 and institutionalize school IPM practices.

21 The first bullet point there is building the
22 change agent core. Probably everybody in this room is

1 fairly familiar with the concept of using change agents
2 to alter things in society. I want to say at this point
3 that we probably have about 15 to 20 raving fanatical
4 school IPM people who have the badge and the tee shirt
5 and everything else.

6 We probably have about -- well, I can tell you
7 exactly. We have 47 nationally who respond to represent
8 their state or territory when it comes to request for
9 information about school IPM in the state or territory.
10 We have several thousand stakeholders that that core
11 group of us interface with constantly. So, this has
12 really built in the number of people involved and the
13 impacts of the results.

14 So, yesterday we were talking about why some
15 school systems adopt school IPM only to abandon it years
16 later. Changes in personnel being one of those challenges
17 that we deal with. Other school districts, it doesn't
18 matter how many people leave, they are bound and
19 determined to demand high quality school integrated pest
20 management at their facilities.

21 We came to somewhat of a consensus that the
22 more of the school community that you can engage from the

1 onset -- and that is all of the stakeholders, not just
2 the school site people themselves, but all of the
3 stakeholders that are associated with the school system.
4 The more that you can engage from the onset, the better,
5 the more sustainable a program is.

6 We talked about marketing and brand recognition
7 and the fact that IPM, for whatever reason -- I like it.
8 I love it. I know what it means. But the general public
9 doesn't seem to like it very much. It's really hard to
10 stick an IPM label on something and get it to stick. So,
11 we decided to call our particular initiative Stop School
12 Pests as a result.

13 We talked a little bit about EPA's approach at
14 wholesaling school IPMs. We talked about the difference
15 between wholesale and retail efforts. Really, what we
16 see that's being presented to you hear today is both.
17 It's the top down, the bottom up. We're really doing it
18 from both sides. I think that's a really good way to go.

19 We're building new partnerships with
20 stakeholder associations. Some of them it takes more
21 than one try. But eventually we find the right people
22 and we get engaged. We feel that those stakeholder

1 associations are terrible important. So, if you're here
2 and you represent one of those and you're not involved in
3 school IPM, please let us know that you want to be
4 involved.

5 So, Stop School Pests, Juliann referenced in
6 her presentation that Carrie Foss and Juliann are a team
7 in Washington. They will be developing a Stop School
8 Pests recognition program. I can't emphasize how
9 terribly important this is and what great ramifications
10 come from these recognition programs of various kinds
11 that are around the country.

12 But we talked at length as a team, as a group,
13 yesterday on the benefits. It's a modest investment in
14 energy to run some of these programs, considering the
15 great benefits that they return to us. Juliann and
16 Carrie will have a tiered approach. So, everybody can
17 get involved right from the onset.

18 We talked about procurement contracts and model
19 policy and how very powerful having the model policy that
20 is endorsed by a significant agency, and of course
21 collaborative agencies and organizations, could be for us
22 at this moment in time. Everybody wants to do the right

1 thing.

2 Having a definitive document to place in front
3 of them that really means something that commits the
4 school to partnering with the pest management
5 professionals, whether they're in house or external, and
6 forces the pest management professional, whether he's in
7 house or external, to partner with the school staff will
8 have great effects.

9 We talked about having environmental health
10 committees at our schools. This is a very helpful way to
11 institutionalize school IPMs in a district. It really
12 has to be district by district, and we know that some
13 districts have got small numbers of schools and others
14 have many, many schools. But irrespective, having an
15 environmental health committee has been enormously
16 helpful. Those districts that have one, IPM is a part of
17 that health committee.

18 In many ways, it connects them with the Public
19 Health Department, which is next on the list. The Public
20 Health Department, I have a slide on that. I'm just
21 going to talk about that in a minute.

22 Statewide enhancement projects, like Juliann

1 and Carrie Foss from Washington State University, will be
2 profoundly helpful to the rest of us. This is the very
3 first time we have had an experiment like this, a pilot
4 program, where we're aiming at statewide implementation
5 and diffusion of the IMP innovation. So, it's superbly
6 exciting.

7 So, here's my go public health people slide. I
8 have this in animated form, but I didn't have 15 slides
9 to show you the animated form today. So, here's the
10 abbreviated version. Lots of people think that the
11 reason why we don't die in our 20s and 30s and we live
12 longer, we don't lose our children, is because of
13 antibiotics, various things.

14 As you see there, the state health departments
15 undoubtedly played a pivotal role in declining mortality
16 rates over the last century. So, clearly, they couldn't
17 do anything about flu in the 1920s, but we won't hold
18 that against them at this point.

19 So, we discussed some of the tools for
20 sustaining school IPMs. I would like to invite anybody
21 from the team that has anything to add to anything that I
22 talk about in the next couple of slides to just please

1 chime in.

2 Demand side IPM messaging, I wasn't entirely
3 clear on this. It took several conversations for me to
4 really get it. But the idea of having consumers be
5 receiving IPM messaging is credibly important. Who
6 recalls the days when your mom would smack you if you
7 didn't put your hands over your mouth when you coughed?
8 Okay, nobody's mother hit them over the head? I guess
9 not. Things where I come from are a little different.

10 Those days are gone now, right? Anybody do the
11 whole vampire cough? So, somebody decided that perhaps
12 it wasn't a good idea to cough into your hand and then
13 touch everything. It can spread the flu. It could have
14 been avoided that 1920s disaster if we'd only known how
15 to do the vampire cough.

16 But overnight, when H1N1 arrived, we were
17 messaged to heck and back with the do not put your hands
18 over your mouth. After years of belt with my mom, we
19 completely eliminated by a mass media event that
20 successfully gets me to do this 99 percent of the time.

21 So, Environmental Health and Safety Committees
22 we've talked about. I just want to ask the team if

1 there's anything that anybody wants to add, any examples
2 specifically of instances when they've been incredibly
3 helpful.

4 UNIDENTIFIED MALE: Just the idea of the makeup
5 of the team is not just internal as far as the school
6 nurse, the nutritionist, the IPM coordinator, who may or
7 may not be the pest management professional, and then the
8 pest management professional, principals, teachers, head
9 custodians, but also some of the internal people like
10 athletic directors are also part of it, and then using
11 external people, someone from the county health
12 department and from the hospital as far as the community
13 person that all hospitals basically have to have. So,
14 you have external people that are also part of this.

15 The reason for these kind of committees is it's
16 a sustainability tool in that it provides cover for the
17 IPM coordinator when they need to make a decision that
18 might be slightly unpopular, like we're going to have a
19 different threshold for dandelions or for lice. But even
20 more important is the idea when that IPM coordinator
21 leaves or the pest management professional leaves and the
22 contract changes, this committee provides continuity.

1 That's what we're really looking at is how do we keep IPM
2 in schools continuing.

3 MS. GOUGE: Thank you. We talked a little bit
4 about pest presses. I just grabbed a couple of pictures,
5 one of ours. We learned a few things about pest presses.
6 It's a good way to connect with your stakeholders en
7 masse regularly. I mean, probably twice a month I
8 interface in electronics form with every school district
9 in my state and many, many more in other states.

10 We've really got rather good at this. In fact,
11 we have run workshops asking our school folks what do you
12 want in a pest press and how do you want it delivered.
13 And so, several of them now are specifically tailored to
14 exactly what they told us they wanted. That really helps
15 with the distribution.

16 Having pest management professionals partner
17 through thoughtful procurement, having meaningful high
18 quality integrated pest management contracts that make it
19 crystal clear for everybody involved, who is responsible
20 for what, what everybody's expectations are is enormously
21 helpful.

22 Does anybody want to add anything to that?

1 We didn't talk about this, actually. This was
2 something that I added. That is, I wanted to emphasize
3 the importance of being genuine and caring about the
4 stakeholder's priorities. That's not just the school
5 staff or one particular parent or a concerned parent or a
6 student, but actually having genuine, genuine
7 consideration for all stakeholders involved in the
8 community.

9 Really, I love this. I think he was an
10 American author and a pastor, John Maxwell. Quite
11 interesting. He had some interesting public books that
12 he's written. He coined the phrase, people don't care
13 about how much you know until they know how much you
14 care. It really couldn't be any clearer working in
15 school environments, childcare environments, public
16 housing environments, those kinds of situations.

17 So, I think we sometimes do an awful lot more
18 listening and we respond to the priorities that are
19 relevant for those particular situations. As an
20 academic, I have this great plan for school IPM. I want
21 to do this, this, this, and this. You know what, maybe
22 two things will resonate with the staff at that site. I

1 have to focus on those first. I mean, usually, anything
2 public health related comes first, but that's usually
3 their priority as well.

4 So, I think that that's critically important as
5 we build sustainability, to make sure that those change
6 agents are out there and do address the school's
7 priorities first.

8 Area-wide coalitions, I think one of the
9 reasons why Washington State was considered so seriously
10 -- and we had lots of discussion on the phone on this
11 topic -- was the fact that they had one of the largest,
12 longest running state coalitions for school IPM called
13 UPEST. It's currently run by Carrie Foss from Washington
14 State University. It's just the longest in existence and
15 has a very broad stakeholder's team associated with it.

16 So, it has proven to be extraordinarily
17 helpful. I think, with the exception of Texas and
18 perhaps one or two others, they have a very, very high
19 rate of numbers of students already in attending public
20 schools at some level implementing IPM to some extent.

21 So, that's actually an Arizona picture. You
22 might recognize a few of those people in there. But the

1 gentleman that is talking is the school IPM coordinator.
2 He is an expert in many things. So, when we visited his
3 school, he did most of the talking and the other school
4 guys listened.

5 Again, we talked a bit about the recognition
6 programs. We ran our own certificate system just
7 recently where we recognized people who had engaged in
8 school IPM, education efforts specifically. So, on their
9 certificate it says thanks for being a great educator.
10 As a result of those nine individuals who got those
11 certificates, we expanded our stakeholder teams
12 significantly. We expanded the number of change agents
13 involved in the Arizona effort.

14 There's just been great impact for the
15 individuals who received the certificates, that they've
16 given me feedback. They feel that their school is
17 looking at them with a whole different level of
18 credibility and professionalism. So, that was wonderful
19 to hear.

20 This was a mock slide, get dirty, mostly
21 because it's fun, but it does make a difference. It
22 really does, actually, make a difference. I've cleaned

1 drains. I've been in dumpsters. I've done pretty much
2 everything you can possibly think of. I've cleaned tons
3 of rodent poop correctly, using 10 percent bleach and
4 waiting for it to soak and all of that. The great thing
5 is that you get to demo and everybody gets to watch.
6 Having your stakeholders see something demonstrated in
7 front of their eyes, it really does work. But it's lots
8 of fun.

9 Then, finally, having some non-pesticide rules
10 and regs. I didn't put legislation because I thought I'd
11 be like instantly burst into flames or something saying
12 that in here in this building. So, I'm not going to say
13 that. But rules and regs can come in many forms.
14 Schools can institute their own rules and regs and
15 policies. Quite often, that is where they start.

16 Focusing on pest resource reduction has been
17 phenomenally effective. Who is going to argue with you
18 when you say your sanitation standards need improving.
19 Your clutter needs reduction. Your waste management
20 program is generating problems with rats and flies, et
21 cetera, et cetera. Nobody argues with those things.
22 They're such common sense. I haven't had anybody argue

1 so far.

2 I'm going to ask Mark to cover this particular
3 slide. This is one of the things that he teachers, so
4 he's better qualified than I.

5 MARK: Well, it's just what it says. What we
6 want to do as change agents is work out way out of a job.
7 Basically, we want to reach a point of critical mass,
8 which is the point that individuals in a system have
9 adopted an innovation so that the innovation's further
10 rate of adoption becomes self-sustaining.

11 It actually goes back to what Dawn was talking
12 about earlier with behavior. Once the resources are out
13 there to get that momentum going, then you have to spend
14 more resources to keep that momentum going. But, at some
15 point, it will continue. So, how do we do that is the
16 question. There are ways of doing it. That's what the
17 workgroup hopefully will be working on in the future.

18 MS. GOUGE: This is just a final reminder.
19 People are motivated by perceived threat. They're
20 motivated to change their behavior based on perceived,
21 being the important word, threat. All of this change is
22 made individual by individual.

1 I'm going to just ask, who is more terrified of
2 sharks than mosquitos? Come on. Sharks, put your hands
3 up. Come on, people. Be honest. Okay, mosquitos. Oh,
4 you guys, seriously. You know, mosquitos are way more
5 deadly. But I still stand by the fact that for those
6 five people who are eaten by sharks every year, it's
7 going to be a bad day for them.

8 And one final thought, individuals are
9 motivated. They take action based on perceived ease and
10 efficacy. How easy is it to make this change and how
11 effective is it going to be if I put the effort in? So,
12 I got on a website, the American College of (inaudible)
13 Medicine.

14 They recommend that if you want to reduce your
15 blood pressure, so you're a little hypertensive, you can
16 do it this way. You could engage in 30 minutes of
17 exercise 5 times a week. You also need to be doing some
18 strength training at least twice a week. You can park
19 your car away so you have to walk, take the steps, take
20 your kid out to the park. Oh, yeah, you can't eat
21 anything either.

22 So, then again, you could take some pills.

1 What's easier? Who wants to go for the walking and all
2 of that? Good man. So far, one person in the entire
3 room. So, we have to make sure that we really can
4 motivate people and give them something that is
5 relatively easy. We cannot make it too complicated as we
6 continue to expand this across the country.

7 We have to stay focused on making is simple,
8 easy, and with huge benefits at the end of the process.
9 I think as a group, we realize we've been doing a lot of
10 that already, and we're just going to continue on.

11 So, with that, any questions?

12 MR. JONES: Jimmy?

13 DR. ROBERTS: Nice presentation. Jimmy Roberts
14 from MUSC. I wanted to point out one thing. You had
15 mentioned partnerships. The American Academy of
16 Pediatrics, which represents 60,000 pediatricians, has
17 come out with a policy statement on pesticide exposure in
18 kids. In that, they strongly recommend the use of IPMs.
19 So, that might be, number one, useful for you as your
20 group, but also your local pediatricians might be a great
21 partner in every place that you go to.

22 MR. JONES: Mark.

1 MARK: Yes, thank you. By the way, we have two
2 pediatricians in the room that I know of. One is Jimmy
3 Roberts and the other one is Geoff Calvert. Between the
4 two of them, they wrote, probably, the articles that I
5 use the most in trying to diffuse IPM out there.

6 Geoff did an article five years ago now, five
7 or six years ago, with regard to pesticides and children
8 and exposures with schools. It wasn't just children; it
9 was the school community. Then, what Jimmy is talking
10 about, I actually just found out that he was the author
11 of that American Academy of Pediatrics paper. I use that
12 all the time.

13 It's quite valuable in that people don't have
14 to believe me when I stand up in front of them as an
15 entomologist or whatever they want to think of me. But
16 when I say this is something that is recommended to you
17 by the doctors of your children, that is very powerful.
18 So, I want to thank him and the Academy for doing that.

19 What is really nice, and it's part of what Dawn
20 was talking about, is finally feeling like we're not
21 climbing uphill all the time. We have pediatricians that
22 are also coming to us and willing to help implement

1 integrated pest management. That's a powerful tool out
2 there both with schools but also with agriculture, I'm
3 sure.

4 First, I want to say how impressed I've been in
5 the past couple years with the agencies, particularly
6 this office's commitment to school integrated pest
7 management. I've been doing this for 20 years or more
8 and it's been a long slog. It's really been good and
9 it's really reaching that critical mass slide that Dawn
10 put up there. As far as I know, other offices in the
11 agency and some other agencies are getting on the
12 bandwagon and partnering up with this office.

13 So, that said, I would like to ask a few
14 questions, which I know I had that opportunity earlier,
15 but I wanted you guys to get through your slide show.
16 Probably one is to Thomas. In slide 9, there was a
17 reference to one of the major activities of the offices
18 to provide technical assistance. Could you give some
19 examples of that? Then I have a few other questions.

20 THOMAS: Sure. So, a level of technical
21 assistance we've been able to provide as we're working
22 hand in hand with our regional coordinators, obviously,

1 is either outreach efforts or connecting them with
2 partners or external partners. But to the level of
3 actual on the ground technical, we're looking to utilize
4 the existing partnerships we have through the PPDC and
5 subject matter experts on the ground. So, no, we haven't
6 had that degree of assistance reach out to us yet to this
7 date.

8 MARK: Well, in a sense, you're brokering with
9 the change agent core that you have out there, so that
10 works better anyways, the leverage of resources.

11 THOMAS: Correct.

12 MARK: That's good. I wasn't quite sure if you
13 guys were on the ground doing that or if you were acting
14 as brokers.

15 THOMAS: We're utilizing all the existing
16 resources we have.

17 MARK: Okay. Then, I guess this one is going
18 to Frank. I think one of the drastic differences out
19 there that have changed things is the idea that we've
20 gone from grants to cooperative agreements. So, that's
21 where there's a substantial federal involvement. So,
22 could you give us some examples of what that means and

1 what the difference is?

2 FRANK: Sure. The last round of grants that
3 were issued prior to the three that we just awarded were
4 initially set up as grants. As Mark said, the key
5 difference between a grant and a cooperative agreement is
6 the term substantial federal involvement. We converted
7 several of those initial grants to cooperatives
8 agreements kind of midstream.

9 With these three that we just awarded, we felt
10 that it was important at first to set those up as
11 cooperatives. That does allow EPA folks to be more
12 involved in the projects. We don't get to help with the
13 initial project proposals or those types of things. The
14 ideas are generated by the applicants. But we are
15 allowed to participate in the project's implementation.

16 So, we can have EPA folks participate in
17 meetings, provide webinars, provide information as far as
18 ideas and guidance on how the project may be steered in
19 different directions. So, it provides a more
20 collaborative environment for the project as it goes
21 forward.

22 So, we think that this is a better mechanism.

1 We think that it can get us working more collaboratively
2 with the recipients. It will, in the end, result in
3 better outcomes of the projects than we could achieve
4 with just awarding money through a grant process.

5 MARK: Thank you. I see that, and I'm learning
6 about it in that it's a work in progress. When I work
7 with folks in the states that have these cooperative
8 agreements, I think it will behoove us to try to come up
9 with a list of ways that they can work with the agency.
10 This has lots of benefits, tangible ones, for the
11 diffusion of IPM on the ground, but it also would for
12 future projects that, in fact, don't entail money but
13 partnership.

