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US EPA ARCHIVE DOCUMENT

UNITED STATES

ENVIRONMENTAL PROTECTION AGENCY

PESTICIDE PROGRAM DIALOGUE

COMMITTEE MEETING

October 7-8, 2008

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. GULLIFORD: Good morning. Thank you all
4 for heeding the advice of your Chair, Debbie Edwards, and
5 responding to the two-minute warning that she gave. I
6 think that people have made it through security for the
7 most part, and we're ready to get started.

8 Again, I'm Jim Gulliford. I'm assistant
9 administrator of the Office of Prevention, Pesticides,
10 Toxic Substances. It's my pleasure to welcome you to
11 this the 25th meeting of the Pesticide Program Dialogue
12 Committee. I know that to be true because I went to the
13 web site just yesterday and pulled it up and there are
14 minutes from 24 previous meetings of the Pesticide
15 Program Dialogue Committee. So, this is your silver
16 anniversary. So, congratulations to you as a committee.

17 I suspect that not many of you have been on the
18 committee for that long, but if you have, your
19 perseverance and strength is certainly appreciated. I
20 also took the opportunity, then, since I am a strong
21 believer in traditional anniversary symbols -- it's been
22 a key to my marriage. I went back and looked and this is

1 my fifth Pesticide Program Dialogue Committee meeting.
2 And, not surprisingly, the traditional anniversary symbol
3 for five is wood.

4 So, if you're out there thinking about -- I
5 suspect you're out there thinking that wood, that's
6 certainly appropriate, two by four blunt instrument, an
7 object. I'm thinking differently. I'm thinking about
8 the formaldehyde irritation ANPRM that we're looking at
9 for pressed wood products. So, we're into wood over at
10 the toxic side of what we're doing as well. So, I accept
11 the appropriateness of the wood symbol for my anniversary
12 meeting with you here.

13 I have found these meetings to be very
14 interesting, very productive. We, as an agency, very
15 much value your comments. We tell you that every time
16 you come here, and I hope that you can see the
17 appreciation for your efforts in the actions that we
18 take, not only the way we listen to comments that you
19 bring to the meeting, appropriate as they are. I think
20 that you should see the impact of your thoughts and your
21 contributions to this process. We hope that that is the
22 case.

1 We know that there is agreement, that there is
2 disagreement, but we clearly believe that there -- that
3 open constructive dialogue is helpful to us to understand
4 the range of interest that are a part of every decision
5 that we make.

6 Again, this is a busy time of year. We thank
7 you all for making the journey, whether you came from
8 across the country or made the harder journey of working
9 your way through traffic in this town. Again, the --
10 again, as you look around the room, you can see that the
11 chairs are filled and that members of the committee,
12 again, take this work very much to heart and come to
13 participate. And we're grateful for that.

14 I also look back to when I was thinking of the
15 wood analogy to the issues that were discussed at my
16 first PPDC meeting with you. I think you know I came in
17 July of 2006. At the time, the agency was on the verge
18 of coming very close again to meeting the FQPA
19 requirement of reviewing all of those (inaudible)
20 tolerances by August of 2006. That was a very busy time
21 for us. The staff was working very hard. I can tell you
22 that they work no less hard today than they did then.

1 Last week was the end of our fiscal year and it was also
2 the time where we completed the final registration
3 eligibility decisions or REDS on all of the FQPA required
4 uses.

5 So, again, we get an opportunity to look at
6 many, many pesticides, many, many uses. We've again
7 reached another milestone, but it's only a milestone. I
8 can assure you that work will continue just as hard with
9 the challenge of implementing the REDS that are before
10 us.

11 So, it's not just a matter of getting to an end
12 there; it's a process that really continues to evolve,
13 because as we work on many challenges implementing these
14 REDS, they're challenges for the uses of those
15 pesticides, they're challenges for us to come up with
16 mitigations that are effective and also implementable.
17 Those are two of our big challenges, and we have some
18 litigation regarding some of these REDS that will
19 ultimately be resolved as well. So, there's plenty of
20 things to do there.

21 Finally, I would be remiss if I didn't say that
22 again the pesticide program under Debbie's leadership has

1 moved into the registration review phase. We're getting
2 up to a full speed there as well. You can see the
3 dockets that are opened each year in the registration
4 review process.

5 So, we will -- I think it's a very productive
6 process. I think it's a very good statute and it makes
7 us continue to look at the state of the science that
8 exists with regard to the use of pesticides in our
9 country. It assures that again we have pesticide
10 products that can be used to meet our pesticide needs.

11 At the same time, they're the safest products
12 and that concerns regarding those products are
13 effectively mitigated so that we can again assure for a
14 very effective agriculture and effective commercial --
15 or, excuse me, consumer products as well in our homes.
16 So, it's a very good process and I've very happy with
17 that.

18 You've got a very exciting agenda for the day.
19 I took a chance -- the opportunity to look at it. I'm
20 going to spend a little bit of time with you this
21 morning. I'm very interested in the first two sessions.
22 I'm interested in all of the sessions but I'm going to be

1 here for the first two looking at the endocrine disruptor
2 program, as well as the Endangered Species Act program as
3 well.

4 You're going to have an opportunity to hear
5 some presentations on each of these issues and provide
6 some of your feedback on them. I want to talk just a
7 little bit about the endangered species program that
8 we're implementing because it's one that I certainly
9 spend a considerable portion of my time working on and
10 again supporting our staff in it.

11 Given again the broad -- the large number of
12 pesticide active ingredients, over 600 active
13 ingredients, over 10,000, roughly, or nearly 10,000 uses
14 for those products, given the large number of endangered
15 species, the breadth of habitat that is appropriate for
16 those species, you can clearly come to an appreciation
17 for the fact that there are thousands, if not hundreds of
18 thousands, of iterations as to how products are used, the
19 overlap of products, where those agricultural lands are,
20 where the species are, the potential habitat for those
21 species, you can see that there's again a tremendous
22 workload ahead of us that continues to exist for how we

1 meet our responsibility as an action agency with respect
2 to protecting endangered species.

3 We continue to work with the services and to
4 try and develop an effective path forward to meet those
5 responsibilities. We're working to develop a common
6 understanding for how we'll measure risks, how to assess
7 those risks appropriate to protecting species in -- with
8 respect to the use of pesticides. Looking for an
9 effective and a predictable process as well.

10 Clearly, it's a big challenge for us to develop
11 a process to carry out all of the consultations that are
12 going to be necessary again as we seek to implement our
13 responsibilities to the Endangered Species Act. We're
14 going to have to find effective ways to mitigate any
15 risks that are identified through the process, and
16 clearly there continues to be a process challenge itself
17 to assure that the assessments are made. We want them to
18 be timely.

19 We're going to have to get to some type of a
20 production process to assure that we can meet our
21 obligations. We clearly want them to be open and
22 transparent. If you look at our web sites, you can see

1 as the process evolves on all of them that we're working
2 on. We do posts to that web site regularly.

3 Again, we need to assure that rigorous and
4 sound science is applied to the development of packages,
5 to the review of those packages, and to all of the work
6 that follows, particularly again with respect to the
7 biological opinions.

8 You know that we're working through the process
9 with respect to salmonids in the Pacific Northwest. We
10 have draft biological opinions that we have reviewed and
11 our comments again have been posted to the web site and
12 returned to NMFS and we expect that they have deadlines
13 that they need to meet now to issue final biological
14 opinions.

15 The reality is that we anticipate that it's
16 going to be very difficult to come to agreement on the
17 science of those final biological opinions based on our
18 comments on the draft biological opinions. If that's the
19 case, if we are unable to come to agreement, we will
20 continue to look for scientific agreement. We think that
21 that's a very important part of the process and we will
22 explore opportunities for external and independent review

1 if that's necessary for the future.

2 Again, it's a task and a responsibility we take
3 very seriously. We want to implement those programs. We
4 want to meet our obligations. We want endangered species
5 to be protected as we use pesticides in agriculture and
6 in our homes.

7 So, again I'm going to be very interested in
8 the presentations that we hear on both that subject and
9 endocrine disruptors. And I'll have to leave after that,
10 but I will stay for the break afterwards. So, if you
11 have additional specific things that you want to speak to
12 me about, I'd be happy to have an opportunity to talk
13 with you. I found it very helpful to hear your
14 interests, your candid opinions, and it's also very
15 enjoyable for me. I've gotten to know many of you that
16 are a part of this committee over the last couple of
17 years.

18 So, now I'm going to turn it over to Debbie
19 Edwards, chair of the PPDC, again to welcome you as well
20 and get this show running. So, thank you for being here
21 and thanks for your support of this process.

22 MS. EDWARDS: Thanks, Jim. Again, I would like

1 to welcome you all as well to our 25th PPDC meeting.

2 I think what I'm going to do is just simply go
3 through the agenda and describe what's up for the next
4 day and a half very briefly so we can get into our
5 presentations. But I will say that I think you can see
6 from this agenda that the pesticide program is keeping
7 its eyes and ears on the pulse of the pesticide issues of
8 the day, and we're making every effort to address them.
9 So, I hope that's clear from many of the issues we've
10 brought forward today.

11 To begin with, session one is on endocrine
12 disruptors. I'm very pleased to have Bill Woogey
13 (phonetic) here from the Office of Science Coordination
14 and Policy who will be joining Bill Jordan, our senior
15 policy advisor in the Office of OPP, to give you an
16 update on that.

17 Session two again is endangered species issues
18 with Don Brady who was selected to be the director of the
19 Environmental Fate and Effects Division since the last
20 time we met. We'll then take a break.

21 And then session three we'll hear from the PPD,
22 Marty Monell, our deputy office director, on the new PPDC

1 work group on comparative safety statements. This group
2 met yesterday, so we'll look forward to hearing an update
3 from them.

4 We'll then have a lunch session and come back
5 for session four. There will be discussion again by
6 Marty Monell of OPP's resources and how we utilize those.
7 Then, following this, on session five there will be a
8 discussion of our performance and outcome measures work.
9 MaryAnn Petrole, who is the chief of our financial
10 management and planning branch, is going to lead that
11 discussion. We're also very pleased to have several
12 representatives from USDA joining us to make
13 presentations.

14 In session number six, it will be Martin Miller
15 who will provide an update on the NASS program. Dr. Amy
16 Brown and Dr. Jim Parochetti will cover the pesticide
17 safety education program. And Dr. Marty Draper will
18 provide a brief update on the IPM PIPE, which is the IPM
19 pest information platform for extension and education.

20 Then, following another break, we'll have a
21 topic of very high interest nowadays in the news and that
22 is pollinator protection. Dr. Tom Steeger of our

1 Environmental Fate and Effects Division will give you an
2 update on current efforts to address this issue. And
3 we're also very pleased to have Dr. Jeff Pettis of the
4 USDA's Bee Research Lab here to provide an update on
5 colony collapse disorder.

6 Before adjourning today, we're going to have a
7 public comment period. Interested members of the public
8 who are attending today as well as tomorrow should sign
9 up on the comment sheet request time at the registration
10 table.

11 Tomorrow morning we'll begin with session eight
12 on our activities with respect to the use of incident
13 data. We'll hear then from Ann Overstreet, who is
14 chairing OPP's Incident Work Group.

15 In session nine we'll have several brief
16 updates that we thought would be important to include as
17 part of the agenda. These include efforts with respect
18 to pesticide volatilization, pesticide usage information,
19 resistance management, and also an update on regulatory
20 development -- regulations development.

21 In session 10, we'll cover the current work of
22 our new PPDC Work Group on 21st century toxicology and

1 the new integrated testing strategies. This work group
2 is chaired jointly by Vicki Dellarco and Steve Bradbury.
3 This work group is focusing on our vision and our
4 strategy around the National Research Council's report on
5 toxicity testing in the 21st century, which is a very
6 exciting area not only for the pesticide program but for
7 toxicologists in general throughout government and
8 throughout the research community. This work group is
9 also planning to meet again on Wednesday afternoon after
10 we conclude.

11 In session 11, Bill Jordan will provide you
12 with an update on the PPDC work group on web distributed
13 labeling which met just last week. There's a lot going
14 on in this program to revolutionize the way we handle and
15 make public labeling information for pesticides
16 available. The work group was set up to provide advice
17 to the PPDC regarding a process to ensure that the most
18 current version of pesticide labeling is available to
19 users and purchasers electronically.

20 We'll wrap up on Wednesday with a planning
21 session for the next PPDC and then we'll have another
22 public comment period.

1 So, I think you've been great. We have a very
2 fully agenda. It's going to be challenging to stay on
3 track. We'll try our best to do that because we think we
4 need to cover all of these topics during the next day and
5 a half.

6 Now, I would like to go around the room and
7 have each of you briefly introduce yourself, provide your
8 affiliation, and also, if you're representing someone
9 else, state who that is. Thanks.

10 MR. SMITH: I'm Burrelson Smith (phonetic) with
11 the U.S. Department of Agriculture.

12 DR. WHALON: Mark Whalon, Michigan State
13 University.

14 MR. PEARCE: Chris Pearce, SC Johnson, for Jim
15 Wallace.

16 MS. KENNEDY: Caroline Kennedy, Defenders in
17 Wildlife.

18 DR. ROBERTS: Jimmy Roberts, Medical University
19 of South Carolina.

20 MR. KLEIN: Phil Klein with the CSPA.

21 DR. SCHELL: John Schell with ENTRIX.

22 MS. RAMSAY: Carol Ramsay with Washington State

1 University Extension.

2 MR. JAMES: Allen James, Responsible Industry
3 for a Sound Environment.

4 DR. FERENC: Sue Ferenc with the Chemical
5 Producers and Distributors Association.

6 MR. CONLON: Joe Conlon, American Mosquito
7 Control Association.

8 MS. LIEBMAN: Amy Liebman with the Migrant
9 Commissions Network.

10 MR. VROOM: Jay Vroom, CropLife America.

11 MR. TAMAYO: Dave Tamayo, California Stormwater
12 Quality Association.

13 DR. BERGER: Lori Berger, California Specialty
14 Crops Council.

15 MR. THRIFT: Jim Thrift, Agricultural Retailers
16 Association.

17 DR. SHAH: Haz Shah, American Chemistry
18 Council.

19 MR. HOWARD: Dennis Howard, Florida Department
20 of Agriculture. I represent state lead agencies for
21 pesticide regulation.

22 MR. BROWN: Amy Brown, University of Maryland.

1 I represent the American Association of Pesticide Safety
2 Educators.

3 DR. MENCHEY: I'm Keith Menchey of the National
4 Cotton Council. I'm sitting in for Cannon Michael, with
5 the California Cotton Growers Association. He had a
6 family situation and couldn't make it.

7 MS. COX: Caroline Cox, Center for
8 Environmental Health.

9 MR. SCHERTZ: Scott Schertz, Schertz Aerial
10 Service, representing the National Agricultural Aviation
11 Association.

12 MR. GUSKE: Marco Guske with the Travel
13 Pesticide Program Council.

14 DR. GREEN: Tom Green with the IPM Institute of
15 North America.

16 MS. BRICKEY: Carolyn Brickey, Center of
17 American Progress. Is it still Tuesday? It's a big
18 group.

19 MR. ROSENBERG: Bob Rosenberg, National Pest
20 Management Association.

21 MS. SPAGNOLI: Julie Spagnoli, FMC Corporation.

22 MR. LEAHY: Rick Leahy, Wal-Mart.

1 DR. KEGLEY: Susan Kegley, Pesticide Action
2 Network.

3 MR. KASS: Dan Kass, New York City Department
4 of Health.

5 MS. HERRERO: Maria Herrero, Valent BioSciences
6 in representation of the Biopesticide Alliance.

7 MR. FRY: Michael Fry from American Bird
8 Conservancy.

9 MR. BOTTS: Dan Botts, Florida Fruit and
10 Vegetable Association.

11 MS. BAKER: Cindy Baker, Exigent (inaudible)
12 Company.

13 MR. BARON: Jerry Baron, IR-4 Project.

14 MS. SULLIVAN: Kristie Sullivan, Physicians
15 Committee for Responsible Medicine, representing Animal
16 Welfare Community.

17 MR. WEGMEYER: Tyler Wegmeyer, American Farm
18 Bureau Federation.

19 DR. FLORIN: David Florin for the Department of
20 Defense.

21 MR. BERU: Nega Beru, Food and Drug
22 Administration.

1 MR. SAYERS: Rick Sayers, U.S. Fish and
2 Wildlife Service.

3 MR. COLBERT: Rick Colbert, EPA's Office of
4 Compliance.

5 MR. JENNINGS: Al Jennings, USDA, and this is
6 my 25th PPDC.

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

9 MS. EDWARDS: I think we have at least one
10 person on the phone. Is that correct?

11 MS. HONNIGER: Joy Honniger, Monsanto
12 (phonetic).

13 MS. EDWARDS: Okay. I think Matt Keifer may be
14 joining us later.

15 All right, well, let's get started then with
16 our first session of the day which is endocrine
17 disruptors with Bill Woogey and Bill Jordan.

18 MR. JORDAN: Thanks, Debbie. I'm Bill Jordan.
19 On my left here is Bill Woogey. This is also my 25th
20 anniversary with PPDC. My wife and I recently celebrated
21 our 30th wedding anniversary, despite my having suggested
22 that our first wedding anniversary was the pepperoni

1 anniversary. Thank you, Cindy, for laughing. Pepperoni
2 pizza, but she stayed married to me anyway.

3 So, I'm going to talk today about the endocrine
4 disruptor screening program and this is another one of
5 the major initiatives that keeps the folks here in EPA
6 busy. We are moving from one stage to another, as you'll
7 hear in my presentation. For a number of years, we've
8 been working to validate the -- do research and validate
9 the assays that will be used to screen pesticides for
10 their potential to interact with the endocrine system.
11 We hope -- and I'll explain how we're moving ahead to
12 realize this. We hope to begin issuing test orders that
13 will start that testing early next year.

14 For the time since the Food Quality Protection
15 Act was amended -- it was passed in August 1996 -- until
16 now, the primary lead has been in the Office of
17 Compliance Coordination and Policy. My colleague, Bill
18 Woogey, has been, for the last several years, the person
19 who shepherded most of the Federal Register notices that
20 you've seen through the process to make sure that we are
21 getting input on the program.

22 So, let me turn to the statutory authority

1 under which this program is operating -- slide 2.

2 Is somebody going to flip the slides for those
3 who are watching the screens, can't read the small
4 handout?

5 The Food Quality Protection Act directed EPA to
6 develop a program using appropriate validated test assays
7 to -- and other scientifically relevant information to
8 screen pesticide chemicals for their ability to cause
9 effects in humans that are similar to those effects
10 produced by estrogen. It also authorized EPA to look at
11 other endocrine effects. And based on the advice of one
12 of our advisory committees, the EDSTAC, that which I'll
13 speak a little bit more in a moment, we have broadened
14 that to include androgen and thyroid systems.

15 The Act also authorizes us to go beyond
16 pesticide chemicals and to look at other chemicals that
17 may have an effect that is cumulative to pesticide
18 chemicals. We also have authority in the Safe Drinking
19 Water Act to require testing of substances that are found
20 in sources of drinking water if there's a substantial
21 human population that may be exposed.

22 To implement this authority, we convened a

1 group called the Endocrine Disruptor Screening and
2 Testing Advisory Committee, or, as in Washington,
3 everything has an acronym, EDSTAC. That's how we
4 pronounce that acronym. We used the advice of EDSTAC
5 which met for several years and included wide
6 representation across all of our stakeholder groups and a
7 lot of really expert scientific input to develop the
8 program. We've also taken advantage of the FIFRA
9 scientific advisory panel on the science advisory board
10 to get their scientific advice as well.

11 It has led us to develop a program that has
12 three large pieces. The first is validating the assays
13 that will be used to test chemicals for their potential
14 to interact with the estrogen/androgen or the thyroid
15 systems. The second is a priority setting system for
16 selecting the chemicals that will be the first ones to
17 receive test orders. The third piece is defining
18 procedures and policies that set some boundaries or
19 describe how we are going to issue test orders and
20 implement them in order to achieve some of the goals that
21 are articulated in the Food Quality Protection Act
22 amendments.

1 I'll be talking about these three large pieces
2 which are all necessary components of getting the --
3 moving from the early stages into the testing stage for
4 the endocrine program.

5 The next slide is about our assay development
6 -- it should be slide 5. I think we're ahead one.
7 EDSTAC directed us to create a -- recommended that we
8 create a two-tiered approach. The first tier is a
9 battery of assays including both short term in vitro and
10 longer in vivo assays that will be capable of identifying
11 substances that have the potential to interact with
12 estrogen, androgen or thyroid hormone systems.

13 Simply put, this is a screening system. It is
14 quicker and cheaper than other ways of approaching it,
15 for the most part, and it is only to identify chemicals
16 that have the potential to interact. It doesn't
17 necessarily indicate that they have adverse affects or
18 that further regulation is needed.

19 That's something that would be determined after
20 we get the second tier of testing, typically, multi
21 generational studies that will identify and establish a
22 dose-response curve for the -- exposure to the chemical

1 and adverse affects. Then we can use that as we do in
2 our typical risk assessment approach to decide whether or
3 not there are risks that need to be mitigated.

4 The next slide shows the list of assays, 11
5 different assays, that would be included in the tier-one
6 screening battery. EPA presented these 11 different
7 assays to the FIFRA scientific advisory panel in a
8 meeting this past March, reporting to the SAP on the
9 validation work that we have been doing for a number of
10 years. You'll see that the validation on all of these
11 assays is complete except for the estrogen receptor
12 binding assay which we expect early next year.

13 The SAP reviewed the information and basically
14 endorsed the proposed tier-one screening battery. You'll
15 see that in a report that's available on the SAP web site
16 dated June of this year. So, we are moving ahead with
17 those as the battery of assays.

18 We've also been working on the tier-two assays,
19 which are listed here. There are five multi-generational
20 studies in different species; mammals, birds, amphibians,
21 fish, and invertebrates. These studies will give us
22 those response data that we can then use in a risk

1 assessment approach.

2 Next, I want to move on to the priority setting
3 approach. We have described in a series of Federal
4 Register notices a priority-setting scheme that is built
5 around the potential exposure to different chemicals,
6 primarily human exposure for pesticide active
7 ingredients. We looked at four different pathways to the
8 chemical. Are people going to be exposed to the
9 pesticide active ingredient in food, in water, as a
10 result of use of the pesticide in residential settings or
11 as a result of the use of the pesticide in certain use
12 patterns that are associated with high occupational
13 exposure?

14 The endocrine disruptor screening program also
15 covers pesticide chemicals that are inert ingredients.
16 For those, we focus on inert ingredients that are also
17 high production volume chemicals under the programs that
18 the Office of Pollution Prevention and Toxics
19 administers. We looked at the potential human exposure
20 through water, through air, and through human tissue, and
21 ecological tissue sample monitoring.

22 Using those criteria, we have developed a draft

1 list. We put that out for public comment in a Federal
2 Register notice in June of 2007. We have listed in that
3 64 active ingredients and 9 high production volume inert
4 ingredients for a total of 73. I want to stress that
5 that list of 73 chemicals is not a list of chemicals that
6 we suspect of being endocrine disruptors or that we know
7 are being endocrine disruptors; rather, they are a list
8 of chemicals whose uses in monitoring data suggests that
9 there's potential for widespread and even high levels of
10 exposure.

11 The public comment period was extended three
12 times and came to an end in February. We are looking at
13 the data, looking at the comments that were submitted,
14 and we've prepared a response to those comments. We've
15 prepared a draft final list which we have sent to the
16 Office of Management and Budget along with our response
17 to comment and we think OMB will finish its review of
18 this reasonably soon.

19 Now I want to turn to the third part of the
20 endocrine disruptor program which is the policies and
21 procedures that we'll use to issue test orders and
22 implement the testing phase of the program. The Food

1 Drug and Cosmetic Act, Section 408(p)(5), amendment that
2 was added by FQPA sets certain policy goals for the way
3 that we run the program.

4 We are to minimize duplicative testing. We're
5 to develop procedures that lead people who receive test
6 orders to share the cost of doing the studies in a fair
7 and equitable way. And we are to develop procedures to
8 protect the confidentiality of trade secret or other CBI
9 information that we may -- that may come into the agency
10 as part of the program.

11 So, using these directives -- next slide please
12 -- we've developed a Federal Register notice that lays
13 out our policies and procedures. For the most part, we
14 are modeling the testing program under EDSP on a program
15 with which I'm sure many of you are very familiar, that
16 is, the data call-in program under FIFRA Section
17 3(c)(2)(B).

18 Basically, our goal is to encourage people who
19 receive test orders to form agreements, consortia, data
20 development consortia, to respond to the test orders so
21 that when, say, 20 companies get a test order, they band
22 together and agree on doing the required test only one

1 time on that particular chemical. We'll also be using
2 existing procedures to protect CBI and to encourage data
3 compensation.

4 We also have put out in our Federal Register
5 notice a draft of the test orders that shows what they
6 would look like and how we would figure out who gets the
7 test orders, how people should respond to the test
8 orders.

9 All that appeared in a Federal Register notice
10 issued in December 2007. We also made the draft order
11 templates and a draft ICR, information collection
12 request, available. Public comment period ended this
13 spring. We've reviewed those comments. We've prepared
14 the response to public comment. We have revised the
15 policies and procedures, and we've submitted all of that
16 to the Office of Management and Budget. They are looking
17 at those materials as well.

18 So, before I talk about some additional things
19 that are going on with regard to this process, let me say
20 that the Office of Management and Budget -- and we have
21 met to talk about all of these materials. We think we've
22 answered their questions. They are now becoming immersed

1 in the details of how we did all of this stuff. I'm
2 confident that if they have additional questions, we'll
3 be able to field them as well. We are looking forward to
4 them wrapping up their reviews and moving ahead with
5 that, as I say, early next year.

6 In addition, we've been getting some other
7 submissions that I'll take just a moment briefly to
8 discuss. The Center for Regulatory Effectiveness sent in
9 a request for correction under the Data Quality Act. A
10 request for correction is the name of a letter or a
11 document that is sent to EPA when somebody thinks that
12 EPA or any other federal agency for that matter has put
13 out information that is factually inaccurate.

14 It came in in July after all of those Federal
15 Notice comment periods had ended. They said that we had
16 made statements in our response to the peer review of the
17 amphibian metamorphosis assay that they thought were
18 inaccurate. We've prepared a response. The process
19 calls for OMB to review that response. We've sent it to
20 OMB, and OMB is looking at that as well. They request a
21 little bit of additional information. We're providing
22 that to them shortly.

1 In addition, CropLife America, the trade
2 association for the pesticide industry, agricultural
3 pesticide industry, submitted a petition to EPA on EDSP
4 in July. We are currently reviewing that petition and
5 we're preparing our responses that will also go to OMB
6 for their review so they can see how we are addressing
7 the questions that were raised by CropLife.

8 Then, the physicians committee for responsible
9 medicine asked for and got a meeting with OMB which EPA
10 attended and listened to in July. That meeting, PCRM
11 raised a number of questions about the proposed EDSP and
12 particularly what EPA was doing to minimize the number of
13 animals that would be used in required studies. We are
14 talking with OMB about all of that as well.

15 So, based on all of this, you can see that
16 there are three different pieces that are moving ahead;
17 the assay validation, which we think is pretty much done,
18 the development of the procedural framework and the
19 identification of chemicals, as well as these additional
20 initiatives.

21 All of those pieces are, in our view, pretty
22 well wrapped up and at the final stage of review in the

1 Office of Management and Budget. Based on the schedules
2 that the Office of Management and Budget maintains for
3 review of EPA and other agency's activities, we are
4 looking to wrap up all of the work and start issuing test
5 orders early in 2009.

6 So, the last slide gives you the web site at
7 EPA where you can find additional information about the
8 endocrine disruptor screening program. That concludes my
9 presentation. Debbie, questions now?

10 MS. EDWARDS: Yeah, I think it would be good to
11 take questions/comments on this until around 10:00.
12 Cards up. Start around the room.

13 UNIDENTIFIED MALE: I was just interested in
14 the two-one screening. It's gone through a review
15 process. According to the time line, you're just about
16 done with it. Is there a mechanism that would simplify
17 modifications to those tiers? You know, we're talking
18 about toxicology in the 21st century and all the OMICS
19 (phonetic) that are coming along. Is there a process
20 that you all envision that would allow incorporation of
21 some of these newer testing procedures and eliminating
22 some of the other ones?

1 MR. JORDAN: Well, there are several things
2 that I can say. First is that the battery of 11 assays
3 went to the scientific advisory panel and they endorsed
4 the approach that EPA has proposed to them. So, at least
5 for the time being, I can -- I expect that's what we're
6 going to use.

7 When we issue a test order, it will invite
8 people to respond according to a variety of choices. One
9 of the choices will be I don't need to do that study,
10 either it's already been done or I've got other data that
11 will satisfy that requirement, or I need to change the
12 assay in some way. We'll look at those requests but our
13 starting point would be the tier one battery that the SAP
14 has endorsed.

15 The last thing I'll say is that EPA's Office of
16 Research and Development is working on developing new
17 assays. They are a major supporter of this 21st century
18 toxicology and some early briefings indicate to me that
19 they're very, very promising research initiative that may
20 not immediately but sometime in a few years allow us to
21 simplify the -- and do an even better job of screening
22 chemicals for their potential to interact with the

1 endocrine system.

2 UNIDENTIFIED FEMALE: Have you submitted the
3 ICI yet to OMB? If not, when?

4 MR. JORDAN: I'll let Bill Woogey talk about
5 that.

6 MR. WOOGY: No, we haven't. We're waiting for
7 the clearance from the policies and procedures first.
8 That's how OMB wanted us to cue it up.

9 UNIDENTIFIED FEMALE: Do you have any
10 guesstimate on when you might be? I mean, is it ready to
11 go after their response to the policies and procedures?

12 MR. WOOGY: It's pretty much ready to go.

13 MR. JORDAN: So, the policies and procedures
14 notice, once that's cleared, the last piece of work will
15 be the ICR. It'll go out for public comment -- mandatory
16 30-day period and that will signify that everything that
17 leads up to that has been wrapped up.

18 MR. WOOGY: OMB can't actually act on the ICR
19 until that 30-day public comment period has ended.

20 UNIDENTIFIED MALE: So, Bill, congratulations
21 on all the progress and know that out of your 25 years of
22 PPDC experience, these few years here have been very

1 interesting and trying at times. The one thing that
2 seems to stand out in the 11 assays that you summarized
3 is that only one is not complete and won't be complete,
4 according to your slide, until the second quarter of
5 2009, which is the endocrine receptor binding assay.

6 Many in the scientific community, as I
7 understand it, would say that that's if not the keystone,
8 one of the keystones to this entire process. I think we
9 at CropLife have a real concern about ability to start
10 issuing test orders until that real important assay is
11 completely validated.

12 Could you speak a little bit more to the
13 process of how that got behind the other assays and how
14 to catch up and what it means to the entire program?

15 MR. JORDAN: I'll try, but I'm not the expert
16 on the validation process by a long shot. It isn't that
17 this particular assay was neglected in any way or fell
18 behind in terms of our work on it, but simply that the
19 assay validation result hadn't come together as quickly
20 as the others did.

21 We are aware of the role that this particular
22 assay plays in the overall battery. We're looking at how

1 fast we can wrap this up, and how it affects the timing
2 of the issuance of the orders, and whether the orders
3 will cover 10 assays or 11 assays. That's an issue
4 that's still under discussion and I don't think I'll
5 speculate on how that is going to get resolved.

6 MR. TAMAYO: Dave Tamayo, CASCA (phonetic).

7 I had a couple questions. One is, what was the
8 nature of the CropLife petition and what's the potential
9 for that slowing down the process?

10 Then, my other question was, you said that the
11 choice of the 64 or so initial chemicals to be screened
12 was based on a high potential for exposure. I was
13 wondering, was there any consideration done at all,
14 looking through the existing literature on the chemicals
15 that were chosen or not chosen, to identify things that
16 were more or less likely to be suspect? I mean, you
17 specifically said you didn't have any suspicion that any
18 of those chemicals were at issue. I found that puzzling.

19 MR. JORDAN: The criteria were exposure driven
20 and we did not review the public literature or extensive
21 databases on the active ingredients to try to
22 characterize at all whether or not those chemicals had

1 the potential to interact with the endocrine systems.

2 I'll let Bill Woogey talk about the CropLife
3 petition.

4 MR. WOOGY: The CropLife petition was very
5 similar to the CropLife America comments to the policies
6 and procedures. They indicated that the agency was not
7 following sound science, that they had concern with the
8 validation process of the individual assays and the
9 timing, the fact that the policies and procedures haven't
10 been published as of yet before we were issuing orders.
11 We will public the final policies and procedures before
12 we issue orders.

13 They were general. They weren't really
14 specific to individual assays but more on the program in
15 general.

16 UNIDENTIFIED MALE: One other important aspect
17 of our petition has to do with the statutory requirement
18 to avoid, if not completely, to the extent practicable of
19 duplicative testing as well.

20 MS. EDWARDS: Thank you.

21 Caroline.

22 CAROLINE: At this point, do you have an

1 estimate on when you'll actually be in compliance with
2 FQPA? That is to say, screened all pesticide chemicals?

3 MR. JORDAN: First of all, we think we are in
4 compliance with FQPA. They told us to develop a program
5 and we have developed that on a statutory time frame.
6 We're planning after the first round of testing to -- of
7 the initial group of chemicals -- to merge the program
8 with our registration review program for active
9 ingredients.

10 As we move through the registration review
11 process, make sure that the active ingredients are
12 screened for their potential to interact with the
13 endocrine system. So, basically, it will take us about
14 15 years to get through the registration review process
15 and that will cover the active ingredients in the testing
16 phase.

17 MS. EDWARDS: Susan.

18 SUSAN: I guess I'm concerned that OMB is
19 acting like a big blockade in almost of all of this
20 testing. The list of -- the prioritization list was
21 released way back last year, right, about this time?
22 They still haven't reviewed it and still haven't gotten

1 it back to you? Is there any way that you can speed that
2 up and get them to work a little faster on it? It's a
3 list of 72 chemicals.

4 MR. JORDAN: I don't remember exactly when we
5 submitted all the materials to OMB. Bill may be able to
6 recall the dates more accurately than I, but the process
7 that we're going through with regard to OMB review of
8 these materials is really no different from the process
9 that we follow on all of the regulations and major
10 initiatives that EPA conducts in the pesticide program.
11 From my experience, it's really no different from what I
12 see other agencies like USDA or the Food and Drug
13 Administration going through.

14 That said, OMB has not had these materials for
15 what strikes me as an overly long period of time. We've
16 told them that this is an important initiative for us and
17 we want them to review it as quickly as they can. I
18 think they're giving it a fairly reasonably high
19 priority.

20 MS. EDWARDS: Michael.

21 MICHAEL: Yes. I may be a little biased, but
22 if there's ever been a program that comes close to

1 motherhood and apple pie in this agency, this is it.
2 This one is the one that has the potential for really
3 disrupting the motherhood part of it.

4 It is now, what, 12 years, but, you know,
5 Caroline's comment or question about compliance, all of
6 this stuff was supposed to have been done in 1998. It
7 really does seem to be an overly long process. I'd like
8 to find out what the specific expertise in OMB is that
9 provides them sort of the gatekeeping on the review of
10 this program.

11 MR. JORDAN: Well, the Office of Management and
12 Budget is responsible for looking at the regulatory
13 actions of federal agencies in order to ensure that they
14 are consistent with administration policies and statutory
15 obligations in terms of being the most effective way to
16 use the taxpayer's dollars, make sure that they are
17 allocating burdens in a sensible and reasonable fashion.

18 The kinds of questions that I've historically
19 seen, not necessarily on EDSP, are things like, how does
20 this work, will people understand this. Sometimes people
21 at OMB have asked questions that have led us to include
22 the clarity of the way in which we're expressing things.

1 They suggested ways of making things simpler and easier
2 to work. That's not to say that there haven't been
3 disagreements on policy issues, but when those issues
4 come up, we talk them through and work them out.

5 MICHAEL: Would it be possible to have someone
6 from OMB come and give a presentation at some point if
7 this goes on any longer? I mean, is there a way to ask
8 them to do this or do they just say no?

9 MR. JORDAN: I can't make a commitment on their
10 behalf, but we can note that you're interested in that
11 and see where we stand next time around.

12 MICHAEL: And the other really important thing
13 is you've picked 64 chemicals not based on their
14 likelihood for endocrine disruption. All of the other
15 chemicals are going to be put into the normal
16 registration review 15-year cycle. So, there are
17 compounds like vinclosolyn (phonetic) and disulcan
18 (phonetic) and chlorperofos (phonetic) that -- well, if
19 chlorperofos is reviewed now, it's not going to be
20 reviewed for 15 years.

21 We already know these are endocrine disruptors
22 but they've not been screened in the registration review

1 with this in mind. You know, putting known chemicals
2 back on the market without reviewing them and then saying
3 we'll get to them in the 15-year cycle is unconscionable,
4 frankly.

5 MS. EDWARDS: Chrissy?

6 CHRISSY: I have a question about the tier-two
7 slide that you had up, specifically of the mammalian two
8 generation protocol. Do you expect that to be different
9 than the mammalian two generation that is currently used
10 to register pesticides?

11 MR. JORDAN: It's my understanding, and as I
12 said earlier, I'm not the expert on assay validation, but
13 it's my understanding that the mammalian two-generation
14 study that would be part of tier 2 for EESP will
15 correspond pretty closely, if not exactly, to the post-
16 1998 version of the mammalian two-generation reproductive
17 toxicity study.

18 UNIDENTIFIED MALE: As a procedural question,
19 insofar as I understand the entire review process as laid
20 out, it seems to me that everything seems to be moving in
21 blocks as opposed to in streams. I can understand why
22 that would happen sort of at the regulatory and the

1 procedural level.

2 I wonder if you could comment, though, on the
3 screening on the tier-1 and the tier-2 screening as they
4 sort of proceed forward, whether it's EPA's intention to
5 sort of act product by product or active ingredient by
6 active ingredient based on findings, or whether like the
7 validation procedures, like the policies and procedures,
8 they're all going to be treated in blocks and sort of the
9 first action is delayed until the last one?

10 MR. JORDAN: The expectation I have is that we
11 will issue the test orders for the first group of
12 chemicals, some or all of the 73 that were identified in
13 the initial list. Companies will then respond to that.
14 We will begin to start processing things on an active
15 ingredient by active ingredient basis, looking at --
16 companies will say -- request a waiver, saying I don't
17 need to do these studies because of the following
18 reasons. We'll look at that and answer that.

19 They'll have an obligation, then, to do certain
20 kinds of testing. We'll get the results in. As we get
21 the results in, we'll start to evaluate the need for
22 tier-2 type assays. For those chemicals that have the

1 potential to interact with the endocrine system, those
2 that go through the screen and the results are basically
3 clean, well, that will be the end of the story. But I
4 think we'll move at that point to active ingredient by
5 active ingredient basis.

6 Now, there is a hope and an expectation that
7 once we get the data in for the group of chemicals that
8 are the first to receive this initial round, that we'll
9 go back and have enough information in order to be able
10 to fine tune and make refinements to the tier-1 battery.
11 This was a recommendation from the FIFRA scientific
12 advisory panel to see what happens across different
13 chemicals and perhaps we'll be able to get by with fewer
14 tests.

15 Perhaps we'll discover things about chemical
16 classes that might allow us to adjust the way the tier-1
17 battery operates. But that will be an undertaking that
18 happens after we've had a chance to get in all of the
19 tier-1 assays and look comprehensively at them.

20 MS. EDWARDS: Okay, thank you very much. I
21 think now we'll move to the endangered species session.
22 Thank you, Bill and Bill.

1 MR. BRADY: Okay, as Debbie said, my name is
2 Don Brady. I'm the new director of Environmental Fate
3 and Effects Division. So, this is my -- to pick up on
4 Bill, this is my pepperoni meeting, my second PPDC. It
5 didn't work for Bill either.

6 I wanted to just pick up today on Jim
7 Gulliford's point, one of the points he made in the
8 opening, that what we want to share with you today is
9 part of this evolving process that we here in the
10 pesticide office are going through with, in this case,
11 national marine and fishery as we respond to the first
12 biological opinion that we have received from them.

13 So, Artie Williams is going to take folks
14 through a few slides today that describes the steps
15 undertaken relative to the first biological opinion,
16 applicant opportunities for participation, and public
17 opportunities for participation.

18 So, Artie, if you would.

19 MS. WILLIAMS: Good morning. It's a pleasure
20 to be here again and address what seems to be an ever-
21 growing group, my goodness. I think we need a new
22 facility, Debbie. It's getting too small -- new building

1 -- either that or my eyes are getting worse. I remember
2 last time I could see about halfway to the end and this
3 time I can't even see halfway to the end. So, if I can't
4 recognize your name, I apologize. I'll do the best I can
5 with the eyes God has given me.

6 We would like this morning to talk to you for a
7 short time and then open it up for discussion about the
8 items that Don mentioned. One of the things I wanted to
9 do was kind of try and explain what the process is
10 normally that we foresee when we get a biological
11 opinion. This is demonstrated on this first slide.

12 Basically, the clock starts for consultation
13 once a complete package is provided to the service. I'll
14 use service as shorthand for both national marine
15 fisheries and U.S. Fish and Wildlife service. There's a
16 90-day clock normally in which the service will develop a
17 draft biological opinion. Working with the action agency
18 -- in our case, that would be us -- and the applicant --
19 in the pesticide world, that would be the registrants of
20 the chemicals to develop that biological opinion.

21 After that 90 days, a draft would be provided
22 to the action agency, EPA, and there would then be a

1 period of about 45 days in which EPA and the applicant,
2 the registrant, if they requested a copy of the draft,
3 could take a look at it, provide comments. Then, after
4 that 45 days, a final biological opinion would be issued
5 by the service. Now, that's kind of the ideal time
6 frame.

7 Obviously, there are exceptions to every rule.
8 I don't really want to focus on the exceptions today in
9 the normal context of things, because it's kind of an
10 abnormal issue that we're dealing with right now. I
11 think I would be -- your time would be better spent
12 focusing on that.

13 On the left of this slide is the same graphic
14 that you just saw. But added to it on the right hand
15 side are the things that EPA anticipates doing during
16 that 45 days in which we've got the draft biological
17 opinion to look at. What we plan to do during that 45
18 days is a couple of things both internally and
19 externally.

20 The first is to use that time frame to obtain
21 input on any reasonable and prudent alternatives or
22 reasonable and prudent measures that the services provide

1 in their draft biological opinion. Now, these are
2 alternatives to the action which are -- it's an
3 alternative to the normal registration of a pesticide in
4 this case that the service recommends to avoid jeopardy
5 in a situation where they've determined that the
6 pesticide's use causes jeopardy. Reasonable and prudent
7 measures are measures that the service tells EPA they
8 believe need to be taken -- steps with the action that
9 need to be taken to avoid take.

10 So, we would be obtaining public input on those
11 measures and alternatives which ultimately would be
12 translated into label changes for a pesticide, which is
13 why we want some input on those, because they directly
14 impact the registration status, they directly impact
15 people using the pesticides. Hopefully, they'd directly
16 impact in a positive way the environment.

17 So, during that 45 days we would take comments
18 on those. We would also attempt to sponsor some meetings
19 between the service, EPA and the applicants, in this
20 case, the registrant, to allow the registrant to engage
21 in a discussion with the service about the registration
22 of their chemical and about the draft biological opinion.

1 Thirdly, during this time frame, EPA would
2 formulate its comments on the biological opinion and
3 submit those back to the service in a time frame that
4 would provide the service -- I think we shoot for at
5 least 15 days -- to take a look at our comments and
6 address those.

7 In this process, because up at the top part of
8 it where the service formulates the biological opinion,
9 they're doing that in conjunction with input from the
10 agency and the applicants. We wouldn't anticipate that
11 the comments at the end of the process would be very
12 significant. In fact, ideally, it would be great job,
13 here's what we heard when we took public input, and this
14 is what we think about that. So, that's kind of how we
15 envision the process to go in a perfect world.

16 Now, during this process, there are some
17 specific points where the applicants or registrants have
18 opportunity for participation. These are opportunities
19 that are provided and articulated either in the services
20 consultation handbook, which is a handbook that lays out
21 very specifically kind of what their obligations and
22 processes are during consultation, and also in the

1 Section 7 regulations under the ESA. Some of the
2 opportunities that the applicants have in this process is
3 that EPA would need to provide them an opportunity to
4 submit information during consultation. That goes back
5 to that area where the service is developing their
6 opinion.

7 Secondly, they're entitled to review the draft
8 biological opinion. We have to make sure that we provide
9 that to them if they choose to look at that and then
10 provide comments on that.

11 Thirdly, the services are obligated to discuss
12 with the applicants the basis of their biological
13 determination and to seek the applicant's expertise in
14 identifying reasonable and prudent alternatives or
15 measures since the action kind of belongs to the
16 applicant.

17 Then, finally, the services are obligated to
18 provide the applicant with a copy of the final biological
19 opinion for their information. So, there are specific
20 opportunities outlined for the applicant.

21 In terms of public opportunities, as far as I
22 can tell -- and perhaps Rick Sayers can correct me if I'm

1 wrong, but I don't believe there are specific
2 opportunities such as those for the applicant for the
3 general public in the handbook or the ESA regulations.
4 Because of our own -- EPA's own way of doing business,
5 we're trying to provide some opportunities for public
6 input, again specifically not necessarily to the
7 biological opinion, which is a product of the service,
8 but to any reasonable and prudent alternatives or
9 measures contained in that biological opinion, which EPA
10 then would be looking at implementing relative to
11 pesticide use in the field.

12 So, we are trying to provide that opportunity
13 by posting the draft biological opinion publicly on our
14 web site or in a docket so that the public can see what
15 those RPAs and RPMs, reasonable and prudent alternatives
16 and reasonable and prudent measures, are and provide us
17 some input on that.

18 So, that's all kind of in a perfect world. We
19 are currently working with the National Marine Fishery
20 Service. This says the first NMFS biological opinion.
21 It's actually, I'm sure, not the first NMFS biological
22 opinion; it's the first one we've received relative to

1 consultations we've requested over the last several
2 years. But this is the first one that we've been working
3 on with the National Marine Fishery Service in my
4 recollection, which goes back pretty far.

5 The draft biological opinion that was given to
6 us was given to us in a time frame that was driven by a
7 settlement that the National Marine Fishery Service
8 entered into to address litigation that was being brought
9 against them. There was limited opportunity because of
10 the time frame involved to discuss the RPAs and the RPMs
11 with the action agency, EPA, and the applicants while the
12 draft was being developed.

13 The extent of our ability, then, to take
14 comment and to get public input on those RPAs and RPMs as
15 they're being developed kind of goes outside the process
16 that I described in the ideal world.

17 We did publish the draft biological opinion to
18 our web site. We have opened a docket to contain that
19 and to take comment. But the fact of the matter is that
20 this particular draft biological opinion does not contain
21 reasonable and prudent measures or alternatives. I think
22 that's a direct result of the fact that there was not

1 time during the development -- adequate time during the
2 development to have that interaction between National
3 Marine Fishery Service, the agency, and the applicant to
4 look at reasonable and prudent alternatives or measures.

5 So, this first one that we're trying to get
6 through already right from the start falls outside kind
7 of the norm. So, we're kind of struggling with a couple
8 of things which we'll point out in a couple of slides.

9 Just to give you kind of a chronology of this
10 one, we received the draft on July 31st. We posted it,
11 as I mentioned, to our web site, and we did establish a
12 public docket to receive comments on the RPAs and RPMs.
13 Again, unfortunately, there weren't any to comment on at
14 this point for this particular biological opinion.

15 We intend to use that docket and the web site
16 mechanism for future biological opinions as well to make
17 sure that we can get that in front of the public and get
18 comment on RPAs and RPMs. We've prepared and provided
19 EPA's comments on the draft, and those two are posted to
20 our web site.

21 Since July 31st, we've hosted two meetings and
22 one phone call among EPA, National Marine Fishery

1 Service, and the applicants for the chemicals involved in
2 this first biological opinion under the Section 7
3 regulations and the opportunities provided to the
4 applicant laid out in the complication handbook.

5 We also are scheduling at the current time a
6 meeting between EPA, National Marine Fishery Service and
7 the applicants for a couple weeks out from now, mid-
8 October, to further discuss the basis for the draft
9 determination and the science behind that. If you'll
10 recall, that's one of the opportunities for the applicant
11 is to have the service discussed within the basis of the
12 biological determination. That's going to take place
13 mid-month this month.

