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In the Matter of:

Environmental Protection Agency

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*Pesticide Program Dialogue Committee Meeting
Day 1*

Condensed Transcript with Word Index



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1	3
1	1 look at what's in the future. Some of it is near-term
2	2 future but some of it, as we'll go through our
3	3 workgroups, maybe five or seven years out.
4	4 But if we don't start talking about what the
5	5 world can be like five or seven years from now, all of a
6	6 sudden it will be five or seven years from now and we
7	7 won't be prepared or ready to take on some of those
8	8 challenges.
9	9 So, we appreciate the time and effort you spend
10	10 on the near-term issues as well as the time and effort
11	11 you're spending on the long-term issues working with your
12	12 partners and your colleagues and the different
13	13 organizations you present, as well as across federal
14	14 family, state, and tribal family in terms of working on
15	15 some of these tough issues.
16	16 We've got a pretty full agenda. A lot of work
17	17 has been going on in the work groups. We've got seven
18	18 active work groups with our Federal Advisory Committee.
19	19 We'll be sharing over the course of the next day and a
20	20 half activities going on from four of those committees.
21	21 As I touch on the agenda a little bit, we can go through
22	22 some of those areas. Again, as with the work groups and

2	4
1	1 as with the full committee, getting sort of a diversity
2	2 of opinions and ideas that you all have is really
3	3 important.
4	4 Steve Owens will be visiting with you tomorrow
5	5 morning. He's on travel today. He's got some speaking
6	6 engagements at the front end of the week and the back end
7	7 of the week. So, he's going to be back in town, I think,
8	8 tonight and be here Thursday. So, he'll be meeting with
9	9 you Thursday morning and give you some thoughts over the
10	10 last six months since we met with you last and sort of
11	11 how things are looking, and probably share some time to
12	12 talk with you about some questions you may have as well.
13	13 So, before we fully go through the agenda and
14	14 touch on that, I think it is probably good to go around
15	15 the big room here and introduce ourselves, what your
16	16 organization is, and just kind of get reacquainted. Some
17	17 of us don't see each other except for e-mails and phone
18	18 calls over the course of the six months or so. So, why
19	19 don't I start on my right and turn it over to Marty.
20	20 MS. MONELL: Marty Monell, Deputy Director,
21	21 OPP.
22	22 MS. KUNICKIS: I'm Sheryl Kunickis. I'm the

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5	<p>1 Director of Pest Management Policy at USDA. 2 DR. CALVERT: I'm Geoff Calvert. I'm with the 3 Centers for Disease Control and Prevention in Cincinnati. 4 I head up the pesticide poison surveillance efforts 5 conducted by CDC, along with state health departments in 6 11 states. 7 DR. VERDER-CARLOS: I'm Marylou Verder-Carlos, 8 Assistant Director for the Department of Pesticide 9 Regulation in California. 10 MR. BARON: Good morning. I'm Jerry Baron, 11 Executive Director, IR-4 Project. 12 MS. SMITH: I am Cindy Smith with the Gallon 13 Group of Companies. We're a basic manufacturer in crop 14 protection. We have retail facilities, feed, and we 15 actually grow some dates. 16 DR. GREEN: Tom Green. I direct the IPM 17 Institute based in Madison, Wisconsin. 18 MR. TAMAYO: Dave Tamayo, California Stormwater 19 Quality Association. 20 MR. THRIFT: Jim Thrift, Agricultural Retailers 21 Association. 22 MR. BUHLER: Wayne Buhler with North Carolina</p>	7	<p>1 Care Network, lawn and landscape industry. 2 MR. VUKICH: Jake Vukich, registrations, DuPont 3 Crop Protection. 4 MS. LUDWIG: Gabriele Ludwig, Almond Board of 5 California. 6 MR. SHEEHAN: Pieter Sheehan, Director of 7 Environmental Health and Protection for St. Charles 8 County Government in St. Charles County, Missouri. 9 MS. STARMANN: Allison Starmann with the 10 American Chemistry Council, biocides panel. 11 MS. LAW: Beth Law, Consumer Specialty Product 12 Association. 13 DR. LAME: Marc Lame, Indiana University School 14 of Public and Environmental Affairs. 15 DR. ROBERTS: Jimmy Roberts, pediatrician at 16 the Medical University of South Carolina. 17 Dr. WILLETT: Mike Willett, Northwest 18 Horticultural Council, Yakima, Washington. 19 DR. KEGLEY: Susan Kegley, Principal at 20 Pesticide Research Institute and representing Pesticide 21 Action Network. 22 MR. COX: Darren Cox representing the American</p>
6	<p>1 State University, pesticide safety education specialist. 2 MR. NYE: Ken Nye, Michigan Farm Bureau, 3 general farm organization. 4 MR. KRABILL: Ryan Krabill, National Potato 5 Council. 6 MR. CONLON: Joe Conlon, American Mosquito 7 Control Association. 8 MS. COX: Caroline Cox, Center for 9 Environmental Health in California. 10 MR. McALLISTER: Ray McAllister with CropLife 11 America. 12 DR. GILDEN: Robyn Gilden, University of 13 Maryland School of Nursing and also the Alliance of 14 Nurses for Healthy Environments. 15 MR. SCHERTZ: Scott Schertz, Schertz Aerial 16 Service and AAA. 17 MR. SMITH: Steve Smith, S.C. Johnson. 18 MR. SANCHEZ: Valentin Sanchez, committee 19 worker with the Oregon Law Center. 20 MR. JACKAI: Louis Jackai, North Carolina A&T 21 State University. 22 MR. DELANEY: Tom Delaney, Professional Land</p>	8	<p>1 Honey Producers Association. 2 DR. CLEVELAND: Cheryl Cleveland, Dow 3 AgroSciences out of Indianapolis. I'm in the human 4 health risk assessment group. 5 DR. WHALON: Mark Whalon, Michigan State 6 University. 7 MS. HERRERO: Maria Herrero, Biopesticide 8 Industry Alliance. 9 DR. KEIFER: Matt Keifer National Pharm 10 Medicine Center. 11 DR. KASHTOCK: Mike Kashtock, Food and Drug 12 Administration, Center for Food Safety and Applied 13 Nutrition. 14 MR. BRADBURY: All right, thanks, everyone. If 15 I could ask -- oh, yeah, on the phone, sorry. Anybody 16 from the committee on the phone? 17 MR. GJEVRE: Eric Gjevre, Coeur d'Alene Tribe. 18 MR. BRADBURY: Thanks, Eric. Sorry about that. 19 If I could ask everybody to make sure you put 20 your name tag with your name facing out. I think we've 21 got everybody doing that, but just to doublecheck. 22 Although we're all getting pretty good at names and</p>

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1 faces, it's still sometimes a little hard. It's also
 2 very helpful for me. As you recall, when we have
 3 discussion, I can see your name tags coming up and try to
 4 keep order of that.
 5 I also wanted to let you know a few changes
 6 since last time. Michael Frye no longer works for
 7 American Bird Conservancy. He's now a part of the
 8 federal family. He's joined the Fish and Wildlife
 9 Service and is a contaminant biologist in the Hawaiian
 10 Islands in the northern Pacific.
 11 I was talking to him the other day. He's got
 12 quite a range of habitats to look after from the Hawaiian
 13 Islands, to midway, to all sorts of stuff in the Pacific.
 14 So, Michael is no longer part of the committee. Ann Law
 15 - I don't think she's with us today -- will be coming
 16 from ABC to sit in that chair.
 17 Then, Marco Gusky also has a new position now,
 18 so he won't be on the PPDC in the future. So, a couple
 19 of changes there. Best of wishes to those colleagues as
 20 they go forward in their careers.
 21 We can spend a couple of minutes walking
 22 through the agenda, and then we'll hit it. As I

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1 indicated in my opening comments, we're going to be
 2 focusing a lot today on outcomes and perspectives coming
 3 out of our work groups and have our discussions around,
 4 in many cases, some ideas and proposals coming out of the
 5 work groups, as well as updates out of the work groups.
 6 Last April we formed two new work groups. One
 7 was in the area of pollinator protection, and the other
 8 work group was in the area of integrated pest management.
 9 We'll be hearing from both of those groups today, the
 10 first session, in fact, being a report out from the
 11 pollinator protection work group and some of the first
 12 meetings they've had.
 13 That group is going to be reviewing its
 14 objective, provide us some information as they've sort of
 15 thought through what their goals and objectives are going
 16 to be. Again, a focus of this group is to help provide
 17 some advice on options for trying to mitigate risk to
 18 pollinators when that's an appropriate course of action,
 19 how to try to reduce exposures in the context of a risk
 20 perspective. Also, during the course of that discussion,
 21 provide an update on the science and some of the
 22 activities that have been going on terms of risk

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1 management efforts.
 2 After we hear from that work group, we'll then
 3 move to session 2, which will be some brief updates.
 4 Again, our goal here, and most of the time with output
 5 from the work groups -- I'm looking at Cindy to make sure
 6 I'm tracking this correctly -- at least provide five-
 7 minute snapshots of some key activities that are going
 8 on. I'll look at the clock. If we've got some time for
 9 a quick clarifying question, we may do that. But I'll
 10 probably be very firm on the clock. Mostly it will be a
 11 five-minute report out.
 12 There's also some information in your packet
 13 that isn't going to be part of any oral presentations but
 14 provide you some written updates of activities that are
 15 ongoing as well.
 16 So, in session 2, we'll get an update on spray
 17 drift, an update on the work group that's dealing with
 18 comparative safety statements, inerts disclosure, and
 19 we'll have a discussion and demo that will spill over
 20 into the lunch hour on some new software tools that have
 21 been developed.
 22 One tool gives some increasability to search

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1 active ingredients that cross different parts of our
 2 program so we can quickly see what's going on with a
 3 chemical in terms of its risk mitigation status or
 4 regulatory status, its science status. It makes it very
 5 easy to search chemical information. It's also a tool
 6 that makes it easier to keep track of inert ingredients
 7 and what some of the statuses are of inert ingredients.
 8 There will be a demonstration as well as a presentation
 9 on that.
 10 After lunch, we'll hear from the integrated
 11 pest management group which met on Tuesday. We'll get
 12 some feedback from them. You can get some feedback to
 13 the group as well. Then, session 4 will be a follow up
 14 from the 21st century toxicology work group. They had a
 15 workshop all day yesterday looking at the state of the
 16 science and the application into our program in terms of
 17 biomarkers for exposure and effect and how that can play
 18 into medical diagnostics, to biomonitoring studies, to
 19 epidemiological studies for the complement to other
 20 aspects of the 21st century tox area.
 21 Then, we'll close out the day with another
 22 update session which will include a brief update on

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1 status of the endocrine disruptor screening program, hear
 2 from the public health work group. They'll be meeting
 3 Thursday afternoon as well. Give you an update on the
 4 NPDES general permit for pesticides with Allison Wiedeman
 5 from the Office of Water, update on the human subjects
 6 rule, and an update from Wayne Buhler on the pesticide
 7 safety education program. We'll have a public comment at
 8 the end of the day.
 9 As I mentioned, Thursday morning Steve will
 10 give us welcoming comments and give you some
 11 perspectives. Then, the big session of the day tomorrow
 12 will be with regard to endangered species and some ideas
 13 coming out of the PRIA process improvement group, in
 14 particular, focusing on some of the things we talked
 15 about last time.
 16 One is how to take a look at the reg review
 17 process and how could that be adapted/enhanced to try to
 18 increase information flow into the process that could
 19 ultimately lead to consultation packages with the
 20 services, how to make that as efficient as possible,
 21 ensure we're getting the best information we can at the
 22 front end rather than at the back end of the process so

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1 that everybody has a better chance of getting everything
 2 done.
 3 I think that gives you a pretty good sense of
 4 what we're going to do over the next day and a half. Of
 5 course, like other meetings, we'll wrap up with thinking
 6 about what our goals and objectives for the next six
 7 months will be and what are some of the main topics we
 8 want to have in that pool of potentials for the agenda
 9 when we meet the next time.
 10 Assuming there aren't any questions on the
 11 agenda, which I appreciate everybody's input with Margie
 12 as we got started on this, why don't we get rolling.
 13 We're going to hear from Rick Keigwin, Don Brady, and
 14 other members of the pollinator protection work group to
 15 give us an update on their deliberations thus far, and
 16 get some conversation started with the bigger group.
 17 MR. KEIGWIN: Good morning, everybody. Like
 18 Steve said, we wanted to cover two things. The bulk of
 19 the time this morning we want to spend on a report back
 20 to the PPDC on a series of work group meetings that the
 21 pollinator protection effort has had since the last PPDC
 22 meeting.

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1 But, what we thought we would do first is to
 2 help frame the discussion and maybe help to stimulate
 3 some questions and some ideas from all of you. We'd like
 4 to have Tom Steeger and Tom Moriarity come forward and
 5 give you all a brief update on some pollinator protection
 6 activities that are ongoing at the agency right now. So,
 7 Tom and Tom.
 8 MR. STEEGER: Good morning, and thank you for
 9 this opportunity to speak. I'm Tom Steeger. I'm a
 10 senior science advisor in the Office of Pesticide
 11 Programs Environmental Fate and Effects Division. I'd
 12 like to give you an update on our understanding of the
 13 science relative to pollinator declines and pollinator
 14 protection.
 15 It's the agency's current understanding that a
 16 number of factors and agents have been hypothesized as
 17 potential contributors of colony collapse disorder and
 18 pollinator declines in general. At this time, no factor,
 19 no single factor, has been identified as a cause.
 20 Rather, the available science suggests that pollinator
 21 declines are a result of multiple factors that may be
 22 acting in various combinations.

16

1 Research is being directed at identifying the
 2 individuals and combinations of stressors that are most
 3 strongly associated with pollinator decline. While the
 4 exact causes of general declines in pollinator species
 5 and the phenomena characterized as CCD have not been
 6 determined, potential contributing factors, including
 7 disease, habitat destruction, urbanization, agricultural
 8 practices, monocultures, pesticides, nutrition, and bee
 9 management practices have to be considered.
 10 Researchers at the USDA have hypothesized that
 11 CCD may be caused by many stressors, parasitic varroa
 12 mites, nutrition, and pesticides that may in turn cause
 13 honeybees to become more susceptible to disease.
 14 Pesticides have been identified as one of the
 15 factors associated with pollinator declines. Based on
 16 national surveys conducted by the USDA, a broad range of
 17 pesticides have been detected in managed honeybee
 18 colonies. Based on these surveys, the most frequently
 19 detected pesticides and the pesticides detected in the
 20 highest quantity are those used by beekeepers to control
 21 mites. These include the organophosphates insecticide
 22 Coumaphos and the synthetic pyrethroid Fluvalinate.

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1 Although multiple pesticides are detected in
 2 honeybee colonies, these residues are not consistently
 3 correlated with the incidents of CCD or pollinator
 4 declines in general. While colony collapse disorder
 5 remains an issue and can result in sudden losses of large
 6 numbers of bee colonies, the focus of the federal
 7 agencies is on a broader picture of losses attributed to
 8 declining bee pollinator health.

9 As we have reported in several previous PPDC
 10 meetings, EPA staff participated in a Society of
 11 Environmental Toxicology and Chemistry Pellston work
 12 shop, which is a global workshop, entitled "Pesticide
 13 Risk Assessment for Pollinators." The workshop consisted
 14 of 48 panelists representing five continents consistent
 15 with SETAC policies.

16 The work shop included roughly equal
 17 representation from government, academia, and industry,
 18 regulators from the US, Canada, Australia, and the
 19 European Union, work with researchers from academia and
 20 agricultural industry, chemical industry, and with
 21 beekeepers and environmental groups to develop a risk
 22 assessment process for quantifying risks to honeybees,

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1 Apis mellifera, and non-Apis bees.

2 Similar to the process used by many regulatory
 3 authorities globally, a tiered process was proposed for
 4 fully early applied contact pesticides and chemicals
 5 which may be taken up into plants and act systemically
 6 via soil or seed application.

7 The workshop also identified the exposure and
 8 effects studies that would be needed to inform different
 9 tiers of the risk assessment process. These include
 10 recommendations for studies to document exposure through
 11 pollen and nectar and expanded testing to include larval
 12 honeybee studies and non-target arthropod studies at
 13 higher levels of refinement.

14 The workshop provided an opportunity to discuss
 15 the difficulties with conducting full field studies of
 16 free foraging bees that can forage up to distances of 10
 17 miles. The utility of semi-field or tunnel cage studies
 18 and their limitations were also discussed.

19 The workshop provided an opportunity to examine
 20 the many sublethal effects that have been included as
 21 measurement endpoints and how they can or cannot be
 22 linked to different regulatory authority assessment

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1 endpoints which impacts the survival, growth, and
 2 reproduction that are known to impact populations.

3 As many of you are aware, SETAC published the
 4 executive summary to the pollinator Pellston workshop in
 5 September. This is available online. This is a hard
 6 copy of it. We can make more copies if anyone is
 7 interested in having a copy. The full proceedings of the
 8 workshop, we're currently working to get all the chapters
 9 completed, and we hope that SETAC will be able to publish
 10 the full proceedings in the spring of 2012.

11 One of the most promising chapters of the book
 12 will be the statistical analysis of actual laboratory and
 13 field data that will guide users or risk assessors, or
 14 serve as a guide to risk assessors, of how to move
 15 through these different tiers of data and make
 16 statistical inferences from that information.

17 The efforts discussed at the SETAC Pellston
 18 workshop expand on OPP's current process for evaluating
 19 potential effects to honeybees. At this time, OPP bases
 20 its assessment on contact toxicity, toxicity of residues
 21 on foliage, and full field pollinator studies.

22 However, this approach has not provided

20

1 consistent measure of exposure to honeybees. Even the
 2 effects testing, the current battery of tests, is more
 3 appropriate for pesticides that act on contact rather
 4 than on systemic pesticides where effects may be due to
 5 ingestion of pollen and nectar.

6 The Environmental Fate and Effects Division,
 7 Office of Pesticide Programs, is developing interim
 8 guidance for the risk assessors to consider when
 9 recommending additional studies to inform the regulatory
 10 decision. These studies are required on a case-by-case
 11 basis and may include acute oral toxicity tests with
 12 young adult honeybees. These tests are regularly
 13 required in Europe: acute larval toxicity tests, semi-
 14 field studies at the colony level, and laboratory and
 15 field studies to determine residues in pollen and nectar.

16 OPP will present a proposed process for
 17 quantitatively estimating risk to insect pollinators to
 18 the FIFRA scientific advisory panel in the summer of
 19 2012. This effort will be informed by the proceedings of
 20 the SETAC Pellston and by the research conducted by
 21 government and non-government organizations, both
 22 domestically and internationally.

21

1 Tom Moriarity, my colleague on the pollinator
2 protection team, will talk about efforts to advance risk
3 management.

4 MR. MORIARITY: Hi, and thank you. As you
5 know, following the last PPDC meeting, a work group has
6 been formed to explore risk management options to protect
7 pollinators. It's our hope that the work group and, in
8 turn, the PPDC will provide advice to OPP on options that
9 are appropriate in the short term while OPP moves towards
10 the quantitative risk assessment process and options that
11 are appropriate in the longer term when we move into that
12 process and start quantitatively assessing risks to this
13 (inaudible). As Rick noted, that work group is going to
14 report out shortly.

15 OPP continues to coordinate and participate in
16 the OECD work group on Pesticide Effects to Insect
17 Pollinators, the PEIP work group. That workgroup is
18 broken into four sections as well, risk mitigation, risk
19 assessment process, incident reporting, and research.
20 It's our hope that there will be synergism and sort of an
21 exchange between that group and the PPDC work group on
22 insect pollinators as the two move forward.

22

1 While OPP works on various fronts to improve
2 its risk assessment and its risk management tools, as Tom
3 noted, we continue to stress that the best long-term
4 solution was going to involve management, the multiple
5 stress factors affecting pollinator health. This
6 includes nutrition management as well as pathogen
7 management and others.

8 Managing the different factors involves
9 cooperation and coordination between fellow partners and
10 stakeholders to find sustainable solutions that are going
11 to integrate all these factors. To this end, EPA is
12 working with the partners of the CCD steering committee,
13 headed by USDA, to consider holding a national
14 stakeholders conference towards the end of 2012.

15 The aim of that conference will be to
16 synthesize what information and what has been learned by
17 research and practitioners over the past several years
18 that have affected the various factors and to identify
19 practices and management means to improve on those
20 factors and overall support pollinator health.

21 The conference will hopefully also identify new
22 areas for action research to be undertaken by federal

23

1 partners and stakeholders and continue to support
2 pollinator health. So, I think that the hope is that the
3 PPDC pollinator workgroup will integrate nicely and
4 directly into that sort of effort.

5 So, with that, I'm going to turn it back over
6 to Rick to walk through what the work group has been
7 doing.

8 MR. KEIGWIN: Just real quick, if there are any
9 quick questions for either Tom, we could entertain those
10 now.

11 (Whereupon, there was no verbal
12 response.)

13 MR. KEIGWIN: Okay. So, if we could have the
14 next presentation pulled up.

15 UNIDENTIFIED MALE: The staff's analysis guide,
16 will that be publicly available?

17 MR. KEIGWIN: The interim guide?

18 UNIDENTIFIED MALE: Yes.

19 MR. KEIGWIN: Once it's developed, that would
20 become public.

21 UNIDENTIFIED MALE: Thank you.

22 MR. KEIGWIN: So, just a quick refresher on the

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1 work group charge, as Steve mentioned, we formed the work
2 group on pollinator protection coming out of the last
3 PPDC meeting. During that meeting back in the spring,
4 you all charged the work group with exploring four basic
5 areas of work.

6 One was to looking at developing some
7 preliminary science-based risk assessment approaches,
8 including potential changes to labels and training while
9 the science that Tom Steeger talked about earlier
10 continued to be developed and evolve.

11 The second charge area was to explore and
12 develop information on state approaches and what
13 different authorities might be in existence today to help
14 with pollinator protection efforts.

15 The third area was one really in the area of
16 technology transfer and applying lessons learned from
17 various stakeholders, perhaps regionally or in different
18 pockets of the country, and disseminate those more widely
19 in order to improve existing management practices, and
20 then to foster continued international cooperation.

21 Then, the final area would be a catch all of
22 any other issues that the work group decided to explore

25	<p>1 and thought needed to be brought to the PPDC's attention.</p> <p>2 To date, the work group has met three times.</p> <p>3 The first meeting was in early September of this year</p> <p>4 where we came together and discussed ground rules, had a</p> <p>5 further discussion of the charge and our work group's</p> <p>6 understanding of the charge. From that, we broke into</p> <p>7 four subgroup areas that I'll talk about shortly.</p> <p>8 At the end of September, we had our second</p> <p>9 meeting where the subgroups had been formed and we then</p> <p>10 charged the subgroups to further explore how they would</p> <p>11 recommend efforts in those various thematic areas. Then,</p> <p>12 we had our most recent meeting yesterday to get broader</p> <p>13 input from the entire work group.</p> <p>14 The work group, as you can see, is fairly</p> <p>15 large. There's about 45 people and growing. There's a</p> <p>16 good group of people representing a broad cross section</p> <p>17 of stakeholder groups, including growers, registrants,</p> <p>18 beekeepers from around the country, pesticide</p> <p>19 applicators, a number of state-lead agencies, cooperative</p> <p>20 extension and academia, as well as a number of non-</p> <p>21 governmental groups, and the Department of Agriculture.</p> <p>22 As I mentioned, the group initially divided</p>	27	<p>1 three main points that we discussed yesterday and</p> <p>2 concluded with. The work group is to explore information</p> <p>3 that currently exists or what works now for growers and</p> <p>4 beekeepers.</p> <p>5 When we had the discussion yesterday, most of</p> <p>6 the beekeepers and growers were there saying that there</p> <p>7 are already best management practices out there that are</p> <p>8 being used by both groups that help them to make sure</p> <p>9 that the bees are protected, or the pollinators are</p> <p>10 protected. So, as a work group, we need to explore that</p> <p>11 and see what works and what doesn't.</p> <p>12 Then, the next one is to explore voluntary</p> <p>13 registries. If you remember last April, we had done a</p> <p>14 survey on the different states, on what states had</p> <p>15 voluntary bee registries. There were about 9 or 10 of</p> <p>16 them that had both. So, most of the input from the</p> <p>17 beekeepers said that they would like to have it just</p> <p>18 voluntary instead of mandatory, and to see what models</p> <p>19 are out there that work. What are those registries that</p> <p>20 have been successful in making sure that their bees are</p> <p>21 protected, and is there an opportunity for communication</p> <p>22 and information exchange between the growers and the</p>
26	<p>1 into four subgroups, the largest group focusing on</p> <p>2 management strategies, loss of interest in that area, and</p> <p>3 the smaller groups focusing on communication, enforcement</p> <p>4 and certification, and developing reliable data and</p> <p>5 databases.</p> <p>6 So, what we wanted to do for the rest of the</p> <p>7 morning was for representatives from the work group to</p> <p>8 give you a flavor in our four thematic areas: ideas that</p> <p>9 we've discussed, approaches that we might pursue, some of</p> <p>10 the challenges that are associated with each -- pursuing</p> <p>11 protection activities in each of those areas, and framing</p> <p>12 both some short-term and long-term efforts that we might</p> <p>13 undertake.</p> <p>14 So, the first group that's going to present to</p> <p>15 you is going to focus on best management practices. That</p> <p>16 will be led by Mike Willett and Marylou Verder-Carlos.</p> <p>17 MS. VERDER-CARLOS: Okay. The best management</p> <p>18 practices work group had a very lively discussion about</p> <p>19 what management strategies we can use while we wait for</p> <p>20 the risk assessment process through the SAP will work out</p> <p>21 with USEPA.</p> <p>22 So, one of the things that we had -- there's</p>	28	<p>1 beekeepers themselves.</p> <p>2 Then, the third one was to explore case studies</p> <p>3 where stakeholders work together for successful</p> <p>4 protection of pollinators and crops. There's examples</p> <p>5 from Washington State between pollinators and growers and</p> <p>6 USEPA working on labels, although it took some time.</p> <p>7 That was one of the things that we had talked about.</p> <p>8 Outside of working on the labels, there were successful</p> <p>9 stories about working between the growers and the</p> <p>10 beekeepers on what things that they could do mostly on</p> <p>11 communication.</p> <p>12 So, those were the key areas that we had talked</p> <p>13 about and concluded from best management practices. So,</p> <p>14 there's still work to do for that work group. So, with</p> <p>15 28 members in that management strategies group, I think</p> <p>16 we can come up with some more things.</p> <p>17 MR. KEIGWIN: Ken Nye was going to give us a</p> <p>18 report back from the group looking at training and</p> <p>19 education opportunities.</p> <p>20 MR. NYE: Well, training and education got</p> <p>21 quite a bit of discussion in our conference calls and</p> <p>22 work group yesterday. Obviously, I think everybody</p>

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1 understands that the more education, the better. Some of
2 that comes with expenses of other areas. So, we all have
3 to be cognizant of if you spend too much time in one
4 area, you lose something else. But the beekeeper and
5 pollination part of this is very important.

6 We have various groups to reach out to that are
7 part of this process, the users first and you get down to
8 the certified users, commercial users, and so on. We
9 also have homeowners, so we have some people that are
10 fairly well versed in these issues. We have homeowners,
11 some of which might not think of these issues at all.

12 So, we have a fairly diverse spectrum out there
13 that we have to deal with. Obviously, we have the
14 beekeeper's side of that also in terms of education and
15 how we work together. User and beekeeper is very
16 important.

17 Then, you look at that and you say, well, we
18 have beekeepers that are relatively large and quite
19 mobile. We have other ones that kind of stay home. We
20 also have probably some hobby folks out there. So, the
21 universe is fairly broad, and that makes a challenge out
22 of our whole training and educational effort.

30

1 In terms of training, we think, I guess
2 primarily, of those certified users that go through some
3 sort of core training effort to get certified. There is
4 a process in place to help those people and to get them
5 recertified. The training material has information in
6 it. Is it the right kind of information? Do we stress
7 that enough in terms of pollinator protection? Are the
8 recertification credits -- the process put together so
9 that we're providing the right kind of information?

10 Again, if you put too much time into pollinator
11 protection, then you lose other things that may be just
12 as important in worker safety or handler safety, and
13 those kind of things. So, people have got only so much
14 time. So, we have to do the best possible job of making
15 sure that this information is put together correctly and
16 as outreach to those that need it the most.

17 So, we have some challenges certainly on the
18 training and educational side but a lot of opportunity
19 because the systems are in place. There's a lot of
20 information available. We just have to make sure that
21 it's adequately provided.

22 We did talk a little bit about the label, and

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1 we have another work group that's going to report on
2 that. But we kind of looked at it and said is the right
3 information available on the label? Is it in the right
4 place for the right people? Again, if you look at
5 commercial applicators, certified applicators, and then
6 homeowners, there's a fairly broad spectrum of users out
7 there. We want to make sure that we're reaching out to
8 all of them and they understand as clearly as possible.

9 Then, you get back into that discussion between
10 the pollinators and the users out there. Do we have the
11 system in place so that those folks can communicate? I
12 think that goes hand in hand with the training and
13 education also.

14 So, Rick, we had a lot of things that we had
15 good discussion on. Have we solved every issue? No.
16 You'll see in the report here that it says we need to
17 explore and we need to continue to work. So, there may
18 be others in the work group that want to make some
19 comments on that, but we had a good discussion.

20 MR. BRADBURY: If you're on the phone, please
21 make sure you've muted your phone. Again, if you're on
22 the phone, please mute your phone or else we'll hear who

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1 you are talking to.

2 MR. KEIGWIN: So, the next area was enforcement
3 and Gabriele Ludwig was going to (inaudible).

4 (Whereupon, a phone ringing
5 over the sound system was
6 muting out the speaker's
7 voices.)

8 MS. LUDWIG: Enforcement, just to explain a bit
9 about the issues from (inaudible) they feel like there's
10 a number of times when they have had bee kills or their
11 bees hurt. They (inaudible) get much follow up from the
12 enforcement agencies within the state.

13 There's a couple of issues with that. The
14 beekeepers don't feel heard. The growers get frustrated
15 because there's a lot of accusations but no data to back
16 it up. EPA or the other regulators are also (inaudible).
17 Again, you have a lot of accusations and no data to back
18 it up.

19 So, given that, it would also be helpful to
20 have better information as to when is a bee kill really
21 due (inaudible) try to figure out when we have real
22 issues. The suggestion is to really encourage how do we

8 (Pages 29 to 32)

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1 strengthen investigations of (inaudible). Some of the
 2 ideas there is basically to just come up with a unified
 3 protocol that states can work with (inaudible) harmonize
 4 that. From my understanding, there are such protocols
 5 already in existence (inaudible) they would work.
 6 Similar to that would be if there is
 7 (inaudible) encourage follow up in reporting an incident.
 8 So, there's also been (inaudible) all the way to EPA and
 9 understanding that.
 10 In terms of communication, EPA has a regularly
 11 scheduled meeting with the state lead agencies called
 12 SFIREG (inaudible) EPA people for the translation of that
 13 acronym. It's like state federal something regulatory
 14 people. They meet every three to four months. So, I
 15 mean, it's already an institution. It's an opportunity
 16 for the states and EPA to talk about exactly such issues.
 17 So, I think that's a place partly to explore
 18 why enforcement or just investigations have been lacking.
 19 Is it a question of time? Is it a question of money? Is
 20 it a question of training? Then, if a protocol is agreed
 21 upon, that would be the place to sort of move it into the
 22 state process.

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1 Part of the education side is whether to look
 2 at if there's a need to do education about how to do an
 3 investigation, how do you get information, and so forth.
 4 I think some of the issues are challenges. As I said,
 5 currently, at the end of the day, investigations are up
 6 to the state.
 7 So, trying to get that more evenly done is
 8 going to be a challenge, especially in budget-tight
 9 times. Again, I think at least taking some time to
 10 understand what those challenges are and whether anything
 11 can be done about it is necessary.
 12 Then, for example, if the desire is to do
 13 actual residue testing, let's say, on the honeybees, that
 14 is a definite expense and where is that money supposed to
 15 come from, just to give you some ideas of what that
 16 discussion has been about.
 17 I don't know if anybody has some additions to
 18 my comments, or summary of it.
 19 MR. KEIGWIN: There's a lot of cross efforts or
 20 ideas that sort of cross across the work groups. So,
 21 that actually generated a lot of discussion during
 22 yesterday's work group meeting about where to sort of

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1 bend some of these ideas. So, we appreciate PPDC's
 2 feedback in that area as well.
 3 The last area is the area of labeling. Cindy
 4 Baker Smith was going to give us a report out on that
 5 effort.
 6 MS. SMITH: So, what Marylou and I learned
 7 yesterday is don't leave early from a work group and
 8 don't show up for a work group that you're not on or you
 9 end up presenting the next day.
 10 But, seriously, I think as a plug for these
 11 work groups, it's hard to do justice in a presentation
 12 like this to all that transpires. In this case, I think
 13 it was a four-hour meeting where there was a lot of good
 14 dialogue and people outside of just the PPDC who
 15 participate. So, I think if you haven't participated yet
 16 in a work group, there really is a lot of value, I think,
 17 in doing those.
 18 So, I'm not on this work group but I'm going to
 19 present labeling because I do have labels. So,
 20 basically, what we talked about here is a theme that I
 21 think you heard carried out through a couple of the
 22 presentations, which is there are some short-term

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1 immediate kinds of things that we think we can work on to
 2 help address the awareness of the issue and things that
 3 can be done easily.
 4 There are some longer term things that are
 5 going to take some time for either data generation or
 6 risk assessment process improvements or other things that
 7 need to be implemented through the states and the
 8 agencies.
 9 So, in the area of short term fixes for labels,
 10 the things that we talked about are that there's already
 11 some existing language on labels. In most cases, it's in
 12 the environmental hazards sections of the label. It
 13 says, in some cases, things like this product is toxic to
 14 bees. Do not apply when bees are actively visiting or
 15 foraging in the treatment area. Then, there are other
 16 examples.
 17 So, one of the very logical things that the
 18 work group talked about was having some people come in
 19 from EPA and talk about how does that language get
 20 derived. What gets put on the label? What are the kinds
 21 of things that you look at? What are some of the
 22 examples that are there today?

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1 I think a next longer term logical step is to
2 pull together some beekeepers, some registrants, some
3 state officials, some folks from EPA, and talk about is
4 there a better way to put this on the label? Is it going
5 to be in exactly the same place on every label? Get some
6 consistency across that.

7 Maybe there are ways to provide through
8 information bulletins or web sites or extension programs
9 some additional information about what that means. So, I
10 think, like in the other areas that have presented,
11 there's some opportunity to share additional information
12 there.

13 There was quite a bit of discussion about the
14 difference between a commercial agricultural product and
15 a homeowner product. A homeowner product, just by
16 nature, is a smaller product with a label with probably
17 smaller font and more things on it. So, are there things
18 that we could do in the labeling of homeowner products or
19 in things that go out with those products to help
20 sensitize people if there are concerns about bees with
21 respect to the use of those.

22 I think that covers most of those points, Rick,

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1 that we shared there.

2 MR. KEIGWIN: Thanks, Cindy. She did get roped
3 into volunteering as a non-work group member. So, that's
4 not a plug for not showing up if you're not a work group
5 member. There was lots of good conversation.

6 So, that sort of summarizes where our work
7 group is right now. As we begin to pursue efforts in
8 each of these areas, we wanted to get some input from you
9 all and reactions to what you've heard this morning to
10 help inform our course of action between now and the next
11 PPDC meeting.

12 So, with that, Steve, I think we could open it
13 up for questions and comments.

14 MR. BRADBURY: Why don't we try to organize
15 this since you've got four thematic areas. It might be
16 helpful to take a look at them. But why don't we first
17 open it up for clarifying questions from the PPDC in
18 terms of just things you've heard that you'd like to get
19 a little more background or it wasn't clear to you.

20 Then, what I'd like to do is go through 1, 2,
21 3, and 4, and we can dig in a little deeper in terms of,
22 for me at least, where the group is in terms of specific

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1 action items. Cindy gave a little bit of a sense of
2 immediate action items for the labeling group. The one
3 thing I'd like to hear is some ideas from all of you on
4 what you think are tangible next steps for some of the
5 groups.

6 First, are there any clarifying questions? Why
7 don't we start with Jennifer, then Jim, Caroline, then --

8 JENNIFER: I think mine is a clarifying
9 question. But if you think it's not, you can table it to
10 Section 1, the best management. So, my clarifying, I
11 think, question is, the second point on volunteer
12 registries, you mentioned, whoever presented, that you
13 guys were preferring at this time voluntary.

14 I just wondered two things. One, will that
15 include also thinking about an incident reporting system
16 in that? Then, the second thing is, what was the
17 discussion on preferring voluntary? Is it just to test
18 something to see if it works or is it voluntary forever?
19 What was your thinking on that?

20 MR. WILLETT: I can answer that question, Rick.
21 Marylou did a really good job, but she found out this
22 morning that she had to make the presentation.

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1 The reason why the voluntary part of the
2 registry was because there is not a clear agreement
3 amongst the folks involved that registration of where bee
4 colonies should be all the time is a good idea. There is
5 some resistance to that because beekeepers have concerns
6 about theft of colonies. They have concerns about people
7 identifying foraging areas that they consider
8 proprietary.

9 So, mandatory registration with bee colonies
10 wasn't universally endorsed by everybody in the work
11 group. So, that was the reason why it was left as a
12 voluntary.

13 JENNIFER: (Inaudible) registry references
14 referring to location of where bees are then.

15 MR. WILLETT: That's how we understood it,
16 unless there's some other understanding within the work
17 groups.

18 JENNIFER: No, I'm asking.

19 MR. WILLETT: That's how we understood it, yes.

20 JENNIFER: Okay, thanks. Then, I guess my
21 second question was, is there talk about an incident
22 reporting system or is that in a different section?

41	<p>1 Would that be on enforcement? So, under enforcement, 2 they're saying the difference between an incident and an 3 investigation. But is there a reporting system that 4 you're talking about? I guess my question is, are you 5 talking about an incident reporting system in here 6 somewhere?</p> <p>7 UNIDENTIFIED MALE: I think Gabrielle was going 8 to -- we had put that under the enforcement theme.</p> <p>9 MS. LUDWIG: The short answer is yes, it got 10 talked about. The issue was we had so many issues that 11 we felt like we were trying to figure out which ones were 12 really top priority. So, on the incident reporting, 13 several things got talked about. One is just simply, as 14 I just mentioned, from a state perspective, making sure 15 that whatever they learn gets transmitted to EPA. That's 16 one aspect that got talked about.</p> <p>17 Another aspect that got talked about in a 18 subgroup is just simply beekeepers are still leery to use 19 the existing incident reporting system. We need to 20 explore more why. Again, I think it comes back to a bit 21 like what Mike was just saying about their experiences 22 with the government haven't been that great.</p>	43	<p>1 databases available already that have the ability to 2 overlay the data. The same things that Michael just 3 brought up about some resistance, I have no problem with 4 the voluntary registries.</p> <p>5 My net point is, if the committee or work group 6 would like any liaison with any of these groups that can 7 do this type of data overlay that my members use on a 8 regular basis -- Agran, CDM mass, several others 9 (phonetic) -- do this already but they don't do it for 10 pollinators unless they're given the information.</p> <p>11 So, if there was a repository, my members would 12 really prefer that it go to one place so they don't have 13 to source multiple databases. The database uses right 14 now, particularly Agran users, is actually you might call 15 it danger zones. It could be schools or other 16 environmental hazards. Pollinators would fit into that 17 very very well. Some states actually require some of 18 that information.</p> <p>19 So, we like the idea of a registry. We do not 20 like the idea of a new one. We think that it could be 21 actually fairly easily recorded. For the simple reason 22 why we like it, if my members know when they're making</p>
42	<p>1 So, there's a lot of details that are being 2 asked in the system. Is that really useful to them at 3 that point in time? So, there's some need to look into 4 that. So, that definitely got talked about as something 5 that needs to be floored more about how to do it better.</p> <p>6 UNIDENTIFIED MALE: To build on what Gabriele 7 was saying, too, just a reminder that there is a portal, 8 via the EPA web site, for someone to report bee kills. 9 Part of the discussion during yesterday's meeting had to 10 do with maybe getting some consistency in terms of what 11 information elements we ask people to submit through that 12 portal now.</p> <p>13 Right now, it essentially brings up an ability 14 to send an e-mail to EPA. Some people were concerned 15 that maybe because of what was being reported or what 16 people didn't know might be helpful in reporting an 17 incident, if we provided some clarity there, it might 18 help with the enforcement investigation aspect of things.</p> <p>19 UNIDENTIFIED MALE: Actually, taking off on 20 Jennifer's question, I was going to start with that. So, 21 I'll skip that part but go back to registries. At the 22 last PPDC meeting, I mentioned that there are commercial</p>	44	<p>1 applications where the bees are, they can simply go to 2 the beekeeper and say, look, keep a tarp around your 3 bees. When we know we're going to make an application, 4 we'll throw a tarp or a protective cover, or notify you, 5 or something where we're working closer together.</p> <p>6 I'm all for the label restrictions and the 7 language and everything, but I think at least in the 8 pesticide area -- and I'm not at all indicating at all 9 that pesticides are the cause of the issue because 10 they're probably likely not. But, in order to keep 11 direct causes from pesticides on bee kills, we would be 12 very interested in helping you with location. Now we're 13 back to the registry.</p> <p>14 UNIDENTIFIED MALE: Jim, one of the things we 15 talked about in the work group yesterday was some of the 16 existing programs that exist like Direct Watch where 17 there is an ability to register into that system. We 18 talked about exploring maybe having some of those 19 organizations come in and give presentations to the work 20 group on existing models that are out there.</p> <p>21 UNIDENTIFIED MALE: Yeah, drift watch is one. 22 There are already national organizations that are far</p>

<p style="text-align: right;">45</p> <p>1 bigger than the Perdue program. We have no problem if 2 you want to put it in multiple places. But some of the 3 national ones are far more used by CCAs and PTAs than the 4 others.</p> <p>5 MR. BRADBURY: Caroline.</p> <p>6 CAROLINE: Are we still on the clarifying 7 questions?</p> <p>8 MR. BRADBURY: I'm hoping that's what people 9 are trying to hold themselves to.</p> <p>10 CAROLINE: The question I had was about the 11 slide about the SETAC workshop. It said that there was 12 no consensus about how to deal with sublethal effects. I 13 was wondering if we could get some more details on that 14 and more clarification of what that discussion was like.</p> <p>15 MR. STEEGER: The intent of that comment was 16 that multiple measurement endpoints are reported with 17 studies. Some of them are sublethal effects that could 18 not at this time be linked to agency or regulatory 19 authority assessment endpoints. Behavioral effects, 20 while they might impact individual bees, do they affect 21 the colony as a whole and cause it to ultimately decline 22 to the point of death.</p>	<p style="text-align: right;">47</p> <p>1 Office of Pesticide Programs or through regions, plays a 2 role in investigation of bee incidents, either through 3 funding, or off-state authorities, or directions to state 4 authorities, or in sample testing?</p> <p>5 UNIDENTIFIED MALE: I'm not sure I heard all of 6 it because I was trying to get the slide back up.</p> <p>7 UNIDENTIFIED MALE: I was just asking what role 8 OPP or EPA's region plays in the investigations and 9 reporting of bee kill incidents. Is there any funding of 10 state authority specifically to do this or any role in 11 testing of samples that may arise in the investigation?</p> <p>12 UNIDENTIFIED MALE: So, we're engaged in an 13 ongoing dialogue with the enforcement office as well as 14 the regions on a wide variety of issues, including 15 pollinator issues. It's becoming a higher priority for 16 the regions and the states as part of those efforts.</p> <p>17 In the area of support for enforcement, there 18 have been instances where EFED has provided support to 19 state investigations or regional investigations of 20 incidents. We have had on occasion requests for OPP's 21 laboratories to do some laboratory analysis of, you know, 22 hives data, or pollen data, or honey data, or the bees</p>
<p style="text-align: right;">46</p> <p>1 Making those linkages from endpoints in 2 individual bees that aren't killing the bees but might be 3 impairing them in some way, like the proboscis extension 4 reflect (phonetic) that could impact feeding, that could 5 in turn impact the extent to which nutrition plays a role 6 in the decline of the colony, the SETAC Pellston 7 Conference went through a number of those endpoints and 8 decided that for some of these, we don't have clear 9 linkages.</p> <p>10 That doesn't mean that in the future those 11 linkages won't be made. But it's just laying open the 12 ground for further research that needs to be done in 13 order to make those types of linkages clearer so that 14 these endpoints could potentially play a role in a 15 regulatory context.</p> <p>16 UNIDENTIFIED MALE: I think this is a 17 clarifying question regarding enforcement. I was in the 18 work group meeting yesterday and I got the impression 19 that most of the enforcement investigations and 20 activities and reporting is done through or by state 21 regulatory authorities.</p> <p>22 I was wondering if EPA, either the national</p>	<p style="text-align: right;">48</p> <p>1 themselves.</p> <p>2 MR. BRADBURY: So, just to clarify, Ray, the 3 enforcement activities are undertaken by the states. The 4 EPA enforcement office, OWECA (phonetic), compliance and 5 enforcement, we're working with them closely in terms of 6 coordination across the states and engagement in the PPDC 7 groups that have now been informed as well as prior to 8 that. So, states have the primary authority. OWECA 9 helps provide some continuity and some consistency in 10 approaches.</p> <p>11 Clearly, this has been one of the challenging 12 areas in terms of people's perceptions and experiences in 13 terms of what's playing out at the state level, the 14 regional level, and then the national level. So, we're 15 working hard -- and this work group will help -- in 16 trying to knit things together a bit more coherently and 17 effectively.</p> <p>18 The states have quite a challenge, which I 19 think some of our speakers have pointed out, in terms of 20 enforcement and compliance, from worker protection to 21 water quality to bees. So, what we're trying to do and 22 what we have been working through with the states and our</p>

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1 national program guidance from the pesticide program and
2 aligning that with the enforcement office is to first try
3 to make sure that the left hand and the right hand are
4 working together so that the states aren't getting mixed
5 signals in terms of priority areas. We want to try to
6 make sure they're complementary.

7 We're working towards some flexibility with the
8 states so that their national objectives in all states
9 have to deal with that allowing some degree of adjustment
10 to emphasis within certain areas, because some parts of
11 the country may have different issues to deal with that
12 are higher effort or challenge than other parts of the
13 states.

14 So, that's what we're trying to work through.
15 It's all kind of coming out of the same basic budget and
16 set of resources. So, I think a number of you mentioned
17 the importance of as we think through options, how to
18 make sure that we're coming up with very effective and
19 cost effective techniques to try out, try to make sure
20 we're taking advantage of tools and technology that may
21 have been used for another purpose but could be adapted
22 to this area. That will be an important part of this.

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1 We'll want to maximize protection
2 appropriately, science-based, and have it be as efficient
3 as we can and as helpful to the states as we can. So, I
4 think across these different work groups, some of the
5 ideas that will come out will be helpful at the state
6 level, at the regional level, and at the federal level.

7 Darren, you were next.

8 MR. COX: On the best management practices, we
9 have a model that we kind of looked at with California.
10 They do have the registry that's voluntary. The
11 beekeepers can go ahead and register their locations if
12 they are concerned about usage in the areas that may be a
13 safety factor for their bees. There's a number of other
14 states where they also will have registrations.

15 But, what seems to be the constant thing here
16 is when the farmer needs the bees for that specific crop.
17 The crop is protected with consideration of the bees.
18 There usually is not a problem. Where we run into
19 problems is where there's not that need by the farmer for
20 the bees. As far as the voluntary registration, it's
21 kind of like, as Steve mentioned, the right hand knowing
22 what the left hand is doing if we have a farmer that does

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1 call us up, we can communicate to possibly say, okay,
2 select a product with less residual.

3 That's one beneficial tool. But if we don't
4 have usage reporting to where we understand what is being
5 sprayed in our areas at many points, these products will
6 get sprayed and the beekeeper will not be notified. So,
7 it kind of turns into a two-way street.

8 UNIDENTIFIED MALE: So, my question has to do
9 with evaluation. I enjoyed listening to all of these
10 different actions and activities, but with these times of
11 budgetary constraints and meager resources, how do we
12 know which of these activities actually is effective?
13 How do we know if the problem is getting better or
14 getting worse? So, I'm wondering if there are systematic
15 surveys of bee populations nationally and regionally, or
16 are we tracking like numbers of incidents of bee kills?

17 MR. STEEGER: This is Tom Steeger. The USDA is
18 tracking through monitoring of commercial hives the
19 incidents of pollinator decline. Our understanding,
20 EPA's understanding of incidents, though, depends on the
21 willingness of the states and the public to report that
22 information to the agency. That, we know, is not working

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1 effectively.