14 MR. JONES: Thanks, Mark. Good point.

15 Fawn, go ahead.

16 MS. PATTISON: Thanks. I want to commend you
17 all on the great work. Dr. Gouge, thanks for your great
18 presentation. It's nice having educators give power
19 points.

20 I have worked on school IPM a fair bit in North
21 Carolina. Now we're doing a lot of work on childcare
22 IPM. I'm curious about -- and I think I've asked about

1 this before -- but I'm curious about whether the Center
2 for Expertise or the workgroup have talked about doing
3 more work in the childcare arena. You all have
4 referenced in several ways how important it is to have an
5 authoritative agency, an authoritative source speak to
6 why this is a good idea.

7 It seems so intuitive that if it's good for
8 schools, it would be good for childcares. It is, but the
9 folks who work in that completely different arena look to
10 different sources, use different lingo. I would love to
11 have more of those authoritative reference points saying
12 yes, this is great for childcare.

13 Once we get over that initial hurdle with them,
14 they're so receptive and so much less red tape than in a
15 school environment that the ball rolls downhill a lot
16 faster. But getting over that initial hump, especially
17 once you get into the for profit childcare networks that
18 serve a lot of vulnerable kids, it's been very, very
19 challenging.

20 So, we would love to have more to be able to
21 point to to say not just that it's a great idea but we're
22 not the only ones who think that.

1 MR. JONES: Dave.

2 DAVE: Thank you, Dawn. That was actually a
3 very good presentation, although I looked puzzled. I
4 must have been asleep when I made that quote. I'm not in
5 the habit of quoting physicists, but I'll take your word
6 for it.

7 I wanted to thank EPA for actually moving on
8 the recommendations. It took us a while to get to them.
9 I think once we sort of landed on some more specific
10 recommendations of direction, I think you guys have done
11 a good job of moving forward with that.

12 In the discussion yesterday, one of the things
13 that we landed on was well, what's next. I mean, I think
14 we kind of landed on a lot of the sustainability things
15 that Dawn touched on. But we also wanted to talk about,
16 what is the role of the workgroup and what would we
17 recommend to EPA to do.

18 I think that as a group we decided that we
19 would continue to advise EPA on what is its ongoing role
20 or what is its role, at least for the time being, in
21 promoting sustainability out in the very large country
22 and getting it to the points that it's not so much EPA's

1 initiative or any one person's initiative, but we get to
2 the point where these systems are in place and
3 sustainable on a statewide and regional and district
4 level, and looking for whatever it takes.

5 I know that there's going to be some trial and
6 error. Obviously, there's some good information on what
7 really does work. But focus on what EPA's role can most
8 constructively be in getting that fully sustainable
9 throughout the country so that it just takes on a life of
10 its own and it becomes the way people do pest management
11 in schools.

12 My vision is it's been 20 years and people
13 think well, you mean you used to do it a different way?
14 So, anyway, I'm looking forward to the workgroup moving
15 in that direction.

16 MR. JONES: Ray.

17 MR. McALLISTER: We'd like to encourage the
18 workgroup and the various projects coming out of that
19 workgroup to adhere in their efforts to the IPM
20 definition that's codified in FIFRA, which states that
21 IPM is a sustainable approach to managing pests by
22 combining biological, cultural, physical, and chemical

1 tools in ways that minimize economic health and
2 environmental risks. If you leave out some of the tools,
3 you may hamper your efforts to minimize those risks
4 across the board.

5 MR. JONES: Mark

6 MARK: First of all, Ray, I certainly agree.
7 You want to be able to use all tools, as long as they're
8 safe. That's the important thing, with our children in
9 particular.

10 By the way, thank you for allowing me to talk
11 about. I wanted to mention something that I was talking
12 to some of the other offices to the other day about what
13 are the advantages of setting up an IPM program in a
14 school besides reducing the risks from pest and
15 pesticides.

16 What I have seen over the years and what I
17 think is really valuable for taxpayers to think about is
18 that schools have an infrastructure in place for
19 children's health. That infrastructure, whether it's
20 with regard to pests or pesticides, that same
21 infrastructure deals with nutrition. It deals with
22 athletic injuries. It deals with indoor air quality.

1 So, once these infrastructures are set up and have had
2 some success to where they become part of the
3 institution, you have a more efficient system.

4 So, this is something that is, for me, an
5 unanticipated consequence, because when I just started
6 this it was about pests and pesticides. So, this is what
7 I see now, that availability. Then, that same model can
8 be moved to childcare facilities, elderly care
9 facilities, hospitals, public housing, et cetera. That
10 is what is happening. So, it's not just their bed bug
11 management; then it goes to nutrition and indoor air
12 quality as well. Thank you.

13 MR. JONES: Tom.

14 TOM: I think that the group would like to
15 know, because I'm not sure myself on the committee, how
16 long is the pilot project supposed to go? Is there a
17 plan for another pilot project? It may be based on your
18 funding or whatever, but other than us working on the
19 sustainability, what are the plans, so that the group
20 would know, of how you're gong to bring it forward?
21 Would another group get a small grant to implement what's
22 already been done in Washington?

1 UNIDENTIFIED FEMALE: Sure. So, the pilot
2 project is supposed to be 18 months long, starting just
3 recently. We are definitely going to document everything
4 that goes into this project, the outputs and outcomes.
5 We hope to do a webinar at the end of the project to the
6 other regions and states really being honest about what
7 worked and what didn't and how we were able to strengthen
8 the program statewide.

9 I don't know if you wanted to add anything else
10 about diffusion.

11 UNIDENTIFIED MALE: I think, Tom, we're looking
12 to see how well the pilot is. We assume it's going to be
13 successful. We anticipate it will be. If it is, then
14 the idea is to take it and work with other states, maybe
15 not on a one-on-one basis like we did with Washington,
16 but maybe get a couple of states, two or three or four
17 states, onboard with the same kind of model and work it
18 from there.

19 We haven't thought as far as funding or
20 anything like that I think we want to look to see how
21 much we can do with the resources we have with this
22 project. Then, like Juliann said, do a good

1 documentation so that it is a well-documented model that
2 is applicable to other places. So, I think we see that
3 as the next step a couple years down the road.

4 UNIDENTIFIED MALE: Dawn, I wanted to
5 compliment you on a great presentation. I know yesterday
6 you were a little hesitant, but you did a superb job. So
7 did Tom and Juliann as well.

8 I know looking down the road, it appears you
9 have a really school IPM program overall. One of the
10 things, and I think you had it on one of your slides, is
11 to be able to show the benefits of impact as we go along.
12 Sometimes there are unintended impacts or benefits, one
13 of which I think would be to determine how (inaudible)
14 school IPM, the kids or other folks who are involved in
15 it.

16 Has there been or do you know (inaudible) spill
17 over into their homes as a result of the knowledge that
18 is acquired from (inaudible) from the school IPM? That
19 would be really a big deal if we can document that as a
20 result of school IPM other things that are happening.

21 DR. GOUGE: Thank you very much for that
22 comment. It brings up a really good point. Yes, we have

1 had spillover in two particular kinds of situations, the
2 first and most obvious being when we're training in a
3 school environment, the staff and the faculty are
4 engaged. They receive the pest presses. They get
5 topical information constantly. They are involved
6 sometimes in inspections but always in the training
7 aspect. Teachers are by far the most hostile audience I
8 ever engage with. Within the first few minutes of
9 explaining that everything that I'm going to explain to
10 them about the school pest environment is applicable in
11 their home environment, they are, like, oh, okay, all
12 right, because they don't necessarily initially see pest
13 management in their school as their job. It's somebody
14 else's. Little by little, they get on board with the
15 whole pest management is everybody's job in a school or a
16 childcare facility.

17 So, first of all, faculty take it home. We've
18 had great impacts from that. There are a number of
19 states and some great advocates for teaching students IPM
20 as part of IPM in schools programs. That also has had
21 some follow-on effects where the kids take the message
22 home to parents and then parents get more involved.

1 MR. JONES: Jerry.

2 JERRY: I want to congratulate the team on what
3 a great job you've done. I was involved in this issue
4 many, many moons ago when Bob's predecessor's
5 predecessor, Janet Anderson, convened a workshop and I
6 was asked to facilitate it. I've just seen this come
7 light years from where we were 12 or 14 years ago to
8 where we are today. So, congratulations and Kudos.

9 The question I have for the team is are there
10 necessary biopesticides and conventional chemical
11 pesticides needed to sustain this IPM system that are
12 difficult to obtain and retain due to data requirements
13 and how are you going to get around that issue?

14 DR. GOUGE: I have not been aware of any, but
15 I'm based in Arizona. So, I can't speak for all parts of
16 the country. I would like to open it up to anybody on
17 the team or anybody that's aware of a situation where
18 that's occurred.

19 UNIDENTIFIED MALE: In my experience, I have
20 not seen that as a problem. We get into situations on
21 who can apply some emergency stuff occasionally, but it's
22 not too big of a problem. With my research on looking at

1 the efficacy of IPM in schools as far as the amount of
2 pesticides that are used and the pests, I measure all
3 pesticide applications no matter.

4 I don't take into consideration toxicity
5 because I don't want to get into that. So, if it's boric
6 acid, if it's diatomaceous earth, if it's fipronyl
7 (phonetic) on the outside, I measure it all the same.
8 But as far as availability, I've never run into any
9 problems. Obviously, it's nice to have alternative, but
10 from my point of view, I look at IPM as pollution
11 prevention.

12 So, if you look at pesticides as a potential
13 pollutant, then what is the source reduction for that,
14 and that's not having pests. So, I always hesitate to
15 provide more of those pills for people who need exercise.

16 UNIDENTIFIED MALE: I guess the only warning is
17 to learn a lesson from what's occurred in the agriculture
18 IPM where a lot of the fruit crops had tremendous IPM
19 systems. Then comes the brown marmalade stink bug and
20 it's all gone in one quick swoop. So, you don't want
21 those kids or that spike going back to the 1920s with the
22 flu. So, you have to be prepared.

1 MR. JONES: Dave, do you have another comment?

2 DAVE: Yes. It's sort of reflecting on what
3 Ray commented on. I'd say that the discussion in the
4 committee isn't really centered on oh, okay -- I haven't
5 heard any move towards defining IPM as the goal is to
6 reduce pesticides and focus on good pesticides versus bad
7 pesticides. Really, I think it is consistent with the
8 definition that considers the use of all tools and really
9 focusing on overall and long term effectiveness.

10 I haven't really heard any effort of let's try
11 and measure this by how much did we reduce the use of
12 this pesticide or that pesticide. So, I'd say we sort of
13 started from a standpoint of an understanding of it,
14 using all the tools.

15 I don't think this is explicitly stated, but I
16 think we all recognize that pesticide reduction can be
17 one of the benefits, if you will, of having a system that
18 really focuses on what is the whole system that reduces
19 the pests.

20 So, I think we've kind of accepted that
21 definition and sort of moved on from there in trying to
22 get people to understand it's not a trivial or

1 uncomplicated concept.

2 DR. GOUGE: I did want to just qualify that.

3 Thank you, Dave, for putting that so succinctly. There

4 are situations when I prohibit the use of a chemical

5 approach in certain instances. I say that

6 unapologetically to each and every one of you. I'll give

7 you some examples. I could go on and on for hours, but

8 I'm just going to keep it to a few.

9 Many of us dealing with school situations or

10 dealing with roving bed bugs, the initial reaction to a

11 single bed bug in a classroom is to want to evacuate the

12 classroom, to spray it down with as many different things

13 as they have on hand at any given time for the one roving

14 bed bug that's being caught, squashed onto tape or mashed

15 into the desk. Those very, very few instances that I've

16 ever come across amongst many, many situations where I

17 would ever think that anything beyond cleaning, vacuuming

18 and monitoring for additional bed bugs was the correct

19 response.

20 So, I recognize that Ray referenced the

21 definition of FIFRA, but by no means are we required to

22 use all of those tools to respond to any one particular

1 pest. On occasions, we're faced with a pest where the
2 knee jerk reaction is not the correct choice. So, there
3 are situations where I absolutely go insane. We're going
4 to deep clean, we're going to monitor, and we're not
5 going to send any kids home today.

6 Then, another situation that we come across,
7 this is special ed rooms where we have a lot of kids who
8 are disabled either physically or mentally or both, that
9 are particularly vulnerable to chemical sensitivities. I
10 will get very animated when people are using strong
11 cleaning chemicals or anything that's going to agitate
12 and adversely affect those kids who are in that room and
13 sometimes in a particular location in the room for an
14 extended period of time.

15 I could go on, but I'm just going to stop
16 there.

17 MR. JONES: Any other comments? Okay, thank
18 you very much. I've never seen anyone so excited about
19 cleaning rodent poop.

20 So, we don't have any public comments. Is
21 there anyone on the phone who wants to make a comment?

22 MS. DUKE: Hi, I'm Marcia Duke with the

1 National Pest Management Association. We represent the
2 structural pest control industry. We are excited about
3 talking about school IPM on a lot of levels. Some of the
4 things that are being talked about are things that we
5 have tried to get happen, not only in schools but in food
6 plants and other very sensitive locations for a very long
7 time. So, we hope this is successful and from a big
8 picture perspective, we can get schools to do all of
9 these things through a health committee or something
10 along those lines.

11 We play a small role in what has been
12 described. But not very long ago, typically, a school
13 IPM was very focused on the person doing the pest
14 management. This is a bigger picture perspective. I'm
15 sort of taking it away from the traditional definition of
16 what one would consider IPM. So, I'm sort of glad we're
17 moving a little bit away from that talking about this is
18 school IPM and some different circles, maybe not here.

19 That all being said, I think there is one thing
20 that maybe is missing from this discussion. Maybe it
21 isn't and maybe I just missed it. One of the reasons
22 that we haven't been successful in different places of

1 actually getting these things to happen is the money
2 behind it. Getting a school to make these changes, even
3 with a core of change agents and other people, and
4 diffusing that out, I do believe will be difficult,
5 although I am very hopeful that this will be successful
6 in the end. And that somehow we're reaching that
7 critical mass and we can push this forward over the hump
8 and it catches on.

9 But I just want to state that I'm a little
10 worried about where the money -- I think we're at the
11 50,000 level. If you take it back to we're on the ground
12 and we're at the 1,000 foot and we're implementing this
13 program, who pays for all of the components that have to
14 be put in place to keep the pests out in the beginning,
15 if that's where we're going. I think that's where we're
16 going and I think it's the best place to go.

17 And then, we need to keep in mind that not only
18 does my group use pesticides in schools, but there are a
19 lot of antimicrobials being used as well. So, we have to
20 keep that in our school and greater pest management minds
21 that we're not just talking about those pests. We're
22 talking about the antimicrobial pests as well and

1 bringing that all in together.

2 I thank you for allowing me to make a public
3 comment.

4 MR. JONES: Okay, thank you. Anybody else?

5 MS. HURLEY: Hello, this is Janet Hurley. Can
6 I comment?

7 MR. JONES: Go ahead.

8 MS. HURLEY: The fact that what Marcia just
9 brought us is extremely true, but this is where I'm going
10 to put a plea out to the PPDC committee and every parent
11 and every person out there. The problem with that cost
12 has to do with schools not keeping up with their
13 infrastructure. I don't know how many people have
14 watched the news, but I've seen things on schools that
15 don't keep up. That's our biggest hurdle when we're
16 doing this. When you walk into a school that will not
17 put money into infrastructure to fix things, that's when
18 we have pest problems. We can do everything we can, but
19 when a school district doesn't want to put money into an
20 old building but wants to build a brand new building --
21 we're working very hard on changing things.

22 But I am applauding everything that I've heard

1 today because I, like everybody else, remember when we
2 sat around and told everybody what we were doing but we
3 weren't doing it. We're now doing it and we've got lots
4 of people helping us. We're welcoming more.

5 So, understand that we understand these
6 hurdles. It's just not always easy, depending on the
7 school system.

8 MR. JONES: Thank you. All right, where has
9 the time gone? It seems like we just started. So, we'll
10 meet back at 9:00 tomorrow. We'll do endangered species,
11 endocrine disruption, screening program, and comparative
12 safety claims.

13 So, have a good night and we'll see everybody
14 bright and early tomorrow. Thank you. I just want to
15 thank everybody for making my first PPDC chair and first
16 day so easy. It's nice to see everybody have a
17 constructive discussion without letting everyone's
18 personal emotions get involved. Thank you.

19 (Whereupon, the meeting was
20 adjourned.)

21

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UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY

PESTICIDE PROGRAM DIALOGUE
COMMITTEE MEETING

June 5-6, 2014

Conference Center - Lobby Level

2777 Crystal Drive

One Potomac Yard South

Arlington, VA 22202

1 P R O C E E D I N G S

2 - - - - -

3 MR. HOUSENGER: Good morning. Welcome back to
4 day two. We have a short day today. I think there are a
5 couple new people sitting in for people who had to leave.
6 If those people could identify themselves.

7 MS. : (Inaudible) USA. I'm sitting in for
8 Scott Schertz.

9 MR. WHITE: Mike White, Council of Producers
10 and Distributors of Agrotechnology, sitting in for Dr.
11 Susan Ferenc.

12 MR. CHEN: I'm Teung Chin, USDA Office of Pest
13 Management Policy, sitting in for Dr. Sheryl Kunickis.

14 MR. HOUSENGER: Okay. I know that people
15 probably will, at some point in the day, leave early, at
16 least some of you. Before that happens, I wanted to
17 thank Margie Fehrenbach who is responsible for getting a
18 lot of people here. So, blame her or congratulate her on
19 doing that. But it is a lot of work. It's a lot of work
20 for a lot of staff here, actually. I want to thank
21 everybody for all the work they put into it, and to you
22 guys as well. I know it's not easy to get to Washington

1 from where everybody is coming from, so we appreciate it.

2 We had a good day yesterday. Let's continue
3 today with endangered species. The people leading off
4 the discussion are Rick Keigwin, Don Brady, and Lois
5 Rossi. Don is going first.

6 MR. BRADY: So, welcome. It's a good topic to
7 take up first thing in the morning. I'd like to also
8 acknowledge Paul Sousa (phonetic) from the Fish and
9 Wildlife Service who, in addition to being a member of
10 the PPDC, is the senior manager in the Fish and Wildlife
11 Service that's helping with the implementations of the
12 National Academy of Science's report.

13 So, today -- oh, and I would like to point out
14 that I got projected, at least on some of the screens.
15 One of them is flipping on and off over there, the web
16 site where people can find the materials that describe
17 the interim approaches that the agencies have adopted and
18 are working through right now to implement the National
19 Academy of Sciences.