14 Now, the kicker in all this is that the final
15 biological opinion is due out under the settlement
16 agreement that National Marine Fishery Service is working
17 under by October 31st. So, you can see the time frames
18 here have been and continue to be very tight.

19 Finally, kind of in this litany of things that
20 have happened since July 31st, I wanted to point out
21 again that while the docket was established to -- as a
22 mechanism to make public and gain input on RPAs and RPMs,

1 that obviously hasn't been able to occur since those
2 weren't developed yet.

3 It is EPA's intention, however, when we receive
4 the final biological opinion, that will contain those
5 reasonable and prudent alternatives or measures to take
6 public comment on those prior to implementing in the
7 field in response to the biological opinion.

8 Then, finally, just to wrap up the talking head
9 and open this up to discussion, just a couple of things
10 that I wanted to point out that we're kind of grappling
11 with right now. The settlement agreement that National
12 Marine Fishery Service entered into calls for the
13 development of nine separate biological opinions covering
14 I think it's 37 chemicals on which we've initiated formal
15 consultation with them.

16 This first one addressed three chemicals,
17 chlorperofos, malathion, and diazinon. The second is
18 going to address three other chemicals. Then, after
19 that, there's like a group of 10, a group of 2, a group
20 of 3. The dates go out to the final one being delivered
21 on February 29th, 2012.

22 For this first one, it's my understanding only

1 for this first one, the settlement agreement required
2 that National Marine Fishery Service make the draft
3 available to the plaintiff in the case and make it --
4 well, if it didn't say to make it publicly available,
5 they made it publicly available and posted it on their
6 own web site. I don't believe that's a requirement for
7 the rest of these. And it's not clear to me for the rest
8 of these when EPA will actually receive the draft
9 biological opinion.

10 Because that's not clear, it's not clear
11 whether for the rest of these there will be better
12 opportunities to get public involvement or an equal
13 opportunity for us to get public involvement in RPAs and
14 RPMs. So, it's kind of an unknown area for us right now.

15 Assuming that we will have limited time on the
16 remainder of these as well as we have on this first one,
17 the questions we're kind of struggling with are, what
18 kind of public process can be structured in cases like
19 this to get input on the RPAs and RPMs? If we receive
20 drafts that do not have RPAs and RPMs on them, should we
21 continue to publish those even though what we really want
22 comment on is the RPAs and RPMs? Finally, what can EPA

1 do to ensure meaningful input on those measures if we
2 don't have an opportunity to get input until after the
3 biological opinion is final?

4 So, under the ideal process, we kind of know
5 the path forward. But under these kind of unusual
6 circumstances, we're struggling with this. So, with
7 that, I'll stop and get us almost back on schedule and
8 see if there are questions about this that I can help
9 answer or if you have suggestions for us on how we can
10 proceed under these circumstances with these opinions.

11 Thank you for your attention.

12 MS. EDWARDS: This time let's go
13 counterclockwise.

14 Susan.

15 SUSAN: Thanks, Artie, for the update. We do
16 appreciate your attention to the possibility of public
17 comments on this. It's very important.

18 I do have a suggestion for how to do this.
19 Like the re-registration division did on the fuming and
20 cluster assessment, they five -- they put out a set of
21 possible mitigations. Once people could see what the
22 possibilities were, then there were at least

1 opportunities for comments. These could be -- and it
2 depends on the pesticide, but there won't be -- well,
3 they're going to be different from pesticide to
4 pesticide, but there's going to be a lot that are
5 consistent, you know, like reducing application rates,
6 reducing number of applications perceived.

7 You know, there's some things that will show up
8 over and over again. So, at least you can have something
9 in that blank space there for people to think about and
10 comment on and add suggestions.

11 MS. WILLIAMS: Thanks. I think that's a really
12 good suggestion and I think if we have an opportunity in
13 that diagram in the box where the biological opinion is
14 being developed, if we do really have a really good
15 opportunity there to work with the National Marine
16 Fishery Service in this case and the applicants, I think
17 that would be a great approach if we could come up with
18 kind of an array of options for people to comment on.
19 So, thank you for that.

20 MS. EDWARDS: Julie.

21 MS. SPAGNOLI: Julie Spagnoli, FMC. Right now
22 I know these are being driven primarily by settlements

1 and litigation, but the plan was to kind of incorporate
2 this into the registration review process. I guess, just
3 from the framework, how will this, from a timing
4 standpoint, be worked into the registration review
5 process? Will it be part of the final work plan? Will
6 it be more towards the end after assessments are done and
7 decisions are being reached? I'm just kind of curious
8 how they see this fitting into the registration review.

9 MS. WILLIAMS: Thank you, Julie. I'll try and
10 answer that and you can tell me if I got the question
11 right.

12 Our plan for registration review is that in the
13 final work plan, we will be articulating what assessments
14 we need to do and how we plan to proceed with those,
15 whether there's data required before we begin or we're
16 going to begin right away, and a time frame for
17 ultimately public comment on the risk assessment would
18 be.

19 Our intention is that that risk assessment that
20 EPA would take public comment on would contain our full
21 analysis of endangered species, in quotations, along with
22 the normal eco-assessments for the entire scope of use of

1 that chemical. It's our intention to initiate
2 consultation, if that's appropriate, as part of kind of
3 the close out for that chemical, not necessarily to
4 complete consultation in that time frame, because that's
5 anybody's game.

6 That's kind of our process. Now, how these
7 litigation-driven consultations fit into that process is
8 another area that I'm just not real clear on at this
9 point. Certainly, if we complete one of these and then a
10 year from now we're assessing the chemical, what we've
11 done today will be considered in our assessment of that
12 chemical. But, beyond that, I'm not sure how they hook
13 up. It's not our intention to keep moving registration
14 review chemicals to match up with litigation schedules, I
15 do know that. That's not our intention.

16 UNIDENTIFIED FEMALE: Well, unlike the
17 endocrine disruptor program, this program is really old.
18 We all know that most things don't age well except for
19 maybe some expensive alcoholic beverages. So, my concern
20 here is not that we don't have enough public
21 participation, although I certainly commend you for
22 worrying about that and making sure that we do. My

1 concern is when are we going to get something going on
2 the ground here. You know, these species are probably
3 dying out. I hate to be macabre about this, but they
4 probably are.

5 So, I'm wondering if there's a role here, Rosen
6 and Al (phonetic), for agriculture to play. You know,
7 RCS, perhaps, can get involved and offer some incentive
8 to people, you know, in the agricultural realm to
9 implement some habitat protection and other things as
10 part of a cost-share program or something like that. We
11 ought to be thinking about ways to get something going on
12 the ground once we get these decisions made.

13 UNIDENTIFIED MALE: Debbie, may I?

14 MS. EDWARDS: Sure. Sure.

15 UNIDENTIFIED MALE: Carol, I think you do
16 understand that there are a number of programs in RCS
17 that are directed towards wildlife development.

18 CAROLINE: Yes.

19 UNIDENTIFIED MALE: With respect to the actual
20 pesticide registration area, obviously, the use,
21 patterns, and the registrations themselves, I don't know
22 that we have a direct role that would be feasible in

1 playing in that. Obviously, we have a very strong
2 interest in cooperating with EPA in developing whatever
3 information we can to assist their efforts.

4 CAROLINE: Is this something we could explore,
5 do you think?

6 UNIDENTIFIED MALE: Certainly. I've taken
7 notes during this.

8 CAROLINE: Okay.

9 MS. WILLIAMS: If I could just add to that, one
10 way in which we see, hopefully (inaudible), USDA playing
11 in this is when we assess a chemical's potential impact
12 to listed species and identify areas where there are
13 issues, USDA is one of the main people that we're going
14 to be discussing with what can the growers do to mitigate
15 this, and can you reduce application rates, can you soil
16 incorporate, can you get rid of aerial applications?
17 Let's just talk about what's feasible in terms of
18 reducing the impact while continuing to provide tools for
19 agriculture, if we can do that.

20 So, I know we're planning on using USDA
21 significantly when we start making those decisions, which
22 should be in the not-too-distant future, by the way. I

1 think the first two under registration review are due to
2 be out for public comment before the end of this year.

3 CAROLINE: And do they know that, that you're
4 going to be using them significantly to do this?

5 MS. WILLIAMS: I sure hope so. I've been
6 telling them that for ages.

7 CAROLINE: Who will you be working with?

8 MS. WILLIAMS: Well, I would be contacting
9 Burleson (phonetic). He would be telling us how to get
10 to the field people that we need to get to, depending on
11 what the chemical is. You disagree with that? Okay.

12 UNIDENTIFIED FEMALE: I wanted to echo what
13 both Susan and Caroline said. Also, I have a question.
14 I apologize if I missed this, but why is it that the RPAs
15 and RPMs are not in the draft biological opinions?

16 MS. WILLIAMS: I'll tell you what I believe to
17 be true. I'm obviously not the National Marine Fishery
18 Service who drafted the opinion, so I can't tell you
19 specifically. It's my understanding that because of the
20 time frame in which they were obligated to issue a draft,
21 there was not time to engage the agency and the
22 applicants in a discussion of RPAs and RPMs, so they were

1 not included in the draft. That's my understanding.
2 Anything more factual than that would have to come from
3 National Marine Fishery Service. But that's my
4 understanding.

5 MS. EDWARDS: Dennis.

6 DENNIS: Thanks for the presentation, Artie,
7 and the questions. I'm going to confess to being a
8 little bit naive on RPAs and RPMs. RPMs I understand
9 from my tachometer, but that's about it.

10 Could you just give a brief primer on what
11 those are and how they work? Then I'll have one more
12 question for you.

13 MS. WILLIAMS: Actually, if I could bother Rick
14 Sayers to do that, I think he can probably do it better
15 than I.

16 MR. SAYERS: Sure, Artie, I'm happy to. RPA
17 stands for reasonable and prudent alternative. RPM
18 stands for reasonable and prudent measures. They're
19 applied at very different points in the process. RPAs
20 will only be involved if you have a biological opinion
21 that says the proposed action is likely to jeopardize the
22 continued existence of one more or species or to cause

1 destruction or adverse modification of critical habitat
2 for one or more species. So, you only talk about RPAs
3 when you have either jeopardy or adverse modification.

4 RPAs are alternatives to the proposed action
5 that we think would avoid jeopardy or adverse
6 modification, are consistent with the intent of the
7 action, are within the scope and authority of the action
8 agency or their applicant -- and I had to make notes to
9 myself to remember all four -- and are technologically
10 and economically feasible.

11 So, basically, RPAs are we've reviewed the
12 action, we think it's likely to jeopardize or cause
13 destruction or adverse modification. But here's a
14 different way that you might be able to undertake the
15 action and still go forward and be consistent with the
16 Endangered Species Act. There's really no limitation on
17 the extent of those changes other than the four things
18 that I mentioned that can come through an RPA.

19 RPMs, reasonable and prudent measures, are part
20 of an incidental take statement. Incidental take
21 statements only come at sort of the tail end of the
22 biological opinion document, after we've been able to

1 decide that there's not going to be jeopardy or we
2 present it in RPA. We will then include an incidental
3 take statement with reasonable and prudent measures.
4 Those are measures designed to avoid or minimize the
5 amount or extent of incident take that will occur if you
6 implement that action, either the originally proposed
7 action or the alternative action that came from the RPA.

8 The big difference between RPMs and RPAs is
9 that RPMs are limited to what's called the minor change
10 rule. There's some regulatory language that basically
11 says anything you put forward as an RPM has to be a minor
12 change to the project.

13 Does that help?

14 DENNIS: I got more than I expected. Thank
15 you.

16 MR. SAYERS: Sure.

17 DENNIS: I guess the other question would
18 probably go to you as well. Artie mentioned that the
19 services consultation handbook doesn't provide an
20 opportunity for public comment. I wondered if the
21 services are thinking of amending the handbook to allow
22 that in the future?

1 MR. SAYERS: Probably not as long as we have
2 the current statutory framework, which, if you look up
3 there, you'll see this whole thing is supposed to get
4 done in 135 days. There just isn't much opportunity
5 within that time frame to go out for public comment on
6 the services analysis. We're going to have to -- if we
7 want to do that, it's going to have to be with the
8 cooperation of the action agency to allow us enough time
9 to do that.

10 MS. EDWARDS: Jay.

11 JAY: Artie, in the case now that you have in
12 front of you with draft biological opinions associated
13 with the court supervised settlement, I presume that the
14 Justice Department is the interface with the court
15 authorities for the federal government. So, what sort of
16 visibility does the agency have in that process
17 dynamically and as well USDA going forward and other
18 opportunities for greater clarity if the agency has more
19 direct transparent kind of interface with court
20 supervisors?

21 MS. WILLIAMS: I know that this particular suit
22 was filed against the National Marine Fishery Service.

1 We were not part of that suit and we -- in any way. So,
2 we weren't involved in developing or reviewing or signing
3 on to the settlement agreement. I don't expect, although
4 I don't know this, that we would have any more clout in
5 it now that it's signed. So, as far as I can tell, we're
6 really just observers and trying to go with the flow here
7 on this one. I don't think I have my counsel here with
8 me. They could probably answer that in far more details,
9 but that's about all I can do.

10 UNIDENTIFIED MALE: I'll speak briefly on
11 behalf of NMFS on this one. The original issue was
12 failure to consult. EPA entered into consultation,
13 presented the material to NMFS and basically NMFS kind of
14 -- and we've done this, too, so I'm not pointing the
15 figure -- taken too long. So, the plaintiffs got a
16 little tired and filed a claim for unreasonable delay in
17 making a decision. So, at that point, DOJ really didn't
18 have much defense other than to say we'll agree to get it
19 done by a date certain. At that point, it really was
20 between NMFS and the plaintiffs as to working out
21 something that would be acceptable.

22 MS. WILLIAMS: I do have counsel in the room

1 who is hiding in the back and he informs me that we
2 actually did have an opportunity to see it before it was
3 signed and did provide some comments. What was done with
4 that comment was up to DOJ, apparently. But we did
5 actually have an opportunity to look at it. I'm going to
6 ask him to sit here in case there are any more legal
7 questions.

8 MS. EDWARDS: Joe.

9 JOE: Good presentation, Artie, and good luck.
10 I would just ask that you keep AMCA involved in the loop
11 on this, as you're going to do with USDA, because, as you
12 well know, our application parameters are very, very
13 different. I notice you caught that 30-foot AGL that the
14 National Marine Fishery Service was using in our
15 application, which is grossly inaccurate and would have
16 skewed the results considerably. So, I would just ask
17 that you keep us in the loop on that. I'd appreciate it.
18 Thank you.

19 MS. WILLIAMS: Thank you. So noted.

20 MS. EDWARDS: Mark.

21 MARK: As I mentioned at our last PPDC meeting,
22 I think that in many ways the affected community, largely

1 landowners, have little alternative in this process and
2 got educated a little bit on Safe Harbor and some of the
3 provisions there. I just wanted to bring the PPDC up to
4 date on some of the things that we've done in Michigan
5 relative to the Karner blue butterfly, which is kind of,
6 you know, an icon of endangered species in the upper
7 Midwest.

8 We've surveyed now with a number of services
9 involved and Michigan State University and we've looked
10 at nine counties now with the Michigan natural
11 inventories and looked at with the forest service, with
12 USDA and RCS. We've identified over a thousand growers
13 affected. Of those, in the cherry industry, 42 of them
14 are willing to do something in Safe Harbor.

15 The incentive, though, is, are there public
16 resources available to help them do transition, because
17 where we're at in this situation is that we've gone out
18 during the two generations, surveyed all these sites with
19 cooperation with the natural futures inventory and forest
20 service and MSU and some of the county extension
21 organizations and we've found no Karner blue butterflies
22 in these sites during the two peak flight periods when

1 they're most visible.

2 That isn't to say that the people who did it
3 weren't informed or knowledgeable or able to identify
4 Karner blue because in the morning we surveyed sites in
5 the national forest that we would see up to 400 or even
6 600 in trends that count. So, people could identify
7 these butterflies.

8 So, the end process in this were that we ended
9 up with a bunch of growers who are very interested in
10 Safe Harbor and very interested in essentially farming
11 Karner blue butterflies by altering habitats to
12 accommodate them.

13 Where do the resources come from? Where is the
14 incentive to do it? There's a lot of negative incentive.
15 If they get a take or get found out before the Safe
16 Harbor provision is in place, then they're liable. On
17 the other hand, the kind of processes that NRCS has done
18 in state -- we've had a thing for native pollinators and
19 some new plantings and some dollars to be available for
20 that. But there really isn't in NRCS or USDA that I'm
21 aware of the means to take this home and bring it home.

22 I'm convinced, understanding the biology of

1 Karner blue butterfly and the habitat it requires that
2 the key to this is the private sector. I think the
3 private sector could save Karner blue butterfly in 10
4 years if the incentives were there.

5 MS. EDWARDS: Thank you.

6 Rick.

7 RICK: Thanks, Mark. I was hoping you'd bring
8 up the Safe Harbors. Getting back to Caroline's question
9 earlier, I think there are a lot of opportunities to
10 explore the Safe Harbor approach in conjunction with some
11 farm built programs. There's a fairly big infusion of
12 funding into the farm built programs I think in '09. I
13 can't remember. It's coming up pretty soon. We have
14 been talking to folks at NRCS about possibilities for
15 that.

16 They're not the easiest programs to get on the
17 ground. They do have a fair amount of bureaucracy that
18 go along with them, so it's not something that you can
19 just walk in, fill out a form and you're all done with
20 it. I wouldn't want to mislead anyone to thinking that.
21 But I think there is a lot of opportunity there.

22 The other thing I wanted to point out for

1 everyone in the group is the services have a proposed
2 regulation out right now to make some fairly significant
3 changes to the Section 7 consultation process. The
4 comment period, I think, is open until October 15th. I
5 know it's a little bit longer anyway. I'm not sure if
6 the 15th is the exact date. I just wanted to make sure
7 everyone was aware of that. Take time if you're
8 interested to look at that and get your comments entered
9 in through regulations.gov portal or you can send them
10 directly to the Fish and Wildlife Service. Thank you.

11 MS. EDWARDS: Thank you.

12 Cindy.

13 CINDY: I guess I just make an appeal for a
14 process fix here. I mean, if I have ever seen anything
15 broken, this is broken. I mean, it is -- I think the
16 agency is frustrated, all three of them. I think the
17 stakeholders are frustrated in that things aren't
18 happening quickly enough. I think all the people who
19 would like to have input into the process are frustrated.

20 A lot of the comments that I heard deal with
21 the tale end of the process. What are you doing with
22 mitigation alternatives? How do you get comments on

1 those? How do you get comments after the draft
2 biological opinions are released?

3 I really think some effort needs to be put into
4 the front end of the process which is, are you really
5 modeling what's going on out there? That entails a
6 number of stakeholders. But at least those three draft
7 opinions that I read, and they're not specifically my
8 product, appears that, you know, a lot of work could have
9 been done up front to prevent the outcome that was there.

10 I don't know why that doesn't happen. I don't
11 know if it's resources or time or what it is, but this
12 process is huge. It has tremendous impact. It is using
13 up very limited resources already for all three agencies.
14 So, it seems to me that a real process transparent
15 understanding of what's going on here is needed.

16 Now, obviously, you're just one of the three
17 agencies. You can't dictate that and put it together.
18 But if anything is screaming for three agencies to get
19 together and figure out how you're going to do it, it
20 seems to me that this is it and that there could be
21 some --

22 I mean, it's not in the best use of NMFS or

1 Fish and Wildlife Service, who have very limited
2 resources in this area, to put something out that could
3 have been, you know, benefitted from some input in the
4 beginning. It's not in EPA's interest to have to go back
5 and look at that and respond to it. It just doesn't seem
6 like it's fitting anybody's interest what's being done.

7 So, I would just encourage to what extent
8 possible we could find a way to develop a process here
9 that involves people who want to be involved and it has a
10 sustainable process going forward because the issue isn't
11 going away. It's only going to get worse as we get
12 through these lists. So, we've got to find a way to deal
13 with this in a way that addresses all those things.

14 MS. EDWARDS: Thank you.

15 Michael.

16 MICHAEL: Thanks very much for this
17 presentation. I've learned a great deal. Rick Sayers
18 answering that question I think was very informative to
19 me. I'd just like to follow up on that just slightly to
20 make sure I've got my understanding right of RPAs and
21 RPMs.

22 Given a chemical like diazinon, the RPA, I

1 would assume, would be not using that chemical but using
2 nonchemical methods or some other chemical instead.

3 Whereas, RPMs would be using the diazinon but at some
4 sort of mitigation, either tail water ponds or increased
5 buffers around the field or reduced application rates,
6 that kind of stuff? Are those the --

7 MR. SAYERS: Well, the answer is maybe. If the
8 action that EPA has before it is to register diazinon, we
9 can't give an RPA that says don't register diazinon
10 because that doesn't meet the purpose of the action. So,
11 in that case, it might be can you register diazinon or
12 more limited use? Could you perhaps exclude -- if it was
13 just one species that the narrow endemic, could you
14 exclude use of the product in that, you know, habitat for
15 that narrow endemic species?

16 But it would not be an RPA in that case to say
17 don't register diazinon, because it's not consistent with
18 the proposed action.

19 UNIDENTIFIED MALE: If could just -- one final
20 thought. We have worked on process -- and I've only been
21 through it for a little over two years. Every time we've
22 thought we've had an agreed-to process, even as it's been

1 putting in the handbooks and guidance, it turns out that
2 it really isn't an agreed-to process because it doesn't
3 get followed.

4 What we believe from a process standpoint is
5 that we've got to grind ourselves through several of
6 these until we can see what a final outcome is. One of
7 the things we're considering is some type of a keystone
8 stakeholder process or meeting to bring all the
9 stakeholders together and look at how one or two or three
10 of these have worked and to offer again good advices to
11 what we can do to improve the process.

12 We think we may be a year or more away from
13 that because we've got a ways to go to get through even
14 the ones where we've gotten draft biological opinions and
15 the outcomes of those are still considerably down the
16 road. We absolutely agree that there's got to be a
17 process.

18 We would have never got through registration
19 review -- excuse me, re-registration without a process
20 that was very clear on what was expected in terms of the
21 inputs into it, the review opportunities for all
22 stakeholders, and time lines that everyone was committed

1 to meeting to get that done.

2 Again, if we haven't got sound science
3 agreement, we've got transparency in the process, if we
4 haven't got commitments to time limits, we're not going
5 to get through all of these that are out there. So, we
6 want to get to that. I think the services do as well.
7 But we're going to have to grind through these. That's
8 the only way we can see, because it hasn't helped to
9 develop documents on process that haven't been followed.

10 MS. EDWARDS: Mark, is your card up? We'll
11 take one last comment here.

12 MARK: I forgot to mention something that's
13 near and dear to my heart, and that is the whole process
14 that EPA is moving ahead to do to -- in the case of
15 endangered species relative to mapping and delivering
16 web-based systems is really crucial to this issue,
17 especially the effected community on the ground, growers.

18 The comment I wanted to make was with specific
19 data. When we look at the map that are available through
20 the current process and then actually go out and do
21 surveys on the ground, there's such an incredible
22 discrepancy on what's real. We're far from -- this is

1 not lost on Artie or anybody else, I'm sure. We're far
2 from having good maps for the affected community to live
3 by.

4 I think this is one of the real technological
5 problem areas to actually get a fair system of
6 promulgating this on the land when maps are pretty
7 egregious at this point.

8 MS. EDWARDS: Okay.

9 MS. WILLIAMS: Thank you.

10 MS. EDWARDS: I appreciate the dialogue on this
11 today. As you can see, it's one of our most challenging
12 issues and continues to be one of our most challenging
13 issues. We appreciate your thoughts and not just here
14 today but as you think of other ideas as we move forward,
15 we'd be more than happy to hear them, to meet with you,
16 whatever you'd like to do.

17 Let's take a break until 11:00. See you then.

18 (Whereupon, a brief recess was taken.)

19 MS. EDWARDS: Okay, thank you. We will begin
20 now. This is Session Number 3 on the workgroup on
21 comparative safety statements with Marty Monell.

22 MS. MONELL: Okay, thank you. If you all will

1 recall at our last PPDC meeting in the spring, at the end
2 of the session Debbie indicated that there had been a
3 request for multiple sources riding the tide of all
4 things green to enable for benefit of the consumer and
5 thus also for the marketers to put some sort of safety or
6 green statements on the pesticide product labels.

7 So, thus was formed a very lengthy named
8 committee under the auspices of this committee. It's a
9 work group. We've shortened it to comparative safety
10 statements on pesticide labels -- product labels. We
11 have 32 members, just a little mini PPDC. It's very well
12 represented, I think, in terms of diversity of interest,
13 a few different stakeholders.

14 We have green cleaning organizations in
15 addition to retail and consumer interest, environmental
16 and public interest, educational and public foundations.
17 We have the industry obviously represented by itself and
18 through trade associations, states. States are very
19 interested in this issue and other federal agencies,
20 especially Federal Trade Commission.

21 We had the first meeting in early September and
22 what we decided to do was to start out with everybody

1 sort of on the same page in terms of awareness of what is
2 currently going on in this kind of -- this area. So, we
3 had presentations from our sister organization, the toxic
4 program, which runs a design for the environment program.

5 We also had a presentation from Greenfield,
6 which is essentially a third party certification program.
7 We heard from Energy Star which is run by EPA's air
8 program. We also heard from USDA's organic certification
9 program with which everyone, I'm sure, is familiar.
10 Then, another third party certification program which is
11 the Eco Logo program run by Carrot Choice (phonetic).
12 They operate both here and in Canada.

13 After we heard all those presentations, we
14 broke up into a couple of work groups, breakout groups,
15 primarily because of our size. We thought it really
16 wasn't conducive to discussions. We basically asked
17 folks how they felt -- is this something that the
18 government, EPA, OPP, should actually pursue? Is this
19 properly a government function? If so, if the answer to
20 that is yes, then how should we run the program? How
21 should we implement it?

22 Should it be -- should we actually allow

1 comparisons to be made on labels or should we just go
2 with straight factual statements about the ingredients?
3 Should we do it ourselves here at EPA? Should we run the
4 program or should we basically rely upon a third party
5 certifying organization?

6 We batted that around quite a bit and then we
7 had a report out and a plenary session in the afternoon
8 that basically there wasn't final agreement on much of
9 anything other than the fact that EPA should definitely
10 pursue this, that there was a great deal of interest both
11 from the consumer point of view and the marketing point
12 of view to pursue something like this for pesticide
13 products. This is already available in many of the
14 chemical areas but not in pesticidal products.

15 So, then we had -- in addition to the fact that
16 this is something -- the decision that this is something
17 we should pursue, there was also unanimous consensus that
18 there's a need to have this all based on sound science,
19 that we have data supporting whatever claim we allow.

20 So, then we had a second meeting just yesterday
21 afternoon. We heard from the Federal Trade Commission,
22 basically on what their role is in all this vis-a-vis the

1 advertising claims that companies might make. They have
2 a very similar statute insofar as products cannot be
3 labeled or advertising cannot make claims that are untrue
4 and that are not based and supportable and verifiable by
5 data. It was very interesting.

6 There is a bit of an overlap between the
7 jurisdictions. He wasn't exactly sure how FIFRA would be
8 interpreted by the FTC in terms of a compliance
9 situation. Clearly, it would be something that we would
10 work with them on when we get to the point of having to
11 address compliance kinds of issues.

12 We also heard from EPA's executive for standard
13 setting, Mary McKeil (phonetic). The agency does produce
14 a lot of standards. They're particularly interested in
15 voluntary consensus standard development. So, she
16 addressed and was very interested in the proposals that
17 we were batting about in terms of setting some sort of
18 standard for the claims that folks may want to make on
19 their product labels.

20 We then had a very long discussion of the scope
21 of this effort. I'm not sure if you all are aware but
22 there was legislation introduced by Senator Feinstein

1 recently on eco-labeling. Essentially, that particular
2 piece of legislation would set up a body within EPA to
3 look at basically cradles to grave kinds of
4 determinations as to the environmental and health claims
5 to be put on labels. There's a whole very elaborate
6 structure that is envisioned in that legislation.

7 That is not what is the focus of our work
8 group. We're looking at what is inside the bottle, the
9 product that's inside the container, and not taking the
10 very broadest outlook that that piece of legislation
11 envisioned.

12 We also talked about -- as I said, there was a
13 lot of discussion of all of the same issues that had been
14 raised at the first meeting. So, we decided to focus the
15 discussion by way of three areas. We have subgroups to
16 the work group that will be pursuing these areas.

17 One of them is there seems to be a desire and
18 sort of a common sense desire to enable products to
19 contain factual statements on them. Right now, if you
20 have a reduced risk designation, you cannot state that on
21 your label. Then, there were other items that came out
22 as things that folks would be interested in seeing on a

1 label or that companies would be interested in putting on
2 a label. So, there's going to be a subgroup that will be
3 tackling those particular ideas.

4 Then, there is a group that's going to be
5 looking at the institutional and industrial products. We
6 thought this was an area that might be ripe for perhaps a
7 pilot to see what something might actually look like,
8 what a program might actually look like. There are
9 already programs in place that enable nonpesticidal
10 chemicals to make claims in this area.

11 The states are very interested in this. In
12 fact, I think 16 states have procurement laws that
13 require the purchase of products that have this sort of
14 designation as being green. So, there's going to be a
15 group that will be looking into the possibility of keying
16 up a pilot around that particular area.

17 Then, lastly, there is a group that -- thank
18 you, Julie and Bob Rosenberg, they are heading up --
19 which is basically to look at a broader picture of this
20 effort and come up with two or three different ways of
21 approaching the problem. It would hopefully encompass
22 models that might either have comparative statements or

1 just a strict statement against a standard. It would
2 talk about the use of logos versus just factual
3 statements. There is a lot of concern that if you put a
4 logo on a label, the consumers will not read any more of
5 the label and thus there will be -- that could cause some
6 harm.

7 So, in addition, this group that's -- the
8 umbrella group is going to come up with sort of a
9 decision tree so it will help focus our discussions going
10 forward because there are so many issues to be fleshed
11 out that we'll have something for our next meeting to
12 actually chew on.

13 So, all of these groups are going to meet
14 within the next month and share information with a
15 broader groups so that when we meet again on December
16 3rd, we'll be able to talk through the three various
17 products that will be the outcomes of these groups.

18 So, does anybody want to add anything from the
19 EPA team?

20 (No verbal response.)

21 MS. MONELL: Okay. Anybody from the actual
22 work group? Comments? Amy?

1 AMY: I know I've made this comment frequently
2 throughout the work group but I think this group needs to
3 also hear the concern -- one of the concerns being that
4 pesticides are different than some of the other products
5 that their logos in that it takes some action by the user
6 to make use of it safer or not.

7 It's not just the ingredients in the products
8 that determine the safety of the pesticide. It takes
9 paying attention to label precautions like buffer zones,
10 where to apply it, whether to apply it to your vegetable
11 garden or not.

12 So, I'm glad that the group yesterday, which
13 I'm part of, addressed the issues -- does understand the
14 concerns of perhaps consumers not paying attention to the
15 rest of the label if there is a logo there. I do think
16 it somewhat undermines the idea that the label is a legal
17 document and all of these precautions must be followed
18 and use directions must be followed, and that EPA has
19 spent the time developing these labels with these very
20 strict directions. If one product is so-called safer
21 than another product, than why do those restrictions on
22 use exist?

1 So, I think we have to be really careful of
2 that. I think it's going to be very, very difficult for
3 this group to come up with some kind of a system that
4 will be able to take uses into account and how those fit
5 into some kind of a matrix. Very important.

6 MS. MONELL: Thank you.

7 Julie.

8 JULIE: I think one of the things we have is
9 concern for unintended consequences. That's part of it.
10 I think one of the key things that we know and looking
11 especially as we're trying to develop some kind of system
12 for conventional pesticides besides the antimicrobials is
13 that there's now a way that there's going to be a one
14 size fits all or that we can look at one set of criteria
15 or one set of parameters that will be applicable to all
16 kinds of uses or all types of products.

17 So I think we're looking -- you know, I think
18 what we're going to look at is maybe a segment by segment
19 approach, you know, that lawn and garden -- consumer lawn
20 and garden products obviously are going to have a
21 different set of criteria than I&I antimicrobials than
22 would an indoor only use product versus, you know, an

1 outdoor product.

2 We haven't even really approached the idea, I
3 don't think, of agricultural uses or what kind of
4 criteria would be looked at for agricultures. But we
5 definitely know that there's -- with conventional
6 pesticides that there's just going to be no one size fits
7 all or for all types of product.

8 MS. MONELL: Thank you, Julie.

9 Jennifer, is that your sign up?

10 JENNIFER: I haven't been on this work group
11 but, Amy, those are really good points. So, I would be
12 interested in hearing more from the work group about the
13 kinds of issues, not necessarily that we comment on them,
14 but just really understand it.

15 I want to understand something. You mentioned
16 that it's only the contents, is that right? So, you're
17 not looking -- I guess my question is, what about
18 products where it is toxic, it's harmful, like, say it's
19 some kind of a cleaning product or a pesticide product
20 that has a harmful ingredient but that the manufacturer
21 has made it more concentrated?

22 Technically, that would make it more potent,

1 but they've done it -- I'm thinking of like my laundry
2 detergent that I buy. So, it's less watered down, it's
3 cheaper transport cost, it's reduced plastics and
4 containers because they put more potent material in the
5 bottle. Are you consider those kinds of things or not?
6 I think you said it was just the contents and I just want
7 to understand that.

8 MS. MONELL: It's the product, not the
9 packaging.

10 JULIE: No. So, okay. So, none of those
11 things count, really, in this topic.

12 MS. MONELL: Well, that's what our initial
13 effort is geared towards. This is a huge effort to get
14 our arms around in the first place. So, it just seems
15 appropriate to start with the product itself. If this
16 mushrooms off, as we've also agreed, we're not going to
17 limit it to just consumer residential products. We're
18 going to be open to having a discussion about all
19 products. But we're starting with the more consumer-
20 oriented products.

21 MS. EDWARDS: Dave.

22 DAVE: Yeah. I was wondering -- I can how this

1 is a very difficult thing to get your arms around. I was
2 wondering if there is maybe some utility to establishing
3 a set of principles or criteria or something like that to
4 decide whether there's -- this should be even pursued any
5 more, rather than -- because sometimes you get into a
6 process and you just sort of get wedded to the process.
7 Oh, yeah, we're going to figure out how to green label
8 these things or whatever and you forget sight of asking
9 the big question of some of the concerns that have been
10 raised.

11 It sounds like you're very clearly aware of the
12 difficulties and the pitfalls of doing it. I can see the
13 value of consumers understanding products that have the
14 potential for being safer or better for the environment.
15 But then you have, you know, what Amy was just saying.

16 It seems like it might be useful to set up
17 those principles or overall guidelines and say, look, you
18 know, if we can't meet this, there's not really a way to
19 ensure that these criteria are met, then we're just not
20 going to do it.

21 MS. MONELL: During the first all-day session,
22 that's exactly what we did do. We went through both

1 break out groups, went through sort of a pro -- what are
2 the advantages of doing this and then what are the sort
3 of the negative factors that we needed to take into
4 account. After that discussion, it was decided that it
5 was worth continuing the discussion if you will, at least
6 to flesh out all of the issues and really understand what
7 the pros and cons would be.

8 I believe that what Julie and Bob's group is
9 going to entertain is development of some sort of a
10 decision tree that would lead to the ultimate decision,
11 well, this is so complicated, we can't possibly do it or,
12 which is, I think, everyone's hope, including not just
13 the trade folks but the public interest groups, is that
14 we can come up with something that's workable,
15 informative, honest, and understandable. I appreciate
16 the comments because certainly we're all very mindful of
17 that and the need to not just let the momentum carry
18 itself to something that's not workable.

19 DAVE: Real quick follow up. So, will that be
20 forthcoming and that will be maybe something that will
21 get settled early so people have a framework to consider
22 as you continue the overall work of the group?

1 MS. MONELL: That's the plan for the next
2 meeting.

3 MS. EDWARDS: Daniel.

4 DANIEL: I want to just commend you. I think
5 it's really interesting work and important. I know it's
6 a big undertaking. You know, we've been struggling for
7 the last couple of years in New York City trying to
8 really get a handle on how to reduce accidental exposures
9 and medically consequential poisonings to consumer
10 products. One of the things we've been trying recently,
11 we just completed the first 10 of what we hope to be
12 about 20 or 25 interviews with people using
13 symestographic (phonetic) research. Specifically, we're
14 trying to get at this question of how people understand
15 and what they do when they consider what the labels say.

16 You know, without sort of going into some of
17 our preliminary findings so much, the gist of it really
18 is that people largely ignore labels and they bring to
19 the reading of their labels a lot of preconceptions, sort
20 of culturally determined, as well as educationally
21 determined, as well as experientially determined.

22 A lot of what we're seeing, common threads, are

1 first of all that the admonition to use little is sort of
2 interpreted by people as overcautious and they believe
3 that using more is better. You have people believing
4 combining products is better. They believe stronger
5 smell products are more efficacious. I say that in part
6 just to ask a question.

7 At what point in this process might there be an
8 opportunity to sort of inform the logic of people's
9 thinking with more information about how people sort of
10 in the real world actually do read and interpret labels?
11 Is there going to be an effort to solicit comment or sort
12 of research findings on those kinds of issues, because I
13 think it really, as complicated as it is now, I think
14 there's a real chance that the assumption of a group like
15 -- about how people might interpret these things could
16 be, you know, erroneous or not adequately informed.

17 MS. MONELL: Well, we haven't gotten to that
18 point yet in our deliberations. We're sort of at the
19 very beginning of deciding whether we're even going to go
20 this route. But just assuming for the sake of argument
21 that we do go this route, clearly communication is going
22 to be critical to whatever plan we come up with.

1 By the way, the plan comes back here to the
2 PPDC. We're providing you with a recommendation. So, if
3 we -- whatever we come to you with in terms of a
4 recommendation, what I've heard, and I believe is
5 probably totally appropriate, is to include a
6 communication piece in it.

7 MS. EDWARDS: Shelly, then Caroline, then Amy.

8 SHELLY: I commend you for taking on this very
9 complex subject, but I'd like to kind of introduce -- get
10 another complexity. There are efforts in the private
11 sector to develop these kinds of labeling initiatives.
12 One of them is being conducted by ANSI which does a lot
13 of these industry-type standards.

14 In this area related to pesticides, one issue
15 that has come up is the extent to which these labeling
16 initiatives should also -- in addressing the sort of
17 broader sustainability criteria take on labor issues and,
18 not too surprisingly speaking from the Farmer for Justice
19 Fund, we would like that -- you know, the sort of fair
20 labor standards to be part of a mix.

21 So, I guess what I would say is I would urge
22 caution as to where you go with this because there is a

1 wide array of interest that would like to be considered
2 in any kind of labeling thing, in part I think because of
3 what someone may have just said, which is people kind of
4 look upon -- those people who tend to be an influence by
5 these labels will look upon it as your total seal of
6 approval. Folks shouldn't get that unless that's what
7 they're really getting.

8 So, I would just say that if it moves passed
9 the utterly theoretical stage, I think you're going to
10 need a wider array of voices.

11 MS. EDWARDS: Thank you.

12 Caroline.

13 CAROLINE: I wanted to copy (inaudible), just
14 repeat what I said a bunch of times at the work group
15 just for the benefit of the people who aren't on the work
16 group. I look at this very much from a consumer
17 perspective and kind of using as my model the national
18 organic program which I think has a huge amount of
19 consumer credibility at this point. And it's not
20 perfect, but I think consumers all across the country
21 actively search for organic products. They're willing to
22 pay more for them.

1 That's a measure that people -- consumers trust
2 that green label, that logo. If we're going to develop
3 one for pesticides, it needs to have that same level of
4 trust in order for it to be successful. What that means,
5 I think, is that it needs to have a pretty high bar,
6 pretty strict standards, so that when consumers see it on
7 a product, they'll trust it, they'll be willing to, you
8 know, actually actively look for it and they'll be
9 willing to pay more for it.

10 MS. EDWARDS: Thanks.

11 Amy.

12 AMY: Again, I'm all in sympathy for providing
13 as much information as we can to consumers, to growers,
14 to whoever is the user of the pesticide product that they
15 can make informed choices.

16 One of the things that has -- one of the stated
17 benefits of such a program would be moving -- that EPA
18 has said from the first meeting was moving the market
19 toward more acceptable products. One of the things that
20 I see while that seems, again, like a very fine goal, as
21 you move the market away from certain products and you
22 decrease the number of classes of pesticide products

1 available, you are going to drive toward resistance
2 development. So, that's something we would not be -- as
3 a benefit, these are the kinds of unintended consequences
4 that I'm certain Julie and Bob and other people on these
5 work groups will be looking for.

6 But also, again, just to build on Caroline's
7 point, yes, we want to give information out but sometimes
8 there's -- you're choosing between two different risks.
9 A product might have very low human toxicity but very
10 high aquatic toxicity. So, it depends on your situation
11 as to whether that's an appropriate product or not.
12 That's just an example.

13 also, I don't want to see it get to the point
14 where people are applying pesticide products that are not
15 effective for the pest problem and site combination that
16 they have. I don't think most people realize that
17 efficacy data are not a required submission of data for
18 EPA except for sanitizers and disinfectants and for
19 products making a public health claim like controlling
20 mosquitos that control West Nile virus. For those
21 things, you do have efficacy data that have to be
22 submitted. For the others, you don't.

1 So, if it gets to the point where we're
2 encouraging people in effect to use a product that is not
3 effective for the pest and site combination that they
4 have, then you have zero benefits. Why would we be
5 applying any kind of a pesticide, regardless of how small
6 the risk is, that has zero benefits? So, I think we need
7 to be very, very careful as we go forward in this project
8 and program.

9 That's another reason to -- if you are going to
10 go this way, I very much support Marty's stated goal of
11 keeping it to what's in that container. I'm all for
12 social justice and lowered carbon footprint, but if
13 that's how you're making your choice on a pesticide
14 product, you're probably not going to be making very
15 appropriate choices for the pest problem that you need to
16 solve.

17 MS. EDWARDS: Thank you.

18 Cindy, and then Dave, are you up again?

19 CINDY: I'll just make a couple of quick brief
20 comments. I guess I would urge the comments that you've
21 heard around caution in this area and I would encourage
22 the work group as they come out of this to address in

1 addition to the topics that we've been talking about this
2 morning that you shared already on your agenda, what does
3 this mean in terms of resources? I mean, there's a
4 number of things, you know, the agency is trying to do.
5 So, if you can capture it at any sort of a level, what
6 does this mean in terms of resources and what are you not
7 doing to do this? What are some creative ways we can
8 look at this outside of EPA, you know, doing this?

9 I know you have a responsibility that whatever
10 is on the EPA approved label has been approved by you.
11 But are there other avenues to look at things to address
12 some of the things that are coming up, rather than
13 keeping it just in the box of that? So, are there other
14 ways to come at this, maybe, than outside of regulating
15 it through FIFRA, FFCCA or whatever you want to do there.

16 MS. EDWARDS: I should mention that one of the
17 things that became very clear in our discussions
18 yesterday was that the states are critical stakeholders
19 and participants need to be active participants in these
20 discussions. So, Bill Baylick is going to share with us
21 the results of a survey he did in the 16 states that
22 currently have procurement laws around this area.

1 We're going to with SPIRIG (phonetic) and our
2 regions to get some sort of their perspective on this
3 issue and the efforts that are going on in the states.
4 We can't march down this street without bringing our
5 state partners along in the discussions with us.

6 Any other questions, comments?

7 UNIDENTIFIED FEMALE: I just wanted to echo
8 some of the comments that Amy Brown said, and that is how
9 important the label information is and the data that has
10 gone into developing that. At the field level, we're
11 opening ourselves up for a lot of confusion if we start
12 deferring to other authorities or characterizations of
13 risk or appropriate practices. So, I think that really
14 needs to be emphasized with any of these programs.

15 We're going through a lot of this now with
16 retailer pressures on what products and practices to use.
17 The ANSI (phonetic) process was referred to and most
18 people know that that has experienced a lot of questions
19 of authority and credibility right now with regard to
20 sustainable practices. So, I think we really need to
21 rely on information that has been generated in a
22 scientific setting.

1 MS. EDWARDS: Okay. I just wanted to add a
2 comment to this discussion. First of all, I appreciate
3 all the feedback. This is obviously going to be a
4 challenging area for us. That's one reason why we wanted
5 to have a work group in which all stakeholders could be
6 represented.

7 I think as most of you know, in the past our
8 position has been -- and, in fact, our current position
9 is that we don't allow these types of logos and claims on
10 pesticide product labels. The reason, historically,
11 among other reasons, I assume, but the main reason that
12 I've been told is that when we register a chemical or
13 product with the labeling that is on the can, we believe
14 that that means that product, if used according to the
15 directions on the can, can be used safely. So, we've
16 always felt that it might, you know, create confusion, as
17 some people have said here in the marketplace, to start
18 trying to distinguish when EPA -- the force of the
19 government's Environmental Protection Agency is behind
20 the safety of every single product.

21 So, having said that, someone else pointed out
22 over the years there's been a lot of pressure through

1 retailers and certain companies to want to try to make
2 distinctions. There may be many, many reasons to do that
3 but one of which is obviously to do with having an edge
4 in the marketplace. If you're selling a product that's
5 claiming to be -- to have greener or safer
6 characteristics, the view, I believe, is that someone
7 will presumably buy that.

8 That's not our interest. That's not our role.
9 We don't sell pesticide products either to retailers or
10 -- you know, we're not retailers. We have no interest in
11 that. That's one reason I hope you saw last week that
12 we've actually come out now very, very strongly
13 discouraging submission of applications for cause
14 marketing on pesticide labels. We've decided not to
15 issue a PR notice providing guidance about that.

16 So, we've pretty much reversed our position on
17 that. The only reason, in fact, that we didn't say it
18 was prohibited is apparently that's not within our legal
19 authority. But it will be extraordinarily difficult to
20 get cause marketing claim on a pesticide label.

21 Having said all that, there's clearly an
22 interest by the public, by retailers, by certain segments

1 of the industry to pursue this as a possibility. So, we
2 decided we'd set up this work group. We are interested
3 in it if and only if there's something in it for the
4 agency. What that would be is a belief that through some
5 sort of distinctions in the marketplace, we can reduce
6 risks to the public and that would require that there be
7 responsible use because you can't have the benefits of
8 that reduced risk unless the products continue to be used
9 according to the label directions.

10 So, it's not -- as someone else mentioned here,
11 it's not just about what's in the can; it's also ensuring
12 that anything we put on that labeling will cause the
13 product not to be used as we've registered it. So,
14 again, it's a very complicated project. I just wanted to
15 make sure everyone here understood where we're coming
16 from on it.

17 So, we're right on time. In fact, we're a
18 couple minutes early. We're going to start sharp at 1:00
19 so that we can be on time when we leave too. Thank you.

20 (Whereupon, a luncheon recess was taken.)
21
22

A F T E R N O O N S E S S I O N

(1:00 p.m.)

MS. EDWARDS: All right, thank you very much for coming back on time. I really appreciate that.

We're going to start -- I have a couple of really good announcements for you I think you'll appreciate, especially those of you in the antimicrobial area. The first thing I'd like to do is announce that on Monday of last week, for those of you that don't already know, we brought in a new division director for our antimicrobial division, a very experienced person that comes with experience in EPA and the Office of Water and the Office of Solid Waste and Emergency Response. Her name is Joan Harrigan Farelly (phonetic). So, Joan, could you stand up and let people know who you are? There she is. That's our new division director. Frank Sanders has moved on to the Office of Science Coordination and Policy. That's the group that we're collaborating with in rolling out the endocrine testing.

The second announcement I have related to antimicrobials is that tomorrow we will be issuing in the Federal Register a proposed 158 data requirements rule,

1 subdivision W -- or subpart W for antimicrobial data
2 requirements for a 90-day public comment period. So,
3 hopefully, people will find that tomorrow and begin the
4 process of developing your good comments. Thank you.

5 So, now we'll move to our session 4, which is
6 resources and funding with Marty Monell.

7 MS. MONELL: Good afternoon. You're all used
8 to this format. We've used it in the past, so rather
9 than change up on you, we decided to continue the same
10 tradition of presenting these numbers. The numbers,
11 however, have been changed to reflect actuals. The '08
12 numbers you see, and will see, reflect the actual
13 appropriated amounts. The '09 numbers are those that are
14 contained in the president's budget.