2 There is a resistance by the public to report
3 to the agency. The web site that Rick alluded to, I've
4 only had one person actually contact me using that web
5 site -- it was Ray McAllister -- just to see what would
6 happen if he contacted the web site. A few people are
7 availing themselves to the National Pesticide Information
8 Center, the NPIC portal. But the process that we
9 recommend is that you report the incident to the state
10 and the state will investigate it or report it to the
11 registrant.

12 Only the registrant is required to report an
13 incident to the agency. So, everything else is
14 volunteer. That volunteer system, unless we can get
15 engagement, isn't working effectively. I'll tell you, as
16 a risk assessor, my ability to ground truth a risk
17 assessment depends on incident data. That's our
18 information of how a chemical is actually being used.
19 Does it actually result in an effect? If no one is
20 willing to tell us that, that means we're blinded to
21 those effects.

22 UNIDENTIFIED MALE: But it seems like if you're

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1 basing it just on incident data, you're not really sure
 2 if you're actually winning the war because you don't know
 3 if -- if you see a decline in incidents, is that because
 4 there's truly a decline in the problem and bee
 5 populations are increasing, or is it just because people
 6 have decided not to report, or maybe there's barriers
 7 that prevent people from reporting. It seems like
 8 ideally you'd want measures of the bee population both
 9 regionally as well as nationally.

10 MR. STEEGER: You're absolutely right. There
 11 is a bias associated with the incident reporting system.
 12 We would like to improve that, but it will depend on
 13 cooperation. The USDA, though, has been -- congress
 14 noted that more needs to be done in terms of actual
 15 monitoring of colony losses from particular types of --
 16 like CCD and pollinator declines in general.
 17 They want to see it expanded from the current
 18 survey. But USDA is not sitting on their hands on this
 19 issue. They are actively trying to collect this
 20 information. Congress would like to see it expanded.
 21 Again, funding has to be provided. The reason why USDA
 22 did not do that is because the funds weren't appropriated

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1 by congress.

2 MR. BRADBURY: If I could sort of weave in a
 3 little bit and then step back as a chair. I think there
 4 are two aspects of getting information from the
 5 landscape. One is the effort that USDA is leading which
 6 is how do we come up with robust national surveys of the
 7 status of pollinators, be they managed pollinators or
 8 native pollinators, and what are the trends.

9 Set up a statistical survey design so that you
 10 can be tracking that. If done well or designed
 11 appropriately, maybe get some insights into potential
 12 associations between different stressors and the
 13 landscape and the trends in pollinator status. That's
 14 helpful for us in a broad context.

15 It's helpful for everybody because you can
 16 start to better understand what the relationships may be
 17 between different stressors and the landscaping status
 18 and what can be done in terms of individual stressors in
 19 the context of the milieu of pressures the pollinators
 20 are facing.

21 The incidence data can give us some information
 22 to complement what we have in our risk assessments for

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1 pollinators or fish or other parts of the ecosystem that
 2 we're looking at. So, we have the laboratory-based
 3 information. We may have field studies or semi-field
 4 studies associated with different tasks as part of the
 5 information base to make the registration decision.

6 The incidence data can be helpful for a
 7 specific compound and specific use scenario and gives us
 8 insights if we're seeing things that we didn't expect
 9 from the information that we collected or that was
 10 submitted to us during the registration evaluation
 11 process, or in going through registration review, taking
 12 a look at the incidence information that's out there, and
 13 is it consistent with what we were expecting or not
 14 expecting and how to go forward.

15 But, as Tom mentioned, that information one has
 16 to look at carefully because just because you don't get
 17 information doesn't mean it couldn't have been something
 18 going on as a function of whether or not it was reported
 19 or not. So, we have to take that into account.

20 So, I've got Cindy, Pieter, Ray, and Gabriele.

21 MS. BAKER: I just want to follow up kind of on
 22 your comment, Geoff, because I think that's where the

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1 work group went yesterday, not specifically to your point
 2 but to the point of how do we prioritize this and what
 3 are the things that will really make a difference.

4 It was interesting to me -- I think it was the
 5 guy from North Dakota who made the comment. We had
 6 something like a dozen things up on the white sheet and
 7 we said how do we prioritize, what are the things that
 8 really make a difference, where are the urgent things.
 9 He said best management practices and training is one of
 10 the things that he has found that really made a
 11 difference.

12 So, one of the overarching themes that I took
 13 out of that whole session and discussion was that there's
 14 a lot of information that is available today. It's a
 15 matter of compiling it and getting it to the right
 16 people. So, whether it be where the bees are, whether it
 17 be information that's already on labels, or whether it be
 18 information about products that we know, it's getting it
 19 out to people. That seemed to be the biggest single
 20 thing that people thought they could get some benefit
 21 from.

22 We have some examples of where it has worked

14 (Pages 53 to 56)

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1 well. That guy from North Dakota had a great testimony,
2 if you will, about how that worked. I think there are
3 some others. So, I think getting that information out
4 into the hands of the people who can make a difference,
5 the applicators, the beekeepers, the growers if they're a
6 private application, I think is the real positive first
7 step that would actually make a difference in what people
8 are doing.

9 MR. SHEEHAN: I want to speak on the idea of
10 information sharing between states and the EPA. It
11 sounds like it would probably be characterized as not
12 fantastic at the present moment. I'd like to offer two
13 things.

14 At a local level, we deal with the federal and
15 state governments all the time. There are two examples I
16 would say you might want to look at in terms of how this
17 communication from a very low level to a very high level
18 rapidly occurs. What I'm talking about is the
19 administration of that communication, their applications,
20 their process.

21 The one that I'm most impressed with is the
22 CDC's communication with local health departments when

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1 there's a recreational water incident, whether there's a
2 disease being spread in a swimming pool, and how rapidly
3 we can communicate to Atlanta with something like that.

4 Then, of course, retail food programs,
5 restaurants, food-borne illness and how those forms --
6 and how the communication moved very quickly from the
7 local level to the state level to the federal level
8 through very simple forms, through an understanding of
9 what the big picture is and how to gather that
10 information.

11 MR. BRADBURY: Thanks. Ray and then Gabriele.

12 MR. McALLISTER: I think that lacking
13 comprehensive surveys on bee kills or bee incidents and
14 perhaps lacking the resources to find out the extent of
15 problems or the extent of success is perhaps one of the
16 most fruitful approaches we can do is look at case
17 studies, like Cindy mentioned, where we know things have
18 gone right.

19 In our discussions yesterday, we identified
20 three or four of those. Apply the lessons learned there
21 to additional (inaudible), additional circumstances. I
22 think there's a big opportunity there for some short-term

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1 quick gains. We also might want to identify some
2 negative case studies where things went bad, went wrong,
3 and find out what we learned there what not to do in
4 other situations.

5 I also just wanted to mention in my test of the
6 incident reporting system, I found out that Tom Steeger
7 is on the other end of that reporting line.

8 MR. BRADBURY: Gabriele, I think you put your
9 tent down, okay. So, Caroline and then Cheryl.

10 MS. COX: I just wanted to comment about the
11 sublethal effects. To me, this is like one of the most
12 critical areas where we really need to move forward and
13 make some progress. If there isn't consensus right now,
14 I think that just shows how important it is to move
15 forward and make progress and figure out how to come to a
16 consensus.

17 I think that's at the core of this issue about
18 pollinator protection as far as pesticides. It seems
19 like a really critical area to make some progress in.

20 MR. BRADBURY: Cheryl, Scott, and then
21 Gabriele.

22 CHERYL: So, almost back to that but in a weird

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1 way, I guess, I am intrigued by the labeling report that
2 they're going to explore what exists today on the labels
3 and how EPA currently determines what goes on that label.
4 What I'd love to see and I think would be a really easy
5 work group activity would be a polling and a survey of
6 what is on the various labels, what works for
7 applicators, and do a survey of homeowners.

8 Do they understand what this means --
9 applicators, commercial applicators, non-commercial
10 applicators, farmers, whatever -- and really dig down
11 into what is on the label today, what works, but take
12 that a step further because you're also way over here on
13 advancing the science, talking about what you might be
14 asking for in terms of a case by case situation for
15 additional data testing.

16 In that same conversation, say, if you ask for
17 these additional tests, what are the outcomes of those
18 tests going to look like in terms of new label
19 statements? Kind of wrap that all back together. That
20 would be really helpful, I think.

21 MR. BRADBURY: Scott and Gabriele, then Mark,
22 and then what I'm going to suggest is that we take our

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1 break at that point. Then, after the break, I'd like to
2 come back to each individual group and go through each of
3 the four areas, get feedback from you all if the scope of
4 each subgroup seems reasonable to you, if there's
5 anything you suggest to broaden or restrict that scope.
6 Then, get from the work group or your advice on specific
7 action items.

8 I'd like to make sure we leave this meeting
9 with knowing over the next six months what exactly each
10 work group is going to do and accomplish before we meet
11 again six months from now. So, clarity on scope. Make
12 sure scope is okay for each of the subgroups. Then, get
13 input from you all on immediate tasks to take on over the
14 next six months so we give our work groups a clear set of
15 instructions, if you will, on things to take on.

16 So, Scott, Gabriele, and Mark. Then we'll take
17 a break. Scott.

18 MR. SCHERTZ: An observation of all this
19 process and being a part of it, this is a very complex
20 issue, a lot of crops, a lot of products, a lot of
21 different stressors, et cetera. There is an interest in
22 the short-term recommendations, but also the SAP is

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1 coming up.

2 Many of these, I think, are so complicated and
3 interconnected that that's a huge interest. Some of
4 these, particularly labeling issues, would take a while
5 to get on and then they would be very difficult to get
6 off if we get them wrong.

7 I would caution that we do need to take that
8 into account. I would request a bit of an update of
9 exactly where EPA/OPP is on the charge and possibly
10 charge questions, et cetera, on the forthcoming SAP on
11 this.

12 MR. BRADBURY: Gabriele.

13 MS. LUDWIG: Well, Scott's comments play into
14 what I wanted to emphasize. I think this is partly in
15 response to Caroline's request. I think one thing that
16 we were very clear on in the work group is we need to
17 figure out what we can do now with science progressing as
18 it is.

19 Anything that is dependent on really sorting
20 out the data is not something the group can deal with
21 right now. For example, if you take labeling, I think we
22 can talk about what's working, what's not working with

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1 the current labels, what are the inconsistencies, what
2 are some ideas for improving the labels once we have more
3 data available.

4 But, just to give you an example, some of that
5 is going to be contingent on when that data is available.
6 Sublethal is not something this group can tackle. I
7 mean, that is just not something that we have the
8 expertise and can tackle. It's not to say it's not
9 important; it is on EPA's agenda. But that is not
10 something we can deal with at this point in time.
11 There's just not enough data to figure out how to do it
12 with any consistency, any fairness across all the
13 products. So, that's the rub.

14 So, I just want to be very clear that when we
15 talked about priorities, and I think this is important
16 for the discussion next, there are limits to what we can
17 do because there's still quite a bit of uncertainties
18 about which of these issues are significant enough to
19 merit an action and which ones are not yet. We just
20 don't know that in so many cases. So, that's the issue.

21 I realize there are those that believe in the
22 precautionary principle, but that is not what we're

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1 working under in the USA. So, just be clear on that. As
2 I say, I just want to be -- we've talked about that on
3 the committees. Some ideas came up. What I suggested is
4 that we come up with a list for research so that there's
5 areas where we say this is where we need research so that
6 we capture those discussions. They don't get lost.

7 So, I just want to be clear that we're not
8 dismissing it, but there are some areas that we just
9 don't have, from a PPDC perspective, the ability to deal
10 with. I just want to be clear with that as we go into
11 the next discussion, the continuing discussion.

12 UNIDENTIFIED FEMALE: I'm not sure what you
13 mean by we can't do acute, but the incident reporting
14 data -- or, sorry, we can't do sublethal and chronic.

15 The incident reporting data is a really important
16 opportunity to just make sure that you're capturing data
17 that's not necessarily bee kills but other kinds of
18 things and start to collect that important information.
19 So, there's lots of ways to consider all these endpoints.

20 So, I'm not sure what you mean by that. But I
21 would suggest that by keeping it front and center and
22 keeping it as a main concern, you're thinking of it when

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1 you're doing the things that you can do, like the
2 incident reporting.

3 MR. BRADBURY: Thanks. Okay, so let's take a
4 break until 20 to the hour. We'll start sharp at 20 to
5 the hour. We're going to go through work group by work
6 group, clarity on scope and clarity on near term
7 activities to be taking on over the next six months. So,
8 be thinking about that. I'll look to the work group
9 members to sort of help us through that conversation.

10 (Whereupon, a brief recess was
11 taken.)

12 MR. BRADBURY: Before we get started, there are
13 some folks that came a little bit after we got the
14 meeting rolling. If they could just introduce
15 themselves. Ann and Jennifer and Nancy, if you could
16 just introduce yourself, your organization, and who you
17 are representing.

18 MS. LAW: Hi, I'm Anne Law. I'm here with the
19 American Bird Conservancy. I'm currently sitting in for
20 Michael Frye who has, as many of you know, left ABC and
21 is now in Hawaii.

22 MS. BECK: Hi, I'm Nancy Beck. I'm here in

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1 place of Kristie Sullivan, and we represent Physicians
2 Committee for Responsible Medicine.

3 MR. BRADBURY: Thanks, Nancy and Ann. Jennifer
4 is having tea. Jennifer Sass from NRDC also joined us a
5 little bit after we started.

6 Okay, so what we'd like to do between now and
7 11:20 is go through each of the four thematic areas, the
8 subareas within the pollinator protection work group.
9 I'd like to get confirmation on the scope of the efforts,
10 get some feedback, if any of the members think it's too
11 wide or too narrow, if we could get clarity on that. And
12 then get clarity on specific action items that each
13 individual group will take on over the next six months.

14 I don't mean to imply that all these issues
15 will be resolved in the next six months, but to get
16 clarity on what specific tasks will get accomplished
17 during the first six months. It could be, in some ways,
18 actually tackling a specific issue and maybe getting, to
19 some degree, a resolution.

20 It could be trying to set up the game plan for
21 something that may take 12 months to get done but there
22 will be a very clear plan prepared in the next months and

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1 make it very clear what's going to happen over, say, a
2 little over a 12-month period.

3 So, I'm not trying to imply everybody gets
4 everything done in six months, but there will be very
5 specific tasks. We'll know very specifically what kind
6 of communications will be coming out to the full group
7 six months from now.

8 So, Rick, Don, why don't I turn it over to you
9 and members of the work group and let's tackle the first
10 area.

11 MR. KEIGWIN: Okay. So, as Steve indicated,
12 let's start with theme one, best management practices,
13 and try to scope out our activities over the next short
14 term six months that Steve indicated that we can either
15 do additional planning if we need to or action items that
16 we can actually adopt and move forward on through the
17 work group, and with EPA's assistance.

18 So, those were the three points that the work
19 group identified as areas to make progress on. So, I
20 guess I'd like to try and hear any thoughts from
21 committee members as to where our priority might be or
22 specific ideas that come.

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1 Mike Willett.

2 MR. WILLETT: Some people in this room are
3 probably familiar with this publication. It's a 25-page
4 publication. It's titled, The Specific Northwest. It
5 essentially summarizes all of the known best management
6 practices, including pesticide specific practices that
7 can be used. It covers honeybees as well as solitary
8 bees, bumble bees and osmia (phonetic) bees in terms of
9 what are the impacts of pesticides.

10 One of the authors of this is on the work
11 group, Eric Johansson (phonetic). He pointed out that
12 this publication needs to be updated. It seems like this
13 publication or information of this sort vetted across
14 whatever sources of information that exists in the U.S.
15 would be helpful not only to ensuring that we have best
16 manufacturers compiled in one place, but also would feed
17 into this OECD effort of building an international
18 database for best management practices.

19 So, trying to do something like that I would
20 submit to the work group might be a worthy effort and to
21 the agency would be a worthy effort.

22 MR. KEIGWIN: Thank you, Mike. That's a good

17 (Pages 65 to 68)

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1 suggestion.

2 MR. BRADBURY: Dave.

3 MR. TAMAYO: One of the things that seems to
4 keep coming up is that there's some pesticide applicators
5 that maybe are very motivated to protect the pollinators
6 because they have a direct interest. Then, there's some
7 pollinators that are less motivated because they don't
8 have a direct interest in pollinators at that particular
9 moment.

10 It seems to me that it would be great to find
11 some cases where that sort of barrier to adopting best
12 management practices or doing the right thing or whatever
13 you need to do. Look at how was that overcome in a
14 particular area or group of growers.

15 Maybe there are no good instances, but I
16 suspect that there are some areas where people have
17 figured out a way to do that and going beyond just legal
18 requirements, just sort of incorporating that as this is
19 how we do it in our area.

20 MR. BRADBURY: Thanks. Go ahead.

21 UNIDENTIFIED MALE: A late entry, sorry. I am
22 not very much familiar with the pollinator partnership,

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1 but I just met Laurie at a meeting this past summer.
2 Since I met her, I know a whole lot more about it within
3 15 minutes than I probably would have if I studied it
4 online.

5 But she presented to me a module that is being
6 developed. It's probably similar to what you had,
7 Marylou, in California. It's kind of an overlapping,
8 cross cutting thing with the education emphasis of
9 another theme. But it seems to me like that would be a
10 good place for contributions to best management practices
11 maybe overcoming barriers.

12 Laurie, herself, is looking to interview
13 growers in several areas of the U.S. that have developed
14 programs or certainly shown care of the pollinators in
15 their region. Maybe there are instances in which, as you
16 were talking about, Dave, barriers could be overcome.
17 This, too, can be brought to light in a video.

18 There is an interest in developing this for
19 pesticide safety education, which is my particular vent.
20 Having it as a re-certification tool for our private
21 applicators and commercial applicators would be a welcome
22 tool or item.

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1 Technical notes are going to be included maybe
2 paralleling, which you have, Michael, with the BMP that
3 you just introduced in a workbook, to try to engage the
4 audience into something that's far more than just
5 listening to a video and maybe tuning out, but actually
6 becoming interactive in teaching it.

7 UNIDENTIFIED FEMALE: Is it possible, then, to
8 maybe talk to growers and commodity groups that use these
9 and see what their best management practices are and see
10 what works and what doesn't? I'm sure there's commodity
11 groups out there already, like Gabriele's almond board,
12 that already have best management practices they're using
13 right now to protect the bees. Maybe we can explore that
14 on a more practical standpoint.

15 MR. BRADBURY: Darren.

16 MR. COX: In Western Farm Press about a week
17 and a half ago, there was an article about soybeans
18 producing heavier yields with the benefits of honeybees.
19 I'm just wondering is it possible to look into some of
20 this for research for just soybeans and canola and other
21 various crops that farmers may not be aware of that they
22 are receiving benefit.

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1 Once they are aware that there is an economic
2 model that's here that's of value for them by having
3 these in their communities and farm fields, then perhaps
4 safeguards would be looked at more closely when it comes
5 to applying the chemicals.

6 The last 30 or so years, the duck and cover, so
7 to speak, that's been happening to the beehives, cover
8 them up or move them out of the way, is really not
9 working. The reason why we're here today is that the bee
10 industry in many of us is really about money. We're here
11 because pollenization costs continue to increase.

12 If we don't safeguard our nation's resources of
13 pollinators, many of these crops could be exported to
14 other countries where they can have cheaper pollenization
15 costs and we will lose out on the big picture. So, I
16 would encourage, if we can, to look at some of these
17 costs that could provide additional benefits.

18 MR. BRADBURY: Okay, thanks. So, I'm just
19 going to kind of reset everybody. What our goal is right
20 now is to take a look at the potential scope of theme
21 one. We've got to get through the other themes. Then
22 identify some near term six-month activity. So, here's

18 (Pages 69 to 72)

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1 what I've heard so far, and then I'll go to Gabriele and
2 Mark.

3 There may be a model, a document, that Mike
4 brought up that could be at least a framework to consider
5 these as a launching pad for the first goal within theme
6 one, which is to try to (inaudible) collecting in one
7 place information about best management practices that
8 currently exist.

9 So, the proposal is to maybe use that document
10 as a starting point. I'll defer to the work group to
11 think how much you could get done in six months, but it
12 may just be scoping out what kind of (inaudible) is
13 before us to try to update it and get a sense of what's
14 current, what's at stake, what's been (inaudible).

15 As far as the third thematic area, I heard
16 working on the case studies. I don't think you can get
17 the case studies done, but identifying what those case
18 studies could be, and getting a sense of one case study
19 around the cropping pattern where the crop is dependent
20 upon pollination. See if you could identify a case study
21 around the cropping pattern where, knowingly or
22 unknowingly, that that crop isn't at least totally

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1 obviously dependent upon pollinators for its
2 productivity.

3 Get two case studies going on those two fronts.
4 Again, not to get the case studies done but to at least
5 have scoped them out, identify players that could be
6 involved in that case study. When you come back six
7 months from now, you have identified the case studies,
8 who the players are going to be, and what the time line
9 is to work through the case studies. So, I'm trying to
10 keep us focused on tasks.

11 Gabriele.

12 MS. LUDWIG: Well, you summarized some of the
13 things I was going to say. So, to add to that, what I
14 would suggest for number one is there are a number of EMP
15 models out there. At least get all of them collected so
16 we have the northwest protocol model, we have the
17 blueberry model that I talked about last PPDC, and we
18 have a bit in almonds, a bit on the ECIPM sites. NAPSI,
19 or pollinator protection campaign, has also been working
20 on this issue. Let's take a look at what they have put
21 together.

22 Yesterday on the call, the Zerksi (phonetic)

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1 Society said they were working with NRCS on some best
2 management practices that I also think need to be looked
3 at for a variety of reasons. What I suggest for step one
4 is to simply in the next six weeks pull together all of
5 these different resources.

6 The other resource that needs to be pulled
7 together as best management practices is for the
8 beekeepers in terms of their pest management needs. I do
9 know that between the cap grant and Project Aphis M, I
10 think especially crop block grant in California, there
11 has also been some BMPs put together in that arena. So,
12 I think that would be something also to pull together
13 just to see what we have.

14 I agree with the statements that the bigger
15 issue is how do we motivate growers that are not
16 dependent on pollinators to think about pollinators. I
17 think I said that at the last PPDC in my presentation,
18 that that needs to be a focus.

19 In terms of voluntary registries, I think,
20 building on what Marylou has developed, look at what's
21 working and what's not working, just figure that out, and
22 have that discussion about what's all involved, what are

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1 the ways a registry would have to be built to make it
2 acceptable, workable, what are the issues that would need
3 to be resolved. I think that can be done in the next six
4 months.

5 Then, as you say, for the case studies, based
6 on these efforts, figure out which case studies would be
7 modeled to look at more closely.

8 MR. BRADBURY: Thanks, Gabriele. On the phone,
9 if you can hit your mute button, that would be helpful.

10 Mark, and then Jennifer, and then we'll move on
11 to theme two.

12 MARK: Let me start with first an observation,
13 Steve. It seems to me that there needs to be a way,
14 actually, for the USEPA to get involved in another
15 dimension. That is, to insert (phonetic) new products
16 for varolla mite control. It's a really small market.
17 There are huge risks associated with it, such that we're
18 forced to use two really old insecticides to control
19 varolla mites in hives; therefore, weakened broods, et
20 cetera.

21 So, there must be an array of other
22 insecticides that could be brought to the market. If EPA

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1 in some way could insert that process, but, right now, I
2 would imagine that it's the last thing a registrant would
3 want to do, is get a new varolla mite material right now.
4 So, when it's really needed -- because you know that
5 coumofos really weakens a brood. That's one thing.

6 The other thing is that in Michigan, we've seen
7 some efforts in the area of foraging bee nutrients and
8 probiotics, things like that. I don't hear best
9 management practice around that. I hear some incentives
10 and I see it advertised and promoted to beekeepers,
11 particularly at the upper midwest expo. There's a number
12 of them. But I'm wondering if there could be some
13 standards of best management practices around that whole
14 strategy that weaken boost hives.

15 There's a tradeoff. One is that if the bees
16 are too well fed and doing too well, they forage less.
17 The flop side of that is that if you keep them really
18 hungry, they forage more, but they die easier. So, it's
19 kind of a balancing. A best management practice around
20 nutrients and hives I think might be another one.

21 MR. BRADBURY: Thanks.
22 Jennifer.

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1 DR. SASS: I think that this is going to be
2 quick because I think that the working group came up with
3 some good priorities and divided itself well. I'll
4 identify just a couple main points. So, I guess I just
5 wanted to sort of put my vote in. I think they're all
6 really important. So, I think that our working groups
7 are going really well.

8 The best management practices, theme one, the
9 second one on the registries -- oh, wait, that's a
10 different registry, sorry. Then, I guess it was the
11 enforcement, the one with the incident reporting.

12 MR. BRADBURY: Can you hold that? We'll get to
13 that one. I just want to make sure we can close out
14 theme one and move on.

15 DR. SASS: We're just doing theme one?

16 MR. BRADBURY: Yes. Speaking for EPA, I'm
17 pretty good with theme one. I'm sort of tracking on what
18 Gabriele was sort of laying out as sort of the task. So,
19 one goal is to pull together the documents that already
20 exist in terms of best management practices for growers
21 as well as best management practices for beekeepers. At
22 least get the list together. Then we can figure out

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1 subsequent where the gaps were, things outdated, whatever
2 it may be.

3 With regard to voluntary registries, a more
4 detailed examination of what's working, what doesn't
5 work, what would be the attributes of a well-oiled
6 machine in terms of being able to have something like
7 that work, both from the sociology of it as well as the
8 IT of it.

9 Then, to at least identify six months from now
10 two potential case studies, one in the cropping system
11 where pollinators are critical in order to produce that
12 crop, a cropping pattern where pollinators, at least on
13 the surface, are not critical to production of that crop.

14 Those could be the two case studies to figure
15 out how to help people work together to figure out how to
16 solve problems. Again, don't do the case study but
17 identify who the players would be and what would be the
18 time line to execute those two case studies.

19 Cheryl.

20 DR. CLEVELAND: As you pull together documents,
21 would you also post them perhaps as part of the -- if
22 nothing else, maybe not sanctioning everyone, but you

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1 could post them as part of the work group documentation.
2 Then it becomes publicly available as well.

3 MR. BRADBURY: I'll defer to the work group in
4 terms of how much work they're going to get done. At a
5 minimum, by six months from now, they'll have reported
6 out here's what we've collected and it will be part of
7 the public report they've got. I'm not going to make
8 them do it two months from now, but they will do it at
9 least a week or two before we meet so you can all see it.
10 I've got to be somewhat respectful to people who don't
11 work for me.

12 So, I want to move on to theme two. Indulgence
13 of the chair watching the clock. So, the second thematic
14 area is training and education. Any feedback from the
15 full committee on the scope? Did the scope seem okay,
16 too big, too narrow, close enough? Not looking for
17 perfection, but ballpark.

18 Ken?

19 MR. NYE: Well, if we start with the basic
20 training program that's already in place, then I think
21 with some help from Wayne and others at the land grants,
22 we can take a look at where this has come from, what's in

<p style="text-align: right;">81</p> <p>1 it, how is it delivered.</p> <p>2 Each state is probably doing it a little bit</p> <p>3 different. How effective is that? Maybe with some</p> <p>4 things we can learn from the case studies and so on, we</p> <p>5 can figure out the best way that that system can operate.</p> <p>6 Are there some improvements that we can make in that in</p> <p>7 terms of trying to improve this pollination protection</p> <p>8 issue as much as we can.</p> <p>9 The next part of that would then be, I believe,</p> <p>10 a concerted effort on the part of the user side and the</p> <p>11 pollinator side. Again, maybe there's some things that</p> <p>12 come out of the case studies and some other things that</p> <p>13 we can get from the pollinator work that has been done on</p> <p>14 what are some of the problem areas that we can have a</p> <p>15 concerted effort in the user groups -- that's both</p> <p>16 commercial, farm applicators, and so on -- to work</p> <p>17 together to try to solve these problems. Education, I</p> <p>18 think, is probably where it's at. Far more difficult to</p> <p>19 actually accomplish than it is to talk about, but we've</p> <p>20 got to start someplace.</p> <p>21 The last part of that is let's take a look,</p> <p>22 with some help from the agency, as to what's on the</p>	<p style="text-align: right;">83</p> <p>1 success here is getting some people together in a room</p> <p>2 and working through a specific issue and then coming back</p> <p>3 and sharing it.</p> <p>4 So, the components of that, I think, are what</p> <p>5 do we do to really make a difference to protect the bees</p> <p>6 while still being able to protect the crops and the</p> <p>7 enforcement component of it together. Then, can we scale</p> <p>8 that up? Can we take that out and can we apply it in</p> <p>9 other crops? Can we apply it in other regions?</p> <p>10 What are the barriers that we're going to come</p> <p>11 up against, whether it's at the state side or the growers</p> <p>12 side or the labeling side, and identifying what they are.</p> <p>13 I don't think until we actually get our hands around one</p> <p>14 and try to do it, we're going to be able to identify what</p> <p>15 those are and do it. Then you can figure out how do we</p> <p>16 communicate the success.</p> <p>17 Maybe ARA or some of Scott's group, the</p> <p>18 applicators, says this is the best way for us to get the</p> <p>19 information that we need. The beekeepers say this is the</p> <p>20 best way we need to get the information about these</p> <p>21 products. Understand is it a timing issue, is it five</p> <p>22 days we wait, the 24 hours wait, whatever. But until we</p>
<p style="text-align: right;">82</p> <p>1 label, where it's at, how usable is it. I realize when</p> <p>2 we talk about making changes on the label, it gets pretty</p> <p>3 complicated pretty quick. But there are some things</p> <p>4 there that we can do that would help the educational</p> <p>5 effort.</p> <p>6 MR. BRADBURY: Thanks. That last point may</p> <p>7 fold around to the fourth thematic area that (inaudible)</p> <p>8 outcome that you're looking at for sure.</p> <p>9 Cindy.</p> <p>10 MS. SMITH: So, I got corrected at the break</p> <p>11 that the North Dakota example wasn't a good example. But</p> <p>12 the reason why I thought it was a good example when he</p> <p>13 talked was that he had talked with the Department of Ag,</p> <p>14 that he had some interaction with applicators, that he</p> <p>15 was the beekeeper, and that there was some looking at</p> <p>16 labeling. So, I think this combination is a critical</p> <p>17 piece of this education component.</p> <p>18 So, I think that if it's Eric Johansson at the</p> <p>19 Washington Department of Ag who is a common link of being</p> <p>20 a Department of Ag guy and having put together that</p> <p>21 document, Mike, and a couple beekeepers that Darren</p> <p>22 suggests and a couple of registrants, the real key to</p>	<p style="text-align: right;">84</p> <p>1 get everybody in the room and work through those on a</p> <p>2 specific case, I think it's going to be hard to make a</p> <p>3 lot of progress.</p> <p>4 So, I would advocate in the area of training</p> <p>5 and education, put a group together of people who are</p> <p>6 ready to engage, have some experience engaging on these,</p> <p>7 and see if then we can duplicate it.</p> <p>8 UNIDENTIFIED FEMALE: I just want to reinforce</p> <p>9 what Wayne said and what's actually already in there. I</p> <p>10 mean, one thing I will say for Lori Davis Adams</p> <p>11 (phonetic) is she knows about how do you change</p> <p>12 behaviors. That has been a focus of her life. So, I</p> <p>13 think that's an expertise we should tie into.</p> <p>14 MR. BRADBURY: Dave.</p> <p>15 MR. TAMAYO: I'd like to have a look taken at</p> <p>16 the training materials to see if there's information on</p> <p>17 how growers could be educated on this. This is the</p> <p>18 impact, economic impact on your area if we don't do this</p> <p>19 right. I know that there's probably sort of generic</p> <p>20 information. Oh, it's a bad thing for ag in general.</p> <p>21 But thinking about this is how it's going to hurt your</p> <p>22 neighbors whether you like them or not and the ability of</p>

<p style="text-align: right;">85</p> <p>1 your community to be successful.</p> <p>2 MR. BRADBURY: Okay. So, let me try to</p> <p>3 synthesize what I think I've pulled together for theme</p> <p>4 two. Similar to the first theme, an effort to collect</p> <p>5 and document what's currently out there in terms of</p> <p>6 training materials, be it state certification and</p> <p>7 training materials, what NAPSI is doing that can augment</p> <p>8 that, but to get a good list of what's out there now and</p> <p>9 what's in that material so we can identify gaps that may</p> <p>10 be associated with the training materials.</p> <p>11 Economic benefit, I think, is in the realm of</p> <p>12 things to be looking to see what's in the training,</p> <p>13 though it's not exactly about how to apply the product.</p> <p>14 But it's training about the notion of this product in the</p> <p>15 context of pollinator protection and crop productivity.</p> <p>16 So, document what kind of training materials</p> <p>17 exist through the state programs, through NAPSI. Do a</p> <p>18 gap analysis in terms of what seems to be missing. Then,</p> <p>19 taking a little bit of liberty with the idea that Cindy</p> <p>20 had, which is maybe some cross talk between theme two and</p> <p>21 theme one as the case study starts to get thought about.</p> <p>22 Theme two may be starting to be able to provide</p>	<p style="text-align: right;">87</p> <p>1 investigating an incident, the types of things that you</p> <p>2 look for. So, could there be some standardization that</p> <p>3 we bring, harmonization that we bring to that effort.</p> <p>4 Then, the second area had to do with improving</p> <p>5 and standardizing the types of information that</p> <p>6 ultimately are reported. There also was some discussion</p> <p>7 about where the appropriate place was to submit that</p> <p>8 information. I think some groups had some concerns about</p> <p>9 information being submitted to certain entities versus</p> <p>10 others. I think that's another area that perhaps needs</p> <p>11 some further discussion.</p> <p>12 MR. BRADBURY: Mark.</p> <p>13 MARK: Sue, I want to follow up a little bit on</p> <p>14 a question that Ray asked. You got some of the answer</p> <p>15 that I was looking for, but I want to be a little more</p> <p>16 specific on my question. Regarding abilities of the</p> <p>17 agency to improve monitoring for compliance and</p> <p>18 enforcement, obviously, there's state agencies that are</p> <p>19 really good at it and are putting a lot of resources into</p> <p>20 monitoring for compliance and enforcement. Then, other</p> <p>21 states are not so.</p> <p>22 So, there's the SFIREG which is basically a</p>
<p style="text-align: right;">86</p> <p>1 some insights. This will be really a critical set of</p> <p>2 concepts to make sure come out of that case study based</p> <p>3 on what we're seeing in the current training materials</p> <p>4 and what may be starting to evolve from case study option</p> <p>5 selections.</p> <p>6 So, synthesize what we've got out there, gap</p> <p>7 analysis, and then be working with the group that's</p> <p>8 coming up with the case studies. That may transcend</p> <p>9 across all four groups, but does that seem like</p> <p>10 reasonable tasks for six months? Good, okay.</p> <p>11 Let's move on to the enforcement theme. We'll</p> <p>12 turn it over to the work group, if you want to just spend</p> <p>13 a minute or two just sort of refreshing us on goals and</p> <p>14 objectives broadly. Then we'll see if the scope is okay</p> <p>15 with the folks.</p> <p>16 UNIDENTIFIED MALE: So, a good part of the</p> <p>17 discussion during yesterday's meeting on this topic area</p> <p>18 had to do with looking at what type of guidance was</p> <p>19 currently out there across the states in regards to</p> <p>20 enforcement, what were some of the basis elements, and</p> <p>21 maybe should there be some standardization employed in</p> <p>22 terms of when you are looking into an incident or</p>	<p style="text-align: right;">88</p> <p>1 venue where the agency communicates and tries to convince</p> <p>2 and improve that monitoring for compliance and</p> <p>3 enforcement. Then, on the end of the spectrum, there's</p> <p>4 basically taking authority back from a state where they</p> <p>5 no longer have primacy for FIFRA.</p> <p>6 In between there, what does the agency have as</p> <p>7 far as tools to do that? So, in other words, I'm talking</p> <p>8 about sticks rather than carrots.</p> <p>9 MR. BRADBURY: Well, you've mentioned the</p> <p>10 biggest stick, which is pull it back, not a pathway of</p> <p>11 choice for a whole variety of reasons. It's working</p> <p>12 through how to define what the goals area, how to try to</p> <p>13 come up with effective efficient ways to do it. I think</p> <p>14 we all realize, and our state colleagues in particular,</p> <p>15 are struggling with reduced resources and less people.</p> <p>16 So, clearly, as we go forward across the board</p> <p>17 on things we're working on, we're looking for</p> <p>18 efficiencies and we're looking for biggest impacts where</p> <p>19 the taxpayer dollars invest in trying to get as much</p> <p>20 harmonization and learning from each other as we go</p> <p>21 forward.</p> <p>22 It's time spent with the states through OWECA</p>

89	<p>1 (phonetic) and through our office as well to take a look 2 at what they've got on their plate, how to set up the 3 priorities, and certainly making sure we provide as much 4 guidance and clarity and insight into how to go forward. 5 It's not that we know everything but in a 6 collaborative process. So, it's partnership and trying 7 to work together to realize they've got multiple 8 challenges. We're all trying to get to the same place. 9 I don't think the notion of pulling things back from the 10 states is a very healthy way to go forward, given the 11 struggles we're all facing. 12 So, we're working hard on trying to use the 13 resources we've all got to get to where we need to get. 14 UNIDENTIFIED MALE: I agree with you. Is there 15 anything between that? I mean, can you withhold funding? 16 I don't know. That's why I'm asking. 17 MR. BRADBURY: Well, I don't want to spend a 18 lot of time on this because I'd like to figure out what 19 this thematic group can do as opposed to try to change 20 the economy. But what we do is provide help through 21 headquarters in terms of guidance and priorities and try 22 to synthesize tools and techniques. The regional office</p>	91	<p>1 standard throughout all the states or is it very much 2 widespread? I know that some states have reported that 3 they are not funded to do enforcement or investigations 4 for beehives. 5 UNIDENTIFIED FEMALE: Through the guidances, we 6 have our national program manager guidance that goes out 7 to the regions and ultimately through the states. And 8 OWECA also has program guidance that directly impacts 9 investigations and enforcement activity. Contained 10 within that guidance are overlapping priorities. 11 The approach that OWECA is now going to take is 12 looking into the possibility of developing centers of 13 expertise, if you will, so that every state wouldn't have 14 to be an expert in every avenue of investigation and 15 enforcement activity. They're not there yet. The 16 current NPM guidance does not reflect that kind of an 17 approach, but I think that we're all realizing, states 18 and regions and ultimately headquarters, that we can't 19 sustain everybody being experts in everything any longer. 20 So, I am not personally aware that there is a 21 specific priority to deal with investigations and 22 enforcement follow up on beehives or any kind of issues</p>
90	<p>1 will also provide assistance and work with the states. 2 We sometimes have to figure out where the 3 regions can provide some assistance across the states to 4 work through these things. I'm not going into it with 5 the assumption the state doesn't want to try to do the 6 right thing, but they're facing a lot of tough choices 7 and challenges right now on how to try to work through 8 the priorities and try to optimize the limited resources 9 that we have available collectively as a country. 10 I appreciate the point, always do, but we want 11 to try to see what we can get done in this third thematic 12 area. 13 Darren. 14 MR. COX: I was wondering if our goal is to try 15 to get consistency through many of these states? Is 16 there any information that has been developed, like a 17 pamphlet, that these states could go off of to where they 18 understood what is the process of actually completing an 19 investigation start to finish? That was one part of my 20 question. 21 The other part is, could you give us a ballpark 22 idea on the funding that these states receive? Is it</p>	92	<p>1 around bees. But it would fall within the purview of 2 general FIFRA enforcement activities. So, it's not that 3 it's not covered; it's just not right now listed as a 4 priority. It's certainly something that we need to think 5 about when we go forward with next year's NPM guidance. 6 UNIDENTIFIED MALE: Just so I'm clear on this, 7 right now there is actually not an enforcement manual or 8 some given direction that is consistent through the 9 states for them to complete an investigation? 10 MR. BRADBURY: I would say probably not in the 11 realm of a pollinator incident. Certainly, OWECA has 12 general guidance across various -- 13 UNIDENTIFIED MALE: Could an action item be to 14 develop one of them for training for the primacy 15 partners? 16 MR. BRADBURY: Yeah. What I was going towards, 17 and maybe look to Marylou to maybe help with APCO and 18 SFIREG to work with OWECA, OPP, and members of the work 19 group, to get a survey across the states and with 20 regional input. Region 9 is our lead region. At least 21 tabulate or document what's going on across the states, 22 or at the regional level at least, if not the state</p>

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1 level, in terms of the variability there in terms of
2 guidance at the state level, guidance at the regional
3 level, guidance at the national level.

4 Again, at least we'll know what we're dealing
5 with in terms of what's universe out there. Maybe at
6 least start a gap analysis in terms of what do we see.
7 At least that's information from which to then figure out
8 what's the next most logical step. I throw that out as a
9 proposal.

10 UNIDENTIFIED MALE: My comment actually is on
11 the same lines but a little bit different approach. Is
12 it possible, looking at bullet item number two about
13 standard process, to set up a template for a 682 for
14 pollinator protection or pollinator incident like that?
15 Has that precedent ever been done for a template?

16 MR. BRADBURY: Tom will shake his head yes or
17 no, but I think we do. It's on our website. So, one of
18 the challenges is that there's so much information people
19 don't want to enter it all.

20 Let's go Gabriele and then Mike and then move
21 on to the last one.

22 MS. LUDWIG: Well, coming back to trying to

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1 prioritize what to do, basically, this whole discussion
2 about coming up with standardized protocol. I think
3 that's something we can make progress on between the
4 entities you just mentioned and, as I say, it sounded
5 like registrants also have some protocols they were aware
6 of. I don't know if they are from the same source or
7 not, but that came up yesterday in the discussion.

8 I think the other issue is also trying to
9 figure out some more about what it takes for the incident
10 reporting. That sort of falls into this as well. Again,
11 sort of understanding what the issues are with the
12 current systems. I like Peter's idea of looking at
13 models that work for quick reporting. That's something I
14 think we can also do, at least get that together and
15 figure out some of what works and what doesn't.

16 MIKE: Very quick. I believe it was Ian Kelly
17 from Bare (phonetic) who actually mentioned that there
18 was a series of templates that he offered. So, I think
19 we just need to make contact with Ian to see what those
20 things look like for investigative purposes.

21 MR. BRADBURY: Cheryl, then Susan, and then
22 we're done.

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1 CHERYL: Okay. So, I'm going to show a little
2 ignorance. From a registrant's point of view, I know
3 what 682 is. I also know that somebody has to have
4 identified and told us as registrants before we are
5 required to report in 682. So, if somebody has a bee
6 kill, the first thing is what caused the bee kill.
7 Somebody else has to figure out and then come all the way
8 back to the registrant before you're going to get a 682
9 from a registrant on a particular compound.

10 Are there other requirements for 682?

11 Otherwise, solving the 682 reporting issue doesn't do
12 anything. It's figuring out how to do the investigation
13 so that that information is communicated.

14 MR. BRADBURY: You're making a fair point and I
15 think your observation is embedded in some of the tasks
16 this group will start to do in terms of synthesizing the
17 different components.

18 Susan.

19 SUSAN: Along those same lines, I'm not sure
20 that the average pesticide user knows that they're
21 supposed to go to the manufacturers to report incidents.
22 So, kind of reiterating what we've already discussed,

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1 that reports to the states get forwarded on to EPA
2 headquarters so that you guys have a chance to note them.

3 MR. BRADBURY: Okay. So, let me try to
4 synthesize this group's efforts. So, one effort will be
5 to try to tabulate or pull together documents, existing
6 guidance on investigations and enforcement process, SOPs.
7 We'll lean on our state colleagues to see if they can
8 help sort of synthesize that information.

9 Look at techniques that may be in play by the
10 registrant community. When they do get calls, they can
11 go out and try to figure out what happened. So, we try
12 to see what the state of the knowledge is or the state of
13 SOPs are, for lack of a better word.

14 The other important task is -- I thank Pieter
15 and Gabriele for reminding me -- is maybe our colleagues
16 at CDC can help us in taking a look at systems that are
17 in play that allow information to move quickly and
18 effectively to the right people. So, you've got to let
19 the registrant know if you think something is going on.
20 Or, you can let the feds know or the state know.

21 Also regarding that is how do you let people
22 know we've discovered that if these combination of things

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1 happen, we seem to be seeing something. We're not sure.
2 How do you get that information out quickly to the
3 interested or the important folks out there? CDC may be
4 able to give us some advice on techniques you brought up.
5 So, the CDC can join in on this area and maybe help feed
6 some of that information in. That would be great.

7 Okay, let's go to the fourth thematic area on
8 labeling.

9 UNIDENTIFIED FEMALE: Maybe we can do this one
10 fast because, as you mentioned, I think that some of
11 these components have come in to some of the other
12 pieces. So, I mean, I boiled it down over the break to
13 really two things. I mean, the work group has a specific
14 charge in the first bullet that's under the charge that's
15 related to label language.

16 So, I think it comes into two areas. What can
17 be done to get label language enforced now? Certainly,
18 there's an education component to it. There's a
19 communication component to it. And then, what can be
20 done to improve label language.

21 So, again, I think the best way for this to
22 happen is to get a beekeeper, a registrant, an

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1 applicator, and a state enforcement person in the room
2 and talk about it so it can come out of these case
3 studies. We can take some examples of labels that exist
4 today that have very specific language about bees on it.

5 We can take some examples that people raise
6 that they think are not clear. And what needs to be done
7 to improve that label language. So, I think there's some
8 immediate stuff that can happen in the context of these
9 groups that you're going to pull together anyway.

10 MR. BRADBURY: Gabriele.

11 MS. LUDWIG: I think I agree those are very
12 good things to do. I would also encourage whatever group
13 or group of people tackles that to also take a look at
14 some of the court cases that have come up recently.
15 Interpretation in the court of law is what's driving
16 things in many cases. There's one incident where the
17 bees were accused of trespassing, which seems a little
18 odd. This is a case in Minnesota. So, there's some
19 really interesting things that need to be looked at
20 through the legal cases.

21 UNIDENTIFIED MALE: Is there any reason why you
22 can't have supplemental material on a label, either added

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1 in or a sticker on, that might help. Of course, that's a
2 nexus between labeling and education. But, it's a matter
3 of partnership between industries to do that. Is there
4 any prohibition on supplementing, adding anything onto a
5 label that way, or in a label?

6 MR. BRADBURY: Yes and no, and it isn't easy as
7 far as what's enforceable, what's not enforceable, what's
8 advisory. Then, how do you make sure what's on the label
9 people can focus in on? So, yes and how is sort of an
10 issue.

11 Gabriele.

12 MS. LUDWIG: Just to build on that, where I
13 think the discussion can go is talk about what kind of
14 symbols or language would be useful. I'm still a little
15 hesitant because there's still a lot of questions about
16 when such a language or when such a symbol should go on
17 the labels.

18 Also, just be very clear, changing labels is
19 actually very complicated. This is not always the
20 fastest route to get anything done. It doesn't mean we
21 shouldn't be tackling it, but I just want to be clear.
22 You're coming back to how you get something quicker.

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1 This is not the fastest route.

2 But I think some discussion about it would be
3 useful. I don't know if I would put that on for the next
4 six months because I think we're still at what's working
5 and what's not working. Then we can get into how can we
6 do it better, which would get at what you're talking
7 about, which is, are there some simple labels. I think,
8 particularly for the home uses, that's a big question
9 mark.

10 UNIDENTIFIED FEMALE: I'm told by my beekeeper
11 friends that there's a good symbol that would actually be
12 very helpful here, a circle with a flash across it and
13 bloom, no applications to bloom. That would be easily
14 interpretable. You could also say that there are many
15 toxicity properties of pesticides that would benefit from
16 symbols or symbolic representation of toxicity rather
17 than a big long string of words.

18 MR. BRADBURY: If you don't dismiss any of
19 those concepts or ideas and formats, labels will be in
20 the future. So, hold that thought.