20 You'll find a white paper. You'll find a
21 fairly involved Power Point. I would remind people that
22 these are evolving approaches. We've had one workshop

1 with CropLife and Defenders of Wildlife. We expect that
2 there will be some additional workshops as we go down
3 this road jointly with Fish and Wildlife, NOAA, and USDA
4 to implement the NAS recommendations. We anticipate that
5 we'll learn and adjust as we go.

6 But having said that and encouraging everyone
7 to pull down that material and take a look at it, we
8 wanted to do three things in this morning's session. The
9 first was to share some information on some of the
10 litigation that's confronted the agencies around
11 endangered species. Then, we wanted to share with you an
12 approach that we are thinking about, really.

13 It's a conceptual approach at this time to
14 dealing with consultations in the future. This is
15 primarily from EPA's viewpoint, but we're very interested
16 in hearing reactions from the committee to this outline.
17 We're going to actually stop after the second point and
18 ask the committee for thoughts and comments.

19 Then, finally, we'll get an update on the
20 interim agreements, and there's two key things that the
21 agencies have agreed on. One will be what Paul alluded
22 to yesterday in terms of the approach for producing range

1 maps of endangered species for use in the interagency
2 work. Then, hopefully, we'll have time for Steve
3 Leonard's (phonetic) from EFED to share some of the work
4 around use data based on USDA's geographic data.

5 So, that will be a busy session. I'll be
6 joined at various points. Paul will chip in, and Lois
7 will chip in, and I know that Rick will, too.

8 So, the first thing we wanted to talk about is
9 that there is a stipulated injunction. It's scheduled to
10 be published for comment today. The injunction would
11 settle litigation against EPA by Northwest Center for
12 Alternatives to Pesticides, or NCAP, and others in the
13 district court in Washington State.

14 The injunction in big picture terms does three
15 things. It reinstates the stream side buffer zones
16 established in the prior Washington toxic litigation and
17 applies to carbaryl, chlorpyrifos, diazinon, Malathion,
18 and methanyl (phonetic). It will remain in place until
19 EPA implements necessary protections for salmon and steel
20 head based on reinitiated consultation with National
21 Marine and Fisheries.

22 It provides notice to certified applicators,

1 state and local governments, federal agencies, land grant
2 universities, and extension organizations of the
3 settlement, and it provides for an updated EPA web site.
4 There will be a 30-day comment period, and EPA will
5 review all comments to determine whether the proposed
6 injunction should go forward or whether we should
7 reconsider or revise it based on the comments.

8 In separate litigation, the National Marine and
9 Fisheries has agreed to complete consultations, any
10 consultations that EPA reinitiates on chlorpyrifos,
11 diazinon, and Malathion by December 2017, and on carbaryl
12 and methanyl by December 2018. These consultations or
13 the work that EPA does will be done in connection with
14 the National FIFRA registration review work plan.

15 Fish and Wildlife also has comments (tape
16 malfunction).

17 PAUL: I think it's safe to say it's an
18 exciting time for consultations with registrations. As
19 we've talked about the last few PPDC meetings, we're
20 trying to figure out how we create this fully unified
21 approach to consultations.

22 So, what Don mentioned previously is really

1 important to us as well, because, again, a year ago we
2 had the National Academy of Sciences report come forward
3 to give us recommendations for how we complete
4 consultations, how we move beyond some of the scientific
5 disagreements that we've had in the past.

6 Before that, we had the public engagement
7 strategy that I (tape malfunction) to providing draft
8 biological opinions along with draft biological (tape
9 malfunction) transparency in an effort to really make
10 these consultations work.

11 So, what we are really interested in doing is
12 figuring out how we align all of our workload. Clearly,
13 litigation has a way of helping identify your priorities.
14 So, as Don mentioned, we have a situation now where we've
15 got three chemicals where consultations would be
16 completed by the end of 2017. That's chlorpyrifos,
17 Malathion and diazinon, with a couple of other
18 consultations a year after. We are very interested in
19 finding a way to ensure that we can bring our full
20 capacity to those consultations as well.

21 The real value in this would be our scientists
22 would be sitting down working together as we implement

1 for the first time in real consultations the National
2 Academy of Science's recommendations. We would, for the
3 first time, be able to use this full public engagement
4 process on some chemicals that historically have raised a
5 lot of concerns in the public.

6 So, we are trying through our litigation and
7 through our staff capability, more broadly, to be able to
8 bring to bear the kind of commitment that is going to be
9 necessary to move through these consultations. 2017
10 might sound a long way off, but to meet that kind of
11 deadline with the registration review process, with the
12 public engagement strategy that we have previously agreed
13 to, we're looking at biological assessments as early as a
14 year from now in draft form, obviously.

15 So, our teams have already started working
16 through this issue. We've outlined a rather ambitious
17 plan to work through the details of the Academy's
18 recommendations. It might seem a bit odd that it takes a
19 lot of time and energy to work through recommendations
20 that were produced a year ago, but the reality is when
21 you apply these kinds of recommendations in a specific
22 context at a nationwide level, you find there are lots of

1 questions that reflect important details that were not
2 apparent as we were developing the interim approaches
3 available at that web site.

4 So, that's really where we stand now. We're
5 still working through this issue. Clearly, there's a
6 public comment period in place, as Don mentioned, for the
7 next 30 days. We are, in the Fish and Wildlife Service,
8 doing our best to figure out if we can bring the capacity
9 necessary to be a full partner in these consultations as
10 they move forward. It's our sincere hope that we'll be
11 able to, because I really see that shared workload moving
12 forward together as the federal family with these
13 chemicals.

14 It's very important for us being able to get
15 the longer term efficiencies that we've talked about.
16 Once we have a number of these consultations under our
17 belt and this new day of National Academy of Science
18 recommendations, we're really hopeful that we're going to
19 be able to expedite the consultation process
20 dramatically. So, this initial kind of go slow to go
21 fast approach is really important.

22 MR. BRADY: Thanks, Paul. I think that it's

1 important to emphasize one of the things that Paul said,
2 which is that this work around the litigation represents
3 a real effort amongst the agencies to align and focus our
4 available resources so that we can demonstrate the
5 utility of our process for implementing the NAS report
6 and start to move through a more concerted implementation
7 process.

8 So, with that in mind, we wanted to share sort
9 of our concept. I think it will generate some interested
10 discussion. I hope it generates some interesting
11 discussion around the table. Basically, given that we
12 can't do everything, and neither can the Services because
13 of the resources that we all are working with currently,
14 we need to focus and put our energy where we think that
15 we'll get the most protection for endangered species.

16 So, we sort of have a three-legged approach
17 here. I'll introduce the first point, and then Lois will
18 pick up on the second two legs. Our main focus will
19 continue to be registration review. That's where the
20 vast majority of our consultation activity will occur.
21 It will remain the primary way in which we accomplish our
22 consultation obligations.

1 We believe strongly that by consulting during
2 registration review, we will be working with the greatest
3 potential impacts to species. And consistent with the
4 interagency shared scientific approaches, principles, and
5 the day forward approach that the agencies have adopted
6 as part of the NAS implementation, we will phase in the
7 National Academy of Science's measures over time.

8 So, the first consultations that we've given
9 you the hard dates for will be the first place where
10 we'll see those NAS measures start to be implemented and
11 jointly used by the agencies. As we said before, we
12 expect that we'll learn from the application of these
13 interim approaches, and that the teams, the science teams
14 that are already working together on these five
15 chemicals, will be providing back to the senior managers
16 and the agencies adjustments or revisions or refinements
17 of those interim approaches that have been identified so
18 far by the agencies.

19 So, registration review will continue to be our
20 primary focus. We will, however, do a couple of
21 additional things in response to some of the concerns
22 we've heard from stakeholders. I'll ask Lois to pick up

1 there.

2 MS. ROSSI: So, in the registration world,
3 we'll have two approaches, and these are basically in
4 response to concerns that we have heard. One is we will
5 complete endangered species assessments for the new
6 herbicide tolerant crop uses that are currently in house.
7 We'll affect determinations as resources allow. It is
8 likely that these registrations will not be nationwide
9 but targeted states, and they'll be focused on situations
10 where EPA can make no effect determination decisions.

11 The second in the registration world concerns
12 new active ingredients. For these, EPA will provide
13 information in the proposed decision document that goes
14 out for a 30-day comment period that compares potential
15 hazards of the new active to already registered
16 pesticides with similar modes of action and use patterns.
17 This will allow stakeholders, when they have the
18 opportunity to comment, to compare the relative toxicity
19 hazards of the proposed registration to the available
20 alternative.

21 Again, following up on Don's remarks, we
22 believe the greatest potential threat to species is from

1 older currently registered chemicals, and that hazard
2 information will illustrate this to stakeholders and
3 allow them to comment. That's it from the registration
4 point of view.

5 MR. BRADY: Okay, anybody else from -- all
6 right, so I think we've tried to share with you sort of
7 our conceptual model here. There's obviously lots of
8 details that we need to work out and continue to think
9 through. But we are interested in hearing remarks from
10 the committee here today on this approach, or at least
11 the umbrella of this approach.

12 MR. HOUSENGER: Well, that's good. Everybody
13 agrees with our approach. We'll take the agreement from
14 you. Mark, go ahead.

15 MARK: Well, as long as I've sat here and
16 listened to endangered species talks, I haven't been as
17 encouraged as I am today about progress. So, love to
18 hear it; want to see it.

19 UNIDENTIFIED MALE: This may be a question
20 that's a little early, but have you contemplated how 21st
21 century toxicology will be integrating into this new
22 approach?

1 MR. BRADY: We expect that it will at some
2 point, but we haven't done a lot of thinking, honestly,
3 about sort of where it starts to come into the play.
4 Right now, we're interested in the kinds of things that
5 were more immediate in the NAS report, starting to
6 develop some of the data and processes around the
7 probabilistic modeling approaches, develop or move into
8 developing some population model work that the agencies
9 can share. That will come at some point.

10 Remember, given the way that we're working and
11 given the bodies available to all the agencies, these NAS
12 measures are going to roll out over time. So, not every
13 immediate action is going to show the impact of every
14 part of the NAS implementation. So, it's a phase-in
15 process, and we hope to keep up with the science as we
16 go.

17 I think the thing that's really encouraging
18 from my standpoint is that even now, as the interagency
19 science teams who are responsible for producing these
20 initial biological evaluations and consultation packages,
21 they're meeting very frequently. They're talking to each
22 other. A little personal marker that I have in my head,

1 quite honestly, is when rather than sitting around the
2 table and having agency scientists say, well, Fish and
3 Wildlife does it this way or EPA scientists say, well,
4 EPA does it that way, come at it from the science,
5 regardless of which agency you represent.

6 So, we're working real hard that way.
7 Eventually it will come, but we haven't had an explicit
8 conversation.

9 MR. KEIGWIN: When I think about the 21st
10 century toxicology model, that outer ring, in the case of
11 endangered species, is, in fact, populated by individuals
12 who will be counting the impact on endangered species and
13 assessing what did it. Again, you'll be faced with the
14 same question we faced in human issues, which is how do
15 we determine what did it.

16 UNIDENTIFIED MALE: Fair enough.

17 MR. HOUSENGER: Ray.

18 RAY: I want to make sure I understood the
19 details. You would be using the new NAS recommendations
20 for the first time in these assessments or consultations
21 on compounds to come out in 2017-2018?

22 MR. BRADY: The consultation, the completed

1 consultation, is scheduled to be completed by NIMS in
2 2017 and 2018, depending on the compound. But there are
3 interim steps that obviously EPA has to go through to do
4 the work necessary to trigger the consultation.

5 RAY: Are those NAS recommendations to be used
6 in the assessments for the herbicide (inaudible) uses
7 that Lois mentioned?

8 MR. KEIGWIN: Probably not initially.

9 RAY: But you are limiting those ESA
10 assessments -- are you limiting the assessments or are
11 you limiting the registrations to the targeted states
12 where you have a no effect determination?

13 MS. ROSSI: Both. I mean, the assessments will
14 be for the states, and then that will equate to where the
15 registrations will be.

16 RAY: How does all of this interact with the
17 reduced risk process for new uses and new active
18 ingredients?

19 MS. ROSSI: Well, for new active ingredients,
20 obviously, the reduced risk -- the reduced risk process
21 will still go on. In that reduced risk process, as part
22 of the rationale and the document that you do to get the

1 reduced risk classification, there actually are a lot of
2 comparative data. That would definitely factor into the
3 decision, as I said. These decisions will have a
4 comparison to alternatives. So, it will actually work
5 very well.

6 MR. HOUSENGER: Gabrielle.

7 GABRIELLE: I'm just trying to understand, and
8 I realize this (tape malfunction). I'm just trying to
9 figure out how does this work in a couple different
10 scenarios. One is, what happens if -- I couldn't be
11 heard again.

12 The question I have, for the new AIs, I'm just
13 trying to figure out how this is going to work in the
14 future in terms of relative toxicities, because I can
15 envision a couple of the following scenarios. One is,
16 let's say for fish it's less toxic but for bees it's more
17 toxic. I mean, I'm just making this up.

18 We definitely have situations now where for
19 humans it's a lot less toxic and for mammals it's a lot
20 less toxic but for aquatic species it's more toxic. How
21 is this supposed to be helpful, because there's always
22 these tradeoffs? So, what does this mean if something is

1 not necessarily less toxic in all scenarios? I'm just
2 trying to figure out what this is going to mean.

3 MS. ROSSI: Well, that's exactly what the risk
4 manager has to do. I mean, each case that you do
5 presents a different risk scenario and a different
6 picture. In this case, you're only even looking at
7 hazard. I mean, that's exactly what the risk manager has
8 to do to figure out what the registration is going to be
9 like.

10 I mean, we have one out there already, a
11 decision that's in the public domain, (inaudible)
12 medicine, which has this comparison and a little bit of
13 the discussion. I think you'll see as we do more, there
14 will be more discussions. But, I mean, that's exactly
15 our job and what we have to do. I mean, we welcome
16 thoughts on that because it isn't easy and it isn't
17 obvious. Some of these, though, it's very obvious that
18 they have a lower hazard profile than their alternative.
19 Some are easy.

20 MR. HOUSENGER: Andy.

21 ANDY: I would just like to make a request,
22 that the PPDC consider forming an ESA workgroup. I think

1 it would be very helpful if that workgroup had
2 representation from Fish and Wildlife Services and USDA
3 at those meetings as well. Thank you.

4 MR. HOUSENGER: Dave.

5 MR. TAMAYO: Thank you. Dave Tamayo. Don, I
6 applied what you said about trying to get it so that the
7 Services and EPA really use the same science and it's not
8 a question of, okay, our science is better than yours.
9 What I wanted to say is that in support of that, I'd like
10 to see a little faster progress in working on the common
11 effects methodology so that the Office of Water
12 evaluations for what's a water quality impact and OPP's
13 evaluations are much more compatible. I think that will
14 be part of avoiding conflicts between the service's
15 evaluations and OPP's evaluations. Thank you.

16 MR. BRADY: Okay, noted.

17 MR. HOUSENGER: Cheryl.

18 DR. CLEVELAND: So, I guess I'm responding to,
19 again, the promulgation of hazards, especially in the
20 context of yesterday's conversation where we're really
21 concerned about the EU's approach overall to hazard
22 cutoff. The answer to Gabrielle's question is it's the

1 risk assessment not the hazard. So, I know you're aware
2 of this and you're trying to do your best to try to put
3 as much information out to move things forward.

4 But I guess, again, my kind of radar went up
5 when you started talking hazard. I think it's going to
6 have to be communicated very well if you back off and
7 don't do a full risk assessment and only do a hazard
8 communication. I was obligated to say that.

9 MR. HOUSENGER: Mark.

10 MARK: So, at the risk of looking ignorant on
11 this, it's because I am, and I need a little bit of
12 education. So, this question goes to Fish and Wildlife
13 Service. With the understanding, or my understanding,
14 that in a registration process, we look at the
15 environmental fate of pesticides and we review
16 environmental fate of pesticides that have been out
17 there. Correct me if I'm wrong, but this has come about
18 because of groups who have brought suit with regard to
19 endangered species and specific chemicals.

20 Could you tell me what the service is doing or
21 the agency, but I think this is a service question, with
22 regard to once these products hit the field, sometimes

1 they perform differently. There are unanticipated things
2 that happen. We know that that is the case. So, what is
3 in place to proactively deal with this to where the
4 service can deal with this before it comes to a lawsuit?

5 MR. KEIGWIN: That's a great question. Let me
6 try to explain a little bit of context about the
7 consultation process. I think that the lawsuits, by and
8 large, have focused on the process required by law more
9 so than the actual after effects of a chemical that's
10 been used on the ground for a long period of time.

11 For a long time, probably as long as ESA has
12 been around, and FIFRA as well, there's been a real
13 challenge between linking these two statutes. We had,
14 really, different cultures within EPA, the Fish and
15 Wildlife Service, and also the National Marine Fishery
16 Service. We had different needs regarding the scientific
17 assessments that we complete.

18 By law, if a federal action proposed by EPA,
19 any other federal agency as well, the Corps of Engineers,
20 for example, the Federal Department of Transportation, if
21 they propose an action that may affect a listed species,
22 they have to consult with us.

1 Truthfully, for many, many years, decades even,
2 we did not have a very effective engagement on these
3 consultations. The kinds of analyses that we do were
4 different than the common risk assessment policies used
5 by EPA. So, because we had not created an effective
6 merger, if you will, of the FIFRA and ESA process, we
7 started to see the lawsuits. The courts, I think,
8 encouraged us to figure it out.

9 It must be three or four years ago now we
10 recognized that we were still having scientific
11 challenges in terms of the disconnect on the processes
12 that we have to follow separately. So, we commissioned
13 the National Academy of Sciences to look into this issue,
14 unpack all the details, and help us figure out a model
15 for moving forward.

16 That report was finalized about a year ago.
17 The interim approaches that Don mentioned, represent the
18 agency's best attempt to translate those recommendations
19 into a process that we could use for consultations. So,
20 the way that we avoid lawsuits is by effectively marrying
21 the FIFRA and ESA requirements.

22 Another point I mentioned that's really

1 important, the public engagement strategy we finalized,
2 even before the National Academy of Sciences report was
3 issued about a year ago, allows us to try to recast how
4 the consultation occurs so that we've got early
5 engagement with the registrants, this notion of focus
6 meetings where we sit down with the registrants early on.