15 You'll see from '08 to '09 that there is a
16 fairly significant decline in the resources proposed for
17 the pesticide program. This amount, the \$137.9 million,
18 that you see for 2009 includes all of our appropriations.
19 We get money from the EPM, Environment Program
20 Management, account, which is a primary appropriation, a
21 little bit in science and technology for our labs. That
22 is money that is devoted for a research. ORD has the

1 bulk of this appropriation. But because of our labs, OPP
2 gets some as well, and then the STAG account, that's the
3 State and Tribal Assistance Grant. We have a fairly
4 substantial amount of that. We also, as you know, get
5 fees.

6 The next slide depicts our FTEs. This is a bit
7 misleading because it includes the FTEs. FTEs are full-
8 time equivalents. It's the government's way of
9 addressing staffing. So, we managed two FTEs. These
10 numbers depict the regional portion of our FTE as well as
11 the headquarter's portion. Although we are primarily a
12 headquarter's-driven program, managed program, we do have
13 FTE in the regions, about 85 at this juncture.

14 They do program implementation for us. They do
15 -- that would include the endangered species, work on the
16 ground when we get there, as well as the SAI program
17 implementation. It also includes about 30 FTEs for the
18 AA's office, the support that our senior management chain
19 provides to the program.

20 The next chart, the importance of this chart
21 really is to depict the numbers -- the reduction in FTE
22 that we were given by way of appropriation and our need

1 to offset that reduction by increasing the number of FTE
2 that we support by fees. So, you'll see that although it
3 looks minuscule there, we lost 20 FTE under the
4 president's budget for 2009.

5 We're going to have to make that up because we
6 have people on board and we don't want to have to let
7 people go. So, we'll make that up by having those
8 employees, those FTE covered by PRIA to the extent that
9 the work is registration related. If you'll recall, PRIA
10 does not put a cap on our FTEs, so it really provides us
11 with much needed flexibility.

12 Here we see the proportion of salaries to other
13 expenses that we utilize. We are FTE-rich. We believe
14 that in fact government employees doing the pesticide
15 work are more -- it's more efficient and more financially
16 feasible and economical to have OPP staff do the work
17 rather than contracting everything out. We do have --
18 and I'll get to those specifics in a minute -- but we do
19 have substantial amounts of money invested in contracts
20 and IAGs, but you'll see the increase in salaries.
21 That's due not only to our need to cover COLAs but also
22 to allow for the reduction in the number of FTEs that we

1 receive through the appropriation.

2 A big bulk of our contractual money is spent in
3 the area of information management. Obviously, to run a
4 program of this magnitude with the amount of data that we
5 have that is needed to make well informed decisions, we
6 have to invest heavily in this arena to make sure that
7 the data that we have is available to our scientists and
8 our regulatory managers to make appropriate decisions.

9 We also are committed to a government-wide
10 effort as well as an interest that PRIA-2 contemplated
11 which is to make our registration process electronic to
12 the maximum extent possible. So, we have e-submission
13 investment which is we are now able to accept electronic
14 submissions via CD or DVD.

15 Our program, or project I'll call Documentum,
16 that is the management tool that enables us to manage all
17 the information that comes in as well as manage all the
18 information that we already have in house, to sort it in
19 a useable format.

20 We've also done a lot of work for the
21 requirements that we needed under PRIA-2. There's an
22 additional 90 to 140 categories of actions, registration

1 actions. We had to adapt our systems to be able to track
2 those. Then, of course, there were the fees that are
3 submitted in association with those categories have to be
4 tracked. We have to track the 25 percent of the fee that
5 the agency is required to keep under PRIA-2 if an
6 application is rejected as incomplete and in certain
7 other instances.

8 Also, we've been developing a system which was
9 originally going to house all of our -- it would be like
10 a knowledge database for all of our endangered species
11 work. Once we have done all of the work on locations and
12 identification, we want to be able to store it in a
13 useable format so that we don't have to reinvent the
14 wheel when it comes to us again. We're also -- just as a
15 side note -- trying to work with the services to perhaps
16 share databases and the ability to track information.

17 E-label is a big project, as you know.
18 Hopefully, if you're a registrant, you can submit an
19 electronic version of your label and we will review it
20 electronically. That's been a project that's been in
21 place for a number of months now. As the culture has
22 shifted with the registrant community, it is also

1 shifting within the OPP communities, so people are much
2 more comfortable reviewing electronic label submissions.
3 We've invested in that whole effort.

4 Enterprise architecture, it's always had sort
5 of a mystique to me. Basically, what it means is that
6 you take a look at all of your processes, the
7 registration, the re-evaluation portions of our program,
8 and you map the process. That's how you build your
9 architecture for a system such as Open, as you may know,
10 which is becoming Prism which has more functionality to
11 it.

12 Then, we've got configuration management.
13 That's the operating system. It's a support function.
14 Then the desktop infrastructure, we maintain a continuous
15 investment in our computer systems so that everyone in
16 the program has a relatively new computer, a PC or a
17 laptop, whichever they're more comfortable with, and a
18 docking station here if they have a laptop. They can
19 take it home, take it on travel. We support all of that
20 with this overall \$11.4 million investment.

21 In the area of sort of public service kinds of
22 information, we invest \$1.8 million in things such as the

1 NPIC, which is the National Pesticide Information Center,
2 as well as the National Pesticide Medical Monitoring
3 program. We've done this for a number of years. We
4 continue with that support. Cost of living naturally
5 goes up a little bit every year, but we believe it's a
6 worthwhile investment and provides a lot of very useful
7 information to the public.

8 We also invest about \$3 million in our science,
9 toxicology and our chemistry contracts. That's sort of
10 the basic science work of the program. Mission support
11 contracts, again primary data reviews are often done
12 through contractors. Obviously, the final review is done
13 by staff with the decisions made by staff.

14 We invest in the field program, contracts and
15 grants. We don't really call it the field program
16 anymore. It's more outreach and international
17 cooperation tribal kinds of areas that we invest in. It
18 totals about \$1.1 million.

19 At the last meeting, several of you indicated
20 an interest to know exactly how much and on what projects
21 OPP spent both appropriated dollars and PRIA-2 dollars on
22 two particular areas. One was the Worker Protection and

1 Certification and Training. Then the other was the PESP,
2 the environmental stewardship grant. We'll start with
3 the worker protection grant. For the certification
4 training support, this is \$1.7 million.

5 We have an IAG and have had for a number of
6 years with USDA. Through the state extension services,
7 we provide or they provide training to applicators.
8 That's recently been cut down to a reduced \$1.2 million
9 for this particular inter-agency agreement. PRIA
10 provided for an additional \$500,000 to support these
11 kinds of efforts.

12 As a result of meeting with the stakeholders in
13 this particular area, the decision was made to add that
14 to the \$1.2 million so that they wouldn't be spread small
15 in effective pots of money but that you'd had a full \$1.7
16 million to put into the USDA-led training programs
17 through the extension services and to then focus on areas
18 for improvement, areas for possibly reevaluating the
19 formula by which those funds are distributed to the
20 states.

21 In the worker protection area, from
22 appropriated funds, this is non-PRIA, we have allocated

1 \$600,000. You can see on this page and the next the
2 kinds of things that have been supported. A lot of these
3 are ongoing efforts that we believe are appropriate and
4 of high value to our program.

5 Then, you move on into the PRIA-funded areas
6 and where PRIA-2 gave this area an additional \$1 million.
7 These are some of the things that we're using that
8 particular allocation for. You'll see many of them
9 support that which have already been started with the
10 appropriated funds that we believe were really worthwhile
11 investments and provided the kinds of activities and
12 outreach that are valuable to the community as well as
13 obviously the workers.

14 This is more of the PRIA funding, more of how
15 we have spent that \$1 million set-aside program. Again,
16 you'll see some new ones here, but basically they follow
17 the same theme. Kevin Keeney (phonetic) is here. When
18 I'm through this whole presentation and if you're
19 interested in any particular one of these projects, he'll
20 be able to describe it to you in more detail. Those of
21 you that participated in the PRIA-2 coalition meeting
22 heard a complete breakdown of all the programs, but

1 obviously not all of you were there. So, Kevin is here
2 to talk about specifics if you're interested.

3 The other area that you all requested
4 information on was how we were spending money on
5 environmental stewardship type grants. Here you'll see a
6 couple of graphs. By and large, the \$3.6 million is
7 primarily disbursed through grants, if you're not
8 familiar with them -- actually give money out to the
9 recipients with the idea that the money will be used in
10 an area that is of importance to the program, but
11 generally it's regarded to be for the benefit of the
12 recipient, unlike a contract where the activity that is
13 supported is for the benefit of the agency.

14 So, all of these environmental stewardship
15 grants -- grant-type activities are to be -- although
16 they support programs and ideas that we're very
17 interested in, they are for the benefit of the
18 recipients. So, 81 percent of this \$3.6 million is for
19 grants and then a smaller amount for contracts and even a
20 minuscule amount for travel.

21 The other graphs or chart depicts the types of
22 activities that the grant supports. So, you see that

1 SAI, Strategic Agriculture Initiative, takes up about a
2 third of it. Biopesticide demonstration grants is a very
3 small amount. Then our pesticide environmental
4 stewardship program, per se, another third and then the
5 PRIA-2 funded environmental stewardship grant another
6 little less than a third.

7 For the partnership grants, PRIA-2 provides for
8 \$750,000 for the first two years to be allocated towards
9 partnership grants. We believe that the intent was to
10 build upon a program that the program has felt was vital
11 to the community at large.

12 So, what we've done is we started up a grant
13 program, a competitive grant program. The request for
14 proposal was issued back in May. The grants could be for
15 a year or two years, could not exceed \$250,000, and we
16 received 37 submissions for \$6 million of work. I should
17 note that the program matched the PRIA set-aside with
18 \$250,000 of appropriated funds. So, that the total
19 amount available for this grant project was \$1 million.

20 We decided to fund five of the partnership
21 grants. The first one -- this is slide 14 I'm on -- the
22 first one was submitted by the California Department of

1 Pesticide Regulation and it was to reduce volatile
2 organic compound emissions from pesticide use in tree
3 fruit orchards in California's San Joaquin Valley.

4 The second was awarded to the Central Coast
5 Vineyard Team which happens to also be a PESP partner.
6 It's to reduce pesticide risk through the adoption of
7 integrated farming practices in central coast vineyards
8 and marketing certified sustainable products.

9 Third grant was high level IPM. Oh, this was
10 awarded to the IPM Institute of North America, which is
11 also a PESP partner. It's to ensure that we have high
12 level IPM in all United States schools by the year 2015.
13 Very admirable goal.

14 The fourth grant is to the Michigan State
15 University. It's to increase adoption of reduced risk
16 management practices in Midwest blueberries to prepare
17 for FQPA implementation.

18 And last but not least to the University of
19 Florida supporting reduced pesticide use for Bemisia
20 tabaci and greenhouse white flies on greenhouse tomato
21 using protected culture IPM techniques, parasitic wasps
22 and papaya bankar plants.

1 Again, when I'm through with this presentation,
2 Janet Anderson and Mike McDavitt (phonetic) are here and
3 they can give you more detail about those particular
4 awards. But let me finish my presentation.

5 For travel, we get 930 -- in 2008, we are
6 allocated \$930,000 for travel. You can see the breakdown
7 here. Invitational travel to this organization ran us
8 \$48,000 last year. Foreign travel supporting treaty
9 implementation was about \$39,000 last year. That's for
10 treaty implementation related to methyl bromide and the,
11 of course, (inaudible) and so forth.

12 We also have increased the amount of
13 international travel that we have done to support work
14 sharing and harmonization. That's \$360,000 for 2008.
15 While this is a fairly significant investment right now,
16 we believe that the benefits are very high and in the
17 long run should result in reduced travel costs because
18 we'll be sharing the work more. And then domestic
19 travel, which includes stakeholder meetings out around
20 the country, conferences, training of staff, and so
21 forth.

22 PRIA fees, as I mentioned earlier, because of

1 the reduction in FTE under the president's budget for
2 2009, we have been planning to increase the number of FTE
3 that will be supported by PRIA. This shows that we'll go
4 from about 40 percent to 66 percent of the cost of our
5 salaries for employees being borne by PRIA salaries.
6 Conversely, the amount available for contracts to be
7 funded by PRIA will go down.

8 Ever since we've had maintenance fees under
9 FIFRA, we have supported salaries. It was originally
10 part of our design or plan to accomplish the FQPA mandate
11 and then the PRIA mandate with regard to the non-food use
12 REDS and now registration review, now that we're able to
13 use the maintenance fees for registration review related
14 expenses. So, you'll see that we've gone from about 80
15 percent of the maintenance fees going for salaries to a
16 projected 87 percent in 2009. Again, that reflects the
17 reduction in the appropriated amounts available to us to
18 cover salaries.

19 You're all familiar -- those of you that are
20 involved with PRIA, its development and implementation
21 are familiar with this. The law provides that if our
22 appropriation goes below a certain number, that we cannot

1 collect fees. So, our magic number is \$126 million. I
2 just have that glued to the back of my mind as everyone
3 in our budget shop does. We have to make sure that our
4 budget at least gives us that amount so that we're able
5 to continue to collect fees. Very important. Under both
6 scenarios, obviously, we're fine. We were fine for '08.
7 We should be fine even with the reductions in '09.

8 This just shows the two fees which we are
9 authorized to collect right now, notwithstanding the
10 president's budget that provides for collection of other
11 fees. As of right now and for the foreseeable future, we
12 are allowed to collect registration service fees under
13 PRIA-2 and in accordance with the chart that was included
14 in that legislation with a 5 percent bump up this year,
15 as well as maintenance fees in the amount of \$22 million
16 every year for five years. I'm pleased to announce that
17 we hit it very, very closely this year.

18 This chart depicts the total PRIA fees that
19 we've collected and shows you that for 2008, we have had
20 a banner year. We collected \$15.8 million in PRIA fees.
21 We have yet to do an analysis as to whether this increase
22 -- if you see, in 2007, we collected a little over \$13

1 million.

2 So, we're going to do an analysis to try to
3 ascertain how much of a role our ability to keep the 25
4 percent in the event that incomplete packages are sent in
5 or rejected versus the increased amounts in the various
6 categories or the additional categories. Just try to get
7 a sense for why the amount went up so much collected and
8 yet the number of submissions did not go up as high. So,
9 we'll have more to report on that.

10 Just a brief overview. All of this data will
11 be available in our annual report. But just so that you
12 have a sense, we registered 20 new AIs, including 9
13 pesticides, 3 antimicrobials, and 8 conventionals. We
14 registered 12 reduced risk new active ingredients of
15 which 9 were biopesticides and 3 were conventional
16 pesticides. We registered 327 new food uses which were
17 made up of 300 conventional pesticides, 15
18 antimicrobials, and 12 biopesticides. Included in the
19 327 new food uses were 14 reduced risk uses.

20 FIFRA fees, these are the maintenance fees.
21 You can see for 2008 we collected our \$22 million and we
22 anticipate doing the same for 2009. We have a wizard who

1 is able to compute based on history and numbers and
2 anticipated cancellations exactly what the per product
3 fee should be. He's pretty darn close.

4 Then, the performance -- again, broad-brush
5 performance by the re-registration program, which is
6 over, we completed 27 REDS. Well, you can read this for
7 yourself. I think of particular note to me is that our
8 goal for product re-registration for '08 was \$1,075 and
9 we were able to complete \$1,192. So, we really are
10 putting a lot of focus on completing the cycle. The RED
11 is just sort of the beginning and then you have to
12 implement the portions of the REDS that are called for
13 and then ultimately re-register the product. We're also
14 very proud that 46 registration review dockets were
15 opened during this fiscal year.

16 So, that's all that I have. Open for
17 questions. If you have anything in particular you'd like
18 to find out about the worker protection certification and
19 training expenditures or the environmental stewardship
20 program, we'd be happy to take questions.

21 UNIDENTIFIED FEMALE: I just have one question.
22 Thank you for that overview. It's really helpful.

1 Obviously, you're getting a little bit of a budget cut
2 next year, but you're keeping, you know, and rightly so,
3 good attention going to your full-time employees.

4 What are you doing with your PRIA funds now
5 that you're going to not do in fiscal year '09 with that
6 shift of funding? You're using your PRIA funds to make
7 up the difference for your cut in full-time employees,
8 right?

9 MS. MONELL: We'll be doing exactly the same
10 work; we'll just be funding it differently. So, in other
11 words, we can't use PRIA for anything other than
12 registration-type activities or for the registration
13 service fees. Then, for the maintenance fees that are
14 provided for under PRIA, we have to use those for
15 registration review now and registration review related
16 activities. So, the same work will get done. It will
17 just be paid for differently.

18 UNIDENTIFIED FEMALE: What about your contracts
19 that you do with the PRIA funds now getting cut,
20 according to your --

21 MS. MONELL: Well, what we've done is we had
22 all of the divisions fund their mission support, critical

1 contracts or grants, IAGs primarily, through half of the
2 fiscal year so that we would be able to manage the
3 redirection of the contract money to cover salaries. We
4 were also fortunate we collected more money this past
5 year than what we needed so we have some carryover.

6 UNIDENTIFIED FEMALE: Thank you.

7 MS. MONELL: Anyone else?

8 Shellie.

9 SHELLIE: Just a couple quick questions. How
10 much of the worker protection money goes to the state?
11 If you could, what's the largest state grant and the
12 smallest?

13 MS. MONELL: I'm going to defer to Kevin for
14 this.

15 KEVIN: Out of the PRIA money?

16 SHELLIE: No, in general. I mean, money is
17 money as far as I'm concerned.

18 KEVIN: We don't divide that particular money,
19 the discretionary funds for grants and contracts that
20 way, nor do we deal with the PRIA money that way. In the
21 PRIA money that adds to the money that's in the
22 interagency agreement with the Department of Agriculture,

1 there is a disbursement then to the states to help
2 support the cooperative state extension services work and
3 training.

4 But the other money, the million out PRIA for
5 worker safety and then the other monies out of
6 discretionary budget for worker safety, aren't
7 specifically distributed to states. There is state money
8 that goes out under the account that Marty mentioned, the
9 acronym is STAG, it's state and territorial assistance
10 grants. That's distributed by formula. But as far as
11 the certification and work that they do, that's
12 distributed by formula to the individual states.

13 UNIDENTIFIED FEMALE: And what is that formula
14 based on?

15 KEVIN: Well, as far as the certification
16 program support, it's based on the numbers that the
17 states report to us as far as the numbers of certified
18 applicators in the commercial and private categories.
19 Then there's a waiting -- the state regulatory agencies
20 devote more resources to the commercial applicator rather
21 than the private applicator. The money that goes out
22 through the interagency agreement of the Department of

1 Agriculture goes to the extension service.

2 They devote more to private applicators than
3 commercial applicators. So, there's a slight difference
4 in the weighting given to those figures. There's a base
5 amount that's given to each state and each extension
6 service, \$15,000 for the extension services as a base and
7 \$30,000 to the states. Then, the remaining money is
8 distributed by that formula, a new formula, I might add,
9 that we're using.

10 Amy can speak about that relative to the
11 extension service monies.

12 MS. MONELL: Julie.

13 JULIE: I just have a question on the PRIA-2
14 partnership grant. You said that there was 37 proposals
15 submitted. Obviously, understanding that not all of them
16 could be funded, but are those proposals published
17 anywhere so they can see all the types of proposals that
18 were submitted?

19 MS. MONELL: I'm deferring to Dr. Anderson
20 (phonetic) as soon as she's able to make her way to a
21 microphone.

22 DR. ANDERSON: No.

1 JULIE: Simple question, simple answer.

2 DR. ANDERSON: Only the five that we've
3 recommended for funding will get officially announced.
4 But if you'd got an extra \$5 million, we could have
5 certainly funded a whole bunch more. There were some
6 really, really great projects that we couldn't get to.

7 MS. MONELL: Jay and then Jerry.

8 JAY: Under the PRIA-funded worker protection
9 contracts and grants, we've been four or five years and
10 it hasn't always been a million dollars a year but maybe
11 this will be actually addressed in the next agenda
12 session on performance measures. But I'm just curious to
13 kind of know if you've tracked those over the years that
14 these monies have been available and if there's any way
15 to kind of cross walk progress and ability to sunset some
16 programs and looking ahead to anticipate how to keep
17 momentum and the like.

18 Also, is there a specific stakeholder group
19 that's continuously been advising in this area and how is
20 it made up? Again, I'm just thinking about opportunities
21 for synergism and collaboration. When you look at a
22 million dollars, it sounds like a lot a year but it

1 really isn't when you start to look at the subparts. So,
2 I'm really curious to know about collaboration with
3 states with some potential registrant work that might be
4 going on around individual products that might also
5 connect to some of this kind of work.

6 KEVIN: PRIA-1 was \$750,000 a year less some
7 money in the first year, PRIA-1. I can send Marty or
8 Marty has the sort of historical tracking of projects for
9 the PRIA-1 and PRIA-2. You can see that. I can give you
10 more detail on that. The annual report gives you a lot
11 of details. The annual report on PRIA gives you a lot of
12 detail on the projects.

13 The projects are -- and we could discuss in
14 some other session a little more of these interlocking of
15 the projects, but they are interlocked and feeding a
16 number of our goals, obviously. In many cases, they are
17 cooperative agreements, in some cases interagency
18 agreements. In many cases, cooperative agreements
19 because it allows us to work cooperatively with the
20 recipient and to evolve the project over the term of the
21 cooperative agreement.

22 So, a number of them are five year exercises.

1 Obviously, if the five years run out and if that's
2 accomplished its goal, then we move on to something else.
3 All of them are competed. The cooperative agreements and
4 grants and contracts have to be competed. So, these
5 things that are winding down in '09, for instance --
6 collection that will wind down in '09 and have to be
7 competed at some period in '09 for start up again in '10
8 for continuance of the type of work that's being done, if
9 that's appropriate, or focusing on new initiatives.

10 A lot of them did come out of the national
11 assessment that we had that involved stakeholders around
12 the country, and they expressed needs for activities in
13 certain areas, a lot of concern for raising the awareness
14 in health care community about the health implications of
15 working with pesticides. So, the migrant clinicians
16 grant and the grant with the Northwest Safety and Health
17 Center is focusing on that.

18 The Recognition in Management Manual, the
19 International Use Manual needs updating. That was a '99
20 vintage, so we're doing a new manual there, starting a
21 new manual, under a cooperative agreement. But they are
22 interlocking serving the ends of our particular focus on

1 pesticide worker safety and health. I think when you see
2 the nature of the projects in some detail, you can see
3 how they interlock and serve the goals of the program.

4 We also do work with registrants, as you know.
5 We work with CropLife Latin America and Central America
6 through one of our grants to do health and safety work
7 there in the various Central American countries under
8 CAFTA (phonetic). We've gotten -- because of that
9 initiative and the support in Central America and the
10 support through the State Department, we've managed to
11 leverage the monies, the relatively small monies we put
12 forward fairly significantly with the State Department
13 money and USAID money in country to help those projects.

14 MS. EDWARDS: Okay. Jerry, and then the last
15 question from Caroline.

16 JERRY: I want to find out what Janet said
17 about produce \$5 million more for the partnership grants.
18 Is there a matching funding component for the
19 environmental stewardship grants and the PRIA-2
20 partnership grants?

21 UNIDENTIFIED FEMALE: No, there's not.

22 JERRY: Would you consider that to increase the

1 amount of money that you could be having on the street
2 for that work?

3 UNIDENTIFIED FEMALE: I would consider it. I
4 guess I would want to go back and look at the legislative
5 history and language in PRIA-2, that I wasn't violating
6 the statutes.

7 MS. EDWARDS: Also, EPA grants policy has some
8 pretty strict guidelines around requirements for match,
9 so we'd have to look into that as well. It's not a bad
10 idea, though, certainly to stretch the dollar.

11 Caroline.

12 CAROLINE: I just wanted some clarification
13 about one thing in the re-registration performance
14 measures. So, as far as product re-registration, there's
15 about 13,000 products that are waiting for re-
16 registration, if I'm reading this right, and somewhere
17 around 1,000 a year is the goal. So, does that mean it's
18 going to take 13 years to finish product re-registration?

19 MS. EDWARDS: No. Several of the active
20 ingredients that we did toward the end of the REDS
21 process had a large number of products associated with
22 them. I don't want to name them all right now, but we

1 could get you that information later if you're
2 interested, with a breakdown of that.

3 In addition, though, and possibly even more
4 importantly, we hope to increase the velocity with which
5 we're able to do this because we're now done with the
6 decision. So, some of those resources -- I would say in
7 the past that we put into the REDS production, we're
8 definitely interested in putting them into the
9 implementation because we've said here many times before
10 it's not in our interest to make the decisions on the
11 REDS, move on to registration review and not implement
12 the decisions that everybody worked so hard to get to.

13 So, we'll be -- that's probably -- if you had
14 to say our engines right now, they're REDS
15 implementation, registration review and our registration
16 PRIA program. So, that's where we're moving those
17 resources. If anyone would -- I mean, we could easily
18 put together and get out where those products are.

19 All right, well, thank you very much. I hope
20 that was helpful.

21 UNIDENTIFIED FEMALE: I was just going to make
22 a clarification, that on the USDA AIG funds as well as

1 the STAG funds, there are matching requirements for those
2 dollars. So, some of theirs there is a match
3 requirement.

4 MS. EDWARDS: Caroline, I'm worried that I
5 didn't entirely answer your question as to what year
6 we'll be done. We don't actually know the answer to that
7 fully. I think we have a schedule behind it. But for
8 the one sure example that we did this year, the next step
9 is getting the data call-ins out and then you get the
10 data in, so it will be a few years before we can actually
11 get through them all. But it won't be anywhere near 13.

12 So, the next session, and it's only a 30-minute
13 session, so we'll have to play this by ear, depending on
14 your interest -- I just wanted to remind you, though,
15 that there are two really good sessions following that
16 that I think you're going to have a lot of interest in.
17 You know, we're estimating here the times that we think
18 we need for these sessions to roll through them, but we
19 have some flexibility.

20 Anyway, it's Maryann Petrole, chief of our
21 financial management and planning branch, will be leading
22 us through this.

1 MS. PETROLE: Does that mean I can go fast?

2 Good afternoon. My name is Maryann Petrole and
3 the I'm the branch chief in the Financial Management and
4 Planning Branch in the Information Technology and
5 Resources Management Division. I'm also the co-chair of
6 the Measures Improvement and Implementation Team which
7 I'll be talking about a little bit further along in the
8 presentation.

9 Along with the budget and resource management
10 activities that goes on in my branch, we're also
11 responsible for managing and responding to the agency's
12 strategic planning process to anything having to do with
13 performance measurement under the Government's
14 Performance and Results Act, good old GPRA, still around.

15 So, I'd like to today provide you with a little
16 brief update at the 30,000 foot level of where OPP is
17 today and what's on the horizon in the performance
18 measurement arena. First, I'd like to revisit the
19 current strategic plan. I'd like to tell you about the
20 organizational framework that OPP has in place to address
21 measures in OPP, give you a brief snapshot of what the
22 '08 progress was on the strategic measures, and tell you

1 what's on the horizon as far as the agency with what
2 reporting requirements and documents that we're preparing
3 in the next fiscal year, and also our plans in OPP for
4 developing and implementing measures, and how we plan to
5 do that.

6 As you may be aware, since there was a lot of
7 participation by the PPDC in the measures improvement
8 project about two years ago, OPP took the opportunity in
9 2006 to revise the strategic plan to incorporate and
10 focus on environmental outcomes in three particular
11 mission areas; protecting human health from pesticides
12 risk, protecting the environment from pesticides risk,
13 and realizing the value of pesticides availability. As
14 part of the strategic plan revision, the agency required
15 OPP to develop strategic measures.

16 To ensure that there is continuous improvement
17 and refinement in the performance measure area, OPP
18 undertook a programming evaluation of the measures
19 improvement project back last year. It was conducted by
20 the Federal Consulting Group. One of the recommendations
21 that came out of the final report that was published last
22 October was that OPP -- and that OPP acted on -- was to

1 establish a permanent internal working group for
2 performance measurement. Debbie chartered the measured
3 improvement and implementation team in March of this
4 year.

5 We're organized as the team reports to the
6 senior management steering committee, which is comprised
7 of Debbie and Marty and each CD from the divisions. They
8 provide guidance and direction on all performance measure
9 efforts within OPP. They render final decisions to edit,
10 add and develop performance measures. They stay informed
11 of what's going on in the individual divisions having to
12 do with measure development. They introduce any emerging
13 issues that we might want to discuss. They meet monthly
14 with the co-chairs, of which I am one and which Ricky
15 Dumas, who is enjoying a wonderful vacation in Europe, is
16 missing today.

17 The measures improvement and implementation
18 team again is co-chaired by Rich and I. We have a
19 representative from each division and an alternate, and
20 also from our lead regions, so we have the regional
21 perspective.

22 We've been meeting regularly since March and

1 also on an ad hoc basis. The members of the team have a
2 working knowledge of the details and the background for
3 each performance measure that we're responsible for.
4 We've got a subgroup. We've got several subgroups, one
5 which is developing education and training materials
6 regarding performance measurements. The team members
7 participate in the subgroups as needed to be able to
8 develop, analyze and refine the measures in our focused
9 areas.

10 In conjunction with the development and
11 implementation of measures, the team is also responsible
12 for reporting progress on existing measures to include
13 those output measures that Marty just talked about that
14 are an integral part of the agency budget and performance
15 process.

16 Fiscal year 2008 was the first year of
17 reporting on our strategic measures. As you can see,
18 there's been quite a mixture of results. In some cases,
19 we've met, exceeded or not met the strategic targets.
20 However, I really, really want to point out that this
21 slide is a recap of the annual progress on the strategic
22 2011 outcome measures.

1 This was the first year that we received the
2 data on our data sources, had it analyzed, and regardless
3 of whether the annual target was met, exceeded or not
4 met, was not the point of receiving the progress report.
5 We've taken this information to be able to build on the
6 future of the measures. We have the opportunity to
7 refine our analysis and to be able to identify any data
8 gaps or limitations in our current measures over the next
9 couple of months.

10 With the team firmly in place and meeting on a
11 regular basis, our intention is that we will have
12 baselines and methodologies to update over the next
13 couple of months to re-evaluate what the next steps are.
14 The team, even though this is a 2009 beyond slide, the
15 team has a full plate for 2009. From the agency's
16 perspective, they're also going -- there's an opportunity
17 to revise the strategic plan. Obviously, since OPP just
18 revised the strategic plan in 2006 and because we've just
19 received the first reports on our measures, we're not
20 part of the first revision of the strategic plan.

21 Another schedule that the agency will be
22 looking at will be the annual performance report, the

1 2008 performance accountability report. That again is on
2 the output measures as well as the strategic measures for
3 the organization.

4 And then, sometime down in the spring of 2009,
5 there will be a full text draft of the 2009-2014
6 strategic plan that will be released to the public and
7 review. This actually is the opportunity that OPP will
8 be working toward if they have -- after the analysis of
9 the existing measures and strategic targets.

10 Let me go briefly over some of the things in
11 the cue and on the plate of the measures improvement
12 implementation team. Let me be clear that some of these
13 measures that are here are in the very early -- are in
14 various stages of development and that the team and the
15 subgroups are working on.

16 We received direction from the steering
17 committee to discuss some of these such as reducing
18 children's exposure to Rodenticides, increasing the
19 number of children in school IPM programs and, as you can
20 see, some of the other areas in human health area that we
21 were tasked or charged to look at over the next few
22 months.

1 In the ecological front, the team is also in
2 the very, very early stages of looking at developing
3 measures for the endangered species as it applies to
4 registration review using the environmental monitoring
5 assessment program to develop ecological measures and
6 also looking at possible terrestrial measures.

7 Even though we're under a continuing resolution
8 on the budget side of the house, the -- actually measures
9 development and team has an awful lot on their plate to
10 handle in the next couple of months. We're finalizing
11 the 2008 annual performance measures. Again, these are
12 agency-driven processes. Our plan is to reevaluate the
13 baselines and the methodologies to the strategic targets
14 and measures. We then prepare for the 2009-2014
15 strategic plan revisions. We plan to develop targets
16 beyond 2011 for that process.

17 Like I said, Rich Dumas and I co-chair the
18 measures improvement implementation team. If you have
19 specific questions about the strategic measures or human
20 health environment, I have a full team of experts behind
21 me that can address your questions. Thank you.

22 MS. EDWARDS: Any questions for Maryann or the

1 team?

2 UNIDENTIFIED MALE: Thanks. That was a great
3 overview. I have just a couple of questions. I'm not
4 sure they're sort of well formulated yet.

5 On the current indicators that you're tracking,
6 one of them was a goal of a 10 percent reduction in human
7 exposure based on the endomine (phonetic) data. You only
8 had five. Can you describe what the process is
9 internally for identifying actions the agency can take to
10 try to realize that particular goal, and then maybe
11 thoughts about why you're maybe coming up short?

12 MR. DUMAS: This is actions the agency can take
13 in terms of -- we have done cumulative assessment on the
14 OP pesticides. We do the individual assessments. The
15 cumulative brings it essentially all together. It's a
16 matter of evaluation as registrations, re-registrations,
17 come in, for example. It's a matter of evaluating those.
18 The risk managers make decisions in terms of what to
19 register, what to not register, what to -- to kind of
20 deal with this.

21 UNIDENTIFIED MALE: Right. But to realize, you
22 know, a quantitative reduction in population level

1 exposure, I'm just not sure how you get there without
2 considering, like, do we register, you know, do we try to
3 reduce use by 10 percent, do we sort of embark on
4 specific programs to protect watersheds, do we, you know,
5 sort of raise the bar on re-registration, that kind of
6 thing?

7 MS. EDWARDS: I think that had to do with the
8 OPs principally, is that correct? I think our feeling
9 was that we would -- we had predicted that over time you
10 would get significant reductions simply from the removal
11 of these products from residential environments. In
12 addition, as we move through the re-registration process,
13 we were removing uses, lowering rates. But I don't
14 believe we had any specific --

15 You know, it's a little bit of a guess.
16 There's a chance that we're wrong. But I think this
17 program, more than many, at least, in particular, for
18 acute types of effects and these kinds of measures, we
19 were truly trying to find outcome oriented measures as
20 opposed to how many of something we did.

21 So, this one actually doesn't even get to a
22 true outcome. It gets you very close, though, because

1 it's measuring levels. It's not measuring cholinesterase
2 inhibition, for example, but it's measuring exposures.
3 The ones that Maryann talked about that had to do with
4 incidents are actually outcomes. If you're looking at
5 levels in water systems, which are some of the other
6 measures, that's also getting very close to outcome
7 because it's exposure.

8 So, we're trying hard but we're not going to --
9 I don't think the science is advanced enough at this
10 point that you're going to be able to say, with this
11 action, we expect a 33 percent reduction in 18 months or
12 something, you know. They're good goals.

13 UNIDENTIFIED MALE: Right. I raise it in part
14 because we haven't published these studies. We did our
15 own (inaudible) that included a suite of -- the same
16 ename (phonetic) suite of organophosphates and
17 pyrethroid metabolites. And our urban levels were about
18 three to six times higher than the national level for
19 various metabolites, even measuring a couple years after
20 the last ename suite. The two greatest predictors that
21 we've observed so far in preliminary results of exposure
22 were the visit of a professional pesticide applicator to

1 the home and frequent consumptions of various either
2 green leafy vegetables or fruits, depending on the
3 pyrethroid organophosphates.

4 So, if you think about -- I mean, I really
5 endorse this kind of indicator. I think it's extremely
6 useful, but I think there might be some data mining
7 that's for solicitation of opinion on this that could
8 really support, you know, reduction efforts.

9 MS. EDWARDS: Thank you. I think, you know, we
10 may want to chat with you further with the team about
11 some of those ideas.

12 Susan.

13 SUSAN: I'd just like see some comments that
14 we're missing. The same page, same slide, under percent
15 of urban watersheds that exceeded EPA aquatic life
16 benchmarks, Malathion 30 percent comma met or 30 percent
17 met, 30 percent of the target is met?

18 MS. EDWARDS: I believe the goal was 30 percent
19 and it was reached. That's what that meant.

20 SUSAN: So, comma, okay. Then, the next one,
21 40 percent exceeded 25 percent, 40 percent comma exceeded
22 25 percent targeted?

1 MS. EDWARDS: Forty percent exceeded. The goal
2 was 25 percent. So, we did not meet our goal.

3 SUSAN: And chlorpyrifos goal was zero percent
4 -- sorry, the target was 25 percent and 0 percent met
5 that goal?

6 MS. EDWARDS: Right. Zero percent was the
7 actual. So, 0 percent of the sited -- of the sites
8 exceeded an (inaudible) benchmark.

9 SUSAN: Got it. Thank you.

10 UNIDENTIFIED MALE: I wonder on the 2009 goal
11 slide, what exactly do you mean by the toxicity weighted
12 exposure to the carbamates and OPs?

13 MR. DUMAS: That's for the toxicity weighted
14 exposure to the OPs. That is very similar -- as you
15 know, we've done th cumulative assessment for the OPs.
16 What this is doing is -- and that was essentially using
17 the year's worth of data. What this toxicity weighted
18 exposure to OPs does is looks over time.

19 So, it looks at PDP, essentially the USDA
20 pesticide residue data over time, combines that with
21 consumption data, combines that with the toxicity,
22 essentially the relative potency factor, and you get

1 essentially indexes associated with each of those. We
2 track that over time.

3 So, it marries together the consumption data,
4 the residue data by year, as well as the toxicity,
5 basically the relative potency factor, and combines those
6 on a year by year basis to establish a trend in
7 eventually toxicity weighted exposure. So, it's a take
8 off from the cumulative assessment except it does it on a
9 year by year basis.

10 I don't know if I'm being clear on that.

11 UNIDENTIFIED MALE: Thank you. Yeah, that's
12 fine.

13 MS. EDWARDS: Caroline.

14 CAROLINE: If I could just go back to the
15 performance measure that has to do with the aquatic life
16 criteria in urban watersheds, because I still don't quite
17 understand it. So, you set targets and then what data
18 did you use to assess whether you've met the targets?

19 UNIDENTIFIED FEMALE: Okay. The baseline was
20 established from (inaudible) data, the 10 year report of
21 pesticides in the environment. The baseline was an
22 update of those sites.

1 UNIDENTIFIED FEMALE: Can you speak louder? I
2 can't hear you.

3 UNIDENTIFIED FEMALE: The baseline was an aqua
4 data that was reported in the 10-year Decata (phonetic)
5 report. We got an update from USGS on the same sites
6 that were reported to establish the baseline. Of the 30
7 original sites that were reported for the baseline, we
8 had an update for only 20 sites. So, there was a little
9 bit of difference in some of the quality of -- or at
10 least the number of sites that we were able to update
11 from. We are aware that there are other data sources out
12 there and we may be looking at refining some of the data
13 sources that we use.

14 UNIDENTIFIED FEMALE: So, for that updated
15 data, what years did that come from?

16 UNIDENTIFIED FEMALE: Those were from the years
17 2001 through 2004. So, for only those three years.

18 UNIDENTIFIED FEMALE: Thanks.

19 MS. EDWARDS: Jennifer.

20 JENNIFER: It's the same thing. I'm just going
21 to go through the sentences slowly and try and write it
22 down. So, you set a goal of the percent of urban

1 watersheds that you -- I don't understand that you're --
2 a percent that you're allowing to exceed your goal is to
3 have a certain -- I don't understand what your goal is?
4 Your goal is a certain number of percentage of watersheds
5 exceed and you're trying to get it below 25 percent or 30
6 percent exceeding? I really don't understand this
7 sentence, I'm sorry. I'm going to write it down as you
8 say it.

9 UNIDENTIFIED FEMALE: I'll do my best to
10 clarify. So, my understanding, the way that it works is
11 we had a baseline from this base amount of data. There
12 were a number of sites that had an exceedance of an
13 aquatic life benchmark. So, the baseline, for example,
14 for diazinon, 40 percent of those sites exceeded at one
15 point or another through the first 10 years any aquatic
16 life benchmark.

17 So, our goal, I think, by 2011 is to reduce all
18 those numbers by 60 percent. So, these are interim
19 targets getting to that goal. So, the idea is that if
20 we've taken regulatory actions on some of these chemicals
21 in urban settings that we would -- depending on the
22 phaseout agreements -- be lowering our exposures in urban

1 watersheds.

2 JENNIFER: So, 60 percent reduction is the
3 goal?

4 UNIDENTIFIED FEMALE: I believe it's the goal
5 for 2011.

6 JENNIFER: So, to be parallel with the bullet
7 above it, the goal itself is a 60 percent reduction?

8 UNIDENTIFIED FEMALE: Right. So, for 2008, the
9 interim goal or the target were the 25 percent for any
10 site for diazinon, 25 percent for chlorpyrifos, and 30
11 percent for Malathion.

12 UNIDENTIFIED FEMALE: You want to reduce the
13 number of exceedances by one quarter. So, if you have 10
14 watersheds exceeding, you want to reduce that down to one
15 quarter of 10. Is that right?

16 UNIDENTIFIED FEMALE: I'm not sure I understand
17 what you're saying.

18 UNIDENTIFIED FEMALE: Well, let me try it,
19 then. You have 10 watersheds exceeding for Malathion,
20 let's say, and by 2011 you want to have that reduced to 6
21 watersheds. No, you want to reduce it by 60 percent.
22 You want to have it to four watersheds, is that right?

1 UNIDENTIFIED FEMALE: Right.

2 UNIDENTIFIED FEMALE: Is that legal? I mean,
3 can you set a goal that allows exceedances? Isn't your
4 goal supposed to be the nonexceeds?

5 UNIDENTIFIED FEMALE: Yes.

6 UNIDENTIFIED FEMALE: Okay. So, what year will
7 that take place?

8 MS. EDWARDS: I'd be happy if it were next
9 year, but we're taking steps to see how fast we can get
10 there.

11 UNIDENTIFIED FEMALE: But if you keep going by
12 percentages, you'll never get there. Like, if you set it
13 always by reducing by percentages, you'll never get to
14 it. You've got to reduce by numbers of watersheds or get
15 it down to zero. You can take something and break it in
16 half a bazillion times.

17 MS. EDWARDS: Like I said before on the other
18 benchmark, I think we're taking steps that ideally and
19 hopefully will get it to zero, to be honest with you.
20 These numbers were put into the strategic goal -- and I'm
21 not sure what exactly that process was that it wasn't to
22 get to zero, but I would say that's the program's goal

1 and that's what we're trying to achieve.

2 UNIDENTIFIED FEMALE: Then, I agree with that
3 goal. But that should be articulated as a goal. I would
4 think that is a goal is to not have exceedances, right?

5 MS. EDWARDS: Right, absolutely.

6 UNIDENTIFIED FEMALE: And I would think that a
7 good way to get those down would not be to reduce them by
8 percentages but actually just say we need to get these
9 exceedances down and have the number of watersheds --

10 MS. EDWARDS: (Inaudible).

11 UNIDENTIFIED FEMALE: Like, what is Malathion
12 is only two watersheds? Why not just get it down to
13 nothing, then?

14 MS. EDWARDS: I think next time maybe what we
15 should do is give you the process that people go through
16 to put these program measures in because they require
17 these incremental changes.

18 UNIDENTIFIED FEMALE: Yeah, and also actual
19 numbers because working in percentages can be very
20 misleading, as you know. What if you have 600
21 exceedances or what if you have only 2? It's totally
22 different numbers, and we have no idea where we're going

1 to be in 2011 with these kinds of percentages.

2 MS. EDWARDS: Hopefully, zero.

3 UNIDENTIFIED FEMALE: Well, you won't be.

4 MS. EDWARDS: No, no, no, we might. We're not
5 aiming to do less than zero. That's not our goal. We're
6 aiming that that -- in order to meet the performance
7 measures requirements, that would be the minimum. But I
8 would say clearly that this program's goal is that there
9 are no incidents, you know, and no exceedances of the
10 benchmarks, period. It's always going to be the goal.

11 UNIDENTIFIED FEMALE: And I would just add, for
12 chlorpyrifos, we are at zero.

13 UNIDENTIFIED FEMALE: So, for chlorpyrifos you
14 had zero exceedances and your target was to reduce that
15 by 25 percent?

16 UNIDENTIFIED FEMALE: Our target was to reduce
17 it to 25 percent. We had 0 percent exceedances.

18 UNIDENTIFIED FEMALE: Great. So, maybe that
19 should be highlighted. That's like a really great point.
20 Highlight your victories and give us some number ranges
21 to work with and help us out here.

22 MS. EDWARDS: I'll tell you what we're going to

1 do. For tomorrow morning, we're going to have these
2 numbers more clearly spelled out and at least give you a
3 piece of paper with it on there. I'm not positive that
4 the way it's being presented is correct. I want to be
5 sure that it is correct.

6 Dave.

7 DAVE: Well, you might guess that I've got
8 something to say about the urban watershed stuff.
9 Actually, I'll start it out with some of what I think is
10 really good news. At least in the stormwater programs
11 that have looked at the diazinon and chlorpyrifos, I'm
12 pretty much -- actually, even under our state water
13 quality objectives, which are below the aquatic life
14 benchmarks, and pretty much across the state.

15 So, we think that taking them out of the urban
16 market actually worked. Surprise, we're not seeing
17 aquatic toxicity from diazinon or chlorpyrifos in urban
18 areas of California, where before they were way above our
19 water quality objectives. Everywhere we looked they were
20 acutely toxic to the target organisms.

21 That being said, one thing that I would
22 encourage EPA to do is to not just rely on the NAQA

1 (phonetic) data because it's so limited in what they look
2 at. I'd really like to see there be a more comprehensive
3 program of figuring out what are the pesticides that
4 really ought to be looked at, what are the things that
5 are most being used in urban areas that are likely to be
6 problematic, and support a monitoring program, either
7 directly or getting somehow some funding to state or
8 local agencies. Right now it's largely local agencies
9 that are saddled with the burden of monitoring for these
10 things. We get some really high quality data but we'd
11 rather see it be your burden than ours.

12 Really, what I'm getting at is I think that,
13 for instance, the replacement products with diazinon and
14 chlorpyrifos -- I know that you're very aware that it's
15 pyrethroids now that are being used. Coming up now it's
16 depreynel. I just as soon that those are not the three
17 key pesticides of concern to be looking at anymore. Of
18 course, unless something drastically changes in what's
19 available in the urban market, diazinon and chlorpyrifos
20 shouldn't be your key pesticides any more. It should be
21 the ones that are replacing them. There's a wide body of
22 evidence that they're the problems now. Anyway, thank

1 you.

2 MS. EDWARDS: Thank you. I think we are
3 looking into that and we understand that issue.

4 Joe.

5 JOE: I noticed under the strategic measures
6 for realizing the value from pesticide availability, both
7 of them that have been met here. Was there any
8 consideration given to reduction of vector-born
9 (phonetic) disease and how that might be quantified or if
10 it's just not one of those things that can be quantified
11 to be met as an avoidance of such and such -- how many
12 cases of West Nile virus, things like that? Does it just
13 not lend itself or is that not something that we want to
14 deal with here?

15 MS. EDWARDS: We would love to have that kind
16 of a measure in place. I'll let Rick talk to it, but
17 yeah, we would like to have such.

18 MR. DUMAS: When we were exploring measures
19 development two or three years ago, that concept was put
20 on the table. One of the difficulties was having
21 verifiable data to evaluate the measure against. But as
22 we look at some of our other regulatory initiatives

1 ongoing in the future, we're going to resurrect that and
2 see if we can't bring that one back up onto the table.

3 UNIDENTIFIED MALE: I wanted to speak to that.
4 I'm on the board of my local vector control district in
5 Sacramento. One of the things I'd be cautious about
6 doing is using that type of measure and there being any
7 sort of presumption that improvements in public health
8 are just tied to the application of pesticides.

9 I mean, our district is really focused -- in
10 fact, our district manager tells his management staff our
11 goal is to control these mosquitos without using
12 pesticides. That's a stated goal that he has to our
13 board and to his top staff. We're not really able to
14 accomplish that, but we do believe that most of our
15 mosquito control success is the nonpesticide stuff.

16 So, if there was some sort of a performance
17 measure -- I mean, it's great from a public health
18 standpoint to say that there's a reduction in vector-born
19 diseases, but I really don't want there to be an
20 implication that it's due to application of pesticides.
21 And not to say that there aren't instances where that's
22 the case, but I'd hate there to be some sort of general

1 conclusion to that effect.

2 MS. EDWARDS: Yeah. I think that's true with a
3 lot -- and that's just one example, the mosquito control
4 situation, where the government's goal as a whole is to
5 have these type of vector-born diseases low. But
6 figuring out which part of the suite of tools is within
7 your baseline and which one is actually contributing the
8 most is going to be difficult.