21 But I agree with Gabriele -- and I think Cindy
22 was saying it, too -- I think our first step is to see if

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1 we can, with EPA helping, get a cross section of some
 2 labels that are on products now. We've done this before.
 3 We'll do it carefully so that all that's okay.
 4 Then, get some people together and start
 5 establishing what's on a label now that seems to make
 6 sense, and it's logical and it seems like people should
 7 get it -- I don't mean that in a negative way, but it
 8 seems clear -- versus where there are examples where,
 9 oops, that's pretty hard to figure out what EPA really
 10 meant when they wrote that down. Why was that there?
 11 So, we can start again to get a better sense of
 12 what the world is like out there, which then could help
 13 us think about next steps, which could be, how does that
 14 feed back into the educational programs we're talking
 15 about, how does that feed back into some of the training
 16 education? You can see where it could then plug into
 17 even the case studies in terms of how that could play on
 18 the case studies.
 19 So, I think surveying some labels -- Cindy, is
 20 that right -- and then (inaudible) at least some
 21 representative (inaudible) start to document what seems
 22 to be working, what's not working, sort of a gap

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1 analysis.
 2 So, for myself, on behalf of the program, I
 3 think that gives us a pretty robust set of activities to
 4 do over the next six months, which will be challenging.
 5 But, with help from the work group members, I think it's
 6 doable and we can make some progress. Kind of getting
 7 our information base clear, getting our gap analysis
 8 clear, and then I think that sets up the launching pad
 9 for the next steps that we take on.
 10 I'll thank APCO and SFIREG ahead of time for
 11 jumping in, and CDC for jumping in as well. We continue
 12 to work closely with USDA on this as well as we go
 13 forward.
 14 Thanks, everybody. That was helpful. I know
 15 we took quite a bit of time, but I think we made some
 16 progress. I thank all the folks on the work groups for
 17 that effort they put in, three meetings already.
 18 We're going to move on to our first update
 19 session. Again, the idea here is to give you a snapshot
 20 update on activities. I'm going to probably be pretty
 21 firm when I see name cards come up and not recognize them
 22 unless I see that we've got time maybe at the end around

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1 noon. If we're doing okay, maybe we can come back to the
 2 specific topics. But, right now, they're just going to
 3 report out. The first update from Rick is on spray
 4 drift.
 5 MR. KEIGWIN: So, in the interest of time,
 6 there is a five or six slide presentation, I believe, in
 7 your packet. I'm not going to go through that
 8 presentation, just give you a snapshot of where we're at,
 9 because spray drift has had much longer presentations at
 10 this meeting over the many years. Obviously, the work
 11 that has occurred, particularly over the past couple
 12 years, has been greatly informed by the efforts of the
 13 PPDC in the past.
 14 So, as you know, a couple years ago we
 15 developed and issued for public comment a draft PR
 16 notice. We received several thousand, in some cases tens
 17 of thousands, of comments relative to that proposed PR
 18 notice. The biggest issues we've discussed here before
 19 had to do with the language about drift that could cause
 20 an adverse effect or harm. We acknowledge that.
 21 Drift does occur. Small amounts of spray drift
 22 may, in fact, be inevitable, even under the most careful

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1 application scenarios. Many interpreted the "could cause
 2 standard" to be a zero drift standard. That was not our
 3 intention, nor does EPA believe that such a standard is
 4 currently feasible.
 5 In response to that and after some discussions
 6 with many folks up here around the table, as well as some
 7 additional stakeholder outreach that we've done, the
 8 current approach that we are analyzing and pursuing is
 9 one that would prohibit spray or dust drift that harms
 10 people or other non-target organisms or sites.
 11 As part of that, there's been a great deal of
 12 discussion with some groups about how harm intersects
 13 with the FIFRA adverse effects standards. EPA believes
 14 that both are wholly consistent. And there's a slide in
 15 your packet that goes through EPA's analysis of why we
 16 think the standard of harm or no harm is consistent with
 17 a standard of no unreasonable adverse effects under the
 18 statute.
 19 As part of that better definition or
 20 elucidation of what we mean by harm -- and some of this
 21 was in the draft proposal that we put forward a couple
 22 years ago -- there's a series of examples that are being

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1 developed, or have been developed, that define what we
2 intend by harm in the context of spray drift and focusing
3 on not having a negative physical impact on humans, on
4 the viability of beneficial insects and other non-target
5 species damage to agricultural commodities, as well as
6 other types of accedences, either water quality standards
7 or tolerance levels.

8 So, we're in the final stages of analyzing
9 those comments. We are in an internal agency review
10 process at this point. Our current goals remains trying
11 to complete this effort by the end of the year.

12 MR. BRADBURY: Thanks, Rick.

13 I'll turn it over to Marty now for two updates,
14 one on the PPDC work group on comparative safety
15 statements and then inerts disclosure.

16 MS. MONELL: So, as many of you may recall,
17 about three years ago this committee, the then committee,
18 asked the agency to consider the use of comparative
19 safety statements or logos on pesticide labels. We had
20 heretofore not consistently allowed it. A few slipped
21 through, but we basically had taken the position that
22 they were not appropriate for pesticide labels.

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1 But, in light of sort of recent consumer
2 interest and demand for information about the greenness
3 of products, we agreed that it would be the appropriate
4 subject of a work group. So, we formed a work group
5 under the auspices of PPDC.

6 About a year ago, we announced to this group
7 the creation of two pilot programs. One is to permit the
8 use of the DFE logo on pesticide product labels, where
9 the product was able to pass our sister organization's
10 DFE, Design for the Environment.

11 I'm sorry. I'm so used to acronyms. The
12 Design for the Environment is a screen through which the
13 chemicals and a product can be filtered and determined
14 whether or not it's appropriate for obtaining the DFE
15 logo.

16 Under this pilot, if a product makes it through
17 that general screen, it is then eligible to have the logo
18 put on the label if it also passes our requirements.
19 This pilot, I guess the focus of it is on antimicrobial
20 products. To date, we have had two products that have
21 made it through the DFE screen and our process, two
22 products that now bear the logo. There are four that are

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1 in cue.

2 We're also working on expanding this pilot to
3 enable us to get a larger breadth of products and
4 experience with the DFE screen. What they now go through
5 is called the general screen. There are other screens
6 that are more sector focused that we're going to try to
7 work with them to see if other pesticide chemicals might
8 be appropriate for including in this pilot, as well as
9 possibly biopesticides.

10 The second pilot, if you will, is one we call
11 factual statements. That is allowing pesticide product
12 labels to contain statements that are factual. The first
13 two statements that we thought were appropriate were die
14 free or fragrance free, something that is easily
15 determined through review of the CSF and something that
16 we felt that consumers would want information about.

17 So, thus far, we've had eight products that
18 have made it through the process in our screening or
19 enable that statement to be on the product label. We
20 recently -- and I believe we spoke about this at the last
21 PPDC meeting -- where we were encouraged by work group
22 members to look at biodegradability as a factual

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1 statement that perhaps ought to be considered for
2 placement on a pesticide product label.

3 We did a lot of work. We consulted again with
4 our sister organization, the toxics program that runs the
5 DFE, because they have a screen for biodegradability.
6 They keep a list of approved surfactants that we could
7 use.

8 So, what we've recently posted, because we knew
9 we wanted to go forward with this program, was a sort of
10 web guidance on how a product could be submitted to the
11 agency to enable it to make a statement about
12 biodegradability either of all of the ingredients in the
13 product, the entire product, or of the biodegradability
14 status of the surfactant in the product.

15 So, that's up and running as of earlier this
16 week, I believe. Several months ago, Kristie Sullivan of
17 the Physicians Committee for Responsible Medicine,
18 presented a proposal to our work group regarding animal
19 testing. It would involve the allowance of a factual
20 statement on a pesticide product label that the product
21 met essentially the registration requirements of the
22 statute while avoiding animal testing.

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1 The work group is very interested in this
2 concept and have agreed -- because it's complicated.
3 There's some nuances around. For instance, some of our
4 guidelines require animal testing. So, we have to work
5 around those kinds of issues.

6 So, we have a subgroup now that's going to be
7 led by Kristie that's going to be looking into some of
8 the options that we might entertain to go forward and
9 present back to this group for further discussion,
10 because we think it's a concept that is timely.

11 Lastly, we're looking at USDA's bio-preferred
12 program. This was a program that came about as a result
13 of reauthorization of the Farm Bill earlier. I think it
14 was 2002. It provides for the use of a logo -- actually,
15 it's called a mark as opposed to a logo, which is kind of
16 interesting -- on products that have been certified as
17 being bio-based according to very specific standards for
18 both the products themselves and the packaging.

19 You can go on the USDA web site and find this.
20 It's bio-preferred program. We're looking at a process
21 where we could integrate this congressionally mandated
22 program into our legal construct, if you will, for

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1 pesticide labels. So, stay tuned for more information on
2 that.

3 The second item that I have to update you on is
4 inerts disclosure. As you probably all are aware, I
5 hope, in response to two petitions that were submitted to
6 the agency that requested EPA require the disclosure of
7 all inert ingredients that had been deemed to be
8 hazardous under other environmental and other statutes,
9 that we require the full disclosure of those inert
10 ingredients on pesticide labels.

11 What we did in response to that was publish an
12 advance notice of proposed rulemaking seeking comments on
13 options for increasing public availability of the
14 identities of inert ingredients in pesticides registered
15 under FIFRA.

16 The comment period closed last spring. We've
17 been sorting through the several hundreds of comments,
18 while also considering our options under our statute. We
19 received a lot of comments that provided us with legal
20 analysis, on the one hand, of our constructs that
21 precludes us from mandating full disclosure to yes, under
22 the statute, you can require full disclosure.

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1 So, at the same time that we've been mulling
2 through the comments, we've also been addressing or
3 seeking to address the legal opposing points of view.
4 Our plan has been, and continues to be, that we will have
5 options for an approach that will increase inert
6 ingredient disclosure.

7 I mean, I think that the ANPRM is clear that,
8 as a matter of policy, the agency believes that we should
9 be increasing public availability of this information.
10 So, we're going to present some options to our office
11 director later this month or early November with the
12 ultimate decision on a regulatory approach to occur
13 sometime early in the 2012 calendar year. So, stay
14 tuned.

15 MR. BRADBURY: Thanks.

16 Now, I'm going to turn it over to Oscar Morales
17 who is the director of Information Technology and
18 Resources Management Division. He's going to give you a
19 demonstration and update on some new tools that have been
20 recently developed to help assist in what's going on in
21 the program.

22 MR. MORALES: Good afternoon. Nicos (phonetic)

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1 and I are what is standing between you and lunch, so I'll
2 try to make this quick. Since I'm the IT manager,
3 though, I must tell the people in here from EPA that have
4 been checking their Blackberrys, it's not yours or your
5 IT guys, but it's down. Some of you got the message, and
6 some of you don't. So, don't throw your Blackberrys
7 away. It's down for the agency at this time. For some
8 of you, you don't have anything. Don't know when it's
9 going to be up.

10 I'm here to give you a quick update on some
11 projects. As some of you may know, a couple of months
12 ago, internally we started a strategic IT process in
13 which we were going to first examine existing pesticides
14 processes to see if they needed re-engineering and then
15 to determine and to prioritize the IT that's needed for
16 any of these re-engineered processes, even given the
17 resource concerns that we have.

18 There are a couple of projects, however, that
19 we had already begun that I want to share with you today.
20 The first one is the electronic submissions. As some of
21 you may know, since 2008, we had the ability to receive
22 via CDs or DVDs electronic submissions. Roughly 10 to 15

28 (Pages 109 to 112)

<p style="text-align: right;">113</p> <p>1 percent of our submissions are electronic. These are for 2 section 3s, conventional, the UPs, tolerance partitions, 3 renewed and (inaudible) submissions. 4 We are about to launch something we're calling 5 e-DEL CA which is, in effect, a better version of what's 6 out there right now. It's a downloadable, simple-to-use, 7 program to help companies assemble e-submissions. Right 8 now, there's about 12 industries or companies that are 9 testing this software out in the last couple of months. 10 Once we collect their comments -- although 11 there haven't been many negative ones -- we are going to 12 make it available around the 20th of October for those 13 registrants that want to submit their EDST test orders. 14 We're trying to make it ready for broader use by the 15 rest. The instructions are going to be posted on the web 16 relatively recent. 17 Now, there are two demos that we are not going 18 to show here. We're just going to give you some screen 19 shots in a minute. But when you take a break or if you 20 want to at lunch, for the next couple of hours in the 21 break room, we will have a demo on chem search and on 22 inerts.</p>	<p style="text-align: right;">115</p> <p>1 Google-like search interface where we allow searching by 2 chemical name, cast number PC code, if you happen to know 3 that. 4 We've also collected a lot of synonyms, around 5 100,000 synonyms, to help drive this. So, if somebody 6 knows an obscure, say, IU pack name or ISO name, it will 7 help lead them to the right page. We have all these 8 pages organized by common chemical name. 9 Then, when you get inside of it, here's an 10 example for athrozene (phonetic). We can demo this for 11 you over in the room next door. But a wealth of 12 information about the chemical, a tab structure across 13 the top of where you can find regulatory actions, the 14 science reviews, section 18s and all the dockets that are 15 associated with that chemical. 16 MR. MORALES: Okay. The second demo that we're 17 going to have out there is what we're calling an inert 18 finder. Our division and the registration division got 19 together and posted this. This will allow a user to 20 search approved inert ingredients dynamically to see if 21 an ingredient has been approved for use, for food, non- 22 food, or fragrance use.</p>
<p style="text-align: right;">114</p> <p>1 The first one is chem search. We created it 2 because we realized we had so many public separate lists 3 of pesticides -- there was roughly 25 plus -- and they 4 were hard to find, difficult to navigate, and they didn't 5 really communicate the whole story of what happened to 6 AIs over time. For us, it was difficult to maintain so 7 many static web pages. 8 Chem search is a simple-to-use, online search 9 tool that provides users with a one-stop shopping for all 10 publicly available pesticide chemical information. It's 11 data that was published on the pesticide web site in 12 regulations.gov. It contains roughly 20,000-plus 13 documents, registration, re-registration, cleared science 14 reviews, public participation, and open comments, roughly 15 800-plus links, and links to other important resources 16 like the tolerance from ECFR and other agency's web sites 17 like NIH's hub chem. 18 Nicos is going to just roughly go over -- 19 NICOS: Just quickly, this application is not 20 yet live. It is in the pipeline to go live very shortly. 21 So, we hope to have it up on the web site within the next 22 couple weeks. This is what you'll see as a simple</p>	<p style="text-align: right;">116</p> <p>1 In inert finder, the ingredients are searchable 2 by ingredient name and by cast reg number. The results 3 also include status, approved status, synonyms, and food 4 use tolerance information from 40 CFR. And, as of about 5 two hours ago, it's now live on our web site. Again, if 6 you go to our demo, we'll give you that web page. 7 NICOS: Again, here's what you'll see when you 8 go to the web site. This is up live. Some background 9 information there at the bottom, the ability to search 10 again by the chemical name or the cast registry number, 11 if you know it. 12 On the left, there are some quick links to 13 dynamically-generated lists for the food use and non-food 14 use, the non-food use only in the fragrance list. Then, 15 if you went inside, you'll see, for instance, acetone 16 here is approved for food use. 17 There are some details about that, including a 18 hot link to the CFR site, which is sometimes a little 19 difficult for people to navigate. Also, there's some 20 information on approved for non-food use and a fragrant 21 list as well. 22 This will vary depending on the status of a</p>

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1 particular chemical. We're just hoping that this is a
2 little easier for people to navigate. It does not
3 replace the legal information that's published in the
4 CFR, but as a way to help guide you to easier finding of
5 that information.

6 MR. MORALES: Lastly, I wanted to remind you of
7 something that we discussed in past meetings, and that's
8 the new and revised PPLS. We've upgraded over 170,000
9 labels to make them text searchable PDFs. We've offered
10 now new ways to search, including searching by product
11 name or by company name. If you remember the old PPLS,
12 you had to know numbers.

13 We're also providing information on the status
14 of a product, whether it's actively registered or
15 inactive, and information on product transfers. I
16 strongly recommend if you haven't gone and checked out
17 the new PPLS, that you do so.

18 If you want to take a look at the demos on chem
19 search and inerts, my folks are going to be in the room
20 next door for the next couple of hours. They can let you
21 navigate and play around with it. Thank you.

22 MR. BRADBURY: Thanks, Oscar. We've got about

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1 five minutes. So, we can open it up for five minutes if
2 there's some questions. Then, we'll break at noon and
3 take advantage of the demos if you want. Then, we'll
4 come back at 1:15.

5 Cheryl.

6 CHERYL: So, the inerts database, how does that
7 relate to data compensation for approved inerts?

8 NICOS: Right now, we have a very simple flag
9 at the bottom of the page, which we can demonstrate to
10 you. It's just a big check mark. That check mark
11 indicates whether you need to contact the agency on data
12 compensation or not. It's basically a yes or no
13 question. There's some help text there. But it doesn't
14 have all the details, but it does indicate when you do
15 need to contact the agency. So, we send you to the
16 inerts branch for that.

17 MR. MORALES: Let me just add that we're going
18 to be having the inerts, this particular inerts finder,
19 as part of the chem search eventually. Right now, we
20 just have the AIs. It's going to be a one-stop place
21 literally by merging them together.

22 MR. BRADBURY: Caroline, Gabriele, and then

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1 Susan.

2 MS. COX: A quick question for Marty about the
3 inerts disclosure time line. It seems like that time
4 line has slipped a little from what you said in the past.
5 Am I correctly interpreting that?

6 MS. MONELL: No. I said it has always been
7 October that we would present the options to the decision
8 makers. I did recently just say it might be the first
9 week of November, if it's not by the end of October.
10 That's because of things like this. You know, we just
11 get pulled in different directions. But our basic time
12 line is the same as it's been for the past six months.

13 MS. LUDWIG: This is for Rick in terms of the
14 spray drift. You said by the end of the year it would be
15 completed. Does that mean, then, you start putting the
16 language on the label? What does completed mean, because
17 I need a reminder?

18 MR. KEIGWIN: In terms of completed, what we're
19 looking for is issuance of the PR notice by the end of
20 the calendar year. The PR notice will go into an
21 implementation or a description of how we would go about
22 implementing and phasing in the new language.

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1 MR. BRADBURY: Susan, Matt, and Allison.

2 SUSAN: This is a quick one for Oscar, I guess.
3 Will all of the old links break?

4 MR. MORALES: Eventually, of course.

5 NICOS: Well, not immediately. When we do
6 launch chemical search in the future, we are going to
7 have a transition period from the old static pages of the
8 lists of fact sheets or re-registration/registration
9 review, what not. So, we'll put a banner on the top of
10 those pages which will indicate that you should try
11 chemical search for a while. But yes, eventually those
12 pages will come down and they will be redirected to
13 chemical search.

14 For inerts, nothing is going to break. It's
15 the same. This is a new feature. So, nothing will break
16 in that area.

17 SUSAN: What about the documents that were
18 archived on the CD? Will those be available? These were
19 a lot of documents on the OPs and their re-registration
20 process that got archived off of the EPA server and off
21 of the docket even onto a CD that you have to ask -- I
22 don't know what it is now, but you have to ask for it

30 (Pages 117 to 120)

121	<p>1 specifically. Will those documents be included in chem 2 search?</p> <p>3 NICOS: I will check into that. I'm not 4 familiar with that. Right now, we are linking to the 5 stuff that is live in the dockets. But if it's been 6 removed from a docket, I think -- I'll have to check on 7 that and see.</p> <p>8 MR. KEIGWIN: There was a size of files issue 9 that we had to a certain point remove information. As 10 Susan said, people now have to request a specific CD from 11 us. So, let's have a discussion about how to best make 12 that available in a more user friendly manner for 13 everybody.</p> <p>14 NICOS: I think now we can do that, so we will 15 look into that.</p> <p>16 DR. KEIFER: I realize that this is probably 17 anticipated to be used by people other than clinicians, 18 but is there some way to link this information to 19 information about the toxicity that would be useful to a 20 clinician, or treatment, or the green book that Jimmy is 21 writing, or something like that?</p> <p>22 NICOS: We can certainly, and we've been adding</p>	123	<p>1 recommendation, we bring them back to this group as being 2 pilots, proposed pilots or extensions of pilots. So, 3 we're not changing pesticide policy or regulatory 4 guidelines; we're proposing pilots to see if these kinds 5 of approaches to labeling issues or the like would make 6 sense in the long run.</p> <p>7 MR. BRADBURY: Okay. I want to thank everybody 8 for a really good morning. I appreciate the input and 9 the efficient, effective discussions. The demos are next 10 door.</p> <p>11 UNIDENTIFIED FEMALE: You should have some 12 options to eat, meet, and play. If you don't have them 13 in your folders, they're right outside.</p> <p>14 MR. BRADBURY: Okay. Then, we'll be back at 15 1:15 based on this clock. So, see you in a bit. 16 (Whereupon, a luncheon recess 17 was taken.) 18 19 20 21 22</p>
122	<p>1 links to other government resources such as you'll see in 2 there. We've linked to EPA's DSS tox database. We're 3 linking to the substance registry service. So, we can 4 add more links. Generally, EPA's policy, though, is that 5 we can link to other governmental resources, but we don't 6 link to stuff that's privately published, as a 7 generalization.</p> <p>8 There are some exceptions to that. But if you 9 have suggestions about things that would be useful to 10 you, we can certainly add them into what we have now. 11 But we have quite a lot of web services already set up.</p> <p>12 MR. BRADBURY: Allison, and then we'll take a 13 break.</p> <p>14 MS. STARMANN: For Marty's presentation, the 15 things that you're considering about the human or no 16 animals testing and the bio-preferred, will those either 17 pilot or consider things be available for public comment 18 or how will that be rolled out for broader participation?</p> <p>19 MS. MONELL: What we have historically done, 20 since the work group is convened on the auspices of this 21 committee, PPDC, we bring proposals once they're fleshed 22 out pretty much, and that we have a unanimous</p>	124	<p>1 2 AFTERNOON SESSION</p> <p>3 MR. BRADBURY: Before we get started, Virginia, 4 if you could introduce yourself to the crowd.</p> <p>5 MS. RUIZ: Thank you. I'm Virginia Ruiz of 6 Farmworker Justice here in D.C.</p> <p>7 MR. BRADBURY: Thanks.</p> <p>8 Okay, so this afternoon we'll have two sessions 9 that are fairly extensive report outs from a couple more 10 work groups. The first one being a report out and get 11 some feedback from the full committee on integrated pest 12 management.</p> <p>13 Keith Matthews, Director of the Biopesticides 14 and Pollution Prevention Division, will kick it off. 15 But, as I understand it, like the previous groups, we'll 16 get report outs from work group members on where they 17 are, where they're heading and get some feedback from you 18 all. So, Keith, take it away.</p> <p>19 MR. MATTHEWS: Thank you, Steve. Good 20 afternoon, everyone. So, yes, I am reporting out on a 21 work group meeting that we had yesterday for the IPM work 22 group. We actually have a group of very experienced and</p>

125	<p>1 IPM experts who are working with us on this work group. 2 What I'm going to do is we actually -- this is 3 the first face-to-face meeting that we had of the work 4 group. So, we had a fairly useful introductory 5 discussion. Then we broke up into two subgroups. So, 6 I'm going to speak to the introductory portion of our 7 meeting. Then, we're going to have report outs from 8 subgroup one, which will be Marc Lame, and then subgroup 9 two. 10 Cindy, you and Dave are going to do subgroup 11 two? Yes. Then, we'll have Dave Tamayo and Cindy Baker- 12 Smith will report out for our subgroup two. 13 So, if I may, the first thing I'd like to do is 14 just review for everyone the charge for this particular 15 work group. So, this work group will provide advice to 16 the agency on one, the development of metrics to assess 17 the effectiveness of the new school IPM initiative, and 18 two, on appropriate ways to assess quantitatively the 19 benefits of IPM and agriculture public health setting and 20 schools, and three, other issues relating to the 21 promotion and use of IPM that the agency brings to the 22 work group. So, at present, we're only dealing with</p>	127	<p>1 school IPM front in terms of moving forward. Had some 2 discussions to kind of look into different options for 3 how we as an agency will organize this new initiative. I 4 will report that we're making progress. 5 One thing that I did promise to our subgroup 6 was that as soon as we actually have a plan going 7 forward, a concrete plan going forward, then I'll share 8 that with the work groups. Then, everyone will know kind 9 of how we are planning to move that forward in the 10 future. 11 So, once I had kind of explained that, then we 12 got into -- this is the work group as a whole -- got into 13 a general discussion of IPM itself. So, we began with 14 the statutory definition of IPM, or at least one of the 15 statutory definitions of IPM. 16 There's a definition in the Food Quality 17 Protection Act which defines IPM as integrated pest 18 management, as a sustainable approach to managing pests 19 by combining biological, cultural, physical, and chemical 20 tools in a way that minimizes economic, health, and 21 environmental risks. 22 So, we had a fairly robust discussion in terms</p>
126	<p>1 charge one and two. 2 So, to begin, the work group meeting yesterday, 3 I started off with a review of the work group mission and 4 an update of school IPM activities at EPA. This was 5 actually fairly important because, as was pointed out by 6 more than one member, to the extent that we're asking for 7 advice on the development of metrics to assess the 8 effectiveness of the new school IPM initiative at EPA, it 9 would be good to know what's going on with the new school 10 IPM initiative. 11 I had to apologize somewhat to the group 12 because, quite frankly, the development of that 13 initiative is still in the formation stage. It's still 14 fairly formative. We have a number of ideas that we are 15 working on within the agency, both the headquarters and 16 our regional offices, in terms of what's going to be the 17 actual structure of the school IPM initiative going 18 forward. 19 We don't have any final decision yet made in 20 terms of how that is going to be structured, but we are 21 moving forward. In fact, this morning I had a meeting 22 with a number of our regional representatives on the</p>	128	<p>1 of, well, looking at that definition, are there things 2 that we would add to it, are there things that we would 3 detract from it? To the extent that we are asking the 4 work group to help us develop metrics to assess the 5 benefits of IPM, well, it's useful for everyone to have 6 the same definition going forward in terms of what 7 exactly are we assessing the benefits of. 8 So, the ultimate recommendation was to just 9 keep it simple. Since we have a definition of IPM, it's 10 a definition that's been codified into a statute, why 11 don't we just keep that and just work with that as 12 opposed to -- and this is after about a 45-minute 13 discussion of different ways that we could alter or 14 improve upon the definition -- why don't we just stick 15 with the definition that we have. 16 So, there was also a bit of discussion in terms 17 of what constitutes IPM. IPM, of course, is managing 18 pests, minimizing health risks, reducing associated 19 costs, how to measure risks or risk reduction. There was 20 a definition given of social risk, which equals exposure 21 times toxicity plus outrage. 22 We also had an enumeration of benefits that the</p>

129	<p>1 work group perceives to come from the use and the 2 utilization of IPM. So, some of the benefits that were 3 enumerated were that it provides alternatives for 4 conventional pesticides. These may actually result in a 5 lower number of applications, fewer pest complaints. You 6 can have IPM both before and after the utilization of 7 conventional pesticides.</p> <p>8 There are impacts, beneficial impacts, on non- 9 target species. There may be decreased risks to non- 10 target species, including humans from the use of IPM. 11 One way to look at IPM is to consider acceptable 12 practices such as monitoring, inspection, prophylactic 13 treatments, eliminating food, water, and shelter.</p> <p>14 A concept that came out is that IPM is a 15 process, and that it must be verifiable. This is 16 something that we actually are paying a lot of attention 17 to in the school IPM context. One of the things that we 18 want to make sure as we go forward with the school IPM 19 initiative is that the increase in the utilization of IPM 20 in the school setting is verifiable.</p> <p>21 It's one thing to say that -- and this came out 22 in our subgroup discussion, and Marc may get into this --</p>	131	<p>1 given the charge that we gave the work group, is, well, 2 what is EPA's strategic plan for school IPM? In the 3 school IPM initiative, what is your strategic plan?</p> <p>4 We don't really have a "strategic plan" right 5 now. We have an overarching goal. That overarching goal 6 is to increase the utilization of verifiable IPM in the K 7 through 12 school system. In terms of a strategic plan 8 for how we get there, that's coming. That will come as 9 our organizational structure for the school IPM 10 initiative is further fleshed out and established.</p> <p>11 So, with that, I think I'll leave that as our 12 introduction to our work group meeting and turn it over 13 first to Marc Lame to report out on the discussions that 14 we had for our subgroup 1. And then, after that, Cindy 15 and Dave will take over.</p> <p>16 MR. LAME: Thanks, Keith. Interesting group of 17 folks, and they worked hard yesterday. Also, a few of 18 them worked a little bit hard last night because they 19 sent me some additions. So, there's one extra slide in 20 here. Not any big surprise to anybody, but I did want to 21 say that.</p> <p>22 So, moving forward, what can we measure? We</p>
130	<p>1 it's one thing to say that we, we being an overall noun, 2 use IPM in our school system. But the question is, how 3 do you verify that? What constitutes IPM? Oftentimes, 4 you get different definitions for IPM. IPM in one 5 context may not be viewed as IPM in another context. So, 6 verifiable IPM is going to be a very important concept 7 for us going forward.</p> <p>8 Other benefits include reduced costs. A very 9 important benefit, which I think sometimes is not 10 discussed as much as it should be, is that you can 11 actually have reduced health care costs in the future. 12 So, if you're looking at chronic diseases or chronic 13 effects, the utilization of IPM, not using conventional 14 pesticides, can actually have benefits further down in 15 time from reduced chronic effects.</p> <p>16 Something else that we as an agency are looking 17 at more today in the present context is the resistance 18 management. IPM can certainly be of benefit in 19 resistance management.</p> <p>20 So, I guess the last thing I will point out is 21 that again another question that came up -- and this is 22 actually a very useful question -- for our work group,</p>	132	<p>1 can measure state and district policies. But, of course, 2 state and district policies have been measured before and 3 have been used as an indicator. Well, they're doing IPM 4 because they have a policy. I've heard this at the 5 district level and I've heard it at the state level. It 6 doesn't mean much, but it is one measure. Actually, MPMA 7 has done a really good job of measuring the state 8 policies, and they've been doing so for years. So, they 9 have that together.</p> <p>10 Implementation programs can be measured as far 11 as educational activities, demonstrations, et cetera. 12 Models of integrated pest management can be measured, not 13 only that there's a model in place but what kind of model 14 is it.</p> <p>15 It can be an in-house model, where in a large 16 school district, like a county-wide school district, they 17 can -- Mike Page mentioned this -- that you would 18 actually hire somebody that would just be in charge of 19 running the pest management for the district as a 20 professional.</p> <p>21 Then, of course, another model would be using a 22 contractor, a pest management professional, a firm on the</p>

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1 outside. Those can be measured. As well can be measured
2 is the procurement instruments, the contract itself. Do
3 they have verification standards and are those standards
4 being met?

5 Verified best management practices, such as
6 monitoring, training, treat as needed, documentation, as
7 well as other best management practices, those can be
8 measured. In fact, a number of these things have been
9 measured for years with IPM Star with the IPM Institute
10 in their certification program. So, this has been done
11 for a long time.

12 Risk reduction can be measured. We had a
13 discussion on that. That's probably going to take a bit
14 longer. Risk reduction, the technical definition of risk
15 is toxicity times exposure. So, one of the things that
16 we've been doing for years is measuring risk reduction
17 just by looking at the number of applications as a matter
18 of exposure.

19 Toxicity should and will be measured. Because
20 it's such a hot topic, we can still look at risk
21 reduction by looking at reducing the number of
22 applications. That's just one of the measures. Then you

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1 can also measure degree of partnership, which I will
2 explain later in this. There's more to come when we do
3 have a strategic plan.

4 In all fairness to the agency, this is
5 something that is in development right now. As Keith
6 just said, when they have it, they're going to give it to
7 us. That will help us more because it is difficult to
8 really put precise metrics to something until we have it.

9 Shift to integrated pest management program
10 requires added value for the school community. Our group
11 talked about the idea that this is something that the
12 school administration has to have the political will and
13 desire to do. It's what I called, when I gave a
14 presentation in our last meeting, demand side IPM. So,
15 in order to make this shift to integrated pest management
16 in schools, they need to see an added value, which
17 there's a number of different things that would be added
18 value.

19 Of course, this is, again, why we measure
20 things. Reduced risk to school inhabitants, reduced
21 administrative headaches -- for instance, pest and
22 pesticide incidents -- more efficient pest management --

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1 that goes to time and money -- school community approval
2 where the school community, in fact, approves of the
3 administrative efforts to provide a safe learning
4 environment.

5 Then, there are externalities. Every school
6 district that I've worked in that has successfully
7 integrated pest management has always mentioned that
8 their buildings, in fact, are maintained in a better
9 state than they were before. So, that's an externality.

10 I can also tell you that when it comes to bed
11 bugs, schools that I've worked with that have an
12 integrated pest management program in place are usually
13 asked to be part of the leadership in a community
14 regarding bed bug management.

15 It also requires partnership. So, you can see
16 the different facets. I left out nursing. I wanted to
17 mention that before you got me, Robin. In the school
18 district, we've gone from the old PCO as an exterminator
19 to a pest management professional that, in fact, is
20 partnering with the school. There has to be a
21 partnership. It's a two-way street to figure out the
22 problem and to fix the problem. Pest prevention is

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1 everyone's job.

2 So, this partnership that can be measured and
3 is required for integrated pest management is a
4 documented and evaluated working partnership of a trained
5 diagnostician/educator in the school community based on
6 pest monitoring and information sharing regarding how to
7 monitor, how not to attract pests, how to exclude pests,
8 and how to control pests with the safest, most effective
9 methods. All of those are measurable.

10 Other partners for demand side IPM, that part
11 of IPM that is value added for the school district
12 administration, is that there needs to be state and local
13 change agents, state lead agencies, universities, health
14 departments, pest management professionals, and
15 children's environmental health advocates. They would be
16 examples of those types of change agents.

17 Federal facilitators would fall under that as
18 well, but with the particular role of providing support
19 and facilitating the partnerships. Within EPA, we
20 discussed the idea that the Office of Pesticide Programs
21 would work with children's health and Indian
22 environmental programs. The USDA and the CDC also are

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1 working on school IPM. Again, there are opportunities
2 for everyone to work together on this. This degree of
3 partnership is measurable.

4 Existing tools for metrics -- this slide I
5 don't believe is in your packet -- these are just --
6 school IPM has been going on for quite a while. I know
7 that we have 16 years worth of project reports that were
8 required and delivered to EPA as a funding agency for
9 school IPMs. So, 16 years of those -- and we had to put
10 down what did we accomplish and what were the outcomes.
11 So, those are metrics right there. It's something to
12 look at and go back and list what works.

13 Also, there are logical models for a number of
14 different IPM programs, including school IPM, where
15 they're looking at the short-term, the mid-term, and the
16 long-term outcomes. They're evaluating those outcomes.
17 Those are already out there. So, the point of the slide
18 is so folks know that even though this is an initiative
19 from the agency, the agency has been doing this for a
20 long time. The rap book goes back probably 20 years.
21 Folks have been measuring IPM for a long time.

22 There's a new tool that's out there, the iPest

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1 manager that Salt Lake City uses. It's an outstanding
2 web-based program that not only monitors and teaches, but
3 it also measures. It measures pest problems. It
4 measures pesticide applications, both type and amount,
5 that is available. Then, there was an attempt to do a
6 school IPM report card, which there are good and bad
7 parts of. But, nonetheless, they can take the good parts
8 from that report card that was developed several years
9 back as part of a metric program.

10 So, our goal is to move from what we believe is
11 about 8 percent of schools in the United States that are
12 practicing verifiable IPM to 100 percent.

13 MR. MATTHEWS: Thank you, Marc. Do we have any
14 questions for Marc on the report out from subgroup 1?

15 Cindy?

16 MS. SMITH: I don't have a question for Marc.
17 I would just offer maybe a suggestion, Marc. I think
18 that putting on my school board hat, getting to school
19 board members is the critical piece of this because
20 they're the ones who approve the budget. So, they're the
21 ones that are wrestling right now with do I put money
22 into teacher staff and to books and to curriculum and to

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1 new playground equipment, or do I look at pest
2 management.

3 So, I think that your point about what's the
4 value proposition for schools is really an important
5 point. I think if you included some school board members
6 -- I don't know if National School Board Association is
7 the right place to go, but I think if you could get them
8 somehow engaged in your partnership discussion, because
9 they're the ones who are going to adopt the board
10 policies in a number of states and they're the ones who
11 set the budget for these kinds of things. So, there
12 might be an avenue there to talk to people about how they
13 do it that way, too.

14 MR. LAME: I couldn't agree more. I mean, they
15 are the elected decision-makers regarding schools, their
16 policies, and their budgets. So, that's very important.

17 The group also discussed the idea of what is
18 happening with school IPM. Most of us agree that it's
19 really moving into an exponential phase. Part of that
20 reasoning comes from the fact that in the past two or
21 three years, we have gone to many more school business
22 official meetings, plant manager meetings, and school

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1 board meetings, and association meetings. It's my
2 opinion that when you go to schools these days, they know
3 what IPM is; whereas, five years ago most of them did
4 not. That's my opinion.

5 MR. MATTHEWS: Robyn.

6 DR. GILDEN: Real quickly. I don't know if
7 this was discussed or I'm not even sure how it would
8 work. But when you say K through 12, is it public and
9 private schools or just public?

10 MR. LAME: For now, to begin with, we're
11 focusing on public schools.

12 UNIDENTIFIED MALE: This question is as much
13 for Geoff Calvert as it is for you two. Geoff, is there
14 some way the censor system could be used to monitor
15 decreases in pesticide reports from schools?

16 DR. CALVERT: As I said in my introduction, I
17 kind of oversee the pesticide poison surveillance program
18 across the country. We did write a report in the Journal
19 of the American Medical Association back in 2005 that
20 documented the numbers of pesticide poisonings associated
21 with pesticide exposure at schools, both pesticide use at
22 schools as well as off-target trips from agricultural

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142	<p>1 regard to not only pesticide use, but it would be nothing</p> <p>2 to put incidents on there. So, that would also work with</p> <p>3 CDC, with NIOSH in particular. Also, CDC is doing</p> <p>4 workshops for county and state public health folks</p> <p>5 throughout the country on insect and rodents, and that</p> <p>6 includes schools.</p> <p>7 MR. BRADBURY: Jennifer and then Tom.</p> <p>8 DR. SASS: What's the ability of people that do</p> <p>9 that kind of work with schools, like what you're</p> <p>10 describing to us, to reach out to daycares?</p> <p>11 UNIDENTIFIED MALE: Technically, it's the same</p> <p>12 as far as the type of pests. Of course, you're dealing</p> <p>13 with children and trying to protect them that way. So,</p> <p>14 there's a tremendous overlap. I would say this, that</p> <p>15 daycares are small businesses, typically. I mean, there</p> <p>16 are some like Head Start that are not. So, they have a</p> <p>17 different model of management. So, there is some</p> <p>18 difference. But as far as overlap and ability to do it,</p> <p>19 I would say yes.</p> <p>20 What do you say, Tom? You've actually</p> <p>21 certified both.</p> <p>22 DR. SASS: My question is to actually do reach</p>	144	<p>1 different projects. But they're pretty far along. They</p> <p>2 should have some good information on what works and what</p> <p>3 doesn't work.</p> <p>4 One of the things that they were doing was</p> <p>5 piggybacking on existing networks of providing health</p> <p>6 information and other types of information to that</p> <p>7 network of small businesses.</p> <p>8 TOM: One of the issues that didn't come up in</p> <p>9 your presentation, Marc, and I don't know if it came up</p> <p>10 in the session because I was on the ag side, was the</p> <p>11 potential benefit of increasing consumer and taxpayer</p> <p>12 awareness and appreciation for IPM by getting IPM in all</p> <p>13 of our schools.</p> <p>14 It's certainly one of the reasons that we got</p> <p>15 involved in school IPM back in 2000. Public awareness</p> <p>16 and appreciation for IPM is stuck in the mid teens, and</p> <p>17 it's been there since the early 90s, since Cornell has</p> <p>18 been measuring it periodically. You compare that to</p> <p>19 organic where nearly all consumers are confronted with</p> <p>20 organic every time they go in the store.</p> <p>21 IPM was just absent in the marketplace because</p> <p>22 it has no currency there because people have no</p>

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1 understanding of it or appreciation. That leaks out into
2 our public funding as well. Public funding through USDA
3 for IPM programs has declined by 36 percent since 2000
4 and by 29 percent since 2010. We really need to build
5 the public base of support for IPM, certainly in support
6 of organic and sustainable as well where funding has
7 increased on USDA.

8 So, I think the EPA should think about that in
9 their strategic plan as a real benefit. If we can get
10 IPM in all of our schools, it potentially has benefits to
11 agriculture as well down the road. If you want more
12 information about the IPM funding situation, you can look
13 at IPMvoice.org.

14 Then, my final comment, in terms of the timing
15 for the EPA's strategic plan for school IPM, it would be
16 great to be thinking about the IPM symposium in March in
17 Memphis, the 7th international IPM symposium, as a place
18 to showcase that. Assistant Administrator Owens is on
19 the planning program for that. EPA has organized a
20 session as well. That's the end of March in Memphis.
21 The last time we had over 700 IPM professionals there.

22 MR. BRADBURY: We're plugged into this to

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1 planning and getting abstracts.

2 Caroline.

3 MS. COX: I just wanted to add to what Dave
4 said about the California project regarding IPM and
5 childcare centers. They did produce some really nice
6 outreach material, kind of a handbook for doing IPM and a
7 little IPM checklist that a daycare center can hang on
8 its refrigerator. All of that stuff is available for
9 free download.

10 So, if anybody has contacts with daycare
11 centers and wants to send it out -- I mean, I think it's
12 oriented around pests that are important in California,
13 but it's probably applicable to the common pests in most
14 daycare centers.

15 MR. BRADBURY: Robyn and then Mark.

16 DR. GILDEN: I just wanted to mention that the
17 Children's Environmental Health Network also has a
18 nationwide program called the Eco Healthy Childcare
19 Program, and pesticides are a very big part of that and
20 IPM in daycares.

21 MARK: I know that in my discussions with EPA
22 on this, you can look at the funding. The funding for

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1 daycares for IPM in daycares goes back almost as far as
2 IPM in schools. It was a choice to look at schools first
3 with an idea of moving on to using IPM in other sensitive
4 accounts, daycares, hospitals, elderly care, because so
5 much of it is similar.

6 I can also say that EPA funded a program with
7 the Indiana Department of Environmental Management
8 probably eight years ago where they actually have a star
9 rating program for different businesses. One of the
10 businesses is daycare where IPM has to be part of it for
11 them to get that certification, and with lots of outreach
12 materials.

13 MR. BRADBURY: Geoff.

14 DR. CALVERT: So, I also wanted to make another
15 point about daycare centers. So, in that 2005 report
16 that I described that we published in the journal of the
17 AMA, we looked at rates of poisoning for adults, for
18 children over the age of five and for children under the
19 age of five.

20 So, for adults and children over the age of
21 five, the rates were pretty much stable, maybe decreasing
22 a little bit. But for the kids under age five, the

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1 daycare center kids, their rates were actually increasing
2 over time. So, I think that's another argument that
3 maybe we need to focus more resources on daycare centers.

4 UNIDENTIFIED FEMALE: Were there classes of
5 pesticides that rose or was it just in general?

6 DR. CALVERT: I don't think we drilled down to
7 that level in that report. We could probably do that.
8 When we update the report, we could explore that.

9 UNIDENTIFIED FEMALE: Because with the adult,
10 what we're seeing, not surprisingly, and maybe good news
11 or certainly a step forward anyway, is that the OP
12 poisonings are going down, right. But then we see like
13 pyrethroids and stuff sort of going up as their use is
14 replaced. So, the poisoning is less severe. The
15 endpoint is less severe, but we're still seeing that.

16 So, I was wondering if that trend was also in daycare.

17 So, I guess, maybe to recommend that this get
18 compiled, some of this really good information get
19 compiled with your work group so that it can be available
20 for us.

21 MR. BRADBURY: That was a good lead in. I was
22 going to ask Steve, Marc, in terms of your next steps for

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1 this part of the effort -- I greatly appreciate the point
2 where the strategic plan comes along. That provides some
3 focus, clearly. We're working, as Keith said, with the
4 regions and having meetings these last couple of weeks
5 and starting to get the structure together which will
6 help facilitate getting the function, the strategic plan
7 and the tactical plan, in place.

8 But, in the meantime, to what extent are some
9 of these sources you summarized at our fingertips, we,
10 collectively? Just idle and wait or is there some effort
11 that could be done in terms of cataloging, making sure
12 we're up to date? I imagine there will be different
13 aspects of these metrics you measure and will probably be
14 all relevant to some degree as we get started.

15 So, I'm just sort of curious are we in a
16 holding pattern or is there some effort that could be
17 helpful even though you don't know exactly what the
18 strategic plan is going to be yet?

19 DR. LAME: There is a lot of resources out
20 there. The Institute has compiled a lot of them. The
21 short answer is that I don't believe that we need to be
22 in a holding pattern. We have lots of stuff we can be

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1 moving forward on. It depends on what Keith feels the
2 work group can do. I know that anything I have anyone
3 else can have. There's a lot of stuff out there.

4 I do feel that there probably should be some
5 coordination with the measuring tools that we have right
6 now, at least to get them to where they are up to where
7 when the initiative really gets going, that they're going
8 to be used and they have lots and lots of measurements.
9 The work group can truthfully just catch up with that.

10 UNIDENTIFIED MALE: Actually, I think that's a
11 very good answer, Marc, so we will make plans and make
12 sure we're moving forward. While we, EPA, develop our
13 organizational structure and our strategic plan, that we
14 also involve the work group with making progress on the
15 data and information that's already out there.

16 MR. BRADBURY: One of the things I'm thinking
17 is insuring that this will all be public and posted and
18 what not for everybody to see. Obviously, we've got to
19 do some work internally to get the strategic plan
20 together. We have folks across all the regions that will
21 be part of that.

22 But if the work group can be helping to get

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1 pointers, examples, or illustrative activities that have
2 gone on using the various tools that this work group
3 defined to show sort of how it's working, that can help
4 inform some of the strategic and tactical planning that
5 will be going on.

6 So, I guess I encourage Keith and the work
7 group to think about some ways that make it easier to
8 drill into some good examples or some insights into how
9 these different metrics complement each other or maybe
10 sometimes confuse it because they're not --

11 I think you're getting at the point that
12 documenting some things doesn't necessarily mean other
13 outcomes are happening. It might be helpful to pull that
14 together. I know this sounds a little amorphous but
15 citing some real hands-on sort of cases studies or
16 examples might be helpful.

17 UNIDENTIFIED MALE: I was just going to say
18 that I'm pretty sure I understand what you're talking
19 about. We can do that. I can even think of how to
20 funnel it to Keith's group to where it's available to
21 everyone.

22 But I also note, Tom, you just completed a case

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1 study, right, or is it in the works on the economics?

2 TOM: We just finished the business case for a
3 school IPM document. That's on our website. We're also
4 creating a three-prong measuring tool, the second
5 generation of state report card in terms of what
6 activities are going on in the state, what laws are
7 present, how many FTEs in the state are working on school
8 IPM.

9 There's a school district level survey that was
10 piloted in Oregon last year and had over a 40 percent
11 response from each school district. So, we've revised
12 that and want to roll that out in every state over the
13 next year.

14 Then, the third piece is the PSP program and
15 the metrics for schools that want to participate in that
16 program and earn the highest level participation. So, we
17 have those three pieces that we can contribute
18 immediately.

19 MR. BRADBURY: Anybody else on this specific
20 topic? We'll have time if you could come back around and
21 sit back and take a look at the whole effort before we
22 wrap up the session.

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1 Keith, next group.

2 MR. MATTHEWS: Thank you, Steve. The second
3 subgroup was actually looking more generally at how best
4 to measure the benefits of IPM and agricultural public
5 health and other non-school settings. The genesis of
6 this charge actually came, I don't know, a year or so ago
7 when we were sitting around talking.

8 I'll admit that I'm somewhat new to this. I've
9 been involved with this for a couple of years, so I come
10 at it with a different perspective. Sometimes it's a
11 perspective of someone who just doesn't know. So, I was
12 talking to my branch chief, Tom Brennan, about well, Tom,
13 what's out there to determine or to help assess and
14 calculate the actual benefits of IPM?

15 IPM is one of those things that's feel good. I
16 mean, obviously, IPM is good. Everybody knows IPM is
17 good. But why is it good? How is it good? How good is
18 it? So, it turned out, in talking to Tom and to Frank
19 Ellis, that as far as we know, there really aren't good
20 metrics out there for really assessing the actual
21 benefits of using IPM versus non-IPM approaches.

22 So, we thought this would be an area where this

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1 particular work group could really help us at EPA out
2 because obviously, as I say, everybody knows that IPM is
3 a good thing, but sometimes you have to be able to
4 quantify how good it is. So, that's what this second
5 subgroup is working on.

6 Dave Tamayo and Cindy Baker are going to report
7 out on the discussions that our subgroup number two had
8 yesterday.

9 MS. BAKER: So, thank you, Keith. Dave and I
10 agreed that I'll do the first half and he'll do the
11 second half.

12 So, the specific charge for subgroup two was to
13 discuss the appropriate ways to assess quantitatively the
14 benefits of IPM and agriculture, public health settings,
15 and schools. So, we kind of carried into our work group
16 meeting the three buckets, what I called them, that Keith
17 identified in his introductory remarks, which were
18 managing pests, managing risk, and assessing cost.

19 Then, we just started talking about what are
20 some of the metrics that would target those three areas,
21 so things like, first and foremost, pest control. Did
22 you control the pests? What about resistance? What

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1 about treatment thresholds? What about training and
2 education about the best way to manage pests? What about
3 impact on beneficials? What about reduced exposure both
4 to the pests and to the treatment of the pests?