7 We bring scientific information about wildlife
8 to those conversations. When appropriate, we discuss
9 whether or not mitigation could be brought to bear in a
10 way that would avoid or eliminate all together effects.
11 So, we don't have what, truthfully, we had for too long.
12 That's a situation where we tried in the 11th hour to
13 complete a consultation on a risk assessment and a
14 registration review process that had been undertaken for
15 a long time. We identified issues of concern, and we had
16 conflict with those 11th hour questions.

17 So, really, that early engagement plus the
18 shared scientific methodologies is, I think, the path
19 forward for completing consultations that will avoid
20 litigation in the future. In the end, we all want the
21 same three things. We want to have effective
22 registrations. We know EPA has a registration review

1 process with very specific time lines. We want to have a
2 transparent process. Lots of people raise questions
3 about what was perceived to be the black box of the
4 analyses behind the endangered species consultation
5 process. And, of course we want to have effective
6 conservation from periled species.

7 So, the implementation and in the path forward
8 that Don described for bringing the agencies together
9 basically from the beginning to the end, working through
10 these issues, I think is the way that we avoid litigation
11 in the future and achieve those three goals.

12 MR. JORDAN: This is Bill Jordan. I wanted to
13 add a couple of other thoughts prompted in some part by
14 what Cheryl Cleveland said in her comments. We, in EPA,
15 absolutely agree with what Paul has been saying about the
16 importance of getting the science right, of doing it in a
17 transparent process, and moving ahead as efficiently as
18 possible.

19 We would all love to be able to snap our
20 fingers and make that happen right away and put it in
21 place and do it for all of the many, many decisions that
22 EPA makes both in registration review and on the

1 registration side. Unfortunately, that's not possible.

2 We have finite resources at EPA. We have
3 finite resources at the Services and USDA. We can't make
4 all of that take effect right away. So, we have to pick
5 and choose where we're going to put our energies and make
6 sure that we are directionally correct in dealing with
7 what are the most important things first.

8 The most important thing first is to get
9 science right. The next thing is to apply that science
10 where we think it will do the most good for protecting
11 species. As Lois and Don have said, we think that the
12 chemistries that are being brought to us as part of the
13 application process for registration, new active
14 ingredients, are, as a general matter, safer than the
15 chemistries that are in the marketplace and being used
16 today. That's a good thing, and we are really pleased to
17 encourage that process.

18 But folks might ask, well, how's that going to
19 be transparent? How are we sure that new active
20 ingredients that EPA approves are indeed better for the
21 environment, better for human health, and not going to do
22 unacceptable things for protected species? That's why

1 the hazard assessment, the hazard comparison, is going to
2 be part of our path going forward for new active
3 ingredients.

4 We don't have the resources to do a full ESA
5 analysis for every new active ingredient right now. We
6 don't even actually know the science about how to do
7 that. We're working through that. We're getting our
8 arms around that. But we think that the hazard
9 comparison will give people a basis for understanding
10 that yes, indeed, our assertion, our general proposition
11 that new active ingredients are better is a valid
12 conclusion.

13 By the same token, we're not going to be able
14 to do everything right away on re-registration,
15 registration review front. We're focusing in on the five
16 active ingredients that are identified in the proposed
17 settlement agreement and stipulated injunction. As those
18 evaluations proceed and as we move closer to biological
19 opinions, the science teams will work out a lot of the
20 details that Paul talked about, and we'll begin applying
21 them. But we don't yet have all those in effect.

22 So, it means that some of our registration

1 review decisions will go out with only some elements
2 reflecting the NAS understandings, other registration
3 review decisions will go out with full NAS type compliant
4 analysis, and some won't have all of the NAS.

5 The last thing to say is that even though we
6 may not have all of the NAS elements implemented in all
7 of our registration review decisions, we are doing, as
8 you will see on some preliminary risk assessments that
9 have come out and proposed decisions, we are applying our
10 standard ecological risk assessment methods to the review
11 of individual active ingredients.

12 When we make those assessments, sometimes they
13 identify issues/risks that we need to address. We are
14 implementing risk mitigation measures for those chemicals
15 that we think will lessen the ecological risks for all
16 wildlife, not just threatening endangered species.

17 So, as we move forward on the registration
18 review front, we will be seeing progress that we think
19 will provide protections for species in scientifically
20 defensible ways, even though we may not have done all of
21 the NAS compliant analyses that we hope eventually to
22 make as the standard for our registration review work.

1 MR. HOUSENGER: Ray.

2 RAY: Bill, your repetition of hazard
3 assessment or hazard comparison in the context of new
4 product registration raises more alarms. As Cheryl
5 mentioned earlier, we feel it's the obligation of the
6 agency to do a risk assessment and risk comparison. In
7 the context of new product registration, how is all of
8 this going to fit into PRIA obligations and time lines?

9 MS. ROSSI: Actually, Ray, we've started on the
10 pending. We have about 14, maybe, new active ingredients
11 right now pending. We are starting with our Benefits and
12 Economic Analysis Division to do that work as the other
13 divisions are doing the EFED analysis and the HED. So,
14 it's incorporated. It's not added on to; it's
15 incorporated into the review in the PRIA time line.

16 MR. KEIGWIN: So, just one thought. I know the
17 hazard raises an issue, but that's kind of a 50,000 foot
18 look at it. If we were to do more than that, I think
19 then we're talking about a lot more resources.
20 Obviously, if we see something with the initial screen,
21 we'd have to do more work. But we think that we can get
22 away with doing this and showing that the new AIs are

1 better for the environment.

2 MR. BRADY: Okay. It looks like we've had the
3 questions here, so we'll take back what we heard. We'll
4 think about our model a little more.

5 Having said that, there's sort of two topics
6 that we'd like to share with you, the progress that we've
7 made on the interagency level on two key questions that
8 relate to the completion of the biological effects
9 documents and the, ultimately, biological opinions by the
10 Services.

11 So, the first topic we'd like to talk about is
12 to have Paul share with the group the approach that the
13 interagency team has adopting or is adopting in working
14 through for developing endangered species range maps.

15 PAUL: First, let me characterize the problem
16 here for those folks that might not be intimately aware
17 of it. We've got about 1,500 federally threatened and
18 endangered species across the country. The way that our
19 organization is set up, we have 80-plus field offices
20 that work very closely with private land owners, with
21 federal agencies, to evaluate the effects of proposed
22 actions at the local level.

1 As we talk about national consultations of
2 pesticide registrations, that model that we have as an
3 agency has posed a challenge. We really rely on our
4 field offices to be the holders of the best available
5 science to be able to analyze in specific details what
6 the effects of a proposed action would be on the ground.
7 With a pesticide registration, we need to be able to work
8 at a much broader scale.

9 One of the things that's become very clear to
10 us as we have tried to figure out how to most effectively
11 complete these consultations is we need the most refined
12 species range maps that we can get. Right now, sort of
13 our default model, we have species maps at the county
14 level. So, we can tell you if a species is found within
15 a specific county.

16 When it comes, however, to being able to
17 provide meaningful information to EPA and to a
18 registrant, to environmental organizations and other
19 interest groups that are interested in really
20 understanding the details, we need more refinement so
21 that we can have a conversation that would allow us to
22 have an early dialogue with registrants about the degree

1 to which --

2 In this specific sensitive area for threatened
3 and endangered species, could the application of the
4 pesticide be modified in some way to avoid impacts all
5 together, in which case, ESA obligations would be met in
6 full or, if not to avoid them, to minimize them in a way
7 that's consistent with their business model and also
8 protective of the species?

9 So, we're in the process now of trying to
10 figure out a method for how we drill down to those county
11 level maps, to that level of specificity. Where is the
12 species found? What's the occupied range? We've had, I
13 think, really fruitful discussions since the Academy of
14 Sciences reported a year ago to think about how we
15 complete this effort.

16 Some of you might be aware of the group FESTF,
17 the Federal Endangered Species Task Force, that is a
18 composite of a number of the registrants. They have
19 already created a data base that includes the county
20 level maps that we have. It also reached out to many of
21 our field offices across the country and attempted to get
22 more refined maps when they're available.

1 It also has a contract with an organization
2 called Nature Serve that has element occurrences,
3 essentially data from states that show where endangered
4 species have been identified in the past. Working with
5 them, they are looking into a way through which we can
6 organize this information that would be useful for our
7 field structure.

8 We have a plan in place now that essentially
9 will use this information coupled with what I'm hopeful
10 we'll get to if we have time today for the first time
11 providing our field offices with a very clear footprint
12 of the application areas for these chemicals, including
13 the off site transport from wind and water flow.

14 So, for the first time, our field offices are
15 going to have those two important pieces of information.
16 We're going to request our field offices to provide a
17 more refined species range map, when possible, that will
18 be, essentially with that application use footprint, the
19 action area for the analysis of these consultations.

20 I want to make it clear it's not as easy as it
21 sounds to put together a species range map. We have, in
22 many cases, just holes in the data. We don't know what

1 the full occupied range is. We have to make assumptions
2 based upon habitat where we think they might be. There
3 hasn't been, in many cases, comprehensive surveys for
4 species. So, we've got to use our best professional
5 judgement. That is our job as the Fish and Wildlife
6 Service and the National Marine Fishery Service to use
7 the best available science to come up with the range that
8 makes most sense.

9 I don't expect, and I don't want to set an
10 expectation that through this process, which will unfold
11 over the next three months, we're going to have a refined
12 species range map for 1,500 species. But I think we're
13 going to be able to move the ball down the field. It's
14 very clear to us that in the mid to longer term, this is
15 a real need that will make national consultations more
16 effective.

17 We need to find a way where we've got a data
18 base that is available to people, including the EPA, and
19 registrants, and environmental organizations, the public
20 more broadly, that helps them understand where the
21 species are found. That will go a long way to speeding
22 up the process for consultations. We won't have to reach

1 out to 80-plus field offices to get that data. It will
2 also make it more transparent, again one of the major
3 goals that we have.

4 I think from a conservation perspective, what's
5 most exciting about it is we will have in our hands
6 information that will allow us to implement conservation
7 measures through conversations early in the registration
8 review process.

9 MR. BRADY: Thanks, Paul.

10 Steve Leonard will provide the other half of
11 the picture here, and then we can take additional
12 questions.

13 MR. LEONARD: Thanks. I'm Steve Leonard. I'm
14 a GIS analyst here at EPA. Paul sort of set up the first
15 half of the equation, which is to say, okay, where are
16 the species in question and where do they co-occur with
17 where pesticides are being applied. So, that's the half
18 that I'm looking at.

19 What we're trying to do is find the best
20 available data that shows where different agricultural
21 crops are grown on a nationwide level. What we've come
22 up with is using the USDA's crop land data layer, or CDL,

1 land cover data that they produce annually, the remote
2 sensing techniques for over 100 crops. Every year, they
3 show where on the landscape these crops are grown.

4 What we can do with that is instead of looking
5 at all 100-plus crops, we can aggregate those different
6 classes into 11 very general crop groups. What that does
7 is it helps improve the accuracy in which the different
8 crops are mapped, and it helps us account year after year
9 where the crops are rotated and where they could be in
10 the landscape at any given time.

11 So, another thing we look at for best available
12 data is we combine the crop land data with the
13 national agricultural statistics services census of
14 agriculture county-based statistics for acreage for any
15 given crop, and we compare the crop land data with
16 that on a county by county basis. We're able to improve
17 the land cover data using those statistics.

18 Once that's in place, we can then take the
19 registered label uses for each one of these pesticides
20 and cross walk that into our categories, our crop
21 categories, to say if a registered use is for corn, we
22 can say where is corn grown in the United States and add

1 that to a potential application footprint for that given
2 species. So, we do that for all the different
3 agricultural registered label uses.

4 We also do it for the non-agricultural
5 registered label uses. So, through conversations with
6 the Services, we've come to agreement on the method that
7 we would use for the agricultural crop types and the way
8 we would leverage the crop land data from the USDA
9 to establish that footprint.

10 What's ongoing right now and that we're still
11 in discussions with is what is the best available data
12 for the nonagricultural registered uses. There are a
13 couple different options for that that we're working
14 through the national (inaudible) dataset. It's a great
15 resource that we plan on leveraging, but there are
16 several other details that we're working through, as far
17 as different registered label uses.

18 Once we establish a footprint of where all the
19 different label uses are in the landscape, where a
20 pesticide could be applied, then we can say depending on
21 the application method, whether it's crop dusting or on
22 the ground, how will that application be carried off

1 site, whether it be through spray drift or from water.
2 We have models to take those scenarios and expand the
3 footprint out to account for those types of off site
4 transfers.

5 That's essentially how we're leveraging the CDL
6 and establishing a footprint.

7 MR. BRADY: Okay. Does anybody have questions
8 for Paul or Steve? Matt.

9 MATT: In light of changing weather patterns,
10 both with an increase in -- a change in water
11 distribution across the country, as we saw in Wisconsin
12 with the huge rains. Runoff was much greater than it has
13 been in the past -- and the changes in
14 temperature/weather.

15 How accurate are those two sources in terms of
16 what might come? How often is NAS updating that crop
17 information and keeping it current? How are you
18 accounting for changes in, say, water distribution
19 throughout the country?

20 MR. LEONARD: Well, the USDA updates the crop
21 land data lair every year. What we do is we take each
22 vintage that comes out and aggregate it to the current

1 model. So, if corn was grown in a field last year, now
2 it's soybeans, that field could either be a potential
3 application site for any registered use for corn or
4 soybeans.

5 So, over time, we can see in the landscape any
6 given spot in the landscape isn't just one crop or
7 another; it's any crop that's been grown there for as
8 long as the crop land data layer has been produced. So,
9 since we aggregate over time, we're accounting for these
10 different scenarios for a given crop.

11 As far as water is concerned, we use a
12 downstream pollution model that leverages the national
13 hydrography dataset -- the NHD Plus is what we're using
14 -- and that's the best available data for the different
15 streams.

16 MR. BRADY: I would also add that generally in
17 EFED, we update the MET files, the weather files that we
18 use to feed our models. Most of our models will work
19 within certain parameters of variations in climate and
20 water flow.

21 Gabrielle.

22 GABRIELLE: I've got a couple questions and a

1 comment. So, similar to what Matt was just asking, how
2 does seasonality of pesticide applications tie into this
3 database? I mean, are you accounting for either what the
4 label says or based on actual data when these compounds
5 are really being used? Is that being accounted for in
6 the GIS system?

7 MR. LEONARD: In the first phase, we're just
8 looking at proximity, step one. But then, as we move
9 into the more detailed analysis in step two, we start to
10 look at actual application. The trick here is to balance
11 the label use with the typical use. That's a
12 conversation that is going on amongst the agencies right
13 now.

14 Just to re-emphasize, this is why it's
15 important to us to have the focus meetings and get as
16 much information up front about what the actual use of
17 the pesticide will be.

18 UNIDENTIFIED MALE: If I could just add one
19 thought on that, I think your point is extremely
20 important because the original footprint is just the
21 first question. It could very well be that because of
22 the seasonality of the application, there are no issues,

1 even if that first step showed an overlap.

2 GABRIELLE: So, my other comment/question is,
3 nowhere was it mentioned that California, the other
4 country of California, does things differently. We have
5 pesticide use reporting, at least from the ag sector.
6 There's a lot of detail there as to where and so forth
7 that is. Where is that information going into this whole
8 system?

9 UNIDENTIFIED MALE: So, we're aware of that
10 information. We've been in the interagency sort of
11 discussion. We've been through a series of workshops on
12 that use reporting data. I think the challenge for the
13 agencies is that that is specific to California. You
14 have to think about whether it can be used in other parts
15 of the country.

16 So, I think you might have different scales of
17 analysis at some point based on the data that's
18 available. But that is honestly something that we're
19 still trying to work through.

20 GABRIELLE: So, I would like to have credit for
21 it.

22 The other thing I wanted to mention, and this

1 is just an FYI. I'm trying to figure out how it fits
2 into it. But the almond board funds research. Over the
3 years, we've been approached at different times by
4 companies who said, oh, we can remote sensing, we can
5 tell you where the almonds are, blah, blah, blah. Most
6 of the time we looked at it and we said, not really very
7 good. You've got five or six different pruna (phonetic)
8 species going on in California. How do you differentiate
9 them, plus all the other trees.

10 In a project that we funded that actually was
11 about greenhouse gas and sequestration, we realized that
12 we needed better mapping. We're actually working with a
13 private company on this. They developed a remote sensing
14 combined with pattern recognition software. So, really
15 looking at it with ground (inaudible). So, we now have a
16 system where they can differentiate between almonds,
17 pistachios and walnuts in the 95 to 98 percent range.

18 We are hopeful to actually get a grant to get
19 that totally mapped for the central valley in the next
20 year or two. We're co-funding it. It's going to be
21 moving forward. It's a question of whether it goes
22 forward more slowly if it's just us funding it versus

1 getting some grant funding.

2 The reason I asked that is, our experience with
3 a lot of the NAS data, the almonds are getting big enough
4 that we're on the map. But for specialty crops,
5 especially the short term specialty crops that you have a
6 lot, how well does currently the NAS data even capture
7 those crops and map them?

8 So, if it's not that good, then I really
9 suggest you sit down with this company and explore what
10 they're doing, because what we have seen -- I have a
11 committee chair who is, like, we're going to spend the
12 money even though we have drought and we're going to be
13 getting less money this year. We're going to spend the
14 money on this, which is pretty rare for them to jump on
15 new technology that adamantly.

16 MR. LEONARD: That's a good question as far as
17 the accuracy is concerned with any given crop. As I
18 mentioned with the crop land data lair, there's over 100
19 categories, including various orchard species, whether it
20 be almonds or peaches, you name it, apples.

21 So, in an effort to look at the different
22 accuracy levels, major commodity crops have very high

1 accuracy, whereas some of these specialty crops that you
2 mentioned have lower accuracy. So, in order to improve
3 the accuracy overall, we have grouped the different
4 classes into both phenological and, what makes sense in
5 accuracy terms, aggregated these into broader groups. We
6 went from 111 categories of crops down to 11 categories
7 of crops.

8 So, in your example, almonds would be lumped
9 into a category we called orchards and vineyards. So,
10 from a remote sensing perspective, the way that's handled
11 from a physiognomic perspective would be trees, right, the
12 architecture of these agricultural trees in rows, and
13 vineyards, which would generally be these rows of
14 trellises as well. So, it fit nicely and it also worked
15 out in terms of the way that the original CDL produced
16 errors of commission and omission between the multiple
17 categories. It just lumped them into the one orchards
18 and vineyards class.