9 The same is true, I think, with hospital
10 disinfectants and figuring out when you have infection
11 control in hospitals, which part of it can be contributed
12 to the use of the hospital disinfectants and so forth.
13 There are other examples, but that's -- you know, we have
14 a strategic goal of realizing the benefits, in particular
15 the public health benefits, the large agricultural cost
16 benefits, the termiticide benefits, that sort of thing,
17 of pesticide products and finding good measures where you
18 have good baseline data continues to be a challenge. So,
19 once again, that's an area we're happy to have ideas.

20 Mark.

21 MARK: I was happy to see that EPA was going to
22 begin to look at terrestrial environments and develop the

1 same kind of system that they pioneered in the EMAP
2 (phonetic) program and in aquatic systems. The thing I
3 would say, though, is that in both public and private
4 terrestrial ecosystems, there are well developed
5 ecosystem measures out there. I would strongly suggest
6 that EPA consider partnering with USDA, with the Forest
7 Service and the Park Service who have done immense amount
8 of work in that area.

9 In particular, there's a sixth international
10 symposium on IPM adoption in Portland, Oregon, in March
11 of next year. One of the symposia sessions in that
12 meeting is going to be on ecosystem services and measures
13 through integrated pest management. Integrated pest
14 management virtually, when you look at private lands and
15 even public lands, there are very few acres that aren't
16 visited by integrated pest management monitoring folks.
17 They're already monitoring native pollinators, they're
18 already monitoring ecosystem services.

19 So, why not marry these systems and not
20 reinvent the system but take advantage of what's already
21 being done and what you champion in many cases since the
22 formation of this agency in terms of IPM, in terms of IPM

1 in terrestrial ecosystems, but not only there but urban
2 environments and now in education, et cetera. So, this
3 is an area, I think, where you don't have to reinvent.
4 You can go and capitalize on what's being done and what
5 has been done.

6 MS. EDWARDS: Thank you.

7 Let's take the three cards that are up and then
8 we need to close this session.

9 Cindy.

10 CINDY: I guess a point I want to make is I
11 don't want to leave the perspective that the work that
12 has gone into this area isn't very valid because I think
13 the change that you are proposing here where you start
14 looking at what are the actual consequences of your
15 actions is really valuable and important. So, I think
16 what we've got here is a little bit of semantics and
17 context discussion going on.

18 I mean, you clearly have goals, but to get to
19 those goals you've got to have benchmarks which you
20 measure, which is why we're talking about measures. I
21 think it is important to say that, you know, we have a
22 goal here to improve public health and the environment.

1 Here are some benchmarks that we have set up to do that.

2 But I think you have to keep context in there.

3 We could start with, for example, in some of
4 those areas and how much have you improved it. You know,
5 avoiding \$1.5 million in crop loss as compared to what
6 and in what context? You know, was that happening, those
7 kinds of things. So, I think what I'm seeing here is
8 that you've got clearly a very valuable way to look at
9 performance measures. Put a little context around where
10 you started, where you are, and why you're doing it.

11 Here's your goal. What evidence do you have
12 that you're meeting that goal? It's really what you're
13 reporting here. That's going to come in a variety of
14 different ways. But I wouldn't want to leave the
15 impression that what you're presenting here isn't
16 valuable because I think it's very valuable.

17 I think a lot of work went into not only the
18 work group in developing how you get at that, but in the
19 agency in trying to define how do we measure -- what's
20 the evidence that we're moving the right way in those
21 goals.

22 The other thing I would say is this issue of

1 consequences is an important issue. When you pull out
2 diazinon and chlorpyrifos, whatever, it gets replaced
3 with something else because the pest problems don't go
4 away, necessarily. So, whether it's organic or
5 nonchemical or chemical, whatever it is, there's a
6 consequence to every time you pull something out
7 somewhere else. That needs, I think, to be characterized
8 in your impacts and what's happening in terms of meeting
9 your goals as well.

10 MS. EDWARDS: Thank you.

11 Thomas.

12 THOMAS: I just want to suggest that childhood
13 asthma incidents related to pests should be one of the
14 measures to look at in terms of human health. Six
15 percent of kids nationally and something like \$3 billion
16 a year in treatment costs, that would be a great one if
17 you could come up with a measure to work on that.

18 MS. EDWARDS: Thanks.

19 The third card disappeared. Well, thank you
20 very much. Obviously, this is a topic we're going to
21 need to continue talking about. It makes sense because
22 it's probably one of the most important things that we do

1 to try to show the value of our work and try to use the
2 measures program to steer our work in the right
3 directions. I think that's the value of having such --
4 kind of ambitious goals, actually.

5 The next session -- again, I mentioned this
6 morning we were pleased to have three presentations today
7 from the USDA. They're on the NASS program, Pesticide
8 Safety Education Program, and the IPM-PIPE. The first
9 presentation is by Mark Miller on NASS.

10 MR. MILLER: Mark Miller with the National
11 Agricultural Statistics Service. I'm the section head of
12 the environmental demographics section. NASS is a data
13 collection agency of the U.S. Department of Agriculture.
14 Our main things are the census of agriculture. We also
15 put out the crop production reports, livestock reports
16 and economic reports. Right now we're very busy with the
17 2007 Census of Agriculture. It will be published on
18 February 4th of 2009. Just some background into what the
19 agency does.

20 Most people know NASS mainly for one thing; we
21 were in the movie "Trading Places." There was a scene
22 where the citrus report came out. It was big news. NASS

1 is that agency. It doesn't quite work the way they
2 showed it in the movie. But the other thing is you'll
3 sometimes hear people talk about government bean
4 counters. I am a government bean counter. We do
5 soybeans, green beans, dry beans, pinto beans, whatever.
6 At one point, my career got even worse; I counted rice.
7 But overall, that's just a quick background into what the
8 agency does. Now, on to what we're here for.

9 The chemical usage program at NASS began in
10 1990 with the Department's water quality and food safety
11 initiative. We've grown from basically three programs,
12 field crops, fruits and vegetables, to where we now have
13 been doing nursery and flora culture chem usage,
14 livestock chemical usage. Our initial funding was for
15 chemical usage, but we've got into pest management and
16 overall goes into food safety and worker protection as
17 the data has been published.

18 What we've done, our field chemical use, we've
19 picked up what kind of pesticides farm operators have put
20 on their crops for the major field crops. Also,
21 fertilizer usage. We've got into pest management
22 practices. We've done the same for the fruit chemical

1 use and the vegetable chemical use.

2 When we were doing post-harvest surveys we also
3 -- chemical use and pest management practices, same for
4 nursery and flora culture, and the livestock surveys.
5 We've picked up the applications that are put onto the
6 livestock themselves as well as the facilities where the
7 livestock are housed.

8 What we've done is we had a regular rotation on
9 our chem use field crops. In the odd years, we would
10 survey corn, upland cotton and fall potatoes. The even
11 years it was soy beans and the three wheats, durham
12 (phonetic), other spring and winter. On odd years, we
13 would survey about 29 different fruit crops; whereas, on
14 the even years in vegetables, we had about 24 vegetable
15 crops we would do. Our nursery and flora culture survey
16 was conducted every third year, in '01, '04, and the last
17 one was just conducted on the '07 year. As I've said,
18 we've done the post-harvest and the livestock.

19 We reached a decision point in 2007 where we
20 had to prioritize our programs because of budget. Our
21 listing of priorities was looking at those reports which
22 contributed to the principle economic indicators, those

1 that go over to the Bureau of Economic Analysis. Some of
2 those are our hogs and pigs report, cattle report, and
3 stocks reports, data that directly impact the market.
4 Our monthly crop report, which goes out about the 12th of
5 each month, winds up being what the markets react to on
6 the Chicago board.

7 We also have data series which are necessary to
8 implement USDA programs. Our price series is used by the
9 farm service agency when they look at market year average
10 prices and to determine whether farmers are eligible for
11 counter cyclical payment. Then, the fourth one, data
12 which there are no other sources of information
13 available.

14 So, when we did this prioritization within the
15 agency, we lost one quarter of labor but the chemical
16 usage program took the biggest hit. We just really got
17 cut back. We couldn't support it with the funds we had
18 available.

19 Where we are now, for the 2007 year, when we
20 first looked at it, we picked up upland cotton, apples
21 and organic apples. Now, '07 was an odd year and in
22 normal rotation we would have been picking up corn and

1 potatoes also. '07 would have been a real good year to
2 have done corn chemical usage because we went from about
3 84 million acres up to 93 million acres of corn. It
4 would have been nice to be able to look and find out,
5 okay, what did it take to produce corn on corn as a lot
6 of those acres would have had to have been. The only
7 fruit crop we got done in '07 was apples. We also did an
8 organic component of it. We published that on May 21st
9 of this year.

10 As we look ahead, the rest of my report is
11 mostly what we're not doing. We are doing no chemical
12 usage surveys in '08, nothing, no field crops, fruits,
13 vegetables, post-harvest or livestock. So, we will have
14 nothing to release next year.

15 In 2009, for the 2009 crop year, we are working
16 with the Economic Research Service and we will do a
17 chemical usage on the wheat crop and also on organic
18 wheat. But that's the only commodity we've got scheduled
19 right now. That will be published in May of 2010.

20 For the 2010 production year, we do have it
21 scheduled with the Economic Research Service that we will
22 survey chemical usage on corn. Then, the following year,

1 we will do soy beans in 2011 and publish that in 2012.
2 But at the current time, that's all we have scheduled
3 looking out three years. We don't have any fruit surveys
4 scheduled, no vegetables, no post-harvest surveys on the
5 docket. Nursery and flora cultures we don't have
6 scheduled, and no livestock surveys. These are just
7 budget-driven decisions the agency has had to make.

8 So, after that rosy presentation, I'm open for
9 any questions from the committee here.

10 UNIDENTIFIED MALE: I was on NASS's advisory
11 board for five years and chaired it for one. I'm really,
12 really sad to see the administrative decisions that have
13 been made in this particular area because percent crop
14 treated is vital in all kinds of areas in terms of
15 assessing pesticide impacts and the impact of programs
16 both in the public and private sectors. So, although it
17 doesn't affect the markets, it affects the human health
18 dramatically. So, I'm not sure that had I been there I
19 would have felt like that was a really good decision,
20 personally.

21 I know it's hard budgetary times and all of
22 that, but these are decisions that are made at various

1 levels. I would even have preferred to see something
2 like a three-year rotation or even a four-year rotation,
3 some measure rather than no measure, particularly in
4 these kinds of times, because the organic portion, for
5 example, came online when I was there. We were strong
6 advocates of that.

7 Actually, you can infer a lot. Rather than
8 doing a separate survey, you can infer a lot by the
9 pesticides that are being used, whether it's organic or
10 not. It's not 100 percent but it is 85 probably, in my
11 estimation. So, there might be ways of getting more
12 mileage out of it instead of diversifying your things,
13 for example, in apples and organic apples.

14 Comments also say that I still believe in NASS.
15 I think it's a wonderful organization. It's one of the
16 most efficient U.S. government organizations that I've
17 ever been involved with, considering the money they get
18 and what they do. So, I appreciate what you do, but I
19 didn't appreciate this decision.

20 MR. MILLER: Thank you for the sentiment for
21 what we do. You're not alone in expressing the need and
22 the desire to have the chemical uses program back. As an

1 agency, we've been receiving letters and our
2 undersecretary has been receiving a number of letters
3 also in support of the program.

4 MS. EDWARDS: I wrote one of them.

5 Jay.

6 JAY: Well, Mark, thank you for being brave
7 enough to come here and for being open and transparent.
8 One thing that you didn't provide us, however, which I
9 think would be useful for this advisory committee is if
10 you would explain and put into context the total budget
11 footprint for NASS and what it, in my view -- now I'm
12 going to editorialize -- what a tiny fraction the
13 agricultural chemical usage program for pesticides and
14 fertilizers and animal health applications this data set
15 was.

16 Put it into context and maybe this is not
17 something that you're prepared to do off the top of your
18 head. If not, perhaps, Debbie, we could get that
19 information circulated to this group after the meeting,
20 because I think that's what really resonates and
21 compounds the frustration of so many of us in the context
22 of what NASS spends and the resources that are out there

1 that the undersecretary who has heard certainly from us
2 resoundingly and will continue to do so was party to
3 making that decision and what we believe is an arbitrary
4 and unfortunate one.

5 MR. MILLER: On the budget side of things, just
6 depending on where we are in the census cycle, we're
7 looking around \$160 million -- \$150 to \$160 million for
8 total agency budget. The information we sent across the
9 street to the undersecretary's office was that it would
10 take \$8.4 million to fully fund the chemical usage
11 program.

12 MS. EDWARDS: Okay.

13 Dave.

14 DAVE: It seems like everybody supports or
15 understands the need for this. It's such a travesty to
16 lose that information. It's such a huge issue of how and
17 where pesticides are being used. It's been incredibly
18 useful in California because we have a very comprehensive
19 pesticide use reporting system. That's really helped us
20 understand where our problems are coming from. There's
21 some gaps in that and we're trying --

22 I'm advocating for an increase in reported

1 information. It's really sad to see the rest of the
2 country going basically back to the dark ages where
3 there's nothing being collected. How can you manage this
4 huge amount of information or huge issue without the
5 information when it's actually being used? It's just --
6 it seems to me that there's a lot of reasons why there
7 needs to be some advocacy on the part of EPA to say we
8 need to figure out a way to have a comprehensive national
9 reporting system for all the pesticide uses so that when
10 you're trying to analyze what the impacts are, trying to
11 analyze what particular uses are causing the problem, you
12 can't really fully do your job. So, anyway, I'm hoping
13 that there's some way that you can start advocating for
14 that.

15 MS. EDWARDS: We'll take the four cards that
16 are still up and then move to the next topic.

17 UNIDENTIFIED FEMALE: As someone also from
18 California like the last speaker, Mark, we have a lot of
19 specialty crops and this data is incredibly important to
20 our types of agriculture in assessing these patterns and
21 issues that might arise.

22 Also, thank you, Debbie, for writing your

1 letter to them.

2 We would also like to -- we've heard that there
3 might be possibly some sort of reduced program that might
4 be put in place. But you're saying -- according to your
5 report, it's kind of all or nothing. But I did hear that
6 there might be some sort of intermediate program
7 installed as sort of a stop gap. Have you heard anything
8 to that nature?

9 MR. MILLER: I have not. What I reported today
10 is what I know as our program right now. We're going to
11 do wheat next year in cooperation with the Economic
12 Research Service. We've always said as an agency that
13 should we get funding, then we can look at bringing the
14 program back. But what I've presented today is what I
15 know of the status of the program right now.

16 MS. EDWARDS: Dennis.

17 DENNIS: I represent state lead agencies for
18 pesticides. California, we've heard about their program
19 which, of course, is an exception for the rest of the
20 states as far as reporting goes. Most states don't have
21 a reporting system and they rely heavily on NASS's data.
22 It's important to us today and it's going to be important

1 to us tomorrow. We've heard earlier sessions about
2 endangered species protection. A big part of that is
3 going to be knowing what pesticides are used in what
4 geographic areas and what the patterns of use are going
5 to be. Without those data, the agency is going to need
6 to --

7 I don't want to speak for the agency, but I
8 think the process will err on the side of conservatism
9 and assume that there's more application going on in
10 broader areas than otherwise. So, the cost is going to
11 be passed on down to the growers who aren't going to be
12 able to make a strong argument for more refined use of
13 pesticides and therefore allowing the use of pesticides
14 in areas where they might otherwise be prohibited from
15 use.

16 When you talked about the criteria that the
17 agency looked at, one of those was data where no other
18 sources are available, was one of the concerns. I do
19 know there are commercially-available services but those
20 are expensive services. For the states, those are
21 proprietary so we can't share them. That puts us in a
22 difficult spot to take proprietary data and use it for

1 regulatory decisions without some transparency.

2 I wondered if that was a factor that USDA took
3 into consideration when thinking about other sources. I
4 mean, registrants may have some access to that data.
5 Other groups may have access to the data. But states
6 that make regulatory decisions about pesticides may not
7 be able to avail themselves of that data.

8 MR. MILLER: We do know that Doans (phonetic)
9 puts out chemical usage information and I believe one of
10 the subcommittees on the NASS advisory -- looking at the
11 issue, their conclusion was that all parties that look at
12 the chemical usage data support what we do and they
13 didn't see a lot of --

14 At the time, what they were looking at, is
15 there any support for expanding the program. The result
16 was that no, there wasn't support for expanding. I don't
17 know that that got conveyed clearly. Some folks may have
18 mistook that for being soft support for the program
19 overall, but there was the comment -- notation that yes,
20 the private entities were out there. So, that helped put
21 it lower on the list of priorities.

22 MS. EDWARDS: Daniel.

1 DANIEL: I'm just appreciative of you coming
2 also. As a person in local government whose job is to do
3 surveillance, it's always tragic to lose information. I
4 have a couple of questions. First is, I'm struck -- I
5 don't mean to sort of pit one sort of interest group
6 against another, but at the same time, this is a
7 minuscule amount of money. If I think about all of the
8 ways in which there is industry support surveillance --
9 the Chemical Manufacturers Association was (inaudible).
10 For example, I've been sort of struck that, you know,
11 there's got to be some sources of funding out there if
12 from no one else, then from the industrial side to
13 support this. So, I appreciate you giving us the numbers
14 because I think it strikes two questions.

15 The first is, is there some point of no return
16 for USDA where because of these (inaudible) letting go of
17 staff or reassigning them or losing the sort of muscle
18 memory that goes on for this kind of surveillance in an
19 agency? If so, how long does everyone have to try to add
20 the case for a restoration of funding? That's one
21 question.

22 The second question that I just -- I don't know

1 if there's an easy answer to this, but does anyone stand
2 to benefit from the loss of this kind of surveillance
3 effort? If so, who or what interests are those?

4 MR. MILLER: The second question first. I
5 don't know who benefits. I don't know if anybody feels like
6 they benefit.

7 As far as the staff loss, currently I haven't
8 lost anybody on my staff right now. We are extremely
9 busy with the 2007 Census of Agriculture. Given that
10 that's going on and will continue to go on until
11 publication for the next few months, I haven't had to
12 administratively move anybody out of my section of the
13 folks who have worked on the chemical usage programs in
14 the past.

15 I've got -- two out of the three people that
16 are working on it are very committed to the program.
17 That's why they came to DC. They very much want to get
18 the program back. So, today, no, we haven't had staff
19 movement, but at some point, you know, if it's not back,
20 we do need to look at okay, what are people going to do
21 if we're not doing the chemical usage survey.

22 We also know that next year with wheat coming

1 in in cooperation with the Economic Research Service, I'm
2 going to need at least one or two people in my section
3 just to maintain the databases, get the questionnaires
4 ready to go, run the summary systems and do those types
5 of things. So, it is coming back at a reduced level. I
6 will have people continuing to keep their skills up to
7 date. So, at a point we do go back to what's been a more
8 normal rotation, I will have some history in this
9 section.

10 MS. EDWARDS: Okay.

11 Michael.

12 MICHAEL: I think there's a very important
13 public right to know what is going on here. There's no
14 economic sector that directly responds to your chemical
15 use data as there is with the data on livestock and other
16 commodities. By the same token, you know, it is the
17 public who really has an interest in knowing what the
18 chemical use patterns are.

19 I question what chemical use data can USGS use
20 to compare its NAQA (phonetic) water quality survey data
21 with? If it has to go to the private sector to purchase
22 that, then, you know, it can't release that data. That

1 data is proprietary. Same with EPA. Does EPA rely upon
2 your agricultural statistics on any of its performance
3 measures comparison?

4 If they go to Doans, number one, you know, it's
5 expensive for the private person to go and spend \$100,000
6 a year to get information from Doans. If EPA gets it,
7 they can't release it. So, everybody is working in the
8 dark. If you want to indulge in conspiracy theories,
9 there are who benefits from the lack of the public
10 knowing what the chemical use is.

11 You know, I don't particularly want to go there
12 with a public agency, but, you know, if you have a broad
13 sector of the public that you're serving that gets some
14 economic benefit from this, the market and commodities,
15 the livestock markets, they ought to be paying for it,
16 part of it, you know, if there's that interest. Or, all
17 you have to do is cut out part of theirs, the real public
18 interest stuff, the chemical use, use it. You know,
19 you've got a huge, then, group of people that want to
20 increase your budget rather than cut it.

21 So, I will ask the EPA what other sources of
22 chemical use data you have that you can analyze and

1 provide to the public?

2 MS. EDWARDS: We're actually going to touch on
3 that tomorrow in a presentation in terms of what data we
4 do still have available. I think there's actually a --
5 let me see if I can find it here -- pesticide usage
6 information, we'll be talking about that there. So,
7 thank you.

8 Thank you very much, Mark.

9 UNIDENTIFIED MALE: Debbie?

10 MS. EDWARDS: Yeah.

11 UNIDENTIFIED MALE: Was this passed out? I
12 didn't have it in my packet.

13 UNIDENTIFIED MALE: No, it was not.

14 UNIDENTIFIED MALE: Is it possible that we
15 could get that?

16 UNIDENTIFIED MALE: Yes.

17 UNIDENTIFIED MALE: Great.

18 MS. EDWARDS: And we can get that to you. So,
19 let's move on to the pesticide safety education program
20 with Amy Brown, University of Maryland, and Jim
21 Parochetti, USDA.

22 MS. BROWN: What's being passed around right

1 now is a report that Jim Parochetti prepared and I'll
2 talk about that in a moment. Jim Parochetti is our
3 national program leader for pesticide safety education
4 with USDA. He had that position many, many years ago,
5 actually, when I first came. He's now back at it as a
6 part-time program leader.

7 I've lead the Maryland program for a number of
8 years and have been active at the national level in
9 leadership of our organization, our professional
10 organization. So, I know most of the state programs.
11 Also here is Carol Ramsey who is president-elect of the
12 national association and knows a lot of the programs.
13 And, of course, Kevin Keeney (phonetic) is here. So, I
14 think between the four of us, we can answer a lot of good
15 questions that you all may have.

16 My goal today is to give you a brief overview
17 of the program, what we are, what we do, why we do it,
18 and what you can expect from us in the future. I think
19 the focus probably for the reason why we were asked to
20 give a presentation was perhaps because, in part, you'd
21 like to know what has happened with the EPA and the PRIA
22 funds that support this program. So, I'll address that,

1 too.

2 The first thing I want to make sure you
3 understand is that Pesticide Safety Education Program,
4 PSEP, is not the same as Pesticide Environmental
5 Stewardship Program, PESP. If we had known that we were
6 coming up with two such similar acronyms, I think both of
7 us programs might have changed.

8 So, just a brief history. The National
9 Extension Service was established in 1914. Way back in
10 the 1960s, we actually had a pesticide safety coordinator
11 at each state funded through USDA. So, when EPA came
12 into place and we started to classify pesticides as
13 restricted use or general use, there was an expectation
14 that the USDA and Extension Service would be involved
15 without region education of restricted use pesticide
16 applicators.

17 The Extension Service already had the ongoing
18 outreach and that safety coordinator in each state to do
19 it. By now, we've expanded our programs very broadly.
20 We no longer train just the people that we used to train
21 and our scope is much, much broader.

22 Each state, though, does have a pesticide

1 safety education program coordinator. Some states have a
2 lot more staff. Some have just a part-time person. An
3 integral part of the PSEP is the county level educators
4 as well in most states are very involved in doing
5 outreach, particularly to the agricultural community. Of
6 course, we also reach out to other pesticide users.

7 We form a lot of partnerships throughout the
8 states. We form partnerships with the other state PSEPs.
9 We have a national meeting held once every other year and
10 sponsored in part by EPA. We have regional meetings. We
11 have relationships with our state lead agencies. Some
12 have better relationships between the two than others,
13 but we do try.

14 One of the new requirements under the new
15 contracts that we are forming will be to have annual
16 meetings at the very least. Most states have more. We
17 partner with stakeholders and also with other experts, so
18 we involve as many sources of information and outreach as
19 we can to strengthen our PSEPs.

20 We educate not just those restricted use
21 pesticide users that we started out with, particularly
22 not just in the Ag community. We have education and

1 training programs on pesticides for private applicators,
2 commercial applicators, in a whole lot of categories,
3 depending on the state.

4 Some states have registered technicians or
5 employees. Those are people who apply pesticides under
6 the supervision of others, people whose jobs require
7 occasional application like employees at schools and
8 daycares, janitors and others who are responsible for
9 occasional pesticide use within the facility, other
10 people who are exposed occupationally through re-entry
11 such as handlers or workers but not necessarily actually
12 applying pesticides, nonoccupational users, people
13 exposed incidentally like consumers, certainly other
14 educators. So, we run train the trainer programs. And
15 some states are involved in outreach to the health care
16 community, physicians, nurses, first responders, and
17 migrant clinicians.

18 We started out -- even when we first started
19 teaching, when the FIFRA standards -- when the restricted
20 use pesticides came into play, we were still, even then,
21 teaching more broadly than what the FIFRA standards
22 required in many of the states. Today, we essentially

1 teach almost any subject that will enhance understanding
2 of how to use a pesticide in the safest and most
3 effective way. Many of us also teach about alternatives
4 to pesticides in our formal pesticide safety education
5 programs. So, we are actually very broad.

6 I also do want to say that although we provide
7 the bulk of the training, we by no means are the only
8 source of training even for restricted use pesticide
9 applicators. There are certainly other sources, but we
10 do the bulk of it.

11 I don't want to belabor this point. I want to
12 skip to some other topics that show you more what we do
13 in our outreach, but just to show you the background of
14 the professional development that we do ourselves, these
15 are some of the current topics that were covered during
16 this summer. Typically, we train ourselves during the
17 summer so that we can come back home and update our own
18 training programs for our clientele, for our audiences,
19 throughout the less busy season during the winter months.

20 So, these are some of the topics at the
21 regional meetings for pesticide safety educators this
22 summer. You can see that there are a lot of very, very

1 different things on here. The reasons for some of the
2 breadth of the topics at these various regional meetings
3 is that different states and different regions have to
4 focus on different problems.

5 We've partnered in part with our state lead
6 agencies to find out what the historic problems during
7 that year have been with regard to pesticide use in our
8 own state and region, and that forms a big basis for what
9 we might decide we need to ramp up our own training and
10 ramp up the training for those who help us do the
11 training in our own states, like in my case, my county
12 agents. I take these kinds of things back to my own
13 training and inform them and then we work it into our own
14 training throughout the year.

15 So, let's talk briefly, then, about PSEP
16 funding. There are a number of sources that we have used
17 historically. EPA, as Kevin said before, forms the base
18 funding -- has provided the base funding for this program
19 for a number of years in the form of pass-through dollars
20 through USDA. That's very, very important funding for
21 us.

22 As I think everybody here knows, we use that to

1 match and to leverage other sources of funding. Very,
2 very important historically. USDA provides funding
3 primarily in kind through things like Jim's leadership.
4 Also, occasionally, they've provided competitive grants
5 or money for particular projects that have gone out to
6 the states, and they track our data.

7 Cooperative extension at the state level,
8 that's a land grant, universities contributes quite a lot
9 of sometimes direct funding but a lot of in-kind
10 contributions. Most of my salary is paid for by
11 cooperative extension at the state level. That will vary
12 depending on the state. But the states and the counties
13 put in a lot of money in in-kind contributions to this
14 program.

15 Some states -- many states get assistance from
16 their state lead agencies. That could be, again,
17 indirect dollars that they can use in their program or
18 very often assistance with training. We have a lot of
19 state lead agency people who are directly involved in the
20 training program.

21 Some states get money from their state
22 legislature. Many of us have gotten competitive grants

1 or other block grants from a variety of agencies,
2 including EPA and USDA, but also organizations, sometimes
3 grower cooperatives, sometimes pesticide registrants, and
4 sometimes other sources as well.

5 Many states can take fees for their training
6 activities or for the materials they develop. Not all
7 states can. So, the amount that that would contribute to
8 a state program will certainly vary. But those are the
9 historical sources of funding.

10 You can see these data are taken from the
11 report that Jim Parochetti and Elizabeth Ley (phonetic)
12 prepared for you on a summary of the last period for the
13 interagency agreement. These data show the amount of
14 funding from EPA versus other PSEP support. That other
15 would include all of the kinds of things that I just
16 talked about. That's in the report that was passed out
17 to you just here.

18 So, you can see that EPA's share of funding for
19 PSEP has decreased. It's dropped from about 50 percent
20 in 1976 to about 10 to 20 percent currently. Partly
21 that's because the EPA funds have decreased, but it's
22 also because state PSEPs have gone out and found other

1 sources of funding to cover some of the more
2 nontraditional type of training that we do and other
3 audiences other than the restricted use pesticide
4 applicators and so forth. So, it's not all a bad thing
5 that we've gone out and looked for other sources of
6 funding.

7 Of course, in the FY '08 allocation was the
8 first time that we received or will be receiving money
9 from the PRIA fund. I want to emphasize that although
10 that was '08 money, we have not yet received that at the
11 state PSEP levels. The agreement is right now in the
12 works and I believe we have 30 days -- by the end of
13 October, we will be applying for and receiving our money.

14 But states can no longer forward fund their
15 programs the way that we used to be able to do. Our
16 state deans and directors of extension used to be willing
17 to let us count on the EPA money coming through until
18 2004 when we had that break in the funding. So, they're
19 not allowing us to forward fund yet. Therefore, we
20 haven't been able to ramp up for the anticipated money
21 that we will be receiving from the PRIA fund.

22 So, I wanted to show you some accomplishments

1 today. Some of it is outcomes and some of it I would
2 refer to more as impact. But the data that you have in
3 the USDA report to EPA that Jim Parochetti prepared, the
4 things that you can find out in there are the numbers
5 trained for each of these types of categories, train the
6 trainer, initial certification, recertification, and
7 others, what were the funding sources.

8 Jim provided a snapshot of four different state
9 programs. The way that USDA is organized, we have -- and
10 we are organized following their approach. We have four
11 regions; western, north central, northeastern, and
12 southern. Jim has provided you a snapshot of a program
13 from each of those areas. So, I encourage you to take a
14 look at that.

15 This does show you the numbers of people
16 trained during that period, that five-year period. It's
17 about one and a quarter million per year. But exactly
18 who we train depends in part on the state's cycle of when
19 -- we have different requirements for when people come up
20 for recertification and that causes quite a bit of
21 fluctuation in the yearly numbers that come through our
22 program. So, we also need flexibility to address that.

1 I also wanted to show you more than the numbers
2 and actually look at some of the accomplishments that our
3 state programs have done. So, I went to the performance
4 planning and reporting system that USDA has developed for
5 reporting on PSEP and one other program, the IPM program.
6 This is required reporting for each state that receives
7 EPA pass-through dollars. Again, in 2002 -- it hasn't
8 always collected the same type of information. It's
9 based on the federal fiscal year, so our reporting is --
10 we will report this winter for the programs that we have
11 just now finished up in September.

12 I'd like to show you some outstanding examples.
13 I went through the files from PPRS for the last five
14 years and looked at some things that I consider
15 innovative programs that the states are doing but also
16 very characteristic of the breadth of what we do and the
17 reasons why we need flexibility, because they showcase
18 things that various states need.

19 Idaho and Montana have done some regional fly-
20 in workshops where they actually have aircraft in and
21 they calibrate them, they test them, they show different
22 spray patterns, different patterns of drift and so forth.

1 Washington State, Carol's state, has PestSense and
2 HortSense which is a great online pest management
3 decision tool which nicely highlights -- has a stop sign
4 directing the user to further information when they are
5 making the decision to use a pesticide.

6 Illinois has a virtual spray table which they
7 developed so that -- it's an online tutorial. Users can
8 actually see the influence of different nozzles,
9 different weather patterns, different climate conditions.
10 We do something like this many of the states. USDA
11 funded spray tables for us to use in the states where we
12 can do the same kind of things, hands-on approach.

13 Pennsylvania has a really interesting little
14 portable mini golf course where they have a theme each
15 year. In 2006, they had a theme of the meaning of signal
16 words. They went over that. They reached over 15,000
17 participants at state fairs and other venues with this
18 mini golf course that people play but they also learn
19 through it.

20 Illinois has a really interesting drift garden
21 where they can take people through and show them the
22 effect of drift and discuss how to avoid drift.

1 Project Good Neighbor in Kansas, they have a
2 registry containing 121 sensitive sites and a lot of
3 their growers have actually been instrumental in
4 publicizing that program to let others know where the
5 sensitive sites are so they can, again, avoid drift.

6 We have bilingual training. That might have
7 been Indiana. That might not have been Illinois.
8 There's master gardener education in many, many states.
9 South Dakota has a really nice program that they
10 highlighted in one of those years.

11 The Latitude Bridge in Illinois is a
12 combination of teleconferencing and online content. Most
13 states are doing some form of distance education, but we
14 can't rely on it for everything because a lot of -- in
15 particular, a lot of our Ag sector may not have high
16 speed internet connection. Certainly, that's a problem,
17 I know, in the western states where connections are few
18 and far between in Montana and Idaho.

19 Even in Maryland, something like 70 percent of
20 our Ag producers don't have access to high speed
21 internet. So, it's wonderful to have online programs and
22 teleconferencing and all of these things where we can

1 take advantage of them, but we still rely a lot on one to
2 one.

3 Virginia has built a very nice pesticide media
4 database, which is an example of how we share materials
5 across the country between programs. California had a
6 wonderful outreach program for healthcare providers. And
7 in 2004, with a combination of losing funding and having
8 the primary person responsible for that program retire,
9 that person was not replaced. But they had a wonderful
10 outreach program for healthcare providers.

11 Delaware incorporates some principles of social
12 marketing into their training, and they ask the
13 applicators to list barriers. Then, they go through and
14 -- barriers to why didn't you adopt these good practices.
15 Important to understand why people aren't adopting the
16 things that we think are good common sense approaches.
17 Then, we can help them understand other ways to implement
18 that.

19 But they also utilize the fluorescent dye
20 approach to using a nonpesticide in an spray applicator
21 or a granule applicator that has fluorescent dye in it
22 and showing the people where it actually went. This is

1 one of the most influential methods of teaching that our
2 applicators tell us they find, when they can see where
3 that fluorescent dye went. It's very, very persuasive to
4 them. A lot of states use the fluorescent dye approach.

5 So, if we want to look at direct PSEP impact,
6 that is where were we able to influence behavior change,
7 we are able to see some things. We didn't used to
8 collect these data through the PPRS and it's still not a
9 required element because conducting surveys of this type
10 is very expensive.

11 Most states prefer, if they -- they don't want
12 to negatively effect where they can put their resources
13 in development and implementation of good programming.
14 So, if they don't have a cheap way to get at the
15 reporting of impact, they may simply not do it. As I
16 said, it's not a required element.

17 But we do have some data that I think are
18 impressive. One of the things that you have to keep in
19 mind when interpreting these data is that we don't yet
20 have a way to find out how many people already have
21 implemented these things. So, if I see something that
22 tells me that 74 percent of our people adopted at least

1 one improved practice, that means it was a practice that
2 they were not already implementing. Many of them are
3 already implementing things like that.

4 So, in Maryland we are going to be looking next
5 year at how we can track things that people already have
6 adopted and track in that subset who is adopting better
7 practices. In fact, these data are very good if you
8 don't know what the percentage is of people who have
9 already adopted them from the education they've got.

10 Incidentally, we also do have, but it's not
11 reported through PPRS, virtually every state, I am
12 certain, keeps track of the knowledge that they have
13 influenced through PSEP. It's sort of a crux of
14 cooperative extension that you evaluate your programs
15 with regard to change in knowledge. But that, of course,
16 is only the first step, making sure that people
17 understand better and have gained knowledge through the
18 training and the teaching that we do. We want to make
19 sure that they're actually changing their practices.

20 In the interest of leaving time for questions,
21 I'm not going to go through these examples. But there
22 are examples presented in the PPRS that go through types

1 of practices and improved behaviors that applicators,
2 consumers, and others have adopted as a direct result of
3 PSEP programming.

4 So, our future PSEP expectations for reporting,
5 we'll continue to report through the PPRS. It is
6 publicly available. On the last slide, I've given you
7 the contact information, so I've given you the URL for
8 that. You'll be able to get numbers and categories
9 trained, the outputs and outcomes of new materials that
10 are developed, special accomplishments and success
11 stories, and again impacts, if states can cover the cost
12 of the survey.

13 I do want to tell you that the funding sources
14 for this are all pooled. I showed you the great variety
15 of funding sources that we get. So, it's difficult to
16 break down exactly which funding went to which program or
17 which of these efforts. It's very important to keep all
18 these sources of funding and keep the flexibility within
19 it so that we can continue to address emerging issues in
20 the states and to address regional issues, take advantage
21 of new technologies when we can, and so forth.

22 The only things that we'll probably be able to

1 track in a defined way are cases where we get competitive
2 grants, which we don't always have to report through the
3 PPRS, because, for instance, I may get some other funding
4 from USDA, completely different, that's a competitive
5 grant that has an element of research, which I don't
6 report through PPRS, and an element of implementation
7 back into my PSEP. So, there are also other data that we
8 actually don't even track very well on top of what we do
9 track through PPRS.

10 Again, the FY '08 funds won't reach the state
11 PSEPs until late in 2008. We cover the accomplishments
12 of the previous federal fiscal year and all of the
13 sources are pooled. So, the first report covering the
14 PRIA monies will actually be submitted electronically in
15 winter of 2009, covering what we did with your 2008
16 money, which will actually be most of 2009.

17 The contact information doesn't show up too
18 well on here, but that's why you have the handout, so
19 that you can get this information. There is a list of
20 state pesticide safety educator coordinators up on the
21 web. You can contact the American Association of
22 Pesticide Safety Educators, which is our professional

1 organization that most of us belong to. You can directly
2 access the Performance Planning and Reporting System to
3 look at the plans of work and to look at the report. Jim
4 Parochetti has given you his contact information here as
5 well. Thank you.

6 MS. EDWARDS: Okay. Thank you, Amy.

7 Maybe we can have questions for maybe five
8 minutes and then take a short break, actually. So, a few
9 questions?

10 UNIDENTIFIED FEMALE: Because I'm a
11 coordinator, I'll just add one thing. In looking at the
12 impact slides, because that's always, as we talk about
13 measures today, it's something that's very important on
14 what changes are being adopted. One of the things that
15 we learned about at our last training meeting that we had
16 in Portland, Maine, was a device that you can see on TV,
17 the audience response system, where you can -- and many
18 of us are now, if we can expend the money to put those
19 into our programs --

20 I spent \$17,000 this past year to integrate
21 those into our program. But it's going to be a nice way
22 at the end of both precertification training to do pre-

1 and post-test evaluations, as well as when I do a module,
2 let's say, on drift, spray drift mitigation, at the end
3 ask, you know, how many of you are changing these
4 practices.

5 The only thing I won't be able to do is go a
6 year later potentially and ask who really did change that
7 practice. But I think we have some tools out there that
8 will help us improve some of the impact assessments.

9 MS. BROWN: I'll just say that we discussed
10 this also at our eastern region meeting this year,
11 northeastern region meeting.

12 I'm spending \$8,000 and ordering them for my
13 state. We are using them in part exactly the same way.
14 If you're not familiar with them, it's an anonymous way
15 for the audience to respond to a question, but you can
16 track the data. So, you can ask the question of how many
17 of you plan to adopt an improved practice from this
18 session and they can press the button.

19 You can also ask them how many of you -- I go
20 back and do this every year by paper -- I say 30 percent
21 of you told me last year that you would start wearing
22 gloves, which you didn't used to do. How many of you

1 actually did it? So, I can do that right immediately at
2 the meeting and track those data.

3 But again, it's anonymous and everybody has
4 one. So, it's better than doing a survey. Once you get
5 over the initial cost of those things, it's great and
6 cost effective.

7 MS. EDWARDS: Maybe we should put those on the
8 tables here.

9 Any other comments or questions before break?

10 (Whereupon, there was no verbal response.)

11 MS. EDWARDS: Okay, thank you. Let's come back
12 about close to 3:25 as possible. We will start no later
13 than 3:30.

14 (Whereupon, a brief recess was taken.)

15 MS. EDWARDS: All right, it's time to sit down.
16 Thank you. I'd really like to get through the entire
17 agenda today because we have speakers here to touch on
18 the colony collapse and pollinator protection issues.
19 I'd like to get through that today. I think we should be
20 able to do that.

21 Closing out the USDA updates, Marty Draper is
22 here, national program leader for CSREES, USDA. Marty.

1 DR. DRAPER: Thank you, Debbie, and thank you
2 for the opportunity to visit with you today about
3 something that I'm actually passionate about, the
4 integrated pest management PIPE, an acronym that we have
5 for this tool. It stands for Pest Information Platform
6 for Extension in Education. Al Jennings has assured me
7 that we have an hour and a half this afternoon, but I
8 don't get to use it all. So, I'll try to move along here
9 as quickly as I can.

10 If we look back at the history of the IPM-PIPE,
11 this is a tool that was really developed out of a need to
12 track soybean rust when it was introduced -- the
13 introduction was imminent in 2004. It really came out of
14 a grower outcry that we needed to have some kind of tool
15 out there that could be used to follow this organism.
16 Some of you may have a familiarity with this tool. I'm
17 going to back up and kind of give the basic explanation
18 to get everybody up to the same point.

19 While we have one basic IT platform for display
20 of this tool, I really want to emphasize that it's not
21 bound by that platform. That is just one way of doing
22 it. Really, the IPM-PIPE is a concept. The most

1 important points of this concept are visualization and
2 communication. This is a tool that enhances both of
3 those.

4 There's no better way to explain, particularly
5 to a grower, where a threat might be to him from some
6 airborne organism than by showing a picture. So, this is
7 a web-based tool that we can use to track high
8 consequence pests generally that occur over a wide area.
9 So, it allows us to show people -- in this case, what
10 we've been using is county-level resolution -- where that
11 pest might be relative to them.

12 Really, we believe that with good
13 communication, we can enhance the management of that
14 pest. When we're talking about something like this where
15 there was a great concern of widespread spraying of
16 fungicide over 73 million acres of soybeans, we really
17 wanted to do anything that we could to encourage
18 judicious use of those products.

19 Now, it's important to recognize that this IT
20 platform has to be plastic, has to be dynamic. It's
21 adaptable to whatever it is that we need to be working
22 with. When we look at a soybean rust example for the

1 IPM-PIPE, we're really looking at the full package, all
2 of the tools combined that really have been put in place
3 to do the best that we can to manage the pests and put
4 the grower in the best position to make economical and
5 wise decisions in managing his crop. The tools really
6 get the pest.

7 It's a versatile tool. It is a tool. It's a
8 package. It's a suite of tools that we can use. It's
9 adapted to whatever pest system we're working with.
10 While soybean rust may have been the first that we used,
11 it's not the only pest system that we're applying this
12 concept to.

13 I think what's really important about this is
14 it really is mere real-time advisory information that can
15 provide planting decision aid in certain situations, and
16 certainly actions you might take on that crop with
17 pesticide applications can be moderated by this tool.

18 It's really important to remember it's not a
19 cookie cutter. We've heard a number of criticisms of
20 this tool that what we're trying to do is take pest
21 systems that are round pegs and pound them into a square
22 hole. That's simply not the case. That's what I talk

1 about with it being an adaptable tool. We can take the
2 pieces of the concept that fit a particular pest system
3 and apply them to the appropriate pest system.

4 So, for example, if we don't have something
5 that's airborne, let's say we're talking about something
6 like herbicide resistant weeds, let's say we're talking
7 about something that's variable across cropping areas
8 like soybeans cynematode where there may be multiple
9 pathotypes of that organism that are place bound, this
10 does give us an opportunity to do just basic mapping and
11 show producers where this thing is at and they can have
12 an idea whether or not they should be watching that crop
13 more closely for those particular problems.

14 As we look at the pest systems that we have
15 under the soybean rust -- or excuse me, under the IPM-
16 PIPE umbrella right now -- and we do like to think of the
17 PIPE as the platform or the umbrella. The flagship is
18 kind of soybean rust. We've had that program going since
19 2005 when it was first developed by APHIS and then in
20 2006 it was handed off to CSREES as the agency that would
21 maintain the program.

22 Since that time, we added in 2006 a Soybean

1 Aphid PIPE. It was a very easy transition to another
2 pest that has invasive and explosive potential that was
3 already out there on a crop that we had monitoring going
4 on in already.

5 In 2007, we added a Legume PIPE, and I call it
6 a Legume PIPE because this is all of a sudden a broader
7 perspective on what kind of pests we can monitor. It
8 initially included soybean and track viruses. Since
9 then, we've really moved into cool season legumes, dry
10 beans, lentils, chick peas, field peas, looking at a host
11 of different pathogens and insect pests that might be
12 present in those crops. This really kind of developed
13 because we were looking at the threat of soybean rust
14 moving into these related crops that are known to be
15 hosts of that fungus.

16 Now, as the years went on, we really developed
17 a partnership with the Risk Management Agency to help
18 make this thing go. CSREES has not really provided
19 funding directly for the program. We've administered the
20 program, but since the APHIS handoff, it's been the Risk
21 Management Agency that has really kept this thing going.
22 They provided enough money a year ago that we were able

1 to hold a competitive program, a competition for new pest
2 systems to be implemented into the PIPE.

3 The winners in that program were Cucurbit Downy
4 Mildew PIPE. There had been a version of this program
5 that had been going on out of North Carolina State
6 University for the last several years that had grown out
7 of the tobacco blue mold program. And also the Pecan Nut
8 Casebearer PIPE was launched out of Texas. That program
9 is a little bit farther behind trying to get themselves
10 established. But the Cucurbit Downy Mildew PIPE actually
11 was in operation this last year. The important thing
12 about this umbrella is that we really do provide a level
13 of producer security through this wide area pest
14 tracking.

15 Now, when we start looking at what we're doing
16 with the PIPE, this is really based on classic early
17 detection rapid response. If you take a look at the
18 APHIS-PPQ model, they talk about prevention,
19 preparedness, response, and recovery. As we consider how
20 some of the CSREES associates through the land grant
21 university system fit into this model, we really have to
22 look even a little bit broader than the IPM-PIPE.

1 But you'll notice that under the prevention
2 recognition bullet, we're really seeing that the NPDN
3 comes into play as well, the National Plant Diagnostic
4 Network, because of the first detector program that's a
5 part of that program. That fits in very well with what
6 we're trying to accomplish with the IPM-PIPE in that
7 we're training people to recognize some of these specific
8 problems and then that fits in very well with more
9 specific scouting that may be done later through the
10 PIPE.

11 Preparedness has an NPDN role. When we really
12 move into response and recovery, that doesn't fit as well
13 with the land grant mission, other than through the
14 education role.

15 When we look at the first detector network,
16 there are six modules that are out there. Actually,
17 right now the training is available online in an
18 interactive system. You can reach that going through the
19 NPDN.org website and follow the links through training
20 and education.

21 But the Module 1 is crop biosecurity; Module 2
22 is monitoring high risk pests; Module 3, quality and

1 secure sample submission, which we think is really
2 critical. Any time we're looking at integrated pest
3 management, I've heard some disagreement among some of my
4 colleagues, but I think that really diagnostics is at the
5 heart of pest management. If we don't know for sure what
6 we're managing, what are we managing? What are we doing
7 out there? So, I think that really that fits in very
8 well with the bigger goal of integrated pest management.

9 So, as we look at how all these things fit
10 together through the land grant system, I think we can
11 consider the partners that are in this. The NPDN and the
12 IPM-PIPE are two major components. I think what's
13 important here is to differentiate what their roles are.
14 The NPDN is out there -- and we're collecting a
15 tremendous number of samples every year from the NPDN.
16 However, this is very broad sampling across a lot of
17 different crop species, a lot of different plant species,
18 and it doesn't go very deeply.

19 At the point that we identify some problem that
20 we need to have greater information about, the IPM-PIPE
21 is a great tool for very focused sampling that can give
22 us tremendous volumes of information on those pests.

1 APHIS PPQ is certainly a partner in this process.
2 Depending upon where that organism might be in the
3 regulatory process, that's really going to determine what
4 APHIS' role might be within the NPDN. That's where our
5 expert labs might be.

6 As we're looking at this problem coming up with
7 the UG 99 race or pathotype of wheat stem rust, it may be
8 ARS that has a role in this. They are probably the
9 experts on that particular organism. But certainly there
10 are other places where we have partnerships. I don't
11 want to exclude the National Research Initiative, soon to
12 become the Agriculture and Food Research Initiative,
13 AFRI, which is where the funding has started for a number
14 of these programs that have been moved into the PIPE.