5 In the area of managing risks, we talked about
6 environmental impact. We talked about exposure. We
7 talked about toxicity. We talked about risk of the pests
8 to human health or crops or whatever the case might be
9 there, and managing the risk to human health. So, it
10 linked in quite nicely, I think, to the IPM definition
11 that is in FQPA.

12 We also talked then about assessing costs,
13 costs of controlling the pests, costs of not controlling
14 the pests, costs of health care related events associated
15 with pest control and ways to do that.

16 One of the themes that I think has come out in
17 Marc's remarks and in the discussion that we had
18 yesterday was let's not reinvent the wheel here if we
19 don't need to. I mean, to everybody's point, we've had
20 IPM around for a while. We've had some programs around
21 for a while.

22 So, let's begin by looking at things like Tom

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1 talked about, the national IPM evaluation group and the
2 logic models that they have there. Maybe start with
3 something like that and say, now what's missing, rather
4 than how do we start from scratch going forward with some
5 of these things. So, I think that's kind of the flavor
6 for how we try to put into buckets the different areas of
7 metrics we could assess there.

8 Dave is going to talk about information sources
9 and the rest of our discussion.

10 MR. TAMAYO: Cindy mentioned a number of
11 different areas we'd want to look at. So, we kind of
12 spent quite a bit of the session trying to brainstorm
13 where we could get that type of information, who could we
14 work with to help get us more information and interpret
15 it, and, really, kind of like what's a meaningful way to
16 use this information either to synthesize this or to
17 communicate it out or really understand what the heck
18 does all of this mean.

19 I'm going to reflect that we didn't really come
20 up with some grand answer of how to do this, but we did
21 come up with some ideas of existing places that we could
22 go for information and tools to use and partners.

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1 Some of the very clear sources of information
 2 will be pesticide use data. Obviously, California
 3 identified the California Pesticide Use Report database
 4 as a very strong source of data. I expressed a
 5 frustration that maybe we're going to be hampered in our
 6 ability to do this on a nationwide basis because there's
 7 not comparable information. There were alternative
 8 viewpoints that there actually are some private -- I
 9 think it's Doane marketing research has some data
 10 available that can be used to support knowledge of
 11 pesticide use patterns.

12 So, the data that's out there obviously needs
 13 to be used. We need to identify whether we need
 14 additional data. So, that's a question that needs to be
 15 answered, and what level of effort do we need to go to
 16 develop new sources. That was just kind of left hanging.

17 Now, a lot of the information sources are going
 18 to be from partners, people who are already very much
 19 involved in this, or, say, for instance, people in the
 20 health professions. The National School Nurses
 21 Association would be one source of information.

22 Where is the data that indicates where there's

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1 some health impacts associated with either pest pressures
 2 or pesticide use or a combination of the two? The
 3 American Public Health Association and trade associations
 4 like the American Mosquito Control Association. Then,
 5 some of these organizations that we might partner with
 6 might have some already really good systems for
 7 evaluating how good their IPM system works.

8 So, the Golf Course Superintendent's
 9 Association of America apparently works pretty hard to
 10 evaluate the IPM efforts of their membership. I hope I'm
 11 representing that correctly. But knowing that
 12 organization, I wouldn't be surprised.

13 Then, the Loadi Woodbridge Grape Growers
 14 (phonetic) have a Loadi Roles program, a sustainable
 15 vineyards program, that could be potentially a very good
 16 source of information and methodology, really, for how to
 17 do this.

18 It came up once again that there's a national
 19 IPM evaluation group. Some members of the group -- and
 20 I'm not that familiar with it, but a number of members of
 21 the group thinks that's a really great starting point.
 22 That's a tool that may answer many of these questions on

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1 how to evaluate this.

2 Now, there may be a need to develop data
 3 sources to plug into that or to get people to use it
 4 correctly. But that's actually an existing set of tools
 5 that seems like there's a lot of good potential to use
 6 that. That's obviously an avenue that we should explore.

7 It was mentioned that there's a system called
 8 Prime which is used for assessing the potential for a
 9 particular pesticide use at a particular place that are
 10 causing impact. It will rate the different potentials.
 11 So, I think that there's a tool that's available to look
 12 at both retroactively and looking forward to evaluate
 13 impacts anyway.

14 So, other partners that might be involved on
 15 this are the CDC, commodity groups. The National Potato
 16 Council apparently has done some good work in
 17 implementing an IPM survey of their growers. They may
 18 have some information that would be useful.

19 Then, there's various types of ways of looking
 20 at the benefits. Some of the things we came up with were
 21 looking at benefits of IPM. Some of them were looking at
 22 level of implementation, which I think is still a useful

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1 thing to do.

2 These are some kind of specific types of things
 3 that we might look at to give us some insight into some
 4 benefits that may have accrued from IPM. It's not clear
 5 how we would use these in some ways. So, for instance,
 6 looking at sales of particular products or active
 7 ingredients going up or down, but within the context of
 8 what was going on with the crop at that point.

9 Looking at crop profiles over the years.
 10 Apparently, there's a set of USDA crop profiles that look
 11 at how were these things done 20 years ago. I don't know
 12 what the time scale is, but it sounds like it was at
 13 least 20 years. What's going on now? So, were there
 14 reductions in pesticide use, pesticide exposure? So,
 15 those might be some very helpful sources of information
 16 for us to look at for what the benefits would be.

17 Looking at trends in equipment that are coming
 18 out. Are there more types of equipment that are being
 19 sold and made available to the users that are associated
 20 with IPM or reduced risk? Looking at other ideas or
 21 looking at EPA reduced risk registrations and tracking
 22 how chemical manufacturers and pesticide products changed

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1 through the years with respect to reducing toxicity.
 2 So, those are some examples of sort of looking
 3 at sort of more specific things. Then, I guess the one
 4 thing that seemed to be pretty clear to the group as a
 5 whole is that it would be really hard to just sort of
 6 mush everything together and say, yeah, there's an IPM
 7 benefit. You can't do that really on a national or
 8 regional basis necessarily.
 9 But the most useful way to look at it, or at
 10 least to illustrate it -- I didn't even think about it --
 11 is sort of like a commodity by commodity and maybe a
 12 reduced limited geographic areas, case studies. This is
 13 how it worked. These were the benefits. Looking at
 14 those in a fair amount of detail so that you understood
 15 that if a pesticide use went up or down, was it because
 16 of just the weather or a number of other factors,
 17 something to do with registration, or was it because
 18 people figured out how to do this better.
 19 But looking at specific subsectors in a
 20 sufficient amount of detail and with some very deep
 21 understanding of what actually went on there. We came up
 22 with three likely candidates. It was actually kind of

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1 agreed that if you looked at too big of an example, that
 2 it would be too complicated. So, maybe corn wouldn't be
 3 a good example because it's just so big and so varied
 4 across the country.
 5 So, we came up with potentially looking at
 6 almonds. There's a lot of information available on
 7 what's been going on with that -- so, we volunteered you
 8 to come up with a grand scheme of how to do that. Thank
 9 you very much -- and mosquitos and potatoes. Three of my
 10 favorite subjects.
 11 I think one of the clearest sort of action
 12 items was let's really work on that idea of figuring out
 13 how we're going to pick a case study and what would that
 14 be. I think that was pretty clear that we needed to do
 15 that. I think the overall sense was yes, we got some
 16 good ideas. Some of these ideas we need to develop
 17 further and come up with a more concrete way of looking
 18 at that. But let's say we made some good progress.
 19 I'd also like to say if that sounded a little
 20 rambling, that probably reflected the nature of the
 21 discussion, too. But we covered a lot of ground.
 22 MR. BRADBURY: Thanks, Dave.

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1 Mark.
 2 MARK: I actually think that USDA and USEPA
 3 have at their fingertips a lot of the kind of information
 4 that you're after in crops in the pest management
 5 strategic plan process, such that, for example, we just
 6 turned in one for apples and cherries this year. We
 7 updated our last one. They're very explicit, very
 8 detailed, have a lot of statistics, and identify a lot of
 9 the changes that have happened.
 10 In fact, the changes may not be going the way
 11 you think they are. Reduced spraying may be going the
 12 other way in some crops, things like that. So, there's a
 13 template out there for you to look at anyway. With
 14 invasives and things like that happening, it is going the
 15 other way.
 16 MR. BRADBURY: Robyn and then Gabriele.
 17 DR. GILDEN: I just wanted to say if you're
 18 interested in IPM in hospitals -- I think hospitals and
 19 health care are like the fourth largest sector -- there's
 20 an example of an IPM project with the Maryland Healthy
 21 Hospitals for the Environment and the Maryland Pesticide
 22 Network. They've been doing it for a long time. They

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1 have advisories and technical assistance. So, they have
 2 a lot of information, too.
 3 MR. BRADBURY: Gabriele and then Jerry.
 4 MS. LUDWIG: Well, speaking of case studies --
 5 and I have no problem with almonds being part of this,
 6 okay, because we do have a lot of information -- I think
 7 coming back to Mark's point, one of the case studies
 8 needs to be something where you do have a new pest coming
 9 in, whether it's apples on the East Coast or the wine
 10 grape situation, and how that got handled.
 11 We are finding a bunch of IPM programs being
 12 completely scrambled by new pests. So, I'm with Mark
 13 that some of this underlying assumption that everything
 14 is moving towards less product or lower risk products and
 15 that that's the only measure of success, it doesn't
 16 account for the biological variability. That's always my
 17 concern in these discussions, how do we account for that
 18 biological variability. I realize it's a hard question,
 19 but I'm just saying, how do we do that?
 20 UNIDENTIFIED MALE: One of the things that we
 21 discussed a little bit but didn't come to any conclusion
 22 on was the need to look at things on different scales.

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1 So, like, the example that you gave, there's a way of
2 approaching invasive pests as integrated pest management.
3 That's a larger scale than an individual commodity.

4 Then, the other thing is time, looking at
5 things over time. Certainly, it's going to go up and
6 down. Pest pressures are going to go up and down, some
7 reaction, and the need to adjust. Oh, if we do this a
8 little bit differently, then maybe we won't have that
9 problem in five years, after you've learned there's this
10 new pest or something else changed.

11 So, I think that's something that we really
12 need to look at. I think your knowledge of the almond
13 system could provide some really good examples of how
14 scale makes a really important difference in how you look
15 at things.

16 MR. BRADBURY: Jerry.

17 MR. BARON: As everyone else is making
18 suggestions, I'll throw one at you as well. Shortly after
19 FQPA, there was a process started from the agency
20 developing transition plans for a couple crops. I recall
21 Hetch Mino (phonetic) spent a lot of time on peaches.
22 There was a lot of collective effort put in, both by the

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1 agency registrants and USDA.

2 That may be one to at least track down that old
3 document and look at it, because I think it will give you
4 some real good baseline information of where we came
5 from, probably even more detailed than some of the
6 strategic plans, pest management strategic plans.

7 MR. BRADBURY: I've got a question, two
8 actually. Oh, sorry, Louis, go ahead.

9 MR. JAKAI: I just thought I should mention
10 that we need to talk a little bit about the fact that
11 IPM, no matter how we measure it or want to measure it,
12 is not static. It's a continuum. We look at time
13 periods. This is important, particularly -- Marc, I
14 think, mentioned something about turning in a new
15 strategic plan for apples.

16 I would assume that in that particular case,
17 even if they use a pesticide or saw a decline in apples,
18 with the brown (inaudible) stink bug, it's going to swing
19 back in the other direction. But that doesn't take away
20 from the fact that at some point there was a decline.

21 One would look at time periods. That's the way
22 we're going to have to look at it, not an indefinite time

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1 to make the point that there is a gain and there are
2 benefits to it.

3 UNIDENTIFIED MALE: So, I was part of the work
4 group with Cindy and Dave. You guys did a great job
5 reporting out. But after we met, I thought more about
6 the case studies and I realized that there's something
7 like what Ray mentioned this morning with the
8 pollinators, talking about the need for case studies,
9 looking at both the model programs as well as the
10 programs of what went wrong, what could we have done to
11 prevent that situation.

12 So, I'm thinking with our case studies, in
13 addition to writing up model programs, also write up
14 situations where IPM wasn't present. This is what
15 happened. Maybe if IPM had been adopted or used, we
16 could have prevented those problems.

17 With our pesticide poisoning surveillance
18 program, when we write reports, typically, one of our
19 recommendations is the need to implement IPM. So, we
20 have lots of case studies for the situation of what went
21 wrong for here. We'd be happy to share those.

22 MR. BRADBURY: Michael.

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1 MICHAEL: I'd like to add on to what Gabriele
2 said. Just a cautionary note. Mosquito control has been
3 conducting IPM for over 100 years. We do it because it
4 works, not because it lowers pesticide load. It's
5 because it works.

6 Lowering of pesticide load in the environment
7 is a welcome outcome of it, but it's not the reason why
8 we do it. That's not a distinction without a difference,
9 because once you go to where your goal is to lower
10 pesticide load, that gets warped in a lot of ways. It's
11 happened with mosquito control in the past.

12 Whereas, if you did an aerial application of
13 nyl lead (phonetic), which is a hot chemical -- I'll
14 admit that -- at one time in the season, you might have
15 foregone 8, or 9, 10 different applications of a less
16 toxic pesticide later on.

17 I've also run into situations where in the race
18 to utilize less pesticide or less adulticide, people are
19 saying, well, we've got an epidemic going on, and we need
20 a larvacide. No, you don't need a larvacide. You need
21 an adulticide. So, it's just a cautionary note.

22 I'm not saying that we should use adulticide

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1 right off the bat or anything like that. All I'm saying
2 is that if the reduction in pesticide load becomes the
3 goal and not an outcome of what you're doing, you're
4 going to run into problems sooner or later, at least in
5 mosquito control. With cockroaches, I'm not familiar
6 with that. But I'm dealing with potentially lethal
7 diseases here.

8 When you serve at the pleasure of the public,
9 you better be controlling mosquitos, regardless of how
10 you do it. But the best way to do it, again, is
11 integrated pest management. How we're going to measure
12 that is going to be very, very difficult, because the
13 ones that are not likely to be using integrated pest
14 management is the guy who is on collateral duty on the
15 roads department out in Lizard Thicket, Idaho.

16 We have no way of getting the information about
17 that person anyway. Whereas, if you go down to Florida
18 in the districts, yeah, they're very well represented and
19 they all practice IPM because it works. That's why we do
20 it; it works.

21 MR. BRADBURY: Caroline and Dave.

22 MS. COX: I'm part of the IPM work group but I

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1 wasn't able to attend the meeting yesterday because of
2 the conflict with the 21st century toxicology meeting. I
3 did have one thing that I just wanted to toss out, which
4 is, if OPP would really like to make a significant
5 commitment to IPM, I think that one of the really
6 important things that OPP could do would be to consider
7 IPM in the registration of pesticides.

8 A product that is a broad spectrum product and
9 is being used and the use that's being proposed for it is
10 a very non-targeted use for it, it really doesn't fit in
11 an IPM program. I think EPA should consider that in the
12 registration process and maybe with an eye towards
13 promoting registration of products and uses that are
14 really IPM compatible.

15 MR. TAMAYO: I just wanted to point out that I
16 am from Lizard Thicket. Actually, I wanted to make it
17 crystal clear that our discussion about IPM was not just
18 focused on how does it reduce pesticides. It also was
19 how does it provide better pest management. It's like a
20 co-equal goal.

21 The fact is pest management is what we were
22 talking about. The other things -- while reducing

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1 overall risks. I think it's risks from both pesticide
2 use and from the pests.

3 MR. BRADBURY: Ken or Marc, if you could
4 describe -- I won't get the words quite right, but the
5 State of Michigan has a program where growers can -- and
6 I won't have the label right, but the Minnesota
7 Department of Ag or Natural Resources looks at all sorts
8 of practices, worker protection practices. I think IPM
9 is included in that.

10 They go through a fairly rigorous evaluation
11 process, auditing process, to confirm that this cherry
12 producer or this apple producer is following (inaudible)
13 stewardship. I don't know if that's the right word, but
14 it's a process to go through. I'm pretty sure, as I
15 recall from visiting with you guys, that there is an IPM
16 or some aspect of pest management tactics that are
17 employed.

18 I was just wondering if you could share that
19 with the group. That may also be sort of a --

20 UNIDENTIFIED MALE: We have a certification
21 program in the state called MEAP. The MEAP program is a
22 grower -- it was initially a state program but the

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1 growers and landowners in the state really appreciated it
2 because what it does is that it puts them through a whole
3 series of things. For example, I'll just give you an
4 example out of cherries and the management of harvest of
5 cherries and delivering them to the processor.

6 These people in their warehouses in their
7 handling of water, in their pesticide applications, the
8 residues resulting from that process, all of that stuff
9 is monitored. They track it over a number of years. To
10 get MEAP certification in that arena, they have to meet
11 certain standards. When they get that MEAP
12 certification, then they're reviewed periodically. So,
13 that's an example of one.

14 Another one is, say, corn production. Such
15 considerations as rotation, chemistries used, GMOs are
16 not, what kind of runoff occurs, whether or not they're
17 using sustainable practices in terms of cultivation, et
18 cetera. So, that's another example.

19 So, MEAP certification is something that's
20 handled by the state. The standards are manual stick by
21 crop. So, to be MEAP certified, for example, I think in
22 the apple and cherry industry in Michigan, well over 70

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1 percent of the growers are certified. That would be also
2 targeting things like runoff, not only insecticide,
3 fungicide, rodenticide, but nutrient runoff would be a
4 real big target.

5 So, the standard is about 270 criteria long.
6 It's adjusted variously by crops. I think in terms of
7 (inaudible) crop growers in Michigan, a lower enrollment,
8 but in terms of acreage, very significant. Well over 50
9 percent of the growers I think in major areas are
10 certified.

11 So, it's a certification process across a whole
12 series of things, including hiring/firing practices,
13 management of people, et cetera. So, it's much more
14 comprehensive, but there is the pest management component
15 which is very important, and also the nutrient and water
16 use.

17 MR. BRADBURY: Thanks.

18 UNIDENTIFIED MALE: The question is, what is
19 the benefit to the grower? If you're MEAP certified and
20 you're selling into a marketplace where a lot of export
21 products today are run through a screening process and
22 you want to get your product to market, being MEAP

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1 certified in Michigan is huge, a huge opportunity for you
2 and market access. So, it's an assurance program put on
3 by the state.

4 MR. BRADBURY: Thanks.

5 UNIDENTIFIED MALE: Well, it is a voluntary
6 program. The State Department of Agriculture has a key
7 role in making sure that people are walking through the
8 process here. It is fairly rigorous in terms of what you
9 have to do to become environmentally certified. There
10 are different systems in terms of cropping, livestock,
11 farmstead, and so on. Some growers have achieved all of
12 those things; some have achieved some of them.

13 There are some regulatory advantages that you
14 accrue if you go through the process. That would be
15 along with some opportunities in the marketplace that our
16 growers are visualizing there. That's the hook to get
17 people to do things. It's a pretty rigorous program to
18 go through. It is not going to be free. You're going to
19 have to make some changes. It's a state program.

20 UNIDENTIFIED MALE: Another comment on that.
21 That is that fuel storage and management are all part of
22 that. Pesticide storage and management are all part of

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1 that. If you go into a meat certified farmer who is
2 storing pesticides on his farm, not only does he have to
3 have the fire end of it but he has to have the retention
4 capacity. The refrigeration processes, all of that, it's
5 a very comprehensive program.

6 UNIDENTIFIED MALE: I just wanted to mention
7 that there are a number of systems like that out there in
8 the private sector, too. The Food Lion, for example, is
9 non-profit certifier that requires IPM practices for
10 their participants. They certify millions of acres in
11 the U.S. The Rainforest Alliance is another, certified
12 mostly in Central America. Massachusetts Partners With
13 Nature is a now defunct program. But all of these
14 programs have measuring tools that help identify how much
15 IPM you're implementing.

16 These days, everybody is doing some IPM. The
17 question is really how much. These lists of standards
18 really give you a measurement tool to assess the state of
19 IPM in a specific crop and area, because all the key IPM
20 practices are there.

21 You can say the industry is doing 80 percent of
22 the available practices now; whereas, 10 years ago they

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1 were doing 40 percent. The potato industry is
2 implementing a large on-line survey this fall for the
3 first time using that type of model.

4 MR. BRADBURY: Gabriele.

5 MS. LUDWIG: A quick question to the Michigan
6 guys. Who pays for it?

7 UNIDENTIFIED MALE: Well, the Department of
8 Agriculture has some regulatory authority and they have a
9 couple of people on the ground to do those things. So,
10 there is some state money that goes into this training
11 and so on. But the producer is going to have to
12 implement some things on the farm to be able to qualify
13 with these.

14 I guess I couldn't tell you, Gabriele, how much
15 people spend to do this. Easily, in terms of some of the
16 things you're going to have to go through with some of
17 the engineering kinds of things and so on if you have to
18 make some changes, it could be in the thousands of
19 dollars.

20 MS. LUDWIG: I guess my question wasn't concise
21 enough. I would say for almonds, when we explored
22 certification, it didn't make any monetary sense. So,

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1 for us going with certification was just not an option.
 2 We do not see anybody paying us for the cost of doing the
 3 certification. What we do have is a voluntary program
 4 that is based on practices. The concept is the same as
 5 going through and defining what are the best management
 6 practices.

7 Actually, the pest management modules, rather
 8 than going by pest, is based on the IPM principles. So,
 9 what you do to prevent with a list of practices, what you
 10 do to monitor a list of practices, depending on what the
 11 issue is. Then, if you do need to treat, how do you
 12 decide when and how to treat a list of practices? So,
 13 the whole module is based on IPM.

14 It's also the same idea of best management
 15 practices, how many are doing what. But I just want to
 16 be very clear that for us, certification is an absolute
 17 no go because at the end, it comes out of the grower's
 18 pocket and we don't see anybody willing to pay for that
 19 substantial expense.

20 I'm not even talking about implementing any
 21 changes. I'm just talking about paying for the
 22 certification, someone to come on the farm and verify it.

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1 So, that's what I was trying to understand for the
 2 Michigan model, how is that working?

3 We are struggling with the question of what's
 4 in it for the growers, and would like to see some more
 5 tying it in with some of the regulatory issues.
 6 Certainly, in the marketplace it will make a difference,
 7 but that's definitely been, I'd say, one of our
 8 questions, what's in it for the growers?

9 UNIDENTIFIED MALE: Our program is not designed
 10 to be -- you go through a certification and so on, but
 11 it's voluntary. There's no requirement. We've got a lot
 12 of growers yet to go through this thing. Some of them
 13 don't necessarily resist but they just don't want to go
 14 through all of those things.

15 There is certainly a cost to the individual
 16 farm to be able to qualify with those. But again, it's
 17 voluntary and nobody is going to say you're going to have
 18 to do this.

19 USDA has some support systems for implementing
 20 various practices. With the marriage of the state system
 21 with the federal system for various conservation
 22 measures, fuel storage, sites where tractors are washed,

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1 et cetera, and capturing of the effluent from that
 2 process, there are federal dollars available in a
 3 competitive mode.

4 This MEAP thing shakes hands with that process.
 5 Some of the infrastructure resources come that way. But
 6 it's really true, as Ken said, that the growers are the
 7 ones who pay the price.

8 MR. BRADBURY: I didn't mean to divert us from
 9 the overall conversation, but I was just trying to
 10 explore some models that are in play that might have
 11 sufficient data, information, that can be part of those
 12 case study options we're looking at in terms of helping
 13 you take a look at some programs over time and get a
 14 sense of what kind of IPM practices were in place and how
 15 does that track with the various metrics.

16 People are talking about everything from
 17 effective pest control for resources invested and
 18 diseases averted to different patterns of pesticide use
 19 and how that all sort of lines up with different kinds of
 20 IPM practices or models that may be in play in different
 21 sectors.

22 I apologize if I diverted us a little bit, but

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1 it was a way to kind of probe about some other places
 2 where there may be programs and data that could be tapped
 3 to explore some of these.

4 The observation I had when I heard Cindy and
 5 David talk was at first I was going, where is this going.
 6 I was hearing all these different metrics from lower risk
 7 pesticide use to X, Y, and Z. I'm trying to think in my
 8 head about how all those things happened. How would we
 9 trace it back to trends in those parameters, including
 10 diseases averted or whatever, something like that, or
 11 productivity maintained and all these other metrics, and
 12 back to an IPM practice so you could sort of see how that
 13 plays out?

14 I was thinking some of the same things about
 15 over time pest pressures are going to change and systems
 16 have to be adapted. It's a combination of controlling
 17 the pests as optimally as possible and optimum from a lot
 18 of different perspectives.

19 Then, David sort of came around second base,
 20 coming towards third, and coming back to home plate. It
 21 started to kind of jell as to how we could maybe find
 22 some case studies that could get us some experiences and

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1 some insights as to how would you even do this and what
2 are some of the maybe straightforward ways to do it and
3 what would be some of the conundrums of trying to set up
4 a set of metrics that are actually tracking some of these
5 issues.

6 Tom and some others have been saying that some
7 of these things are in play. The idea is you could maybe
8 document people have done this following IPM practices
9 but then being able to link that up to mosquito larvicide
10 populations kept below a critical threshold or pests in
11 cherries kept below the economic threshold with less
12 dollars spent. I can imagine all the different metrics
13 that can be in play to do that.

14 I think it would be helpful if the work group
15 could continue to explore two or three different
16 scenarios. Maybe you would have to look at a wider
17 universe to figure out two or three that might be
18 practical and doable.

19 I think the hospital scenario would be a good
20 one to explore, as well as a mosquito control scenario,
21 public health pests, and then picking an agricultural
22 production system. Those three sectors seem like good

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1 sectors, the hospital and maybe something else,
2 retirement homes.

3 But that's sort of part of the world. Crop
4 production is part of the world. Public health pest
5 management control is part of the world. Don't try to
6 get the case study done over the next six months, but do
7 some research, if you will, to figure out which systems
8 have the highest probability of getting us the kind of
9 information that we could explore, how close we could be
10 to being able to track that, as well as what some of the
11 challenges are in terms of the information that would be
12 needed to link in IPM implemented, boom, boom, boom, but
13 also what are the outcomes of that in terms of all the
14 different components that IPM is all about, detecting the
15 pests early, what kind of components were put in play to
16 control -- at the end of the day, it's controlling the
17 pests efficiently, effectively, and safely. Try to avoid
18 pest pressure when you can. That's my spin on it.

19 Does that seem like sort of a reasonable charge
20 to that group? They could come back and say, okay, we
21 evaluated bing, bing, bing. For the following reasons,
22 we think these are three case studies that could, as

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1 Geoff said, illustrate how it's struggled, but maybe
2 complement that with some examples of (inaudible) can
3 actually start to piece the story together. I think the
4 time dimension is going to be critical.

5 UNIDENTIFIED MALE: A comment. I have a lot of
6 faith that we can develop a number of different cases and
7 scenarios that way. But, by way of advice to the agency,
8 it's my recollection that not too many years ago, you all
9 used to have a newsletter where different cases were put
10 out in the newsletter. Sherry Glick (phonetic) did that
11 with her interns some years back.

12 So, I'm one of these people that thinks if
13 folks are going to work and put these things together,
14 that they probably should be used. So, I would advise
15 the agency to make sure that there's some kind of way to
16 disseminate it appropriately. I'm not aware right now.
17 I'm confident that you would do it, but I'm just not
18 aware that that's going on anymore.

19 MR. BRADBURY: Let me make sure I understand.
20 So, assuming we did some case studies, making sure that
21 the outcome/results of those case studies were publicly
22 and widely distributed?

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1 UNIDENTIFIED MALE: Right. They can always be
2 thrown up on a web. But I know that there was some
3 newsletters that used to go out to folks. I know that
4 there was one on the economics of IPM in schools probably
5 five years ago or so. So, I just want to make sure that
6 there's an endpoint of the tunnel to where stuff actually
7 gets used out there.

8 MR. BRADBURY: I agree.

9 UNIDENTIFIED MALE: Steve, with respect to the
10 specific question that you asked, I wonder, Cindy and
11 Dave, do you two feel comfortable taking the initiative
12 and agreeing to that proposal for your subgroup in terms
13 of moving forward?

14 MR. TAMAYO: It's kind of funny because people
15 were deferring to us like we were in charge of it. I was
16 just the messenger. I'm not responsible for any of this.
17 It just really strikes me that that's kind of where we
18 ended up anyway. I would say that that's very consistent
19 with -- we didn't make an actual decision, but it seemed
20 that was the direction we were going.

21 MS. BAKER: I think my recommendation is we
22 threw out a couple of -- I'm not going to speak to the

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1 mosquitos or the hospital example because it's not an
2 area that I'm most familiar with. I mean, I think those
3 two should be in there because you want to get across the
4 spectrum beyond agriculture for sure to get the other
5 ones.

6 But I think we could take cherries, we could
7 take peaches, we could take apples, we could take
8 almonds, we could take potatoes. So, I think that the
9 discussion now needs to be around what's the best
10 examples to illustrate where we have some pros, some
11 cons.

12 I think because this is for EPA, kind of to
13 Mark's point, we're supposed to be giving you advice.
14 What did EPA decisions impact, or policies impact, any of
15 that IPM? So, I think we now need to take those and look
16 at where's the best example to showcase that. Then, work
17 with that commodity group to see if we can bring it
18 forward.

19 MR. BRADBURY: So, that will be the charge.
20 Let me ask Keith or any of the others on the work group,
21 do you feel like you've got the diversity of folks with
22 background in public health, pest control, or in the

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1 hospital setting?

2 You're in the group and Joe is in. Are you
3 willing to pitch in? At this stage, it's just over the
4 next several months to sort of identifying if there are
5 places or programs that could be useful for this
6 analysis, not necessarily doing it but just to do the
7 research to figure out which examples may have access to
8 enough data over a long enough period of time to sort of
9 illustrate how this might play out.

10 UNIDENTIFIED MALE: Just on that point, I'd
11 just like to mention the fact that this work group came
12 together more or less. People volunteered for the work
13 group. We did not go out and hand select folks. So,
14 given the way that it actually came together, I've
15 actually been very surprised and quite pleased with the
16 diversity that we have in terms of people's expertise.
17 So, for both subgroups, we have, quite frankly, a really
18 good mix of talents and expertises here.

19 MR. BRADBURY: All right. So, that will be the
20 game plan. We will revisit everything tomorrow morning
21 as we kind of document exactly what we're going to do
22 over the next few months. At least I've got in my head

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1 what the game plan will be.

2 So, thanks for the efforts of the members of
3 the work group and their presentations and discussions.
4 We'll take a 15-minute break, if I've got my agenda right
5 in my head, and we'll reconvene at 3:00 with the report
6 out from the 21st century tox work group. Thanks.

7 (Whereupon, a brief recess was
8 taken.)

9 MR. BRADBURY: We'll be into our last session
10 today that's based on work group activities. This work
11 group is our work group that's dealing with 21st century
12 toxicology risk assessment approaches. As its opening
13 slide shows, a lot of the concept that this work group is
14 dealing with flows from, in part, the National Academy of
15 Sciences report of 2007.

16 This review was commissioned by EPA, although
17 working in partnership with our colleagues in FDA and
18 NIH. The backdrop to that effort in 2007 was taking a
19 look at a number of different realities, realities being
20 that everyone, the government, the public, and the
21 regulated community, looking towards how the science was
22 evolving, and the fact that as the science evolves, you

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1 can probably be able to harness tools that allow us to
2 more effectively understand what the potential effects of
3 chemicals could be, pesticides in this case.

4 In the process of advancing that knowledge,
5 create the ability to more efficiently and effectively
6 get insights on the information that's needed to make our
7 risk assessments and to try to come up with ways that are
8 more effective, more efficient, in how we do the
9 business.

10 As a backdrop, all sorts of advances in
11 molecular biology and genomics and (inaudible) and the
12 tabalomics all starting to come into play about -- in
13 2005, even, we were starting to see how this was going to
14 change and some of the work that led up to the proposal
15 to go to the National Academy of Sciences. And
16 colleagues in FDA, same thing, realizing how information
17 that supports evaluation in drugs is changing rapidly.

18 This was going on in the U.S. and Europe,
19 similar insights and activities were ongoing. So, at the
20 OECD level, Organization for Economic Cooperation and
21 Development, countries across Europe, Asia, Australia,
22 North America were also seeing this change coming and,

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1 through OECD's efforts, were also trying to ensure that
2 this international harmonization on the new approaches
3 and techniques were going forward with toxicity testing.

4 This area is the very significant area of
5 investment by EPA, not just the Office of Pesticide
6 Programs, but also with the Office of Research and
7 Development and with our colleagues in the Office of
8 Water and other components of EPA that are realizing that
9 the change is coming in terms of technology and the way
10 to gather information and come up with more informed
11 decisions about the potential risk of chemicals and maybe
12 start to tackle some of these hard questions around
13 mixtures and subtle effects and how they relate to other
14 aspects of the biology of not only homo sapiens but
15 wildlife and other animals as well.

16 We've been working on the science ones, if you
17 will, with our scientific advisory panel and others in
18 the scientific community. We had a peer review through
19 the scientific advisory panel this past May in which we
20 laid out our directions in terms of advancing the
21 science. Our colleagues from the Office of Research and
22 Development were involved and other parts of the federal

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1 government, either some presentations or some sitting on
2 the review panels as well.

3 We sort of laid out sort of where we saw the
4 science today and what we could start doing today as well
5 as what the science was looking like several years out
6 and how to approach that. The report posted on the
7 scientific advisory panel's website was a very positive
8 report in terms of the direction the office was taking
9 and moving forward.

10 A very important aspect of that report was that
11 -- well, the good news is OPP is thinking in the future
12 and trying to be part of the future instead of chasing
13 the future. There's clearly no way our office can do
14 this by itself. It really can't do it by itself in EPA,
15 so they were happy to see Office of Research and
16 Development of EPA plugged into this and seeing the
17 significant investment the administration is making in
18 this effort.

19 But also, across the federal government there
20 needs to be a partnership and collaboration beyond just
21 the public sector in terms of the importance of
22 collaboration and open transparent peer reviewed manner

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1 with the NGO community, with the scientific community at
2 large, the regulated community, and the talents and
3 expertise that are in all those sectors.

4 Clearly, this all needs to come together if
5 you're going to make the breakthrough that needs to
6 happen. We have to harness all these resources and
7 talents in a coordinated fashion. Otherwise, we could
8 have a thousand flowers blooming, but you don't really
9 have the direction being set and the harnessing of the
10 resources.

11 So, consistent with this area being a high
12 priority in EPA and within our programs -- I just want to
13 make that clear, that we're really making investments to
14 go there. The change is happening. The question is, are
15 we going to chase the change or can we help with all your
16 input and advice, help make sure this change is
17 effective, open and transparent and gets done what it
18 needs to get done.

19 It was because the science was moving and we
20 knew that we were going to be part of sort of the science
21 (inaudible) part of this, that assuming the science is
22 really neat and it's like the best thing anybody could

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1 ever envision, if that science isn't evolving with
2 thoughts about how is this science going to play out in a
3 risk assessment and how does it play out into regulatory
4 decision making, it won't really matter if it was the
5 best gee-whiz science anybody came up with.

6 If that science isn't involving by
7 understanding the regulatory context of the science and
8 then the regulatory context and the policy context
9 evolving with the science, you could have real wasted
10 opportunity.

11 That's why we created this work group, probably
12 almost three years ago now, or at least the beginnings of
13 forming this about three years ago. We were all talking
14 about this in this context to complement what was going
15 on in the scientific federal advice that we get so that
16 as these tools evolve, we're thinking about how do you
17 appropriately start to put these tools into practice.
18 That's got to be in an open, and public, and transparent
19 manner.

20 So, long introduction but just to sort of check
21 in again about the importance of this, we think, across
22 the board. What Vicki will be talking about with members

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1 of the work group is -- one of the important areas that
2 our work group has been focused on came up at the SAP,
3 and you'll hear more about it.

4 If you look at that figure that comes out of
5 that NRC report, it really gets at this toxicity testing.
6 I think a lot of people have in their mind that it was
7 all about how we were going to come up with smarter ways
8 to use cell lines or other kinds of toxicity testing
9 paradigms to get the information to inform a regulatory
10 decision.

11 But that outer circle in that figure has a
12 component about population and exposure data. It's
13 actually a key part of that report that actually brings
14 the whole report back to where it needs to be in terms of
15 a pathway going forward. It's the importance of this
16 science and how it will help inform our understanding of
17 what's happening in the human population. Or, if we take
18 this to ecological, what's happening in ecosystems in
19 terms of the kind of information that the systems feed
20 back into our decision making?

21 So, how can this technology improve our
22 understanding of biomarkets for exposure and (inaudible)

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1 advance diagnostic techniques and medical settings, how
2 it could advance our ability to have more informed and
3 effective biomonitoring, how it can help inform more
4 insights, if you will, and I don't mean that in a
5 negative sense, but more advanced epidemiological
6 studies, because you'll have a better tool set of
7 biomarkers that can give us information in the
8 population, which is part of the overall process that the
9 NRC laid out.

10 That workshop that we had yesterday was getting
11 at some of those issues. With that, I'll turn it over to
12 Vicki.

13 MS. DELLARCO: I think I've become a regular on
14 the agenda to update you about what we're doing in this
15 work group. On the next slide, this is the charge of the
16 work group that we always put up. I've highlighted, by
17 underlining, in the box there.

18 From day one when we were discussing our charge
19 as a work group, it was realized among our members that
20 if we're going to change the paradigm, it had to be
21 holistic. So, we had to advance not only the science and
22 being able to better evaluate hazards that also advance

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1 the exposure science, too. So, both the toxicity and the
2 exposure are crucial components of the new paradigm that
3 we're envisioning.

4 When we had our workshop last December, in sort
5 of broadening the dialogue about our strategic vision in
6 this area, that was one of the key points that was made
7 during that meeting. We needed to have sort of a check
8 system in place if we're going to change the way in how
9 we evaluate hazards by using this new technology. We had
10 to know that that paradigm was working. So, it was very
11 important to put a population surveillance system in
12 place.

13 Stressing the need for biomarkers and new
14 biomarkers, simply stated, we need these biomarkers just
15 as reality checks, a feedback mechanism. If things
16 weren't working in terms of the new paradigm, we could go
17 back and make appropriate adjustments.

18 So, one thing that we've been doing as a
19 committee is sort of developing and holding these one-day
20 FACA workshops on key areas. Yesterday, we had one on
21 the topic of biomonitoring, looking at the state of the
22 science, the challenges, the opportunities.

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1 Really, the important goal of that meeting was
2 to stress the role that these tools play in different
3 perspectives in the clinical setting or in the public
4 health setting in terms of identifying what the pesticide
5 exposure has been, to manage that appropriately as a
6 surveillance tool, and the need for it in epidemiologic
7 research so it can better make those linkages between
8 exposure and disease outcomes that we see.

9 I would say that we had pretty good attendance
10 yesterday. There was over 100 people either in the room
11 or on the phone representing a broad group, people from
12 different parts of government. We had people from CDC
13 and OSHA, and, in addition, from EPA. There were people
14 from different universities attending. We had several
15 industries and various health advocate groups.

16 So, this is the program. The way the program
17 was set up, there was a science program to discuss some
18 of the critical issues around biomarker development and
19 the interpretation of biomonitoring, how it's been used,
20 the value of it, and what's on the horizon, what's new
21 that's being developed. Then, after, presenting a
22 discussion that science -- there was a panel discussion

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1 to begin looking at that science. How do we move this
2 agenda forward in terms of a regulatory approach or
3 framework?

4 So, let me just kind of highlight for you.
5 It's difficult to summarize a meeting that was packed
6 full of lots of presentations and discussions over our
7 entire day. So, what I'm going to do is kind of
8 highlight for you some of the messages I got out from the
9 presenters that resonated with me.

10 We started the meeting with critical scientific
11 issues. While biomonitoring provides a valuable exposure
12 approach, the interpretation is not so simple. So, it's
13 important that these studies are conducted appropriately
14 and that the data is interpreted very carefully.

15 So, we started with some fundamental technical
16 issues that cannot affect interpretation of biomarkers,
17 particularly the toxicokinetic properties of the compound
18 and how that can differ in different individuals and how
19 it can affect the concentration of the compound in the
20 body over time.

21 We also discussed some of the exposure issues
22 around biomonitoring with respect to the critical windows

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1 of effect when you do samples and some of the issues
2 about spot urine samples which is the common method that
3 is used.

4 I think one message -- we were lucky to have
5 two speakers who have a wealth of experience in this area
6 and in interpreting biomonitoring. That was Lisa Elward
7 (phonetic) and Dana Barr (phonetic). One thing that Dana
8 Barr said that resonated with me is that you have to
9 design these studies carefully, and you have to select
10 your biomarkers carefully for the question that you're
11 trying to answer.

12 So, it may not be the same biomarker or study
13 design, depending on what your purpose is, whether you're
14 a clinician and you need to diagnose overexposure or
15 whether you're conducting an epidemiologic study and
16 looking for causation.

17 She also stressed the need for repeated
18 exposure (inaudible) exposure over time and how important
19 it was to understand the impact of a variation within an
20 individual and variation among individuals. In fact,
21 that was something that kept coming up among the
22 different speakers.

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1 After we talked about the technical issues, we
2 moved to the next part of our agenda, which was the role
3 and the need for these biomarkers. Jimmy Roberts, who is
4 on the PPDC, gave a perspective from the medical
5 management need. I think one thing that Jimmy said
6 yesterday that resonated with me was that there's not
7 very many biomarkers. I think cholinesterase is about
8 it.

9 If we had more of a suite of biomarkers for
10 physicians and a way of testing, it would likely increase
11 the physician's ability to consider and diagnose
12 appropriately. They would be incorporating this more
13 into education programs. It was also important from a
14 public health perspective that it allows the provider to
15 reassure the patient or family that we can rule things
16 out.

17 Lynn Goldman (phonetic) talked about the work
18 that she has done with looking at poor blood samples in
19 the Baltimore area for epidemiologic research. She
20 stressed a number of important things. She was looking
21 for markers of epigenesis changes that can be associated
22 with outcomes in children. But she also was showing some

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1 of her results. We all know this, the reality is that
2 you're going to see exposure to multiple (inaudible).
3 That's the beauty of biomonitoring. It's more real-life
4 reality situations.

5 We also had Asa Bradman (phonetic) from the
6 Center for the Health Assessment of Mothers and Children
7 of Selenas talk about the work that he's been doing on
8 evaluating pesticide exposures in pregnant women and
9 children living in an agricultural community.

10 He also emphasized the message that although
11 people are exposed to many pesticides, they don't have
12 biomarkers for many of the pesticides other metabolites.
13 There's no laboratory method to measure these pesticide
14 specific metabolites in biological samples. This really
15 is a major limitation for the researchers who are
16 essentially acting as our post-market evaluators.

17 He also emphasized the need to evaluate this
18 intra/inter person variability in terms of exposure
19 because we are complex as individuals and we do handle
20 things differently. So, we can't look at average
21 characteristics or responses.

22 Matt Keifer, who is sitting next to me, talked

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<p style="text-align: right;">201</p> <p>1 about a case study, the Washington Cholinesterase 2 Monitoring Program, the value of that, and how that 3 information has been used. I think one thing that I got 4 from his talk is by having that program in place, it 5 actually increased the hazard awareness and it led to 6 improvements and overall workplace safety by guiding the 7 ways that you could reduce worker exposure. So, 8 monitoring can motivate change and practices. 9 The next part of our program was, okay, so 10 what's new, what's out there that's promising. We had 11 three different speakers. We had Dean Jones (phonetic) 12 from Emory University. He talked about an approach 13 that's called the Universal Exposure Surveillance as a 14 Component of Personalized Medicine. 15 So, it was sort of a -- it's hard to explain 16 technically, but I guess you would say it's a high 17 throughput method to look for exposure, high performance 18 metabolic profiling, where you can look at hundreds of 19 thousands of natural chemicals in the body, antibiotics, 20 in a very cost effective way. You can do this in 20 21 minutes. This is what we call metabolomics. Maybe that 22 will be another topic we'll take in another workshop.</p>	<p style="text-align: right;">203</p> <p>1 and put it in practice. There's still some more work to 2 be done. 3 After listening to all this science, we had a 4 panel discussion. There's six people on the panel that 5 represented different affiliations and perspectives. We 6 had somebody from state government, federal government, 7 FDA. We had industry representatives. We had academia 8 and health advocates. 9 The purpose of that panel discussion was to 10 share views on what could be the regulatory approaches 11 and policies, advance this issue. What would be some of 12 the challenges? In other words, we were trying to get at 13 some of the solutions to move forward. Also, what can we 14 learn from other federal agencies? 15 I think everybody who participated in this 16 meeting and on the panel agree of the need and importance 17 of biomarkers. It's a critical part of this 21st century 18 vision. Some of the things that I captured in my notes 19 that came out of the panel discussion is there is some 20 existing information. Perhaps we need to harness that 21 better. There's information that we have in OPP. 22 There's also information that various industries have.</p>
<p style="text-align: right;">202</p> <p>1 Actually, I think that does have a great deal of promise. 2 We also had Michael Alavonya (phonetic), who is 3 one of the lead epidemiologists in an agricultural health 4 study, talk about his work, particularly the next phase 5 that they're going into in terms of developing molecular 6 markers of particular diseases or cancers, especially 7 those cancers that are common in farm workers. 8 Then, we ended up with a speaker from NIHs to 9 see what they're doing and what they're sponsoring. This 10 was David Bowshaw (phonetic). They're funding a number 11 of things. It ranged from wearable badge sensors that 12 you could put on people and protect what their airborne 13 exposure is. 14 Also, making antibodies to unique chemical 15 adducted proteins or peptides. They had an immunological 16 method. That was more of a dipstick method. One method 17 they had developed is a dollar to do, and it was a very 18 quick assay as a diagnostic kit. 19 Although there is a lot of promising techniques 20 on the horizon being worked on, from what I heard and 21 what I understood, they're promising but they're not sort 22 of key-turn methods yet, off the shelf, anybody can do it</p>	<p style="text-align: right;">204</p> <p>1 Maybe it's not in user-friendly form, so we need to look 2 at that. 3 I also heard that there's a lot of chemicals 4 out there, a lot of pesticides. Perhaps we should think 5 about a stepwise or triage approach, maybe prioritizing 6 the things that are important to develop biomarkers. The 7 point was made that EPA has no requirements for 8 monitoring, and we needed to move in that direction. 9 But, on the other hand, the point was made that 10 the technology is not ready for a data requirement today. 11 There are issues about the complexities, particularly 12 around some of the new actives and/or chemistries that 13 we're seeing. So, there's more work to be done. 14 We also got the perspective from FDA who has 15 been dealing with the issues of biomarkers like us for a 16 very long time. They have a biomarker program. The 17 message there is this takes a lot of time. It takes a 18 lot of resources to move this issue. But the way that 19 you move forward is through a collaborative effort. It's 20 a collaborative-effort government working with academia 21 or working with industry. 22 Let me get to the last slide, which is, are we</p>

205	<p>1 done? Is this workshop it? No. I think we've just 2 begun. There was a proposal yesterday -- I think it was 3 a very good proposal -- from one of our PPDC members and 4 also a member of our 21st century work group, Jennifer 5 Sass, that we go back to our work group and redevelop a 6 proposal to advance this issue of biomarkers and have it 7 ready for the next PPDC meeting and put it to you for 8 consideration for your input.</p> <p>9 So, what we'll be doing is trying to schedule a 10 special meeting to have that discussion about what the 11 scope, the depth, and the shape of that proposal needs to 12 be. It needs to be a consensus approach among all our 13 members. We haven't had that discussion.</p> <p>14 I have my own thoughts about what that proposal 15 should look like. We need to talk about it as a group. 16 I think it's going to have to be a multi-prong approach. 17 There is a number of issues to consider. There is the 18 scientific issue. There is the ethical issue. There is 19 sort of a policy and legal issue. I think we have to 20 think through the details of all of that.</p> <p>21 What we will do is we won't do a summary. I 22 gave you a very short version and probably a little bit</p>	207	<p>1 where my comment resonated with Vicki. There's a lot of 2 biomarkers but there's really not anything for diagnosis 3 other than cholinesterase testing. The importance of 4 that is a number of things.</p> <p>5 Probably the most important from an educational 6 standpoint, physicians are very familiar with diagnosing 7 organophosphates poisoning. But the problem can be that 8 a lot of these symptoms in times of organophosphates 9 poisoning can also occur with other insecticide poisoning 10 as well.</p> <p>11 When they see somebody who might have seizures 12 or some other sign or symptom, they automatically get 13 cholinesterase testing and it's not really appropriate. 14 They might start management for organophosphates on a 15 poison that's completely unrelated to organophosphates. 16 So, it's important to identify the poisonings, but I 17 think it's also equally important to identify when it's 18 not a particular poisoning.</p> <p>19 There's also some educational issues that are 20 important. We've touched on a little bit about what 21 clinicians do know and don't know, CME, or continuing 22 medical education, fix that. It can help. But CME is</p>
206	<p>1 biased because it resonated with me. But we'll do a 2 workshop report and put it on the web site. I think 3 we'll continue to do these one-day FACA meetings. 4 There's already been some suggestions for the next fall 5 of 2012 meeting.</p> <p>6 So, what I'd like to do is -- there are a 7 couple people from our work group that were at the 8 workshop. Give them an opportunity if they want to add 9 to something I've said or correct something that I've 10 said or give a different opinion.</p> <p>11 UNIDENTIFIED MALE: So, first off, I'd like to 12 thank Vicki and the EPA for supporting and putting on 13 that workshop. I think it was very important and 14 necessary.</p> <p>15 I did want to clarify a little bit about 16 biomarkers versus diagnostic tools. They can be the same 17 thing, but they're not always the same thing. So, for 18 example, Enhanes (phonetic), has a lot of chemicals that 19 they can test, a lot of pesticides that they can test. 20 So that can be a biomarker. That's really well used for 21 research.</p> <p>22 But for diagnosis, it's not useful. So, that's</p>	208	<p>1 only as good as the people who attend the sessions.</p> <p>2 For example, after our meeting, I was invited 3 by the American Academy of Pediatrics to do a session at 4 next year's AAP meeting on pesticide exposure. So, 5 there's about 5,000 people that come to the meeting, the 6 overall AAP meeting. But, on average, I'll probably 7 speak to maybe 50 to 75.</p> <p>8 So, while CME is great and it reaches some, it 9 doesn't reach the masses necessarily. So, it's very 10 important to get this into the medical education 11 curriculum to an extent. We've already done some. It 12 sort of depends on the teaching physicians who are at the 13 institution.</p> <p>14 So, if kids come into my clinic, they're going 15 to hear a lot about pesticides, but not necessarily the 16 same at all universities. So, that's one other thing.</p> <p>17 MR. BRADBURY: Cheryl and then Jennifer.</p> <p>18 CHERYL: So, it was a great session yesterday. 19 I enjoyed it a lot. It was very diverse in the fact that 20 we went over past history, future, and then where can we 21 be today. I would like to reiterate one of the things 22 that you named. I don't think we're making very good use</p>

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1 of existing information, getting it all the way out to
2 physicians.