19 So, for example, if there is a registered use
20 for almonds for a specific chemical, the footprint of
21 almonds would be lumped into the greater footprint of
22 orchards and vineyards.

1 UNIDENTIFIED FEMALE: I could see from a
2 planting perspective or potential planting, there is
3 overlap there. I think what I'm also worried about is
4 just you take Philaenus Valley and all these different
5 crops and some of them are there only for eight weeks. I
6 mean, the multiple plantings and so forth, you have a
7 temporal spacial variability. Tree crops, (inaudible),
8 they stay put for a while.

9 MR. LEONARD: Right. And I think a lot of
10 those minor specialty crops that are only there for a few
11 weeks are generally lumped into another one of those 11
12 categories. We look at the National Agricultural
13 Statistic Services Census of Agriculture, which gives us
14 county level acreage statistics, which are considered the
15 gold standard of on-the-ground numbers. We compare those
16 numbers with the CDL, and we're able to refine the CDL
17 based on those values.

18 You had mentioned some of the pattern
19 recognition work that the consulting firm is doing. My
20 experience with that is it's great for the smaller
21 projects, but we haven't really seen the national level
22 effort that's produced annually to really get that into

1 production level work yet. I hope to see that in the
2 future. But right now, it's not part of the best
3 available data conversation.

4 MR. BRADY: I mean, I think it's important if
5 that information is out there that we -- going back to
6 sort of the focus on early awareness on the agency's part
7 of any information that's out there that may influence
8 our work. I think we all realize that there may be
9 certain industries or certain parts of the landscape
10 where there may be information we're not aware of which
11 may be relevant to our analysis. But it's much better to
12 have it come in early in the process than later on in the
13 process.

14 MR. HOUSENGER: Was Ray next? Ray.

15 RAY: Well, in addition to the seasonality
16 question that Gabrielle raised, there are multiple other
17 factors ultimately affecting whether a pesticide is even
18 used on those acres where the crop is planted. How and
19 in what state do you take into account those factors, for
20 example, the pest profile that that pest treats, when
21 that pest occurs in the crop, what other competing
22 products might be used? There's lots of layers here.

1 How do you take them into account and at what stage?

2 MR. BRADY: I think that some of those
3 questions will come to bear initially in the step two
4 analysis where we actually start to try to move beyond
5 simple proximity of the pesticide application and the use
6 and start to get a better picture of what the use profile
7 really looks like. So, I would assume that some of the
8 information about pest pressure and when it occurs would
9 be related to application. That would be something that
10 we'd be wanting to look at.

11 But I caution you that the answers today --
12 we're giving hypothetical answers to your first set of
13 questions. Again, the teams are working through this on
14 these first five as we go. We fully expect that we'll
15 learn as we go and refine our approach.

16 MR. KEIGWIN: If I could add a thought as well,
17 we've been living and breathing the National Academy of
18 Sciences report for the last year and the process that
19 led up to it for about three. So, the NAS came up with
20 this three-step process in an effort to try to marry the
21 ESA and the FIFRA approaches.

22 From the Endangered Species Act review, step

1 one, as Don said, is just a simple first cut might there
2 be an effect. It's that's simple. So, the easy screen
3 for that is overlay the sort of maximum footprint of the
4 application use with its off-site transport with the
5 species. If there's no overlap, you're done. You don't
6 go any further.

7 Step two, if there is an overlap, you sit down
8 with smart, informed people that actually are registering
9 the pesticide, that know about the potential seasonality
10 and the impacts to species potentially, and you determine
11 whether or not there may be an adverse effect. If the
12 answer is no, then you're done. ESA consultation is
13 complete.

14 If we think there may be an adverse effect,
15 then we go to step three, and we determine how big that
16 effect is. In most cases, even if there is an adverse
17 effect, you measure it, you quantify it, you exempt it.
18 Endangered species consultation is done. If there is a
19 really significant population level effect that could
20 jeopardize the very existence of the species, then you
21 have more conversations about how you avoid that level of
22 impact.

1 MR. HOUSENGER: I think Dawn, you were next.

2 DAWN: Just really a comment. When it comes to
3 the tier where you are actually looking at actual use
4 data, Arizona, along with California, we have at least 10
5 years of historical data in a use database that we gather
6 in collaboration with Arizona Department of Ag. I'm sure
7 there are other states as well, but certainly not only
8 what's going on now, but the historical data might be of
9 great value.

10 MR. HOUSENGER: Thank you.

11 Patricia.

12 PATRICIA: Hi. I was just curious to know if
13 you're using any of the water quality monitoring data
14 either from the GS, the states, or the feds on more or
15 less pinpointing maybe where pesticides are showing up in
16 the aquatic environment.

17 MR. BRADY: We do have approaches. We've
18 described how we're going to use monitoring data in the
19 analysis. The challenge here is to distinguish what the
20 appropriate use of general water quality monitoring data
21 is in the assessment from targeted monitoring data that's
22 designed to specifically tie a use to a condition in the

1 water or a concentration in the water. So, we're aware
2 of it. We're considering it.

3 The pesticide program in other ways -- I think
4 we talked about this yesterday a little bit -- is making
5 a concerted effort to ask all stakeholders if they have
6 water quality data that may be relevant to our analyses.

7 Jerry.

8 JERRY: Just a suggestion that when you're
9 bringing these crop groups down, that you use the
10 existing crop groups. There are 20 and you're targeting
11 11. A lot of those crop groups are redundant.

12 (Inaudible). It's redundant, so you're not going to be
13 much more. but probably the benefit would be that then
14 you could back it into where the labels are. If you go
15 different crop groups and make your own, you're going to
16 have a hard time backing into the labels.

17 MR. BRADY: Okay, thank you. That's a good
18 suggestion. We'll look at it.

19 Mark, I think you were next.

20 MARK: My question or thought or comment kind
21 of follows through on what the folks are talking about in
22 terms of how you actually implement something (tape

1 malfunction) process. So, I was thinking that if you
2 establish thresholds much like any IPM kind of approach,
3 as you've suggested, and you begin to arrive at decisions
4 based on the three-step process that Paul was talking
5 about, and you begin to move into a regulatory mode or
6 action mode, then the kind of thresholds that you'd need
7 would, in some instances, be very crude and in other
8 instances where you've got good overlap data and good
9 precision. You've got to (inaudible) or better process.

10 So, understanding that, the question I had was,
11 how is the agency and the Services going to arrive at
12 those threshold processes?

13 MR. BRADY: Are you talking about when we
14 determine that there's an effect? We actually have set
15 out that in these interim approaches for each step
16 one/step two part of the process, we've described exactly
17 how we're going to determine when there is an effect that
18 we need to be concerned about.

19 So, I think we've got a good outline there and
20 some very clear points of where we think we have a
21 problem that we need to be concerned about and when we
22 don't have a problem. To be honest, I can't pull one out

1 of my head.

2 MARK: It's very hard to define now because
3 it's so nebulous. But I guess the thing I think that
4 many, particularly from the grower perspective, would
5 want to know, what kind of probability. Are you going to
6 take a 96 or a 99 or are you going to take .9999
7 probability.

8 MR. BRADY: Anita is much more adept at the
9 memory on these things. Let her give you an example.
10 She may kill me later.

11 ANITA: So, if you look at the agreements, we
12 are trying to move towards more of a probabilistic
13 approach. So, one of our thresholds is based on species
14 (tape malfunction). In the past, what we would do is we
15 would take the most sensitive value from a particular
16 (inaudible) group.

17 But now what we're doing is we're looking at
18 all of the available data and developing a distribution
19 and then taking the fifth percentile of that distribution
20 for acute mortality. That would be one of the thresholds
21 that we would use as we move through the process for
22 chemicals that have robust data sets, which the chemicals

1 in these pilots do. That's just one example.

2 UNIDENTIFIED MALE: (Inaudible)?

3 ANITA: That would be something we would look
4 at in step two as part of the species biology. Right now
5 we have an ES knowledge base. We're gathering
6 information on enlisted species, including not only where
7 they are in the landscape but where they are temporally
8 in the landscape. So, migration patterns would be
9 considered as part of that step two analysis.

10 UNIDENTIFIED MALE: (Inaudible) around water
11 potentially?

12 ANITA: That could be part of the mitigation,
13 yes.

14 MR. BRADY: Jack, are we about out of time?
15 Before we close, I want to acknowledge one thing. Folks
16 who have heard various reports over at these meetings in
17 the past years know that Rick and Kathy Eiden (phonetic)
18 from PRD and Anita Peas (phonetic) from EFED in our
19 organization have done a lot of work on this.

20 But in addition to that, I want to publicly
21 acknowledge the work of the scientists on the interagency
22 teams. We come to these meetings and we're the sort of

1 talking heads, but they're the folks who have actually
2 worked through the Academy recommendations and are
3 working collaboratively now to get us to a successful
4 process.

5 So, let the record show that we understand the
6 stress we're putting them under, and we appreciate their
7 work.

8 MR. HOUSENGER: Okay. I guess like ESA, EDSP
9 is one of those activities within our program that
10 requires a lot of our resources to do. So, we have today
11 David Dix who is the director of the Office of Science
12 Coordination Policy here to talk about our efforts and
13 kind of again some of the early thinking about how we're
14 approaching EDSP screening programs, as you've heard with
15 the ESA approach. These are our initial thoughts. We're
16 still kind of tweaking it as we go along, but we thought
17 it was useful for everybody to hear what we're doing.

18 MR. DIX: Thanks, Jack, and good morning. I'm
19 getting set up here with the clicker and with the slides.
20 I think we all have paper copies, if we want it, of the
21 slides. I don't have a lot of slides to go through.

22 As Jack mentioned, we're at a very pivotal

1 point in the program. There's a lot of plasticity and a
2 lot of change going on within the program. I wanted to
3 leave plenty of time for discussion with this FACA on
4 some of the new science that we're bringing to bear.

5 For those of you who don't know me, I've been
6 with the agency for about 20 years. Up until last year,
7 it was all with the Office of Research and Development.
8 When I left there, I was the acting director of the
9 National Center for Computational Toxicology.

10 As you know, the agency has invested deeply in
11 computational toxicology over the past 10 years with an
12 eye towards bringing it to bear on just this topic, the
13 topic of potential endocrine disruption and the program
14 that addresses that, the endocrine disruptor screening
15 program.

16 So, I guess in some ways, it's not a surprise
17 that I've ended up in this position. But some days, it's
18 a little bit more of a surprise than others. It's been a
19 good year. I've worked with Jack at OPP, with Wendy
20 Clalin-Hammett (phonetic) in OPPT (tape malfunction) in
21 the Office of Water, and with Tina Bahadori (phonetic) in
22 the Office of Research and Development. I think we have

1 matured the science and prepared it for translation and
2 putting it into practice first in the endocrine disruptor
3 screening program and then, as it applies, across our
4 other chemical programs.

5 So, I'll start with the legislative mandate
6 that established the program in 1996. I'm sure many of
7 you are quite familiar with the FFDCA and Safe Drinking
8 Water Act amendments that basically charged the agency
9 with establishing a program on endocrine disruption and
10 led to the establishment of the endocrine disruptor
11 screening program under these two separate authorities,
12 one relevant to pesticidal chemicals, actives and inerts,
13 and the other relevant to drinking water contaminants,
14 pesticidal or otherwise.

15 In response to that legislative mandate, the
16 agency established a FACA, the EDSTAC, the Endocrine
17 Disruptor Screening and Testing Advisory Committee. The
18 produced a report in 1998 that (inaudible) legislative
19 mandate to include both human health and (inaudible) to
20 include the estrogen and androgen and thyroid pathways,
21 again a bit of an expansion because the legislative
22 mandate only mentioned the estrogen pathway. And as far

1 as implementation, a plan to develop a two-tiered
2 screening and testing program.

3 So, since that conceptual framework has been
4 put into practice with the tier-one screening for
5 potential for chemicals to interact with the biology to
6 demonstrate activity and then a second tier of testing,
7 it determined the dose response of that interaction with
8 the endocrine system and to link it to adversity.

9 So, since that time, since the late 1990s, EDSP
10 has implemented that two-tiered screening and testing
11 approach. At this point in time, we've had the first
12 list of chemicals, list one, which started at 67
13 chemicals (inaudible) out and have test orders issued for
14 tier one screening.

15 Fifty-two of those chemicals were supported for
16 moving forward, and test orders were responded to either
17 with other scientifically relevant information, which was
18 accepted by the agency as a satisfaction of the test
19 order requirement for some of the assays in the tier one,
20 or, in other cases, the testing of the compounds in those
21 tier one assays following established guidelines and the
22 submission of those data to EPA. So, we now have a

1 complete data set, or close to complete data set, for
2 screening for these first 52 list one chemicals of about
3 500 different studies.

4 The agency is in, I would say, the outer stage
5 of the process of reviewing these data and making a
6 weight of evidence determination for these 52 chemicals
7 of whether we see estrogen, androgen, or thyroid
8 activity, evidence of estrogen, androgen, or thyroid
9 related activity.

10 I apologize in a sense. I may have lost a few
11 of you (inaudible) one screening assay slide next. This
12 is slide 5, by the way, for those on the telephone, if
13 you're not tapped into -- I don't know if we're doing a
14 webinar.

15 So, this lays out the 11 tier one screening
16 assays in the current battery. But you need to be open
17 to the concept as we apply it that the screening and
18 testing assays and tests are open to change over time as
19 the science develops. We're open to other scientifically
20 relevant information as we apply it to the list one
21 chemicals.

22 They are a series of in vitro and in vivo

1 assays ranging from low throughput cell, or cell free
2 based assays, to in tact animal assays, such as the
3 pubertal male and female and rat, that address the three
4 pathways that are relevant to the program, the estrogen
5 pathway, the androgen pathway, and the thyroid pathway,
6 EA and T in this diagram. This is a diagram that lays
7 out the 11 different assays in the first round of tier
8 one testing and how they address either the estrogen
9 minus estrogen antagonists. So, you can think of
10 estrogen agonists as the first column, estrogen
11 antagonists as the second, androgen activity, androgen
12 antagonist activity, A minus, thyroid activity or
13 estrogen activity, again --

14 On the far right -- and this is a table that's
15 been presented many, many times and used in a variety of
16 different scientific advisory panels, et cetera. On the
17 far right, HPG and HPT refer to hypothalamic pituitary
18 (inaudible) and hypothalamic pituitary thyroid networks
19 or pathways, systems that are interrogated by these more
20 in tact in vivo systems. So, that's the assays for which
21 test orders went out on tier one, and those are the 500
22 studies that are referred to in the previous slide.

1 The next slide, slide 6, is labeled EDSP
2 implementation. Here I've added in EDSP list two, which
3 was published last year. In fact, I had the pleasure of
4 being able to sign off on the revised list two being
5 published my first week in the role of office director.

6 This 109 chemical list, in combination with
7 list one, represents these two small spots you see on
8 this universe of chemicals. In 2012, the program
9 published the universe of 10,000 chemicals that are
10 relevant to the EDSP. It's a very large universe of
11 chemicals and compounds that are relevant, pesticidal
12 actives and inerts, as well as many different drinking
13 water contaminants.

14 So, we have the 52 chemicals in this figure at
15 the bottom here for EDSP list one, and the 109 chemicals
16 for EDSP list two. The EDSP list two is comprised of 41
17 pesticidal chemicals and 68 drinking water contaminants.
18 So, unlike list one, which was predominantly pesticidal
19 actives and inerts, list two is, at least in the
20 majority, drinking water contaminants. So, it's a
21 diverse list.

22 But the point that I want you to take away from

1 this slide is that list one and list two are a very small
2 fraction of the EDSP universe. So, our screening program
3 is challenged at this point in the approaches that we've
4 taken to date to properly screen and address this large
5 universe of chemicals.

6 For that reason, we've been evolving the
7 endocrine disruptor screening program. We realized at
8 some point over the past several years that based on the
9 current pace, it would take literally decades, many, many
10 decades, many millions of dollars, many thousands of
11 animals, to screen all 10,000 chemicals using the current
12 tier one/tier two approach in assays.

13 At the same time, concurrently with that
14 realization, the computational toxicology research
15 program had made progress and matured to the point where
16 they could provide solutions to that throughput issue to
17 address the thousands of chemicals in that universe, that
18 10,000 chemical universe that's relevant to the EDSP.

19 On slide 8, just to emphasize those points, the
20 computational toxicology approach, combinations of
21 encylico (phonetic), so computational and in vitro, non-
22 animal screening approaches offer the ability to rapidly

1 screen chemicals and to take those data together to -- to
2 rapidly screen these thousands of chemicals and use
3 predictive models to evaluate them for potential risk to
4 human health and the environment in terms of these three
5 relevant endocrine pathways.

6 I used the term risk specifically here.
7 Computational toxicology is not only biological assays,
8 not only in vitro assays for biological targets,
9 computational toxicology also includes assessment of
10 potential exposure.

11 We are very motivated to take a risk-based
12 approach throughout the endocrine disruptor screening
13 program from prioritization to screening to testing. As
14 you know from the pesticidal program, the agency has a
15 commitment to identifying real world risks, quantifying
16 those risks, and managing them appropriately in all of
17 our chemical programs.

18 So, the computational toxicology research, as
19 we translate it into practice in the EDSP, will increase
20 our capacity to prioritize, screen, and predict chemical
21 toxicity and exposure and to overcome through throughput
22 limitations that I pointed out in the preceding slide

1 with the current tier one/tier two set of assays and
2 tests.

3 Moving on to slide 9, this will eventually lead
4 to potential replacement of some of the existing assays
5 and tests in tier one. Tier two continues to evolve as
6 well, especially with a focus on providing non-animal
7 alternatives and reducing the burden of animal use in the
8 program.

9 We've been partnering not only across EPA in
10 the program, but with other federal agencies, states,
11 industry and non-governmental organizations to continue
12 to evolve these tools and validate them for appropriate
13 use.

14 We continue across the agency and across the
15 program, and particularly across OSCPP, continue to make
16 our data, underlying data, and scientific decisions more
17 open and transparent to others. So, a good example of
18 that is the can view portal that our sister office of
19 OPPT, the toxic's office, has recently put on line.

20 All or much of the computational toxicology
21 data that we'll be incorporating in the EDSP is online
22 through Office of Research and Development websites and

1 portals, particularly the ICSS dashboard. That's the
2 Chemical Safety for Sustainability dashboard that has
3 gone online in the past year.