15 We've got some new programs coming along that
16 are very PIPE-like in their emphasis. Critical and
17 emerging issues, grants programs, Risk Management Agency,
18 and the regional IPM centers have also funded programs
19 that are supplemental to both NPDN and the IPM-PIPE.

20 So, let's talk a little bit about some
21 specifics in the PIPE. I'm going to use the soybean rust
22 example because it's probably the most complex of any

1 that are out there. But it's really multiple components
2 that are involved in this reporting and visualization
3 tool. We have detection through scouting that reports in
4 through this web site which allows producers to look at
5 where the problem is relative to where they are, do risk
6 assessments, and then there's communication among those
7 that are doing the scouting, as well as extension
8 specialists across the state.

9 This is an observation network that's at the
10 heart of the PIPE with an IT platform for reporting.
11 Now, I like this as a sentinel system plus. We have both
12 repeated observations in sentinel locations. We have
13 single observations through mobile scouting. Really,
14 there are some advantages that we can gain through having
15 sentinel observations at the core of this scouting
16 system.

17 Perhaps, foremost is the experimental control
18 that we have. We know what the host genetics are. We
19 know whether or not there have been pesticide
20 applications made. It's really tough to come up with
21 observations when you're looking for a disease if the
22 crop has been protected against that disease or you're

1 looking at a resistant variety being planted in that
2 field. So, when we go out and do a random survey, it's
3 tough to know exactly what we're seeing. We have a much
4 better handle on it through a sentinel system.

5 Here's an example of the web site from a page
6 that you might not normally see. You'll often see that
7 green and red page that we've been looking at earlier
8 that's showing up in the upper right hand corner of the
9 screen. But as you scroll down on some of the maps that
10 are on the right hand side, you actually have additional
11 options that are out there. This map shows when updates
12 have been posted for various states. So, the dark blue
13 show that the updates for recommendations for producers
14 have been done today, the lighter blue have been done in
15 the last 10 days, and if it's turned white, it's more
16 than 10 days old.

17 So, we've got an observation map. We have a
18 national commentary that tells us where the disease is in
19 the country. We have an opportunity for e-mail alerts so
20 if something is popping up in your part of the country or
21 anywhere in the country, you can have an e-mail that
22 comes to you and says this is going on. I would warn

1 anybody that thinks they want to do this, it can fill up
2 your inbox really fast.

3 State commentary that we're looking at right
4 now -- and, in fact, to back up a little bit on the state
5 commentary, if you were to click on any one of those
6 states, you would actually be able to see a specific
7 commentary for that state. So, a producer in Texas, for
8 example, could see commentary that had been posted within
9 the last three days telling them what the risks are
10 relative to them in their state.

11 Disease forecasting, this is one of the models
12 that we have up there where we actually are approaching
13 forecasting through a number of different approaches.
14 There are two actual forecasting systems that are in the
15 maps on the right hand column. Those are actually on a
16 backside system right now that can be used by the state
17 specialists.

18 There's also a high split model that can show
19 wind currents and how the organism may have been spread.
20 Through all of those forecasting systems that we have up
21 there, you can come up with a pretty good idea on where
22 the greatest risk is. When you're looking at about 14

1 days, 10 to 14 days before you're going to see disease
2 development, there's actually an opportunity for response
3 if you look like you're in a high risk area.

4 The mapping tool on the far side, on the left
5 side, actually gives you both a historical reference as
6 well as an up to date mapping of where the pathogen might
7 be or the pest might be. Then, over in the upper right
8 hand corner, you can see you actually can choose
9 different pests. There are drop down menus there so you
10 can choose soybean rust or soybean aphids, for example.

11 Then, management tools, the last one I want to
12 point out, where you see GFP tool down there, that stands
13 for good farming practices tool. This is one of the
14 tools that was developed from RMA, the Risk Management
15 Agency, through the Agricultural Risk Protection Act.
16 What we're really trying to do here is give producers an
17 opportunity to record information that they have used in
18 managing the crop in respect to this pest so that they
19 can have that documentation as they go in to make a claim
20 on crop insurance.

21 So, where are we going with this, with this
22 IPM-PIPE? What's our forecast? What's going to go on in

1 2009? What's going to go on in 2010? Well, we're really
2 at a critical stage with this program. I've been working
3 in integrated pest management to various degrees for over
4 25 years. This is one of the most exciting near real
5 time programs that I have ever worked with in IPM.

6 We're going to continue to support this through
7 CSREES through national program leader time. Where we go
8 beyond that is where the real questions come in. We are
9 at a funding crisis with the program. As I mentioned, we
10 have not seen any appropriation for this program. We've
11 been kind of pasting it together.

12 I mentioned that RMA has been the partner
13 that's been funding the program for the last several
14 years. Due to a budget cutback in language and ARPA that
15 tells them that they can develop programs but not
16 maintain them, they've pulled out of support of this
17 program. So, as we go into 2009, we're looking to be
18 creative and find ways to keep this thing going.

19 I just was at a meeting a week ago with our
20 slaving pathology specialist from the extension service
21 across the country that have been working on slaving
22 rust. They've come up with a scaled-down version of this

1 program. If we can come up with change out of the couch,
2 about \$300,000, we can keep this thing going for another
3 year. But then, where we're going to go in 2010 is
4 another question. So, I mean, this is really an
5 inexpensive program to run, but we're not exactly sure
6 how we're going to make it continue into the next year.

7 Now, this is also complicated by a change that
8 we've had in the farm bill this last year, a couple of
9 months ago, that changed some of the funding in the state
10 IPM coordination programs where we have previously funded
11 a base program in integrated pest management at each land
12 grant university, each 1862 land grant university, to a
13 base level. Not a huge program in most states. But the
14 IPM coordinators in many states have been closely
15 involved with this program and with this new change in
16 the farm bill that causes those formerly formula dollars
17 to become competitive.

18 We're going wind up with about a seven to nine
19 month shortfall where some universities are not sure
20 they're going to be able to support that person. So, we
21 had a network of IPM coordinators out there in the states
22 that have been involved in a number of IPM programs.

1 Right now, I can't tell you what that's going to look
2 like when June comes around next year.

3 So, as I said, we're at kind of a critical
4 stage in a number of these programs. How they stay
5 together is going to be dependent on some creativity and
6 really, I think, some collaboration across maybe some
7 nontraditional alliances to try and make this thing work.

8 So, thank you for having me and I'd be happy to
9 entertain some of your questions, or not.

10 MS. EDWARDS: Thank you, Marty.

11 Questions? Comments?

12 (Whereupon, there was no verbal response.)

13 MS. EDWARDS: Well, you did a good job.

14 DR. DRAPER: I guess, or it's really late in
15 the day.

16 MS. EDWARDS: Oh, we did have a question, good,
17 or a comment. No, we don't. All right, well, thank you
18 very much. We appreciate it. Okay, we do have one.

19 DR. BERGER: Thanks very much for your
20 presentation. I'm Lori Berger from California. We are
21 very concerned in our state. A lot of the -- some of the
22 extension dollars, a lot of the publications cost and so

1 forth come through this program and it has been switched
2 to a competitive program. We're just extremely concerned
3 that the UCIPM and other systems like it in other states
4 will be seriously impacted by you guys moving to a
5 competitive system versus formula. We just really
6 utilize those dollars a great deal. And with other
7 budget shortfalls, it's serious.

8 DR. DRAPER: We've heard from many states that
9 those dollars, while they're small, are leveraged to
10 really make a lot of things happen for IPM in their
11 universities. I would encourage you that up until
12 November 15th, we have a comment period, a public comment
13 period, on the IPM 3D program and you can post those
14 comments to an e-mail box that we have put up at CSREES.
15 That e-mail address is neweipm, as in a new form of the
16 extension IPM programs, neweipm@csrees.usda.gov.

17 DR. BERGER: Could we also get a copy of your
18 presentation, please?

19 DR. DRAPER: Sure. There are several of them
20 around here. I think they were passed around. If we
21 missed somebody, we'll get that back to you.

22 MS. EDWARDS: Okay, thanks again.

1 We'll move now to the last session of the day
2 which is on pollinator protection, a very, very important
3 issue on agriculture these days. I think we're switching
4 the order, I believe I've been told. So, tell me if I'm
5 wrong. We'll start with Colony Collapse Disorder Update
6 by Jeff Pettis of USDA's Bee Research Lab.

7 DR. PETTIS: Thank you very much. It's a
8 pleasure to be here. I'd like to talk to you today about
9 -- Tom Steeger and I will share this session about
10 pollinator issues in general.

11 I'll focus my talk at the beginning on all
12 pollinator declines, but then most of my talk will be on
13 colony collapse disorder, which is effecting honey bees,
14 apis mellifera. To do that, I'll talk about the symptoms
15 of CCD a bit and then I'll talk about our surveys over
16 the last two years in which we've tried to document
17 what's happening with pollinators, honey bees in
18 particular and those losses, and some of our research
19 efforts both at USDA-ARS and also at University and
20 trying to understand the causes behind colony collapse.

21 The National Academy of Sciences was very
22 forward thinking in that they began to look at pollinator

1 decline about three years ago and convened a panel. They
2 published a report in 2007 which the basic conclusion of
3 which was pollinators are in decline, wild pollinators,
4 native pollinators, honey bees.

5 But one of the problems that they faced was
6 that there's very little consistent data on pollinators.
7 Either you don't know the species you're working with or
8 there's not year-to-year data on how these honey bees or
9 other pollinators are affected. The one case that they
10 did have was consistent data over time with honey bee
11 colonies in the U.S. and that data was collected by NASS,
12 the National Agricultural Statistics Service.

13 Similarly, though, in Great Britain, they
14 published a study about -- they looked at two different
15 pollinators in the Netherlands and Great Britain, and
16 they also concluded that there were declines in both
17 bumble bees and other pollinators in Great Britain and
18 the Netherlands. So, there's an abundance of data out
19 there that in fact pollinators are in trouble. What I'll
20 do now is switch to some of the conclusions that they
21 drew about why pollinators are in decline and some of the
22 things that we know are affecting honey bees.

1 Certainly, things like pesticide use and
2 habitat destruction were both pointed to in both of these
3 publications, habitat destruction perhaps being one of
4 the primary things. If you turn land into either urban
5 areas, farming areas, or disrupt it in some way, you're
6 disrupting the natural habitat that those insects rely
7 upon for nesting and for forage.

8 Similarly, and I work in agriculture, but large
9 agriculture produces large monocultures of plants. All
10 of these pollinators rely on pollen as their protein
11 source. So, if they're getting nothing but soybean
12 pollen or nothing but sunflower pollen, perhaps that
13 pollen is, in fact, nutritionally deficient for them.
14 It's always best to get a mixed diet.

15 So, the other thing that comes up with
16 monocultures is we have very little edge effect. If you
17 look in that picture of soybeans, you see an edge of a
18 field there. A number of our native pollinators depend
19 on those field edges for their nesting habitat. So, the
20 larger fields that we get, the more disruptive it is,
21 especially to the native pollinators, but also even to
22 honey bees. Honey bees placed on these crops may not be

1 getting the nutrition that they need.

2 This is the data I was referring to from the
3 National Agricultural Statistic Service. In the 1940s
4 and 50s, you see that we managed in the U.S. about five
5 million colonies. So, about five million colonies of
6 honey bees in the country and we've been on steady
7 decline since that time period. The current time we
8 manage about 1.4 or 1.5 million -- or, sorry, 2.4, 2.5
9 million colonies. So, we've had basically a 50 percent
10 reduction in the number of managed honey bee colonies in
11 the U.S.

12 Now, parasitic mites, you may or may not have
13 heard of them, but we have two introduced parasitic mites
14 that came in in the 1980s and 90s. That's been some of
15 the major things that bee keepers face as a problem.
16 But, in addition to that, the honey bee declines have
17 been continuous and we're having trouble maintaining our
18 numbers over the past few years.

19 This pollinator decline in honey bees comes at
20 a time when in fact we have increasing demands for
21 pollination. If we lived out in California, the almond
22 crop alone in California requires almost 1.5 million

1 colonies currently to pollinate almond. So, we need 1.5
2 million of our 2.5 million honey bee colonies in
3 California every year.

4 Well, to do that, we have to truck bees, load
5 bees on trucks from all over the country, move them into
6 California for a two to three month period to pollinate
7 just that one crop. In the past, we've moved bees from
8 the Midwest into California to meet that need. But
9 currently we're moving bees from upstate New York, Maine,
10 Florida, all the way on the east coast all the way to
11 California.

12 Those bees then, after mixing for quite a while
13 in California -- and these bees are packed in the central
14 valley -- they then go out to apples, blueberries and the
15 like to complete the pollination cycle throughout the
16 season. But there's an increasing demand, not only in
17 almonds but in other crops, blueberries and apples and
18 the like at a time when we have a decreasing number of
19 honey bee colonies.

20 Just to highlight that, if we look at the
21 almond acres, the estimated number of honey bee colonies
22 required for the almond acres in California, in the

1 middle there you have 2008, we needed almost 1.5 million
2 colonies. We met that demand, so we were just able to
3 meet that demand.

4 By 2012, we'll need over two million colonies
5 in almonds and we don't have those bees. We don't have
6 those honey bees. I know that the California almond
7 producers are looking at Mexico, they're looking at
8 Canada. We're importing from Australia currently to meet
9 that need. So, those plants are already in the ground.
10 That increasing demand is real. It's not just projected.
11 It's real.

12 Another thing in supply and demand is in
13 California almonds, about five years ago the price per
14 colony was \$75 per colony. Currently, it's \$150 a
15 colony. So, the price has doubled. And even with the
16 price doubling to \$150 a colony, we're still barely
17 meeting that demand. We're pulling bees from all around
18 the country.

19 Likewise, in blueberries, the price has gone
20 from about \$40 a colony to almost \$80, and sometimes \$100
21 a colony. So, we are right at our carrying capacity for
22 commercial honey bee colonies for pollination.

1 Couple that with the fact that we have some
2 increasing diseases and this phenomenon of colony
3 collapse disorder and our industry -- the honey bee
4 industry is really in trouble. You're looking at a queen
5 in the center there with workers and the brood and comb
6 that constitutes the honey bee colony. I just wanted to
7 point out that there's a number of pests and diseases
8 that are trying to gain access to that rich resource.

9 So, in the environment, if you think about a
10 honey bee colony, it's full of wax and pollen and honey
11 and the bees themselves. There are a number of organisms
12 and I've only shown a few there. I mean, it starts from
13 bears and goes all the way to bacteria. There's a number
14 of things that are trying to take advantage of that
15 colony. The colony has to martial a variety of defenses
16 to fight off these pests and pathogens.

17 So, recently we described a new phenomenon in
18 honey bees we call colony collapse disorder. It's
19 characterized by the rapid loss of worker bees from those
20 colonies. We know that the loss of those worker bees is
21 rapid because in those colonies, we still see abundant
22 frames full of young developing bees. If that adult

1 worker bee population has been lost, there had to be a
2 strong colony there prior to rear that young brood. So,
3 those two factors together, the rapid loss of worker bees
4 and the excess brood, is what we're defining as colony
5 collapse disorder.

6 Now, I don't want you to get the impression
7 that all problems in honey bees right now are colony
8 collapse disorder. You'll see that as we go through.
9 But certainly, it is a new phenomenon. These
10 characteristics don't fit other things that we see --
11 other ways of bee colonies dying in the past.

12 Our working hypothesis for what is going on in
13 honey bees with colony collapse disorder is that we have
14 some form of a primary stress, whether it be these
15 parasitic varola mites pictured there on the very top on
16 the bee with the wrinkled wings or we have some
17 management issue where the bees are moved further
18 distances. We could have nutritional issues with
19 droughts in various parts of the country. Certainly,
20 pesticides could be playing a role, low level exposure to
21 pesticides.

22 Some of these primary stressors are putting the

1 bees in a weakened state so that then these pathogens are
2 always present and the pathogens have been allowed to
3 replicate and kill the colony. Those could be viruses.
4 Nosema is a gut parasite that lives in bees. We have a
5 number of fungal and other bacterial diseases of honey
6 bees.

7 So, the idea is that the bees are stressed by
8 some primary stressor that may not, in fact, be enough to
9 kill the colony, but coupled with the pathogen, we are
10 seeing colony deaths.

11 Last year we reported on the Israeli acute
12 paralysis virus. It's the best predictor of colony
13 collapse disorder in a paper. That fits this model where
14 the colony is stressed. And, in that case, this Israeli
15 acute paralysis virus was present, replicated and killed
16 those colonies.

17 This past year we saw in California the sister
18 species to Israeli acute paralysis virus which is
19 cashmere bee virus (phonetic). We saw that virus at
20 higher than normal levels in colonies that were not doing
21 well. So, we think this fits this model. What we need
22 to do is understand these primary stressors better and

1 how we can limit those, as well as being able to take
2 care of the pathogens.

3 You're looking at a set of a gene diagnostic
4 tool that we've developed. It became possible to do this
5 kind of diagnostics because of the sequencing of the
6 honey bee genome. You see Gene Robinson and May
7 Barinbaum (phonetic) pictured there under the detoxicity
8 group. They're working on genes that are turned on and
9 off in response to pesticides.

10 In the middle, you see immune genes. That's
11 genes that are turned on in response to some pathogen.
12 Again, most of this is made available because we have the
13 honey bee genome now sequenced. In the pathogen column
14 are those things that I've already mentioned, the
15 viruses, the bacteria and the fungi. We can screen for
16 those. Most of that was developed by Jay Evans and Judy
17 Chin (phonetic) in my lab. We can screen for all of
18 these things at one time in a bee sample. Then we get a
19 picture of what that colony was like when it collapsed.

20 Now, I think what I'm about to show you next is
21 a very complicated set of lines and designs, but I'll
22 take you through that. It's not as bad as it looks upon

1 first glance. First of all, just look on your left.

2 Those are strong colonies and on your right are weak
3 colonies.

4 The hexagon, the sides of the hexagon indicates
5 the amount of the pathogen that was present. So, NOSC is
6 Nosema. BQCV is black queen cell virus. And there's
7 other ones, deformed wing virus and stuff. So, the sides
8 of the hexagon denotes the amount of pathogen that was
9 present. The strength of the line indicates the strength
10 of the association. So, you're not supposed to make too
11 much sense out of that, other than to get from it that
12 the weak colonies had a lot of different pathogens
13 present and there was a lot of interaction. So, those
14 strong lines are all the interactions present.

15 If you look at the strong colonies, there was
16 some pathogens present but there was only one strong
17 association. It was between cashmere bee virus and IAPV.
18 Those are sister species, so those were linked in our
19 analysis.

20 The take-home message from that is it fits our
21 model. Those weak colonies, whatever organisms are there
22 will take advantage of that honey bee, that weakened

1 honey bee colony. But to try to understand the
2 relationship between all these is becoming very
3 difficult, but we're trying. But again, the power of
4 this analysis, it does allow us to look -- if there were
5 a single pathogen that was causing colony collapse
6 disorder, we'd pick it up with this type of analysis.

7 That brings me to a point I'd like to make that
8 in research, we like to eliminate all other variables and
9 focus on one thing. We may want to focus on the effect
10 of pesticides on bees, so we'll try to control viruses,
11 nosema, parasitic mites and control the nutrition of
12 these colonies and focus just very simply on pesticide
13 exposure. We tend to think in single terms of one
14 factor. It's much easier to test for.

15 What we do is we tend to ignore interaction.
16 It's very hard to set up experiments to test interactive
17 effects, but I think that's where we're going with the
18 research. In fact, I know that's where we're going with
19 the research because we have some studies underway in
20 which we begin to pull these things together and say,
21 what happens if you have low level pesticide exposure and
22 nosema in that colony and then viruses are present. Or,

1 how do parasitic mites and nutrition interact?

2 We began to look at that at both the university
3 and at the federal labs. So, again, our goal in the past
4 has been to eliminate all other variables and focus on
5 one variable at a time. I think we really have to move
6 into these interaction studies.

7 Also, if we look around the world, we're in
8 contact with researchers around the world. It is
9 entirely possible that interactions that we see here
10 won't be the same interactions that we see perhaps in
11 Europe.

12 So, the past year and two years, we went out
13 and collected a number of samples from weak and dying
14 colonies and also from health colonies in those same
15 areas. We looked at the bees. We looked at the
16 pathogens. I've shown you some of that. We also
17 collected the wax, the honey and the pollen from those
18 colonies. I want to share with you some of the pesticide
19 analysis that we did on the pollen from weak CCD-like
20 colonies.

21 What we found was there's a variety of
22 pesticides that are coming in or are present in the

1 pollen. The pollen is approaching the bees requirement
2 for development. So, it's an important food source. So,
3 this graph just shows the frequency of all the samples
4 that we had for pollen, the frequency of the various
5 compounds that are listed on the bottom, the various
6 pesticides, fungicides and herbicides that we found in
7 pollen in these bee colonies.

8 The first two items on the list, the
9 Fluvalinate and the Coumaphos, are bee keeper applied.
10 So, they are items that bee keepers put in the colony to
11 control parasitic mites. We've known that those build up
12 in wax. They're present in the wax. They're lipophilia.
13 They stay in the wax. But, in fact, we're finding them
14 in the pollen as well. I think chlorpyrifos is the third
15 item there. Most of the other compounds didn't fall
16 below 20 percent prevalence in our pollen samples.

17 But we were very surprised by both the breadths
18 and the variety of things that we were finding in the
19 pollen, which is a protein source for bees. We're
20 beginning to do studies where we look at the effect of
21 some of these either alone or in combination on bee
22 health and longevity.

1 What I want to share with you now is just a
2 study. I could have chosen Fluvalinate or Coumaphos. I
3 chose Coumaphos at this time to do a study where I expose
4 young developing bees in beeswax who was artificially
5 impregnated with Coumaphos.

6 So, what you're looking at is a comb that has
7 four different levels of Coumaphos in it, a control
8 section and then three different levels, 100 parts per
9 billion, 500 or 1,000 parts per billion, incorporated
10 into the beeswax of Coumaphos in this case. The queen
11 has come along and she's laid eggs in that comb. You're
12 looking at -- everything is capped over. There's kind of
13 a white color there. That's a successful bee developing
14 under that cap.

15 So, you see -- in the control in the 100 parts
16 per billion you see better survival. The brood has
17 survived to the cap stage, whereas in the other two
18 groups you see a lot of missing cells, open cells. We're
19 assuming that the queen laid in all those cells. In
20 fact, she did. We measured that.

21 So, the queen comes along and she lays. We're
22 measuring larval and pupil development in these bees.

1 So, I'll show you the sum of this across numerous
2 colonies. Again, this is artificial levels of Coumaphos
3 impregnated into the beeswax. Just for reference, the
4 100 parts per billion is allowable by EPA in beeswax in
5 colonies.

6 So, if we sum those over all the replicas, we
7 see that in the control, the 100, that in fact we get
8 about 90 percent survival in the controls and just less
9 than 80 percent survival in the 100 parts per million,
10 and only about 50 percent survival in the brood stage of
11 workers developing in any of those combs. Now, that 500
12 and 1,000 are very high levels, but we wanted to include
13 those just for comparison sake.

14 Now we're going to take the surviving workers
15 from those combs. We're going to let those surviving
16 workers emerge and we're going to allow them to -- we're
17 going to look at longevity in those. So, we take the
18 combs out of the colony. We cut it into four pieces. We
19 let those bees emerge by themselves in different cages.
20 We simply follow their longevity.

21 So, we look at longevity after following
22 treatment of these various compounds. What you see here

1 is the control bees lived on average 21 days in the
2 incubator as compared to about 16 days -- well, 16 to 17
3 days in the 100 parts per billion. You also may notice
4 that 500 or 1,000 parts per billion of Coumaphos actually
5 increased longevity. That's simply amazing. What that
6 is, it's an artifact of the fact that we've already lost
7 50 percent in those last two groups. We've actually
8 already lost -- if we look back at the previous graph,
9 we've lost 50 percent of those workers up front.

10 So, we've gone through an artificial selection.
11 We've eliminated the very susceptible individuals and now
12 when we look at longevity, we see that the ones that
13 survived the Coumaphos treatment lived longer. But I
14 would submit to you that the controls living about 21
15 days versus the 100 parts per billion, that was
16 significantly different. To me, that's a sublethal
17 effect of the Coumaphos in these combs.

18 That slight reduction in longevity may not seem
19 like much to you, but it becomes important when we're
20 trying to push these colonies and get these colonies to
21 produce honey and also when we're trying to get these
22 colonies to make it through the winter. So, that slight

1 reduction in longevity could be significant in them
2 actually making it to the next season, because they stop
3 rearing bees in most temperate areas around
4 October/November and they have to keep that work force
5 until the next spring. So, a slight reduction in
6 longevity is important.

7 We have a number of things that we've been able
8 to document coming into the colony. Both things like
9 Fluvalinate and Coumaphos are bee keeper induced. We
10 have a number of other compounds coming in and we're
11 beginning to try to look at pesticide interactions,
12 sublethal effects and some interactions with these other
13 stressors, like parasitic mites. Those studies are
14 underway and we hope to be able to report them in the
15 near future.

16 I talked about surveys that we've done over the
17 past two years to try to get a handle on what is the loss
18 of honey bee colonies over the past couple of years. Two
19 years ago, the APR Inspectors of America did a survey in
20 which they estimated that we lost about 30 to 31 percent
21 of all honey bee colonies.

22 Now I'll contrast that with prior to parasitic

1 mites coming into the country, we lost between 5 and 10
2 percent of our colonies every year. So, prior to
3 parasitic mites, it was 5 to 10 percent loss. When
4 parasitic mites came into the country, we began to lose
5 15 to 20 percent of our colonies. Now we have about a 30
6 percent loss with what we're calling CCD.

7 So, in essence, it's about a 33 percent
8 increase in our losses. This past year we surveyed again
9 -- in fact, we did a larger survey -- and the losses were
10 about 35 to 36 percent nationwide due to all causes, not
11 due just to CCD. But again, if we use that 20 to 25
12 percent level with parasitic mites, we're still looking
13 at about a 33 percent increase in colony losses compared
14 to what we think is normal. Normal was 25 percent loss.

15 I'd also like to submit to you that if there
16 are any dairy farmers in the room, if you lost 25 percent
17 of your herd, you'd think it was anything but abnormal.
18 The bee keepers, in fact, are willing to deal with 25
19 percent loss, but this 30 and 35 percent loss is becoming
20 unsustainable.

21 So, they have ways of making these numbers up.
22 They can make colonies up and things so they don't suffer

1 quite as much as you would if you were in a dairy herd
2 and had cows dying at that level. But it becoming
3 significant.

4 So, we continue to do research in at least four
5 areas, things like nutritional stress, moving stress. We
6 continue to look at parasitic mites. We know they have a
7 major impact on honey bee colonies. Pathogens also, we
8 know that they're interacting with some of these -- we
9 know they interact with parasitic mites and also perhaps
10 with pesticide exposure. So, we're doing a number of
11 studies. In fact, most of these are combination studies
12 where we're trying to combine more than one variable at a
13 time.

14 Honey bee colonies are, in fact, continuing to
15 decline in this country. But if you listen to the media,
16 if you listen to the media out there, you'd think that
17 the only problem in honey bees currently is colony
18 collapse disorder. I'm just trying to represent it this
19 way.

20 Some of the media knew about parasitic mites,
21 but they -- every problem in the bee industry right now
22 is colony collapse disorder. That's the picture you get

1 from the media. If you ask the bee keeper, they'll say
2 that parasitic mites are their number one problem.
3 They're fighting that every day. They also might say
4 that they have some problem with colony collapse
5 disorder, and they also probably have some other
6 problems. There's bad weather and things like that. But
7 they also would never look at management as an issue. We
8 know that poor management can be an issue.

9 The reality of what's going on in honey bees is
10 probably some combination of that. The reality of what's
11 going on in honey bees today in the U.S. is we know
12 parasitic mites are having an impact, but I believe those
13 bottom three factors are interacting and perhaps those
14 interaction factors are causing CCD.

15 But it's still conceivable that we do have a
16 new pathogen or a new parasite in the country that we've
17 missed. I really don't believe that's the case. I
18 believe that what we're dealing with is interactions of
19 those bottom three which is manifesting itself, as what
20 we call colony collapse disorder.

21 So, to conclude, crop acres in the U.S. that
22 demand pollination are continuing to increase, almonds,

1 blueberries and other crops. Over the past two years,
2 we've lost between 30 and 35 percent of our colonies.
3 That leaves us in the country with very few reserve
4 colonies. We can't marshal that extra million colonies
5 out of people's back yards, so we have about 1.5 million
6 colonies currently for pollination and currently we need
7 almost all of those in almonds in that one crop. So, we
8 either have to increase our survivorship of colonies or
9 we have to get more bee keepers involved or we have to
10 import them offshore.

11 I'd just like to close with the ability to
12 produce our own food in the U.S. should be seen as a
13 national security issue. I think the role of pollinators
14 in that food production is vital. So, thank you very
15 much.

16 MS. EDWARDS: Thank you. I just had a
17 question. Do you have to leave before 5:30?

18 DR. PETTIS: No.

19 MS. EDWARDS: I thought it might be useful,
20 then, actually, to have Tom go ahead and do his
21 presentation. We can treat this more as a panel and then
22 you can direct your questions or comments to whichever

1 speaker.

2 DR. PETTIS: That would be great.

3 MS. EDWARDS: Okay, thank you.

4 Tom Steeger from Environmental Fate and Effects
5 Division.

6 DR. STEEGER: Okay. Thank you for this
7 opportunity to speak here today. I'd like to thank Jeff
8 Pettis for his presentation on the decline in bee
9 populations. Jeff and I -- I should say the agency --
10 have worked frequently with USDA and Culture Research
11 Services, Bee Research Lab, over the past couple years.
12 It's likely that we're going to continue to do that more
13 so in the future.

14 I'd also like to thank you for the opportunity
15 to speak here and to present on the agency's efforts to
16 deal with pollinator declines. Also with me today is
17 Mary Clock-Russ (phonetic). She is the lead of the
18 pollinator team that has been established here in the
19 Office of Pesticide Programs.

20 I'd like to say up front that the agency is
21 keenly aware of the declines that are taking place in
22 pollinator populations, whether they are due to increased

1 disease or this phenomenon of colony collapse disorder
2 that hasn't been completely characterized as of yet.

3 Across numerous fronts, including regulatory,
4 research, voluntary, and communication and outreach
5 programs, the agency is endeavoring to increase its
6 awareness both within the agency and external to the
7 agency on pollinator issues. These efforts are intended
8 to better insure that the agency actions minimize
9 potential effects to pollinators.

10 A major regulatory program activity in which
11 the agency is engaged involves refinements in the
12 ecological risk assessment process for pollinators and
13 the data required to document potential effect. At
14 present, the agency relies on a tiered approach.

15 At tier 1 the potential toxicity of all
16 pesticides that have outdoor uses are evaluated using a
17 96-hour acute contact toxicity test and it can also
18 involve an oral acute toxicity test. If the 48- or 96-
19 hour median lethal dose is less than 11 micrograms per
20 bee from that study or if there's data indicating that
21 prolonged toxicity of pesticide residues on foliage or if
22 there's data indicating that there's a problem for bees,

1 the agency will routinely require a tier 2 toxicity of
2 residue on foliage test. If residues and foliage exhibit
3 prolonged toxicity and/or if there are data indicating
4 that toxicity to the bees through open literature, we may
5 also require a field pollinator test.

6 Where lower tiered tests focus on toxicity to
7 adult forage bees, the tier three pollinator studies
8 focus on both adult bees and their brood. Growth
9 survival and reproduction end points are measured.
10 Historically, the field pollinators test have been ad
11 hoc; that is, there isn't a formal design to them as of
12 yet. They were designed to address specific hypotheses.

13 The agency, though, is working towards the
14 development of more standardized chronic toxicity tests
15 for the tier three studies. The agency is working with
16 stakeholders in developing more refined field pollinator
17 study approaches. These studies include the traditional
18 end points of growth reproduction survival, but they also
19 include field studies to look at the honey bee adult and
20 brood survival and brood development. But they're also
21 measuring a broader range of end points, including the
22 incidence of disease, abnormal behavior, adult longevity

1 and overwintering success of the colony.

2 CropLife America has also met with OPP assigned
3 staff members to discuss their proposed approach for
4 conducting ecological risk assessments for bees. The
5 proposed process relies on a tiered approach using
6 existing data to the extent possible where potentially
7 high risks are identified, higher tiered refinements have
8 been proposed that may require additional test data to
9 address uncertainties.

10 CropLife America has recommended that the
11 agency, along with stakeholders, engage in a three-day
12 workshop to develop a formal risk assessment process for
13 pollinators that can be routinely incorporated into the
14 agency's risk assessment paradigm and to identify higher
15 tiered data requirement that could be used to inform the
16 process. Industry is proposing a Pellston-like
17 conference in 2009 to achieve this goal.

18 The agency continues to work with stakeholders
19 to develop appropriate label language to help mitigate
20 potential effects for bees. Although the label review
21 manual, which serves as generic guidance for bee warnings
22 and advisory language based on the tier-1 and tier-2

1 tests exists, we're looking to develop more refined
2 language that is being developed on a case-by-case basis
3 to account for effects that have been observed in the
4 field pollinator or the tier-3 study.

5 In many cases, the registrants themselves have
6 been proactive in helping to develop pollinator label
7 language. The agency is also participating with the
8 North American Pollinator protection campaign labeling
9 breakout group to look at additional types of label
10 language. We'll actually be participating in their
11 international conference the week of October 22nd.

12 OPP assigned staff also participate in the
13 colony collapse disorder steering committee and the work
14 group. This committee has been established at the
15 request of Capitol Hill. The steering committee is
16 headed by USDA and has members from government, industry
17 and academia. And through its participation in the
18 steering committee, the agency has kept abreast of
19 efforts to address CCD in terms of its definition, its
20 potential causes and its solutions. The agency assigned
21 staff are reviewing study protocols to better insure that
22 the studies have the best opportunity to be useful in a

1 regulatory context.

2 The agency assigned staff also has been
3 tracking on pollinator studies at universities across the
4 U.S. and we have conducted site visits of the several of
5 the universities that are doing studies intended to
6 address whether pesticides are affecting pollinators.
7 Lately, there has been considerable interest in whether
8 certain classes of pesticides --

9 For example, the neonicotinic insecticides are
10 affecting pollinators. EPA is participating in two
11 studies at the University of Maryland and at USDA and the
12 EPA Biological and Economic Assessment Division, the BEAD
13 labs in Fort Meade, are conducting chemical residue
14 analyses on bee and bee product samples from these
15 studies to better document exposure.

16 OPP is also increasing staff awareness of
17 pollinator related issues. The agency has offered two
18 seminars by Pennsylvania State University and USDA on the
19 status of pollinators and CCD and research related to
20 colony collapse disorder. This week, in fact yesterday,
21 approximately 40 Office of Pesticide Program staff, along
22 with representative from Office of General Counsel,

1 participated in a day long workshop on bee biology and
2 ecology conducted by USDA and Penn State.

3 The agency is also monitoring international bee
4 kill incidents related to the use of pesticides. It is
5 in contact with the government through their respective
6 countries to better understand the circumstances leading
7 to the incident and whatever actions the government has
8 proposed to reduce the likelihood of future incidents.

9 The Pesticide Environmental Stewardship Program
10 is a voluntary program that forms partnerships with
11 pesticide users to reduce the potential health and
12 environmental risks associated with pesticide use and
13 implement pollution prevention strategies. EPA
14 established the PESP in 1994 as a voluntary partnership
15 program to reduce pesticide risks. The PESP is always
16 looking for PESP partners. So, if your organization is
17 interested in becoming one, contact Tom Brennan
18 (phonetic), branch chief of the stewardship branch.

19 While government regulations can reduce risk,
20 PESP is guided by the principle that even in the absence
21 of additional regulatory mandates, the informed actions
22 of pesticide users reduce risks even further. PESP

1 promotes the use of biopesticides and advocates the
2 adoption of integrated pest management or IPM programs or
3 practices. IPM is the coordinated use of PESP and
4 environmental information with available pest control
5 methods to prevent unacceptable levels of pest damage by
6 the most economical means and with the least possible
7 hazard to people, property, and the environment.

8 By joining, organizations pledge that
9 environmental stewardship is an integral part of the pest
10 control and they commit to working towards pesticide
11 practices that reduce risks to humans and the
12 environment.

13 The North American Pollinator Protection
14 Campaign, NAPPCC, has been a PESP member since August of
15 2003 and has been furthering its goal to encourage the
16 health of resident and migratory pollinating animals in
17 North America. The North American Pollinator Protection
18 Campaign, which has developed an action plan for
19 pollinator protection, also promotes annual conferences.
20 And EPA staff members, as I said earlier, will be
21 participating in their annual international conference
22 here in Washington, D.C. in two weeks.

1 Members take strategic approach to risk
2 reduction and undertake specific measurable activities
3 toward achieving their risk reduction goals. EPA
4 recognizes the need to protect public health and the food
5 supply with efficient cost effective pest control. To
6 that end, EPA promotes the adoption of innovative
7 alternate pest control practices that reduce potential
8 risks. PESP is coordinated by the Office of Pesticides'
9 environmental stewardship grants.

10 Each PESP member is assigned a liaison from the
11 Office of Pesticide Programs or an EPA regional office.
12 The liaison works with the member to provide assistance
13 in developing and implementing the strategy. The liaison
14 shares information on EPA activities and funding
15 opportunities to support strategy implementation.

16 The agency is continuing to pursue
17 communication and outreach programs informed by data to
18 support the registration and re-registration of
19 pesticides. Reducing the risk to pollinators will likely
20 depend heavily on effective communication between
21 stakeholders. These stakeholders represent beekeepers,
22 growers, applicators, industry and federal, state, tribal

1 and local government representatives.

2 Increased areas of communication should include
3 recommendations on which pesticides to apply, pesticide
4 application timing, notification to beekeepers of
5 pesticide applications and information on what additional
6 steps can be taken to minimize impacts to pollinators.

7 The Office of Pesticide Programs has
8 established a pollinator protection workgroup. This team
9 consists of members from each of the divisions in OPP and
10 the Office of General Counsel. The workgroup is intended
11 to enhance opportunities for communication and research
12 on the potential effects of pesticides on bees and on
13 developing strategies to limit those effects. The team
14 has also provided a forum in which to interact with
15 stakeholders including beekeepers, growers and
16 registrants.

17 As such, the team is intended to provide a
18 venue for information exchange between all OPP divisions,
19 keep updated on current pollinator related issues that
20 OPP is working on and enable OPP to share its efforts
21 with public -- through OPP's feed and to seek
22 opportunities to improve the OPP/EPA protection for

1 pollinators through regulatory programs such as data
2 requirements and nonregulatory programs such as PESP.

3 So, our question to PPDC is, across the number
4 of programs that we've identified, the agency is engaged
5 in better understanding and promoting pollinator
6 protection. Given the various activities outlined in the
7 presentation, this PPDC believes that the additional
8 efforts should be expended in a particular area. If so,
9 where should additional resources be brought to bear and
10 why?

11 Current data suggests that pesticides may not
12 be the direct cause of colony collapse disorder or on
13 pollinator declines that have been described by Jeff
14 Pettis in the previous presentation. However, there are
15 insufficient data to determine whether pesticides may be
16 playing an indirect role such as serving with an
17 additional stressor rendering the bees more susceptible
18 to disease.

19 To what extent does the PPDC believe that the
20 agency should invest in research that examines the
21 potential sub-lethal or indirect effects of pesticides on
22 pollinators?

1 That -- if there are any questions.

2 MS. EDWARDS: Thank you, Tom. Hoping we'll get
3 some dialogue here. Start with John Schell.

4 DR. SCHELL: This is really interesting stuff.
5 You've got a lot of folks working on it and you've
6 probably already addressed this question. It seems like
7 one thing you have going for you is sort of a temporality
8 issue. It appeared from one of the slides that Jeff did
9 that there was sort of a steady decline and then all of a
10 sudden '85, '86 or so, there was a real sharp decline.

11 Looking at it from a pesticide perspective,
12 have you all looked at whether there were changes in
13 pesticide uses, the applications or the type of
14 pesticides that coincided with that dramatic decrease to
15 even suggest that pesticides may play a role in this?

16 DR. STEEGER: I believe that the beekeepers
17 certainly believe they have. They believe that the
18 neonicotinics have been the change that they believe is
19 responsible. The surveys that Jeff alluded to and that
20 EPA has discussed with USDA through our connection with
21 the CCD working group suggests that there is no pattern
22 in pesticide use that is correlated with declines in bee

1 populations that are being observed.

2 Clearly, in the samples that were collected
3 that Jeff reported residue analyses on, you do see high
4 pesticide residues for those pesticides that are actually
5 used to treat hives for varola mites. That would be for
6 Fluvalinate and Coumaphos. But the pattern that you see
7 in the distribution of pesticides, while there are many
8 detects that you're seeing, the level of those pesticides
9 that are being detected are relatively small
10 concentrations.

11 But, I guess to answer your question, to our
12 knowledge, there's no data showing a correlation between
13 the use of a particular pesticide or class of pesticides
14 and the prevalence of pollinator decline.

15 DR. PETTIS: I'll just comment briefly. In the
16 last two years when we've looked at where these declines
17 are occurring, we looked at where those bees had been
18 over the past four to six months and try to make any
19 association within natural areas, were they on soybeans,
20 were they -- and we saw no pattern come out of that for
21 two years, not to say it's not there. There was nothing
22 glaring in that -- looking at it from that standpoint.

1 I can't speak -- perhaps it's just a way that
2 NASS is collecting their data. NASS catches a lot of
3 flack. Actually, that is the only data we have to work
4 with. Certainly, there's been a decline and it's been
5 steady, or very low, for the last 10 or 15 years.

6 MS. EDWARDS: One plug and two questions. One
7 thing I'd like you to know is that Judy Chen probably,
8 who is on the slide, will be doing some pesticide re-
9 certification programs for me in Washington State now
10 that she's a graduate student in our department. So, we
11 will be covering colony collapse disorder this winter in
12 our pesticide certification program.

13 Two questions I know that my applicators would
14 probably ask Judy is, if we're importing bees from other
15 countries, what sort of quarantine controls are in place
16 so that we're not concerned about them bringing in the
17 future mites and the future pathogens and parasites that
18 could be the next colony collapse disorder? That's
19 question number one.

20 DR. PETTIS: USDA is a huge agency and I'm from
21 Agricultural Research Service. You're really speaking to
22 APHIS, Animal, Plant, Health Inspection Service. There

1 is some safeguards in place. They ask for inspection.
2 Right now we currently only import from Australia and New
3 Zealand. They have a couple of fewer pests than we have,
4 but they also are located in areas of the world where in
5 Southeast Asia or near Southeast Asia where we do have
6 some pests that we're worried about.

7 Free trade, we can only take reasonable fido-
8 sanitary measures. In fact, the almond growers will tell
9 you that whatever it takes, we need bees. But we do
10 believe that there are risks involved in that. Importing
11 from offshore, there are risks importing bees from other
12 places of the world.

13 MS. EDWARDS: Second question, then. If it
14 ends up looking like the secondary pathogen may be the
15 key player, what would be the biological reason that the
16 bees are not dead at the hives?

17 DR. PETTIS: Well, we've seen a lot of theories
18 about why they've gone off and joined another dimension.
19 Perhaps they have. Actually, it's really not unusual at
20 all for worker bees to die away from the colony. In
21 fact, if they have (inaudible) virus or a few other
22 pathogens that we're familiar with, we understand the

1 biology, it's almost like the bees are sacrificing
2 themselves to take the pathogen away and break the
3 transmission cycle. So, that is actually how they should
4 die.

5 The problem currently is that they're dying in
6 such short time frame and in such high numbers. So, it's
7 actually completely normal for bees to die away from the
8 hive, just not to die in such high numbers.

9 MS. EDWARDS: Thank you.

10 Jennifer.

11 JENNIFER: Thanks. Because it's getting to the
12 end of the day, I have two things to say first and then
13 my question, two unrelated things.

14 The first is to remind everybody that EPA staff
15 provided all those munchies in there and I didn't see a
16 whole lot of dollar bills in the basket. So, please
17 think about that next time you pop in to get a muffin.

18 Then, the second thing is also just to mention
19 that we also really supported the NASS chemical use and
20 survey data. We put that in writing and sent the letter,
21 that whole bunch of NGO signs. We'll continue to support
22 that program, too.

1 On this issue, I want to just try and
2 understand something and maybe -- it's on slides three
3 and four, but I'm not sure that will really help you. I
4 just want to try and understand. So, right now, all
5 pesticides do have to have a tier-1 acute toxicity test?
6 Is that right or no?

7 UNIDENTIFIED MALE: All pesticides with outdoor
8 uses based on the new 158 guidelines.

9 JENNIFER: Okay. So, I've been looking at some
10 of those and I guess that goes to my next question. On
11 your slide 3 there at the bottom, you say that mortality
12 and signs of abnormal behavior reported. But the ones
13 I've been looking at they don't actually report abnormal
14 behavior at all. They just say that they observed
15 abnormal behavior. But it's not reported.

16 Actually, because I'm looking at the DERs, the
17 data evaluation records that EPA evaluates and I'm not
18 looking at the original data, I can't see the submitted
19 data, which is fine. I don't want to a room full of
20 data. But in the DERs, it actually says that EPA didn't
21 see that either.

22 So, they're coming in to EPA saying that there

1 were signs of abnormal behavior reported and they're
2 saying things like -- I don't have them here so I can't
3 remember, something like flying funny or walking funny or
4 shaking or tremors or funny bee things that bees aren't
5 supposed to do. But it doesn't give you numbers and it
6 doesn't give you -- it doesn't say anything. It doesn't
7 give you how many and it doesn't give you how --
8 sometimes it says that they recovered after four hours,
9 which is the first time point looked at.

10 So, they might not have had those at the 12 or
11 24 hour mark, but EPA doesn't seem to be getting that
12 either, like how many, what percentage, what incidents,
13 what were they, you know, some kind of marker. Also, I
14 can't see it. So, I don't think they are reporting it.
15 I think that they're just reporting that they're
16 observing but there isn't reporting to you and then
17 they're just reporting mortality to you. So, I actually
18 think that might be a problem.

19 Then, my second point is so then you trigger --
20 you do that for all the registrations and then it somehow
21 triggers a tier 2. At what point do you trigger a
22 decaution? Like, I don't understand. I guess what I

1 want to understand in this tiered approach is where
2 there's some kind of actionable item.

3 UNIDENTIFIED MALE: Well, in answer to your
4 first question, you're correct that not all studies
5 provide the details on the exact nature of the sublethal
6 effects. The point of the acute toxicity study is to
7 estimate an acute LD 50, a lethal dose to 50 percent of
8 the organisms. So, the information on sublethal effects
9 is ancillary to the study.

10 Typically, on the acute toxicity studies, you
11 don't tend to get specific numbers. The data evaluation
12 records that are recording the information from the study
13 tend to focus on the LD 50 value itself and the numbers
14 that were used to generate that particular value, because
15 that's the value that will ultimately be used to
16 determine the nature of the label language.

17 Some studies, however, do provide information
18 on the nature of the sublethal effects whether it's
19 ataxia or lethargy. These are not organisms in a hive or
20 in a cage, so that is on pretty much an ad hoc basis as
21 to whether that information is provided. So, you're
22 absolutely right.

1 JENNIFER: Yeah, but they're still comparing to
2 controls, so it's still valid, whether in a cage or in a
3 hive or whatever. They're comparing the controls that
4 are treated under the same conditions. If the company is
5 performing it, then why wouldn't you want to see it? I
6 want to see it. I'm sure you do.

7 UNIDENTIFIED MALE: The information -- I think
8 that because of the issues that are coming up on
9 pollinators, we're more inclined now to be interested in
10 that very information. You're absolutely right. So, the
11 fact that it has not been captured as detailed in the
12 past, I believe you will see that certainly in the
13 studies that we expect in the future. The regulated
14 community would probably be best advised to provide
15 information on the nature of any sublethal effects that
16 are being observed.

17 But, with that said, because it is an acute
18 toxicity study, you would expect to see a gradient of
19 sublethal effects leading up to lethality as it's just
20 the nature of the endpoint that's being measured.

21 In response to your second question, the label
22 review manual that I alluded to gives specific guidances

1 as to the results of the tier 1 and tier 2 studies as to
2 what type of label language is best applied based on
3 those data. All label language that the agency uses,
4 particularly for environmental affects is based on data
5 and there are particular triggers that are used to
6 generate those label advisories and label warnings.
7 Those are available in the label review manual.