3 I'm sure there's much more information that's
4 held within the user community, within OPP, and within
5 the registrant's data packages that could advance the
6 science. I'm not saying all the answers that you need
7 are there, but I don't think, from your description, that
8 it's being leveraged as well as it could be.

9 Particularly, if you're looking for biomarkers from a
10 research perspective, I think the registrant packages
11 have a lot of information.

12 It was brought out yesterday, but it wasn't
13 resonated loudly, and that is for global products that
14 are being developed in Europe, there are urine and blood
15 methods right now, but they're not going to be down in a
16 diagnostic kit. They would be available to start to
17 answer some of these questions from a research
18 perspective.

19 There's also, in some cases, additional
20 toxicokinetic data being developed. Even within just the
21 existing studies that EPA has within (inaudible) these
22 studies and the animal testing that happens, you get a

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1 lot of research information that could take you a lot
2 deeper than what was discussed yesterday in terms of all
3 we have is cholinesterase. So, I think that's not being
4 leveraged near as well as it could be.

5 Two other points. One point was that in the
6 very beginning of the workshop, it was reiterated that
7 having information on worker exposure, human, the types
8 of things that the HSRB is looking at for studies, those
9 same types of studies are very valuable in putting
10 biomarkers and biomonitoring in perspective. Yet, right
11 now, HSRB is sometimes a roadblock to getting additional
12 information on new compounds. That was a point made that
13 wasn't re-echoed here.

14 The last thing was that wasn't stressed very
15 much yesterday is if we're talking about overexposure, in
16 a lot of cases we're going to be talking about places
17 where the label wasn't followed, PPE wasn't followed.
18 Whose responsibility is it for enforcement? That never
19 got brought up in terms of what are we going to do there.
20 So, that's something that I felt was unaddressed.

21 UNIDENTIFIED FEMALE: So, Carol Burns raised
22 the point about the packages that are submitted to the

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1 (inaudible) about developing the analytical methods, your
2 chemicals and metabolites and blood and urine. Are we
3 talking about the standard admin data that we get too, or
4 is this something different?

5 MS. DELLARCO: No, it's not new.

6 UNIDENTIFIED FEMALE: When was it put into
7 practice?

8 MS. DELLARCO: We're talking about analytical
9 methods. Again, they're going to be (inaudible) or
10 something along these lines. But we're talking about
11 analytical methods and blood in the urine. I don't know
12 if I can speak for all registrants. I certainly can't
13 speak for -- I can't say that every compound has it, but
14 I can say it's typical in our company. I think it's
15 typical of those things that are going through the EU,
16 that they will have those methods.

17 One other point I would make, too, is it's an
18 operating principle for our company and our sciences that
19 we don't guard our methods very tightly. There are times
20 when the rest of our package for data comp or proprietary
21 reasons we hold things kind of close to the breast.
22 But methods, analytical methods, we tend to put

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1 those out there as much as possible. We don't want
2 people going off and misidentifying things. We want them
3 to learn from our science. If they're going to do
4 monitoring, we want to give them the best information
5 that we have. So, methods are something that should be
6 shared as freely and as broadly as possible so that it
7 advances the science. That's my perspective.

8 MR. BRADBURY: Jennifer and then Jimmy.

9 DR. SASS: So, thank you. That was really
10 great, Vicki, your summary. I'm impressed. I was there
11 all day. It was really complicated. I'm impressed you
12 can do such a nice summary.

13 It occurs to me in listening to your summary
14 that I think we do need some kind of a glossary of terms
15 for biomonitoring and biomarkers and diagnostic tests. I
16 think I know what they mean, but actually, it would
17 probably --

18 MR. BRADBURY: Jimmy and then Matt.

19 JIMMY: This is sort of a clarification
20 question. In terms of the registrant packets that has a
21 lot of that information and a lot of that data and a lot
22 of the methods, how do we get that? Is that publicly

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1 available? I've used the reds for when I've worked on
 2 recognition of management of pesticide poisoning.
 3 I don't really see that level of detail and
 4 that level of science in there. Is it somewhere else
 5 that's in the packet that stays at EPA? If so, how do we
 6 get that back out to the laboratories that would need to
 7 go on and take that information and put it into a
 8 clinically relevant test?
 9 UNIDENTIFIED FEMALE: This is what I was asking
 10 Cheryl. Is this a new data requirement by the EU,
 11 because I haven't seen this. I've seen this from Dow
 12 because Dow has the corporate policy to do this kind of
 13 PPA work in all their studies. But is this a routine
 14 requirement in the EU, because I haven't seen this
 15 routinely?
 16 CHERYL: I believe that it is. I'm 90 percent
 17 sure that that's true.
 18 UNIDENTIFIED FEMALE: We're going to have to go
 19 back, Jimmy, and look into this more and get back with
 20 our work group on this, and see how we can make that
 21 available.
 22 CHERYL: Can I just finish? I don't want to

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1 overcommit here, but what I do think is I know there's
 2 existing data here. Instead of going through and making
 3 a blanket cookie cutter requirement that everybody turn
 4 this in, what I'd really encourage you to do is explore
 5 what's there and see what makes sense.
 6 Know that we'd be happy to share in the methods
 7 that we have. I think there's other companies that would
 8 be willing to do that, too. Instead of making it, okay,
 9 now EPA has got to go through and make this a
 10 requirement, too, step back and see what's there. See
 11 what makes sense to require.
 12 MR. BRADBURY: Back to Jimmy's question, a
 13 couple different components to answering the question.
 14 One is that the data evaluation records or the summaries
 15 of the studies once the compound is registered, those are
 16 publicly available. Methodology, we've got to work
 17 through some of these issues as to what extent some of
 18 the detailed methodologies are claimed (inaudible) or
 19 not. It's just a detail that we've got to work through.
 20 I appreciate Cheryl's point that many of the
 21 methods, analytical methods, many of them with regard to
 22 how the tolerances were figured out -- there's got to be

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1 methods for water quality monitoring. That's all
 2 publicly available in many of these (inaudible)
 3 techniques and adaptations that you're just applying the
 4 different tissue metrics. I don't think there's a big
 5 challenge there in getting that stuff open.
 6 Then, the presentation you saw just before
 7 lunch was the chem search, that is part of the process
 8 we're going through to make it easier to get at this so
 9 that loading up of the risk assessments -- we can start
 10 loading up the DERs so it's easier to take a caste number
 11 or a chemical name to start drilling through it so you
 12 don't have to make a phone call for us to dig it up and
 13 get it out to you.
 14 We can start to make it easier to get the
 15 information on the fly. That's part of this 21st century
 16 issue, just how to get your hands on the information.
 17 You don't do something you don't need to do because
 18 somebody already did it, or you're far enough along that
 19 you just have to adapt something that already exists and
 20 not have to reinvent the wheel.
 21 I think part of this conversation is really
 22 important. I think it sort of creates a pretty

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1 straightforward next step, a scoping exercise that we can
 2 do in terms of where are we in the agency, in terms of
 3 things that are getting coded up in that chem search tool
 4 we described this morning. It's just time to get it
 5 linked and available.
 6 There may be some aspects of the packages that
 7 we'll want to talk to industry and see to what extent can
 8 we clarify that this is okay to start loading up
 9 analytical methods. It may be a non-issue but it's
 10 something we just need to explore to start going there.
 11 So, anyways, I think that's a good snapshot. I think
 12 we've got an action item that we can start tackling
 13 pretty quickly in terms of some of the methodologies,
 14 analytical methods, and what not, we can make sure are
 15 available.
 16 UNIDENTIFIED MALE: I wanted to compliment
 17 Vicki, too, for taking a very complex group of
 18 presentations and delivering them to you in a way that
 19 made perfect sense to me, much more than the
 20 presentations did yesterday, in fact.
 21 It was actually pretty thrilling to hear so
 22 much of the work that was being done around biomarkers in

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1 various trends. Now, most of these were not about
 2 pesticides but the capabilities, particularly -- I don't
 3 remember -- from Emory, Dr. Jones, Dean Jones.
 4 Remarkable presentation. It was delightful to listen to
 5 that.

6 One of the things I wanted to emphasize, tried
 7 to emphasize yesterday, is the value of telling somebody
 8 they weren't exposed to pesticides. I don't think I can
 9 overstress how important it is to be able to tell a
 10 patient, that's not what happened. You have a virus.
 11 It's critical.

12 The difference between the person's perception
 13 of recovery between getting over a virus and getting over
 14 a pesticide exposure is day and night. You tell them
 15 they were exposed to a pesticide, they believe they were
 16 exposed to a pesticide. They're going to be months
 17 getting better. You tell them they have a virus, and
 18 they're going to be better when the virus goes away,
 19 they're going to be better when the virus goes away.

20 Believe me, this is one of the most valuable
 21 things we can do for a patient, tell them they were not
 22 exposed to a pesticide. So, the tool has an incredible

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1 value from that perspective in terms of worker
 2 compensation, in terms of patient's health, in terms of
 3 employer stability, because nobody is going to be suing
 4 that employer because they think they were exposed to a
 5 pesticide. Very valuable information. So, I just want
 6 to make sure that that's clear that that's on our agenda
 7 as well from a clinical perspective, because that's very
 8 important.

9 I agree with the terminology that we have to
 10 get the dictionary. When we had our guest from FDA talk
 11 to us about biomarkers, they were talking about
 12 biomarkers of tissue damage that were nonspecific. If
 13 the drugs they were testing did that damage, they knew
 14 that the drugs were toxic.

15 That's not at all what we were talking about.
 16 We were talking about the specifics of particular
 17 chemicals and how to identify them. I think that was a
 18 little bit lost in the shuffle, but that was important to
 19 point out.

20 The last thing I want to point out is the value
 21 for occupational medicine decision-making. One of the
 22 things that most people don't understand about

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1 occupational medicine is that we work not on the medical
 2 model of making a diagnosis, expecting 95 percent
 3 certainty that the disease is present.

4 What I mean by that is when, for instance, you
 5 develop a new test for some serum activity or some serum
 6 level, normally, what you'll do is you'll go out to a
 7 normal population and you'll collect 100 samples. You'll
 8 cut off the end of the curve and say the top 2.5 percent,
 9 two standard deviations above the means, would be the
 10 abnormal value.

11 So, medicine, when they make a decision about
 12 an abnormal value, they're actually using a pretty high
 13 standard for proving that it's an abnormal value and that
 14 the disease is present. In occupational medicine,
 15 because it's based on tort law, it's a 50 percent
 16 standard of reliability or a 50 percent standard of
 17 proof, which means it just has to be more probable that
 18 it's work related than that it's not, just 50 percent.

19 So, when we talk about the value of a biomarker
 20 for clinical diagnosis in medicine and clinical diagnosis
 21 in occupational medicine in determining whether something
 22 is work related, it's actually different. I can use a

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1 biomarker that if it is identified as being outside the
 2 Enhances range for normal, it's likely that this person
 3 was overexposed in that event and related to their
 4 condition. That can potentially be a work-related claim.
 5 It gets me, as a physician, to the 50 percent mark in
 6 terms of probability.

7 So, I can use biomarkers and occupational
 8 medicine can use biomarkers in a way that general
 9 clinicians might not. It would help guide clinicians but
 10 it wouldn't necessarily cinch the diagnosis for them.
 11 So, that's just one other distinction that we didn't get
 12 to yesterday.

13 It was a great session, and you did a great job
 14 summarizing. Thank you.

15 MR. BRADBURY: Nancy and then Cindy.

16 MS. BECK: I just wondered if there's a more --
 17 it seems that there are disparate approaches on the
 18 hazard pathway donation side and the biomarker
 19 development side. How do you get -- so, there's a
 20 systematic approach on the hazard side to sort of define
 21 pathways.

22 It seems like a lot of the information that's

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1 coming out of the definition of those pathways would be
2 relevant biomarkers on the clinical at the exposure side.
3 But I don't feel like that was being connected as much as
4 it could be. Are these groups talking?

5 I mean, I know there's not like the Department
6 of Biomarker Developers. That's not really a part of Tox
7 Cast (phonetic) or some of the other EPA efforts that I
8 know. But would it make sense to have it more, and I
9 don't know if institutionalized is the right word, but
10 part of the Tox Cast. So, there's sort of both sides
11 talking to each other. You can take advantage of what's
12 coming out of the hazard side.

13 UNIDENTIFIED FEMALE: Actually, articulated in
14 the 2007 NRC report, that's part of their approach. As
15 you understood pathways and biological events that are
16 happening, that would lead to the development of these
17 biomarkers. So, they are tied. You're right, it's
18 important to try to make those connections in the
19 research.

20 MR. BRADBURY: I think Vicki said it, and we
21 talked about it in sort of the opening part of
22 yesterday's workshop, that circle was intended to mean

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1 that all these different tools need to be interconnected.
2 But yes, you start to figure out adverse outcome pathways
3 and what are the key events along that pathway and the
4 markers that could help interpret the experimental study,
5 that same technology probably has --

6 I'm not in that business, but they're probably
7 reasonably straightforward modifications that could be
8 used to measure urine from the population as well as
9 urine from the rats, that you were getting insights to
10 make sure that pathway is really on or not on. So, I
11 think as the research goes, they can be linked together.

12 I think you raise a good point, though, in
13 terms of the parts of the organization that are trying to
14 guide the research again to make sure they're not losing
15 sight of the beauty of that vision. This is all
16 interconnected. It isn't this and this. It's starting
17 to be -- I use multiple lines and signs to reach a more
18 complete understanding.

19 Cindy and then I think we'll let Vicki wrap up,
20 and we'll move on to the next session.

21 MS. SMITH: Mine is just kind of a follow on to
22 the conversation that Cheryl was having with Jimmy.

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1 Matt, I know you and I had this conversation once before
2 when this came up. I guess I would just make a plea that
3 I think this is a great example of where you pull a
4 couple of us together, maybe somebody from Diagra
5 Sciences (phonetic), an intoxicologist from Gowan
6 (phonetic), and Jimmy, and Matt.

7 We could sit down and get a better
8 understanding of what is it you need so that we don't go
9 down the road of blanket data requirements and
10 assumptions and things like that. We let this effort
11 keep moving in the way that it does. This isn't separate
12 from this effort, but it's a bit of a side issue that
13 we've been talking about for a while.

14 It's an important issue and it's something that
15 I think both of us recognize the value in. I think it's
16 just a better understanding of what exactly is it that
17 you need. What do we have? Are there ways to view what
18 we have? So, I would suggest taking that kind of one off
19 with a couple of us rather than going blanket out there
20 and doing it, and seeing if we can't come to some
21 resolution just talking about the next step.

22 MR. BRADBURY: Just to clarify, that's where I

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1 certainly was coming from. I think this could be low-
2 hanging fruit in terms of what is it, what's always
3 coming in the data packages. Maybe it's in the pipeline
4 in terms of the search tool we all saw this morning, or
5 we just add it to the list of stuff to get linked up so
6 it's easy to get our collective hands on it. I think it
7 can be a low-hanging fruit, fairly focused effort.

8 UNIDENTIFIED MALE: So, I wanted to make the
9 point that these diagnostic tools, biomarkers, can also
10 be a driver for -- or surveillance can be a driver for
11 the development of these tools. A lot of pesticide
12 poisoning is not pathoneumonic, meaning it can resemble
13 many other diseases, like upper respiratory infections or
14 gastroenteritis.

15 Thirty states require that physicians report
16 pesticide poisoning. But a physician is not going to
17 report that personally identifiable information to public
18 health authorities unless that clinician is certain that
19 that patient's disease is caused by pesticides. So,
20 currently, they don't have that certainty without these
21 diagnostic tools, without these biomarkers. So, we're
22 not getting these reports.

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1 Also, there's the problem with false positives.
2 So, sometimes we are getting reports of pesticide
3 poisoning and maybe it's not truly a pesticide poisoning.
4 Maybe it was a viral infection. So, we can maybe address
5 the underreporting in our system, as well as do a better
6 job with teasing out false positives in our surveillance
7 systems if we had better diagnostic tools and biomarkers.

8 MS. DELLARCO: If we're done with this topic,
9 there's another topic. We had a request to get back to
10 this committee with the cost of studies. TJ did an
11 analysis, so he's going to present that because they talk
12 about making our paradigm certainly more reliable but
13 more cost effective. So, what's the cost of the current
14 paradigm?

15 MR. WHITE: Hi. I'm T.J. White from the
16 Biological and Economic Analysis Division. I've got my
17 colleague back here, John Faulkner (phonetic), to back me
18 up in case there are any questions that I can't handle.

19 As Vicki said, and Steve alluded to, part of
20 this process is to make our system more efficient. There
21 are a number of ways that might happen. It could be in
22 terms of the cost of data, the number of lab animals that

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1 are used, the resources EPA puts into the review of the
2 data. But in order to understand how we're improving a
3 process, we sort of need to understand where we are now.

4 So, one of the things we can do is look at
5 where we are in terms of some of these measures. I want
6 to stress that this little analysis that I'm presenting
7 right now is not the sort of detailed analysis that we
8 would want to conduct to really understand where we are
9 at this point in time.

10 These estimates were really developed in
11 response to several questions that have arisen, several
12 numbers that have been floating out in the media. So,
13 it's more for communication purposes. So, it's a much
14 more broad brush than we would really want to do. A more
15 detailed analysis could be conducted if we thought that
16 information was useful.

17 So, this is not an average cost of
18 registration. This is really what is the expected cost,
19 that is, the cost of any particular data requirement
20 times the probability that that data would be required,
21 given the use to which the pesticide would be used. I
22 put up the little mathematical equation because I figured

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1 this was a group that could handle that. We're looking
2 right now simply at conventional pesticides, and this
3 would represent a single use.

4 Now, our tests costs have been obtained from a
5 survey of various commercial labs that do these sort of
6 tests. We maintain a database along with our colleagues
7 over in the Office of Toxics on all the guideline studies
8 that may be required. We collected this over a period of
9 time for various purposes.

10 As you may know, we've recently revised a lot
11 of our data requirements. So, as part of that
12 rulemaking, we looked at the costs. We use these costs
13 when we issue DPis. So, they're maintained for a number
14 of reasons. As we go through time, we may update them
15 for various purposes.

16 The tests have all been obtained within the
17 last, say, five to six years. As to the probability that
18 they would be used, we looked at the CFR. As you may
19 know, data requirements are tagged as either being
20 required, not required, or conditionally required.

21 Just as a ballpark figure, we said if it's
22 required, that's going to be 100 percent probability, not

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1 required zero, conditionally required 50 percent. So,
2 again, this is a very broad brush. As you probably know,
3 certain requirements can be waived. Sometimes the not
4 required end up being necessary for a risk analysis.

5 Conditionally required could actually be quite variable.
6 So, the results here show pretty much what you
7 would expect, I would say, in terms of the difference
8 between food uses and non-food uses, between uses that
9 are in a fairly confined area versus those that may
10 engender large amounts of exposure. They range from
11 about \$4.3 million worth of data for an indoor
12 residential use to nearly \$10 million for registering a
13 terrestrial food product.

14 Going from non-food to food, as you can see
15 from the comparisons, is about \$2 million in additional
16 costs. And say from a greenhouse that runs \$4 to \$6
17 million, as you go into a terrestrial environment, those
18 costs go up to \$8 to \$10 million.

19 Just some points to remember about this study.
20 This is for a new chemical and only for a single use.
21 Now, if you have a second use, obviously these costs
22 don't double because a lot of the product chemistry, the

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1 toxicology, those sorts of studies can be used for the
2 additional use. You may, for example, need to do some
3 additional residue chemistry for a second food use.
4 Those sorts of studies can run anywhere from \$450,000 to
5 almost \$900,000.

6 The other thing about this analysis is that
7 we're assuming that all the data have to be newly
8 generated for this registration. That's not a bad
9 assumption for a brand new AI, but it doesn't take into
10 account that some of the studies required aren't actually
11 chemical specific. There's a whole group of human
12 exposure studies that have to do more with the
13 application method and the formulation than for the
14 chemical.

15 So, a lot of those can be cited, even for a
16 brand new study. Those are actually -- if you had to
17 generate some all anew, it would cost about \$975,000. I
18 guess the other question that has come up a lost is
19 simply the number of studies that are required.

20 For example, for a terrestrial food or feed
21 use, there are 85 data needs that are required, according
22 to the CFR. There's about another 50 that are

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1 conditionally required. So, for any given pesticide, new
2 registration, you'd probably be looking at 110, 120
3 studies that may need to be generated or submitted. Of
4 course, not all these studies are necessarily lab tests.
5 Some of them are more narrative or product descriptions.

6 So, that's what we have right now. If anyone
7 has any questions, I'd be happy to answer them.

8 MR. BRADBURY: Quickly. Jennifer.

9 DR. SASS: So, like, let's say you had a
10 chemical like the old (inaudible) before SQP eliminated a
11 lot of the residential uses. So, that was registered for
12 approval in almost all these categories. I kind of think
13 off my memory it is all of these categories. So, would I
14 just like add up this list of numbers to get what it
15 costs to register chlorpyrifos?

16 MR. WHITE: No. Like I said, this is just for
17 sort of the first use. Additional uses, since they can
18 count on existing toxicology data and other forms, you
19 wouldn't simply add them together.

20 DR. SASS: So, then, it would be like \$10
21 million for terrestrial, well food and non-food, so it
22 would be like \$17 million. Is that what you're saying?

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1 MR. WHITE: No. Say, for example, you
2 registered for a non-food use at about \$8 million. If
3 your next one was a terrestrial food use, you would
4 really only have to do sort of the additional residue
5 studies that correspond to that particular use.

6 If you're going from a non-food to a food,
7 you'd also have to establish another set of probably
8 residue studies and that sort of thing. So, it would be
9 like another \$2 million for the additional food use.
10 Every additional use thereafter might be a very narrow
11 subset of the residue study, \$500 to a million dollars.

12 DR. SASS: So, then, for something like a
13 chlorpyrifos, which had a lot of uses in pretty well all
14 these categories, it would be somewhere between \$5 and
15 \$10 million plus these half million increments for these
16 other uses?

17 MR. WHITE: Like I said, this is not really a
18 detailed study. I would not want to talk about any
19 particular chemical associated with this particular --

20 DR. SASS: Any chemical (inaudible) that has a
21 lot of these categories.

22 MR. WHITE: If you wanted to think about

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1 looking at the cost of registering a chemical over a
2 large number of uses, I mean, we could do that. We have
3 the data. We could put together some sort of scenario.

4 DR. SASS: But this isn't it?

5 MR. WHITE: This would not really give you that
6 picture of what all those various uses would have been.

7 DR. SASS: And then, my second clarification
8 point, then, is going to be these probabilities here in
9 slide number 2. So, it seems to me that if you
10 conditionally require data, it's the probability --
11 you're guesstimating. You're just using a rough estimate
12 that the probability requiring that data or not is 50
13 percent.

14 But it's a discrete variable. It's like if you
15 require it, it costs the amount of the data. If you
16 don't require it, it's zero, right? I mean, it's not
17 like the data costs 50 percent. It's more like the
18 probability of you requesting it is 50 percent, right?

19 MR. WHITE: Right. This is an expectation. If
20 you were thinking about bringing a chemical to the
21 market, you had a vague idea of what use you were going
22 to do but you didn't know any particulars about the

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1 chemistry, this is sort of an expectation. It would be
2 similar to an average if we looked at a large number of
3 chemicals and said, well, some of them were required and
4 some of them were an average. Here's how much it would
5 cost.

6 DR. SASS: That's kind of my point. So, these
7 estimates aren't really an expected data generation cost
8 of a new conventional pesticide. It's more like the
9 average expected generation cost over a whole bunch of
10 pesticides. I don't know how to take out the 50 percent
11 probability. I'd like to see the math without that.

12 MR. BRADBURY: Jennifer, I can jump in. I
13 don't want particularly want this topic to consume our
14 agenda. So, if people just have some clarifying
15 questions, that's cool.

16 DR. SASS: I'd like to understand about how
17 much it costs to register a pesticide for my own media
18 communication ideas. I don't understand how to get it
19 out of here.

20 MR. BRADBURY: I'm cool with that. We're just
21 trying to answer one broad question with sort of a
22 general sense. If people are really dying to know more

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1 and more, that's cool. We can help share information.
2 We'll go around the table really quick. If this is a
3 really burning issue, we can figure out a way to come
4 back around to it.

5 So, Cheryl and then Maria, or was Maria first?

6 UNIDENTIFIED FEMALE: It doesn't matter because
7 we're probably going to indicate the same thing.
8 (Inaudible) are way low. There are a lot of hidden costs
9 in doing this study, like doing the range finders, doing
10 the analysis of the compound within your study,
11 generating radial label material so that you can run this
12 study.

13 So, to me, your costs -- yes, if I counted each
14 study, just lean it at a lab, that's what the lab tells
15 me. But then, they don't tell you that on top of that,
16 you're going to have to add analysis costs. You have to
17 give me the radial labels material. There's a lot of
18 hidden costs which you're not covering.

19 UNIDENTIFIED FEMALE: There's Q/A and there's
20 method development, there's all the range finding. It
21 takes eight years, is our industry's model, two years of
22 screening about 10,000 compounds before you find anything

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1 that you even advance, another three years to develop
2 your full data package, and then three years to sit in a
3 regulatory cue.

4 In conjunction with what goes into a regulatory
5 package, there's a whole suite of biology testing and
6 efficacy testing that goes on in the field. There's
7 figuring out how you're going to do your manufacturing,
8 how you're going to package, how you're going to supply.
9 There's way more to this than what's here.

10 So, when you call this data generation, this
11 must be contract study costs for a minimal package. Ray
12 can probably quote the number better, but CropLife
13 America has done some of its own surveys of people. I
14 believe the cost to bring something new to the market
15 over those eight years, when you screen through all the
16 rest of that, is over \$200 million.

17 MR. BRADBURY: Just to clarify, clearly there's
18 a spectrum from screening 50,000 structures in the
19 computer to bringing a specific structure and all its
20 data to the agency. Somewhere in there it's R&D costs
21 the company is investing. It may or may not pan out.
22 That's truly not a cost to EPA. You're clearly going to

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1 get to a certain gray zone where you're still sort of --

2 UNIDENTIFIED FEMALE: But you're saying this is
3 a cost to register a chemical.

4 MR. BRADBURY: Right, and we're just getting at
5 some of the --

6 UNIDENTIFIED FEMALE: Literally, I'm just
7 trying to understand. You had a word for it. You said
8 the contract study cost. I would like to understand
9 (inaudible), not R&D, not three years of sitting in cue,
10 not your secretarial, your air conditioning, your
11 heating, your computers. I just want to understand what
12 does it cost to do these tests? So, you're calling it
13 the contract study cost.

14 UNIDENTIFIED FEMALE: But even beyond that,
15 there's going to be some other hidden things just to do
16 the research.

17 MR. BRADBURY: All right, folks. Enough.
18 Stop. You two, stop.

19 Jerry, did you want to say something?

20 MR. BARON: I'll say it real quick, Steve.
21 Just one other point on that is for these additional crop
22 uses, that does not account for crop groupings, which is

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1 using data developed on a few crops to support
2 registration on many. So, when you ask the number about,
3 let's say, a chemical like chlorpyrifos or oxystroben
4 (phonetic), or whatever, large registration, crop
5 groupings reduce that cost.

6 UNIDENTIFIED MALE: Well, Cheryl and Maria have
7 clearly explained that this is a small slice of the total
8 cost of developing a compound from scratch knowing
9 nothing and taking it clear to market. In general, the
10 food or feed terrestrial use listed here is the most
11 expensive.

12 In general, the data generated to support that
13 use will cover most of the other uses. So, if you got
14 that one, there's generally not a lot more data to
15 support those other uses. That's a very general
16 statement. It doesn't hold in all cases. Like they
17 said, there are many more costs associated with these
18 studies than just the contract cost. This is a small
19 slice of the total picture.

20 MR. BRADBURY: Thanks, all. Thanks for letting
21 me be a little belligerent to try to keep this moving.
22 So, having said that, if overnight there's something that

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1 could be helpful from the PPDC in terms of information
2 sharing, ponder that. Tomorrow morning, we kind of go
3 over objectives and topics for future meetings. I'm not
4 saying that we can't explore this, but I just want to
5 kind of keep track of the clock as we go forward.

6 So, let's move into our last session of the
7 day, which will be a series of updates, session four.
8 The first update will be from Karen Whitby on the
9 endocrine disruptor screening program.

10 I wanted to announce, because I don't think
11 we've had a chance with the group, that Tina Levine
12 retired a few months ago. Karen Whitby is now the Acting
13 Director for the Health Effects Division. Karen has
14 worked with the program for a number of years, a risk
15 assessor and branch chief in the Human Health Effects
16 Division. Karen also is spending some time in the
17 Environmental Fate and Effects Division. So, she sort of
18 sees the signs from multiple perspectives.

19 She spent the last few years in the immediate
20 office helping OPP working with our other colleagues in
21 our agency in advancing the endocrine disruptor screening
22 program and working through everything from some of the

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1 scientific issues to how it gets connected into the
2 regulatory processes that are part of our program.

3 So, with that, I'll turn it over to Karen. I
4 think you folks have a handout in your folder so you can
5 kind of follow with that while we get the Power Point up.

6 MS. WHITBY: Good afternoon. Due to the
7 limitations on the amount of time on the agenda for an
8 EDSP update, I've provided background slides on the EDSP,
9 its scope, the tier one assays, and proposed tier two
10 tasks, and an appendix that's included in your handout.

11 As most of you know, FQPA required the agency
12 to screen pesticide chemicals for endocrine (phonetic).
13 The agency issued approximately 750 EDSP test orders for
14 list one chemicals starting October 29th of 2009.
15 Chemicals were selected for the first list on the basis
16 of being present in either four out of four or three out
17 of four exposure pathways, those being food, water, post
18 application worker exposure, and residential exposure.

19 Tier one data are due to the agency 24 months
20 from issuance of test orders unless an extension was
21 granted. The agency expects to receive approximately 500
22 EDSP tier one studies for 53 list one chemicals. The

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1 detailed response and status for each chemical and test
2 order may be viewed at the agency web site, which is
3 provided on the last slide.

4 List one data may be submitted to the agency
5 using formatted CDs similar to what is done for
6 submission of new active ingredients. A web-based tool
7 is available to expedite formatting to create the CD.
8 The CD should be labeled TRD-EDSP upon submission.

9 Paper submissions are also acceptable. MRIDs
10 will be made available to registrants on the web site in
11 advance. The agency is actively developing web-based e-
12 submissions. As we get closer to implementing web-based
13 e-submissions, we will be encouraging industries to
14 participate in the testing of the applications.

15 The agency published a notice of availability
16 and posted the revised weight of evidence document to the
17 docket on September 28th of this year. The standard
18 evaluation procedures, data evaluation record templates,
19 and templates for raw data spreadsheets have been posted
20 to the web. If you go to the EDSP web site, there are
21 links to all of these documents in the highlights box on
22 the right hand side of the page.

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<p style="text-align: right;">241</p> <p>1 To evaluate variability of key endpoints and 2 promote consistency in agency interpretation, the agency 3 will consider several studies for each EDSP tier one 4 guideline as a group before we begin the weight of 5 evidence analysis. 6 For some of the chemicals, it was necessary to 7 grant extensions for individual assays for reasons such 8 as contract lab capacity. Therefore, all of the studies 9 for a chemical may not arrive on the same date, which 10 will impact the timing of the weight of evidence 11 analysis, since the tier one assays are considered to be 12 a battery. 13 Once all of the studies have been submitted and 14 reviewed, then the agency will conduct the weight of 15 evidence analysis for each chemical to determine if the 16 chemical has the potential to interact with the estrogen, 17 androgen, or thyroid hormonal pathways and which, if any 18 tier two tests will be required to further characterize 19 potential hormone interactions observed in tier one 20 screening, and to establish a dose response relationship 21 for risk assessment. 22 The agency weight of evidence analysis will</p>	<p style="text-align: right;">243</p> <p>1 screening to allow the agency to more quickly and cost 2 effectively assess potential disruption of hormonal 3 pathways. These tools may be used to prioritize 4 chemicals for screening and testing, where the longer 5 term goals may include possible enhancement or 6 replacement of current tier one assays. 7 For additional and more detailed information, I 8 would encourage you to visit these web sites. Thank you. 9 MR. BRADBURY: What I'd like to do is go 10 through all the updates. If we've got some time left, we 11 can hit the specifics. 12 So, the next update will be from Susan Jenning 13 on the PPDC Public Health Work Group efforts. 14 MS. JENNING: Lois Rossi is ill today, or she 15 would have been here herself to deliver this information. 16 I know we've had some change over in the 17 members of the PPDC since we've generated and formed this 18 work group about 18 months ago. So, I'm going to do a 19 little bit of background. So, if you all can just -- for 20 the people who have been here, it won't be long. 21 The public health work group was created about 22 18 months ago specifically to address issues that involve</p>
<p style="text-align: right;">242</p> <p>1 consider tier one results and other sources of scientific 2 and technical information submitted as relevant to tier 3 one screening. Such information may come from any number 4 of sources, including pesticide registrants and published 5 or publicly available peer reviewed studies. 6 To develop a second list, the agency identified 7 candidate chemicals that are either contaminants 8 regulated by the Office of Water with the national 9 primary drinking water regulation or are unregulated 10 contaminants that are listed on the third chemical 11 contaminant list. 12 The agency included pesticide chemicals that 13 were scheduled for docket openings for registration 14 review during fiscal years '07 and '08 that were not 15 included on list one. The agency published Federal 16 Register notices with information on the proposed second 17 list in November of last year. The agency is working on 18 the response to comments received on these documents, and 19 the next step will be to submit our revised documents to 20 the Office of Management and Budget. 21 EPA is considering development of efficient use 22 of computational toxicology methods in high throughput</p>	<p style="text-align: right;">244</p> <p>1 pesticides and pests that impact public health. It's a 2 very broad area and it tends to have a fairly distinct 3 stakeholder work group, stakeholder set. So, we wanted 4 to generate a work group that would work on these issues 5 specifically. Many of these issues can be regulatory, 6 policy, scientific. The work group is designed to do any 7 of that. 8 The work group itself has defined three 9 critical roles for its interaction with the EPA. The 10 first one is as an advisory panel to seek FACA advice 11 under FACA for input into some of our processes and 12 projects. I think this is especially important because a 13 lot of what we do is more -- we have a lot of federal 14 groups and work with federal agencies on these types of 15 issues. Under the FACA umbrella, it allows us to again 16 seek that broader input from non-federal participants and 17 interested parties. 18 It's also a portal for stakeholders to bring 19 issues of concern to us. So, if there are issues that 20 perhaps we have not realized our issues or need to have a 21 little bit more focus put on, this is a portal for people 22 to bring these into the EPA. Lastly, it's a forum to</p>

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245	<p>1 discuss items of common interest.</p> <p>2 What we try to do is when we hold our meetings,</p> <p>3 we try to kind of touch upon each one of these three</p> <p>4 roles within those meetings. Again, it provides us with</p> <p>5 broader stakeholders. The stakeholders for public health</p> <p>6 are up there. There's a whole host that aren't up there.</p> <p>7 Lastly, it provides us a venue for collaboration with the</p> <p>8 public.</p> <p>9 The kickoff meeting was 18 months ago. The</p> <p>10 work group itself has been working in identifying issues.</p> <p>11 Each work group we identify and discuss different</p> <p>12 separate issues.</p> <p>13 The four key areas of interest that the work</p> <p>14 group has identified are improving the toolbox of</p> <p>15 pesticides used to control public health pests. As Ray</p> <p>16 McAllister said earlier, if you have that terrestrial</p> <p>17 use, you might be able to add a public health use for</p> <p>18 little to no additional data generation. We're always</p> <p>19 looking to try to improve that toolbox for various public</p> <p>20 health tests.</p> <p>21 Blanket tolerances for mosquito adulticides,</p> <p>22 this is a funny little issue because depending on where</p>	247	<p>1 standards, the communication of efficacy to the user</p> <p>2 community and to the public. There's a lot of discussion</p> <p>3 about resistance, pesticides that work, pesticides that</p> <p>4 don't work. The bottom line is some of that is just</p> <p>5 communicating.</p> <p>6 Efficacy and resistance is a very complex</p> <p>7 topic. I think that it is difficult for the public</p> <p>8 sometimes to understand that when they sprayed and it</p> <p>9 didn't kill it, therefore, the pesticide didn't work.</p> <p>10 Well, you might not have sprayed the right place at the</p> <p>11 right time. It's not always as simple as that.</p> <p>12 Some of the issues are very pest specific. So,</p> <p>13 bed bugs, tick-borne disease efforts are some of the more</p> <p>14 recent things that we're covering and bringing to this</p> <p>15 group. Development of performance measures for public</p> <p>16 health. This is an issue. Concerns about the NPDES</p> <p>17 permitting process and its effect on public health and</p> <p>18 pesticides and how they're used.</p> <p>19 Coordination with EPA about urban IPM and</p> <p>20 community IPM and how IPM -- IPM and public health are</p> <p>21 linked inextricably together in most cases. In an urban</p> <p>22 setting, if you're not doing IPM, you are not going to</p>
246	<p>1 you are in the nation, they look at tolerances for</p> <p>2 mosquito adulticiding differently. So, when they're</p> <p>3 doing an adulticide, it's difficult for them to target</p> <p>4 non-crop land. So, if you've got an adulticide label</p> <p>5 that says not to be used over crop lands, you're going to</p> <p>6 get some restrictions.</p> <p>7 So, IF4 is working and some of the other -- Joe</p> <p>8 Conlon and the MCA, they're trying to establish blanket</p> <p>9 tolerances for some of these. The work group provides a</p> <p>10 way for other groups to have input into this process as</p> <p>11 well. Efficacy issues, people are always ready to</p> <p>12 discuss the efficacy of pesticide use for public health.</p> <p>13 The last issue that we had identified, that the</p> <p>14 work group had identified, is IPM in housing, schools,</p> <p>15 and communities. Now that there's a new work group</p> <p>16 that's specifically targeting at least a generation of</p> <p>17 metrics for measuring the impact of IPM in these areas,</p> <p>18 we're going to be discussing how we can work together</p> <p>19 with that group so that there's no overlap between the</p> <p>20 two. I don't think there really will be a whole lot.</p> <p>21 Additional areas that the work group is</p> <p>22 interested in is again, efficacy, product performance</p>	248	<p>1 get long-term control.</p> <p>2 These public health pests are pests that are</p> <p>3 living with people, on people, eating their food,</p> <p>4 drinking their water. If you do not control their food</p> <p>5 source, their water source, their habitation, you're not</p> <p>6 going to get good control of that pest no matter what</p> <p>7 pesticide you use. So, that's an issue that's ongoing.</p> <p>8 And lastly, resistance concerns, which ties to the number</p> <p>9 one issue, which was efficacy.</p> <p>10 So, the next steps for the work group, I think</p> <p>11 by focusing only on public health initiatives, we're able</p> <p>12 to work more effectively and efficiently with the</p> <p>13 stakeholder community. The work group is a very valuable</p> <p>14 resource for OPP. Again, the fact of the umbrella, it</p> <p>15 gives us access to a broader stakeholder group.</p> <p>16 We're going to be having a meeting tomorrow</p> <p>17 afternoon from 1:00 to 4:30. Most of the meeting</p> <p>18 tomorrow, I'd say three-quarters, will be focused on bed</p> <p>19 bug initiatives and next steps. We'll be talking about</p> <p>20 next steps for the work group itself. For the bed bug</p> <p>21 initiatives, we'll be talking about -- some of our</p> <p>22 members of the federal bed bug work group will be there.</p>

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1 We'll be covering some of the work that we've been doing
2 to establish a federal strategy for bed bugs control.

3 So, that's all I have.

4 MR. BRADBURY: Thank you, Susan. Susan will
5 hang around if we've got time at the end and you have any
6 follow-up questions.

7 So, Allison Wiedeman, you're on the phone,
8 right?

9 MS. WIEDEMAN: Yes, I am.

10 MR. BRADBURY: Okay, Allison, thanks. And
11 Susan Lewis from OPP is coming up to the table. Allison,
12 with help from Susan, will give you an update on where we
13 are with the NPDES general permits for pesticides. So,
14 Allison, take it away.

15 MS. WIEDEMAN: Thanks, everyone. I'm assuming
16 everyone can hear me. I first want to say I extend my
17 apologies for not being at the meeting. These are very
18 important meetings to us. I've tried to be or my senior
19 managers have tried to be at every one, but this one we
20 just couldn't make it. I'll do what I can over the
21 phone.

22 So, this is an update of where we are in the

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1 pesticides general permit. I'm sure folks are wondering
2 if we're really going to make the October 31st deadline,
3 which, in fact, we will be. So, we do plan to have a
4 final permit by October 31st, which is in just a couple
5 of weeks.

6 It will be published both in the Federal
7 Register as well as on our web site. The items at that
8 time that will be released on our web site include the
9 permit and its accompanying fact sheet, which is a
10 document that describes in more detail what the
11 requirements in the permit mean and why EPA developed
12 them that way.

13 We also will be putting up accompanying forms
14 that are either required to be completed by the permit,
15 such as notices of intent to be covered under the permit,
16 or are available to assist permittees in documenting their
17 compliance activities.

18 We also intend to have our electronic NOI
19 database up and ready for permittees to use which will
20 make it easier to get coverage under the PGP. We also
21 plan to have an updated what we call decision tree web
22 tool to assist permittees in determining whether they need

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1 to apply for permit coverage. If so, what permit
2 requirements would apply to them. So, all of that will
3 be up and available.

4 Of course, the agency's final permit will cover
5 operators who apply pesticides that result in discharges
6 from the same four use patterns that we've been dealing
7 with for over a year and a half now, which is mosquito
8 and other flying insect pest control, weed and algae
9 control, animal pest control, and forestry canopy pest
10 control, where those activities result in a discharge to
11 water (inaudible).

12 The EPA posted a version of its permit on April
13 1st of this year. That version of the permit has
14 everything in it except for any provisions that would
15 result from our consultation with the services under the
16 Endangered Species Act. The requirements that were
17 permit for everything but the ESA related provisions have
18 not changed. So, the permit that folks saw up there then
19 is the same permit with the same requirements in it,
20 except for the ESA provisions. I'll talk about ESA
21 consultation in a moment.

22 We recognize that this is going to be

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1 problematic in our timing in a number of ways by
2 publishing a permit by October 31st, which is essentially
3 on the effective date of that permit, or essentially on
4 the same day that folks are required to comply with it.
5 It's been unable for us to avoid that. What we are going
6 to do is to allow notices of intent to be covered under
7 the permit.

8 They do not have to be submitted to the agency
9 until January 12th of 2012. So, while requirements of
10 the permits still need to be met, the notices of intent
11 to be covered do not. That will give permittees time to
12 get into compliance and do what they need to do to submit
13 the notice of intent.

14 We're still covering the same things that we
15 said we were going to cover and not covering the same
16 things we said we weren't going to cover. So, for
17 example, the PGP does not cover, nor is permit coverage
18 required, for pesticide applications that do not result
19 in point source discharges to waters of the United
20 States, such as terrestrial applications for the purpose
21 of controlling pests on crops and forest floors and range
22 lands.

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1 Agricultural runoff and irrigation return flows
2 continue to be exempt from permitting under the Clean
3 Water Act. So, these will also not be requiring permit
4 coverage. The PGP will also not cover non-target spray
5 drift or discharges of pesticides to water bodies that
6 are impaired for a particular pesticide.

7 That latter part of the sentence means that if
8 there is an impairment in a water body in the U.S. for a
9 given pesticide such as malathion, this permit would not
10 cover -- if an applicator wanted to spray malathion, this
11 wouldn't cover the application for that pesticide, but
12 rather the operator would have to seek coverage under an
13 individual permit.

14 Turning to, for a moment, the ESA consultation,
15 folks know that we are in consultation with the National
16 Marine Fishery Service. NAMFS has submitted a biop that
17 we made available on our web site. We asked for public
18 comment on that biop. We received them and submitted
19 those comments to NAMFS for consideration and development
20 of their final biop and the reasonable and prudent
21 measures that they've also included in that document that
22 they believe EPA needs to implement in the permit and

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1 order not to cause jeopardy to the species or their
2 habitat.

3 We are still in consultation, nearing
4 completion of it. So, NAMFS plans to issue their final
5 biop, and we plan to incorporate what we believe are
6 appropriate provisions to protect the species into our
7 permit. That will be in there, of course, with the
8 version that will be published at the end of this month.

9 A couple of other things about that. Remember
10 that this permit only covers six states, and I can name
11 them if folks ask me a question on that, the District of
12 Columbia, certain U.S. territories, an Indian country,
13 and some federal facilities.

14 For the 44 states that are authorized to issue
15 NPDES permits, they have had since we posted the
16 pesticide permit in April the information that they need
17 to go ahead and complete development of their general
18 permits. They are issuing a state permit that is not a
19 federal action that would be required to undergo
20 consultation as we are, because this permit that EPA is
21 issuing is a federal action.

22 So, the 44 states not conducting a federal

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1 action are not bound by the same requirements under ESA.
2 States can certainly include ESA requirements, but they
3 are not required to include the ones that we will have in
4 our permit.

5 States are able at this point to go ahead and
6 finalize their permits. In fact, we know that 35 out of
7 those 44 states will have final permits by the October
8 31st deadline, and we're working with the others to get
9 them on board as well.

10 We believe that the provisions in the permit
11 that are related to consultation are not going to be
12 significant enough to warrant public comment. So, we
13 will not be engaging in another round of public comment.
14 So, we will be moving forward to publishing the permit
15 then, on October 31st.

16 I think some folks would also ask, well, what
17 is the status of consultation with the Fish and Wildlife
18 Service? We are in consultation with them as well.
19 Frankly, the outcome of that is to be determined. We
20 will actually not be able to discuss it until the permit
21 is finalized.

22 I'll stop there and see if anyone has any

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1 questions.

2 MR. BRADBURY: Allison, can you remain on the
3 phone for a bit because I'd like to get through two other
4 updates and then open it up for questions. Do you have
5 some time?

6 MS. WIEDEMAN: Okay.

7 MR. BRADBURY: She does now. Kelly Sherman is
8 going to come on up and give an update on the humans
9 studies protection rule. Then, the last update will be
10 Wayne Buhler, who is going to talk a little bit about
11 pesticide safety education. Then we'll open it up and
12 kind of go through the topics and field some clarifying
13 questions.

14 Kelly.

15 MS. SHERMAN: Hi, everybody. This will be
16 really short, just a brief update. As many of you may
17 know, last year EPA entered into an agreement with NRCG
18 to settle litigation over the 2006 human studies rule.
19 As part of that agreement, EPA is committed to propose
20 several revisions to the rule.

21 In accordance with that, in February, we
22 published a Federal Register notice announcing the

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1 proposed revisions and opening a 60-day comment period.
2 That comment period closed in April. We received a total
3 of 10 comments. Four were from industry task force
4 groups, two were from NGOs, and four were just from
5 interested citizens.