4 Within the EDSP, we will continue to make the
5 data available publicly through a series of mechanisms,
6 including what we bring to the scientific advisory panel,
7 which the next one is scheduled for late July, if you
8 haven't heard. We'll be bringing the high throughput
9 exposure prediction models to the SAP for peer review, s
10 well as additional OCSPP web portals and dashboards
11 specifically for the EDSP.

12 Moving on to slide 10 and the next series of
13 slides, I'll show you some of the new information that
14 we're bringing to bear to the program to help us with
15 this evolution. There's a big emphasis right now on
16 translating data from two research projects from Office
17 of Research and Development, the ToxCast project, which
18 is a high throughput screening project, and the ExpoCast
19 project, which is a high throughput exposure assessment
20 or determination and prediction project, bringing that
21 activity data and that exposure data together to support
22 a high throughput prioritization that approximates or is

1 associated with potential risks for endocrine disruption
2 in the case of this program.

3 The next slide, slide 11, shows us, in a broad
4 view, our goals in this prioritization effort, first, to
5 prioritize and target the screening of the list two
6 chemicals, the 109 chemicals of list two that I mentioned
7 before, the 52 list one chemicals, as I said, have
8 complete screening data sets and are going through weight
9 of evidence determinations for activity (inaudible)
10 pathways.

11 For list two, we have yet to issue any test
12 orders for these compounds. We are actually awaiting
13 Office of Management and Budget approval for those test
14 orders on list two. But, in the meantime, we are
15 translating the science to prioritize and target the
16 screening for the list two chemicals.

17 Many of the list two chemicals, we have data
18 from computational toxicology that already gives us
19 strong indications of whether we can expect activity in
20 the estrogen or androgen pathways and some indications,
21 though not as much information and data, on the thyroid
22 pathway.

1 Beyond the current list two, we are also able
2 to address thousands of the universe chemicals, those
3 10,000 chemicals in the EDSP universe, and to look to
4 that universe of chemicals beyond list one and list two
5 for those compounds that actually do show estrogen
6 activity, androgen activity, or thyroid activity.

7 One of the lessons we are seeing from our list
8 one experience, whether we're talking about the weight of
9 evidence determinations based on the tier one screening
10 or the ToxCast data, is that certainly for list one
11 chemicals, which I think many people might have
12 predicted, we did not and do not see a lot of estrogen
13 activity. Yet, we've spent quite a few years and quite a
14 few dollars and quite a few animals confirming that
15 negative.

16 So, we're looking to prioritize and target our
17 screening for list two to be more efficient and to apply
18 the resources where there is actual potential for
19 activity and, ultimately, risk, and also to turn our
20 attention to compounds in the universe where there is
21 actual potential for activity, exposure, and risk.

22 Slide 12, which is the blank slide on the

1 screen, and I apologize for that, but it did come out in
2 your printout. What it shows is a ToxCast estrogen
3 activity score. I won't go into any more details on
4 that. That will be presented in a series of scientific
5 publications over the next several months, but a
6 compilation of results for 16 different high throughput
7 screening assays relevant to determining estrogen agonist
8 activity.

9 For the list one and list two chemicals in the
10 slide that you hopefully have on paper in front of you,
11 you can see that for the majority of compounds that we
12 have these results for, and that's 49 of the 51 list one
13 chemicals and, I believe, 56 of the 109 list two
14 chemicals, the majority of those compounds have a
15 negative result, a zero. They show no evidence of
16 activity.

17 For those who show a low evidence of activity,
18 they're all below 0.1 on a scale of 0 to 1. To give you
19 some sense of scale, a compound like ethonyl estrodial
20 (phonetic), a very potent, synthetic estrogen agonist,
21 has a score of 1 on this scale. Disphenol A (phonetic),
22 a moderately potent estrogen has a score of 0.8.

1 Fornonephenol, the branched form, the more active
2 estrogenic form, has a score of 0.4, I believe. And
3 relative to things like ethonyl estrodial or estrodial, I
4 would consider a moderate to weak estrogen.

5 So, all of the list one/list two chemicals that
6 we have ToxCast estrogen activity scores for don't even
7 approach 0.1. If you look at comparable reference
8 chemicals, those are the types of scores you see for
9 compounds that are commonly referred to as negative for
10 estrogen activity.

11 This is the driver for us to refocus some of
12 the efforts in EDSP away from confirming negative results
13 for estrogen, androgen, or thyroid activity in some of
14 these compounds, and to focus on other chemicals in the
15 universe -- this is in the third piece of this plot --
16 that do show appreciable activity.

17 So, for those of you who have the piece of
18 paper, you can see there is a series of I think it's 78
19 chemicals from about 1495 chemicals that we have ToxCast
20 data for that are in the EDSP universe. Approximately,
21 78 of these chemicals have ToxCast estrogen activity
22 scores of 0.1 or above. In fact, those include a variety

1 of different phenols and parabins (phonetic) and a number
2 of other pharmaceutical and agroceutical agents that are
3 all in the EDSP universe.

4 So, there are chemicals in the universe that
5 show estrogen activity through not only the ToxCast
6 assays, the 16 assays here and additional ToxCasts in tox
7 21 assays, but also uniformly across the literature. So,
8 there is evidence of activity. As the program continues
9 to evolve, we want to marry that evidence of activity
10 with strong predictions of exposure from the ExpoCast
11 project and to prioritize these compounds moving forward
12 in a risk-based context.

13 Moving on to slide 13, this is a figure that
14 was published in our EDSP 21 work plan. It was published
15 in 2011. It shows the staging of the evolution of the
16 EDSP in the near term supplementing data from tier one,
17 the current EDSP tier -- this is the top row of this
18 figure -- supplementing the current EDSP tier one battery
19 with additional data from basically the ToxCast project,
20 the high throughput screening assays.

21 In the intermediate phase, which is where we
22 are now, we're starting to compare the results from those

1 ToxCast assays and other sources to the tier one results
2 that we have from the list one chemicals that are already
3 available to us in the literature, to target the
4 screening for list two chemicals, and then also consider
5 additional chemicals for the program.

6 And then, you see in the bottom row of this
7 diagram the longer term goal of eventually replacing some
8 or much of the tier one battery, which is low throughput
9 and animal intensive, with higher throughput, more
10 quantitative and less animal intensive types of assays,
11 similar to what the ToxCast project brings to us.

12 Moving on to slide 14, just a quick recap. The
13 52 list one chemicals with complete tier one data sets
14 are going through their weight of evidence
15 determinations. The 109 list two chemicals are going
16 through OMB review for tier one screening.

17 The EDSP universe, including list two, is being
18 prioritized for screening using computational toxicology
19 and other tools. And, as I mentioned, we have a series
20 of scientific advisory panels being cued up for the
21 exposure prediction models in late July followed by risk-
22 based prioritization SAP in the coming months.

1 Now, finally to the 15th and final slide, a
2 topic that I'm happy to discuss if it's relevant; I'm
3 happy not to if it's not. But there is an activity
4 that's been going on over the past several years within
5 the agency. Last year, we published a white paper, a
6 scientific paper on the state of the science around non-
7 monotonic dose response relationships. We charged an NRC
8 panel to provide us comment on that white paper.

9 In May of this year, we received those comments
10 from the NRC. We are currently looking at those
11 carefully internally and considering next steps from
12 these recommendations to develop a plan of how we might
13 select chemical case studies, the pathways discussed in
14 the EPA and MDR state of the science paper, and how this
15 might be relevant to assessing potential impact to these
16 key findings to regulatory programs such as the EDSP and
17 our other chemical programs.

18 So, with that, I'll stop. I actually went a
19 little long and didn't leave a lot of time, but, Jack,
20 perhaps we have time for some questions.

21 MR. HOUSENGER: Yes, thanks, David. Hopefully,
22 that gives you an idea of what we're doing in EDSP.

1 David could talk all day, believe me. I've heard him on
2 this subject. But we can take questions now.

3 Fawn, you want to go first?

4 FAWN: Thanks so much for your presentation.
5 You mentioned in a couple of points OMB approval needing
6 to be obtained for steps moving forward. I apologize if
7 this is in the statute and I should already know it. But
8 I'm curious about OMB's involvement, how many points in
9 your flow chart of your process, do you need to go to OMB
10 for approval, and also, how long does that take? How
11 long have you been waiting, for example, for the example
12 that you gave?

13 MR. DIX: The example I gave, the reference I
14 was making to was to the list two tier one testing
15 information collection request or ITR approval. I think
16 in that case it's somewhat on the order of about a 12-
17 month process. But I think it's been with OMB for about
18 a total of 12 months, somewhere on that order. Bill
19 might be able to help me out with this one because some
20 of this precedes my tenure.

21 That will be necessary. That approval will be
22 necessary before we can issue test orders for tier one on

1 list two chemicals. So, we're in the process of, as I
2 said, continuing to refine the science and refine the
3 plan for list two testing while we await that OMB
4 approval.

5 MR. JORDAN: This is Bill Jordan. The
6 Paperwork Reduction Act requires an agency any time it
7 tells a member of the public that they have to submit
8 data to the government, information to the government to
9 go through a clearance process, the information collect
10 request and clearance.

11 David is right that we've been working on this
12 one with OMB for a little over a year. I'm thinking that
13 this one, they want to understand what happened with the
14 list one chemicals and, as David has mentioned, the
15 sciences evolving. So, that's, I think, why it's taking
16 a little longer.

17 Once we get an information collection request
18 in place, then the process moves ahead without any
19 further OMB engagement. And I expect for future lists,
20 for future test orders, having ironed out the science and
21 established a track record, we'll be in a position to
22 move them more quickly.

1 MR. DIX: For those that don't know, I'll just
2 mention that the OMB process involves a series of public
3 comment periods. So, it's a very robust process and, I
4 think, a very useful process because, in part, those
5 series of public comments and our responses to those that
6 are built into it. We found that very helpful, I think,
7 in the past and continue to find that helpful with the
8 list two tier one ICR to have those public comments
9 coming in.

10 MR. HOUSENGER: Patricia.

11 PATRICIA: Hi, Dave. Thank you so much for the
12 update. It's really exciting to see the progress that's
13 being made with the computational toxicology work. I am
14 just wondering, on list two, do you foresee actually
15 being able to exclude some of the chemicals now based on
16 the results of the high throughput or the comp tox
17 methods for some of the pathways for testing? Do you
18 foresee it being able to actually say we don't need to
19 test for estrogen with this compound or this compound or
20 so forth?

21 MR. DIX: So, we have to be careful with the
22 words, or I have to be careful with the words we use. I

1 wouldn't call it exclusion. We are taking a couple of
2 steps, and one of them is relating to exclusion. But
3 that's based on physical chemical properties.

4 In January 2013 SAP, we took a series of
5 physchem filters -- and I think this was the second go at
6 this -- and asked for feedback from the SAP, who was very
7 encouraging, to use certain physical chemical filters to
8 exclude compounds that were not able to be bioavailable
9 or not stable in the environment and, therefore, had no
10 potential for activity, and then also had a real
11 challenge in terms of any kind of testing.

12 So, those are being applied, and that's part of
13 the science that's being applied to list two and will
14 impact and potentially could lead to exclusion of some
15 chemicals on list two from testing. But you don't want
16 to call it exclusion; you might want to just think of the
17 competition on toxicology data as similar to any other
18 scientifically relevant information.

19 If we already know that a compound is or is not
20 estrogen active, we will use that if it's reliable,
21 reputable, repeatable, reproducible type of science. In
22 the case of some of the ToxCast data for some of the list

1 two chemicals, yes, we feel strongly that that is the
2 case, that we already have an answer and we're moving
3 towards making use of that.

4 That also played out in the list one chemicals.
5 I think somewhere on the order of about 25 percent -- it
6 might be a little off, but some significant percentage of
7 the test order requirements were met by other
8 scientifically relevant information.

9 Now, in some cases, and I think maybe many
10 cases, it was other scientifically relevant information
11 coming from results from assays that were either
12 guideline assays or very much like the guideline assays.
13 So, taking other scientifically relevant information that
14 may be high throughput may be a little bit different.
15 But the data and the answers are oftentimes proving
16 themselves to be just as reliable and oftentimes more
17 quantitative as well, which has great value.

18 For those of you familiar with the current tier
19 one screening assays, they are not going to give us dose
20 responsive information. They don't have enough dose
21 groups, they don't have enough information for us to
22 understand the full dose response.

1 But for some of the high throughout screening
2 types of assays, many of these are run in 8 point, or 14,
3 or 15 point concentration response formats that allow us
4 to understand the dose response of the activity, which is
5 very useful as we continue to move and put this into a
6 risk based context.

7 MR. HOUSENGER: Given the time, I'm going to
8 take the remaining cards that are up and then call it a
9 day.

10 Liz, go ahead.

11 LIZ: Yes, thank you. It's my understanding
12 that OMB attached some conditions to the first list, one
13 ICR. It sounds like EPA has done a lot of work towards
14 completing or meeting those conditions. But can you
15 maybe comment on where you are on meeting all of the
16 conditions of the first ICR, which will then let us know
17 when to expect the next list to be issued?

18 MR. DIX: Yes. There were a number of
19 conditions. I'm going to struggle a little bit to
20 remember them all or get this exactly right. Bill might
21 be able to help, but probably not.

22 One of the requirements was for a report to the

1 assistant administrator, in this case Jim Jones, an
2 internal review, if you will, of the program. There's
3 also additional cost analysis/burden analysis reports to
4 OMB. Those have all been submitted. The reporting
5 requirement on the cost I think is an annual requirement.
6 And the review of the program to the assistant
7 administrator is also an annual requirement. So, I can't
8 recall if we're in our first or second iteration on both
9 or either of those. But those requirements from the
10 first list one tier one ICR have been met.

11 MR. HOUSENGER: Mae.

12 MAE: I hope I don't take up too much of your
13 time, but I have a bunch of questions. First about that
14 OMB part, you said that the tier two list has been in OMB
15 for about 12 months. Then you said that was to
16 incorporate some notice and comments. Have you already
17 taken notice and comment on the tier two list or are you
18 planning to?

19 Do you want the whole list or one at a time?

20 MR. DIX: My memory probably would ask for one
21 at a time.

22 MAE: Okay.

1 MR. DIX: List two, not tier two.

2 MAE: Sorry, yes, list two. You're right.

3 MR. DIX: There is a tier two process as well.

4 My understanding and recollection is that we're waiting
5 for word from OMB for list two tier one. It's gone
6 through the two step public comment phase.

7 MAE: And then, list one tier two will there be
8 notice and comment period on that or will things just
9 move directly into tier two?

10 MR. DIX: No, that follows the same process.
11 That is ongoing.

12 MAE: Same processing meaning like there will
13 be notice and comments and all that going through OMB?

14 MR. DIX: Correct.

15 MAE: Do you have a sense about when you may be
16 finishing with the list one tier one and when we might
17 see that?

18 MR. DIX: So, we expect to be complete with the
19 weight of evidence determinations at the end of the
20 calendar year, which will bring us into FY 2015. With
21 internal reviews, et cetera, we expect to be making these
22 public in FY 2015.

1 MAE: Sometime in FY 2015, okay. Will you be
2 making the data publicly available from that or just the
3 determination?

4 MR. DIX: Well, I can say a few things. The
5 determinations will be made public. The determinations
6 are based in a very typical approach to the pesticide
7 program in what are called data evaluation records.
8 They're derived from the test results. At that point,
9 I'll let Bill address the data and the relationship
10 (inaudible).

11 BILL: As you know under FIFRA, EPA has legal
12 obligations to protect information. Consistent with
13 that, we'll make the data themselves available. But the
14 DERs, stripped of confidential business information,
15 should be available.

16 MAE: Okay, so just the DERs?

17 BILL: No. We can make the studies themselves
18 available, provided that people who are requesting it
19 comply with the limitations under FIFRA section 10G.

20 MAE: Okay. So, when you finish with the tier
21 one and there's a chemical that does not come through as
22 positive through tier one, what happens to that? Then,

1 kind of the corollary to it is, if at the end of tier two
2 you have this list of chemicals, what is the plans for
3 ones that are positive coming out of tier two?

4 MR. DIX: So, this will be a general response
5 and then Bill, I think, can put some general nuances
6 relevant to pesticidal chemicals.

7 Chemicals that don't show activity in tier one
8 screening or perhaps maybe the more important way to put
9 that is in the weight of evidence determination of
10 whether they show activity in the three relevant
11 pathways. So, that won't be dependent on just tier one
12 screening assays; that's including all other
13 scientifically relevant information.

14 So, if we already have, in the case of a
15 pesticidal active extensive in life testing in
16 multigenerational tests, et cetera, or if we have
17 extensive computational toxicology data and other
18 scientifically relevant information, and we determine
19 that there's no activity for a compound in that pathway,
20 then it would not go forward to tier two screening. If
21 it went forward to tier two screening, the tier two
22 assays, whether it's one or all four of those different

1 multigenerational assays that are run, they would give us
2 definitive dose response information and linkages to
3 adverse endpoints.

4 Then, depending on whether the chemical is
5 pesticidal active, it would be involved in a risk
6 assessment process in OPP. If it's a drinking water
7 contaminant, the risk assessment would be handled through
8 the other appropriate offices within EPA, either the
9 Office of Pollution Prevention and Toxics or Office of
10 Water.

11 You can also imagine -- and if you look at the
12 universe of compounds and chemicals that are part of the
13 EDSP and relevant to the EDSP, there's also probably some
14 shared responsibility for these risk assessments and
15 potential risk management steps with other sister
16 agencies across the U.S. government.

17 MAE: I guess maybe I was a little unclear.
18 What I was wondering is if something -- I realize you
19 wouldn't go through a tier two if you're a negative. Is
20 there some kind of review of like something that does
21 come out negative on tier one like every blah, blah, blah
22 years you're going to come back and look at it to see if

1 there's, like, a lot of new stuff out there and whether
2 it would trigger?

3 MR. DIX: Outside of exclusions for phys chem
4 properties that make a compound not possibly be available
5 or et cetera, a compound is never excluded from the
6 potential for further screening and testing. In the case
7 of a pesticide, I would imagine with registration review,
8 it would be a proactive process following a prescribed
9 cycle over the years. In a nonpesticidal chemical, it
10 would still remain relevant to the EDSP as the science
11 evolves.

12 So, I speak to these three pathways, estrogen,
13 androgen, and thyroid. My guess is that you're implying
14 or referring to the possibility for continued development
15 of our scientific understanding of biological activity
16 that's relevant to those pathways. Certainly, we'll be
17 open to that.