8 The label review manual has just been updated
9 and there is a placeholder in there that I alluded to in
10 my slide presentation that we are in the process of
11 developing chronic bee toxicity warnings that will be
12 consistent, hopefully based on certain criteria that
13 would be observed in standardized tests that would be
14 developed as field pollinator studies.

15 JENNIFER: Okay. I'm not going to discuss the
16 data issue further in public, except to say that we're
17 going to be wanting to see that -- and I'm sure you will
18 -- and I wouldn't just look at it for new registration.
19 It's not the registrants. The registrants are conducting
20 the studies or sponsoring them and those people are
21 collecting the data. It's being reported. It's just not
22 getting to you or you're not looking at it or something.

1 So, I'll just talk to you about it offline.

2 UNIDENTIFIED MALE: Okay.

3 MS. EDWARDS: Dennis.

4 DENNIS: Two questions, one on the label and
5 one toxicity related also.

6 For the tox question, how does the agency
7 access the acute toxicity of insecticides that are
8 applied through systemic routes rather than foliar
9 routes? So, if the material is applied to the soil and
10 it works its way up into that flower, how would you be
11 screening for toxicity in a situation like that rather
12 than a foliar test itself?

13 UNIDENTIFIED MALE: As I indicated before, all
14 pesticides that have outdoor uses, whether they're
15 systemic or foliar applications, undergo the same type of
16 toxicity tests where the acute 96-hour contact toxicity
17 -- where the compound is applied directly to the thorax
18 of the bee.

19 If it proves that the toxicity is less than 11
20 micrograms per bee, then it moves to tier-2 testing where
21 the compound is then applied to alfalfa and the bees are
22 put on alfalfa residues that are on the alfalfa leaves.

1 They're timed to see how long it takes for the residues
2 to decrease in toxicity.

3 The systemic pesticides, I think, are offering
4 a greater challenge to us. I think that that's part of
5 our process for improving the field pollinator studies
6 which would be better able to look at potential effects
7 due to residues that might be accumulating over longer
8 periods of time as opposed to an acute exposure that you
9 would expect from a foliar application.

10 DENNIS: Thank you. And the question about
11 labeling, you mentioned a stakeholder group that's trying
12 to tweak the label language. Do you include the state
13 lead agencies on that at this point or do you plan to vet
14 whatever language you come up with with enforcement
15 agencies so that they can take a look at whether the
16 language is going to be interpretable and enforceable or
17 is it going to be advisory language? What are your
18 thoughts there?

19 UNIDENTIFIED MALE: I'm not that familiar with
20 the agency's process for vetting the label review manual.
21 I believe that the manual is public and it's subject to
22 public scrutiny.

1 DENNIS: I wasn't referring to --

2 MS. EDWARDS: We'll vet it with you.

3 DENNIS: Okay, thank you.

4 MS. EDWARDS: Anything else, Dennis?

5 DENNIS: No.

6 MS. EDWARDS: Carolyn.

7 CAROLYN: I wanted to respond to this question
8 saying should the agency invest in research on sublethal
9 and indirect effects and actually found that coumaphos
10 research that you presented to be really fascinating and
11 kind of an example of the kind of research that's not
12 typically done in the registration of a pesticide. I
13 know that indirect and sublethal effects have been, you
14 know, a continuing source of controversy, if that's what
15 you want to call it, in the endangered species program.

16 It seems like this is an area where the tests
17 that are required for registration are really too simple
18 to actually demonstrate the kind of effects that occur in
19 the real world and that some effort into how do you test
20 for sublethal and indirect effects would be really,
21 really important in understanding the ecological effects
22 of pesticides.

1 MS. EDWARDS: Okay, thank you.

2 I believe, Julie, were you next?

3 JULIE: Addressing the two questions that were
4 posed to the committee. As far as does the PPDC believe
5 that additional efforts should be expended in this
6 particular area, where should additional resources be
7 brought to bear, the presentation from USDA was excellent
8 and I think raised the issue that there seems to be some
9 types of interactions.

10 Clearly, there's not been one single cause
11 identified. I think until that interaction is better
12 known and/or even in the realm of pesticides, a
13 pesticides isn't a pesticide isn't a pesticides. They're
14 all different chemicals, have different modes of action.
15 I think until there's really a better understanding of
16 what are these interactions and what role do pesticides
17 play or do they play a role, what pesticides may play, I
18 just see from the agency's standpoint as -- from
19 registering products, assessing the risk of products,
20 mitigating risks, until you really know what it is you're
21 trying to assess and/or mitigate, I just don't see
22 jumping too far forward because you might be addressing

1 the wrong thing.

2 As far as research in this area, I guess the
3 question is, do you mean independent research that the
4 agency would be conducting? I think with all the work
5 that USDA is doing in this area, I really wouldn't want
6 to see independent research done just on pesticides
7 that's not coordinated with the work that USDA is doing
8 on looking at interactions.

9 UNIDENTIFIED MALE: Well, our connection with
10 the colony collapse disorder steering committee has
11 provided a segue for understanding what kind of research
12 is being done to look at the declines in pollinators over
13 all the different factors that have been identified as
14 potential causes. Our focus has obviously been on what
15 type of research is being done to look at the potential
16 role that pesticides have played and where studies have
17 been identified.

18 We've been very proactive in trying to meet up
19 with those researchers, understand the protocols that
20 they're using and identify where there might be certain
21 weaknesses that would limit those studies in terms of
22 being able to be used in a regulatory context.

1 In some cases, as I've indicated, we've taken
2 it a step further and have actually utilized agency labs
3 to conduct residue analysis. That's an unusual step
4 because generating data for the purposes of registration
5 and re-registration of pesticides is the task of the
6 regulated community and not the taxpayer.

7 But because of the magnitude of the issue and
8 the agency's interest in helping to resolve it or to at
9 least participate in its resolution, we have become more
10 proactive in being involved in these studies,
11 particularly because we recognize that once the protocol
12 is written and the projects are funded, it's difficult to
13 go back and say, well, EPA is not going to get much use
14 out of this because there's this missing component and
15 they tend to be the exposure analyses which are one of
16 the driving costs of proposals. So, rather than throw
17 out the study, take that extra step and offer to provide
18 the analysis for the study.

19 JULIE: So, you're saying more that the agency
20 wants to be interactive in research that's being done as
21 opposed to doing their own research?

22 UNIDENTIFIED MALE: I guess the question would

1 be put to you. Do you think that the agency should be
2 playing this role, that it should be more proactive in
3 being involved in the research as opposed to our process
4 of typically saying this is an uncertainty that industry
5 is really tasked with identifying or resolving and wait
6 until those data come in?

7 JULIE: To the extent that the agency's
8 involvement helps them see what role this would play in
9 an assessment process, then I do think it would be
10 valuable.

11 UNIDENTIFIED MALE: We have been brutal in
12 informing researchers who don't tend to be toxicologists,
13 they certainly don't have the perspective of doing
14 regulatory science, what it is that we look for in some
15 studies. I have reviewed several studies and I never
16 heard back from the people, but there was more in the way
17 of comments on the study than there was text in the
18 proposal.

19 I think that that's been really helpful because
20 with a lot of researchers -- and it's not just limited to
21 pollinators, but it's across a number of environmental
22 studies -- are frustrated when they generate data that

1 they feel the agency should embrace and regulate on. The
2 standards that we apply to data, the scrutiny, the rigor
3 that those data have to stand up to, are different than
4 what many journals require or what the researcher has
5 typically generated in the past. So, I'd like to think
6 it's been a two-way street.

7 We try to get to them early so that they have
8 the option of at least putting some of these elements
9 into the study or at least recognizing that when they
10 generate those data, the agency has up front identified
11 certain uncertainties that would limit our capacity to
12 establish a clear dose response relationship, a clear
13 cause effect relationship. To the best of your ability
14 you've focused in on just that issue that allows us to
15 make some conclusions and say it wasn't something else,
16 that we feel comfortable in moving forward on it. So,
17 we've tried to be very proactive in that area.

18 UNIDENTIFIED MALE: I just have to comment
19 quickly because I don't want to belabor the point. But
20 Tom and the agency have been very helpful in criticizing
21 or critiquing our protocols. It has been very helpful
22 because obviously we think we know what we're doing. In

1 fact, oftentimes we don't. So, it's been very good
2 dialogue and very helpful.

3 MS. EDWARDS: Michael.

4 MICHAEL: You mentioned neonicotinoids a couple
5 of times. This hypothesis has been around actually for a
6 few years both in Europe and in this country with the
7 hypothesis that exposure to bees in the field leads to
8 sublethal behavioral kinds of effects where they don't
9 find their way back to the hive. It would be a perfect
10 description of the kind of description that was given on
11 the colony collapse disorder.

12 Are you addressing this kind of a question in
13 field tests particularly or with the University of
14 Maryland Fort Meade collaboration? Are you looking at
15 this? I think this would be an important kind of
16 additional possibility for turning into a regulatory kind
17 of assessment, you know, very specialized albeit. How is
18 this hypothesis being addressed?

19 UNIDENTIFIED MALE: Let me say up front out of
20 fairness to the registrants for the neonicotinoids, that
21 is a hypothesis that has not been thoroughly vetted.
22 It's certainly one that the bee keepers have a very

1 strong opinion about. We are aware of the data that's
2 been generated particularly in France and the actions
3 that the French have taken to address that. Our
4 understanding of those data, though, at this point is
5 that they lack the consistency that we need to actually
6 establish a uniform cause/effect relationship.

7 The study that is being conducted by Gail
8 Endivley (phonetic) at the University of Maryland looks
9 at this very issue. He has exposed watermelons to
10 (inaudible) treatments at typical application rates,
11 established what kind of concentration we'll expect to
12 see in the pollen and nectar of watermelons, and then fed
13 bee bread which is a combination of honey and pollen at
14 those residues and at higher levels. He is measuring
15 what behavioral effects the ability of the bees to get
16 back to the hive, a number of sublethal effects in terms
17 of growth and weight of the brood and brood development.
18 It's the exact type of study that we look for to answer
19 that very uncertainty.

20 Looking at that study and then working where
21 it's not just the neonicotinics that we have concerns
22 about -- there are other groups of pesticides where

1 because of the concerns that we have about pollinator
2 declines, we are really trying to incorporate into the
3 design of these studies some of these behavioral -- are
4 the bees able to make it back to the hive.

5 What Jess is alluding to, the ability of the
6 bees to put on sufficient stores that they can sustain
7 themselves through the winter. Then, once the brood
8 emerge, what kind of longevity can you expect from the
9 adults, how much of a (inaudible) capacity do they have?
10 All those things we've essentially started to key into
11 because of the pollinator losses that we're seeing.
12 Those studies are being designed and being required and
13 we're hoping to formalize those study designs.

14 MICHAEL: One other area that I think could be
15 potentially very useful is looking at a database -- well,
16 I guess there is only one, the California Pesticide Use
17 Reporting Database -- in which on a field by field date
18 sensitive data is reported to the county and then -- so
19 you have pesticide applications within accuracy of about
20 30 feet maybe. With that kind of database, you can do a
21 retrospective study and look at when colony collapse
22 disorders occur, what pesticides are used in adjacent

1 crops or other things that could be contributing to this
2 disorientation or whatever it is that's causing it.

3 Has that kind of study been looked at or
4 proposed?

5 UNIDENTIFIED MALE: We make considerable use of
6 the California pesticide use database. In fact, for this
7 workshop that we participated in at USDA, we flew out a
8 representative of Cal. Department of Pesticide Regulation
9 to participate and become better aware of some of the
10 issues that are associated with the pollinator declines,
11 and we had discussions with them as to how they plan to
12 use their database to do this very type of survey.

13 USDA's survey has looked at that.
14 Unfortunately, it's conducted across the United States
15 and none of the states have as good of a pest reporting
16 system as California does. It's sort of unparalleled.
17 But the difficult that we've had historically with that
18 survey is that really documenting what were the hives in,
19 what were they surrounded by, what were the pesticides
20 used. That's been missing, but the plan is to make
21 greater use of the Cal. PUR data and California is
22 planning on moving forward with that type of analysis.

1 MS. EDWARDS: Okay. I'm going to take the
2 cards that are up, which I see either three or four, I'm
3 not sure. Laurie, are you still up? Okay, well, we'll
4 get to you last. You get to speak last. We'll go to
5 Cindy now.

6 CINDY: I'll just go real quickly then. I'd
7 like to support the comments that Julie made. I mean, I
8 think -- Jeff, I think you went first and you put up that
9 slide that showed, you know, viruses, pathogens, you
10 know, a number of things that are impacting or
11 potentially impacting bees. I think the issue and the
12 dollars that USDA is spending looking at this is
13 essential and critical and by all means you should
14 continue to do it. I think it's housed appropriately at
15 USDA.

16 I think the role that EPA plays is the role
17 that you talked about to the extent that you have
18 requirements in part 158. You have that data come in you
19 have to look at. You're serving in a role with USDA to
20 look at it. I would say at this stage, the whole -- a
21 lot of the focus of this discussion has been testified
22 that was one little circle of about eight that were up

1 there.

2 So, I would say that, you know, continue the
3 kinds of things that you're doing to the extent you have
4 data to share with USDA and that you work collaboratively
5 on it. Great! I mean, this is a great example as
6 opposed to the endangered species things we talked about
7 earlier this morning where you got two agencies that are
8 actually trying to use the best available information
9 they both have to address the problem. So, I would say
10 continue down that road.

11 MS. EDWARDS: Thank you.

12 Mark, you've been patient.

13 MARK: Not a problem. Thanks. You know, given
14 what I've read in the literature and some of the things
15 that are coming out of Europe, I didn't hear much about
16 hybridization and genetic improvement, those kinds --
17 some nice genetic analysis in terms of interacting
18 factors. So, that's one thing I'd like you to respond
19 to. Maybe what we really need is a, you know, killer bee
20 hybridized colony to compare with, you know, tongue and
21 cheek.

22 Also, we're kind of in a very significant

1 transition in pesticide motive action and its impact in
2 ecosystems. We see it most in perennial systems. We
3 have actually gone through historically and have data on
4 several of these transitions that we've done in the past.
5 These are FQPA driven and economic driven changes. Some
6 of these changes may, in fact, have some very subtle
7 effects.

8 Right now, integrated pest management
9 monitoring of ecosystem services is beginning to yield
10 considerable information on the impact of these changes
11 on biological control agents and nontarget systems in
12 some of the more perennial systems, like almonds and
13 apples and cotton and things like that, certainly, the
14 kind of changes we're seeing moving to the neonics and
15 the oxydiozenes and the IGRs more frequently and to the
16 whole ray of new chemistries that are on board. Yet,
17 most of the chemistries that you tested, Jeff, really
18 weren't any of that group. So, the subtle effects that
19 some of those are having --

20 Personally, I've published quite a bit on some
21 of those subtle effects because we're beginning to
22 capitalize on them. We're beginning to use some kiton

1 synthesis inhibitors to attack on eggs vertically
2 transmitted into the next generation where they can't set
3 enough kytons to user manables to get out of their
4 chorion on target pests. So, you know, I mean, that's a
5 pretty subtle effect. We don't know the parts per
6 million yet, but it's probably less than 10 where we're
7 seeing these effects.

8 In the same way, some of the other compounds
9 actually may pertebate some things like esterase
10 (phonetic) that's critical to things like diapods
11 (phonetic) induction or diapods breaking. You only need
12 one spike to get it done. So, we're using that also in
13 going after plumpeculio (phonetic) which is a critical
14 pest in upper midwest, cherries and apples and peaches
15 and basically tree fruit, and blueberries. We're
16 manipulating that system to put them out of diapods so
17 that they go into the fall thinking it's spring. They
18 mate, they commit their fat body to eggs, and they die.
19 And we can do it at fairly low levels. I mean, we're not
20 even using a full spray in some of these tests.

21 So, if you go back in the literature and
22 you look historically at some of these ecological changes

1 that occurred, particularly in perennial systems where
2 we've got long term data, apples in particular, and mite,
3 apple mite, if you just go back and look at natural
4 enemies in mites, what you see is that when we went from
5 the chlorinated hydrocarbons to the OP and to the -- but
6 the pyrethroids only came in the 80s.

7 So, the transition to the OP and the
8 carbamates, we saw a real downturn in ecosystem services.
9 Then it came back. Then we went in the early 80s to the
10 synthetic pyrethroids; the same thing happened. It came
11 back quicker because the OPs -- there was cross
12 resistance and a bunch of adaptation things that were
13 going on, natural enemies.

14 Now, FQPA mitigated change of preposterous
15 dimensions in the ecosystem in terms of the modes of
16 action that we're asking ecosystem services like the poor
17 introduced invasive species, the European honeybee, to an
18 American system. What we're seeing are the consequences
19 of that. I would predict that we're in 8 to 15 year
20 cycles if it's related to these different modes of action
21 and their impact on the ecosystem.

22 UNIDENTIFIED MALE: I'll just briefly address

1 the first point in that whether or not there were some
2 genetics that could be in the susceptible bees that we
3 are seeing dying. We actually asked that question early
4 on in doing a survey of healthy and CCD like colonies.

5 A fellow at North Carolina State, Dave Tarpey
6 (phonetic), did an analysis to look at the background,
7 the lineage of those bees. We didn't see any patterns
8 there again that showed that this certain race of bees
9 was more susceptible than any other. But it's certainly
10 not to discount that, like you point out, Africanized
11 bees or killer bees are certainly survivors. There's
12 probably lines of bees that we could select from that
13 whatever the cause was would be better survivors.

14 MARK: Are you looking at other ecosystem
15 services to get an idea in the same systems you're
16 getting a downturn in biological control? Have you
17 looked at any of the ecosystem services in some of these
18 systems where you're seeing a reduction in bees with
19 other very sensitive --

20 UNIDENTIFIED MALE: Penn State and others are
21 looking a bit at apples in detail. One of the problems
22 is that the bees are so migratory, honey bees. So, we

1 move them from apples. They're there for three weeks and
2 then we move them to cranberries or whatever. So, we
3 don't leave them in any one place. There's this
4 constant, you know, where were they last, kind of thing,
5 and how long were they there and what did they get
6 exposed to? So, from that standpoint, it's a little
7 difficult.

8 UNIDENTIFIED MALE: Well, maybe they're just
9 overworked and they need Sundays off.

10 UNIDENTIFIED MALE: The beekeepers and the bees
11 would say that.

12 UNIDENTIFIED MALE: Just to touch briefly, as I
13 indicated earlier, the Agency doesn't just rely on its
14 tier-1 and tier-2 tests in looking at potential effects
15 on pollinators. It relies on open literature as well.
16 On the older chemistries, obviously, there will be more
17 open literature that would be available to alert us to
18 potential effects on pollinators and ecological services.
19 But on the newer chemistry, that data is less available.
20 But we do avail ourselves to the open literature to
21 determine whether there are effects that are not being
22 captured by our current battery of tests.

1 UNIDENTIFIED MALE: Just to come back, there
2 was a European symposium last year. I think there's
3 about maybe I think around 40 papers on ecological
4 impacts. I've got the site if you're interested in that.
5 In addition to that, as I mentioned earlier today, not to
6 you specifically, there is going to be an IPM symposium
7 in Portland, Oregon in March. There's a section on that
8 -- I mean, in that meeting, there's a section on
9 ecosystem services and impacts that are being measured in
10 all kinds of crops across the U.S. today. It's a pretty
11 big deal. So, maybe this isn't just bees but it's other
12 sensitive organisms in the system as well.

13 UNIDENTIFIED MALE: Thank you.

14 MS. EDWARDS: Dave.

15 DAVE: Yeah, Laurie. Since Laurie put her card
16 down, she said mine better be good. I probably won't
17 live up to that, so I apologize to everybody. It strikes
18 me that, you know, a lot of it was sort of looking at it
19 that it seems to be probably interaction of numerous
20 factors. From the pesticide toxicity point of view, it
21 seems that the -- looking at the sublethal effects should
22 really rise up to the top of what you look at. If it's

1 interaction, then it's probably not -- you're not going
2 to find it with the LC-50s.

3 So, looking at sublethal effects that are most
4 likely to interact with or that you could guess would be
5 likely to interact with other factors, say like something
6 that's immunosuppression type of effect that's actually
7 -- that you can define pretty precisely biologically -- I
8 don't know how well you can do that in insects, but I'm
9 guessing there may be some types of cellular effects that
10 you might be able to see.

11 And I'm confused about -- maybe I just don't
12 understand what the timing is of that type of testing.
13 Are we going to have to wait through like the regular
14 registration review process to get to those or is there
15 going to be something to accelerate it, identify which
16 types of chemicals are the most likely suspects and bring
17 those up to the front and not wait for the full cycle to
18 come around, you know, if it's a national security issue.
19 It seems like that might be good justification for it.

20 You know, I just wanted to point out some of
21 the -- like systemic stuff -- really, you think about the
22 pathways that systemics can get into the bees and maybe

1 the way to look at those. It's my understanding that
2 some systemics show up in pretty high concentrations in
3 things like pollen. I don't know if the way that you
4 currently evaluate them takes that into account, but that
5 would be something that I would think that you'd really
6 want to look at. Thanks.

7 UNIDENTIFIED MALE: On the sublethal effects
8 issue, sublethal effects are a challenge. They always
9 have been a challenge. There are many researchers that
10 come up with unusual endpoints. Again, they have high
11 expectations that we will embrace them.

12 The challenge is we regulate on what we call
13 assessments endpoints. There's a difference between a
14 measurement endpoint and an assessment endpoint. A
15 sublethal effect can be a measurement endpoint such as
16 decreased -- in salmonids, decreased ability of the fish
17 to smell things in the water, referred to as olfaction.

18 The issue becomes, well, how does that
19 measurement endpoint relate to our assessment endpoints,
20 which are impaired growth, survival, and reproduction.
21 If a fish is unable to smell things, some would say that
22 well, then there you have a decreased ability to avoid

1 predation. Well, you could come back and say, well, if
2 they have a decreased ability to avoid predation, why do
3 the predators not have a decreased ability to sense the
4 prey? You get into this dynamic of will decreased
5 olfaction affect growth or will it affect reproduction?
6 Does it impair the animal's ability to spawn if it's not
7 able to detect chemical receptors?

8 There's a whole cascade of issues that come
9 into play when you attempt to work with a measurement
10 endpoint that isn't clearly linked to our assessment
11 endpoints. That will remain a challenge to us. Until we
12 have sufficient data to make those linkages, our tendency
13 is to work with more frank endpoints such as mortality or
14 frank endpoints where you have a direct measurement of
15 growth or a defined decrease in reproduction.

16 So, we acknowledge that sublethal effects --
17 they're a challenge and we try to work to better
18 understand how they can relate to our risk assessment
19 paradigm. It doesn't mean that we dismiss them. We try
20 to characterize them to the extent possible and estimate
21 how they might impact our risk assessment endpoints based
22 on more frank endpoints such as mortality.

1 So, we are continuing to develop tools, monitor
2 the open literature, as I said earlier, to be aware of
3 where these effects are occurring and to try and develop
4 study methods where we can get a better handle on how
5 they relate to our assessment endpoints.

6 UNIDENTIFIED MALE: I just want to -- I guess I
7 was looking at the one I put forward, the
8 immunosuppression endpoint, however one might define
9 that. I was talking about it in terms of the questions
10 that they were trying to answer, the folks that are doing
11 the research on the broader question of why is this
12 happening.

13 I guess I'm looking at trying to gather that
14 information not necessarily where -- to be used in the
15 usual way but filling in the information that the broader
16 research effort is getting into if one of the things is
17 is there some sort of an immunosuppression going on and
18 might some of that be associated with pesticides.

19 That's a piece of the puzzle that EPA might be
20 able to gather data to plug that in and find out is that
21 a possibility, is that going on. It's not necessarily to
22 fit into the usual type of risk assessment that you're

1 doing. Just a different way or a different reason and
2 use for that data, at least in the short term trying to
3 solve this bigger problem.

4 UNIDENTIFIED MALE: Just very quickly to that
5 point about measuring an immune response, we can measure
6 the individual genes that are turned on and off. There
7 are some things in the honey bee's immune response that
8 we can measure. We're looking at those and manipulating
9 pesticides or combinations of pesticides. We're also
10 beginning to look at if that happens, then we challenge
11 them with a pathogen or pathogens and see if in fact that
12 depressed immune response is leading to additional
13 pathogen reproduction. So, we're beginning to do those
14 studies.

15 We do have some ways of measuring insect immune
16 response. It's not that sophisticated, in part because
17 the honey bee immune system is not that developed. They
18 evolve to feed on nectar and pollen which is a reward
19 produced by the plant. If you think about most insects,
20 they're feeding on leaves and stems and things, which the
21 plant is marshaling a lot of defenses in, but the nectar
22 and pollen is a pure food source. So, bees don't have

1 natural defenses or very good --

2 UNIDENTIFIED MALE: The same thing with
3 parasinoids.

4 UNIDENTIFIED MALE: On the chronic bee studies
5 that are coming in, and particularly on the ones that are
6 being developed at this time, the occurrence or incidence
7 of disease is one of the things that registrants are
8 expected to report on. So, indirectly we're getting
9 information on the potential effects of the pesticide and
10 the ability of the organism to resist disease.

11 MS. EDWARDS: Laurie, did you change your mind?
12 All right.

13 Well, I hope we have achieved one of our goals
14 today which is to ensure all of you that we are focused
15 with our partner agencies very much so on pollinator
16 issues. If anyone has any doubts, let me know.

17 So, I think this was an excellent day. I
18 certainly got a lot out of it. I hope those of you who
19 lasted to end did, too, and that those who left early did
20 at least up to that point.

21 Tomorrow we will meet again here and begin
22 talking about our use of incident data and some ideas we

1 have about that at 9:00 in the morning. Thank you and
2 have a great evening.

3 (Whereupon, the meeting was adjourned, to be
4 reconvened at 9:00 a.m. on Wednesday, October 8, 2008.)

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US EPA ARCHIVE DOCUMENT

UNITED STATES

ENVIRONMENTAL PROTECTION AGENCY

PESTICIDE PROGRAM DIALOGUE

COMMITTEE MEETING

October 7-8, 2008

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 MS. EDWARDS: Okay. Thank you for coming back
4 today. I hope you had a nice evening yesterday evening.
5 I think we have a good session today. We have three
6 jam-packed hours here. If you'll note, there's no
7 mention of a break on the agenda. I don't think that was
8 intentional, but we'll see how it goes. We might either
9 have a structured break or just ask that you get up as
10 you need to.

11 Anyway, our first session is on incident data.
12 We'll be rolling out our OPP Pesticide Incident Workgroup
13 activities. The session chair for this is Ann
14 Overstreet.

15 MS. OVERSTREET: Good morning. If you'll take
16 a look at the handout that we have for this, I'd like to
17 go over some background information, some ongoing work
18 that the incident group is working on, some examples of
19 an incident data use in an OPP decision, a current case
20 study with the pyrethrins/pyrethroid group, and the
21 National Pesticide Information Center's new AVMA,
22 American Veterinary Medical Association portal.

1 In looking at the background, in 2006 OPP
2 committed to presenting a series of reports to the PPDC
3 on incident data. In October of 2007, we presented to
4 you the first report which provided an overview of the
5 main sources and limitations of incident data, how the
6 agency currently utilizes incident information and risk
7 communication, performance accountability, and
8 enforcement.

9 In an ongoing effort, an OPP incident data
10 workgroup was formed to build on past work and develop a
11 strategic plan to improve the agency's management and
12 utilization of incident data. In this effort, OPP is
13 committed to considering the best methods to take full
14 advantage of incident data which includes scrutinizing
15 internal processes and reviewing existing data sources.

16 For ongoing work with the incident data
17 workgroup, we will continue to develop and implement a
18 strategic plan to improve the acquisition, management and
19 utilization of incident data in both risk assessment and
20 risk management within regulatory programs of OPP.

21 Regarding the incident data acquisition and
22 management, the development of an improved electronic

1 system for reporting both internally and externally is
2 very important to us. Externally, a web-based portal is
3 something we're looking into for perhaps the public and
4 companies to report information to us. We also want to
5 improve our outreach with other federal agencies, state,
6 regions and stakeholders in order to obtain more robust
7 incident data information.

8 Recently, we participated in discussions with
9 PMRA, NIH, and SCA in looking at systems that they've
10 currently got up and running, most recently PRMA in the
11 last three or four months. NIH and FTA are revamping
12 their systems concurrently with ours and we're looking to
13 harmonize with them.

14 Under incident data utilization, we're looking
15 to better utilize data to further inform risk reduction
16 through risk assessment and risk management. OPP
17 utilizes incident data in reporting on performance
18 accountability, Specifically, we are looking to these
19 data systems to measure the success and mitigations
20 required in past decision documents.

21 We'd like to facilitate the use of established
22 incident data sources outside of OPP available but not

1 currently being used to their fullest. We are currently
2 looking into expanding our database systems such as
3 Poison Control Center, asking them to -- and working with
4 them -- to actually report EPA RED numbers to us.

5 For enforcement, obviously, this incident
6 information can be used when targeting enforcement
7 activities and can serve as a source of information on
8 compliance with incident reporting regulations. Trend
9 analysis is something very important as well, as we'd
10 like to be able to have an early warning system, if you
11 will, through the use of incident data.

12 Let's also take a look at metaldehyde, an
13 example of a more recent decision using incident data.
14 The National Pesticide Information Center, NPIC, reported
15 a large number of incidents, mainly among dogs that had
16 ingested the pellets, including many deaths. The
17 re-registration eligibility decision, or the RED team,
18 examined other sources of information and found a large
19 number of incidents reported to the ASPCA, their animal
20 poison control center. That data revealed a greater
21 extent of the problem as well as the nature of the
22 exposures in greater detail.

1 This information helps to inform the risk
2 managers in a decision mandating that products for
3 residential use bear labeling to inform the user about
4 risks to domestic animals. The efficacy of the aversion
5 agent is also being tested by the registrant and they are
6 developing a detailed incident reporting system based
7 upon decisions in this RED.

8 Molly Clayton is going to talk about the
9 pyrethroids/pyrethrin allergy asthma work group.

10 MS. CLAYTON: Hello, everyone. The
11 pyrethrin/pyrethroids allergy asthma work group was
12 formed to determine whether or not there's an association
13 between exposure to currently registered products and
14 asthma allergic affects in humans. To do that, we'll
15 review all available data, including incident data.
16 Furthermore, we'll determine whether regulatory action is
17 needed to address any potential associations.

18 The Agency is undertaking this effort because
19 some sources have concluded that pyrethrin and
20 pyrethroids may exacerbate asthma and allergy symptoms in
21 sensitive individuals. The FDA also requires that labels
22 for lice treatment containing pyrethrin warn that use by

1 some individuals may cause breathing difficulty or an
2 asthma attack.

3 In 2006, during re-registration, the Agency
4 obtained a commitment from the pyrethrin registrants to
5 initiate a product stewardship program and to --
6 involving outreach to physicians and the Poison Control
7 Centers and the more extensive monitoring of incidents
8 associated with use of pyrethrin.

9 The Agency is considering whether additional
10 risk management measures are needed for the pyrethroids.
11 So, the group is looking at all available data including
12 Part 158 lab studies in animals, incident information
13 from databases considered to be the most robust for the
14 group's objectives, and we're conducting chemical-
15 specific incident review for pyrethrin and six
16 representative pyrethroids. Where we are now is
17 preparing to brief the division directors and Debbie
18 Edwards later this month.

19 Now, I will turn it over to Frank Davido who
20 will talk about the National Pesticide Information Center
21 update.

22 MR. DAVIDO: Good morning. I'm Frank Davido.

1 I'm the pesticide incident response officer for OPP and
2 also the project officer for the National Pesticide
3 Information Center. If you look at the top of the first
4 slide, the question is, what is NPIC. This project has
5 been in existence for over 20 years. It's a cooperative
6 agreement that we currently have with Oregon State
7 University, and the service is operated on campus at
8 Corvella (inaudible).

9 The mission statement for NPIC is to provide
10 objective, science-based information about a variety of
11 pesticide related topics to the public and professionals.
12 NPIC provides its service via a toll-free 800 number, its
13 web site and e-mail to all the states within the United
14 States and our territories. We frequently review the
15 information and data NPIC sends us. We look at it for
16 trend analysis. It's also a good sounding board as what
17 concerns the public has dealing with pesticide topics.
18 If you want additional information on NPIC, these
19 brochures are on the table outside this room.

20 The American Veterinary Medical Association,
21 AVMA, portal -- the first part I'd like to explain is how
22 this came about. OPP recognized the need for more

1 complete information and data pertaining to domestic
2 animals, especially for companion animals. We believe
3 this portal with the veterinarians reporting will
4 certainly help us provide that information.

5 OPP, NPIC and AVMA working jointly together has
6 made this happen. This portal went live a few days ago.
7 As we involved AVMA, we involved the Clinical
8 Practitioner's Advisory Committee and the Council on
9 Biological and Therapeutic Agents. These two groups
10 comprise about 22 veterinarians. They have endorsed this
11 project. We also have today with us Dr. Angela Demorri
12 (phonetic). She is the assistant director of the
13 Government Relations Division in AVMA. She's in the
14 audience.

15 Now, about the portal pages, I'm not going to
16 show all of them. I'm not going to display all of them
17 but just a few of them to give you a flavor of what the
18 contents look like and what the appearance of the portal
19 looks like. I do want to mention that the portal be
20 marketed by AVMA and EPA.

21 Entry into the portal will be through the AVMA
22 web site. This is password protected and this means that

1 you must be a member of AVMA in order to use the portal.
2 The reason for that is that we really do not want the
3 general public to be reporting through this mechanism.
4 AVMA membership is over 76,000 members and they feel that
5 they have over 86 percent of all the veterinarians in
6 this country within that membership.

7 I had mentioned that we don't want the portals
8 to be used by the general public. However, we do want
9 the public to be aware of it. We aren't going to provide
10 them the URL. We plan to inform them of the portal, its
11 purpose, and hope that they will encourage their
12 veterinarians to use it. Any veterinarian that is a non-
13 member of AVMA can always, as before, report to EPA or to
14 NPIC.

15 Now, let's look at the first page of the
16 portal. This is sort of a welcome page. We also try to
17 stress within this page that we advise the public again
18 not to use the portal. If we find that we're having a
19 lot of problems with the general public using the portal,
20 I mean, there's a number of things we can do. We can
21 change the URL which we sort of hope we don't have to or
22 we can hopefully discourage them by saying that we'll

1 have to take and discontinue this service.

2 If you look at that first page, at the very
3 bottom it says, yes, I'm a veterinarian. If you hit on
4 the no, I am not a veterinarian, as hopefully the general
5 public would do if they find the URL, it takes you to the
6 NPIC web site portion where it tells them how they can
7 call NPIC toll free and actually report a domestic animal
8 case.

9 The second page, the veterinarian part, the
10 pesticide product information, if this were live, I could
11 show you that we could scroll down here on the pesticide
12 registration number. If you mouse over on that, it's a
13 description to the veterinarian as to what the EPA reg
14 number is, what it looks like, and the importance of
15 hopefully providing that information.

16 There are certain parts of this portal where
17 you obviously have to fill it in, like many other
18 portals, or you can't advance to the next page. You have
19 drop downs on the type of pesticide. For example, you
20 can put in insecticide or azenacide (phonetic), whatever,
21 and the same thing with formulation. You might put in
22 Spot On or a dip or a shampoo.

1 The next portal slide is animal exposure
2 information. Here you have some more drop downs. If you
3 look at the very top where it says species, you can put
4 in K-9, bovine, whatever it might be. These are all
5 marked in green and white so these are the areas where
6 you have to enter some piece of information in order to
7 proceed. The other ones on here are the route of
8 exposure, what state it occurred in, the toxicity and
9 signs, and the outcome.

10 Now, those are the only three slides that I
11 have that I'm presenting on that. There are other
12 slides. There are summary slides that actually give you
13 back a report as to what you put in. You can go back at
14 any time and correct any of these former pages that you
15 filled out. There's also a page that's actually being
16 moved up to the very front where the veterinarian or
17 somebody in his office has to identify your name, your
18 address, your telephone number. That will also help us
19 to keep the general public from using this.

20 With that, that's the end of my presentation.

21 MS. EDWARDS: Okay. Comments? Questions for
22 the panel? We'll start here with Michael.

1 MICHAEL: Thank you. Anne mentioned some
2 poison control -- animal poison control data from
3 metaldehyde. I wonder if there has been 6(a)(2)
4 reporting that matches this kind of reporting. And to
5 what extent -- you know, what were the relative sources
6 you get? I mean, how much reporting do you get from the
7 registrants for this? That's the first question.

8 UNIDENTIFIED FEMALE: We certainly get data
9 from a number of sources. Jill can speak directly to the
10 6(a)(2) data. We certainly look at incident data as a
11 whole when we get it in. We compare to look for
12 duplicate reporting, more detail, what have you.

13 Jill, can you speak directly to that?

14 MS. BLOOM: Yeah.

15 MS. EDWARDS: Hey, Jill, can you come up to a
16 microphone?

17 MS. BLOOM: Hi, Jill Bloom. I was review
18 manager for the metaldehyde RED. It was interesting the
19 pattern we saw from 6(a)(2) data to NPIC data and Poison
20 Control Center's data and then ASPCA's animal poison
21 control center data. There was an increase in the number
22 of incidents reported. The 6(a)(2) was very limited.

1 NPIC and the Poison Control were not directly comparable
2 to the ASPCA data, but I'd say there was an order of
3 magnitude difference in the number of incidents that were
4 reported for domestic animals for metaldehyde and those
5 sources.

6 So, it turned out that we didn't really
7 recognize the magnitude of the problem until we looked to
8 the SPCA. Now, their program is similar to NPIC, only
9 their clients are different. They do -- different
10 chemical manufacturers, not just pesticides, will
11 subscribe to their system and then, you know, they'll
12 take the incident calls off the label if -- the number
13 that's listed will be the number for the Animal Poison
14 Control.

15 We couldn't really figure out exactly where
16 that -- you know, why the difference was that except for
17 if you have a problem with your pet, maybe you're not
18 thinking in terms of pesticides so much as you're
19 thinking, oh, I need that generic care and the SPCA can
20 help me with that.

21 Does that answer your question?

22 MICHAEL: Sure, part of it. The NPIC data is

1 for reporting by veterinarians for companion animals
2 primarily. What do veterinarians that work at wildlife
3 care centers or with state agencies or vet schools who
4 have exotic animals, you know, or wildlife things, how do
5 they report incidents of this kind?

6 MR. DAVIDO: Well, currently, they can report
7 to NPIC and they can also report into our agency. I
8 think in our marketing of this veterinarian portal, those
9 are the types of things that we're going to have to
10 address so there's no confusion that if you are not an
11 AVMA member and you are of the category that you just
12 mentioned, how would you report into the agency so we
13 would get that information.

14 MICHAEL: Now, are veterinarians advised when
15 they report to NPIC to also report to the registrant so
16 the registrant can have a listing of incident reports to
17 provide the agency under FIFRA?

18 MR. DAVIDO: I think that would be up to the
19 individual veterinarian, just like the general public.
20 The general public a lot of times reports directly to us.
21 They report to NPIC. They report to the registrant. I
22 mean, I think that's a matter of choice.

1 MICHAEL: Well, could it be put on the NPIC web
2 page for veterinarians to contact the registrant? I
3 mean, the registrant -- you really actually asked for
4 quite specific data.

5 MR. DAVIDO: Yes.

6 MICHAEL: Product registration number. If one
7 of these fields is not filled out, does the incident
8 report not go through?

9 MR. DAVIDO: No, only the ones that are marked
10 in that green and white color are -- you have to fill
11 those out or you don't proceed with the report.

12 MICHAEL: But it would be possible to put in
13 some information for veterinarians so that they could
14 report to the registrant directly?

15 MR. DAVIDO: I think that is something we would
16 need to consider.

17 MICHAEL: I'm just concerned that the 6(a)(2)
18 data is really the least efficient way of getting
19 incident report data. For wildlife, there are not a lot
20 of incident reports anymore.

21 MR. DAVIDO: That's true. We are very
22 interested in wildlife data. So, we have in the past, as

1 we will in the future, try to figure out how to obtain
2 more of it.

3 MS. EDWARDS: Julie, are you next?

4 UNIDENTIFIED FEMALE: Michael, I just wanted to
5 clarify a couple of points. One is that most of us on
6 our labels have 800 numbers. In our particular case, it
7 goes to a company called ProStar. So, that gets reported
8 to us pretty regularly and then gets filed by 6(a)(2).
9 So, there is a mechanism where registrants are getting
10 that information.

11 Frankly, in the experiences that I've had,
12 anybody who has any question at all as to whether there
13 might have been some kind of an incident related to an
14 animal or a person or the environment, we get a lot of
15 that information. Many times we find out it's not
16 connected to a use of one of our products, but there are
17 a couple of different mechanisms out there in addition to
18 what's been discussed there. So, we do get it.

19 The 6(a)(2) reporting requirement is something
20 that registrants take very seriously. I mean, there's
21 some very serious implications of not reporting under
22 6(a)(2). So, if that -- in our particular company, if it

1 comes and we have any doubt, we report it. It's better
2 to report it than not report it.

3 I mean, you do the investigation, understand,
4 from a stewardship perspective, what's going on, but
5 there's also a very real legal requirement there. So, I
6 just wanted you to know there are some other ways that
7 registrants are getting that information.

8 MICHAEL: But, even so, there are very few,
9 especially for wildlife, very few reports that come from
10 the registrants on an annual basis.

11 UNIDENTIFIED FEMALE: I mean, fortunately for
12 me, I don't have a direct link where I've gotten one with
13 respect to wildlife. I have seen things with respect to
14 dogs that have come in. If you have a product that's
15 used at all for lawn use or anything like that, you're
16 going to get somebody who calls at a minimum of questions
17 about it. So, we're getting it.

18 But I haven't combed through the database to
19 know exactly what's in there. I can only speak to the
20 stuff that we have. But there are a number of different
21 avenues where that information comes in.

22 MS. EDWARDS: Okay.

1 Julie.

2 JULIE: I had a question on the pyrethroid
3 review. Where you saying chemical specific incident
4 reviews, are you looking at -- you know, for those
5 chemical specifics, are you looking -- are there more
6 incidents for some pyrethroids versus others or are you
7 looking for a common kind of incident between the
8 pyrethroids? I guess, what is sort of the objective in
9 this chemical specific review?

10 MS. CLAYTON: Well, we're looking at all the
11 data. Actually, we're looking specifically for allergy
12 and asthma effects in various databases. But I don't
13 want to talk too much about what we're doing or what we
14 found yet because we haven't briefed internal management.
15 Did that answer your question, you know, generally?

16 JULIE: I know you were looking for asthma and
17 allergy. I guess, just kind of what was the objective
18 for the chemical specific review? Were you looking for
19 differences between the chemicals or similarities,
20 whatever degree you can say what the objective was?

21 MS. CLAYTON: We're looking at the effects in
22 reported incidents for certain chemicals among the most

1 widely used of the pyrethroids, what type of effects are
2 you seeing and would they be indicative of a causal
3 association between a pyrethroid use and an allergy or
4 asthma effect.

5 JACKIE: Molly, it's Jackie. Can I jump in
6 real quick?

7 MS. CLAYTON: Yes.

8 MS. GARRY: Hi, this is Jacqueline Garry
9 (phonetic). I'm on the work group with Molly.

10 Just to answer your question, if I think I
11 understood it right, the reason we picked the six
12 representative chemicals, as Molly said, they represent
13 the largest used or a use pattern that's prevalent in the
14 pyrethroids. So, to that degree, we can kind of look
15 across the pyrethroids. Now, granted, it's only six of
16 the 23-plus pyrethroids that are registered. And then,
17 we're also looking at pyrethrin so we can get a sense of
18 what the data shows for pyrethroids versus pyrethrin.
19 Then, we're also comparing it to some different classes
20 of chemicals.

21 MS. EDWARDS: Okay.

22 Caroline.

1 CAROLINE: I wanted to say thank you to NPIC
2 for setting this up, and AVMA. It's really a great
3 system to have in place. (Inaudible) asking for what you
4 really want. Would you all be willing to work with the
5 American Medical Association and American Academy of
6 Pediatrics to set up a similar system for reporting
7 incidents with people?

8 MR. DAVIDO: Debbie, do you want to answer
9 that?

10 MS. EDWARDS: I think the answer is yes. This
11 is obviously on a much smaller scale, but I see no reason
12 why we wouldn't be able to pursue that as a -- you know,
13 explore it, at least.

14 UNIDENTIFIED FEMALE: I think in the work group
15 that we're looking at, we've already had discussions with
16 FDA and NIH and looking at the way that they're setting
17 up their new systems and revamping them and looking for
18 commonalities between data sources to see what sorts of
19 information that we could pull from and actually reach
20 across agencies to facilitate that.

21 MS. EDWARDS: I think along those lines, I
22 mean, one of the advantages of this sort of system,

1 especially through the extent that you can get more
2 people using it, is you get consistency in reporting and
3 hopefully more completeness in reporting to the extent
4 that the people that have the information know that we
5 want it.

6 UNIDENTIFIED FEMALE: Can I jump in because my
7 comments are similar to hers? I can wait, but it just
8 seems like it would continue the conversation.

9 MS. EDWARDS: Okay.

10 UNIDENTIFIED FEMALE: First of all, I really
11 wanted to echo what Caroline is saying. NPIC is a really
12 wonderful, wonderful resource. Migrant clinicians
13 network uses it all the time. We also use the medical
14 monitoring program with Dan Sutakin (phonetic) as well.
15 So, we really appreciate the Office of Pesticide
16 Programs' continued funding of this.

17 It's very impressive what you've done with the
18 whole animal aspect. I say this at every PPDC meeting,
19 but we desperately need a centralized place for reporting
20 of human exposures. If we could do something like this,
21 it would be great.

22 But I also -- one question I have that I was

1 unaware, and I'm a user of NPIC, is that it seems like
2 you guys get incident data from NPIC. As far as I know,
3 it's not really being marketed in a way that people are
4 encouraged to report exposures to it. So, is that --
5 even though there's like a nice system now for animal
6 exposures and veterinarians who are a member of the
7 veterinarian association can report, I mean, is NPIC the
8 place that we want to be telling clinicians now to report
9 to? I'm confused.

10 MR. DAVIDO: Well, we certainly can use NPIC.
11 I mean, the major objective when this project was started
12 back longer than I want to admit that I've been here, it
13 was to provide to the public again and to the
14 professionals the science-based information that's very
15 objective. A lot of times the use of this project is
16 individuals have complained that they've gone to state
17 agencies, other federal agencies, wherever, and even to
18 the registrants, and don't like what they're receiving.

19 So, being an independent source through a
20 university, NPIC has become very popular. You know,
21 there's really not a whole lot that they can't do. This
22 is an example of it, this portal. So, I think that's up

1 to upper management as to what further use we can make of
2 NPIC. I know that there are some people that want
3 ecological incidences reported through NPIC.

4 MS. EDWARDS: Probably, I should -- we put
5 together this team. What I have asked them to do is, as
6 Anne was mentioning, look at everything to do with the
7 acquisition of incident information, our data management
8 of it, and our utilization of it in making our regulatory
9 decisions. So, they're supposed to come to me with some
10 strategic plans and proposals and then we will look at
11 how they can be achieved in view of our -- and
12 prioritized in view of our funding situation.

13 So, I'm hoping that by the next session, we'll
14 get -- and as we move forward, we'll get even more
15 concrete. I mean, it's not -- and also, I want to say
16 it's not as if we're not currently using, as you can see,
17 incident information routinely in the program, but I
18 think we can improve.

19 UNIDENTIFIED FEMALE: Right. I think it's
20 wonderful. It's another thing to compliment you on.
21 It's wonderful that you are using incident data. It just
22 concerns me that if this is a source now that you're

1 using, I want to make sure that the incidents are getting
2 reported. I'm at a loss for how to tell our 5,000
3 constituents, you know, what to do in terms of reporting
4 pesticide exposure in humans.

5 MS. EDWARDS: Okay. Well, I mean, you know,
6 another thing that I think I'm encouraging these teams to
7 do is if you would like to come in and meet with this
8 team --

9 UNIDENTIFIED FEMALE: I would, actually.

10 MS. EDWARDS: -- and have some recommendations,
11 we'd be more than happy to hear them.

12 UNIDENTIFIED FEMALE: That would be great.
13 Thank you.

14 MS. EDWARDS: Let's go back to Dennis.

15 DENNIS: This is a very interesting
16 presentation. For state-lead agencies, in some cases
17 states may think that they're detecting a trend in
18 incidents for a particular compound. It helps them to
19 take a look at what other states are finding or actually
20 to go to EPA and find out whether -- what's being
21 detected locally has broader implications or whether it's
22 real or not.