6 Most of the comments related more to the
7 underlying rule rather than the specific revisions that
8 we were proposing. We reviewed the comments and are now
9 moving forward with finalizing the amendments. Our
10 current plan is to finalize the amendments exactly as
11 they were proposed.

12 We finished the intra-agency portion of that
13 process and the rule-making process. We're now beginning
14 the process of talking to other agencies and also
15 beginning OMB review. So, we're targeting to sign the
16 final rule before the end of the year. That's where
17 things are.

18 MR. BRADBURY: Thanks, Kelly.

19 I'll turn it over to Wayne to give an update on
20 safety education.

21 MR. BUHLER: Thank you, Dr. Bradbury. You
22 should have a one pager, both sides, for reports

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1 submitted last night to Marty. Thank you for including
2 it in the packet. This was 18 pages but I wheedled it
3 down to 2, since I was the last speaker of the day.

4 I have compiled some material here actually
5 that came from a Weed Science Society of America press
6 release that was done last month, and also some notes
7 from the president of the professional society for which
8 I belong, the American Association of Pesticide Safety
9 Educators, or AAPSE.

10 Just a short intro with the first paragraph to
11 explain who we are, the PSEP program has been around for
12 more than 40 years now. We were formerly known as the
13 Pesticide Applicator Training Program. I just received
14 in this case acknowledgment or what I refer to as a
15 commissioning from congress with EPA directing the uses
16 of the state cooperative Extension Service to inform and
17 educate pesticide users about accepted uses and other
18 regulations.

19 There is a person like myself, or a person that
20 does work like myself, I should say, in each of the
21 states, with the exception of three states, I think, now,
22 in the U.S., five trusts in territories. We're all part

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1 of the University Extension Service. The primary mission
2 is to educate pesticide applicators that need to become
3 certified either as private applicators, commercial
4 applicators, and the like.

5 Just from the standpoint of some data, in 2010,
6 there are 488,000 certified private applicators, 405
7 certified commercial applicators, 105,000 newly
8 certified, and 227,000 applicators that participate in
9 recertification programs in the state.

10 So, short of living my dream of becoming a
11 professional baseball player, I have a wonderful captive
12 audience in North Carolina. We have about 36,000
13 certified applicators there who come to programs from all
14 over county-based programs and receive their continuing
15 education credit. We also have a pretty good outreach to
16 others that are non-certified audiences, such as master
17 gardeners. We're highly involved in IPM school programs.

18 The table that's included under Federal Funding
19 Decline is just a short history of the funds that we've
20 received from the EPA. We've been very grateful for it.
21 I know it's been extremely helpful and critical in my
22 program.

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1 In recent years, the support has hovered around
2 \$1.2 to \$1.8 million. That was up until 2007, in which
3 case all funds were discretionary. Then, beginning in FY
4 2008 through 2012, Pesticide Registration Improvement
5 Act, or PRIA 2 funds, which are earmarking \$500,000
6 annually, come from company pesticide registration fees
7 to be dedicated for the pesticide education program.

8 On the flip side, the funds, you can see a
9 little bit of description about how some of these funds
10 have, in this case, decreased and the impact it has had.
11 There have been a number of obvious budget constraints
12 and other challenges that EPA has faced. So, the
13 discretionary funding is no longer possible for at least
14 this year. The PRIA 2 funding is really the only thing
15 that our programs are receiving from federal level.

16 So, what that means is there's about \$10,000
17 that's distributed to each state. The universities now
18 can take their cuts through distributions, in my case
19 upwards of about \$2,000. So, I'm really working on an
20 \$8,000 federal budget this year.

21 You can see that that's had an impact of 20 to
22 75 percent reduction to each state, and an 83 percent

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1 reduction compared to 2008 funding levels. The bad news
2 then, of course, is that if PRIA funding were no longer
3 in existence, the PSEP funding would also go to zero
4 starting in 2013.

5 So, in response to these reductions, the
6 executive committee of the AAPSE, or the board of
7 directors, rather, conducted an on-line survey of my
8 colleagues throughout the country. This just describes
9 some of the conditions that they face.

10 Nearly 50 percent of state programs suffered
11 serious setbacks in recent years. Federal funding
12 reduction this year and next will be hard on many
13 programs. Many of our states generate additional funds
14 through education fees, sale of training manuals, and
15 securing outside grants and contracts, as well as
16 partnering with other organizations.

17 Some of the states lack the infrastructure, the
18 support, or legal capability of pursuing those funds,
19 however. So, lack of sustainability has directly
20 resulted in decreased staff, reduced pesticide manual
21 production, reduced education, and realignment to other
22 non-PSEP educational work.

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1 In the case of myself, I do find myself writing
2 more grants, but that's the life of a faculty member.
3 More than two-thirds of the coordinators felt that they
4 would have to seek funding in areas not related to
5 pesticide safety education in order to make up for the
6 federal funding shortfall.

7 Survey results show that national funding is
8 certainly an essential part of the PSEP program in many
9 states. One state in particular no longer has a program
10 due primarily in part to the PSEP program not being able
11 to fund it to the extent that it did in the past.

12 Pesticide users obviously are becoming more and
13 more diverse, including those with organic production who
14 don't think that they use pesticides. With growing
15 complexity of pesticide labels, the public need for and
16 demands on PSEP are also growing.

17 On behalf of AAPSE and the pesticide safety
18 education program, I just wanted to kind of keep this on
19 PPDC radar to help ensure that adequate federal funding
20 is available to our programs for the foreseeable future.
21 It is certainly our hope that PRIA funding will be
22 renewed and authorized for supporting the pesticide

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1 safety education program.

2 MR. BRADBURY: Thanks, Wayne.

3 Why don't we open it up and go through the menu
4 of topics we just went through. We can field some
5 questions. With respect to Allison hanging on the phone,
6 why don't we first start with the NPDES permit and see if
7 there's any questions, which there are, Allison. Susan,
8 why don't you come up and you can help as well with
9 questions on the NPDES permit.

10 I think Susan Kegley was first and then
11 Caroline.

12 DR. KEGLEY: Hi, Allison. I guess I don't
13 quite understand the ESA thing. So, there is an ESA
14 requirement in the permit if you're under the federally-
15 issued permit but not if you're under a state-issued
16 permit?

17 MS. WIEDEMAN: Yes.

18 DR. KEGLEY: So, what will protect the
19 endangered species in those cases?

20 MS. WIEDEMAN: That is up to the states to
21 decide. The ESA is a law that requires any federal
22 actions to consult with the services to protect species.

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1 So, the state actions are not federal actions. So, any
2 time EPA issues a permit, which we're doing for these six
3 states, we need to consult.

4 DR. KEGLEY: Okay, thank you.

5 MR. BRADBURY: Caroline, then Ray, then
6 (inaudible).

7 MR. CONLON: I'm masquerading as Caroline.
8 This is Joe Conlon from the AMCA, Allison. I heard you
9 say that an NOI would not be due until January 12th. If
10 so, what is the discharge authorization date going to be?
11 Is it going to be November 1st that you're going to be
12 able to discharge?

13 MS. WIEDEMAN: Yes. I'm glad you asked me to
14 clarify that. What we are saying is that the effective
15 date of needing to meet the permit requirements is
16 November 1st. So, operators need to be in compliance
17 with the permits requirements, but they do not need to
18 submit an NOI until January 12th.

19 MR. CONLON: Now, is the permit requirement for
20 a PDMP to be on hand?

21 MS. WIEDEMAN: The permit requires a number of
22 things, and it requires different things for different

66 (Pages 261 to 264)

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1 parts of the industry. We have applicators and we have
2 what we call decision makers, which the decision makers
3 are those that are hiring applicators. There's different
4 responsibilities in the permit for each of those groups
5 to meet. I don't think we have enough time for me to go
6 over that in detail.

7 Applicators under this permit are not required
8 to submit notices of intent to be covered, although they
9 are required to comply with the provisions of the permit
10 that pertain to them. The decision makers are required
11 to submit notices of intent. Those are the ones that are
12 required, in the effluent limitation guidelines part of
13 the permit, to conduct IPM-like practices, which have
14 been outlined in the permit. They are also required to
15 document those practices in a PDMP or a pesticide
16 discharge management plan.

17 MR. CONLON: That's going to be by November
18 1st?

19 MS. WIEDEMAN: Yes. Again, those requirements
20 have all been up since April. So, the industry, as well
21 as regulators, know what they need to do to meet all of
22 those requirements, and have since April.

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1 MR. BRADBURY: Ray McAllister, Allison.

2 MR. McALLISTER: I have to say that I feel very
3 uneasy about this "just trust us" attitude. Frankly, I
4 don't, in terms of we don't need to ask for your
5 additional comments on what we're doing.

6 I'm particularly concerned about the total lack
7 of visibility of the Fish and Wildlife Service in this
8 process and the assertion that, well, we just have to do
9 it this way and you won't know about it until the end,
10 and things could be a whole lot different.

11 We've long said this is a train wreck in the
12 making, and it's happening. What's really happening with
13 the Fish and Wildlife Service? Why are they not in the
14 picture?

15 MS. WIEDEMAN: I can't speak to the details of
16 the consultation at this time. We have been able to move
17 successfully through consultation with them. We are
18 still trying to do what we can with Fish and Wildlife.
19 So, it has been more challenging with Fish and Wildlife
20 Service. I know there's a number of aspects to getting a
21 permit out without a lot of lead time. I don't want to
22 minimize that. But that, unfortunately, is the situation

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1 we're dealing with.

2 MR. McALLISTER: But you do have the option of
3 requesting additional time from the court, and the court
4 can say yes or no.

5 MS. WIEDEMAN: Yes, and the agency has decided
6 not to do that.

7 MR. McALLISTER: Is Fish and Wildlife Service
8 expected to provide a biological opinion at some point?

9 MS. WIEDEMAN: Well, the chances of having that
10 done within the next two weeks are rather slim.

11 MR. McALLISTER: Don't they have a legal
12 obligation to do so?

13 MS. WIEDEMAN: I'm not the attorney. I can't
14 speak to that. But I can say that we want to make
15 consultation successful. We are trying to work with them
16 in the same vain we have worked with Fish and Wildlife.
17 We are still working it out.

18 MR. BRADBURY: Any other questions on the NPDES
19 permit?

20 (Whereupon, there was no verbal
21 response.)

22 MR. BRADBURY: Thanks. Any questions on the

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1 endocrine disruptor screening program?

2 MS. WIEDEMAN: Steve, I'm going to hang up
3 then, if that's okay.

4 MR. BRADBURY: That's great. Thanks a lot,
5 Allison, for hanging on.

6 MS. WIEDEMAN: Thank you. Bye.

7 MR. BRADBURY: Any questions on EDSP? Going
8 once, going twice.

9 (Whereupon, there was no verbal
10 response.)

11 MR. BRADBURY: PPDC public health work group?
12 Going once.

13 (Whereupon, there was no verbal
14 response.)

15 MR. BRADBURY: Anything for Kelly on the human
16 studies rule?

17 (Whereupon, there was no verbal
18 response.)

19 MR. BRADBURY: Any follow-up questions for
20 Wayne? Ray and then Darren.

21 MR. McALLISTER: On the PSEP funding situation,
22 I have sat through about three hours of explanations on

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1 how money gets from EPA to USDA to the people who
2 actually do this work. I still don't understand it. I
3 would just ask that you straighten that out. It makes no
4 sense whatsoever. I have been led to understand that the
5 very convoluted nature of getting money from here to
6 there is the reason no money is being put in at the front
7 end. It just doesn't make any sense.

8 MR. BRADBURY: Thanks for the opening. Let me
9 provide a little clarification as to what's in play.
10 Actually, there's a time earlier in time, which isn't on
11 Wayne's chart, where something that just happened this
12 last year played out.

13 Part of it is just the way the cash flow is
14 moving from EPA moving money to USDA and then USDA
15 distributing the money to the states, and just sort of
16 tracking the cash flow. Every once in a while, there's
17 sort of a bottleneck of the funds. So, part of why we
18 didn't fund this year is to let some of the funds move
19 through the system.

20 The other point is that the agency has no
21 intention of not maintaining a reasonable level of
22 funding with the discretionary funds that we have, which

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1 is what would go to USDA and get to the states. Exactly
2 how much that will be, we'll have to see how congress
3 finally does the budgets and things like that.

4 But getting to Ray's point, we're taking a look
5 at some other vehicles or approaches by which to get the
6 money to the states and working with USDA. Maybe there's
7 a way that EPA can just try to directly set up the extra
8 vehicles to get to the appropriate parts of the state to
9 get the funds there. That may help reduce some of the
10 transaction costs in moving the funds around.

11 So, a little bit of what you're seeing in this
12 window right now is part of a cash flow or the
13 equilibration step, which actually happened a couple
14 years after I got here. So, it might have been 2003/2004
15 where we did one of these resets just to get the cash
16 flow straight. This cycle, taking a look at maybe
17 there's a way that EPA can just directly get the funds to
18 the states. That's what we're looking at right now.

19 I'm not going to go through the convoluted
20 stuff, but more about where we're trying to head.

21 MR. BUHLER: Thanks for that explanation. It
22 saves me from having to explain something I don't

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1 understand. But yes, the federal passthrough is one of
2 those complexities that has created problems over the
3 years. There is actually a paper written on it, if
4 you're interested. I could talk to you more about that
5 later, Ray.

6 MR. BRADBURY: Darren.

7 MR. COX: One of the points we brought up on
8 the pollinator protection is education, education,
9 education. Here we're looking at this form and kind of
10 going budget cuts. I can tell you just as a suggestion,
11 beekeepers in my state -- I'm just going to shoot from
12 the hip and throw you a number -- we're going to pay \$50
13 every year to be registered beekeepers in our state.

14 Then, the chemical applicators, they'll come by
15 every three years and we'll pay a \$30 charge every three
16 years to be able to conduct business. So, there's two
17 years where they get a gap. I can see this program as
18 being self-funded by the applicators for a minimal charge
19 to pay for updating their materials and for education.

20 MR. BUHLER: You bring a good point. Actually,
21 there are programs, like my own, that do receive funds.
22 That's the only way I can retain or remain in existence.

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1 That will vacillate, and some states just can't do that.
2 Some of those monies will go to the respected states
3 department of agriculture or environmental management.
4 Others can go to general funds. So, they meander through
5 different rivers and not always go to the education arm.

6 So, there are states that can function well in
7 that way, and there are others, through problems that I
8 don't quite understand, that just are not allowed to do
9 that. But, even at that, there are administrative
10 hurdles to get through. Even in terms of funding, we
11 have an administration that requires us to receive some
12 federal monies before we can be recognized as an
13 identifiable program at the university level.

14 So, in that case, by not having a flow of
15 federal funds, some administrations would just assume
16 think that the program may not even exist in their state.

17 MR. BRADBURY: Jim.

18 JIM: Just to clarify a point, not all training
19 of professional applicators goes through the program.
20 Most of the states that have agricultural chemical and
21 fertilizer associations do a lot of in-house training.
22 Actually, if you look at the real statistics, and I think

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1 it's important, are usually other types of applicators,
 2 independents, PCOs, a lot of other educational projects.
 3 So, I don't want to leave you with the feeling
 4 that applicators are getting federal funding for all of
 5 their training. That is actually not correct,
 6 particularly in recertification. Your point is well
 7 taken; they should be paying. In most cases, they
 8 actually are. This is really supplemental.
 9 UNIDENTIFIED MALE: It's true. The extension
 10 service provides training. Typically, that's done with
 11 no fees. But we can't train every applicator in every
 12 state. So, we're thankful for people like ARA and others
 13 that can do that.
 14 The money, again, is an issue. It relates
 15 mostly to the ability to deliver programs and provide
 16 monies that are used for developing materials. So, if we
 17 have a downturn, or perhaps the governor would prefer to
 18 take those funds away from us, then we have no monies for
 19 that year to actually develop materials. Some of that is
 20 being worked through now.
 21 I do want to recognize Kevin Keeney (phonetic)
 22 in the audience. Kevin is the branch chief for worker

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1 protection as well as pesticide container and containment
 2 here on the 11st floor for the building. Kevin has
 3 really been very helpful in supporting all of the work
 4 that educators are trying to do. There's a lot of work
 5 in developing training materials on a national level that
 6 then can be adopted and used within the states. So, that
 7 kind of effort is really appreciated.
 8 MR. BRADBURY: Gabriele.
 9 MS. LUDWIG: Just to sort of add to this, since
 10 I was at the meeting of the IPM specialists last week, I
 11 think the other merit to having some federal funding in
 12 the game is there is a sense of independence. I think
 13 that's very important in these kinds of things. So, I
 14 just put that out there. That's not always, in my mind,
 15 the best way to go, to go to private funding for certain
 16 issues. I think this is one where it's useful to have
 17 some federal funding in it.
 18 MR. BRADBURY: Okay. I think we'll call it an
 19 evening. Nobody signed up for public comment. Unless
 20 there's any last tidbits, insight, tomorrow morning we'll
 21 meet at 9:00.
 22 Steve Owens, if all his travel and flight

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1 connections work, should be here and spend some time with
 2 us. Then, at 9:30 we'll do a session on endangered
 3 species, in particular, the process improvement work
 4 group activities in terms of how to feed information into
 5 the system. We'll spend a fair amount of time on that.
 6 Then, we'll spend some time charting out what our goals
 7 are for the next meeting.
 8 So, thanks a lot. It was a very good day. I
 9 appreciate the very focused comments. It was very
 10 efficient and effective. So, thanks, all, and have a
 11 good evening.
 12 (Whereupon, the meeting was
 13 adjourned.)
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In the Matter of:

Environmental Protection Agency

October 13, 2011

*Pesticide Program Dialogue Committee Meeting
Day 2*

Condensed Transcript with Word Index



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18 Conference Center - Lobby Level
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1 PROCEEDINGS
2 - - - - -
3 MR. BRADBURY: Good morning, all. Again, I
4 want to thank everyone for all your input in yesterday's
5 meeting, the various topics we went through. I think we
6 covered a lot of ground. It was a very effective
7 conversation.
8 I appreciate again the work that goes on in
9 between the meetings with the work groups getting a lot
10 done and being able to bring to the full committee status
11 of efforts, recommendations for the next step. I
12 appreciate the time you all are spending in preparing for
13 those conversations. So, we got a lot done, on time, and
14 I appreciate that.
15 So, today, we've got a half-day agenda. We'll
16 start with Steve Owens and spend some time going over his
17 perspectives on the program. We'll have a big chunk of
18 time to go over the Endangered Species Act and ideas on
19 implementation and effectiveness of that. Then, we'll
20 spend a little time planning for our next meeting.
21 So, without further ado, I'll turn it over to
22 Steve.

3
1 MR. OWENS: Thanks, Steve. I apologize for not
2 being here yesterday. I was out of the office. I didn't
3 get in until the afternoon. Rather than coming over and
4 disrupting the proceedings at that point, we decided I
5 would come today.
6 This will be an easy morning discussing
7 something that's light-hearted like the Endangered
8 Species Act. So, there won't be much going on anyway,
9 comparable to yesterday, I guess, where you covered a lot
10 of the simple things like spray drift, and EDSP, and
11 pollinator protection, and all that.
12 Actually, it's always fun to be here with you
13 guys. This is one of the things I find -- unfortunately,
14 I can never stay here long enough, but it's one of the
15 things I find most fascinating about the job I'm in, the
16 opportunity to interact with all of you to kind of get
17 advice from you on some very challenging and sometimes
18 longstanding issues that this office is dealing with, not
19 only looking at the range of perspectives on this, but
20 the diversity of efforts that are involved in it and the
21 contributions that all of you make to the process that we
22 have here where we have to not only evaluate things from

2
1 a policy and technical perspective, but from real world
2 impacts on the ground approach as well.
3 Like I've said, just about every time I've been
4 here, it doesn't do us any good to come up with a policy
5 or a decision or anything like that if it actually isn't
6 going to work when it's being implemented out in the
7 field. So, that's one of the very valuable things that
8 this group does for us.
9 I'm going to talk about a few things. But
10 before I do that, I want to also just introduce someone
11 who is new with us, not so much new to the office, but
12 new to this group, and that is Louise Wie (phonetic).
13 You can raise your hand. There you go.
14 Louise is the new Jim Jones. We're not
15 (inaudible) Jim Jones now since Louise has been with
16 OCSPP since July. She came in in the middle part of July
17 to take over for Jim, actually, to really take over for
18 Bill Diamond, who had taken over for Jim. Bill had
19 agreed to serve as the acting deputy of OCSPP for just a
20 couple three months while we went through the time-
21 consuming process that we have to go through in the
22 federal government for filling these kinds of positions.

<p style="text-align: right;">5</p> <p>1 We were very fortunate that Louise was 2 interested in this job. I've known Louise a long time 3 going back to before I joined EPA, back when I was with 4 the State of Arizona in other lives. She's held a 5 variety of positions, none of which I will try to go into 6 -- I might ask her to say just a couple things very 7 quickly, actually before I even start talking -- 8 throughout the agency, so she has a very broad and 9 comprehensive perspective, not only on what this office 10 does, having seen it from the outside looking in in 11 different capacities, but also how it interacts with 12 other offices within EPA.</p> <p>13 That's going to be of immense value to us as we 14 move forward not only on all the things we talked about 15 yesterday and today, but other challenges that we'll face 16 of sort of making all the disparate pieces of EPA work 17 together a little bit better, especially in this arena.</p> <p>18 So, I've often introduced Louise as Jim Jones 19 with better hair. Someone said the other day, no, you 20 mean Jim Jones with hair, which I can say since Jim isn't 21 here. But actually, Louise, I don't know if you want to 22 just say a couple things, and then I'll take it over.</p>	<p style="text-align: right;">7</p> <p>1 actually try to move to conclusion of some of those 2 things.</p> <p>3 Almost everything that was on the agenda 4 yesterday, with the exception of, for example, the school 5 IPM initiative that we've engaged in, and then maybe one 6 or two other small pieces, but just about everything else 7 that was on the agenda yesterday are things that were not 8 only underway when I came to EPA back in the summer of 9 2009, but had been underway for a long time at EPA.</p> <p>10 I know there are very difficult, very 11 challenging, and very complicated issues that have to be 12 wrestled with as we are, and have been, moving forward 13 with those issues. But we're getting to the point with 14 some of those things, as I'm sure was discussed 15 yesterday, where, as I used to say when I was growing up, 16 we have to fish and cut bait. I think we'd much prefer 17 to fish on things than cut bait on things that we've 18 worked on a long time.</p> <p>19 So, it's going to be very important to make 20 sure that we have not only the benefit of your advice but 21 your active involvement as we try to put things together. 22 I won't go into any individual things, we talked about</p>
<p style="text-align: right;">6</p> <p>1 MS. WIE: I'll just say I'm really happy to be 2 here. As Steve pointed out, I've been at the agency for 3 a while. I've circled through a lot of offices from OGC 4 to OSWER, to water, to the policy office. So, I've 5 gotten an inkling of all the statutes. I actually came 6 from -- starting with pesticides. So, I feel like I've 7 circled back.</p> <p>8 I'm really happy to be here. I see some 9 familiar faces, so it's nice to see you. I look forward 10 to getting to know you better and also to hearing your 11 perspectives. So, thanks for having me.</p> <p>12 MR. OWENS: Thanks, Louise. We debated whether 13 we'd do a go around and have people introduce themselves 14 for Louise's benefit. I decided not to do that in the 15 interest of time because I know some of you guys will 16 need to be getting out late in the morning to catch 17 planes and things like that. I don't want to delay the 18 morning proceedings too much by being here.</p> <p>19 I know you went over an awful lot of stuff 20 yesterday. Steve Bradbury was giving me the rundown on 21 the great discussions that you had. What I would like to 22 add to that is how important that process is as we</p>	<p style="text-align: right;">8</p> <p>1 them yesterday, but, over the next few months, as we try 2 to reach a point where we can say, okay, we've really 3 worked this issue as much as we can. We've tweaked it 4 here and there.</p> <p>5 We need to move forward with some of those 6 things, through whatever formal process it will be, 7 because so much of what we've been doing has been not 8 necessarily informal but hasn't gone into official notice 9 and comment and things like that. So, I'm hopeful that 10 at some point in the not too distant future some of those 11 things will be starting to come to a resolution. Again, 12 that's why this group is very important.</p> <p>13 But there are other thing that are out there as 14 well that we really need to start thinking about as we go 15 forward. I've only been in this administration a couple 16 of years now, I guess two years and three months now, but 17 who's counting. When you start actually hitting the end 18 of a third year of administration, people start thinking 19 about okay, what do we really think we want to do in the 20 next year, what can we wrap up, what can we really get 21 done.</p> <p>22 I think we're going to be looking to you in</p>

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9

1 many respects as part of that discussion as well. A lot
 2 of the things that are close enough (audio problems) move
 3 forward and one of the things that's going to take a
 4 little bit longer time to resolve. That will help us
 5 better allocate resources, help us better figure out
 6 where we need to spend our time, where we need to ask you
 7 to spend your time.
 8 Everything is important. We need to continue
 9 to work on as much of that as we possibly can. It's just
 10 that when we're getting close to the finish line on some
 11 of these things, do you sprint or do you keep going or
 12 what do you do? So, that's where we're going to have to
 13 put our heads together and figure that out.
 14 But there are some other things that we've
 15 really been working hard on, which I want to talk about
 16 just for a few minutes, since you're going to be spending
 17 some time on them this morning, which is the Endangered
 18 Species Act issue. I know you touched on it a little bit
 19 yesterday.
 20 Today, I guess, is the bigger, broader picture.
 21 We appreciate Jim Lecky being with us today. Jim, I
 22 think we're going to refer all questions to you on that.

10

1 But I do want to say, actually, Jim has been a very
 2 active participant in this for a long time. I've really
 3 appreciated getting to know him and all the folks over at
 4 NOAA, as well as the folks at Fish and Wildlife Service
 5 as well.
 6 We've been engaged in an invigorating process
 7 over the last couple of years where we've really, I
 8 think, make a fair amount of progress in addressing some
 9 very complicated issues on the Endangered Species Act and
 10 how it affects not only what we do in the Office of
 11 Pesticide Programs with pesticide reauthorizations and
 12 approvals and all that kind of thing, but the work that
 13 gets done in both Commerce and Interior as they have to
 14 do the job that they're charged with doing under the
 15 Endangered Species Act.
 16 It may not feel like it to folks on the
 17 outside, but I don't think anybody on the inside would
 18 disagree that we have come a long way on both sides. We
 19 very much appreciate the level of cooperation from NFMS
 20 and from Fish and Wildlife Service, also the involvement
 21 of the Department of Agriculture, and other folks from
 22 the government side.

11

1 There are many of you around this table who
 2 have been involved in the discussions we've had on how to
 3 address not only the process issues but the science
 4 issues and then some of the more challenging
 5 implementation issues out there as well. That effort is
 6 going to be underway for a while going forward. I don't
 7 think anybody has any expectations that there's a simple
 8 and easy solution to this, and that this is going to get
 9 fixed anytime soon.
 10 But I can say I think, accurately and with all
 11 sincerity, that everybody is absolutely committed to
 12 figuring out how to fix it and how to make it work for
 13 everybody involved, both from the registrant's
 14 perspective, from the grower's perspective, from the NGO
 15 community's perspective, from everyday people's
 16 perspective, as well as from the perspective of the folks
 17 in government who are actually responsible for
 18 implementing the requirements that we're faced with.
 19 What has been going on, which I know you'll
 20 talk about today, is there have been some pretty
 21 significant agreements reached with regard to, for
 22 example, the upcoming National Academy of Science's

12

1 study. I know we've talked about that before in previous
 2 meetings. I just want to say to folks, do not
 3 underestimate the significance of that effort. I say
 4 this to compliment the folks at NMFS and the Fish and
 5 Wildlife Service.
 6 They work very closely with us and also USDA
 7 who has been very active in helping not only to define
 8 the issues that the National Academy of Sciences will
 9 look at but also helping to work on some of the technical
 10 presentation aspects that will go before the NAS when
 11 they commence their work, I guess next week or two weeks,
 12 whenever it is.
 13 It's taken a while to kind of get that effort
 14 going from the time we reached initial agreement to do
 15 that and began to scope out the questions to the NAS and
 16 then to start working with the NAS as they pick the
 17 people who are going to be on their panel. I think
 18 they've got a very good panel that they've proposed, at
 19 least so far.
 20 That's going to take a while for them to get
 21 that done. I think we're looking at probably 18 months
 22 or so. But that group is intended to address the science

13

1 issues underlying the way that we look at Endangered
2 Species Act issues, how the services address the science
3 issues when they're developing biological opinions, and
4 what kind of inputs we have into that process at EPA.

5 We've had lots of discussions between our
6 agencies about how -- I've said this before to you all --
7 how what we do here at EPA can be adjusted so that it's
8 more in sync with what the services do over there and how
9 they can adjust what they do and the information they
10 need so that it's more in sync with what we do.

11 Part of the process we hope that will come out
12 of the NAS review is that we'll get a better perspective,
13 certainly an independent scientific expert perspective on
14 what are the real nitty gritty scientific issues that we
15 need to wrestle with going forward, how do we address the
16 questions that are out there, are we doing it right, are
17 we doing it wrong, are we completely missing the boat or
18 are we right on target.

19 The issue for us at EPA is kind of a two-part
20 question. One is, what is it that we have to do under
21 FIFRA and FQPA and the other governing authorities we
22 have when we're reviewing registration applications and

14

1 registration reviews and those kinds of things, compared
2 to what is it we can do and what kind of information can
3 we provide to the services as they move forward,
4 recognizing the issues that some things may present to
5 registrants and others. We'll have to have those kind of
6 discussions until we get further into the process with
7 the NAS and we see what the NAS comes out with.

8 I don't know that we'll ever actually be in
9 that perfect world that they once tried to achieve with
10 the counterpart regs where we do something and then it's
11 deemed a nirvana. But what we're hopeful for is that
12 we'll be able to keep moving our process a little bit in
13 this direction and the services will be able to have
14 enough information up front early enough in the process.

15 That's something that they have to figure out
16 as well for themselves, what do they need, when do they
17 need it, and how they can use it. So, when we get to the
18 end game on this, we're not that far apart and we're not
19 having the situation that we've been in for the last
20 number of years where there's just a lot of back and
21 forth, which doesn't serve any of the agencies any good.
22 It certainly doesn't serve the public at large good.

15

1 We're going to have to do all of that, I should
2 say, up front. I think there's a genuine commitment to
3 do that, certainly on the part of leadership of the
4 agency. The staff has been working very closely
5 together, Jim and Brady.

6 We put Brady back here on the low section of
7 the room. They sit back there and they go like this when
8 I'm talking. Are they doing that now? Usually, Brady
9 says, what, I wasn't listening, whenever I talk.

10 But anyway, they've been working hard for a
11 long time, long before I got here. But they've been
12 working even harder since I got here to try to get these
13 things figured out. What I was going to say also, we're
14 also operating in the context of litigation. So, we are
15 going to try to have as open and frank and comprehensive
16 discussions with all of you and others as we possibly can
17 going forward.

18 There will occasionally be a situation where
19 because a particular issue happens to be in the middle of
20 litigation or pending in front of a court, we may be a
21 bit circumscribed in terms of what we're able to say or
22 do or something like that. So, I'll ask you to bear with

16

1 us on that.

2 Some of these things may get some resolution or
3 some clarification of some of the more contentious issues
4 based on how some of the court decisions come out, or it
5 may just be that the court decisions make them even more
6 confused and complicated. We don't know. But we're
7 going to continue to work on this as much as we can.
8 We're optimistic that this is going to get worked out.

9 We know there's an awful lot of attention on
10 this, not only from all of you in this room but from
11 people outside who are affected by the decisions we make.
12 There's also a lot of interest on the part of members of
13 congress that we've been working very closely with to try
14 to help them work through these issues as well. So, we
15 again appreciate your involvement in that.

16 I know I unfortunately won't be around for the
17 discussion this morning, but I anticipate it will be a
18 fairly lively one. I would hope that as you get into it,
19 that you not only make Brady earn a living, but you come
20 at him hard with lots of tough questions and things like
21 that. Brady is doing the presentation, isn't he?

22 MR. BRADBURY: And Keigwin backing him up.

<p style="text-align: right;">17</p> <p>1 MR. OWENS: Keigwin is back there as the relief 2 pitcher. This is the opportunity, as you guys know, for 3 those kinds of questions. Not to make him squirm, 4 although that's always fun to see, but the more 5 challenging the conversation, I think the better off we 6 are because it helps us figure out where the 7 opportunities for agreement actually are. 8 I know that sounds a little bit weird to say, 9 but rather than glossing over the key points of 10 contention, I always think it's better to get them out on 11 the table to figure out what is the real nub of an issue, 12 what is the real problem, how can we actually figure it 13 out. Sometimes we can't, but most times we can. 14 So, it's really just a continuation of a longer 15 discussion. But we're going to keep coming back to you 16 with these issues as this process unfolds. My view is 17 that over the next period of time as we go through the 18 NAS process, as we move forward with some of the other 19 issues out there, this is going to be one of the more 20 significant things that we will have done and that 21 certainly all of you will have done in terms of helping 22 us figure out how to address this issue and resolve it.</p>	<p style="text-align: right;">19</p> <p>1 NMFS, which it sounds like they're closer, and Fish and 2 Wildlife Service, which it sounded like maybe they're not 3 even close. 4 So, there still, I think, remains a question 5 about why wouldn't the agency seek an extension to get 6 that resolved so that people have an understanding of 7 when that permit is actually issued, what the 8 requirements are going to be with respect to things that 9 may have changed as a result of the consultation. 10 I don't know if you want to share anything 11 about that. Allison wasn't able to share all of it, but 12 I'm imagining you're having a conversation about that 13 internally. 14 MR. OWENS: Let me avoid answering your 15 question this way. I think that's exactly right. There 16 are a lot of things that are in the works (inaudible) as 17 you noted, officially in our office. There's Office of 18 Water and also Office of General Counsel and others who 19 are looking at all those issues. I think we're close to 20 getting the consultation issues resolved. 21 I think the most important thing to keep in 22 mind about the consultation -- and Jim will probably</p>
<p style="text-align: right;">18</p> <p>1 So, I appreciate your willingness to be part of 2 that discussion. I appreciate the time you're going to 3 give to it this morning. Again, any hardships you can 4 create for Don Brady this morning will be greatly 5 appreciated. 6 With that, I'll turn it back to Steve. Thank 7 you, guys. 8 MR. BRADBURY: Well, maybe we should get right 9 into it and see how Don holds up. 10 MR. OWENS: I know you guys were supposed to 11 get on to the agenda right now, at 9:30. I've got a few 12 minutes before I have to leave. I don't know if anybody 13 has anything easy to ask me before I leave. I do want to 14 listen to at least the beginning of it. I knew Cindy 15 would have questions. 16 MS. SMITH: Steve, yesterday, one of the 17 updates we got was from Allison on NPDES. I know that 18 it's not directly in the shop of OPP; it's in the shop of 19 Water. But one of the things that I think was alarming 20 to a number of people to hear was that there still isn't 21 a final permit that can be out there due to consultation, 22 which we've just been talking about, whether it be with</p>	<p style="text-align: right;">20</p> <p>1 speak to this a little later, if he's inclined to -- it's 2 a limited subset of areas that will be affected by what 3 comes out of the consultation process. Certainly, some 4 areas will be affected. 5 But, for the overwhelming majority of the 6 people who are covered by the permit, who are in 7 activities that are covered by the permit, they're not 8 going to be affected by what goes on in the consultation 9 process. So, I can't tell you exactly what's going to 10 happen when. 11 I can tell you at the moment there is a 12 commitment by or a determination by the agency to just 13 get it done. Part of it is that level of uncertainty 14 that's out there of what's this going to look like. It's 15 a fear of the unknown which I think causes more issues 16 than what might actually wind up being in the (inaudible) 17 when it's done. 18 We do have a court deadline right now at the 19 end of this month. Certainly, that's the path we're on 20 right now. That's about all that I can really say 21 because, as I said, I'm not the decider on that one. 22 There are others who are making those decisions.</p>

21

1 UNIDENTIFIED FEMALE: You alluded to the fact
2 that you had additional conversations, services, but you
3 also mentioned congressional involvement in the
4 classroom. Can you expound on that? What type? And I
5 have a second question.

6 MR. OWENS: There's no mystery on that.
7 There's just been a lot of congressional interest.
8 There's been hearings. Dr. Bradbury has testified. So,
9 there have been hearings on it. There have been a lot of
10 briefings on the Hill with the staff. A lot of that has
11 mostly been just informational, trying to figure out --
12 sometimes with the pesticide general permit, but mostly
13 on the bigger picture, the Endangered Species Act
14 consultation process, kind of what's going on not only
15 with the litigation but as we work towards the National
16 Academy of Sciences review.

17 There's some interest in having us look, for
18 example, at the economic issues associated with it, which
19 we think are a good idea. We just have to figure out the
20 right way to do that. So, we're trying to work between
21 the agencies but also with members of congress and others
22 on making sure that not only are they kept fully informed

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1 of the process as it moves forward and as we work as
2 partner agencies here to develop a process that works,
3 but that we address any questions or issues that they
4 have along the way that they may be hearing, for example,
5 from their constituents, things that come up, that kind
6 of thing.

7 So, there's nothing terribly new or unique.
8 It's just that we're trying to be even more proactive
9 than we have in the past in making sure that people are
10 kept informed of what's going on.

11 UNIDENTIFIED FEMALE: The second question is
12 just real practical. This NES panel coming up, will the
13 charge questions for that be made public? At what point
14 would they be?

15 MR. BRADBURY: The broad charge areas are
16 already public. When the administrator on behalf of USDA
17 and Commerce and Interior wrote the letters to the NAS,
18 it lays out the topical areas that we want to look at.
19 It ranges from how to define best available information,
20 how do you evaluate the information that goes into
21 geospatial information, mixtures effects of sublethal and
22 cumulative modeling, advice on how to use models, and

23

1 then how to talk about, analyze, interpret uncertainty in
2 the overall decision-making process.

3 Those are broad areas and that letter lays out
4 some of the specifics. As you go into the actual meeting
5 the panel and services, USDA and EPA can clarify or drill
6 in a bit deeper. Everything will be public. If you go
7 to our web page, you can see the letter and it lays out
8 the broad topical areas.

9 UNIDENTIFIED MALE: Any meetings coming up?

10 MR. BRADBURY: The first meeting is November
11 3rd and 4th in Washington. These guys will correct
12 everything I say that's wrong, but there's, I think,
13 three public meetings of Washington, out in the Pacific
14 Northwest.

15 So, there's opportunity for public comment and
16 for the public to put things into the record for the
17 panel. The first two-day meeting is November 3rd and
18 4th. I don't know if NRC has scheduled the meetings out
19 west yet or not.

20 Scott and then Joe.

21 MR. OWENS: And then I'll wrap it up.

22 MR. SCHERTZ: Obviously, the OMPDS issue has

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1 been very complicated for the agency. But also, it
2 certainly is relevant that it's going to be complicated
3 for the decision makers to comply. As we understood
4 Allison's comments yesterday of this gap between
5 compliance and the NOI requirement in January, that is a
6 very problematic area for the decision makers.

7 We do have a request that that be formalized of
8 exactly how that takes place. We really think this is
9 very difficult to be in compliance of something like that
10 when you just see the final provision literally days
11 before compliant with it.

12 MR. OWENS: Okay. I'm not quite sure what she
13 said yesterday, but I think the bottom line is that the
14 agency is going to work with really the states who have
15 to implement some of this at the state level. Also,
16 where the federal permits will fly, we're going to be as
17 reasonable as we can to make sure that everybody
18 understands what requirements there are. It's a new
19 thing. We get that. It's been part of the conversation
20 for quite a while.

21 I think people are going to be bending over
22 backwards to make sure the information is out there once

6 (Pages 21 to 24)

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1 the permit goes into effect to try to do the kinds of
2 outreach efforts that need to be done and to be paying
3 attention, again listening to what's actually happening
4 out there on the ground and trying to accommodate those
5 interests as best we can.

6 MR. BRADBURY: Joe.

7 MR. CONLON: I'm well aware of the constraints
8 under which the agency is working in this regard. I do
9 applaud the efforts that are trying to be made to make
10 this as amenable as possible to all. However, the end
11 users, like I am, are a little bit less sanguine about
12 this whole process. We think that an extension should be
13 asked for. I understand that it's probably not going to
14 happen, but we think an extension should be asked for.

15 I think in our role as an advisory committee,
16 this committee -- I would like to see the agency afford
17 us an opportunity to vote as to whether we want to give
18 the advice to the EPA to request this and formalize it as
19 something on the record, that this committee either wants
20 you to extend it or doesn't. Then, you can take it from
21 there. But I think at some time and at some point, the
22 advice that this committee gives needs to go on record.

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1 So, I was wondering whether you'd entertain a
2 motion for a vote on this by the committee to ask for an
3 extension.

4 MR. BRADBURY: The committee works by whether
5 or not we can reach consensus or not on a position.
6 Sometimes the committee reaches consensus and sometimes
7 it doesn't. But we don't vote on motions. I'll just
8 leave it at that.

9 Having said that, you have lots of venues to
10 get the word into the agency. Certainly, the minutes
11 here will reflect varying opinions about where we are in
12 the process and the next steps in the process.
13 Certainly, we're not shifting it to Office of Waters.
14 Office of Water has the point on this that, by all means,
15 people should be communicating with the Office of Water
16 on your views. This isn't to shirk our responsibility,
17 but just to get the information to the right place.

18 Certainly, our minutes can reflect the fact
19 that there's varying opinions on the process and the
20 status and the time line. Obviously, Allison heard it
21 and you can share that with Allison, the diversity of
22 opinions and thoughts on the topic.

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1 MR. OWENS: The only thing I would add is,
2 looking around the room, that certainly not all of you,
3 but from a number of you, we, meaning EPA, the letters to
4 the administrator or to the water program, and sometimes
5 to our office, those opinions have been expressed. So,
6 we do have a record of that in the agency as well.

7 So, I absolutely understand your point, Joe,
8 but I think that the agency has heard that. We got that.
9 We've got, actually, correspondence from a number of you.
10 Some of you have actually been in meetings with us and
11 with Water, as elsewhere. So, we appreciate that.

12 Thank you, guys. I didn't want to delay you
13 too much, but I did want to at least give you guys a
14 chance to talk about that a little bit. We will keep you
15 advised as things are developing on all this.

16 MR. BRADBURY: Thanks, Steve.

17 Why don't we move on to the main part of the
18 morning which will be an update on our efforts with the
19 Endangered Species Act. In particular, this will be a
20 report out from the PRIA Process Improvement Work Group,
21 which was focusing specifically on ESA and processes that
22 can be used to try to make the (inaudible)

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1 determinations, the consultations more effective, how to
2 get the right kind of information in at the right time.
3 You'll hear some presentations that will let us explore
4 some options on how we might take a look at the
5 registration review and perhaps adjust that approach.

6 I think Don and Rick are also going to give you
7 a little bit more update on the NAS process and some of
8 the other things that are going on, as well as some of
9 the process options that are being explored. So, Don is
10 going first.

11 MR. BRADY: Today I go first. Yesterday Rick
12 went first. So, we have a nice block of time set aside
13 this morning to talk about some of the work that we've
14 been doing in regards to endangered species. I'll give a
15 short update on NES. Most of what I was going to say has
16 already been covered, so I'll add one or two small
17 details.

18 Then we'll have a presentation. Rick will take
19 us through some work that we've done internally in the
20 agency that looks at where the appropriate place in our
21 registration review process might be to initiate the
22 consultation discussions with the services.

7 (Pages 25 to 28)

US EPA ARCHIVE DOCUMENT

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1 Then, following that, we'll have presentations
 2 from Tilghman Hall and Mike Willett. They will be
 3 relating some work that has been done through the PRIA
 4 process improvement group as to their ideas that relate
 5 to sort of the timing of where consultations might occur
 6 that would help us fulfill both our ESA obligation, but
 7 also would allow us to meet our schedules under
 8 registration review.
 9 So, we have a couple presentations and then in
 10 your agenda, there are printed five questions which we'll
 11 use to guide the discussion with the PPDC members as we
 12 move through this session and get some views by using
 13 those questions to elicit those conversations.
 14 So, the only thing that I really would add to
 15 the discussion on NAS is just to recap that the first
 16 meeting is set for November 3rd and 4th. It's here in
 17 Washington. There are additional meetings being
 18 discussed. As of yet, they aren't scheduled by the
 19 National Academy folks.
 20 The extent of the conversation we've had with
 21 them is they indicated that they're thinking of having
 22 two additional meetings and probably on the west coast.

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1 One of them probably in the Pacific Northwest. They
 2 haven't said anything further to us about that. So,
 3 that's the thing that we can all watch web pages. As
 4 soon as we know, we certainly will provide that
 5 information to our avenues of communication, our regular
 6 communication avenues with you.
 7 Then, the other thing is that in addition to
 8 the broad charge letter that both Steves talked about,
 9 there will be some more information provided by the
 10 agency that's in process now. There's two blocks of
 11 information, if you want to think of it that way.
 12 One is background materials, which constitute
 13 reading for the panel members. Each agency is preparing
 14 that material now to transmit to the National Academy.
 15 Then, there will be some more detailed explanation of the
 16 questions or the issues that we would like advice from
 17 the National Academy on. The agencies are working on
 18 those issues.
 19 Now, we're loosely calling them charge
 20 questions just because that's the term we're used to
 21 using. The target date to have all of that material to
 22 the academy is Friday, October 21st. Once that gets to

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1 the Academy, it will all be posted on their web site and
 2 made available to the public. So, it's an entirely
 3 transparent and clear process for everybody involved.
 4 So, that's really the only thing I would add in addition.
 5 At the meeting, the first meeting, there will
 6 be time for public presentations. The format will be the
 7 agencies will have presentations to make to the panel.
 8 The panel itself will invite some presentations from
 9 other organizations. Then there will be public time for
 10 anybody who wants to speak to the panels, to address the
 11 panels. So, it will be an intensive two days or day and
 12 a half on endangered species from all sides of the issue,
 13 so to speak.
 14 As was said earlier, I think those of us in the
 15 agencies are really looking forward to the advice that
 16 the panel ultimately provides to us and hope that it
 17 forms a very solid basis for us all to sort of move
 18 forward and find our middle, so to speak, as Steve Owens
 19 was saying. So, I think that's really it on the NAS
 20 panel.
 21 So, the first thing we wanted to talk about was
 22 to have Rick share some work that his group has done on

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1 the registration review process and how ESA would
 2 conceivably fit in or some options that were prepared.
 3 Then we'll have a presentation which addresses similar
 4 issues from Tilghman Hall and Mike Willett that is based
 5 on, as we said, the PRIA process improvement work.
 6 MR. KEIGWIN: Thanks, Don. These next four
 7 slides are not in your packages. We apologize for that,
 8 but they may look familiar to many of you because they
 9 were some slides that we used at the April PPDC meeting
 10 where we began to get some advice from you all and one of
 11 the reasons why we went to the PRIA Process Improvement
 12 Work Group on trying to flush out some ideas on how to
 13 create some efficiencies in the registration review
 14 process for us, for stakeholders, for the services, as we
 15 move forward in trying to complete the program.
 16 So, let me just sort of refresh everybody's
 17 memory, because I think the next couple sets of slides
 18 really set up Tilghman's and Mike's presentations really
 19 well.
 20 The slide that's up here now represents what
 21 the current registration review process is from docket
 22 opening through preliminary risk assessment, final risk

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1 assessment, proposed risk management decision, and final
2 decision with opportunities for public comment at various
3 stages throughout. As originally envisioned, we would
4 consult, where necessary, with the services at the
5 preliminary risk assessment stage. We've done a couple
6 of pilots of this approach, and those chemicals are still
7 in consultation.

8 At the last PPDC meeting, we brought to you two
9 options for consideration and feedback. The first option
10 was to move the point in the registration review process
11 in which we would potentially consult. That would be
12 moving it from the preliminary risk assessment stage to
13 the proposed decision stage.

14 Among the reasons why we discussed why that
15 might be a better way to pursue things was that we would
16 be getting closer to what the actual end game final
17 federal agency action would be. The decision would be
18 based upon a more refined risk assessment. There was the
19 potential to include mitigation at that stage. So,
20 that's potentially what would be the subject of a -- any
21 consultation would be on a much narrower scope and would
22 be more reflective of what the final registration review

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1 decision might be.

2 We also talked about another option where we
3 would wait until we had issued, really, an interim final
4 decision where we had already gotten to the decision
5 phase but for having completed consultation. Some of the
6 discussions that we had in April highlighted that many of
7 the pros of this approach would be the same as were in
8 the previous option, but there was some discussion about
9 whether or not an interim registration review decision
10 could somehow be interpreted to be a final agency action
11 made in the absence of consultation. There was some
12 degree of hesitancy about that approach.