18 That's one of the reasons I put that last slide
19 on the presentation. If you look at a lot of the science
20 that's currently in the research and the very active
21 state of development around nonmonotonic dose response, a
22 fair amount of it is speaking to the potential for

1 nonreceptor mediated estrogen activities, et cetera, et
2 cetera.

3 MAE: So, I guess aside from registration
4 review, which is like every 15 years, it doesn't sound
5 like right now there's anything in place either beyond
6 like that review of these chemicals. And then, outside
7 of OPP, I guess, it would be up to the other offices how
8 they would be reviewed?

9 MR. DIX: Yes, to a point. The EDSPP is an
10 integrated program. So, I wouldn't say it's up to the
11 other offices. The program is a partnership between the
12 three offices of OCSPP, the Office of Water, and the
13 Office of Research and Development. So, it's a little
14 more -- I would characterize it in a more proactive kind
15 of state with ongoing development of the program and
16 incorporation of data for all the relevant chemicals on a
17 consistent and repeated process.

18 MAE: Okay. That's good for now.

19 MR. HOUSENGER: Now Ray.

20 RAY: Can I yield to Cheryl Cleveland? She can
21 probably ask the question better than I can.

22 MR. HOUSENGER: Yes. We like it when you put

1 your card down.

2 MS. CLEVELAND: So, first of all, I want to
3 support the approach, the care that you've taken, the
4 SAPs, the broad science-based approach, especially when
5 we see this contrasted to what Europe is doing. We
6 appreciate the way that you're working through a risk-
7 based framework.

8 I also wanted to commend you as I listened so
9 carefully for how you're framing the communication on
10 this. I think using the term screening and
11 prioritization and against potential risk is exactly the
12 right way to go. We don't want lists that come out as
13 oh, these are confirmed risks. You're prioritizing based
14 on risk, potential risk, and continuing to be very
15 careful about how you communicate it.

16 Apparently, list three will eventually come out
17 on this broader prioritization scheme, continuing to
18 tease out screening, potential risk versus confirmed
19 risk. That's really important for industry as a whole.

20 My question is, I'm surprised that you said
21 there was 25 percent use of the OSRI data. I did not
22 believe that was true when things first came through. Is

1 that a post mortem look at what turned out to be in the
2 weight of evidence? More importantly, going forward
3 through the next round when we hit list two, do you
4 anticipate a stronger use of the existing data?

5 MR. DIX: I think that's high, but we can get
6 the actual number. We just don't have that information
7 in front of us.

8 DR. CLEVELAND: You know, at this point, forget
9 the past, just going forward, maybe is there a better way
10 to use some of that existing data, especially in the
11 pesticide realm where it's data rich. Can you take some
12 learnings from this round and make better use going
13 forward?

14 MR. DIX: Yes. I definitely think we've
15 learned a lot with these 52. Going forward, we'll apply
16 that to the other ones. As far as the percentage, I
17 apologize. I may well have misspoken. But we presented
18 that at several of the scientific advisory panels last
19 year when we were asking for peer review on performance
20 of the tier one assays as well as our strategy for the
21 weight of evidence determination. It was somewhere in
22 the 10 to 25 percent range. I just don't recall. That

1 percentage was published, though.

2 Moving forward, I second what Jack said. We
3 now have a very, very valuable dataset from list one tier
4 one. In combination with the computational toxicology
5 data and probably more significantly the part 158
6 existing data, which is part of the (inaudible), I think
7 we can continue to improve the science underlying the
8 program.

9 MR. HOUSENGER: Wayne.

10 WAYNE: Thank you, David. So, maybe I should
11 be listening to the full day seminar. But what are
12 thoughts on interactions of two or more chemicals or are
13 you there? I know the challenge has been huge just for
14 the single product, but I do hear discussions or concerns
15 rather about interactions of two or more chemicals as
16 being endocrinic?

17 MR. DIX: That's a cumulative risk, which is
18 one way to phrase what you're referring to. It's
19 certainly an important issue and been a challenge for the
20 agency on the regulatory side, as well as on the research
21 side. I think the broader research community continues
22 to struggle with that issue.

1 I think it's still a research issue primarily.
2 I don't see the science to provide us a clear path
3 forward, at least in most cases and in the broader range
4 of combinations that might be considered. We'll continue
5 to move forward with our research partners, both inside
6 and outside the agency on this issue.

7 I do refer back to the NMDR topic. That's not
8 necessarily addressed in the current white paper, but
9 that could be some type of a follow-on product. But I
10 emphasize, consistent with what I just said, that at that
11 point, topics like key motive risk and NMDR are being
12 addressed and handled primarily by our Office of Research
13 and Development.

14 We're looking to that continued development of
15 science to the point where we can translate it into
16 practice. But I don't think it's there right now for us.
17 But I don't know if -- that's for EDSP, for sure. There
18 might be some other follow ups from Jack or Bill.

19 MR. HOUSENGER: And Gabrielle.

20 GABRIELLE: Yesterday we heard quite a bit from
21 the 21st century about interactions, international
22 interactions, and then also from the (inaudible). I know

1 that Europe is also working hard at trying to figure out
2 this whole --

3 MR. HOUSENGER: We can't hear you again. I
4 don't know if it's you or your mic.

5 GABRIELLE: So, my question is about
6 interactions on the international level. We heard about
7 it for the 21st century toxicology. I know that EU is
8 also working on trying to figure out endocrine disruptors
9 both for pesticides and more broadly. So, what kind of
10 interactions are going on between all these efforts to
11 understand the science and figure out how to do it more
12 efficiently? Where is that?

13 MR. DIX: Well, one thing I'm somewhat hopeful
14 about is our engagement through the Organization of
15 Economic Cooperation and Development with our European
16 and other international partners. There's a variety of
17 mechanisms or forums for that. As we get on line, and I
18 got on line over this past year, I've been engaging more
19 broadly with a variety of different OECD task forces and
20 groups that will be starting to address how we harmonize
21 between the US and the EU on the issue of endocrine
22 disruption.

1 One of the more hopeful veins or threads for
2 that is in the development and application of adverse
3 outcome pathways. If you've been paying attention to a
4 couple of the different groups in OECD that are
5 developing those and considering their application in
6 association with test guidelines, we have proposed a
7 potential application of estrogen, androgen, thyroid
8 AOPs, similar to what we presented at the Scientific
9 Advisory Panel in the draft or the preliminary weight of
10 evidence determinations for five case study chemicals in
11 2013.

12 MR. HOUSENGER: Okay, thank you, David. I told
13 you he could talk. Now we're late, but I think we're
14 fine. Let's take a 10-minute break and come back, and we
15 can do comparative --

16 (Whereupon, a brief recess was
17 taken.)

18 MS. MONELL: Okay, everyone, if you'd please
19 take a seat. I am standing between you and lunch. No
20 slides, so you have to listen. I'm here to give you an
21 update on the comparative safety statements workgroup
22 under PPDC. Some of you may recall our berth in 2010,

1 January of 2010, when this committee recommended and
2 moved forward to creating this committee. Basically, it
3 was to acknowledge an interest, widely known interest in
4 the consumer community and all things green and wanting
5 information about the greenness of pesticide products
6 and, of course, industry's interest in scratching that
7 itch, if you will, by being allowed to make certain
8 statements or use certain logos regarding greenness or
9 environmental considerations on their pesticide product
10 labels. Obviously, EPA's interest is in preserving the
11 sanctity of the legal label, such that any statements on
12 it are not false or misleading.

13 So, those were the underpinnings of the work
14 that we began. We came up with a program that allows for
15 the use of the DFE, design for the environment, logo on
16 pesticide products. That DFE, by the way, that program
17 is run out of our sister office in the Office of Toxics
18 and Pollution Prevention. That process involves a
19 screening by a third party screener.

20 There are many different kinds of screens that
21 relate to the industrial chemical community, if you will.
22 Our products, our AIs, actually go through the general

1 screen, so it's very difficult for a pesticide AI to get
2 through the screen as it is currently constructed by the
3 DFE program.

4 Therefore, we have very few products that have
5 made it through the DFE program with approved DFE logos
6 on the pesticide labels. These generally relate to
7 citric acid, lactic acid. Most recently, we've been able
8 to have a hydrogen peroxide containing product that made
9 it through the DFE screen and will be allowed to use the
10 DFE logo after our review.

11 So, it's somewhat limited, but we're hopeful
12 that the result of our working closely with the DFE
13 program will result in a pesticide sector being
14 developed, so that the recognition of the kinds of
15 chemistries that are utilized in the pesticide products
16 that go through our rigorous risk assessment process will
17 somehow be able to develop a sector to recognize those
18 products. We're just beginning those efforts now and
19 more to come probably in a year.

20 We have another part of this comparative safety
21 statement work which involves what we used to call
22 factual statements. Now we just refer to them as label

1 statements. That evolved because everything we say and
2 put on a label is factual. So, we shouldn't be making
3 those kinds of distinctions in a pilot or otherwise.

4 So, the label statement pilot program was
5 initiated to recognize -- we agreed upon recognition for
6 dye free, fragrance free, corporate commitments on the
7 environment or sustainability so we would allow the link
8 between -- web link to be placed on the label so that a
9 consumer could go to the web site and see what the
10 company's environmental ethic or sustainability
11 commitments would be.

12 Of course, when you do something like that,
13 when industry does something like that, the whole web
14 site becomes subject, is part of the label. So, it
15 really involves a solo review of the web site in that
16 regard.

17 So, we have about 30 label statements that have
18 been approved, mostly in the dye free and fragrance free
19 arena. Those are easily ascertained by checking out the
20 CSF and other data that's submitted to us. We also last
21 year added claims regarding or statements regarding
22 biodegradability.

1 In this case, if your product is 100 percent
2 biodegradable, you can make that claim. You have to
3 submit a paper to us to prove that, but we will allow
4 that claim. We also will allow a claim for the
5 biodegradability of the surfactant in your product. Thus
6 far, we do not have any 100 percent biodegradable claims
7 allowed, but we do have a few surfactants, 100 percent
8 biodegradable surfactant claims that have been allowed to
9 be on product labels.

10 If you recall, last year in recognition of
11 USDA's program regarding on biobased products, they have
12 developed a -- so that green purchasing statutory
13 authorization -- they have a program by which they will
14 provide a certification and an official mark for a
15 product's label that indicates the percentage of the
16 product that is biobased. So, we will allow that label
17 to be used on pesticide products if there is --

18 In other words, if you go through the USDA
19 process of obtaining the mark, the certification mark,
20 and then they come to us and they can put it on their
21 pesticide label if there's also a disclaimer that this
22 mark does not mean that the product is necessarily safe

1 and that the user should follow the label directions.
2 So, it's to get around the concern that perhaps having
3 this mark on a pesticide product label might be perceived
4 to be an endorsement of its safety as opposed to what it
5 actually is.

6 The other thing that we mentioned last time was
7 a new claim, a new label statement that was being
8 proposed. This is something that apparently has several
9 year's history in this program, and that is a statement
10 about the safety of the product for the hard surface on
11 which it's intended to be used.

12 So, if you've got granite, let's say, the
13 product, they would like to put a statement on the
14 product label that says this product is safe for use on
15 granite or safe to use on formica or safe to use on
16 whatever. So, historically we've said no, using the word
17 safe on the label in that context could be construed to
18 mean something safe beyond just for application on the
19 surface. In other words, there might be some implication
20 that it would be safe for public health purposes or for
21 the environment beyond the regular FIFRA finding.

22 So, we actually have been pretty consistent in

1 saying no to that. This time, however, the groups
2 representing those types of consumer products came to us
3 and said well, we're willing to do a survey, to construct
4 a survey to really find out how consumers would react to
5 that kind of label language. So, we thought, well, you
6 know, that might be interesting, because certainly, if
7 the survey is designed appropriately, you could get a lot
8 of very useful information out of it. So, we said, sure,
9 we will review what you've come up with.

10 That's an important aspect of our ability to
11 participate in this, because under the ICR rules,
12 information collection rules, we really can't be part of
13 a survey unless we get an ICR for it. So, we're going to
14 review what they're putting together, what their
15 consultants have put together. They're willing to take
16 the risk that they're going to be provided with
17 sufficient information from consumers that will allay our
18 concerns about allowing the use of the term safe for this
19 surface on the pesticide product label. So, that's just
20 an update on where we're at with that.

21 Two other updates, one you heard here a couple
22 of times about the programs repellency graphic mark. We

1 can't call it a logo. We've gone round and round with
2 the legal folks about the appropriate naming for this.
3 But essentially, it's a good thing because it's to put on
4 repellency products a mark that will indicate its
5 effectiveness as a repellent against mosquitos or ticks
6 and then for how long. Rose is here to give us an update
7 on that effort.

8 ROSE: Hi, everybody. I'm Rose Cipriano
9 (phonetic), and I'm with Field and External Affairs
10 Division here in OPP. For those of you who have never
11 heard too much about it, as Marty said, the repellency
12 awareness graphic, as we now like to refer to it, it's
13 similar in concept like putting an SPF on sunscreen. But
14 this would be a graphic that would convey information
15 about an insect repellent.

16 We work extensively with PPDC and discussing
17 this with them over the last couple years. So,
18 hopefully, most of you are familiar with this. We
19 recently, the end of last year, put out the program to
20 public comment. So, what I'm here to give you an update
21 about is that we've gone through the comments.

22 We had about 60 of them. Most of them were

1 from the general public. Overall, they were very
2 supportive of the effort, which is what we were hoping to
3 see. They would love to see this on products. So, we've
4 completed our review of the comments, both of the general
5 public and some of the more technical comments. We're
6 not planning to make changes to the graphic or to the
7 guidance.

8 We are ready to accept applications. We're
9 planning some more communications to that effect, maybe
10 through an OPP update and through the website through the
11 coming months, but did want to come here and let
12 everybody know that we're open for business.

13 Also, if a need or interest exists, we're
14 considering holding a webinar for industry sometime this
15 summer about the process to apply and about data that
16 we'd like to see to support the claim. So, I don't know
17 if there's a couple minutes for people to raise their
18 hands or to say yes or no or if you would just like to
19 get back to me or to my colleague, Ryan Yager (phonetic),
20 if you're familiar with him, just to kind of give a yes,
21 please, or no, thank you for something like that. But
22 please let us know if you'd be interested in having a

1 webinar with us about this program.

2 MS. MONELL: And the last item on which we
3 wanted to give you an update is related to a topic that
4 was discussed yesterday, science related, 21st century
5 toxicology and the use of that tool. Kristie Sullivan
6 (phonetic), a former member of the PPDC, actually came to
7 the comparative safety workgroup and wanted to have some
8 discussion about the possibility of using statements on
9 pesticide product labels related to the lack of animal
10 testing that resulted in the formulation of the product
11 or sort of minimal animal testing.

12 So, we've been working very hard, actually,
13 because we see this as an opportunity to promote an
14 interest that the program has at the same time perhaps
15 giving a little competitive edge to those that would be
16 willing to use these tools.

17 So, Jennifer McLain is going to give you an
18 update on where that effort is at and some of the issues
19 that have arisen.

20 MS. McLAIN: Good morning. This is Jennifer.
21 When Kristie brought this idea to the workgroup, she said
22 there was a lot of common interest in trying to make

1 something work and really viewing it as an incentive to
2 reducing animal testing. So, this would be one way to,
3 for example, encourage registrants to use in vitro tests
4 in their acute tox testing for a product, unless they
5 could get the special label claim. That was the concept
6 that was brought forward.

7 So, I think that was over a year of discussion
8 on various ways to make this work. Through the reduced
9 version of the conversation is that the idea was to have
10 two different types of claims, one claim that would state
11 something like no animal testing for this product.

12 The concerns that were raised with that was
13 that, first of all, the science for the acute tox testing
14 isn't quite there to -- as we talked about yesterday,
15 there's a lot of really exciting work going on right now.
16 It seems like it's not far away from being in reach, but
17 at this time it's not there. So, it would take a while
18 for folks to be able to qualify for such a claim.

19 Then, there was a concern, well, how do you put
20 that on a product when there's other testing that's gone
21 on for the active ingredients, for example. Most of the
22 conversation surrounded the potential for having a claim

1 that would be something like a minimal animal testing to
2 approve this product.

3 There's still that underlying concern about the
4 testing that happened for the active ingredient. There
5 was a lot of discussion about how to set criteria for
6 what would count for that claim, which was pretty
7 difficult in actually trying to segregate where we would
8 say yes versus no.

9 There was a significant legal issue that was
10 brought up during the course of the conversation that
11 would apply to both of these, where there was no way to
12 restrict its use. So, initially, the concept was if your
13 company put the work in to doing these in vitro tests and
14 reducing the animal for their product that you would be
15 able to restrict the use of that claim to your product.
16 But in talking to our legal counsel, we found that
17 there's no way to not allow me (inaudible) that product
18 to happen and for that claim to go on any (inaudible)
19 that came in. So, that was a concern.

20 One of the biggest concerns, particularly with
21 the reduced animal testing, was a concern that having the
22 wording on the label at all would raise the issue that

1 there was animal testing. So, if you say this is minimal
2 animal testing that went into this product, then the
3 consumer is potentially reacting in a negative way, what,
4 there's animal testing going on for this product?

5 So, at that time, after having over a year
6 conversation about it, we thought well, maybe we should
7 set that to the side because it seems like there's so
8 many barriers to a successful implementation. We started
9 to pursue another avenue of providing an incentive for
10 reduced animal testing. That would be to develop some
11 sort of award that EPA would give annually or something
12 to one or more companies that were making an effort to
13 reduce animal testing. This would be something that's
14 not product specific; it would be for the company. It
15 would be something that they could put on their website.
16 We, already through the workgroup, have allowed addition
17 of the website that can provide information about good
18 work the company is doing on the label.

19 So, there were similar concerns about this.
20 Well, first of all, there was one concern that it may not
21 be too much of an incentive because it's not label based.
22 There are some companies that said they were not quite

1 interested in it because of that. Then there was a
2 similar concern that it would again be calling attention
3 to the fact that there was animal testing going on for
4 the product.

5 Not every discussion we had on these was
6 negative, because, like I said, there is a common
7 interest in trying to make it happen. It was just we
8 could never quite figure out a way for either of these
9 ideas to be something that industry folks felt would
10 truly be an incentive and would be providing them with
11 something that they thought would be appealing to
12 customers.

13 That was just a conversation we had. I think
14 that Marty just wanted to let you all know where we are.
15 We thought I wouldn't say that either idea is dead in the
16 water at this point, but we haven't figured out a way to
17 make it work.