1 Just a question for process. Is the best way
2 for a state-lead agency to try to obtain all the
3 different sources of incident data that you have and
4 understand them, is the best way to do that through a
5 product manager or through somebody who manages the
6 incident data who may be more specialized along those
7 lines?

8 MS. EDWARDS: I think initially I would look to
9 one of our -- especially if it's a state organization --
10 to one of our division directors. So, for example, if
11 it's -- probably most of the time you should come in
12 through either Tina Levine (phonetic) or Steve Bradbury
13 (phonetic) right now. Then we'll get you directed to the
14 right person.

15 DENNIS: Okay, thank you.

16 MS. EDWARDS: Jim.

17 JIM: Thanks, Debbie. I believe that OPP is on
18 the right track in looking at incident reporting data and
19 widening the net to other areas. I think that's good.
20 Where I actually have a problem is overhead 5 on
21 metaldehyde, the first bullet point, is as we gather
22 data, there is always a tendency to move ahead and draw

1 conclusions. That first bullet point should have some
2 sort of footnote to quantify it.

3 I would make a wild guess that there are a
4 hundred million companion animals in the United States,
5 being that we have a population of 308 million last
6 count. I would bet you that numbers or indications that
7 large numbers of incidents, including many deaths, are
8 not actually quantified. Even though it may sound
9 sensitive, those kinds of things may -- should be a
10 little bit tempered down to either supported with data or
11 just make the verbiage a little bit more sensitive to the
12 issue, because as you gather more data in numbers,
13 there's tending to be conclusions, or could be, without
14 explaining to the audience that you're giving the
15 information to.

16 MS. EDWARDS: I think the information actually
17 was provided in the materials that we put out with the
18 RED. This is obviously abbreviated. We would have been
19 much more quantitative in our actual assessment that we
20 used to make the decision. Do you want any more real
21 specific information on that right now?

22 JIM: No, as long as --

1 MS. EDWARDS: I mean, I appreciate your point.

2 JIM: This was the only thing I've ever seen.

3 I don't generally follow this, but as long as it was very
4 well quantified and these adjectives are appropriate,
5 than that's fine, because I think if I was sitting in
6 certain situation, I would go, okay, metaldehyde is still
7 on the market, yet you had quite a number of deaths of
8 companion animals, mainly dogs. Well, where's the rest
9 of the data that supports the science one way or the
10 other? It's just this bullet point that I have trouble
11 with.

12 So, I'm thinking that as you gather more
13 information -- the tendency for people to gather data is
14 to then make conclusions that may be appropriate or maybe
15 not. Just have some sensitivity to the people that are
16 reading things that don't know about the rest of the
17 information.

18 MS. EDWARDS: Okay, yeah. I mean, again I
19 think -- like I said, I understand your point. I think
20 in the materials that we produced for the decision that
21 we've reached was all laid out and even put out for
22 public comment and received information back. At the end

1 of the day we felt that there were enough -- that the
2 incident information that we'd received supported a
3 decision to change some of the labeling on these products
4 and, in addition, to set up a system whereby we could see
5 whether or not that labeling was sufficiently effective.
6 If not, we'd have to go further.

7 Jim.

8 JIM: I think this is great stuff and I applaud
9 all that you're working on. I also want to sort of echo
10 what Caroline and Amy had said. I think as perhaps the
11 only AAP member in the room today, I would certainly say
12 that pediatricians would love to have more of a chance to
13 report. I'm actually speaking at the national meeting
14 for the AAP on pesticides, which is I think the first
15 time that's ever been a topic for the pediatricians
16 meeting. So, I can say that if there's another way of
17 reporting, I'd like to do that.

18 Then, the other question is for Molly. Now
19 that we know that you need to report to internal
20 management first, when and how can you disseminate the
21 results? I think we're very interested in that. If it
22 has to be either to us or even perhaps individually, I

1 would like to hear.

2 MS. CLAYTON: Okay. I appreciate your
3 interest. Definitely, a possible next step we have when
4 we talk to management will be thinking about how we
5 communicate the findings of this investigation once it's
6 completed. But thank you for your interest.

7 MS. EDWARDS: All right.

8 Mark.

9 MARK: I'm just a little bit curious. Maybe a
10 little background would help me. This shows my ignorance
11 in some ways relative to SPS and pyrethroids-induced
12 asthma. But I know that about a half of 1 percent of the
13 U.S. population has kyton (phonetic) allergies, and
14 asthma induced in children from cockroaches is a common
15 thing, particularly in government housing and some
16 income-related populations.

17 I'm wondering how you segue between that kind
18 of induction system and a PCO spring, a synthetic
19 pyrethroid stirring up kyton dust from history of
20 uncleanliness in ventilation systems?

21 UNIDENTIFIED FEMALE: You're right about that.
22 It's a good observation. That's one of the things that

1 complicates what we're trying to do and that's the type
2 of issue we're working through now. We haven't reached a
3 definitive conclusion about how you would do that.

4 UNIDENTIFIED MALE: A little background on
5 synthetic pyrethroid induced asthma. I'm not aware of
6 it. I just wonder if you've got a postage stamp size --

7 MS. EDWARDS: Do you want to have Mary or
8 someone touch on that?

9 MS. METABUSSEN: I'm Mary Metabussen
10 (phonetic). I'm the branch chief in charge of the
11 incident team. What we spent a couple months doing is
12 trying to really understand the biology and the
13 differences between pyrethrum, pyrethrin and pyrethroids.
14 I do clearly acknowledge that pyrethroids is very
15 different from the pyrethrin and pyrethrum which has a
16 natural allergic component to it because of its
17 comparison to chrysanthemums. In understanding that, we
18 understand that the synthetic form, the pyrethroids, are
19 laboratory based and should not have that allergic
20 component.

21 One of the challenges that we have on the
22 incident team is trying to differentiate that within the

1 incident databases that we have before us and doing a
2 careful evaluation, in particular looking at allergic
3 responses and anaphylactic responses and asthma. Those
4 type of refines are very difficult when considering
5 incident data. So, we do want to take a step down from
6 just looking at crude numbers of counts of incidents to
7 really looking at the cases and trying to understand
8 whether those cases were associated with pyrethrin and
9 pyrethroids exposure by understanding the text behind it,
10 the persons exposed, when they were exposed and when
11 those particular adverse effects appeared.

12 So, doing a careful evaluation but looking at
13 the weight of evidence, as you've all acknowledged, is
14 really important to put it back into context. So, in
15 terms of looking at whether this class in particular, as
16 you've noted being a highly (inaudible) populations
17 associated with this type of exposure, it requires us to
18 go back and put it back into context and look at other
19 insecticides and whether this particular profile that
20 we're seeing for this class is different for other
21 insecticides that may be irritating to the respiratory
22 track as well.

1 UNIDENTIFIED MALE: That's really helpful,
2 thanks.

3 UNIDENTIFIED MALE: Well, I certainly
4 appreciate the presentation and forgive me because I've,
5 like Jim Thrift, did not review the RED on metaldehydes,
6 so I may have a very basic question.

7 How diagnostic are the signs or symptoms of
8 toxicity to metaldehyde and companion animals?

9 UNIDENTIFIED FEMALE: Well, first of all,
10 metaldehyde is highly toxic and it's a neurotoxin. So,
11 dogs -- and it is mainly dogs, but there are other
12 domestic animals involved, too -- will have tremors,
13 salivation, paralysis of limbs, coma and death. I think,
14 you know, since that's known both clinically and
15 incidentally as an effect of metaldehyde ingestion by
16 mammals, that's pretty clear. And then, also, the
17 relationship to the potential exposures from metaldehyde.

18 In a lot of cases, people said, I saw my dog
19 eating it. Many of the incidents actually occur
20 associated with dogs ripping open bags of pellets, not
21 even applied pellets but bags of pellets. The pellets
22 are formulated with byproducts of grain production and

1 they have a sweet taste. That's to attract the slugs
2 that metaldehyde targets but dogs tend to like that too.

3 One thing that we didn't stress enough is the
4 aversion agent. The registrants had applied -- added an
5 aversion agent to their granular formulations of
6 metaldehyde over the years increasing in concentration.
7 We required that they test that aversion agent against
8 dogs that had never been done. It was very potent, very
9 effective and (inaudible) kids because kids taste -- it's
10 a bitter taste. But it turns out that dogs were
11 practically immune to it and now the registrants have
12 started using a different aversion agent of (inaudible)
13 efficacy.

14 UNIDENTIFIED MALE: Thank you for doing that
15 because -- or for explaining that because I had
16 experience in a previous position with a product that, in
17 fact -- similar situation where animals were actually
18 going into closed containers and ripping them open and
19 exploring the idea.

20 The reason that I was bringing this up was just
21 the interest and yet to voice a concern that by opening
22 up reporting mechanisms, I think that's an excellent

1 opportunity but also to have a valid screening. I guess
2 in looking at it, as the agency opens up to web
3 reporting, is there going to be an ability to provide
4 additional qualification and/or confirmation, because in
5 the past where -- it's gone through additional
6 individuals who could look at, you know, the properties
7 of a specific product.

8 The reason I was asking is that what you just
9 described for metaldehyde sounded very similar to a
10 product that I was associated with, in which case both
11 were used in a -- theoretically, in a homeowner
12 situation. That unless a companion animal owner actually
13 saw the ingestion, it could in fact be massed or could be
14 mistaken for another product. That's why I just want to
15 make sure that unless there are very diagnostic
16 characteristics, that in fact one product might be
17 reported and it might actually be another.

18 So, what can the agency do with this wider
19 reporting to make sure that in fact the proper products
20 are being addressed in the incident reporting?

21 UNIDENTIFIED FEMALE: First of all, for
22 metaldehyde to drill down and confirm the association,

1 since these animals get so very sick, many of them end up
2 at the veterinarian and the veterinarian can do tests to
3 determine that the metaldehyde exposure was real. Also,
4 the onset --

5 UNIDENTIFIED MALE: Do they?

6 UNIDENTIFIED FEMALE: I'm sorry?

7 UNIDENTIFIED MALE: Do they actually do that
8 test? I mean, is it readily available to them?

9 UNIDENTIFIED FEMALE: I can't answer that. The
10 data we get is very spotty which is one reason why we
11 wanted the registrants to do a lot of follow up on
12 incidents. That's the main component of that, that
13 incident reporting system we required them to do as a
14 follow up because we -- you know, we get these symptoms
15 reported through various portals and then you wouldn't
16 know what happened. Did the dog die? Did it survive?
17 What did the veterinarian say?

18 I think all three -- well, not the 6(a)(2) but
19 the NPIC, Poison Control, and Animal Poison Control
20 systems all have a qualifier on the certitude of the
21 exposure. That's a judgement made not by the caller but
22 by the technician that receives the call. I think Frank

1 can talk a little bit about that.

2 FRANK: Yeah. All calls that come in to NPIC
3 that are considered "incident calls" are later looked at
4 by Dr. Sudakin (phonetic). That is obviously for human
5 incidences. But all calls that are incident calls are
6 looked at by the specialist in the small review committee
7 within the NPIC organization, and they're tagged as to
8 certainty, probable, unlikely, whatever. So, they carry
9 that characteristic with each incident.

10 UNIDENTIFIED FEMALE: I'd also like to follow
11 up on this AVMA portal especially. We have the contact
12 information of the reporting individual. That's
13 obviously something we could follow up on and contact
14 them and find out specifically what definitive methods
15 they use in determining -- especially if there isn't an
16 EPA RED number available to see what the exposure could
17 be readily attributable to.

18 UNIDENTIFIED MALE: I think that was one of the
19 things from the presentation that I was very pleased to
20 hear, that there is both the ability to do the follow up
21 and that you would then also be able to do an analysis of
22 whether or not one individual seems to be reporting on a

1 consistent basis. I think that's excellent for follow up
2 purposes.

3 Having been involved with a human exposure
4 incident, which, in fact, a primary physician I think
5 misdiagnosed an exposure attributing it to pesticides
6 when in fact it was a poison ivy toxicity. Based on the
7 fact it was not systemic but it was related to the hands
8 and to the face, the doctor misdiagnosed it. Had it been
9 easy to put in and not being able to be attributed, the
10 product that was used could have been unfairly marked
11 with a pesticide incident. So, I just wanted to
12 encourage that there are mechanisms to follow up and in
13 fact to screen and verify.

14 UNIDENTIFIED MALE: Good. Thank you.

15 MS. EDWARDS: Okay, thanks. The three cards
16 that are up and then we'll have to end this particular
17 session.

18 Christy.

19 CHRISTY: Thank you for the presentation about
20 the AVMA portal. I don't do compendium animal work so I
21 didn't really know about it. Really interesting idea.
22 But I was wondering if there are things that compendium

1 animal groups can do to help publicize it. Do you have a
2 sense of how many veterinarians know about the portal?
3 Is the AVMA planning to do publicity?

4 UNIDENTIFIED MALE: I think we want to use
5 every mechanism that's available to publicize the portal.

6 CHRISTY: Okay.

7 UNIDENTIFIED MALE: So, if any of you want to
8 give us recommendations, I'd certainly be happy to hear
9 that. It's going to take some effort on our part at EPA
10 to figure out all the avenues and roads that we can go,
11 but the more we publicize it and convince the general
12 public this is what we're trying to do to help the
13 veterinarians and to help domestic animals, to convince
14 the veterinarians that they should be obligated almost to
15 report through this portal.

16 CHRISTY: Okay.

17 MS. EDWARDS: Michael.

18 MICHAEL: Most vet schools have a toxicology
19 section and a center for animal health food safety, that
20 kind of thing, that will do the diagnostic analytical
21 chemistry for \$50 to \$100 per sample. Would it be
22 possible to have EPA subsidize some of these incidents

1 through NPIC if that were a question that people had as
2 to what the compound really was?

3 MS. EDWARDS: It would be possible if there
4 were money to do so. I mean, if this is the
5 recommendation that were to come forward -- again, you
6 saw our budget rollout with what Marty presented. So,
7 obviously, every day we make difficult decisions on how
8 we allocate our money. This can be on the table when we
9 make those decisions.

10 I think there's one card left. Jay.

11 JAY: Two questions. One on the human side.
12 EPA does support and have direct reporting information
13 coming from the National Poison Control Centers. I
14 wonder if you could talk about that and how it overlays
15 with some of these other prospective ideas that have been
16 discussed here both in terms of what would be
17 supplemental in terms of good resource utilization, if
18 additional human incident reporting systems, you know,
19 were considered or implemented or are there others that
20 are currently used?

21 Secondly, on the overall incident reporting,
22 with regard to mistakes that are collected, have you done

1 in the past any composite look at, you know, when things
2 are misidentified as pesticide poisonings or incidents so
3 as to have some kind of matrix decision process to enable
4 you to identify early when certain kinds of information
5 comes forward that may not be based in fact with regard
6 to a pesticide incident? Or, is that something that
7 could be developed? And, could industry, including we at
8 CropLife, participate in that kind of an exercise?

9 UNIDENTIFIED FEMALE: Yeah. As we form this
10 work group this year to take a look at a lot of different
11 options, I think -- and as we prepare a strategic plan to
12 present to Debbie here within the next few months, we
13 want to try to present a plan that would outreach to
14 states more. We look at state data on a chemical by
15 chemical basis or when we have information that would
16 lead us to the states. There's obviously a lot of
17 information out there that we don't get currently.

18 I think Mary would be better versed to talk to
19 the question about specific use of the data.

20 MS. LEVINE: There are a couple of things I'd
21 like to say. I'm Tina Levine, director of Health Effects
22 Division. There are a couple of things I want to say

1 about the Poison Control Center data and about incident
2 data in general.

3 I mean, incident data is difficult data to work
4 -- are difficult data to work with. I think Mary pointed
5 out how you really do have to drill down. You can't take
6 it at face value. A lot of it is anecdotal and you
7 really have to take a look at it and try to separate the
8 wheat from the chaff.

9 But the poison control data also we labor under
10 a bit of a problem with that that I think this group may
11 have to address and maybe -- and CLA may be able to help
12 us with. One is that on a routine basis when people are
13 queried in a poison control center, they don't
14 necessarily get registration numbers. The Poison Control
15 Center has its own indexing system and Norm Ferling
16 (phonetic) has worked very tirelessly over the years to
17 try to line up those -- that system with what our reg
18 numbers are.

19 Now, we would like to work with the Poison
20 Control Centers if they do routinely get reg numbers.
21 One way in which we could facilitate that is if there was
22 a standardization of where on product labels registration

1 numbers would play. That would make it a lot easier and
2 then they could always tell people which number to look
3 for because there's a number of different things and
4 sometimes you have distributor labels and stuff like
5 that.

6 So, I think that that would be a big way in
7 which we could maybe work together to help us improve our
8 ability to cross reference Poison Control's data with the
9 other data that we have, because part of this is also
10 that there's a lot of duplication. So, you also want to
11 separate that out. So, that was just something I wanted
12 to point out.

13 UNIDENTIFIED FEMALE: I think just to add to
14 what Dr. Levine had indicated, we start first with the
15 6(a)(2) data because, of course, registrants are required
16 to submit any adverse outcomes for human animal companion
17 data and the environment. So, we start with that as a
18 basis but we do consider other data sources as indicated
19 like NPIC and PCC being a few of the sources that we look
20 to.

21 I just want to emphasize that we welcome and
22 encourage you to report in any way you can because we do

1 this weight of evidence approach. We look across all
2 these different data sources and we look for them with an
3 eye towards reproducibility, because if there is an
4 association, it should not be distinct to one particular
5 database specifically. It should be seen across the
6 different data sources because humans are humans and we
7 expect humans to respond similarly.

8 So, having said that, I hope that gives some
9 clue as to how we're looking at incident data so far.
10 We're beginning to hone in on criteria, as Tina
11 indicated, because you cannot again do a number count
12 when you're looking at incident data. You really need to
13 understand the exposure, time of exposure, and whether
14 that correlates back to that pesticide that's being
15 indicated as the potential actor in that adverse outcome.

16 MS. EDWARDS: Okay. Thanks to the team.
17 Thanks to all of you for participating in this. I think
18 again, much as the pollinator session went late
19 yesterday, you can see that we're focused on this
20 activity and we'll report out again where we are in the
21 next session.

22 MR. KEIFFER: Excuse me, this is Matt Keiffer

1 on the phone.

2 MS. EDWARDS: Is someone on the telephone?

3 Matt?

4 MR. KEIFFER: Yeah, this is Matt Keiffer. I'm
5 sorry. I wasn't getting through. I hate to jump in at
6 the end here, but this is a question pertinent to the
7 presentation.

8 MS. EDWARDS: That's okay.

9 MR. KEIFFER: And I can't raise my card. Can I
10 ask how you've noticed the effect of HIPPA or have you
11 looked at the effect of HIPPA on the willingness of
12 people to report of the frequency of reporting?

13 MS. EDWARDS: What is HIPPA?

14 MR. KEIFFER: Health Care Information
15 Portability Act. There's another P in there but I don't
16 remember what the other P is. It's the law that came
17 out --

18 MS. EDWARDS: Yeah. I think you've brought
19 that up before.

20 MR. KEIFFER: Right.

21 MS. EDWARDS: I don't know if a team is working
22 through that as an issue at the moment or not, but if we

1 -- they should, they need to get focused on that as well.

2 MR. KEIFFER: Well, I emphasize again that I
3 think this is something that could put a chill into
4 reporting in general because if the person reports
5 personal information, there's up to a \$50,000 fine for
6 releasing information on a -- even the fact that a
7 patient has been seen by a doctor is considered personal.
8 So, the willingness of physicians or clinicians to report
9 is going to be really chilled. Unless they are very
10 motivated to report by whatever system is in place,
11 they're not going to do it because there's too much risk.

12 MS. OVERSTREET: This is Anne Overstreet. This
13 is exactly what we're focusing on in the group. As we
14 move from the animal data, releasing the AVMA portal was
15 a short term goal we had because, of course, there aren't
16 privacy issues associated with that. It's a fine line to
17 be able to attribute, finitively, as Mary and Tina were
18 discussing, the effect to a particular pesticide. I
19 think we could -- we're going to be looking at ways to
20 respect the privacy laws and still be able to collect
21 useful incident data information as a line of evidence.
22 I think there can be a way to do that and I think we need

1 to work on that. It's a focus of this group.

2 MR. KEIFFER: I think it's an important focus.

3 Thank you.

4 MS. EDWARDS: Thanks. I'm sorry I didn't focus
5 on -- I will do that in the future, find out if anyone on
6 the phone has something to say.

7 Before we move on to the next session, I just
8 wanted to follow up on something from yesterday that we
9 discussed during our measures piece. First of all, there
10 was some confusion about the way we presented the
11 information that we had on where we are with urban
12 watersheds. So, instead of one bullet, we now have a
13 two-and-a-half pager that will be on the table that
14 explains where we are with urban watershed information.
15 The information in the bullet was correct. It was just
16 not very clearly presented in such an abbreviated way.

17 The second, though, that I wanted to mention,
18 since we did go back -- people went back to a number of
19 things. The inhanes (phonetic) information is actually
20 incorrectly presented. Let me just tell you a little bit
21 about that and then I'll tell you what we're going to do.

22 Our goal for the year was a 10 percent

1 reduction. You saw that. Then we had claimed that we
2 had only reached five percent and still hadn't quite
3 reached that goal. In fact, what has happened was -- the
4 way this works is you're looking at median urinary
5 metabolite concentrations on six OP metabolites that are
6 nonspecific and then one that's chlorpyrifos metabolite.

7 So, the situation that we have here is we have
8 three of the data points in out of the six. We don't
9 even have all the information yet. And of those, the
10 average of the three is a 20 percent reduction, but not
11 one of them is 20 percent. They're varying amounts.
12 This is the problem with having to report into our rather
13 simplistic base program measures on issues within the
14 agency where they require comparisons to one number.

15 Nothing is ever that simple. No matter how
16 many times we tell them that, they require one number
17 comparisons. So, what we'll be doing is providing those
18 one number assessments, but then again, all the
19 information that's behind it as well.

20 So, I actually am not going to give this out
21 today. I think what we were trying to do is be
22 responsive to your request from the last meeting and get

1 you as much information as we possibly could. But this
2 one is, in fact, a little bit premature. We expect to
3 receive the rest of the information pretty soon for this
4 and we'll get it out as soon as we can.

5 So, you're going to have the one on the urban
6 watersheds out on the table. I think that's pretty
7 complete. Then, I very much hope that by the end of the
8 calendar year, we'll be able to send you out to all
9 members of the PPDC a report on where we are with the
10 measures, with more of the detailed information, not the
11 little brief bullets, in a report. Also, we'll just post
12 that on our website but we'll actually e-mail it out to
13 all of you.

14 And now let's just move on to the next piece
15 which I think is -- well, let me talk about this session
16 a little bit before we get into it.

17 UNIDENTIFIED FEMALE: I don't know if it's
18 possible in the system because you might be restricted by
19 this one number issue. But whenever you present a single
20 number such as a (inaudible) number and if it's an
21 average or a mean, it would really help to understand the
22 range.

1 MS. EDWARDS: That's what I mean. That's what
2 I'm talking about.

3 UNIDENTIFIED FEMALE: They don't let you do the
4 range?

5 MS. EDWARDS: It depends on who they is. We
6 can do whatever we want. What I mean is that as we
7 report it up into the strategic measures --

8 UNIDENTIFIED MALE: We've always known that.

9 MS. EDWARDS: -- we have to -- you know, they
10 make us -- we have to fit on something like a tenth of a
11 page.

12 UNIDENTIFIED FEMALE: Well, whatever you can
13 report to us that is actually more descriptive of the
14 data, it would be really helpful.

15 MS. EDWARDS: Sure. I know. I totally agree.
16 That's why we've got two-and-a-half pages instead of a
17 tenth of a page on the urban.

18 Amy.

19 AMY: Real quick. If you're going to
20 eventually post the Power Points like you usually do from
21 this meeting, I hope that if that -- from what I
22 understood you to say, the third bullet there on your

1 performance measures thing in this slide is incorrect.

2 So, I hope that won't be put in there.

3 MS. EDWARDS: We're not going to put that in.

4 AMY: Because we'll use that.

5 MS. EDWARDS: That's why I wanted to talk about

6 this here today because I don't want any of you taking

7 away that information from yesterday and, in effect,

8 misreporting because of us information.

9 The next session is actually only a 45-minute

10 session. You'll notice it's entitled "Brief Update."

11 So, I hope they can be brief. They probably would be

12 something like 15 minutes apiece. Then we would move on

13 to some of the -- I mean, obviously we have several

14 sessions today. We have two more sessions after that.

15 One is a 30-minute and one that is only a 15-minute. So,

16 bear with us here. I think we'll take some comments on

17 each one.

18 Again, at the end of the session this morning,

19 we should probably talk a little bit about whether this

20 kind of format is useful to both of us. But we're trying

21 to get some information out in these meetings, which are

22 only a day and a half, about every major issue that's

1 going on in the pesticides that we want to get out in the
2 public eye and show what we're doing and also hear from
3 you. It's a constant challenge.

4 But anyway, not to take up any more time,
5 volatilization is a very big issue with pesticides these
6 days. I believe Jack Housenger is here to give you an
7 update on that.

8 MR. HOUSENGER: Thanks, Debbie. About a year
9 ago we did a presentation on volatilization. We've been
10 working on it, so I wanted to give you a little bit of an
11 update today about where we are and what our next steps
12 are.

13 For those that weren't listening last time or
14 weren't here, I just wanted to talk a little bit about
15 what volatilization is. It's just a pesticide that's
16 been treated or a field that's been treated and vapors
17 coming off of that field and the exposures that result
18 from those vapors. They may be to workers, they may be
19 to bystanders or people living around the treated area.

20 Since the last PPDC meeting, we've put on our
21 web site an information page about this. It's in the
22 pesticide in the works web site. If anybody has been to

1 our web site lately, they've completely changed it
2 around. Unless you have that site, you probably won't be
3 able to find it. But that whole site talks about, I
4 think, bees and nanotach (phonetic) and volatilization.

5 We've also decided that in December of 2009,
6 we're going to the SAP to take a lot of the science
7 issues that are tied up in volatilization, how we assess
8 it, how we should estimate exposures to people, the time
9 frames, aggregate issues, the tox issues associated with
10 it, which I'll get into a little bit later.

11 Pam has done a lot of work on producing
12 exposures from volatilization and probably the impetus
13 for this update is that they just released a new report.
14 They had done a study in Hastings, Florida. It's a
15 school that was built in the middle of an agricultural
16 area. In 2007, they collected eight samples. They found
17 diazinon, endosulphran and triflurolin. They repeated
18 that study in 2008, collected 39 samples, found the same
19 pesticides plus chlorofalonil (phonetic).

20 These are kind of the results of 2007-2008.
21 Fairly similar results that were seen. One of the things
22 why we want to go to the SAP is there is a lot of

1 uncertainty about how best to assess volatilization
2 exposures. We thought it might be useful to see why
3 PANNA is saying one thing and we're saying another. So,
4 we put up this slide to kind of explain the differences
5 in how we look at these exposures.

6 This one is on endosulphran. So, we take a 21-
7 day exposure or inhalation study. We both start out with
8 that. PANNA puts on a 10 for inter/intra and also a 10
9 for kids which we remove because we've gotten data in
10 that suggests that that can be removed. We're using a 3X
11 for interspecies because we're using a different
12 methodology than they're using.

13 So, what we've done is calculated the target
14 concentration, for lack of a better term here, where
15 we've built in all the uncertainty factors to put them on
16 an even keel. PANNA's target concentration for adults is
17 7,800 and 339 for a one-year-old child. Let me just
18 mention -- and I've coordinated with Susan on this, so I
19 don't think she's going to jump up when I say this -- the
20 339 incorporates a 10X FQPA safety factor and believe
21 that they're going to go back and redo that. So, that
22 339 would actually be 3,339, whatever that comes out to

1 be -- 90, thank you.

2 Then PANNA would -- well, our target
3 concentration using the RFC methodology is 15,400 for all
4 populations. There's no difference between kids and
5 adults in this situation since it's a systemic effect.
6 So, it would be an identical target concentration that
7 we're using. PANNA then would compare the max value that
8 they see in a 24-hour period. We would take an average
9 exposure because we're looking over 21-day exposure in
10 the rat inhalation study.

11 I just want to point out that regardless of
12 which one you're using, the target concentration isn't
13 exceeded by either method. A one-day exposure, if we had
14 a one-day rat inhalation study, would likely be a much
15 higher value than the value that we're looking in the 21-
16 day rat inhalation study.

17 Susan, you may want to chime in here, but this
18 shows the difference. I want to point out that the
19 approach that Pam is using is similar to what OPP has
20 used in the past. We've been shifting more toward the
21 RFC methodology now, but in the past we have used the
22 same approach. It's consistent with what California

1 uses. Probably the biggest difference is that Pam is
2 using the max concentrations -- again, this one-day value
3 -- and assuming that someone is exposed for 21 days with
4 that. Whereas, we would take the average concentration,
5 because we've seen in the PANNA data that those
6 concentrations go down after the first day.

7 Again, using the 24-hour air concentration is a
8 conservative assumption because concentrations decline.
9 It's not likely that an individual be stationary for the
10 24-hour period, but it does happen. Mothers with
11 children at home or elderly people could be in the same
12 area for the entire 24-hour period. The data doesn't
13 take into account the differences between indoor and
14 outdoor concentrations, although there are limited data.
15 There aren't a lot of data on this, but it would be hard
16 to believe that the indoor concentrations would be
17 greater than the outdoor concentrations. That's one of
18 the uncertainties.

19 Then, the PANNA drift catcher isn't only
20 catching volatilization. It may be catching drift or
21 whatever is there. The significance of that is that the
22 particles may not be respirable, so you may not be

1 getting the same exposure from a larger particle from
2 drift as you would from volatilization.

3 Like I said, we're planning on taking this to
4 the SAP in December. We've invited PANNA to make a
5 presentation on their methodology to the SAP, and Susan
6 has agreed to do that. We're going to look at
7 methodology. Obviously, we'll look at the RFC
8 methodology that we're using. That has been to a FACA
9 committee, the scientific advisory board, already, but
10 it's probably worthwhile taking it back.

11 Another question that we're going to be asking
12 is how to estimate exposures. For the fumigants, we had
13 models that were used to model the exposure to
14 bystanders. One of the questions we have is should we
15 use those same models for volatilization. Finally, the
16 issue of toxicity testing, a lot of our tests that we
17 have for inhalation exposures we'll do aerosols. We're
18 dealing with vapors here. Probably vapors are more
19 readily absorbed than certainly aerosols can be. So, how
20 do we account for that?

21 Susan gave me three slides this morning at 2:51
22 a.m. I don't know what she was doing up at that time,

1 but -- and I haven't had a chance to talk to her. I
2 agree with one of the slides but I think there's some
3 science issues that probably we need to talk about on
4 some of the other ones. But if we could put up the
5 inhalation testing -- and you want to say -- go ahead and
6 say whatever you want to say.

7 SUSAN: Thanks, Jack. Basically, there are
8 issues with the way the inhalation toxicity testing is
9 done. Probably the first thing is that if you're going
10 to compare inhalation exposures, you'd like to have an
11 inhalation tox test to compare with. Those are just not
12 available for all pesticides. The reason that's
13 important is because when you inhale something and it
14 absorbs through the lungs, it's very different than if
15 you ingest it and it manages to make its way through the
16 liver's detox system on the way. So, they're often
17 different. The reference there says from inhalation in
18 milligrams or kilograms are often different than
19 references from dietary ingestion. So, that's an
20 uncertainty there.

21 The lab tests done with the rat don't really
22 provide comparable exposures. The rats are dosed for

1 five days a week, six hours a day. So, they have some
2 chance for recovery. For humans -- and the rats also
3 get, or at least you'd hope, a constant concentration,
4 although I think these experiments are quite difficult to
5 do.

6 For people, what you tend to see is a spike.
7 One of the results we got was 1,300 nanograms per cubic
8 meter of endosulphran for 24 hours, which means that you
9 probably got a huge spike somewhere during that day and
10 you've averaged it out over 24 hours.

11 We know from research on aquatic toxicity that
12 pulses of exposures can, you know, be more damaging than
13 just an average lower level exposure. So, more work is
14 needed there for sure. It would be nice if the tox tests
15 were somewhat reliable.

16 The other thing about the endosulphran data is
17 that for Florida is that this grower was apparently
18 applying endosulphran every two weeks. So, we got spikes
19 every two weeks. It took about three days for it to
20 completely -- well, not completely, but mostly, die down.
21 So, we don't know what the effects of that are going to
22 be.

1 Then, like Jack was saying, the effects of
2 exposure versus -- the aerosols versus vapor versus
3 pesticide contaminated particulates that might stick in
4 your lungs, the drift catcher catches all of these and so
5 do human lungs but we're not sure how much they -- you
6 know, you take a breath. Some of what you inhale sticks
7 to your lung tissues; some of it you exhale again. So,
8 there's issues there that we don't know about.

9 Temperature effects, you have to have
10 laboratory animals at about, ideally, 70 degrees. It's
11 against the law to do otherwise. But, in fact, you get
12 the most volatilization off of these things at higher
13 temperatures. It's hard to get enough of this stuff in
14 the air so that you know the animal is getting a dose.
15 It's probably condensing out on their fur, on the walls
16 of the cage, on the food that they're eating. So, you
17 probably have a mix of inhalation and ingestion exposure.

18 So, there's a lot of issues here, you know,
19 related to whether or not these inhalation toxicity tests
20 are giving us a good number. One way or the other, you
21 know, the science of it doesn't look perfect to me.

22 The one thing that we have done -- and Jack's

1 right, we have a little bit more work to do on this. But
2 we did biomonitoring in an area where chlorpyrifos was
3 very high and we were measuring levels of chlorpyrifos
4 that were on the order of 300 to 1,000 -- 1,300 nanograms
5 per cubic meter.

6 We did biomonitoring during a time period when
7 chlorpyrifos use was high. The biggest orange bar over
8 on the side was we worked very hard to try to get a
9 sample set that was not working on the farms or in the
10 packing houses. One person flipped through. So, you can
11 see what happens when someone works in the orchard.
12 They're really highly exposed. This is an orange growing
13 area, by the way.

14 But the black line at the bottom is the inhane
15 biomonitoring average for the metabolite of chlorpyrifos
16 TCP. You can see that people living in this area -- I
17 think we can safely say that people living in this area
18 have higher body burdens of chlorpyrifos. Are they
19 getting it from inhalation? Are they getting it from
20 contacting surfaces in their house that have been
21 contaminated with chlorpyrifos? It's not clear.

22 Richard Senski (phonetic) up in Washington has

1 done quite a bit of work on looking at pesticides and
2 dust as a function of the distance of the house from the
3 orchard and is finding, you know, azinphosmethaline
4 (phonetic) in dust. So, there may be some contributions
5 from that as well.

6 This slide, what I did is I said, okay, well,
7 let's figure out what you're breathing. We're assuming
8 the same absorption through respiratory inhalation as
9 through dietary ingestion. Then, what is that value in
10 milligrams per kilogram per day as a percentage of the
11 population adjusted dose, which is what EPA -- the target
12 dose. You'd like everything to be below that.

13 So, I compared it to the 90 -- this is again
14 chlorpyrifos -- the 99th percentile acute dietary
15 exposure is about 50 percent of the population adjusted
16 dose after you do all the mitigations that EPA put in
17 place for chlorpyrifos.

18 Just breathing for 24 hours in that location by
19 where an application is taking place, at first the very
20 tall bar, you're getting 7,670 percent of the population
21 adjusted dose, milligrams per kilograms per day. We
22 don't need any reference exposure level here or reference

1 concentration. It's just this is the actual milligrams
2 per kilogram, assuming again 100 percent or actually
3 assuming the same as dietary.

4 Then, in our -- so, that's right next to an
5 application. That's data from the California Air
6 Resources Board where they sampled around the edge of the
7 field. They certainly saw those spikes that I was
8 talking about because they were taking shorter samples.

9 Then, for work that we've done in Lindsey,
10 California, in orange grove areas -- well, ARB sampled
11 there as well in '96. We sampled in 2005 and 2004 and
12 also 2006, which is not on there, also in Washington
13 State. You're seeing that, you know, we're exceeding
14 what I think EPA would agree is a level of concern
15 because that's milligrams per kilogram per day.

16 Jack may want to argue about that, and I'll
17 stop here. Thank you.

18 JACK: Yeah. Let me just say, the last two
19 slides I think we have some issues with but we haven't
20 been able to talk to Susan about. But obviously, before
21 the SAP rule, we'll have those discussions and we'll let
22 the experts sort it out.

1 MS. EDWARDS: Okay. Well, I hope everyone
2 enjoyed that update. I didn't actually realize we were
3 going to have the SAP presentation today. Anyway, as you
4 can see, and this is why we're so focused on this, and as
5 you can imagine, with urban/rural interface issues
6 continuing to be of concern to people that live in rural
7 areas, in particular where schools are involved, and in
8 particular when pesticides are being found at some level,
9 which remains to be see whether or not it's a level of
10 concern, people want answers. They want answers from
11 their government. Are you registering these chemicals in
12 a way that's going to cause harm to my children or not?

13 So, our mission through this project is to
14 figure out in what circumstances should we be doing risk
15 assessments for volatilization in our routine work? And,
16 once we know under what circumstances that might make
17 sense, what data might we need that we don't already get
18 and what methodologies are appropriate to do that? Then
19 we would be regulating appropriately once we know that.

20 So, there's a lot of work to do. We're
21 actively engaged. We're very actively looking at the
22 data that are being generated. We appreciate the data

1 that are being generated and we'll be taking it, as Jack
2 said, to the scientific advisory panel meeting this
3 coming year. But I definitely want everyone here to know
4 that the agency is looking into this issue in a very
5 serious scientific technical kind of a way. So, thank
6 you.

7 I think we should probably just move on now to
8 the next update, actually. Hopefully, it's a quick
9 question.

10 MS. BIDEN: (Inaudible) Biden. I'm quick. I
11 just wanted to know when you bring us back and update us
12 about this if we could talk a little bit about what the
13 regulatory folks are doing in California so we can get a
14 basis of comparison. I think that would be real helpful.

15 MS. EDWARDS: Okay. We'll do that.

16 Our next session is on pesticide usage
17 information and also resistance management. So, Rick
18 Keigwin, our director of Biological and Economic Analysis
19 Division, will present.

20 MR. KEIGWIN: In 10 minutes, right? I think
21 what I'm going to do, I'm not going to use all of the
22 slides. You all have them and they'll ultimately be

1 posted to the PPDC web site. In the interest of time,
2 there's still a lot that we wanted to cover this morning.

3 Just to give you a flavor of what's in the
4 presentation and then, if we have a brief time for
5 questions or I'll be around in the hallway. I think what
6 we wanted to do in light of the discussion that we had
7 yesterday and the presentation that we had yesterday by
8 NAS is just to give you all a brief overview of the types
9 of use and usage information that we utilize here in the
10 Office of Pesticide Programs. We can just have a brief
11 discussion about that.

12 There are basically two types of data generally
13 that we seek. The first one is use data which more or
14 less is qualitative information, largely information
15 that's derived from the labels themselves of how the
16 pesticide is used, what the targeted pest is, when it's
17 applied, how it's applied, and at what rate.

18 The second type of data that we look for is
19 usage data which more oftentimes is quantitative
20 information. The label will say it can be used at a
21 certain rate, what are growers actually using it at, what
22 is a typical rate, where is it being used, what are the

1 maximum rates, what are the average rates, when during
2 the crop cycle is the application being made, and how is
3 that pesticide typically applied, even though the label
4 might offer different methods of application.

5 On the use data side, we primarily rely upon
6 two data forces. One is our own, which is Pesticide
7 Product Label System, PPLS, which is already available on
8 the EPA web site. Then, there's a second private source
9 that I know many of the registrants contribute to and
10 that's the Crop Data Management System, or CDMS.

11 We largely use this in the preparation of what
12 we call our LUIS report, which are the Label Use
13 Information System reports that appear in the dockets for
14 registration review. One of our hopes is over the near
15 term to move to a more user friendly system for that.
16 Right now, to populate the LUIS system, it's a manual
17 extraction of the image labels and putting it in a
18 separate system. As we transition to e-labeling, we hope
19 that this will be more of a real-time system so it's not
20 as much of a burden on us to generate the information
21 that the labels say.

22 Then, usage data sources, we have a number of

1 sources that we rely upon. Many of them come from the
2 U.S. Department of Agriculture. Mark talked a lot
3 yesterday about the chemical usage survey. That's one of
4 our primary data sources historically. We also use other
5 information that they generate, including other
6 agricultural statistics. The information that comes from
7 the census of agriculture is critically important. The
8 crop profiles, including those developed by the IPM
9 centers, are sources that we use on a daily basis.

10 In California, as you all know, there's a very
11 good pesticide use reporting system and we rely upon that
12 very heavily. Oregon just recently published their first
13 year of usage reporting. We're still trying to figure
14 out how to use that information. I think they're still
15 trying to figure out how to use that information. So,
16 we've begun some discussions with the State of Oregon on
17 the value of those data and how to incorporate those into
18 assessments.

19 Then we use a number of research data from
20 private sources, Doan (phonetic) being one of them, on
21 agricultural chemicals. We also will periodically
22 purchase data from another private entity called Kline

1 (phonetic). It tends to look at non-agricultural uses.
2 We've recently purchased data on turf uses and pesticide
3 usage in food handling establishments, golf courses, as
4 those data become available.

5 Then, I think I'm just actually going to end
6 there and say basically, that's an overview of the data
7 sources that we use. It's pretty critical to every
8 aspect of the regulatory program that we have here. It
9 helps us refine our estimates and have a much better
10 handle on how these pesticides are actually being used.
11 They become critical information as we are developing
12 risk management or risk mitigation packages for chemicals
13 through the re-evaluation program. It gives us a clearer
14 sense of how growers or applicators are applying these
15 products and under what context.

16 With that, do you have any questions?

17 MS. EDWARDS: Why don't we just go on to the
18 resistance?

19 MR. KEIGWIN: Okay. On the resistance
20 management one, and I don't think I'm going to --
21 Michelle, I'm not going to use that presentation, but
22 folks have it.

1 What we wanted to do here was just to let you
2 all know that we have recently initiated a new effort
3 within the Office of Pesticide Programs to look more
4 routinely at resistance management issues. These are
5 issues that have come up in a number of our re-evaluation
6 decisions and we thought it was a good time to take a
7 second look at sort of our general policy approach to
8 resistance management.

9 I think you all are familiar with the pesticide
10 registration notice that we issued in 2001 that announced
11 a voluntary program for the labeling of pesticide
12 products based upon their mode of action. That program
13 was developed with Canada's Pest Management Regulatory
14 Agency in cooperation with a number of industry groups
15 that have looked at resistance management issues for
16 insecticides, fungicides, herbicides. That program is
17 currently a voluntary program. It's been in place now
18 for about seven years.

19 We're beginning to contemplate what additional
20 steps we might take. There may be some updating that
21 needs to be done to that registration notice. We have
22 heard from some groups that they have an interest in

1 seeing us move that to a mandatory program, so that's
2 something that we're going to think about.

3 We're also looking at what other aspects of
4 resistance management should we be looking at as part of
5 our regulatory programs. Other efforts are afloat,
6 particularly in the EU, on resistance management. So, we
7 want to examine what approaches they are contemplating.
8 This group here within OPP is being led by Ski Jones
9 (phonetic), who is a branch chief in Biological and
10 Economic Analysis Division, and has participation from
11 pretty much all of the groups within OPP that would be
12 impacted by resistance management issues. Then, we will
13 also be launching a coordinated effort with Canada.

14 We were on a call with Canada recently and they
15 said if a resistance management issue develops in the
16 U.S., they'll get it soon enough. So, they want to be
17 working with us collaboratively in this effort.

18 So, I think what we really want to just let you
19 all know is that we've initiated this effort. We'll be
20 beginning some dialogue with many of you. I think this
21 will be an issue that we routinely bring back to you all
22 to give you all updates.

1 MS. EDWARDS: Thanks, Rick. I think a tiny bit
2 more context on this. One of the reasons that we're so
3 concerned about this is some of the chemicals that we're
4 seeing resistance developing for are some of the newer
5 and what we view as lesser toxic chemicals. So, it's
6 very important to us to meet our goals that we ensure
7 that these chemicals have a long enough life that people
8 aren't actually beginning to ask for or use more toxic
9 chemicals still on the market.

10 So, you know, the question for us, much like
11 the comparative or safety statement issue is, should the
12 government have a role or a greater role in trying to
13 ensure that resistance doesn't develop in these
14 chemistries.

15 So, anyway, I think we should probably again
16 move on. You know, for example, for these first few
17 topics, if you have additional questions, if you have
18 ideas, if you want to have a meeting, on the first topic
19 call Jack, second topic call Rick or Ski, actually, for
20 the -- Ski Jones for the resistance.

21 We'll move on now to the third brief update
22 which is Bill Diamond for what we're doing on our

1 regulatory initiatives. He's director of the Field and
2 External Affairs Division.

3 MR. DIAMOND: Good morning. I'm going to
4 provide you a snapshot of what rule-making projects are
5 underway and also just mention a couple that are on the
6 horizon, particularly since a number of these take a lot
7 of time to actually develop. We like to get people
8 involved early so they can have some input at critical
9 formative stages here.

10 You've got a handout that was mailed to the
11 members that include the matrix. It provides a little
12 bit more detail than the things I'll touch on this
13 morning. There's also copies out on the table.

14 There are several broad categories of rules
15 that we've got that are designed to achieve different
16 programmatic objectives. The color ones are ones that
17 are aimed at enhancing public health and environmental
18 protection. These would be to either establish or to
19 upgrade or to modify existing core protective
20 requirements.

21 A second category is ones designed to give us
22 better information or sound science to support sound

1 decisions. Those are rules which improve either the
2 quality or consistency of the information that provide
3 the basis for programmatic decisions, primary licensing
4 but also other types of activities as well.

5 Then, the third broad category would be
6 operation improvement, things that are either
7 modifications or process improvements and tend to promote
8 either efficiency, cost savings, clarity, or hopefully
9 improved understanding and communication of the
10 requirements and the program operations.

11 In these areas here -- and I'm not going to
12 mention all of them in the interest of brevity, but I'd
13 like to touch on a couple that are either critical points
14 or that need some particular attention. The first ones
15 under the enhanced public health environmental
16 protections deal with worker safety. It's a pair of
17 rules that deal with agricultural worker protection
18 standards and the second one with the certification of
19 pesticide applicators.

20 We've had a number of presentations to this
21 group, talking EPLs, and we've had a subgroup that has
22 given us input on these. These basically address either

1 deficiencies or identified needs or hope to apply lessons
2 learned over the last number of years since these were
3 promulgated in both cases more than a decade ago.

4 Currently, these rules are in the pre-proposal
5 stage. We're right in the middle of conducting a small
6 business consultation under the SBREFA statute now with
7 the Office of Management and Budget and small business
8 advocates. These are to get us from small entity
9 representatives, actual businesses who will be impacted
10 by these rules, input on their potential impact but also
11 alternatives that we should consider as we move ahead
12 with the process.

13 This is a process that will end this fall.
14 We'll get a report that comes back to the agency for
15 consideration. That's backed into the rulemaking as it
16 continues to develop. Right now the target date for the
17 proposal of these rules is in 2010.

18 The additional one mentioned under the
19 protective ones is the reconsideration of the 25(b)
20 exemption for insect repellents. That's how we determine
21 trying to get information on efficacy data for skin
22 applied insect repellents. This is in response to a

1 petition that the agency received several years ago and
2 got public comment on.

3 We're also making a determination that we'll
4 probably have to go through a small business consultation
5 on that as well. That determination is based upon the
6 number and extent of small entities that would be
7 impacted. We do an initial screening and make a
8 determination. We've just done that screening. It looks
9 like we'll have to go ahead and do a formal consultation
10 under that. So, we're working again with our
11 counterparts and other parts of the agency and OMB to try
12 and set that up. We're looking at a proposal for that
13 with the new SBREFA analysis again in the 2010 time
14 frame.

15 Under the improved science and data, we've done
16 a number of rulemakings recently that have to do with the
17 explicit data requirements for submission of information
18 for the licensing process. Just today we're proposing
19 that Part 158(w) data requirements for a 90-day comment
20 period that deal with antimicrobial data requirements.
21 That also we've got and will give notice on a stakeholder
22 workshop which will take place on November 6th in town

1 here. That will be to explain the proposal but also to
2 take questions from people early in the public comment
3 period so they can have informed input when the comment
4 period ends, which would be in early January.