13 The third option is an option that actually
14 came about in the course of our discussions in April in
15 this meeting. That was to do a bit of a bifurcated
16 approach to the consultation process where at the point
17 that we would put the preliminary risk assessment out for
18 public comment, we would seek informal consultation with
19 the services to get more refined information about
20 species habitat, species biology, species behavior.

21 Incorporate that information along with public
22 comment that we had received in developing our final risk

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1 assessment and proposed decision and then, if
2 appropriate, based upon all that information, as well as
3 any mitigation that might have come forward during the
4 previous public comment period, make a determination to
5 consult formally at that point on the near final
6 registration decision.

7 Again, we've taken all three of these options
8 to the PRIA Process Improvement Work Group. There has
9 been some interest in this last option because again,
10 it's based upon additional information that helps refine
11 the assessment, has many of the same advantages for both
12 the agency and the services. We had some success with
13 this approach.

14 We actually employed this to a degree with a
15 consultation last year with the Fish and Wildlife
16 Service. This particular use pattern did not have issues
17 that necessitated consultation with NOAA. But we didn't
18 know how sustainable this was to effectively potentially
19 be in a situation of doing two consultations for every
20 registration review chemical every year, particularly
21 given current resource pictures across the federal
22 government.

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1 So, with those three options in hand, we've had
2 two meetings now with the PRIA Process Improvement Work
3 Group. We met with them first over the summer in July to
4 get their feedback on these options. We then had a
5 meeting in September in which CropLife America made a
6 presentation to our committee that we thought would be
7 really useful for you all to hear because there were some
8 really good suggestions that came forward there. So,
9 Tilghman is going to give that presentation next.

10 Also, it was announced at the spring PPDC
11 meeting, the Minor Crop Farmer Alliance held a meeting in
12 Denver that was really focused on how growers might be
13 able to get more involved in the registration review
14 process as it affected endangered species determinations.
15 So, Mike Willett is going to give us a brief presentation
16 on that.

17 Then we'll circle back to some charge questions
18 that are, as Don said, listed in the agenda for today's
19 meeting. So, with that, I'll ask Tilghman to come
20 forward. If somebody could help put Tilghman's
21 presentation up.

22 TILGHMAN HALL: Thank you for the opportunity

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1 to present this. It's some of our thoughts on
 2 registration review in general and how it impacts ESA,
 3 and then some additional thoughts specifically on
 4 consultation.
 5 For the sake of time, I can give kind of an
 6 intro of the slides, which is really -- the whole goal
 7 here, I think, is we have a commonality across all of us.
 8 We all want a predictable process. We all want to
 9 understand that process. We want to make sure there's
 10 opportunity for people to give input into that process.
 11 At the end, we want a comprehensive risk
 12 assessment that we can all interpret and understand. We
 13 want well-documented risk management decisions, how was a
 14 risk or no-risk conclusion reached. We want all the
 15 stakeholders to know when they can participate and how to
 16 participate. We want, basically, a balanced
 17 implementation. We want to protect species but we also
 18 want to protect agriculture, so minimizing that impact on
 19 ag.
 20 This slide is kind of the basic five phases of
 21 registration review as it's currently defined. So, you
 22 have the docket opening, your final work plan, your

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1 preliminary risk assessment, your final risk assessment
 2 with proposed decision, and then your final decision. As
 3 noted already, there's public input at various points
 4 along here.
 5 What we're going to do is just give some brief
 6 comments on each one of these phases and how we might
 7 think things can be improved a little bit. So, in the
 8 first docket opening, registration review up to now
 9 didn't have really the smart meeting opportunities where
 10 the registrants were really going in earlier, much
 11 earlier than when that first docket opens, to explain
 12 these patterns.
 13 So, we think it could be a lot more efficient
 14 to go ahead and reinstate those kinds of meetings to get
 15 that kind of information out so that the first docket
 16 opening isn't focused on did it get the use patterns
 17 right; it's focused on some of the other main issues that
 18 might be coming up in the risk assessment.
 19 We need a clearer mechanism for stakeholders to
 20 supply information, not just the registrants but others,
 21 the states, USDA. It's very confusing to know when to
 22 provide the information given the time line of

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1 registration review. It could take three to five years
 2 for it to be complete. So, when should you give that
 3 information? That needs to be specified a lot more
 4 clearly in that first docket opening as well as
 5 throughout the whole process.
 6 At this point, you can interact. You can
 7 identify what you anticipate the interaction with the
 8 service being. Is it going to be an informal
 9 consultation, a formal consultation, some sort of
 10 memorandum of understanding of how you might work
 11 together. Start giving some indications of how you might
 12 move forward in that type of interaction.
 13 Then we identified that perhaps after the first
 14 docket opening, if the registrants have a lot of
 15 additional information that they're planning on
 16 providing, they could possibly request a second meeting
 17 just to make sure everyone understands all the
 18 information that might be coming in between that period
 19 and when the final work plan is coming out.
 20 So, when we're talking about the final work
 21 plan, again, the focus here is more about the restatement
 22 of the data needs and all the information you want.

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1 Currently, registration review has a one- or two-page
 2 document in there that says please provide us all of this
 3 great information. It is a very good list of information
 4 that they want from the states, from USDA, from the
 5 registrants, from anybody who has that information.
 6 Again, when do you give it? If you have a DCI
 7 and EPA is not going to start that risk assessment for
 8 three years, then really you want that information close
 9 to the end of the DCI and not at the beginning where it
 10 might become quickly outdated. So, that needs to be more
 11 clearly stated in the final work plan of when you
 12 anticipate needing all that type of information.
 13 Again, included in that could also be a
 14 statement of any sort of endangered species data
 15 requirement that might be necessary. That should just be
 16 made clear in the final work plan as well.
 17 This one really talks about the preliminary
 18 risk assessment, but there's a line in front of the
 19 preliminary risk assessment to the final risk assessment.
 20 It's kind of blurry a little bit. Essentially, as you're
 21 working through the preliminary risk assessment, it's at
 22 that point where you need to increase the communication

41	<p>1 with the states and other stakeholders on how you want to 2 use that local information that you can gather. So, 3 there needs to be some outreach to them to make sure you 4 really are getting that information in. 5 As the risk assessment becomes clearer as 6 you're working through it, it starts becoming more 7 obvious what are the drivers of the risk assessment. If 8 there's a risk occurring, is it primarily from spray 9 drift, is it primarily from runoff? What are the drivers 10 behind the potential risks that may or may not be 11 occurring? That's where you can start the dialogue with 12 appropriate stakeholders on those drivers of the risk 13 assessment. 14 If spray drift is a major issue, then let's 15 start talking with the novel groups, the aerial 16 applicators, the people who know more about that type of 17 information. If it's runoff, then maybe USDS or USDA or 18 other experts can help feed information into the process 19 that might help refine that risk assessment and making 20 sure we all understand where things currently stand in 21 the current science. 22 Again, the line between the preliminary risk</p>	43	<p>1 different options of consultation. I don't think I need 2 to spend any time on it, but essentially (inaudible) 3 preliminary risk assessment, the final risk assessment, 4 or a combination of informal versus formal at the 5 preliminary or final decision. So, these are all viable 6 options. 7 What we're going to do now is just give you 8 some general recommendations about consultation and what 9 our thoughts are around that. So, wherever consultation 10 occurs, informal, formal, preliminary, whatever, the role 11 of the applicant has to be identified whenever it's 12 occurring. I think everyone understands very well these 13 days about the role of the applicant being identified as 14 part of ESA. 15 It's a very important step. It's a very 16 important step in terms of the registrant because that 17 gives them an understanding of the process that's going 18 to be used, the timing, and how that's going to be done. 19 So, it should be an easy one to just make sure the 20 letters go out about who are the applicants in this 21 consultation. 22 So, one of the comments made earlier is that</p>
42	<p>1 assessment and the final risk assessment, continue that 2 dialogue as you go along. You'll have to document that 3 dialogue. We understand that. You'll have to include it 4 in there that we talked to this group and these were some 5 of the recommendations that can be documented. 6 Then, what's important is after you have the 7 preliminary risk assessment, you're going to the final 8 risk assessment. Risk management decisions are becoming 9 clearer. Those risk management decisions have to be well 10 documented. How did you reach the no-risk conclusions? 11 If you reached a risk conclusion, what was that risk and 12 how did you get there? 13 That's not necessarily always done on the 14 current registration review in terms of ecological 15 effects type of thing. Risk management decisions aren't 16 not necessarily as transparent as they possibly could be. 17 So, this is a really critical step in order to understand 18 how to move forward, and especially to understand if 19 you're going into consultation. How did we reach our 20 conclusions? So, it's important that this risk 21 documentation phase does occur very strongly. 22 This is our version of what EPA proposed on the</p>	44	<p>1 you can use informal consultation as a way to gather 2 information. I guess we kind of disagree with that a 3 little bit. What we believe is that EPA and the services 4 definitely should interact throughout this whole process. 5 But you don't necessarily have to initiate consultation 6 to do that. If you need information, there should be a 7 mechanism to gather that information without initiating 8 consultation that has all the time lines and everything 9 associated with it. 10 So, our recommendation is that you just 11 continue the interactions through the process as needed. 12 If you're going through an informal one, that's certainly 13 an option, but you don't have to initiate an informal 14 consultation, or shouldn't have to, in order to get that 15 information. 16 We certainly acknowledge that the services are 17 the experts on species location information, on other 18 species biological information that might be needed to 19 help with that risk assessment. One mechanism to do this 20 is just coming up with some sort of MOU, memorandum of 21 understanding, about how you want this process to work. 22 There's an understanding that there might be some</p>

45	<p>1 outreach needed for EPA to do this risk assessment. 2 Hopefully, those databases are kind of generated by the 3 services and this isn't a huge workload. 4 There are options for consultations for sure. 5 We've already outlined a couple of them. The counterpart 6 regulation were not completely overturned in the court of 7 law. The alternative consultation process that was 8 outlined in the counterparts still exist. 9 The alternative consultation essentially says 10 let's kind of do this risk assessment together, so you're 11 kind of initiating it early. You're working together 12 through the risk assessment. So, by the end, you 13 essentially have reached an agreement on the effects 14 determination, as well as consultations. That is an 15 option that could be used. We certainly would encourage 16 trying it. 17 There's also section 402.46 in the counterparts 18 that survived. That actually allows EPA to go and do an 19 effects determination. They could actually make a 20 jeopardy, incidental take statement, RPA and RPM 21 judgments as well. So, they could actually take these 22 assessments, if you'll let me call it that, much further</p>	47	<p>1 significant resource limitation going on between the 2 agencies. So, we do need to think about how best to use 3 those resources. So, our recommendation is to only do it 4 for the decisions that need consultations. 5 The reason we want it to be on the more 6 complete effect determination is if you do it too early, 7 you remove the stakeholder input. That is a very 8 critical point for us. We do have additional data that 9 can be provided that might change a preliminary risk 10 assessment to a final risk assessment. Risk assessments 11 can change. If they change, you would have to reinstate 12 consultation again based on a new risk assessment. 13 So, we want the consultation to consider all 14 the stakeholder input. We want it to be the most 15 informed and refined risk assessment. We want full 16 documentation of any risk management decisions. Again, 17 that helps to clarify what is the need of consultation 18 and maybe perhaps what is not. 19 That would allow a clear identification of what 20 species are at risk, essentially have a no effect or 21 maybe a not likely to adverse effect decision or a 22 species that might be at risk and need informal</p>
46	<p>1 than they currently are. 2 Of course, all of that would be subject to the 3 services review as outlined in the counterparts. But it 4 might be one way to streamline some of the processing if 5 we can get to the point where EPA can make decisions such 6 as that. The services are reviewing them and agreeing or 7 disagreeing with them. 8 Again, we think you use these consultations as 9 needed for regulatory decisions. Don't use consultations 10 as a way to interact with two agencies. Use them to make 11 the regulatory decisions and get to a decision so that 12 you can do it in a more timely fashion. 13 So, our ultimate consultation goal, and this 14 may take a little time to get there, is that if 15 consultation is required and you're thinking about kind 16 of the normal one, where it's formal consultation after 17 EPA completes their effects determination, it should be 18 conducted on as complete an effects determination or 19 biological assessment, whichever term you want to use, as 20 possible. 21 It should only be for that part of the decision 22 that really needs the consultations. We have a</p>	48	<p>1 consultations such as may effect or likely to adverse 2 effect decision. We think this is one way to really get 3 a best use of the services resources as well as EPA 4 resources. 5 We acknowledge, though, things aren't perfect 6 right now between the services, so alternative options 7 may be needed during the next couple of years as the NAS 8 panel continues. We need to think a little bit more 9 about that because there is an underlying assumption that 10 they kind of agree with the risk assessments coming out 11 with EPA. So, we need some of the science questions 12 being answered. As Steve Owen said, you shouldn't 13 underestimate the NAS panel and the influence it will 14 have on how these risk assessments are done. 15 So, that leads to one of the questions that I 16 think are on your sheet about interim decisions. An 17 interim decision could be -- you have interim decisions 18 hanging out there, but the question is, can you have 19 interim decisions based on some uses or species that 20 aren't at risk and some species that (audio trouble) make 21 that kind of interim decision. That's a slightly 22 different question than I think has been asked before.</p>

49	<p>1 Our thoughts are that that's definitely worth</p> <p>2 pursuing, that you have perhaps an interim decision that</p> <p>3 leads down that path where there are no effects decisions</p> <p>4 reached by EPA on certain uses or species. Let's move</p> <p>5 those through the registration review process, and maybe</p> <p>6 others need to go into the consultation.</p> <p>7 That said, there are a lot of nuances to that</p> <p>8 statement I just made when you do that. The first thing</p> <p>9 is semantics. What do you mean by interim? How do you</p> <p>10 define that? How do you move that forward? There's</p> <p>11 issues with ESA. The definition of the action would have</p> <p>12 to be defined. That would have to be very clarified.</p> <p>13 Ultimately, you would need a very clear</p> <p>14 document of the process that would outline how this could</p> <p>15 or could not work. I guess our recommendation would be</p> <p>16 to require more thought and evaluation on whether or not</p> <p>17 it could work. But it's probably worth pursuing at this</p> <p>18 point in time and thinking more about it.</p> <p>19 So, in general, some of our process</p> <p>20 improvements that we think would really help registration</p> <p>21 review but also help with the ESA part of registration</p> <p>22 review, early registrant interaction to help work through</p>	51	<p>1 It certainly needs further evaluation, certainly input</p> <p>2 from this group on what they think about it.</p> <p>3 Some of the potential benefits, again you'll</p> <p>4 have better understanding of those use patterns, if you</p> <p>5 can get that information done quickly. Increase</p> <p>6 understanding of the data and information used in</p> <p>7 submission opportunities so that you are getting</p> <p>8 information you really want.</p> <p>9 You need to better figure out how to integrate</p> <p>10 that local information and any best available data that's</p> <p>11 coming in, the full consideration of all the mitigation</p> <p>12 options and the documentation about what you did there.</p> <p>13 So, again, ultimately leading to that clearly defined and</p> <p>14 fully informed risk assessment and all the assumptions</p> <p>15 behind that risk assessment so people understand how you</p> <p>16 reach decisions. And lastly, more efficient and targeted</p> <p>17 interactions with the services.</p> <p>18 Our conclusions, much of what I just said, are</p> <p>19 restated here. A more open and transparent registration</p> <p>20 review process will benefit all. It will also help with</p> <p>21 the ESA consultations. You need that mechanism for the</p> <p>22 registrant and stakeholders to provide that information.</p>
50	<p>1 use patterns and things like that and help influence</p> <p>2 perhaps a better problem formulation coming out. You</p> <p>3 would have increased communication with stakeholders</p> <p>4 occurring even more, but you would have document anything</p> <p>5 that influenced risk assessment and what came out.</p> <p>6 Concurrent with that is a better understanding</p> <p>7 of the data needs and the timing of the commission of</p> <p>8 those so that the states, or USDA, or the registrants, or</p> <p>9 other people know when to provide the information to be</p> <p>10 more influential in terms of its use in the risk</p> <p>11 assessment.</p> <p>12 EPA and the services should definitely be</p> <p>13 interacting early and often. You could come up with an</p> <p>14 MOU to help define how you want that interaction to</p> <p>15 occur, or some other mechanism. Consultation,</p> <p>16 essentially, the registrant would be clearly identified</p> <p>17 as the applicant.</p> <p>18 Use the counterpart regulations that survived.</p> <p>19 They do provide some good mechanisms just to make things</p> <p>20 more efficient. The more formal consultation process</p> <p>21 should be a more complete effects determination. Then</p> <p>22 there's the discussion on final versus interim decisions.</p>	52	<p>1 You need that early and often interaction with the</p> <p>2 services. You need that final decision to be understood</p> <p>3 by all and lead you down where needed. The consultation</p> <p>4 and needs clearly defines the path of the consultation.</p> <p>5 Better utilization of the counterparts, again,</p> <p>6 our ultimate goal here -- and it might take a little</p> <p>7 while to get there -- is that consultation is completed.</p> <p>8 Make sure you've considered all of the stakeholder input</p> <p>9 and look at it at the more complete effects determination</p> <p>10 phase, and only for those decisions that might need the</p> <p>11 consultation. That's it.</p> <p>12 MR. BRADY: Thanks. We have a few minutes for</p> <p>13 questions if anybody has any.</p> <p>14 Mark.</p> <p>15 MARK: I have several actually. Richard, you</p> <p>16 introduced this and you thought it was appropriate for us</p> <p>17 to watch it. These recommendations, I want to get your</p> <p>18 opinion. Is there any unnecessary time difference or</p> <p>19 delay in implementing these recommendations as opposed to</p> <p>20 what you're currently doing?</p> <p>21 MR. KEIGWIN: I think there are pieces of them</p> <p>22 that -- I mean, we haven't fully considered everything</p>

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1 that Tilghman presented to you all. I think Don and I
2 got this presentation about three weeks ago. So, we're
3 still in the process of entertaining it. But we thought
4 it would be helpful as we were considering these ideas
5 that came forward to get some input from you all and what
6 you all thought.

7 Many of them are probably implementable. Some
8 of them, I think, are probably in some ways intertwined
9 with the NAS review. So, how quickly we could move
10 forward on aspects of what you just heard is unclear,
11 pending the outcome of advice that we would get from the
12 NAS.

13 MARK: My concern is that the folks who do
14 this, you and the agency that do this, you look at it and
15 say if it's an improvement, then we need to understand
16 that you think it's an improvement. But if it's not,
17 then I want to get your opinion on it, too. This is
18 pretty cumbersome stuff for those of us that don't do it
19 all the time. So, as you look at this more, maybe we can
20 get an opinion from you on that.

21 MR. KEIGWIN: Sure.

22 MARK: Which is a tough thing to do, put you on

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1 the spot like that.

2 I do have one more question, and I can come
3 back to others if we have time. But it says on page 3,
4 slide 2, relevant stakeholders may include registrant,
5 USDA growers, crop experts, nozzle manufacturers, aerial
6 applicators, state and local programs, including
7 services, et cetera. Are environmental activists
8 considered relevant at this point or not, I mean, if
9 they're experts?

10 MR. KEIGWIN: So, EPA would consider all
11 stakeholders to be relevant to this process.

12 MARK: Okay. I just wanted to make sure that
13 they were still included on that because they're not in
14 there.

15 MR. KEIGWIN: Remember, this was CropLife's
16 presentation.

17 MARK: I understand that.

18 TILGHMAN HALL: We would agree.

19 MARK: NGOs aren't listed on this.

20 TILGHMAN HALL: No, they're not listed on
21 there.

22 MR. KEIGWIN: On earlier slides I think they're

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1 listed.

2 TILGHMAN HALL: Don't mean to exclude anyone
3 who wants to provide information. Let me just say that.
4 If they have information that should be provided it and
5 it's relevant, it should be used.

6 MR. BRADY: I think what we should do is limit
7 these questions to clarifying questions on the
8 presentation. Then we can have the discussion after we
9 see Mike's presentation.

10 MARK: That was a clarifying question.

11 MR. BRADY: Right, I appreciate that.

12 Dr. Keifer.

13 DR. KEIFER: Mine follows up on that question
14 to some degree because one of the -- I'm just wondering
15 about services when it comes to the species homo
16 sapien/sapien laboralis, the worker. Who is representing
17 that particular species in this process? Where are they?
18 Are they coming in as a service like OSHA, or is it EPA
19 that represents the protection of workers in this
20 process? Do they interact in this process at all? I'm
21 just wondering.

22 MR. KEIGWIN: As part of registration review

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1 overall, there are -- that slide I put up early on that
2 overlays the entire registration review process, each of
3 those public comment areas there's an opportunity for any
4 stakeholder to participate in that effort. But,
5 generally speaking, it's EPA that's making the worker
6 safety determinations.

7 There's not a requirement under OSHA or any
8 other law to consult with OSHA or NIOSH. But, on
9 occasion, where there's a unique methodology or a unique
10 issue, it may. We're trying to focus this discussion,
11 though, just specifically on Endangered Species Act
12 issues.

13 DR. KEIFER: I would argue they may be
14 endangered species.

15 MR. BRADBURY: Just to clarify, Matt, the reg
16 review process is reevaluating everything about the
17 registration. We're looking at if it's a food use
18 pesticide, we're looking at FQPA issues and dietary
19 exposures, aggregates. If it's a cumulative, we're
20 looking at that. We're looking at occupational risks.
21 We're looking at residential uses.

22 We're looking at ecological risks, and we're

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1 looking at endangered species. And if everything works
2 right, we're folding in endocrine disruptor screening
3 programs as well. So, it's looking at everything
4 associated with the registration.

5 What we're doing here is just trying to get the
6 conversation going on how do we try to optimize the
7 efficiency and the effectiveness of getting the
8 endangered species part of this overall registration
9 review process (inaudible).

10 So, why don't we just get clarifying questions
11 on this presentation. Then we'll get to Mike. Then, our
12 charge questions, if you will, kind of get at the meat of
13 what we want to do.

14 UNIDENTIFIED FEMALE: I just have a quick
15 question, and it's clarifying. Has this approach come
16 out of the PRIA Process Improvement Work Group or are
17 they still vetting it and discussing it, too?

18 MR. KEIGWIN: This was the presentation that
19 CropLife made to the PRIA Process Improvement Work Group.
20 But we haven't received yet a recommendation out of the
21 PRIA Process Improvement Work Group.

22 MR. BRADY: I think we'll go to Mike. Thank

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1 you, Tilghman. We appreciate it.

2 DR. WILLET: Thanks, Don. First of all, Minor
3 Crop Farmer Alliance was asked to make this presentation.
4 This presentation is a subset of a presentation that Dan
5 Botts made to the American Chemical Society summarizing
6 the outcome of the Minor Crop Farmer Alliance ESA meeting
7 that was held in Denver in May.

8 Dan's presentation was quite a bit longer.
9 I've cut it fairly short. One of the reasons why I did
10 that was obviously for the interest of time. I knew that
11 the charge questions were going to be there that were
12 going to cover some of these issues. Also, you have the
13 entire text of the summary of the meeting that was
14 distributed this morning, thanks to Margie's efforts. In
15 fact, most of everything that's happened here over the
16 past two days are due to Margie's efforts. So, we
17 appreciate that.

18 Just a little bit of an introduction. Minor
19 Crop Farmer Alliance is an organization of about 30
20 specialty crop producer organizations. We've been around
21 since about 1989 working on pesticide policy issues. As
22 the issue of endangered species started intersecting

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1 pesticide policy, Minor Crop Farmer Alliance decided it
2 was an important thing to get involved and to try to give
3 those grower organizations, who are relatively small
4 organizations with all the employees having other day
5 jobs, a voice in the process in some way. We think that
6 the endangered species process needs improvement. I
7 think everybody agrees that it needs improvement. It
8 needs to be as open and transparent and science-based as
9 possible.

10 So, we put together this meeting. The planning
11 committee consisted of growers, EPA, National Marine
12 Fishery Service, US Fish and Wildlife, USDA, and
13 registrants. You're going to see the word growers in
14 this presentation.

15 Really, this is the grower perspective, because
16 this is one of those unique situations where because of
17 the consultation process, the people that are actually
18 applying the pesticides are not part of the formal legal
19 process. They're not involved. Their information is not
20 considered as part of this consultation. So, it's a
21 challenge, because obviously, those folks that are
22 applying pesticides know how they're used. So, how can

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1 that information be placed in the process? You'll see
2 that that was the subject of significant discussion.

3 So, the goals of the workshop were to try to
4 provide grower representatives an understanding. We had
5 75 people participate in the meeting in Denver. We
6 invited you all. Some of you came. We would have liked
7 to have seen more. But it was a good group, a really
8 cross section of registrants, user groups. Folks from
9 EPA, National Marine Fishery Service, Fish and Wildlife
10 all were there.

11 We wanted to identify, where we could, grower
12 level data that would enhance the risk identification and
13 risk mitigation decision process that's going on, working
14 with EPA and, where we could, work with the Services, and
15 to initiate or at least start the discussions on
16 mechanisms to provide the kind of data that we thought we
17 could provide and was important in the process of making
18 these risk management decisions on endangered species.

19 Well, the first question is, is there actually
20 grower level data that would inform the process. If
21 there is, what information is the most desirable? Most
22 of these organizations that make up the Minor Crop Farmer

15 (Pages 57 to 60)

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1 Alliance are relatively small organizations. They might
2 have one or two staff members. How do you collect that
3 data if it's not already being collected somewhere? It's
4 a real huge challenge for these kinds of organizations.
5 Yet, in the case of the west coast, it's those users that
6 are most impacted by the Endangered Species Act. So,
7 it's a significant issue for them.

8 Once you have data, how is it entered into the
9 process? Right now, if there isn't sort of a full
10 engagement of all the agencies making this decision, we
11 don't have access to the existing consultation process to
12 plug data back in that's is grower level data.
13 Hopefully, that's one of the things we'll work on.

14 Then, of course, at the end, everybody that
15 uses the data has got to agree that it's complete and
16 accurate. So, how is that decision made about whether
17 accuracy and completeness is there? Then, of course,
18 where does it get plugged in?

19 So, what we wanted to determine is how
20 important grower information can be collected and used on
21 the regulatory process, provide an overview of how EPA,
22 National Marine Fishery Service, Fish and Wildlife, and

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1 USDA can use grower data developed in the process, and
2 determine the best places in the biological review
3 process where that data can be plugged in.

4 In that handout, I didn't put it up because it
5 was about three pages, there is a matrix that is really a
6 lot like the matrix that Rick showed. It's an slightly
7 expanded version. We actually produced this matrix in a
8 meeting with 75 people. So, I'm totally impressed with
9 the fact that we actually captured everything that's in
10 that matrix in a group that size.

11 But it's an example of where we think that this
12 information could be plugged into the system. It doesn't
13 vary a whole lot from what Rick had pointed out and the
14 talk that the folks from EPA gave at our April meeting.
15 It doesn't vary a lot from the kind of approach that
16 Tilghman suggested as well.

17 We think it benefits from both formal and
18 informal discussions between growers, EAP, National
19 Marine Fishery Service, and Fish and Wildlife. We really
20 have appreciated that Cheryl's group and the folks at
21 USDA have been really willing to step up and try to find
22 ways to plug existing data and to maybe tweak the way

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1 that the existing USDA data is presented to be able to
2 help inform that process even more than they are now. I
3 know they're working really hard right now to try and do
4 that with some pesticide use data, as a matter of fact.

5 This is the last slide, just sort of a summary.
6 One of the things that we wanted to do -- and I want to
7 say that Dan Botts really did all this work. I am
8 absolutely amazed all the time about how much Dan gets
9 done. He wrote -- and we helped him edit -- the workshop
10 summary that you have in your packs. You have a summary
11 of what was discussed at the meeting. We want to
12 continue this dialogue wherever we can and make it part
13 of this entire process. I think that it's a way of
14 providing what we view as valid information into the
15 system only used on alcolide d-beds (phonetic) and then
16 only on the borders of alcolide d-beds.

17 Well, first of all, the question in most
18 people's mind is, what is an alcolide d-bed. It's a lot
19 smaller than you think, or maybe not. I don't know.
20 Maybe you know. But, at any rate, the discussion is if
21 you know that that's a use and if you knew that was a
22 driver, how can you help inform the process by providing

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1 information about how many alcolide d-beds there are
2 somewhere and how big an alcolide d-bed normally is, and
3 that kind of thing.

4 I think the other question came up when the
5 issue of tank mixes came up. We provided input back, in
6 my particular case, on a specific crop situation. We
7 say, well, these tank mixes are never used. It turned
8 out that the label was a label that was not ever being
9 sold. So, those are the challenges that we face.

10 We'd like to understand how important those
11 things are and how we can help sort out what the
12 important types of information are that the Services need
13 to have as they begin to do these biological opinions so
14 we can find ways to point them in the right direction to
15 collect that information, given the constraints that they
16 have. So, we intend to continue this dialogue with
17 National Marine Fishery Service because, obviously,
18 they've been the most receptive to being able to have
19 those discussions with us. We appreciate that.

20 Then, finally, we want to continue to review
21 and participate in data collection, review and analysis
22 as these processes go forward, and engage in the

16 (Pages 61 to 64)

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1 discussions that are going to appear here and will
2 continue to occur all way through the entire National
3 Academy of Science process, which I think is going to
4 have to be completed before we sort out how all of these
5 things are going to go forward.

6 Thanks for the opportunity to be here and make
7 the short presentation. I suppose, Don, if there's --
8 what do we call these? Clarifying questions.

9 MR. BRADY: Clarifying questions.

10 DR. WILLETT: I'll be glad to answer one.

11 MR. BRADY: Dave, do you have one?

12 DAVE: So, I'm wondering what you're
13 envisioning. It seems like it's a big country and
14 there's different minor crops all over the place. Are
15 you thinking that whatever groups might be affected by a
16 particular opinion are going to interact directly?

17 I'm wondering how much effort do you envision
18 the growers going through to give the level of detail in
19 how these things are used to the Services staff people
20 that need to know this?

21 DR. WILLETT: Well, Dave, you're absolutely
22 right. It's a huge challenge because minor crops are

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1 produced all over this country. But I think that the one
2 good thing is that the Minor Crop Farmer Alliance does
3 represent a lot of those organizations that have folks
4 that are involved in this pesticide decision making
5 process, whether you're a tart cherry grower from
6 Michigan or an asparagus grower from the State of
7 Washington. I think that we would be able to use the
8 vehicle of the Minor Crop Farmer Alliance to inform
9 people about the process.

10 But I think that the only way that any grower
11 organization is going to have input into the process is
12 not going to be through a process that solely relies on
13 us feeding large volumes of paper to National Marine
14 Fishery Service and expecting them to be able to process
15 all that information for every active ingredient on every
16 crop.

17 I think it's going to have to be a process that
18 works through the existing re-registration processes at
19 EPA that are fully transparent and vetted by all
20 stakeholders that are in the process, and are also going
21 to be informed about those processes through the existing
22 registration review process.

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1 MR. BRADY: Gabriele.

2 MS. LUDWIG: Dave, I just wanted to respond to
3 that. In terms of the process for the Food Quality
4 Protection Act, when that got enacted, and then the risk
5 assessments were made public, that was the first time
6 grower groups had an opportunity to be part of the
7 process. It made a big difference.

8 What I would say is that we have experience.
9 If there is the opportunity to provide data on how we
10 really use the product, grower groups will work to get it
11 together. The issue here is that there is no place for
12 us to get it into the process from a services
13 perspective, plus a really lack of transparency of
14 exactly how services get to the decisions that they make.

15 So, it's very hard to figure out what data is
16 most relevant because we can't understand how they came
17 to the decisions they came to. So, that's really where
18 the rub is right now, based on my experience. I had the
19 opportunity to attend that meeting. It was very helpful.

20 I reiterate what Michael said, that Dan Botts
21 is just amazing that he pulled it off. And that he got
22 all these people in the room together was also just a

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1 minor miracle.

2 But I'm just saying that we have experience
3 from FQPA process, even for smaller crops, of getting
4 data in, finding ways to get that data together when it's
5 really needed. The issue here is figuring out which data
6 makes the most sense and how to get it in.

7 UNIDENTIFIED MALE: I just wanted to say I
8 wasn't casting down on the value of it. It just seems
9 like an enormously big project. Each active ingredient
10 and each minor crop opens up a whole new set of
11 interaction. I'm not quite sure how to get a grip on
12 this. I kind of doubt that your constituents would have
13 the capacity to interact each time -- and also the
14 Services -- to interact each time.

15 So, I'm wondering if you have an idea of how to
16 maybe get both sides' level of understanding of each
17 other's issues to a level where you don't have to do it
18 every single time.

19 UNIDENTIFIED MALE: Well, Dave, one of the
20 things about the folks that I work for is they say, geez,
21 we'll let Mike do that. One of the good things, Dave, is
22 that the Northwest (inaudible) Council and organizations

17 (Pages 65 to 68)

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1 like the Northwest (inaudible) Council, the organization
2 that Gabriele works for, the individual producers don't
3 have to make those responses back, which is helpful.

4 Now, obviously, there aren't all organizations
5 that produce minor crops that have staff people. So,
6 that is a challenge. So, it isn't going to have to be
7 the individual growers that make these responses. It's
8 going to be a summary of how growers use a particular
9 product based on information that we have.

10 In many cases, Dave, it's not just numbers that
11 we're collecting just based on communication with our
12 members. It's information that's being collected by the
13 National Ag Statistic Service, because we're a pretty
14 strong supporter of that pesticide use collection or
15 chemical use survey that they do. Most of the minor
16 crops that have significant acreage in each state, the
17 data is being collected on those commodities.

18 We often work closely with, for example, NAS to
19 fine tune their data collection. For example, if they're
20 missing something, we'll try to go back with them and
21 say, well, it looks like part of your questionnaire is
22 not quite picking up all the uses. If you adjusted it,

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1 did it this way, you'd actually get more of the uses.

2 So, we do that. You're right. I represent
3 about 1800 apple growers, for example. I couldn't
4 collect that information on my own. So, we have to rely
5 on other sources. You're right also on the second point
6 -- and I'm not going to speak for Jim Lecky, but I think
7 it would be very difficult if all of a sudden all these
8 minor crop groups started feeding his folks information,
9 because they don't have a very large staff, but just to
10 even process the papers.

11 So, it has to be a partnership arrangement
12 within the existing risk assessment process that's going
13 on within the EPA, which has shown an ability to handle
14 that kind of information and input.

15 UNIDENTIFIED FEMALE: I'm all in favor of more
16 data. That's good. I mean, it seems like one of the
17 things that would be useful to know is what level of
18 awareness do growers have of endangered species in their
19 areas? Is that some information that you might consider
20 collecting? Is there an education task in here as well?

21 UNIDENTIFIED MALE: Well, of course, in the
22 case of these initial issues that are occurring on the

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1 west coast and the northwest, we're dealing with
2 endangered species of salmon or some -- there's a really
3 high understanding of salmon as an endangered species in
4 the northwest.

5 It's just part of the culture, frankly, and you
6 know that, not only in relation to pesticides but in
7 relation to most other issues that impact people's lives
8 on a daily basis in the northwest. You live near rivers.
9 There's dams on rivers. All those issues. So, I think
10 people understand the issue of endangered species.

11 I think that the challenge is trying to sort
12 out and sort of parse out what the contribution of risk
13 is by all the factors that are in there. I think that as
14 we work with growers, what we try to do is not, at least
15 personally, try not to say that the sky is going to fall
16 on you tomorrow if something goes wrong, but here are the
17 issues that we need to address.

18 I think that we need to be extremely honest
19 with people, but I also believe that if decisions are
20 made that can have an impact on their ability to continue
21 farming in certain places, and they're doing things that
22 aren't really representing risk to endangered species or

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1 their habitat, then we need to make sure that we're able
2 to provide that information back.

3 MR. BRADBURY: Scott, and then we'll get to the
4 broader questions.

5 MR. SCHERTZ: To give it a little bit of other
6 insight to Dave's question, I think generally the growers
7 and the grower groups are very motivated. Usually, they
8 have a very limited tool box. These are very important
9 tools for the specialty crops. In this case, I would say
10 there's probably a pretty high level of interest, just
11 because there are very limited choices, even though like
12 IR4, et cetera, works on providing those. But it's a
13 continuing challenge.

14 MR. BRADY: Okay, thanks very much. So, our
15 challenge now is to walk through these charge questions
16 and elicit some help from the committee as we explore
17 these issues further. So, I'll just start with the first
18 one, which is, at what stage in the registration review
19 process should stakeholders provide information to EPA?
20 What types of information should be provided at each
21 stage? I won't read A through E. I think folks can read
22 that.

18 (Pages 69 to 72)

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1 I see Jenn Sass's card up.

2 DR. SASS: Thank you for the presentations,
3 too. I thought they were helpful. I thought the
4 CropLife one had some good ideas in it. So, I just
5 wanted to add a few ideas to it. Number one, obviously
6 the stakeholders came up with the clarifying questions,
7 but I had that written down. I wanted to point out that
8 including all stakeholders is important. You guys
9 already know, everybody knows, that sometimes the issues
10 related to worker health are the opposite of issues
11 related to endangered species protection.

12 I remember a particular pesticide where the
13 worker protection folks wanted it in granular form to
14 protect the workers and the animal folks wanted it in
15 liquid form so the animals wouldn't eat it in granular
16 form. So, that was a learning moment for me, but it also
17 made me realize that you can't actually solve the problem
18 in isolation. So, just make sure that worker protection
19 folks as well as the environmental and public health
20 people are there at all stages.

21 The other thing I felt was interesting, the
22 data, relevant data, and data at relevant junctures is

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1 really important. So, I really support that. But I want
2 to make sure that that data is also publicly available,
3 because, right now, a lot of isn't until we get DERs,
4 especially with the DCIs, the data call-ins, which are
5 identified at stage -- early in CropLife's presentation,
6 slides 1 through 5.

7 EPA does the data call-ins. Well, the public
8 can see what EPA is requesting. You can see what the
9 list of called-in data is, but we can't actually tell
10 when or if EPA has received the data it's called in and
11 we can't see the data it has received. We can't tell
12 where it hasn't received data and we can't see what EPA
13 thought of that data, some kind of assessments or a DER
14 or whatever.

15 So, that's something that should be public.
16 Maybe the chemical search engine system that was
17 presented yesterday at lunch is a good way to compile
18 that. That was an exciting presentation, by the way,
19 just so you know. That was good lunch entertainment. I
20 was excited.

21 Then, the last thing is it also reminded me in
22 CropLife's presentation about having more meetings with

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1 registrants and with stakeholders along the way that I
2 wonder if there wouldn't be a way EPA is supposed to log
3 the meetings so that we can tell when these meetings are
4 taking place and what the subject is. Thanks.

5 MR. BRADBURY: Cindy.

6 MS. SMITH: I guess I'd like to ask a question
7 before I make a suggestion here. You guys have a process
8 already. You have experience through a lot of the work
9 that we did in FQPA. When you open a docket, do you get
10 very many comments?

11 UNIDENTIFIED MALE: It varies. I think it
12 depends upon how high profile the chemical is. For the
13 vast majority chemicals, no. Typically, the registrant
14 will respond with some clarification errors that they
15 find in the problem formulation. Some of the task forces
16 will respond and say, I just want to remind you that the
17 registrant is or is not a member of X task force, so some
18 of the data compensation type things. On occasion, we'll
19 get things like this use isn't that important to us. So,
20 we'll get some early mitigation. But generally, it's not
21 a high volume of comments.

22 MS. SMITH: I asked the question because I

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1 think this point about efficiency, efficiency for you
2 guys, efficiency for registrants, efficiency for grower
3 groups of trying to know the Services, when to put in and
4 use -- anybody who wants to put in information -- it
5 seems like there's a balancing act between -- people want
6 to comment when they know there's an issue. That's
7 generally how it comes in.

8 So, if you open up a docket for chemical A and
9 everything looks great and there's not going to be any
10 problems, you're probably not going to get a lot of
11 interaction. So, I think it sets the stage where you say
12 we've got a concern here that we think we need to refine
13 or we might have to mitigate or whatever it might be.
14 I'm not close enough to know when the exact right time
15 for that is.

16 It seems like you guys are struggling through
17 that in the interactions that you have with the Services
18 as well. You might come to a conclusion that you don't
19 have an issue, only to find out that you do have an
20 issue. So, it seems like it's a challenge to decide when
21 that actually is.

22 But I guess what I would support in that first

19 (Pages 73 to 76)

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1 question is that refinement of what the actual uses are
2 up front is really critical. That piece of information
3 -- and that would come from growers, it would come from
4 NGOs, it would come from registrants, whoever has a
5 concern. I think getting that refinement done up front
6 seems to be a huge efficiency savings for everybody to
7 have an understanding of what are we actually going to do
8 a problem formulation around.

9 MR. BRADBURY: I'll just talk for one response
10 to Cindy's point. So, my philosophy has been at the
11 beginning that it's better to get the information at the
12 end. It's better to refine at the front end than at the
13 back end because that's resource intensive. Most of
14 these registration review decisions aren't starting de
15 novo. They're not new active ingredients for which we
16 know nothing. They're coming out of REDS (phonetic).

17 Some of these REDS, like with organophosphates,
18 had just gotten done. So, looking at the RED and the
19 risk assessments, if you see risk quotients or risk
20 estimates, the ecological attributes that are exceeding
21 our levels of concern, even under FIFRA, they're probably
22 going to be either to direct or indirect the fact

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1 something we need to think about from an endangered
2 species perspective. So, I don't think it's too hard to
3 see, for all of us, going into a specific case where
4 there may be some problems, some issues to resolve.

5 Not surprisingly, most times, not always, those
6 risk quotients are driven by the estimates of exposure,
7 as Cindy was getting at. So, I think it would behoove us
8 all, everybody, all sectors, to take a look at how
9 realistic some of those input assumptions are at the
10 problem formulation stage -- either get information that
11 says nobody is using that much, it just doesn't happen --
12 let's get information on that and how does that sort of
13 factor into the science. Then, maybe we can talk to the
14 registrants, and growers, and others, that it's time to
15 change the labels now.

16 We don't have to wait five years to change the
17 labels. Or, nobody even uses that. Or, that example
18 that somebody had that yes, it's a registered use but
19 it's never been put in the marketplace. Or, let's just
20 get it out of the freezer and throw it away.

21 So, I think it's very important, and I don't
22 think it's necessarily a mystery to figure out where the

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1 challenges are going to be and try to get resolution up
2 front. Or, it may be because we're missing some
3 ecotoxicology data so in the RED we had to make a very
4 concerted assumption due to certain information we didn't
5 have. That could feed into the DCI point.

6 Is there information in the literature already
7 that could cover it or -- all that kind of stuff. I
8 don't think it's as mysterious as it may seem. I think
9 it's pretty straightforward, actually.

10 UNIDENTIFIED MALE: It's been my understanding
11 in many of the biops, or at least some of the biops
12 produced to date by the Services, that it's common for
13 them to assume a worse case exposure scenario based on
14 the labels of the pesticides. All products registered on
15 a particular crop are used together on the same crop and
16 used at maximum use rates, maximum number of
17 applications, et cetera.

18 At what stage can the Services exercise some
19 flexibility in addressing the real-world situation? I've
20 asked that from the perspective of the label itself, the
21 instructions for use of that product on a particular crop
22 are for controlling the pests at a worse case infestation

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1 that is likely to occur.

2 That worse case doesn't come along very often.
3 So, the actual uses of that product are likely to be much
4 less than the potential that's expressed on the label.
5 This is where stakeholder input is essential to determine
6 how often is it really used, how often is it really
7 needed, even for frequently used products. So, what is
8 the likely exposure scenario resulting from typical year-
9 to-year use?

10 We need to know if, when, and how the Services
11 are going to put that information into its evaluation and
12 biop. We can't often or can't always modify a label to
13 bring that use rate down, or the frequency of use,
14 because you have to be prepared for that maybe once in a
15 few years, maybe once in several years, high infestation
16 of a crop or the disease.

17 UNIDENTIFIED MALE: So, that actually is one of
18 the biggest criticisms of the biological opinions that
19 National Marine Fisheries Service has produced. It's
20 relevant to exposure and what assumptions we make about
21 exposure. So, we have heard that argument.

22 We are working closely with Department of Ag

20 (Pages 77 to 80)

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1 and state pesticide regulation agencies to look at how do
 2 we come up with better tools for estimating the actual
 3 use and exposure. Our challenge is that we're consulting
 4 on the federal action. The federal action is those
 5 labels. So, yeah, that scenario that you laid out is
 6 what's authorized.

7 So, we have to render an opinion on that. I
 8 don't think we go so far as to assume the worse case
 9 everywhere all the time, but it is evident that by
 10 looking at the labels and assuming that crop patterns
 11 change over time, that pest load pressures change over
 12 time, the challenge to predict how a particular label
 13 requirement is going to be used for the duration of the
 14 registration.

15 So, we're not only looking at what the cropping
 16 patterns have been for the last several years or the last
 17 decade, but what might they be in the next 15 years while
 18 this label is still active. I understand there's even
 19 issues with how long they stay in place. But we are
 20 looking at what's the affect of the registration
 21 decision.

22 So, it's a challenge for us to refine how do we

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1 come up with a realistic, legally defensible, prediction
 2 of how a particular registration is going to be
 3 manifested on the ground during the duration of its
 4 registration into the future. What will those effects of
 5 that be on the endangered species that will encounter
 6 that?

7 MR. BRADBURY: Dave.

8 MR. TAMAYO: Well, first I wanted to speak to
 9 just that last point. I don't quite get why -- it seems
 10 like you can account for a worse case and maybe have a
 11 separate set of mitigation measures that might apply if
 12 there's a worse case type of application that's necessary
 13 and would still allow for that.

14 But you could have some sort of mitigation to
 15 go along with that. I think that might be necessary
 16 because if you kill something, it's gone for quite a
 17 while. It doesn't matter if you have that impact just
 18 once every 10 years. That's going to be a lasting
 19 impact.

20 But, the other thing is on the other side, it's
 21 like I don't think it makes sense to have the worse case
 22 type of mitigation measures applied to the average case.

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1 I think that really is a very good point.

2 Now, what I really wanted to talk about,
 3 though, is I actually have a lot of -- I support what
 4 Michael was saying, that the need to have that type of
 5 information, relevant information, given to the Services
 6 and to EPA -- we've run into that, and the same sort of
 7 thing that we run into with urban uses all the time.
 8 It's very important.

9 We tried to work very closely with structural
 10 pest control business in trying to make sure that we
 11 understand how those uses are. When we were working with
 12 pyrethroids in an urban area, we had sort of like a
 13 little mini conference at DPR early on in the process so
 14 that we all kind of understood what are the needs, what
 15 are the pest management needs, what are our concerns?

16 So, the DPR staff and everybody else kind of
 17 came to a common understanding. It seems like there's a
 18 need for a general sort of almost like a conference that
 19 would involve staff who are writing these opinions, EPA
 20 staff who are managing these actions, and then the
 21 registrants and the growers that are involved with this.

22 That could be a place where you really get into

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1 this is how this works. This is the type of concerns
 2 that we have. So, raise the general level of knowledge,
 3 not even necessarily about a specific action, but getting
 4 the people who are actually doing the work. Get it into
 5 their head.

6 One thing that's been really frustrating is to
 7 have part of EPA kind of understand what our concerns are
 8 and then start dealing with it. Oh, okay, looks like
 9 they've got it now. And then you find out there's
 10 another group, another little silo, and it's a whole new
 11 set of understanding.

12 I'd be amazed if that doesn't occur in this
 13 type of situation where maybe upper level understanding
 14 of the need for that, but the staff people who are
 15 supposed to apply that in their direct management maybe
 16 don't get the need to have an understanding of how these
 17 things are actually used out in the environment and what
 18 sorts of mitigation measure makes sense and could achieve
 19 both the environmental protection and the affect of pest
 20 management.