18 MS. MONELL: Thanks, Jennifer.

19 Any questions on any of this that we've rattled
20 off for the past 20 minutes? Ray and then Jerry.

21 RAY: I have three or four questions on
22 different aspects. On the insect repellency graphic, is

1 this graphic going to state that repellency is good for a
2 number of hours?

3 MS. McLAIN: Yes. It's specifically either for
4 mosquito or tick repellency, and then it will give the
5 number of hours that a tick is repelled or a mosquito
6 would be repelled.

7 RAY: And what type of data will demonstrate
8 that time period?

9 MS. McLAIN: The efficacy data that is provided
10 to support the registration for the product.

11 RAY: Does that involve human testing?

12 MS. McLAIN: Yes, it does.

13 RAY: So, this could encourage additional human
14 testing?

15 MS. McLAIN: Yes. We've actually spoken
16 recently with the HSRB to bring this to their attention
17 and also to ask them if they are open to receiving
18 different ways of doing protocols that may involve
19 grouping things together instead of doing each product
20 individually. So, they indicated that they would be open
21 to discussing that with anyone who wants to bring in that
22 type of scenario.

1 RAY: And with respect to the animal testing
2 question, did I understand you say this is probably dead
3 in the water?

4 MS. McLAIN: I said it wasn't necessarily dead
5 in the water. We just haven't figured out a good way to
6 move it forward. So, if you have an idea, we would love
7 to hear it.

8 RAY: Well, I'd be surprised if you can find a
9 registration eligibility document that does not depend
10 somewhere on animal testing and making that decision.
11 So, to grant no animal testing on the label, it's
12 disingenuous at best.

13 One other point, the agricultural pesticide
14 market has largely stayed out of this discussion and just
15 observed it from a distance. But one aspect I'd like to
16 raise as a possibility is the reduced risk program. It's
17 been in place for more than 20 years. It's met its
18 incentive to develop and register products which have
19 reduced risks. But we haven't been able to use them on
20 labels or in advertising programs. There might be some
21 possibilities here.

22 MS. MONELL: We will definitely put that on the

1 agenda for a next workgroup meeting discussion.

2 Others? Oh, I'm sorry, Jerry.

3 JERRY: Actually, I was going to say the same
4 comment about reduced risk. I'll just add one thing
5 different. A lot of our stakeholders, especially crop
6 growers, we go to great pains trying to make sure that
7 the products we use when there's choices, we pick out
8 reduced risk products.

9 So, the comments come back. How come this
10 isn't notified or how come we don't see this one? So, I
11 think there's a desire out there to see that.

12 MS. MONELL: Great.

13 Dave.

14 DAVE: With the repellants, I was wondering how
15 you're dealing with interspecies differences and
16 efficacy?

17 MS McLAIN: In the guidance that we have, we
18 have specific species that we would like for tick
19 studies. Then, for mosquitos, since they're field
20 tested, we want to ensure that there's a certain variety
21 of genre that are covered during those tests. Does that
22 answer your question, generally?

1 DAVE: Well, it sounds like at least you're
2 gathering information to identify interspecies
3 differences, but then once they're identified, how do you
4 deal with it? To what extent have you looked at if
5 there's a particular species of tick in a particular
6 region that wasn't tested and then people are relying on
7 the number, how is that dealt with? How are you dealing
8 with that?

9 MS. McLAIN: Okay. So, I think I understand a
10 little bit better. So, the three tick species that we've
11 chosen were based, one, on public health significance of
12 carrying disease. Then, two, are they hovering, kind of
13 that difference between species? We did bring that issue
14 specifically to the HSRB last year to get them to weigh
15 in on this -- I'm sorry, SAP. Too many panels and
16 advisories. So, we brought it to the SAP and asked them
17 if they thought those would be appropriate representative
18 test species for a general tick claim to be protective
19 generally of ticks for people. They concurred on that.

20 JERRY: Could you characterize did AMCA weigh
21 in on it, American Mosquito Control Association? I was
22 wondering if you characterize were they in support or not

1 in support?

2 MS. McLAIN: I didn't realize this would be a
3 memory test. I do remember definitely them being vocal
4 on this issue. I feel like they were in strong support
5 of the concept and offered up a variety of cautionary
6 notes to guide us and to provide us with input and
7 feedback as we moved forward on this, which we have
8 considered a lot of feedback as we move forward,
9 especially from this PPDC.

10 I believe that it was voiced through this
11 advisory panel through past years, and we've taken all of
12 the advice seriously as we've been trying to weigh how to
13 move this forward. So, that's the best I can do.

14 MS. MONELL: Liz.

15 LIZ: Regarding the repellency, I can imagine
16 that once you get HSRB involved, that there's probably
17 the studies that would be involved are going to probably
18 be kind of expensive. Has there been a cost benefit to
19 the efficacy that you're going to be requesting or will
20 it go to OMB and they'll make that decision?

21 MS. McLAIN: No, this is a voluntary program.
22 It also helps to support the registration of the product.

1 So, there's no requirement to put the graphic on your
2 product. If folks want to go through the studies -- a
3 lot of data that we already have in house can be used to
4 support the graphics, maybe not all of it.

5 So, part of the product's information that will
6 support use of the graphic is probably already in house.
7 So, some companies may be looking at one test in order to
8 complete their set of data that they may need. Some would
9 be looking at a complete series of tests, depending on
10 how old their product was and what kind of data they have
11 to back it up.

12 So, really, this is partially a voluntary
13 program, and it's partially trying to encourage folks to
14 bring them up to where we in modern times would like them
15 to be in terms of providing efficacy data to the agency.

16 UNIDENTIFIED MALE: So, I'm from SC Johnson.
17 We make repellants under the off brand, so we've done a
18 few of these tests ourselves in the past. If the agency
19 is open to the idea of clustering or bridging, we'd be
20 happy to talk to you about that, either from an ERC or
21 from a tox standpoint.

22 MS. McLAIN: Absolutely. I encourage you to

1 contact Kelly Sherman (phonetic), and she will work with
2 us to engage you in this.

3 MS. HOUSENGER: Okay, the final topic is
4 discussion topics for the next PPDC. But before we do
5 that, the last time we met with the PPDC, we had a
6 webinar. I wanted to get people's general sense. I know
7 it's always better to be with each other, but did that
8 work and should we consider it in the future? I see a
9 head nodding no. Was that the general sense? It seemed
10 good for us, as they're expensive.

11 UNIDENTIFIED FEMALE: Very expensive. I have
12 to say that the travel alone is about \$30,000.

13 MR. HOUSENGER: Cheryl.

14 CHERYL: It was very hard for me to participate
15 when people could come to me in my office, even though I
16 was in the webinar. I really wasn't all there. I kept
17 getting pulled away.

18 MR. HOUSENGER: You should lock your door.

19 CHERYL: I probably should. I should just have
20 been at home. But there's something about face to face
21 and there's something about multi-tasking. As great as
22 webinars are, they're not as effective as the face to

1 face. We all know that.

2 MR. HOUSENGER: Mark.

3 MARK: Thank you. First of all, I miss that
4 when you send the Leer jet for me, I always appreciate
5 that. I had a hard time with it. I mean, it was
6 adequate, so it was a reasonable form of communication.
7 I think it was certainly not as good as face to face for
8 a lot of reasons, the communication just in general and
9 of course I think people can see from some of the
10 presentations yesterday and today the advantage of face
11 to face presentations and being able to develop Power
12 Points that way. So, I think that's a much better way to
13 communicate.

14 Because of the communication that's always part
15 of the networking of stakeholders, I would say it's
16 inadequate for that. This is much more adequate.

17 VALENTIN: This is Valentin. If I may comment
18 whenever you think I should go.

19 MR. HOUSENGER: Go ahead. You can go now.

20 VALENTIN: First of all, really, I want to
21 apologize for not being able to participate in person. I
22 believe I'm the only one. But the last webinar we had, I

1 think it was really hard to be able to focus on the
2 conversation because we'd have a lot of interruptions.
3 We would hear background songs, music. We would hear
4 people having conversations with their colleagues over
5 the phone. It was really hard to hear. But I think that
6 being in person is always a plus. It's always nice to
7 see the faces of people that are talking and just kind of
8 building relationships with other individuals. I think
9 it's great.

10 MR. HOUSENGER: We have two more.

11 MR. GREGG: Richard Gregg here. I also was not
12 able to participate actually at the last minute. I
13 definitely prefer, if possible, the face to face. I did
14 participate on the first webinar, and I agree with the
15 comments that have already been said about that.

16 MR. HOUSENGER: So, we have two more comments.
17 If they're not positive, then I'm not sure we -- anybody
18 like the webinar? No, all right.

19 Let's talk about discussion comments for the
20 next PPDC. Margie, do you have any dates? Is there we
21 talk about dates?

22 MS. MONELL: No.

1 MR. HOUSENGER: We don't talk about dates here.
2 No, I didn't say that. Topics? No topics. Of course,
3 Ray. Go ahead.

4 RAY: I'd like to suggest three topics for
5 consideration at the next PPDC meeting. Worker
6 protection standards should be an obvious one, drinking
7 water and spray drift issues.

8 MS. MONELL: While I have that thought, the
9 worker protection standard, I just want to remind
10 everyone the closing date for public comment is August
11 18th.

12 MR. HOUSENGER: Mark.

13 MARK: As one might anticipate, I want to have
14 a discussion on school integrated pest management
15 programs, the status from the new Center of Expertise
16 particular to the national change agent core development
17 and the pilot, also workgroup action on incorporating
18 sustainability factors into school integrated pest
19 management, and action on enhancing cooperator and
20 regional activities with regard to cooperative
21 agreements.

22 MR. HOUSENGER: Dave.

1 DAVE: A couple things. One is, and I believe
2 I've requested this before, but it's an ongoing issue
3 with us that there doesn't seem like there's a consistent
4 evaluation of pathways to get into urban waterways, which
5 is the primary thing that brings me here. A discussion
6 of what OPP can do to make sure that each branch and each
7 division that's tasked, whether it's in registration or
8 registration review, that they consistently consider how
9 these things get into either waste water or storm water
10 pathways, because it's too all over the board and it's
11 impossible, really, to keep track of that. I'd like to
12 have some discussion of really the problems that exist
13 and then what EPA can do about it.

14 The other thing, I'd like there to be an
15 exploration of sort of building on what Matt Keiffer said
16 yesterday about the asymmetry and the approach of the tox
17 21 effort, in that there's a lot of -- I think it's good
18 that there's a lot of effort in sort of looking forward
19 technology of being able to evaluate and predict the
20 risk. But there's inadequate effort looking at how can
21 those tools be used to develop the clinical tools, to
22 develop epidemiological tools, and to develop

1 environmental surveillance tools. It's very much
2 underutilizing that capability.

3 I realize that you can't do everything, but I
4 would like to have some sort of a discussion that could
5 possibly lead to that committee looking at what's the
6 direction with that and what is the need for significant
7 resources being applied to those problems, because you
8 can't just rely on the looking forward, the predictive
9 tools, without having that back stop. That's a
10 significant policy issue. I think that's actually what
11 we're really here about, is advising on policy. I'm sure
12 there's other people that have different opinions about
13 that, but I'm thinking that would be a worthy subject to
14 explore.

15 MR. HOUSENGER: Cynthia.

16 CYNTHIA: Thank you. I would like to suggest
17 that we have a session at the next meeting on incident
18 reporting and FIFRA 682. This relates to OPP's efforts
19 on information technology, on endangered species, on the
20 MOU with the Fish and Wildlife Service implementing the
21 Migratory Bird Treaty Act, on 21st century computational
22 technology. Incident reporting is an important back

1 stop.

2 Some things we could discuss would include the
3 thresholds for wildlife reporting, disaggregating the
4 data, for example, for bee specific incidents,
5 biomarkers, and what kinds of incidents we can actually
6 get data for, what do we have the biomarkers for, what
7 tests need to be developed.

8 And we can hear about your efforts to merge
9 incident data reporting with other federal agencies, with
10 states, with other countries, so that registration
11 reviews can be informed by the best possible science and
12 by on the ground experience.

13 MR. HOUSENGER: Cheryl.

14 CHERYL: So, I would like to have more emphasis
15 on the drinking water aspects. I see we had an
16 information piece in here, which is great. But there
17 continues to be -- sorry, he said we could go on our soap
18 boxes if we came back off -- but there continues to be a
19 disconnect between the advanced, data driver, tiered
20 based system that exists for food dietary and what's done
21 with water. A lot of risk cups are full of just modeled
22 theoretical water.

1 There's been some efforts to try to collect
2 more monitoring data. There's been efforts to look at
3 statistical analysis of monitoring versus the models.
4 There's a proposal for biosector. So, I'd like to have
5 an update on that. I think it's really important to have
6 a more cohesive dietary risk assessment for both food and
7 water.

8 MR. HOUSENGER: Matt.

9 MATT: I want to add to Cynthia's list of
10 issues that need to be addressed when we're talking about
11 incident reporting and 682. That is, I think in the wake
12 of HIPAA, we have a problem that we didn't foresee.
13 Those issues may have a substantial impact on the
14 efficacy of 682 and our expectations from it.

15 What I mean by that is, HIPAA, and I'm sure
16 you've all heard of it, it's the Healthcare Information
17 Portability Act -- I think that's the actual name -- and
18 it prevents physicians from sharing information that
19 identifies patients with anyone that is not part of the
20 patient's care. There's substantial fines and penalties
21 associated with doing that. I think that strikes fear
22 into the hearts of a lot of physicians when it comes to

1 reporting anything to anyone other than people that
2 they're required to report to.

3 682 is not a mandatory surveillance system that
4 physicians report to. Therefore, in the absence of a
5 mandatory requirement, they're not released from their
6 HIPAA burden. So, I think this is really going to have
7 an impact that we need to discuss, because the system of
8 682 isn't keeping up with the new healthcare regulations.
9 We need to discuss the implications.

10 MR. HOUSENGER: Doug.

11 DOUG: I think you laid the groundwork well for
12 ESA and I'd like to continue to update on that, plus
13 maybe even considering a working group on that.

14 MR. HOUSENGER: Okay, Virginia.

15 VIRGINIA: I'd also like to echo Cynthia's
16 suggestion about incident reporting and add also efforts
17 by the agency to collect more information about human and
18 worker health and exposures.

19 MR. HOUSENGER: Mark.

20 MARK: I think it would be beneficial to get an
21 update on the situation with invasive species, vis a vis,
22 pesticide tools available, looking at strategies,

1 tactics, and tools where there aren't pesticides to use,
2 particularly in two of our most recent introductions.

3 MR. HOUSENGER: Anyone on the phone?

4 VALENTIN: Yes, this is Valentin. Very
5 quickly. I think it would be kind of nice to get an
6 update with regards to spray drift when it comes to
7 farmworkers and children, since there has been several
8 drifts happening in the State of Washington. There was
9 one that happened last year here in Oregon. I think it
10 would be kind of nice to get an update on the work that
11 EPA is doing regarding drift.

12 MR. GREGG: This is Richard Gregg again. I'm
13 for the drinking water and the spray drift.

14 UNIDENTIFIED MALE: This is not really a topic;
15 it's really more the conduct of the meeting. I thought
16 that this meeting -- and realize that it's always a
17 balancing act, but I think that this meeting, several of
18 the topics were overly loaded with presentation and not
19 enough opportunity for discussion.

20 MR. HOUSENGER: Okay.

21 UNIDENTIFIED FEMALE: This is quick on that
22 note. Could I ask you all to give us some kind of

1 glossary to the alphabet soup? It would be so nice to
2 know what the acronyms stand for before they're repeated
3 over and over. It would be really great.

4 MR. HOUSENGER: That we can do. All right,
5 well, thank you very much to everyone who traveled from
6 afar and even near and for making my first PPDC so
7 enjoyable. I was dreading it. But, hopefully, we'll
8 schedule another one sometime, and we'll get that out to
9 you.

10 Margie, is there anything as DFO that you need
11 to say to wrap it up? Oh, we still have public comments.
12 That's what you were going to say.

13 Julie Spagnoli.

14 MS. SPAGNOLI: This will be very quick. This
15 goes back to endangered species. We heard reference that
16 they are looking at nonagricultural uses. We also just
17 want to make sure that there's consideration for, as
18 we're doing the habitat evaluations and refinements, that
19 there's a consideration that within even an urban area,
20 that you do have distinctions in habitat or habitat
21 potentials within an urban area. You have parks. You
22 have non-developed areas within an urban area that may or

1 may not affect the usage in, let's say, a residential
2 area.

3 So, if a perimeter treatment is being made
4 around a home, even though it may be within, let's say, a
5 half a mile of a park, whether it's going to have any
6 impact on that park. I know this is the whole issue with
7 getting to these refinements, but within urban areas, I
8 think we have to look at that additional refinement that
9 an urban area can have habitats and have areas that are
10 not habitats. So, just taking that into consideration as
11 we move forward on the endangered species assessments.
12 Thank you.

13 MR. HOUSENGER: Marcia Duke, NMPA.

14 MS. DUKE: Hi, Marcia Duke from NMPA. Just a
15 quick comment on the comparative safety claims. I think
16 the agency has done a tremendous job of moving very
17 deliberately before they ever allow a comparative safety
18 claim on a label.

19 We had a recent experience in our industry.
20 There's two parts to the bio-based claim. There's going
21 through and being essentially carbon dated and allowing
22 the claim of bio base, whether that gets to a pesticide

1 or not. It's just a level of carbon in the product.

2 The other part of the bio-based program is
3 putting preferential myths in contracts, US government
4 contracts, for those products. We're sort of concerned
5 from a public health perspective, because, one, there's
6 not very many products on those bio-based lists, and
7 there was a product that was on the bio-based list that
8 was a 25B that recently the FTC took significant action
9 against so much so that it shot the company down.

10 So, we're just concerned because those products
11 are to be given preferential treatment in any US
12 government contract. So, we don't have products on the
13 list for lots of species. And for the species that do
14 have a product, a lot of them there's no efficacy for.
15 And for those that there might be, then that's all there
16 is.

17 So, we're concerned there's a public health
18 pasture out there that might not be able to be treated
19 from a US government perspective.

20 MR. HOUSENGER: All right, I think that wraps
21 it up. Thank you from the federal corner here for
22 attending, too. They're out partners in a lot of this

1 and, I think, shed a lot of light on a lot of complex
2 issues for everybody.

3 So, thank you. Safe travels home. Good
4 weekend. Bye.

5 (Whereupon, the meeting was
6 concluded.)

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