5 Similarly, we've got a plant incorporated
6 protectants data requirements rule that is under
7 development. That is in the early stages. That would
8 give us some information on human health environmental
9 product characterization. We were preparing for an SAP
10 review on the science issues underlying that rule. We
11 would proceed to continue to develop that rule over the
12 next couple of years.

13 The next generation of Part 158 requirements,
14 basically we'll have established the foundation of the
15 existing requirements. This would be the vehicles to
16 improve the devolving science and reflect those in our
17 rules requirements, things like replacing the 2-
18 generation reproductive toxicity study and those types of
19 things. Those are issues that will be discussed in the
20 next session this morning.

21 We've got a target for that in the matrix in
22 terms of 2010 for the initial round proposal on that.

1 That's subject to change based upon the science but also
2 how much we want to try and include in that rule making.
3 We want enough of a critical mass that justifies the
4 rulemaking overhead as opposed to just putting out
5 something every time we've got some small change in the
6 requirements.

7 The operational improvements, we've got several
8 small rules that are kind of clean-up rules but they fill
9 needs that have been identified by our stakeholders. The
10 crop grouping rules allow tolerances on related
11 commodities based upon representative ones. You get,
12 again, more efficient bang for your buck in similarly
13 grouped crops and you don't have to go down each time for
14 different tolerance.

15 The divisions to the pesticide containment
16 rule, we put out a final rule a couple years ago now.
17 Stakeholders suggested that there was some changes or
18 improvements needed in that. We had that proposal this
19 past summer and we're looking to target a final rule for
20 that on November 1st of this year.

21 The last slide I've got is just to provide an
22 overview of our rules on the data requirements. I think

1 it's a good segue to the next session this morning. Our
2 intent over the last couple of years was to improve and
3 update the existing basic data requirements so that we've
4 got not only clarity and consistency but fairness in
5 application of those rules, and basically adopting case-
6 by-case practices that have been in the program or
7 evolved over the last number of years, and also making
8 certain incremental improvements.

9 We think we've made significant progress in
10 that. The large 158 data requirements for conventionals
11 was the cornerstone. That was promulgated several years
12 ago. We promulgated the biochemicals and microbial
13 requirements, in part, 158(u) and (v). I mentioned the
14 antimicrobials, Part 158(w), which was proposed today.
15 You'll see the plants incorporated protectant ones will
16 kind of finish up that process of program tailoring but
17 updating the basic requirements as well.

18 Those are the foundation for moving ahead.
19 Then the next generation requirements would be changes to
20 Part 158 that, as I said, would match the evolving
21 science and changes that we either learn through some of
22 our research or again through case-by-case determinations

1 and licensing. We hope to have a series of those at
2 regular times over the next couple of years so we aren't
3 put in the situation that we've been recently of updating
4 a rule comprehensively after approximately 20 years and
5 having them -- too many inconsistencies, perhaps, in the
6 application of those requirements on an individual
7 licensing determination.

8 So, that's our plan and that's where we are in
9 terms of things that are in the works.

10 MS. EDWARDS: Okay. Thank you, Bill. Again,
11 for updates or information on any of these specific
12 rules, contact Bill Diamond.

13 I think now we'll take a 10-minute break and
14 come back and get short sessions on each of our ongoing
15 work groups that we haven't already discussed. Thank
16 you.

17 (Whereupon, a brief recess was taken.)

18 MS. EDWARDS: All right. These last two
19 presentation sessions are on two of our work groups that
20 we set up since the last PPDC meeting. The first one is
21 Session 10 on the 21st century toxicology and new
22 integrated testing strategies. Our session chair is

1 Vicki Dellarco, and I think we also have a member of the
2 group, I assume, Elizabeth Brown here with us from
3 Steptoe and Johnson.

4 Vicki.

5 MS. DELLARCO: Thank you, Debbie. At our May
6 meeting, Dr. Steven Bradbury and I gave you a
7 presentation on what was happening in the area of
8 toxicology testing, giving the concerted effort that's
9 going on in the scientific community to develop new assay
10 systems, particularly in vitro, develop new computer
11 models that may allow us to predict toxicity better, and,
12 most notably, given the recent National Academy of
13 Sciences report where they laid down their vision for
14 toxicology testing in the 21st century.

15 This really -- this vision is a fundamental
16 change in how we do toxicology testing. It's something
17 that we all need to be engaged in and follow. So, it was
18 recommended and agreed to at the May meeting that we
19 establish a new work group and the work group is called
20 21st century toxicology testing and integrated testing
21 strategies. OPP is actively engaged in this area.

22 We've got some projects going on within our own

1 program. We have a strong collaborative relationship
2 with our Office of Research and Development. It's
3 important that we keep you informed of some of our
4 developments as we get ready to bring them out for SAP
5 review, for example. I would think that they're ripe for
6 a change in data requirements.

7 We're also committed to keep you informed and
8 keep you engaged in this area. So, we're very excited
9 about this new work group. We had our first meeting.
10 We've got our web site up and running. We will have our
11 agenda and minutes of our meetings and the presentations
12 that we do.

13 I'm going to -- we had our first meeting in
14 September. I'm going to turn it over to Elizabeth Brown
15 who is a member of our work group and she's going to
16 report out of that meeting.

17 MS. BROWN: Thank you. As Vicki said, we had
18 our first work group, so the report out is going to be
19 brief at this point. We have a current work objective,
20 which I do want to go ahead and read to you even though
21 it's up on the web site. We're working on, as a work
22 group, modifying this somewhat.

1 The work group will focus on communication and
2 transition issues as EPA faces their new predictive and
3 testing methods over the next three to five years. This
4 work group will help focus EPA's efforts on key
5 activities needed for successful communication and
6 transition, including identifying ways to improve
7 understanding and how best to communicate the complex
8 science to all the stakeholders and providing process
9 recommendations to ensure smooth transitions of the new
10 testing paradigm.

11 As I said, the work group is still working on
12 refining this a little bit. We will be discussing it in
13 our next meeting.

14 The first thing that the work group really
15 decided was that there is so much going on by so many
16 different groups, each of whom kind of has their own
17 approach to things in looking at how do you improve tox
18 testing, how do you do structure activity, the work
19 that's going on with tox cast and looking at new in vitro
20 assays and it's not just within EPA. FDA has things.
21 There are things being done globally.

22 So, the first thing the work group agreed was

1 we really kind of need to be a little bit better up to
2 speed and understand what's available and what people are
3 doing. That's really going to be our focus over the next
4 several months so that we have a better idea -- all of us
5 on the work group -- of what really is available and
6 begin to provide some assistance in how this might be
7 used and how this might be communicated.

8 MS. DELLARCO: So, we have our second work
9 group meeting today at 2:00 in this building. It will be
10 on the 11th floor to the large conference room outside
11 the elevators. Anyone is welcome to attend that. As
12 Elizabeth said, what we're going to be doing is offering
13 a series of seminars to bring everybody up to speed.

14 The first area that we're going to focus in is
15 the one using structural activity relationships and
16 quantitative structural activity relationship modeling.
17 So, we're going to do a primer today. The slides will be
18 available on our web site. We mapped out a couple of
19 presentations over the next several months.

20 So, in November we're going to talk about a new
21 QSAR (phonetic) model that our office of Research
22 Development has been working on. It's a model that can

1 be used to predict the potential to compound to be
2 estrogenic and also some work that EPA is doing to be
3 able to predict degredits (phonetic) or metabolites and
4 their toxicity. So, that will be discussed in November.

5 Then, in December, because it's so important
6 for us not only to be aware of what we're doing in our
7 agency but other agencies, we've invited a speaker from
8 FDA to talk about what they're doing in this area of QSAR
9 modeling.

10 Then, in January, we're going to talk about
11 this new program, Tox Cass (phonetic). It's a slightly
12 different approach. It's using these in vitro systems.
13 We're actually generating some data to predict toxicity
14 potential.

15 Then, in February, we're going to have a
16 presentation to talk about some of the new designs in
17 animal testing that we're looking at. So, this isn't
18 just about doing things in cell culture or in vitro or in
19 the computer, but it's also activities to make our
20 current animal tests smarter. So, we're going to talk
21 about this new reproductive study design that we're
22 looking at as a replacement for the current 2-generation

1 reproductive study.

2 So, that's pretty much. So, again, we welcome
3 you to attend our meeting this afternoon if you can.

4 MS. EDWARDS: Comments or questions for Vicki?
5 Susan.

6 SUSAN: I've always been -- I'm curious as to
7 whether the developmental toxicity test is going to be
8 revamped. I've always been a bit concerned that it only
9 starts on gestation day 6 for the rat. This misses
10 essentially the first trimester, the most vulnerable
11 time, certainly for humans and almost certainly for rats.
12 Is there any move in that direction?

13 MS. DELLARCO: Let me give you our thinking and
14 how we're looking at the various current animal tests.
15 So, we're focusing on the 2-generation reproductive study
16 because it's a mating study and involves a lot of the
17 animals. So, we're looking at the study design that tend
18 to take the largest number of animals in the paradigm.
19 We're going back and we're looking at a half century of
20 pesticide data and what was learned for that and how we
21 can make that test lot smarter, because if you look at
22 our data requirements, it's the 2-generation study, it's

1 the developmental neural tox study and our developmental
2 amniotox study tends to take the largest use of animals
3 and resources.

4 So, we're going to be focused in that area. We
5 are also analyzing our database to see what we've learned
6 from what we call the prenatal developmental tox studies
7 that you're talking about. So, we do have plans to get
8 there, but we just have a sequence of priorities how
9 we're working our way down.

10 MS. EDWARDS: Others?

11 (Whereupon, there was no verbal response.)

12 MS. EDWARDS: Okay, well, I hope you'll -- to
13 the extent that you're interested or certainly if you're
14 a member of the group, that you'll be there this
15 afternoon. Thank you very much.

16 We'll move on now. Bill Jordan will give us an
17 update on the PPDC work group on web-distributed
18 labeling.

19 MR. JORDAN: Thanks, Debbie. The agenda does
20 not reflect the fact that there will be two other
21 presenters, Karen Kane (phonetic) and Jim Thrift
22 (phonetic), who are both members of the work group on

1 web-distributed labeling.

2 Briefly, at the last meeting the PPDC, you all,
3 decided that it would be a good idea to have a work group
4 that focused specifically on this new idea, this new
5 concept that the states recommended and that Debbie said
6 we ought to pursue, namely, making labeling information
7 available via the internet or some alternative delivery
8 mechanism, what we've called web-distributed labeling.

9 We got a good show of interest. We have 32
10 members with very good representation from the pesticide
11 industry, the user communities, state and local groups,
12 but also a number of other organizations, stakeholder
13 groups who have also signed on.

14 We had our initial meeting on October 2nd for
15 three hours. It was largely an organizing meeting. At
16 the end of the meeting, I asked for volunteers to report
17 back to you all about what the work group has done. We
18 actually had more volunteers than I felt we had time to
19 do it, so that's initially a very positive sign. After
20 some discussion, Karen Kane and Jim Thrift agreed to make
21 the presentation. So, I'll let Karen start off and then
22 turn to Jim.

1 MS. KANE: Hi. As Bill indicated, we've just
2 started. We had our first introductory meeting last
3 Thursday, so we're just getting staged and discussing
4 some of the issues. I'm here representing the industry
5 perspective on some of the proposals that we're
6 considering. We support the concept but there are a lot
7 of details that need to be worked out. We have concerns
8 about how those details will be worked out, but we see a
9 lot of benefits and a lot of positives from this
10 proposal. So, we're very eager to discuss this among all
11 of the impacted stakeholders and to work through some of
12 these issues.

13 We specifically have concerns about the
14 liabilities of this, when we're talking about web-based
15 labeling and moving the labels to a different platform
16 and how that will be managed. So, those are some of the
17 areas that we have concerns about.

18 There will be significant impacts on all of the
19 user community, the stakeholders, a lot of impact on the
20 regulators as well, both on the Federal side but also
21 down at the state side. These products are through the
22 two-tier regulatory system you're aware of. So, we have

1 to make sure that all of the state regulators are engaged
2 because the products go nationwide. So, it has to be
3 something that is implemented at all 50 state levels.
4 So, that's a concern that we have.

5 We're still working through some of the
6 details. Michele very graciously -- Michele Devoux
7 (phonetic) has provided us the work papers that we're
8 going to be working on. Right now we're looking on
9 what's the scope of the web-distributed labeling, what
10 type of outreach in education needs to occur. This is
11 going to be a culture change for all of the stakeholders.
12 Where is the web site going to be posted? What is going
13 to be the database that will be hosting these web sites?
14 What's the life span of the labeling? Again, what's the
15 impact on all of the stakeholders and what are the
16 liability concerns?

17 MR. THRIFT: Retail dealers, in general, are
18 very interested in this concept. I frankly want to thank
19 Bill Jordan for his dedicated leadership. For almost a
20 year he has been reaching out to the community. As we
21 spend more time considering where this project could go
22 in a ramification, we are still very interested, but we

1 are uncovering a wide variety of challenges. I believe
2 that the vertical integration of the work group will
3 allow us to go through the majority of those challenges.

4 I agree with what Karen just said on some of
5 the issues. Those are only some. One of them that we
6 have some very strong concerns about is liability. I
7 believe as long as we interact consistently with the
8 registrants, the retailers, and the user grower
9 community, we can work through this.

10 One area that I do have some concerns about
11 becoming more and more evident is that I'm not sure we
12 are all able to really decide if we're the ones capable
13 on a work committee of developing the database. In other
14 words, we're kind of sitting there going, well, this is
15 what it ought to do and this is what it ought to do.

16 Pesticide labels don't have current high levels
17 of consistency. Information is in different places. We
18 want to make sure that whatever system is developed, that
19 the data can be sorted by any field and any line because
20 something as simplistic -- and one of my questions has
21 not yet been answered -- is what's the definition of a
22 label. In other words, is it a piece of paper or is it a

1 computer in an applicator's tractor or is it a
2 Blackberry. We're not quite sure. That seems like a
3 very simple question. However, I think it needs more
4 resolution.

5 I would feel more comfortable if the work group
6 either had its members or maybe ad hoc experts come in
7 from industry that have already developed databases which
8 contain labels, of which there are several companies, to
9 work through this and give me a higher comfort level that
10 we're not trying to challenge the agency to develop
11 something that would be extremely difficult from a
12 practical sense to develop.

13 However, I want to go back to what I said at
14 the beginning. We are very interested from the retail
15 community in having a web-based label system, but there
16 are a number of concerns that have not been resolved.
17 Every meeting we end up with more. But again, I'm back
18 to Bill. He has been very good at accepting all of
19 these. As long as the agency is willing to work through
20 this without a significant time constraint, I actually
21 think we can get there.

22 Cindy, you may want to say something, too,

1 because you were there.

2 MR. JORDAN: Well, there's a very lot of things
3 about the first meeting that I liked a lot, one of which
4 was how much folks knew already about the activity, how
5 engaged they were, as you can hear, and the very
6 constructive tone that folks brought. So, in recognition
7 that this is not just an EPA thing but is really
8 something that needs to work for everybody, I'd like to
9 invite anybody else who was part of the work group who
10 would like to add to what Karen and Jim had said to --
11 here's your chance to chime in.

12 Cindy, if you want to lead off, that would be
13 great.

14 CINDY: I guess I want to talk and I don't even
15 know it. I think that Karen actually hit the points. I
16 mean, I think one of the more productive things to me out
17 of that first work group meeting was characterizing what
18 the issues are and the areas that we need to go down and
19 investigate and dig deeper.

20 One of the big ones in my mind is the impact
21 issue and what does it mean for people every day, whether
22 you're a user, whether you're an NGO, whether you're a

1 state regulator, whether you're a, you know, an
2 independent crop consultant, whether you're a cabbage
3 grower.

4 Everybody is going to have an impact as a
5 result of this. What does it mean in terms of pros,
6 cons, unintended consequences, resources, all of that?
7 So, I think what that call did was really identify where
8 are those key issues.

9 MR. JORDAN: Any other work group members?
10 Michael Fry (phonetic)?

11 MR. FRY: I, unfortunately, had two conflicts
12 last week and couldn't make the meeting. We had actually
13 had meetings previously with Bill Jordan and the
14 environmental community.

15 In general, I think we are very excited about
16 the possibility of doing this kind of thing from the
17 standpoint of being able to integrate much more
18 information on the web than you can just on a label on a
19 can, unless it's 28 pages long and in print that's so
20 fine that no one over 20 can read it.

21 We think there are a great many places to go
22 with this, not the least of which would be endangered

1 species concerns or others that the data on the web could
2 be integrated in quite a few different ways to provide
3 information for growers, other people in applying the
4 pesticides. So, we're looking forward to continuing with
5 this.

6 MR. JORDAN: Thanks. We missed you, Michael,
7 and hope you'll be able to make future meetings.

8 Two other work group members, Laurie Berger
9 (phonetic) and then Scott Shartz (phonetic).

10 MS. BERGER: Yes. Representing specialty crops
11 in California, our membership, we do believe that there
12 are significant benefits to this type of program. We're
13 looking forward to working with the group on helping
14 summarize the benefits as well as characterizing some of
15 the unintended consequences that Cindy mentioned. We'd
16 also like to hear from some of the groups that have
17 existing programs in place. I think it would be helpful
18 for EPA and the work group to learn about.

19 With kind of going back to our spray drift work
20 group, it does seem like the time is right to really
21 revisit a lot of the label organization and so forth and
22 kind of the sorting features that Jim was talking about

1 would be of great use to the person in the field, whether
2 it's the grower, the PTA or the applicator. So, we're
3 really looking forward to learning a lot through this
4 process.

5 MR. SCHARTZ: Thank you, Bill. My perspective
6 as a custom applicator and retailer, there are a lot of
7 benefits possible through this. Currently, we do use one
8 of the internet services for a very similar function as
9 far as what is the most up-to-date information. But
10 there are some real concerns, as Jen mentioned, from the
11 retailer custom applicator standpoint as far as being
12 able to provide this information as needed when products
13 are used or sold. There are just real concerns that need
14 to be dealt with carefully through this process. Thank
15 you.

16 MR. KEIFFER: This is Matt Keiffer on the
17 phone. Can you hear me?

18 UNIDENTIFIED MALE: Sure. Go ahead.

19 MR. KEIFFER: Yeah. I'm one of the work group
20 members and I'm particular excited about the opportunity
21 to utilize this kind of approach to inform the -- not
22 necessarily the licensed applicator but the applicators,

1 which in my area of the country oftentimes are people who
2 don't have licenses and are not particularly well trained
3 but are under the supervision of the applicator. So, the
4 flexibility that this kind of technology brings is very
5 beneficial to that kind of educational experience.

6 UNIDENTIFIED MALE: Thanks.

7 Well, let me -- I'm one of those folks who
8 can't see that far. Caroline.

9 UNIDENTIFIED MALE: Actually, I'm not Caroline
10 but my name tag fell off. How closely involved is the
11 legal section of EPA? How much have they been involved
12 in the discussion so far? It would be tragic to go down
13 this road a long way and get a lot of commitment from a
14 lot of people and have your counsels eventually say, we
15 can't do this. It's only what's affixed to that
16 container that -- has that been addressed sufficiently
17 already? Maybe it's been answered before.

18 MS. EDWARDS: I'll let Bill answer the details,
19 but we don't do anything without our lawyers.

20 MR. JORDAN: Once in a while I do. But on this
21 particular project, I am fortunate to have input from not
22 one but three groups of lawyers. So, we have folks

1 looking at it from the Office of General Counsel and two
2 different parts of the Office of Enforcement and
3 Compliance Assurance. So, the good news is that so far
4 nobody has proposed for this initiative doing anything
5 that will require change in the statute. Almost all of
6 the things that we're thinking about, if not everything,
7 can be done without any change in the regulations.

8 Caroline.

9 CAROLINE: I had a question that actually
10 relates this back to the veterinary adverse effects
11 reporting. A lot of times when there's a pesticide
12 incident, you know, the registration number of the
13 project is not available for a number of reasons. If
14 it's your neighbor who sprayed the chemical, they may or
15 may not be interested in providing you with the
16 registration number. There's other situations like that.

17 So, if the veterinarian is able to, you know,
18 search a web-based labeled database and try to identify
19 what the likely product or products were, I think that
20 would be really helpful. So, if there's some way to set
21 up this database so that it would be searchable in that
22 way -- I mean, you could say for this kind of site and

1 this kind of use, you know, what would the products
2 likely be. So, I think it would be really really
3 helpful.

4 MR. JORDAN: I've heard a lot of other -- I've
5 heard several other stakeholders make similar
6 suggestions, not necessarily focused on incidents
7 involving animals but for lots of other reasons, farm
8 worker, advocacy groups, for example, some significant
9 benefits from being able to search databases to address
10 issues of interest for their constituents. The idea of
11 searchability has a lot of appeal to people who are
12 pesticide users. So, seeing what we can do in that
13 regard is something that I think we'll work on.

14 Other comments or questions? Jen.

15 JEN: This is just really quick. I just want
16 to support Jim White, my next neighbor here. There is a
17 real value in bringing in early the people that do
18 database design and sort of figuring out what's cheap and
19 easy that you can do right away that you don't even have
20 to have a long conversation over and what's going to be
21 much more difficult. Maybe you want to shelf that or
22 something -- and searchable. I'm just glad you guys are

1 on the work group.

2 MR. JORDAN: Good. Thanks.

3 Well, Dennis Howard.

4 MR. HOWARD: I'm not a member of the group but
5 I did listen into the meeting and it was very
6 interesting. I had to tune out before the meeting
7 concluded and I was interested in -- one theme that
8 seemed to be coming up during the meeting was that a
9 number of participants felt like there needed to be a
10 good assessment of what the benefits might be as well as
11 what the impacts might be for different groups. I was
12 curious as to whether the work group decided by the end
13 of the meeting that that was a reasonable thing to try to
14 attempt to do to get some further evaluation of where the
15 pros and where the cons are for the various people that
16 would be affected by this new approach.

17 MR. JORDAN: That's a great way to segue to
18 kind of wrap up what came out of that first group
19 meeting. When we at EPA were thinking about what we
20 wanted to do, we put forward a work plan that identified
21 eight fairly fundamental issues about the web-distributed
22 labeling initiative.

1 Karen identified many of them, such things as
2 what kinds of products would be eligible to participate
3 in web-distributed labeling, would it be mandatory or
4 voluntary, who would host, what functions would the web
5 site have -- searchability, for example, being one of the
6 questions -- how do you bring it up to culture change,
7 and on and on.

8 We figured that would take us several months to
9 work through. We've been working on issue and discussion
10 papers to highlight all of these things. The work group
11 identified, as you've heard, four other major issues that
12 they wanted to talk about. So, we are adding them to the
13 list of eight and we will be taking them up.

14 All four of the issues -- and I want to flag
15 them just for your information -- most of them have been
16 mentioned -- the question of liability, the question of
17 other impacts and benefits, standardizing the format and
18 content of pesticide labeling, and enforcement is the
19 last issue that came up in the discussion.

20 All four of those, it seems to us, depend on
21 the basic design of the initiative, how will this
22 actually work. So, figuring out the impacts and

1 benefits, for example, will depend on the choices of what
2 products are included or not included, how the life span
3 issue is sorted out, and so on.

4 So, we will tackle those topics probably toward
5 the end of our discussion. I project that we're going to
6 be at this for a while. We'll have a series of meetings
7 in which we review the discussion papers developed by the
8 internal EPA work group, get feedback from this PPDC team
9 of folks, and make adjustments. It's all tied together.
10 All of the different pieces relate to each other, so
11 we'll probably need to have some sort of grand synthesis
12 at the end.

13 But we should be a lot farther down the road in
14 terms of our thinking by the time this full PPDC meeting
15 occurs next spring. We'll look forward to making another
16 update presentation on where we stand at that point.

17 MS. EDWARDS: Thank you. Any more comments on
18 this? Carol.

19 CAROL: I've just got one statement. With the
20 issue papers that were delivered to the PPDC work group
21 on this, I think they were sent out -- the first two were
22 sent out last week; is that correct? They were sent out

1 Monday. I was on travel. I haven't seen them yet. Are
2 those going to be posted to the work group web site so
3 that other individuals that aren't on the work group can
4 have access to those?

5 MR. JORDAN: Yes, they will be.

6 UNIDENTIFIED FEMALE: I just wanted to say
7 thank you again. We talked about it at the last PPDC
8 meeting, but I think the process that you guys have used
9 to obtain stakeholder input, take that pretty seriously,
10 and then formed the work group and then continued to work
11 on this, it's a pretty complex issue that you're working
12 on and how to make it accessible to all folks. I really
13 appreciate the process. Although I'm not in your work
14 group, I'm looking forward to what you have to say. I'm
15 really looking forward to the technology that will
16 hopefully make some of the labeling more accessible to
17 farm workers.

18 MS. EDWARDS: Thanks.

19 Julie.

20 JULIE: I guess I'm just a little bit troubled
21 -- and I keep hearing this issue about searchability. I
22 mean, there's currently databases out there if you want

1 to search by active ingredient or for company products or
2 for use patterns or sites. I mean, those databases
3 exist, you know, through M-Peers (phonetic). My
4 understanding of a web-based labeling system is I have
5 this product and it's tied to this label. I guess I'm a
6 little concerned if it's like I buy this product and now
7 I search for which label I want to use, especially with
8 -- you know, you buy a me, too, product but I'll search
9 for the label that's got the best, you know -- the least
10 amount of restrictions or the most, you know -- I'm a
11 little baffled by what this searchability function for a
12 label -- a web based labeling system is.

13 MR. JORDAN: The fundamental core function of
14 the web-distributed labeling initiative is to make the
15 most current version of the labeling available to the
16 user as soon after the regulatory officials have made
17 decisions about it as possible so that new uses can get
18 into the hands of users quickly, so that new risk
19 mitigation measures can be implemented more rapidly.

20 That is the most important feature. But when I
21 have been talking and others in EPA have been talking to
22 stakeholder organizations, lots of folks say, and

1 wouldn't it be neat if we could also do -- and then
2 they'll list off four or five other things.

3 One of those things is well, as long as you
4 have an internet database that contains the information
5 about products that are being marketed with instructions
6 to get the labeling via the internet, it would be a neat
7 feature if the user could also find out about what
8 products are available using some sort of search feature.

9 So, rather than -- not rather than, but in
10 addition to linking specific version of labeling, the
11 most recent current version for a particular product with
12 that product, it would also allow the user who is
13 thinking I want to use a product that controls root worm
14 on corn in Nebraska and I need to make sure that it
15 doesn't -- that I can harvest my corn. So, I need a PHI
16 of less than -- five days or less -- they can go to the
17 web site and search and find products that meet those
18 characteristics.

19 Now, there may well be other databases and
20 search systems that provide that kind of function for the
21 users. There are a variety of other scenarios that one
22 can imagine that might make searching an existing

1 database appealing. But we're going to look at and try
2 to figure out what makes the most sense in terms of
3 additional bells and whistles to add to that core
4 function of having the most current version of marketed-
5 approved labeling for individual specifically identified
6 products.

7 JULIE: So, would you look probably to build
8 off the existing system? I mean, I think M-Peers, you
9 know, is the one that most people use at this point. I
10 mean, that's information supplied by the agency. So,
11 would it be a system built off of that or a duplicate
12 system?

13 MR. JORDAN: Well, Vicki Cassentoo (phonetic)
14 manages the M-Peers program and is part of the work
15 group. You've heard Jim Thrift and others suggest that
16 what we need to do is hear about the available commercial
17 systems like Kelly Regulatory System, Agrian, CDMS. I
18 think we'll do that. I don't start off with a notion as
19 to which way it's going to work. Would it be better done
20 by private sector? Would it be better done by EPA?
21 Better done by M-Peers? I don't know.

22 I think it will require all of us talking about

1 how these systems connect with each other, what features
2 we want it to have, what the existing systems do, so on
3 and so forth. So, I don't want to make it any harder. I
4 don't think anybody wants to make it any harder than it
5 has to be. If there's a way to build off of existing
6 capabilities, we'll try to do that.

7 JULIE: Well, I guess it's maybe another issue
8 to add to the list, because from an enforcement
9 standpoint, you know, if there's not a way to verify -- I
10 mean, if they can -- you know, I downloaded this label
11 for Tall Star but I actually used somebody else's
12 product. Again, it comes down to a liability issue if
13 there's a problem and they say, here, I used -- you know,
14 your product (inaudible) you're responsible and whether
15 it was or wasn't, just being able to verify that the
16 label downloaded was the label for the product purchased.

17 MR. JORDAN: I think everybody would agree
18 wholeheartedly with what you're saying, that this new
19 approach needs to be enforceable. It needs to bring
20 about compliance either at the same level or better
21 compliance than what we have under our existing system.
22 That is clearly an essential attribute of the new

1 approach.

2 MS. EDWARDS: Okay. One more comment on this.

3 UNIDENTIFIED MALE: How is it going to work --
4 say, like, there's a label that was applicable to product
5 A in 2007 and then in 2008 there's an update, do you get
6 to pick and choose which label you're going to follow?
7 I'm just not sure what you're envisioning.

8 MR. JORDAN: Well, the short version is the
9 user needs to have a version that is legally -- that he's
10 legally allowed to use in applying the pesticide. He or
11 she needs to understand whether that label is good
12 forever or good only for a specified period of time.
13 There are several different ways that we can accomplish
14 that.

15 They're written up in a discussion paper that
16 we are going to be taking under consideration called
17 "Labeling Life Span." It's way more complicated than we
18 have time to discuss here, but I'll be happy to talk to
19 you offline about it. The short answer is it needs to be
20 enforceable and the user needs to understand what's
21 allowed and what isn't.

22 MS. EDWARDS: Okay. Well, thank you. I think

1 what I'd like -- I don't believe there were any public
2 commentators signed up. So, what I'd like to do with the
3 rest of this session is talk about the next meeting.

4 There was one other card up. Let's see. Okay,
5 go ahead.

6 UNIDENTIFIED MALE: Something that's kind of a
7 regulatory question. When I go out and do a PEI
8 inspection in a place where pesticides are packaged, it
9 is common to do a word-for-word comparison from the label
10 that was approved by the EPA that the manufacturer has
11 with the label that is going on the actual package. How
12 would this change, or would it?

13 MR. JORDAN: I hope it's going to make it
14 easier. For products that have -- that are taking
15 advantage of web-distributed labeling, they will have on
16 the container certain basic information and then an
17 instruction saying you have to obtain additional labeling
18 from either a web site or a toll-free telephone system or
19 some other alternative delivery mechanism.

20 That means that it will be possible to pull a
21 lot of the information that now appears on a container
22 and with the container off of that container label. What

1 will be left will be much simpler. So, when you do the
2 inspection at the site, instead of reading a 40-page
3 booklet, you'll be looking at something that is much
4 shorter and affixed to the container.

5 As far as making sure that what's available on
6 the web site is current and official, that's a piece of
7 the design of the system that we need to build in from a
8 quality assurance point of view, but I think it will be
9 done by computers, not by people.

10 MS. EDWARDS: Okay. Obviously, this is a work
11 group of this larger pesticide program dialogue
12 committee. So, on a routine basis, they will be coming
13 back and ultimately making recommendations to this group
14 for discussion. That's how these work groups work. So,
15 you'll be hearing about it again and again. Thank you,
16 Bill.

17 So, for the next time, I think we're probably
18 going to be looking at the end of March, sometime in
19 early April, beginning to think about that. We'll start
20 looking at dates and try to get that figured out in terms
21 of logistics.

22 But in terms of the way we run these meetings,

1 you can see that we were pretty ambitious this time. I
2 think we did reasonably well in getting through them all.
3 I have to say that I personally prefer the sessions in
4 which we hear back from you.

5 So, one of the things I have thought about each
6 time that we do this is that it might be good to keep the
7 number of topics to something like no more than nine,
8 period, which would mean three in one morning, three in
9 an afternoon and three in the following morning, in which
10 each session was no shorter than an hour, and that
11 everything else be provided to you in writing as updates,
12 which, if you have an interest in it, there could just be
13 almost like a table of contents, these are the updates
14 we're providing. We could put them on the web page and
15 also provide them out here.

16 That's my -- I would like to just throw that
17 out. But I would definitely like to hear back from you
18 because I'm hoping that this -- this is a FACA to provide
19 advice to the agency, but I also think it's a really good
20 venue for all of you to hear the perspectives of other
21 stakeholders in the pesticide issues. So, I would like
22 to hear back from you as well.

1 We'll start over here.

2 UNIDENTIFIED MALE: Thank you. You know what I
3 was going to say. I was going to sort of say just what
4 you were going to say. Of course you said it much more
5 articulately than I would have. But I think it's always
6 been -- as someone who has been to all 25 meetings,
7 there's always been a balance between sharing information
8 and dialogue and finding the right balance has always
9 been difficult.

10 You know, I think I would agree that fewer
11 topics and more discussion would be valuable,
12 particularly given the much larger size of the group.
13 The opportunities for speaking are many fewer than it
14 used to be when there were 25 or 30 people. What I was
15 going to suggest, though, is I think a lot of the
16 information that's presented during these meetings is
17 very valuable information. I don't really want to lose
18 that.

19 Would you consider, you know, things like sort
20 of a routine presentation, doing something like a series
21 of conference call webinars, updates? You know, January
22 you talk about computational toxicology and you schedule

1 a two-hour conference call, you know, something that
2 doesn't require dialogue but about what you want to
3 communicate, make those briefings available by conference
4 call on a regular basis. Then, take the burden of giving
5 those updates out of these meetings.

6 MS. EDWARDS: Definitely we can think about how
7 that might work. Thank you.

8 Who is next down there? Is that you, Carol?

9 CAROL: I think instead of nine topics, maybe
10 we have four or five max. That would be my suggestion.
11 And I think what -- there's been two things lacking in
12 this meeting, time, where people talk, that you've
13 already recognized, but also context. A lot of times
14 what we hear about we don't have a context for so we
15 don't know what it means or where we fit into it or if we
16 could think of anything to give you advice about, we
17 wouldn't know what that would be.

18 So, we need a lot more context. So, in terms
19 of updates, I think you could probably send them out
20 ahead of time and then have, you know, just a period for
21 a Q&A in case people want to ask about something rather
22 than running through the information that's already in

1 the updates.

2 MS. EDWARDS: Amy.

3 AMY: Yeah, I want to second Caroline Brickey's
4 suggestions that as much as possible could be presented
5 ahead of time. But it really needs to be very focused
6 and kept as concise as possible still because with the
7 number of topics that you need to tell us about that we
8 might want to have the opportunity to ask questions about
9 in a general session, we probably are not going to have
10 the time to take to go through 20 pages on each of the
11 various subjects.

12 So, we really need it bulleted out. Here's the
13 context. Here's what we're doing. And here are bullets
14 that might flag something that you want to say. If then
15 we could have a general question and answer session maybe
16 toward the end of the meeting perhaps or at the
17 beginning, I don't care, just to bring up things that
18 came out in the stuff that you handed us out ahead. But
19 I think as much of that -- I think we've asked for this
20 before, too, and you've tried to do it occasionally to
21 provide us with stuff that we can read ahead. But we
22 really don't need to have the same stuff provided ahead

1 and given in the meeting.

2 The only other thing I want to say in response
3 to Bob's suggestion, I understand the reason why it would
4 be nice to break it up and have conference calls, but I
5 have to say that I don't know about the rest of you, but
6 my department chairman and my dean already don't see the
7 value to the university of my being here for three days
8 each time and being on various work groups. They're very
9 important to me, I think, to be on here.

10 If I spend more time sitting in conference
11 calls and listening to stuff, because I would want to
12 hear it, I just don't physically have the time to do that
13 well. You might end up losing comment from the breadths
14 of people that you have around the table when you try to
15 do it a couple of times a year.

16 MS. EDWARDS: Thank you.

17 Jen.

18 JEN: I want to also second Caroline's
19 suggestion that we -- I think you guys have been really
20 sensitive to this too, that we keep the number of topics
21 short and try to get into them in depth, but I also
22 really like what you did at the end which is sort of

1 these quick updates. Also, I think the USDA NASS update
2 was pretty quick and still valuable. So, I like that
3 mix.

4 So, I wouldn't give you a magic number like
5 nine or five or four, but I would say if you could get
6 some substantive ones where you had time, the real
7 important ones -- like, I thought the bee presentation,
8 the pollinators today, was well worth taking some time to
9 go through the data and the studies. I loved that.

10 Also, I thought that the drift catcher and
11 volatilization discussion today was really really
12 helpful. That's the stuff that if I visually hear it
13 once, I'll remember that forever. So, that was really
14 helpful.

15 I don't read my e-mails and I don't want to get
16 a whole bunch of stuff in advance that isn't discussed in
17 public. To be honest, I don't know -- I'm not a lawyer
18 but I think that the purpose of this is a public
19 discussion with an audience and public participation, so
20 I don't actually think it's appropriate to send us a
21 bunch of stuff in advance and then not really vet that in
22 public. I think there's a value to the discussion that

1 we have and listening to each other and learning from
2 each other.

3 So, yeah, I like the volatilization. I like
4 the bees. I like the little quick ones at the end. And
5 some balance of that I think is really well done.

6 Oh, and the content thing, that's what Caroline
7 brought up. That we can't really advise you if we don't
8 have content. So, I don't want to hear so much you
9 finalize this report and that report, but what I'd like
10 to hear is what the report said. Do you know what I
11 mean?

12 MS. EDWARDS: I thought she said context.

13 AMY: She said context, but I'm saying content.

14 MS. EDWARDS: Okay. We'll try to do both
15 content and context.

16 AMY: Well, yeah, I mean, I really want content
17 and not like the bean counting list. It's not helpful to
18 me. Do you know what I mean?

19 MS. EDWARDS: I do. Thank you.

20 Jay.

21 JAY: So, I would support fewer and more in-
22 depth topics. Obviously, there are a lot of folks,

1 including some of us here in Washington, who are
2 traveling and didn't get the material that came out on
3 Monday. I still haven't had time to review that. So, I
4 think fewer subjects would (inaudible) toward the ability
5 to get the information out earlier.

6 I think something that's really important from
7 this morning's experience is to emphasize process and
8 procedure. Margie, FACA rules do apply. So, if there's
9 been a change in the FACA rules that allow 2:15 a.m.
10 submissions, then they'll be some of us who will be
11 looking to submit at 2:30 a.m. I just don't think it's
12 productive to have individual product assassinations
13 occur.

14 We've got some profound concerns about what
15 happened here this morning. I think others will speak to
16 this. We've got to get back to following those kinds of
17 rules. I don't think that we want to see this process
18 disintegrate into that direction.

19 With the enlargement of the PPDC, we've seen a
20 shrinkage of the number of registrants that are
21 represented on the PPDC. For the first time in, I don't
22 know, maybe the last 25 years, nobody is here

1 representative of one of the major manufacture
2 registrants. So, I think that's a real problem, an
3 oversight that should be addressed. Thank you.

4 MS. EDWARDS: Mark.

5 MARK: I'm sensitive to some of the points that
6 Jay raised as well, but I wanted to approach it a little
7 differently and ask you two questions. Not to put you on
8 the spot or anything, Debbie, but what will you do with
9 the information you got in this meeting? That's one
10 question.

11 And then, second, what are your fiducial, or
12 whatever, your FACA responsibilities are of this
13 committee to you, because that should drive some of what
14 we do, at least, in the process so that you, EPA, get
15 what you need from us?

16 MS. EDWARDS: Well, first of all, what we'll
17 get out of this committee is I have a whole bunch of
18 lists of things here that are clear to me you'd like more
19 information on, several where it's been clear to me that
20 there's some expertise here that is willing and
21 interested in coming in and talking to us about a number
22 of issues in more detail. So, those are of interest to

1 me. It's clear where you have certain concerns. I mean,
2 I don't know whether I want to go through all of that,
3 but I did, in fact, get a fair amount out of it.

4 I think what you owe to us, and you do it here, but
5 to be frank, for the most part, the bigger outcomes, if
6 you will, that we've gotten from this group, is through
7 the subgroups and work groups, because the work groups
8 get together and actually pull, after a lot of
9 deliberation, reports, very clear recommendations and
10 options to the agency in major program area changes.

11 I mean, there have been several that have been
12 extraordinarily successful. Two that come to the top of
13 my head right now are some of the pre-award registration
14 review. I think the regulation came largely out of the
15 recommendations of this group. Spray drift is another
16 one. I think we're having some successful conversations
17 about azinphosmethaline.

18 I'm very hopeful for these newer work groups
19 that we'll get concrete advice from a multi-stakeholder
20 community which, any time you have that, you have a much
21 greater opportunity for success because you have broad
22 support. That's what we seek, because if we come forward

1 with something we only have one stakeholder interested
2 in, it's very difficult to implement it in a successful
3 way. So, I hope that answers your question.

4 Cindy.

5 CINDY: I'll try to do this quickly. First,
6 I'd like to just comment because I was going to comment
7 if Jay didn't. This is sincerely not a criticism of
8 PANNA or the drift model or what was there, but it was --
9 in my mind, it took us off the topic which was
10 volatilization.

11 The topic was for Jack to present where the
12 agency was and get input from us. It quickly came to,
13 you know, a discussion about endosulphran and
14 chlorpyrifos and for many of us around the room
15 questioning, you know, what the appropriateness of having
16 that presented here with no opportunity for the
17 registrants of those compounds, of which I am not a
18 registrant of either one of those compounds, to present
19 their information. Frankly, they do a series of studies
20 that are peer reviewed and validated and under EPA
21 guidance and strict requirements.

22 The agency, through Part 158, which it just

1 revised, addresses all of those things. So, it just
2 quickly went off topic. I think it was unproductive and
3 it was unfair. So, I hope we don't go down that road any
4 more.

5 On the positive note, I think I agree with you
6 100 percent. The work group strategy is a good strategy.
7 What I would say is go back to those work groups and ask
8 them what do they think the PPDC -- what input do they
9 want or need from the full PPDC.

10 I mean, one of the topics we ought to come back
11 with is okay, if we're looking at web-distributed labels,
12 we have a wide variety of stakeholders on that work
13 group. But there are some people in the room who aren't
14 who have an interest. So, what kind of input do we need
15 or want from them and bring that as the discussion point.

16 I would support Caroline's comments that we
17 should limit it to something less than nine.

18 I would support Amy and Caroline and others who
19 said, you know, those quick updates that we get, if we
20 get the quick update here, since we couldn't have any
21 opportunity for questions here, maybe set aside two hours
22 at the end of the meeting for those of us who might want

1 an opportunity to do a Q&A. Maybe the whole PPDC doesn't
2 want to do a Q&A on the updates. They just want the
3 updates. But there might be some of us who are more
4 interested in particular topics and therefore we could
5 stay and do it.

6 MS. EDWARDS: Could you explain again what you
7 said about -- what I think I heard you say was it would
8 be good for the work groups to know --

9 CINDY: The full PPDC, right. So, if we're the
10 web-based distributed labeling group, or whatever we are
11 now -- I mean, we've changed a couple of times -- if
12 we're thinking about our report and coming to the PPDC,
13 what is it we want to ask them? What's the area where
14 some broader input maybe from a stakeholder group that
15 isn't on there might see some value in all that. I think
16 the work groups could actually provide some insight into
17 that and also for other topics.

18 I mean, I think there are some -- we've seen
19 this model work. So, one of the topics that, you know, I
20 thought about is all the activities the agency is doing
21 in international things. I mean, there are clearly some
22 impacts on the decisions that you've made here, you know,

1 whether or not a grower can use a new active ingredient
2 that you approve because there isn't a Kodex MRL or the
3 EU just changed the way they're doing their MRLs and so
4 that has a backlash. I mean, a work group might have
5 some interesting insight for you guys on that. So,
6 that's a potential new topic for a work group. But I
7 think that model of having the work group do it works
8 very well.

9 MS. EDWARDS: Okay, thanks.

10 Susan.

11 SUSAN: Just to respond quickly, I'm not aware
12 that industry is required to do any tests on
13 volatilization groups. So, if that data is out there, it
14 would be great to see it. I think the reason that those
15 slides were in there was there's some question as to
16 whether inhalation is a route of exposure. So, we have
17 data that shows that certainly people are being exposed
18 through some mechanism. It may not be volatilization, it
19 might be ingestion. But anyway, the reason those slides
20 were in there was data to say that well, there may be a
21 problem.

22 What I was really going to say is that I agree

1 with the fewer session. I still like some of the
2 updates, things like Rick Keigwin's and the regulatory
3 update was particularly good, things that there's not --
4 where you're just kind of letting us know what's going on
5 and there's not going to be much discussion likely still
6 works as quick updates, I would say.

7 MS. EDWARDS: Thanks.

8 Julie.

9 JULIE: I guess I also want to agree with what
10 Jay and Cindy said. I think that it was off topic. You
11 know, if there is some problems with the -- how
12 inhalation studies are done or the value of how
13 inhalation studies are done, that's a separate topic.
14 So, I agree that that one is not appropriate for that
15 session.

16 What I've seen -- you know, what seems to work
17 best when we have topics is when specific questions are
18 poised to the committee. As we sort of saw with the
19 pollinator's discussion yesterday, I think it really
20 helps facilitate input from the committee when they're
21 sort of asked specific questions. That seems to also
22 trigger additional dialogue when those questions are

1 answered.

2 So, looking at, you know, when a topic is teed
3 up, really thinking about what kind of input is the
4 agency looking for and posing it as questions to the
5 committee. I think it really helps. It helps us to
6 think about what we want -- you know, what kind of input
7 we want to give you, too.

8 MS. EDWARDS: Okay, thank you.

9 Lori.

10 LORI: My comments about the work group have
11 pretty much been raised. I did want to mention that I do
12 think the concept and utilization of web-based seminars
13 for some of the topics we're going to be talking about,
14 like the 21st century toxicological approaches, I think
15 that there is a benefit for our group to have some in-
16 depth presentations without the cost of time and travel
17 that we could all benefit from. So, I would really ask
18 that you look at that as a possibility, not on a regular
19 basis but kind of as needed for this group. I think it's
20 a very efficient way.

21 Also, just the work group utilization,
22 reporting back is very important and it makes it more

1 interesting and just keeps things going along. I think
2 it's kind of what we're all about.

3 Then, just finally, just a minor thing, this
4 group is really large around the table. As a listener, I
5 would really appreciate it if our speakers could stand
6 when they speak because you can't really see them. A lot
7 of times you actually want to have follow-up
8 conversations with them when we do have break time and
9 you don't know who they are. So, if you could consider
10 that, I'd appreciate it.

11 MS. EDWARDS: Thanks. Good point.

12 UNIDENTIFIED FEMALE: Just to follow up on that
13 point, on the Power Points that you hand out, if you
14 could put the name and contact person of the people that
15 are presenting, that would be really helpful.

16 MS. EDWARDS: All right. Well, thank you.
17 We'll definitely consider all this. I heard a few
18 conflicting things, but it's not uncommon. I think the
19 request for -- I think, though, that we'll be able to
20 come up with a proposal that will at least come close to
21 what all of you are talking about, actually.

22 So, let me close the meeting. I appreciate

1 your participation. I appreciate that we have such good
2 participation for these FACA meetings. This is a large
3 FACA. I don't know how many are bigger than this, but
4 probably not very many. We tried very very hard this
5 time to ensure that we had participation from all
6 sectors. So, if you look around the room, you will see
7 an amazing amount of sector participation and anything
8 and everything to do with pesticides in this country.

9 Secondly, I'd like to thank EPA's management
10 and staff. They do -- we don't do it perfectly but
11 people do put a lot of work into this and it's over and
12 above their ordinary workload that they have. So, I
13 appreciate the work that they put into it.

14 I also wanted to thank -- you know, people that
15 do logistics and that sort of thing behind the scenes are
16 often the least visible. They're often the least
17 appreciated. Let me give you a few names here. I just
18 wanted to mention a few specific names. Michele Devoux,
19 Bill Jordan, Artie Williams, Dena Costiano (phonetic),
20 Millie Gloster (phonetic), Herman Felianflabuaca
21 (phonetic), actually did a lot of work to ensure that
22 this ran smoothly today from a lot of different

1 perspectives.

2 Finally, and always, I want to thank Margie
3 Fehrenbach, our designated federal official, who does an
4 absolutely top notch job. So, I'd like to appreciate
5 that.

6 (Applause)

7 MS. EDWARDS: Thank you very much. For those
8 of you who will be around this afternoon, we'll see you.
9 For others, safe travel. Thank you.

10 (Whereupon, the meeting was concluded.)

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1 CERTIFICATE OF TRANSCRIPTIONIST

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