21 So, having that sort of general discussion
 22 raised to everybody's level and then to sort of repeat

85	<p>1 that on a more specific -- when there's a specific</p> <p>2 decision about specific chemicals that affect specific</p> <p>3 crops, have that same sort of discussion repeated. You'd</p> <p>4 have to sort of have very knowledgeable people on both</p> <p>5 ends, especially since there might be quite a few minor</p> <p>6 crops that have to have their input at that point.</p> <p>7 But I think the general tone of this, I support</p> <p>8 the notion of having very early conversation because it</p> <p>9 just doesn't make sense to be developing opinions under a</p> <p>10 misunderstanding of how things are used out there. It</p> <p>11 just seems like a mess to do it that way. Thanks.</p> <p>12 MR. BRADBURY: Caroline.</p> <p>13 MS. COX: I wanted to follow up with what Jim</p> <p>14 said about making it possible for public interest groups</p> <p>15 and the general public to have input into this ESA</p> <p>16 process, and access to information that isn't currently</p> <p>17 publicly available makes that possible.</p> <p>18 Just one specific example. I know that in</p> <p>19 several of the biops that NOAA Fisheries has done, the</p> <p>20 issue of the inert ingredients in the products has been a</p> <p>21 significant concern. It's really hard for either public</p> <p>22 interest groups or the general public to provide any kind</p>	87	<p>1 assessment?</p> <p>2 UNIDENTIFIED MALE: Right.</p> <p>3 SUSAN: Then, the other thing I'd like to say</p> <p>4 in terms of worse case is the Services did a really new</p> <p>5 approach to looking at shallow water habitats that EPA</p> <p>6 doesn't do. This is perhaps a worse case scenario, but</p> <p>7 it's a very realistic one. It probably happens more</p> <p>8 often than just the every few years when there's a major</p> <p>9 pest infestation. So, I think it's pretty important to</p> <p>10 look at realistic situations that are likely to occur on</p> <p>11 a fairly regular basis.</p> <p>12 MR. BRADBURY: Cheryl.</p> <p>13 CHERYL: So, there's a lot of things that</p> <p>14 impact worse case, rates, numbers of applications. Those</p> <p>15 are going to be really explicit on the label, and there's</p> <p>16 not much arguing that those are worse case. But there</p> <p>17 are also a couple of gray zones that can occur on labels,</p> <p>18 and not all labels are equal.</p> <p>19 One place that gets really gray is how quickly</p> <p>20 do you go back in and retreat? So, retreatment intervals</p> <p>21 not explicit on the label can be a real big difference in</p> <p>22 the way that you interpret worse case. Okay, we're going</p>
86	<p>1 of useful information or feedback when that information</p> <p>2 is not publicly available. So, I just would like you to</p> <p>3 consider mechanisms by which you could help with that.</p> <p>4 MR. BRADBURY: Susan and then Cheryl.</p> <p>5 SUSAN: In response to your question, I think</p> <p>6 earlier is better. I think it's as whoever gave the</p> <p>7 CropLife presentation said, it seems that there should be</p> <p>8 involvement of the Services early on, too, so that you</p> <p>9 know what information they need.</p> <p>10 I think a lot of the problem has arisen in you</p> <p>11 guys thinking you have enough information to do it and</p> <p>12 they say we need more information. So, having them</p> <p>13 involved early in that information gathering process</p> <p>14 seems kind of critical.</p> <p>15 I guess a clarification here. By risk</p> <p>16 assessment, preliminary risk assessment, do you mean</p> <p>17 effects determination?</p> <p>18 UNIDENTIFIED MALE: So, how we've been trying</p> <p>19 to do this is as part of our FIFRA preliminary risk</p> <p>20 assessment, we're also doing our ESA effects</p> <p>21 determination.</p> <p>22 SUSAN: So, it's a piece of the risk</p>	88	<p>1 to go back in one day. A typical grower would say, no,</p> <p>2 I'm not going to go apply a single day afterwards. But</p> <p>3 you're looking for that really worse case on the label.</p> <p>4 So, one of the places where I would suggest</p> <p>5 that this typical information could be better used, even</p> <p>6 in the worse case assessment, would be what is your real</p> <p>7 retreatment intervals? Retreatment reentry for worker</p> <p>8 exposure? PHI for dietary? That's probably not part of</p> <p>9 this ESA. But those gray zones, even in the</p> <p>10 interpretation of worse case, would really benefit from</p> <p>11 user community information.</p> <p>12 UNIDENTIFIED MALE: And that's actually one of</p> <p>13 the areas that we're already now starting to work on. As</p> <p>14 we prepare for the release of a preliminary work plan, in</p> <p>15 house we're going through and some of the older labels</p> <p>16 just say reapply as needed. So, what does that mean?</p> <p>17 So, we're starting to independently ask it</p> <p>18 directly during the public comment process. We're going</p> <p>19 back to the registrants and saying what's really meant</p> <p>20 there and is there an opportunity for some better</p> <p>21 depiction of how the registrant wants that product to be</p> <p>22 used so there's better clarification on the label.</p>

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1 MR. BRADBURY: Ken and then Jennifer.
 2 MR. NYE: I want to encourage the agency and
 3 any others that are looking for this kind of data to try
 4 to seek out and find the actual use data. The worse case
 5 scenario or the label is not normally what's used. It
 6 could be, but growers and users are driven to try to use
 7 as little as they can. These materials are expensive.
 8 There's time involved. There's consequences and so on.
 9 There's worker safety issues and so on.
 10 I'm really pleased that the Minor Crop Farmer
 11 Alliance has recognized this issue and has put some
 12 significant resources into it. They have some special
 13 considerations, given the size of the crops and so on and
 14 their lack of having full-time people to do some of these
 15 things, in all of these little specialty areas.
 16 We certainly have specialty crops growing all
 17 over the country. Some of them I really don't have full-
 18 time expertise, but they'll try as much as they can,
 19 given the opportunity from the agency, to provide that
 20 information. They'll try to do it as well as they can.
 21 I really appreciate the USDA data collection
 22 process. That should be used, I think, by the agency as

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1 much as possible. It isn't perfect. We don't cover
 2 everything there every year, but at least it gives us
 3 some guidance. We need to continue to seek out that
 4 actual use data.
 5 MR. BRADBURY: Jennifer.
 6 DR. SASS: My comment is kind of the same. I
 7 had put my card up earlier but put it down. Dave covered
 8 a lot of my points. I just want to point out that it
 9 would help -- if that were made public, then other people
 10 like me could also help to talk about things. I mean, if
 11 we're talking about worse case or whatever, at least we
 12 know what we're talking about. At least we would have a
 13 sense, if we had the real data, to understand realistic
 14 situations. So, that would help all of us if that could
 15 be public and shared.
 16 MR. BRADBURY: So, I'm looking at the clock and
 17 I think we have some play. Some of the conversation that
 18 you all had has gotten us some aspects of number one.
 19 Some we can sort of imagine, different kinds of
 20 information at different kinds of places. Some of you
 21 talked about mechanisms for transparency in your
 22 comments. That's been helpful. Different venues or

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1 processes by which the information can flow.
 2 So, I think it would be helpful if we could
 3 spend a little time on question 3, which was, how might
 4 the agency make an interim reg review decision for uses
 5 that do not raise ESA concerns and how would you,
 6 perhaps, bifurcate or chunk up a reg review case by ESA
 7 versus non-ESA? Maybe let's get some initial thoughts on
 8 that from you all.
 9 UNIDENTIFIED MALE: So, the idea that the
 10 conceptual thinking is that there may be uses that don't
 11 raise an endangered species concern. Perhaps the
 12 registration review process for those should go forward
 13 on a different time frame, which would allow them to go
 14 through the registration review process while the uses
 15 that do raise ESA concerns would be handled on a slightly
 16 different time table because of the need to complete the
 17 consultation. So, that's one sort of formulation to that
 18 idea.
 19 The other idea that has arisen in various
 20 conversations we've had internally is we were calling it
 21 an interim decision. That was just the term we applied
 22 to it. It has no particular meaning. But the idea

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1 behind that would be that the agency would complete its
 2 work and go ahead and make registration review decisions
 3 while the consultation process is occurring. We would
 4 say, this is the registration decision for now. We've
 5 initiated consultation. Then, when that consultation
 6 completes, we would come back and make any adjustments to
 7 the registration that might be necessary.
 8 So, that's a fairly new idea in terms of things
 9 that we've heard discussed. So, we just were interested
 10 in getting some thoughts from the committee on that idea.
 11 There are other variants of that idea that people can
 12 obviously think of. So, I think that captures it.
 13 UNIDENTIFIED MALE: I appreciate that,
 14 especially in at least two instances where it seems like
 15 the agency would likely have to respond fairly quickly.
 16 One is invasive species. Obviously, in the others,
 17 resistance and resistance management, in those two
 18 instances, there may need to be some sort of consultation
 19 such that a use could be adapted, especially in the crop
 20 area where those two instances are, as we speak,
 21 impacting clear across the country.
 22 UNIDENTIFIED FEMALE: So, those of us who have

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1 been around too long remember IREDS and TREDS and REDS
2 and all of those things that we had back in FQPA. So, I
3 guess my initial reaction was just do it. You allow the
4 uses for which -- I assume what's implied in here is that
5 you have a use pattern that results in no effect. So,
6 you don't need to consult until you're ready to just
7 clear it. With the rest of the stuff that you're ready
8 to clear on your own, you clear. I guess these other
9 uses, then, have to be held up.

10 I mean, the converse of that is that you hold
11 the whole thing up, which then just seems to create a
12 work backlog for you guys and takes away uses that may or
13 may not be necessary to take away in the case of no
14 effect or absolutely not necessary to take away. So, I
15 would think you would go forward and release them.

16 MR. BRADBURY: Or you may have identified some
17 risk mitigation for other reasons.

18 Susan.

19 SUSAN: A couple of things, a clarification.
20 Typically, a label has many uses. So, what would happen
21 if you identified one use, corn, where it wasn't a
22 problem. But if you think about applications in almonds,

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1 it would be different. I guess I don't understand how
2 registrants would deal with that where they have a label
3 with multiple uses. That's question one.

4 UNIDENTIFIED MALE: So, I think this has been
5 part of the confusion about what registration review is.
6 It's not that the registration goes for 15 years and
7 expires and then needs to be relicensed. In fact, what
8 it is is registration review is a cyclical period of time
9 over which we do a periodic reevaluation. But the
10 registrations don't expire.

11 So, under this model, we would sort of create a
12 clearinghouse, if you will, to say these uses for this
13 chemical, we've done what we need to do from an ESA
14 standpoint. We've reached a no effect. We've
15 incorporated mitigation and we're done.

16 There may be some other uses that still trigger
17 the need for consultation, but maybe it's because of
18 worker risk or maybe it's because of dietary risk, we've
19 put some interim mitigation in place. But we sort of
20 have them in the other quadrant, if you will, while we're
21 pursuing consultation.

22 So, it's a way to move forward on decision

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1 making as opposed to putting everything in a band while
2 we try to figure out all of the endangered species
3 problems. But there's a tracking issue that becomes
4 involved, but it doesn't affect the label.

5 SUSAN: So, similarly, then, it seems that the
6 flip side of this should also be true. If you find a
7 particularly problematic use, there should be actions
8 made immediately to solve the problem, rather than
9 waiting for the consultation.

10 UNIDENTIFIED MALE: Right. So, like we do with
11 worker risk or like we do with dietary risk, if we found
12 a major issue that we felt warranted swifter action, we
13 would take that authority now. We would take that action
14 now.

15 MR. BRADBURY: Gabriele.

16 MS. LUDWIG: I was just going to say I forgot
17 the right terms, IREDS and so forth, that Cindy was
18 mentioning. So, what I don't understand is I don't know
19 how it works with the legal world of ESA. But since
20 you've done it before, it doesn't seem like it's that
21 foreign a concept.

22 MR. BRADBURY: Yes, in some ways. In some ways

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1 you probably need to talk to the attorneys, though, in
2 terms of some core cases in terms of when is the FIFRA
3 action done. Is it done when the ESA part is done or is
4 it done when the FIFRA part is done, but you're starting
5 the ESA part? So, that's another dimension to this
6 conversation. But keeping the legal stuff aside, that's
7 where you're getting your initial thoughts on the non-
8 legal practicality, or lack thereof.

9 Jim, I don't want to put you on the spot, but
10 we've worked together for a long time.

11 JIM: Well, actually, I was trying to think my
12 way through some of these things.

13 MR. BRADBURY: One thought that might be
14 helpful to share is from your perspective, when to get
15 information and sort of how you all have to manage your
16 resources, just some thoughts you have about timing of
17 information and iterative steps. How does that sort of
18 factor in?

19 JIM: I'll just reiterate Dr. Willett's comment
20 that probably we aren't going to get there until we get
21 the NAS stuff done. I think we do have issues on
22 disagreement among the agencies with the risk assessment

<p style="text-align: right;">97</p> <p>1 methodology and how certain things are assigned. So, 2 assuming that -- 3 And I don't think NAS is going to give us the 4 magic bullet either, but I'm hopeful they will give us 5 enough information that we can have a dialogue that will 6 allow us to close the gap and we can come up with a risk 7 assessment methodology that we can both agree is 8 sufficiently robust to both FIFRA requirements and ESA 9 requirements. 10 If we can get there, then I think sort of the 11 process that Rick laid out in his slide where there is 12 providing technical assistance rather than informal 13 consultation so we don't trigger any requirements, but I 14 think there's an opportunity up front at the preliminary 15 risk assessment stage to provide relevant information 16 about endangered species to the extent there's 17 information from toxicity studies relevant to a species 18 that's not captured by the overarching process that that 19 should be provided, information about presence, absence, 20 distribution, seasonality. All of that could go in 21 there. 22 It makes sense to me that the other information</p>	<p style="text-align: right;">99</p> <p>1 Hopefully, we are working on that, coming to an 2 understanding on ways to do that. We ought to get that 3 all in to the process up front. I agree with your 4 statement, that getting it in earlier is better than 5 trying to squeeze it in later. 6 UNIDENTIFIED FEMALE: I have a very different 7 question. We've heard about the Denver conference. 8 We've heard about the NES activities. I also know that 9 there was an American Council Society Symposium on ESA 10 recently and there was EPA engagement. I'd really like 11 to hear what EPA's reactions were to some of that 12 conversation. 13 UNIDENTIFIED MALE: There was a session at 14 American Chemical Society in Denver. I can't remember 15 the exact date, some time in the summer. There was a 16 day-and-a-half session which the Services and EPA 17 participated in two ways. 18 The first was, the Services provided between 19 them a very nice description of the process and the ESA 20 requirements and how they viewed those as applying to the 21 FIFRA registration process. Then, we provided some 22 context from the EPA perspective on how we thought those</p>
<p style="text-align: right;">98</p> <p>1 that folks have talked about, can we come up with a 2 realistic assessment of what is likely to happen on the 3 ground over the course of 15 years and what's a 4 reasonable case which can be used for your risk 5 assessment to cover those species. 6 Come up with your final registration decision 7 that includes where appropriate mitigation measures to 8 reduce impacts and consult on that. If we could get to 9 that part, then I think the counterpart regs that still 10 remain in effect actually would be useful. 11 It would be taking advantage of the resources 12 at EPA to put together comprehensive documents that the 13 Services could review. Then, the Services would be able 14 to use our limited resources in that sort of effective 15 review stage rather than having to build up a competing 16 army, if you will. I'm not in favor of doing that. I 17 think we really do need to figure our way forward here. 18 But the service is truly in a consultation mode where we 19 agree on the process. 20 So, I guess that's the long way around saying I 21 think there are some data needs out there that we haven't 22 even quite figured out how to ask for the data.</p>	<p style="text-align: right;">100</p> <p>1 things -- our process worked with their process. 2 There were a number of presentations that 3 focused on the scientific issues, how to determine 4 aquatic exposure, how do you use models to do so, how do 5 you look at the fate of chemicals, and your approach to 6 do that. Most of those were provided by folks from the 7 registrant community or consultants who were making 8 presentations based on work that they had done. 9 I personally -- I don't want to talk for ACS; 10 I'll just talk for me personally -- I thought it was a 11 very useful session. The reason I thought that was 12 because it had broader representation than is typical. 13 It wasn't just the government agencies talking to each 14 other. 15 It wasn't one agency of the government talking 16 to just registrants or to the NGO community. There were 17 folks that were present at the meeting and who presented 18 to or from, as I said, the federal agencies, registrants, 19 state agency representatives, and from the NGO community, 20 the environmental group community. 21 So, that was the first time I'd seen that broad 22 a net cast around this issue. Some of the folks thought</p>

101	<p>1 that this is the beginning of engagement at the science 2 level, sort of at the technical level, where everybody 3 was in the same room and all listening to each other for 4 the first time.</p> <p>5 So, I'll leave it at that. I don't know, Jim, 6 if you heard any feedback, but you had folks there. 7 There will be more formal ACS summaries and whatever 8 coming out. I don't want to speak for them, but that 9 information will become very widely available.</p> <p>10 MR. BRADBURY: Cindy.</p> <p>11 MS. SMITH: I have two thoughts. So, the 12 question I asked about how many comments you got to the 13 docket I asked as my gut was the sense of the answer that 14 you gave, but I wasn't sure because I only see the stuff 15 that I look at that's mine.</p> <p>16 But I asked it because I think that probably 17 the reason that you don't get a lot of comments to that 18 is to your point, Steve, is people haven't gone through 19 that refinement process yet and they're not there. So, 20 these last three questions are similar in what you're 21 asking for.</p> <p>22 So, I think to be really specific, I think that</p>	103	<p>1 mean, for everybody who is concerned about what happens, 2 then that gets shared. So, here's now what is left for 3 what people are going to do and when the labels are going 4 to change, if they're going to change, and the whole nine 5 yards. I think that, to me, seems fairly easy to do and 6 would save a lot of people a lot of headaches up front.</p> <p>7 The 15-year thing that you just mentioned, Jim, 8 creates some confusion for people, I think, because I 9 don't know if that's because you think the agency is only 10 going to look at it every 15 years, so a registration 11 decision isn't going to be revisited again for 15 years. 12 So, you want to look 15 years out.</p> <p>13 But the reality is that, at least my 14 experience, is that that has never played out that way. 15 I mean, we did a RED in '98. We did another one in 2001. 16 We did another one in 2006. I'm doing another one right 17 now in 2010 on one compound. So, it never goes 15 years.</p> <p>18 I mean, prior to FPQA, I think that could have 19 been the case. That was one of the elements that came in 20 there. But that simply is not the reality today for how 21 these decisions happen. If there's a risk that comes up 22 or there's a new use that somebody wants to add, it gets</p>
102	<p>1 there should be a meeting very early on with the 2 registrants -- we don't want to call it a smart meeting 3 or whatever -- where we fully refine what are the 4 assumptions about is this label still sold, is this use 5 still active, can you address the number of applications, 6 the intervals between applications, try to get all that 7 stuff cleaned up up front fast.</p> <p>8 Some of these things, even though they've been 9 through a lot of reviews, some of these types of issues 10 haven't completely been addressed. So, I think there 11 will be some natural refinement and new information 12 shared with the agency at that stage.</p> <p>13 Then, I think that what goes to the Services 14 has to be that refined amount. At least I've heard in 15 some of the discussions when we talked about some of the 16 biological opinions is they looked at labels and model 17 labels that we knew were no longer active, you guys 18 pretty much knew were no longer active, but somehow it 19 didn't all get communicated exactly right. So, I think 20 that really that refinement up front is really important 21 to do.</p> <p>22 Then, all of that can be shared publicly. I</p>	104	<p>1 a full review by the agency again. So, it's not often 2 that you go by more than two or three years without 3 something getting looked at.</p> <p>4 UNIDENTIFIED MALE: So, what Rick said was the 5 registration never expires. That tells me we've got to 6 look forever into the future, not just 15 years. So, 7 that's sort of the opposite end of what you just laid 8 out. I think we are looking for what is a reasonable 9 time frame because the further out into the future you 10 model things, the less reliable your results are. We're 11 trying to come up with a reasonable framework for how 12 long are we going to look at this.</p> <p>13 Certainly, there are triggers for reinitiating 14 consultation, a new use comes up, a new piece of 15 information either about use or about risk or about 16 exposure. All those things can be triggers for 17 consultation.</p> <p>18 But I think, for at least the initial instance 19 where it's the first time we're looking at one of these 20 things under the Endangered Species Act, we need a time 21 frame to kind of bound our analysis. The re-registration 22 review cycle seems to be a good thing to pick.</p>

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1 MR. BRADBURY: So, we're going to start
2 wrapping it up. We don't have any public comment.
3 That's why I let this play out a little bit and keep you
4 all on your schedules and our agenda.

5 So, a couple of perspectives and then a
6 proposal for the process improvement work group to
7 wrestle with. Folks that aren't on those groups from our
8 group can play in this one.

9 So, one backdrop. The National Academy of
10 Science process obviously very important because it will
11 help establish a variety of approaches for doing the
12 science and we do want to get to the day where we've all
13 agreed upon that science of how to move from the FIFRA
14 risk assessment, the non-listed species risk assessment,
15 into the listed species risk assessment, that process is
16 agreed upon, the information needs and how that
17 information is going to get used.

18 So, if we do have to go into consultation, that
19 can be very efficient because the Services are just
20 adding their areas of expertise onto what needs to happen
21 to ensure those in jeopardy if there's a possibility that
22 would be the case, then not redoing everything we've done

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1 because we've done it in a manner that we've all agreed
2 is the way it needs to play out. USDA is involved in
3 feeding critical information into that process as well as
4 all of you in your various roles and responsibilities.

5 Having said that, I don't think we need to wait
6 18 months for that report to come out to start
7 approaching some of the challenges we know that exist,
8 regardless. So, for example, better understanding of how
9 a product is used and what the distribution of those uses
10 could be. All the other permutations we talked about is
11 clearly information that's going to be useful.

12 NAS may give us some advice on how to interpret
13 uncertainty around that information or how to make
14 projections over different time frames or how to make
15 projections over different landscape scenarios. But
16 clearly, having that information is going to be a
17 critical component to the evolution of the risk
18 assessment technique.

19 So, I think there's work we can be doing on
20 process and kinds of information that we're going to be
21 using that can happen right now. Frankly, if there's
22 some things we can do over the next six months or so,

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1 some of that insight could be shared with the NRC panel
2 as they go through their series of meetings.

3 We may be able to get some feedback from them,
4 even though they're talking, kind of brainstorming, at
5 meetings, the public, or us, the Services through work
6 we've all been doing. We can share with them some ideas
7 we're exploring in terms of how information could come in
8 which could inform their recommendations back in terms of
9 how that information can be analyzed and incorporated in
10 the risk assessment.

11 So, I really think that where it would be
12 helpful in the initial stage to get feedback to us, and
13 you all part of that, is that the early stage, the
14 beginning, the beginning of the process. The Minor Crop
15 Farmer Alliance report talks about some process ideas to
16 help that along. You've seen it in some of the Power
17 Points here and some of the other background information
18 that people have shared.

19 There's been some ideas about before you start,
20 so zero at the beginning date. How do you start before
21 zero to start getting information that becomes part of
22 the preliminary work plan? Then it gets more refined and

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1 you finally have your final work plan.

2 I think before the preliminary work plan goes
3 out for comment and while the PWP is out for comment and
4 moving towards final work plan is a time zone, a time
5 frame that we need to concentrate on. Having said that,
6 we have the experience where we know there are chemicals
7 that have just gone, as Cindy implied, pretty much just
8 finished their re-registration. We already know there's
9 certain risk profiles, some ecological perspectives, that
10 need attention. So, there isn't a mystery there. But
11 we're still not seeing a lot of information coming to the
12 dockets, which is sort of a disconnect.

13 So, what I'd like to see, if you all are in
14 agreement conceptually, is that we work with Rick and Don
15 and really try to dig into the details. If you were
16 going to have a smart meeting, or whatever we call it
17 now, what would it be? When would it have to happen
18 before the docket would open? What would be some of the
19 logistics of actually doing that?

20 That means logistics of probably looking at the
21 calendar and figuring out the timing. But how would you
22 get that information out to the public so if some people

27 (Pages 105 to 108)

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1 couldn't make it to the meeting, how are they going to
 2 know what's going on so they can see in some ah-ha ideas
 3 as the team and EPA finally has to buckle down and get
 4 that PWP written, as well as what could be happening
 5 during the comment period during the PWP to again make
 6 sure more ah-ha moments can go on out there, because
 7 people may not have caught up to the other steps. They
 8 can be part of that process virtually, if not in the
 9 room.

10 So, it would be a group that gets together and
 11 really gets specific. Is it 45 days before the PWP
 12 opens? Is it two months before? Is it three months
 13 before? How do you structure those meetings? How do you
 14 identify what the information is? What's the roles and
 15 responsibility of the registrant?

16 What's the role and responsibilities of the
 17 NGOs, of the grower groups, of the states, and the
 18 Services, for that matter, in terms of looking at that
 19 RED and thinking about that RED? What's clearly going to
 20 be the issue that is going to be driving this ecological
 21 risk assessment?

22 I'm convinced that even if we don't know

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1 exactly all the recommendations the NAS is going to
 2 provide, making sure we've got access to the best
 3 available information and understand the distribution of
 4 that information, it's going to be critical to going
 5 forward. Right now I think we're mostly struggling with
 6 lack of appropriate information and it's carrying too far
 7 through the risk assessment process into the consultation
 8 process.

9 We're not going to blame Jim or the Fish and
 10 Wildlife Service if we're giving them use as needed on
 11 the label. That's pretty darn hard for us. It's hard
 12 for everybody. It's hard for all of you. There's just
 13 no reason to have that.

14 I agree with Ray's point. It doesn't mean that
 15 the label -- the label may need to capture those extreme
 16 pest scenarios that could happen. You have to make sure
 17 you can legally use the product when that situation
 18 occurs. But how do we get information that helps
 19 articulate how likely is it that that scenario is going
 20 to happen? So, we've got the information to take a look
 21 at what are the likelihoods of different scenarios
 22 planning out that are going to help inform the risk

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1 assessment.

2 I've kind of talked too long, but I think you
 3 get the idea. Where in the process before our typical
 4 process can we get people around the table in reality or
 5 virtually and make sure it's all public and transparent
 6 so everybody can see it until we get the more refined
 7 information we need to start the risk assessment.
 8 There's a lot of logistics and there's a lot of process
 9 stuff to figure out to make it efficient. I'm pretty
 10 convinced right now we have an inefficient process.

11 With that sort of rough cut, I'll make these
 12 guys write that up so it makes sense. Then we can share
 13 with you to see if -- does something in that domain seem
 14 useful to you all? I think it's useful to us.

15 UNIDENTIFIED MALE: I've got a real quick
 16 question. Are you sure that Don Brady is up to this
 17 task?

18 MR. BRADBURY: I've got my doubts. I just
 19 wonder if there's something in that realm, which I
 20 realized I talked a bit too much, but something in that
 21 universe that seemed reasonable? Then, Don and Rick and
 22 others can try to fine tune it, maybe reaching out to

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1 some of you, get it back out to everybody to make sure
 2 that seems like a reasonable activity, charge. Then we
 3 can formalize it through the PPDC and start working it.
 4 Cindy.

5 MS. SMITH: Yeah. I mean, I think that seems
 6 very reasonable. I think it's what we should do. The
 7 logistics piece of it, I understand, is the hard part of
 8 it. If you have the initial meeting with the registrant
 9 early on, a month before the docket, two months before
 10 the docket -- I'm not sure that that matters too much --
 11 where you address these kinds of general issues that we
 12 talked about, number of applications, intervals, uses
 13 that you're no longer selling or haven't been selling for
 14 years, or whatever, the easy stuff, it seems like I don't
 15 know that anybody else would care to come to that
 16 meeting. I know people would care to comment about other
 17 parts and they want an opportunity to comment on that.

18 But it would seem like if you've got the
 19 registrant in there and did the easy high level cleanup
 20 stuff, and then you have a public schedule so that if
 21 chemicals A, B, and C are critical to apples, they know
 22 chemicals A, B, and C are going to do their refinement

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1 and use of data on this schedule, then they could provide
2 their input.

3 If those are the chemicals that some of the
4 NGOs are most interested in putting some input on, they
5 would know. So, everybody would know then when you're
6 going to have your discussion about those or when the
7 time line is to get input in about those, or however you
8 format what you're going to be able to do with it. I
9 think that in itself would help.

10 But I think part of the problem today is that
11 the docket opens for hexydiasox (phonetic) and you have
12 to read through everything in there and try to figure out
13 is there a worker issue, is there a dietary issue, is
14 there an ESA issue, are the data requirements going to
15 trigger an issue once those -- I mean, it's just too much
16 overwhelming right now, I think, to go at it that way.

17 So, I think if there was a way to capture where
18 you think there -- if you know up front you're going to
19 have a concern about an ESA issue, because you can look
20 at the data that you have available to you today, say up
21 front we think we're going to have to address some
22 endangered species things here, or whatever, and people

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1 are then more ready to comment, I think.

2 UNIDENTIFIED FEMALE: We did an open process
3 before we did our surface water regulations in
4 California. That's exactly what we did. We got the
5 stakeholders together. We talked to them individually
6 and then we talked to them as a group. The registrants
7 were also talked to individually and then as a group with
8 the NGOs. It really worked out.

9 So, I think -- well, for us, it's just
10 California so it's easy to travel. But the federal would
11 be a little bit harder on logistics. But I think the
12 communication piece really is the one that (inaudible)
13 even with the registrants, NGOs, and even with the state
14 water board.

15 We talked to the state water board in the
16 surface water issues. We talked to the regional boards
17 in the surface water issues, stormwater agencies. The
18 PCOCs, we used the urban pest control products that we
19 put in and are now proposing for surface water
20 regulation. So, it works out really well.

21 UNIDENTIFIED MALE: I hope this doesn't
22 complicate this discussion. I think it's a great idea to

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1 do the smart type meeting up front. I would just hope
2 that if possible, and this may help you out a little bit,
3 is to include what's in the pipeline for that particular
4 active ingredient in these discussions.

5 MR. BRADBURY: The uses may be in the pipeline.

6 UNIDENTIFIED MALE: Not new uses in the
7 pipeline but what is going on -- yeah, new uses for that
8 particular active ingredient.

9 MR. BRADBURY: We do try to roll that into the
10 registration with the dockets, but we'll make sure we
11 keep focused on that.

12 UNIDENTIFIED MALE: I think obviously for a lot
13 of grower groups where you're always sort of parsing what
14 issue you have to work on, sometimes it's pesticide
15 policy, sometimes it's a whole other realm of things,
16 making sure that -- and I agree with Cindy absolutely.

17 But trying to find some way to highlight the
18 importance of that first round and being able to really
19 highlight the questions that are important to have
20 information on, that would be really helpful because that
21 would allow you to really look at -- because we don't
22 always feel the need to comment on every single active

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1 ingredient.

2 So, it would give us a chance to sort of go
3 through that start finding some way to put the neon light
4 on the issues so that those folks that are interested, no
5 matter who it is, can comment, would be aware that here's
6 the moment. Then, of course, once you start doing that,
7 I think it's going to become a little bit easier for
8 people to know how to plug into the system once they get
9 started.

10 UNIDENTIFIED MALE: I wonder if some of these
11 discussions could be amenable to having sort of a webinar
12 sort of format so that people who are widely distributed
13 around the country don't feel the need to -- I mean, it's
14 really like a three-day process to come here and
15 participate in something that might last a few hours.
16 So, that might make -- then also, it makes it --

17 There's an inherent transparency to having
18 webinars because then, even if you don't feel the need to
19 go and comment, you can participate and see what's being
20 said. There's really a pretty clear record. Some of the
21 people who would maybe prepare presentations for it, that
22 information would be readily available already and sort

117	<p>1 of help people to focus what their issues are.</p> <p>2 Then, really, I think it's also an opportunity</p> <p>3 for people who are not really sure, well, maybe this is</p> <p>4 going to affect me. It's not worth me traveling to</p> <p>5 Washington because I don't really know. But then they</p> <p>6 start thinking, oh, well, that really is something that I</p> <p>7 ought to comment on either during this meeting or figure</p> <p>8 out a way to follow up on it.</p> <p>9 So, I think that would be very helpful for some</p> <p>10 of these. It may not always be appropriate, but I think</p> <p>11 that could be a really useful tool, if you can fix some</p> <p>12 of the communication issues.</p> <p>13 MR. BRADBURY: Twenty-first century EPA</p> <p>14 technology.</p> <p>15 Cheryl.</p> <p>16 CHERYL: So, you really actually already have a</p> <p>17 mechanism to do some of what you're being asked, if</p> <p>18 that's what the scoping document is supposed to do,</p> <p>19 identify those initial issues. I have seen them be</p> <p>20 better prepared as you've gone through this process a few</p> <p>21 times. But I think you're hearing a call for those</p> <p>22 scoping documents to have one more level of detail and</p>	119	<p>1 maybe because there's so much stuff to read through that</p> <p>2 it's hard to distill out what's needed. So, all this I</p> <p>3 think reinforces some of the topics a group could be</p> <p>4 working on in terms of getting more specific about how to</p> <p>5 make the process more efficient and effective for</p> <p>6 everybody.</p> <p>7 So, the way I'd like to close this session out</p> <p>8 is charge Rick and Don, working through the PRIA Process</p> <p>9 Improvement Work Group, which is under FACA, to fine tune</p> <p>10 sort of what the charge would be for a small work group</p> <p>11 to tackle some of these issues about how to adjust the</p> <p>12 reg review process to take on the things we've talked</p> <p>13 about. See who all wants to do it. Work on that so that</p> <p>14 we certainly, at least by the next time we meet, get a</p> <p>15 report out on here's a proposal of how to do it.</p> <p>16 I will put a little asterisk there. If the</p> <p>17 group is making good progress and we're watching the NAS</p> <p>18 schedule playing out and if we think there's some</p> <p>19 insights that can be useful for the NAS, we'll figure out</p> <p>20 some way to convene all of you so that -- put a proposal</p> <p>21 out maybe before six months from now so the timing is</p> <p>22 useful to the NAS review. Make sure you all are okay</p>
118	<p>1 identification of issues.</p> <p>2 Then, I understand that it's very problematic.</p> <p>3 How do you start before you start? When do you make</p> <p>4 things public and when do you figure it out? It's kind</p> <p>5 of chicken before the egg almost. So, I just think you</p> <p>6 have a call for making those scoping documents as clear</p> <p>7 as possible. That's what you're hearing.</p> <p>8 The other thing is I still think that the</p> <p>9 biggest thing, and I'm just reiterating, it's very clear</p> <p>10 that getting clarification on uses. Uses that might be</p> <p>11 up on a master label and not turned on yet could be a</p> <p>12 really good thing to clarify up front, too. Just all of</p> <p>13 that use information, since it drives everything, that's</p> <p>14 an easy place to not put the chicken before the egg.</p> <p>15 That's your low hanging fruit.</p> <p>16 MR. BRADBURY: So, this is very helpful because</p> <p>17 you all were reflecting on everything from logistics of</p> <p>18 how to have conversations before the PWP opens to make</p> <p>19 sure everybody is engaged, as well as some of the</p> <p>20 specific topics that should be addressed, as well as what</p> <p>21 -- even though the goal was to have a very efficient and</p> <p>22 already cut to the chase PWP, it's not happening, in part</p>	120	<p>1 with it. We wouldn't do anything without talking to the</p> <p>2 full committee.</p> <p>3 But I do think this could be complementary to</p> <p>4 some of the work the NAS will be doing. So, we won't</p> <p>5 rush it, but we'll keep track of what's going on so we</p> <p>6 don't lose an opportunity if it materializes. So, these</p> <p>7 two will get some ideas out to you all quickly so that</p> <p>8 you can see if you'd be interested in participating.</p> <p>9 We all will be looking to make sure we get a</p> <p>10 good cross section of all the stakeholders that are</p> <p>11 involved in this to be part of that process, because</p> <p>12 that's what we all talked about. Everybody has got a</p> <p>13 game. Everybody has done the game. So, we need</p> <p>14 everybody in the game; otherwise, what we create won't</p> <p>15 serve everybody that needs to be involved.</p> <p>16 So, Cindy, did you have one last --</p> <p>17 MS. SMITH: Yes. It's sometimes difficult to</p> <p>18 get information to an NAS panel once they've started</p> <p>19 working, unless they ask for it. So, it's really</p> <p>20 important at these public meetings if you've got</p> <p>21 something to give them before they start their work,</p> <p>22 before they start deliberating, that they can go back and</p>

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1 refer to, it's really helpful. That's really the way to
 2 get it to them. Otherwise, you're going to fight it all
 3 the time. It's not iterative.
 4 It made me wonder whether or not the PRIA
 5 Process Improvement Work Group, if they came up with
 6 something that they could provide at that public meeting,
 7 based on the charge to the panel, that that then implies
 8 we'll still be working here in the background and would
 9 welcome the NAS coming out to them to ask for information
 10 at a future date. Otherwise, it's very hard to get
 11 anything to them. The mechanism isn't there for them to
 12 accept stuff in the middle of their work.
 13 So, those public meetings, the couple that they
 14 have scheduled to allow you to make comments and provide
 15 materials, that's the way to get it in at the beginning.
 16 MR. BRADBURY: Right, total agreement. So,
 17 we'll work through those issues.
 18 Why don't we take a break until 5 to 12:00. I
 19 don't think it will take us more than 10 or 15 minutes
 20 just to go over agenda topics for the next meeting and
 21 still get done at 12:15. I imagine folks need to stretch
 22 a little bit. So, we'll meet in 10 minutes.

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1 UNIDENTIFIED FEMALE: Steve, is there any
 2 reason why we don't just finish up?
 3 MR. BRADBURY: I need a little time just to
 4 collect my thoughts, if that's okay.
 5 (Whereupon, a brief recess was
 6 taken.)
 7 MR. BRADBURY: Thanks, everybody. We'll make
 8 sure we get done at 12:15. I appreciate all your help in
 9 keeping on schedule.
 10 Let's first talk a little bit about the agenda
 11 for next time and kind of get some initial thoughts on
 12 that. Then I'll turn it over to Margie who can give us
 13 some ideas on dates so you can start thinking about that.
 14 Then we'll probably go around real quick if somebody has
 15 got some closing comments. Then we'll call it a meeting.
 16 So, my first ideas on the agenda for next time
 17 I think are pretty self evident based on the work the
 18 work groups have been doing. We gave all of them various
 19 charges to report back out. So, I would think this time
 20 a significant portion of our day and a half would be
 21 hearing back from the work groups on recommendations.
 22 I don't think I'll go through everything I've

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1 got written down, but the pollinator group had a number
 2 of tasks to take on from labels and surveying labels to
 3 what's the status of education, to what's the status of
 4 BMTs. We've got them all written down and they're in the
 5 transcript. So, we can tune that in our EPA folks that
 6 are helping those groups. We'll reach out to them and
 7 start to get that cranking.
 8 On the IPM, we had the school IPM starting to
 9 at least get those metric options ready to roll as the
 10 strategic plan comes along, we can see how to integrate
 11 different metric options with the strategic planning and,
 12 frankly, helping us make sure we get access to the work
 13 of that group. It could influence the strategic planning
 14 exercise that EPA will be doing. As that gets along, the
 15 PPDC will be among many groups to take a look at that
 16 plan as it goes.
 17 We also talked in the IPM about looking at a
 18 cropping practice, a public health scenario, and a
 19 hospital or residential community scenario to take a look
 20 at how would you go about evaluating the effectiveness of
 21 an IPM program. Again, not to do it but to look through
 22 some case study options and report back out on some

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1 options, and then go to the next step.
 2 The 21st century group will be reporting out on
 3 next steps from the exposure biomarker work shop. We
 4 also identified maybe some low hanging fruit that can be
 5 tackled real quickly in terms of clarifying what may
 6 already be in the registration packages through
 7 analytical methods or other information that could be
 8 part of the stepping stone to where we need to go.
 9 Then, we just finished with the ESA effort.
 10 Don and Rick will work through the PRIA improvement group
 11 and get my babbling words into a tight handful of
 12 sentences to describe the outcome of that exercise and
 13 what we're looking for. But the bottom line is how to
 14 make that step at the beginning of reg review as
 15 efficient as possible to get us the best information we
 16 can possibly get at that time to focus our resources on
 17 what we need to focus on collectively in moving forward
 18 with the endangered species effort.
 19 We'll get that description out and look for
 20 people to participate in that. We really need to get a
 21 good cross section of all the stakeholders for it to
 22 work. There's going to be some options there in terms of

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1 who meets when, what, how do you get the information out,
2 that kind of thing.

3 So, I think that probably makes sense, right?
4 Keep mostly focusing on work groups working in between
5 meetings, reporting out, getting them advice, and putting
6 them back to work. We'll definitely feed in some update
7 sections, some verbal, some written. As in the past,
8 give Steve, Margie, any requests you have for update
9 information.

10 What would be helpful, while we've got a few
11 minutes, did you find this session to be a reasonable
12 balance between verbal updates as well as some written
13 materials you got in your packet? We didn't really talk
14 about it, but we put them in your folder. Does it look
15 and feel about right?

16 UNIDENTIFIED FEMALE: Well, I have a three-part
17 response to that. I have first of all an acknowledgment
18 and a thank you, an observation, and a question. So, my
19 acknowledgment is yes, this is very helpful. It is
20 really good to be engaged in this kind of community and
21 listen to all of the different opinions. The updates are
22 very, very helpful. The work groups are very good.

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1 But my observation is that there are some
2 things that are kind of perhaps being left out, because
3 we're either getting really, really deep into an issue on
4 a work group or we're getting a little teeny snapshot of
5 what EPA is already doing.

6 Is there some middle ground? So, that's my
7 question. Joe wanted to take a vote and you said, well,
8 we don't vote. But are there things that don't deserve a
9 full work group drill but deserve more than an update so
10 that this group can really advise and weigh in on the
11 update rather than just kind of hear them as snapshots?

12 UNIDENTIFIED FEMALE: So, I would agree with
13 your comment, Steve, that I think the work group process
14 has worked for those issues. I mean, I'm not on the 21st
15 century tox so those guys have to weigh in on that one.
16 But on the two that I was most engaged in, IPM and the
17 bee pollinator one by accident -- I just happened to be
18 free to show up -- that format I think works really well.

19 I think you guys had the time about right to
20 let people present from the work group and then get
21 discussions from the full committee so we got the balance
22 right. I would say in the update, I like the format of

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1 having an update. But I like what you did this time. I
2 don't know if you did it intentionally or if you just got
3 lucky that there was some time afterwards. But if there
4 is like 10 or 15 minutes afterwards so that people could
5 comment on some of the updates, I think that's
6 productive.

7 I think some issues are bigger issues than
8 others and would be easier to say -- so, part of what we
9 got in this meeting was that spray drift likely will be
10 finalized. Inerts disclosure likely will be somewhat
11 finalized.

12 There was an update in our packet on worker
13 stuff. There was some stuff with workers that -- so,
14 maybe in the area of those three, which are big deals to
15 everybody, we add just a little more time next time. You
16 give an update and there's just a little more time for
17 comments after those. But I think in general, the way
18 it's working is good.

19 UNIDENTIFIED FEMALE: I agree with everything
20 they said. Also, I think we brought it up before, but it
21 would be great if at some point at each one of these
22 meetings, you sort of gave a low down on what you thought

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1 was coming down the pike for EPA.

2 As an advisory group, we're not going to think
3 of it ahead of time. But if you know that there's
4 something that's kind of rumbling, well, it looks like
5 we're going to be facing working on this, or whatever, as
6 sort of a heads up. So, when it does start coming, we
7 have the ability to help advise on it.

8 MR. BRADBURY: Caroline, Susan, and Beth.

9 MS. COX: I have a few suggestions for updates
10 that I'd love to see on the agenda for the next meeting.
11 One, as always, is the inert disclosure rule making.
12 Also, I would love to have an update on veterinary
13 incident reporting portals, or whatever it was called,
14 and what kind of reports are going to be coming into
15 that.

16 Sort of in that same vein, I would love to have
17 an update on also human incident reporting, both the
18 poison control centers and pick -- something that
19 happened a couple of years ago, I think, but not
20 recently, is when you all kind of explained the OPP
21 budget to us, and sources of funding, and how they're
22 being spent. I would love to have an update on that.

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1 MR. BRADBURY: Me, too. I was joking a little
2 bit because congress continues to work. There will be
3 aspects of PRIA-3. As the budget plays out, we can fold
4 that in. Right now, it's kind of uncertain.

5 Susan.

6 SUSAN: I'd like to thank all the EPA staff. I
7 really feel like this meeting we ended up with lots of
8 action items. We're moving in a direction, so that's
9 good.

10 Let's see, I agree with what you said in terms
11 of having a little bit more time to talk about things.
12 But you're fairly new to the committee, right? We've
13 been back and forth on this. We've had short times, long
14 times, intermediate times. We're now in the long time
15 phase, so we'll swing back. But it would be worthwhile
16 having a little bit more time for questions on the kind
17 of confusing or more complicated things.

18 I would like to see an update next time on kind
19 of where -- it'll be six months out and we will have been
20 through part of a fumigation season. I would like to see
21 where we are on the fumigant mitigation measures,
22 implementations, and kind of how is that working, an

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1 update.

2 MR. BRADBURY: Beth.

3 MS. LAW: I agree that this has been a very
4 good meeting. I do like the balance that was struck
5 between the presentations and the actual updates and the
6 written updates. I agree that I think maybe a little
7 more opportunities for just to have a little more
8 discussion about the updates would be great.

9 At the next meeting, I think in addition to
10 Susan's comment about where you see or the things you see
11 coming up in 2012, I'd also like to have an idea of
12 anticipated rule makings for 2012, if you have an idea of
13 what might be coming down the pike.

14 In particular, I'd love an update on the status
15 of 25B rule making. Thanks.

16 MR. BRADBURY: Valentin.

17 MR. SANCHEZ: I understand that farm worker
18 justice and (inaudible) petition back in 2009 to require
19 registrants to provide labels in both Spanish and
20 English. So, it would be nice to get an update on that.

21 MR. BRADBURY: Thanks.

22 UNIDENTIFIED MALE: Just to add one thing.

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1 Process-wise, I believe we're supposed to be an advisory
2 body to you folks. I get the impression that we're
3 providing a lot of individual insights and opinions.
4 There was some talk about consensus versus voting. When
5 issues are brought up, I think the question needs to be
6 asked, what is the consensus of the body to the EAP. For
7 example, I don't know what the consensus is of this group
8 requesting an extension for the NPDES.

9 So, if there are issues that are brought up, I
10 think we should have the body provide a consensus to you
11 of what the body believes to be occurring for next steps
12 or future steps.

13 MR. BRADBURY: Thanks, and that's what we do.
14 To the best of my ability, get input from folks in terms
15 of next steps and action items that we're taking on. I
16 expect people to raise their hands and say, no, we
17 shouldn't do that and then engage everybody to talk about
18 the merits of going forward on an activity or not.
19 Continue to do that.

20 It is an advisory committee, so we don't hold
21 votes. We do try to sort out if we have consensus on an
22 issue or we don't have consensus on an issue. Frankly,

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1 if we don't get consensus on an issue, that's still
2 helpful for us because we can understand what the
3 diversity of opinions are.

4 Using the spray drift example, that work group
5 did a lot of work and they did great work. They couldn't
6 quite reach consensus on every piece of that challenge,
7 but they did on a lot. It helped clarify what the tough
8 issues were. So, it was very valuable even though we
9 didn't reach consensus. So, we'll continue to do that.

10 The NPDES permit one is just a -- we're not a
11 FACA that reports on the Clean Water Act, so it's just a
12 little cumbersome. But many of you have all been
13 involved in a lot of the public processes going on around
14 that, getting your views into the agency. So, that one
15 is just a little odd in terms of jurisdictions on the
16 statutes.

17 Cindy.

18 MS. SMITH: I would just say in response to
19 that, I think one way we might be able to show that is
20 there was a lot of consensus in some of these work group
21 meetings, not on every single point. But I think on some
22 points we had consensus. So, maybe when we present,

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1 maybe one of the things is to say, here's the areas where
 2 we had consensus and here's the areas where we had some
 3 differing opinions. But here they are. So, that might
 4 be a way to help get at that issue.
 5 Then, the other thing has nothing to do with
 6 this. I just wanted to remind everybody about the
 7 donation cup. You know, all the water and food we get,
 8 EPA can't pay for that. So, they pay for it largely
 9 through out donations. So, don't forget about the
 10 donation cup.
 11 MR. BRADBURY: Thanks, Cindy. Your point is
 12 well taken, Mark and Cindy. Sometimes we're sort of used
 13 to the process over the years. I think the clarification
 14 that Cindy is making is good.
 15 Jennifer.
 16 DR. SASS: Two things. One is regarding the
 17 consensus issue. I mean, the thing is we mostly don't
 18 have consensus. It would be painful if we had to come to
 19 consensus on these issues. It's more important that
 20 we're able to give EPA our feedback based on our
 21 stakeholder sort of positions.
 22 I do like Cindy's idea of having some -- I

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1 mean, if we have some sort of way of representing
 2 ourselves without having to individually speak, that
 3 would save a lot of time in the meeting, if we could just
 4 go, like, I, or something, and that would be it.
 5 As for the thanking EPA for the munchies, it's
 6 really great. But I will raise again that I don't think
 7 we should be buying bottled water. Check with your water
 8 office and see what they think about bottled water.
 9 UNIDENTIFIED FEMALE: Back to the consensus
 10 thing, many of these issues have a lot of complexity. In
 11 terms of having an informed opinion on every single issue
 12 and enough so that you could vote on it intelligently, I
 13 think it's going to be difficult. So, I would really
 14 like to avoid kind of knee-jerk voting. I think that
 15 voting is not a good idea.
 16 MR. BRADBURY: Okay.
 17 UNIDENTIFIED MALE: I don't believe in voting
 18 either, okay. So, let's get that clear. I also agree
 19 when we have 35 or 40 people here with diverse opinions
 20 and diverse experience, there's going to be differences.
 21 But when there are areas where we do have consensus, that
 22 should be clearly identified. If we don't have a

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1 consensus, that's fine, too.
 2 But I think there are points in time where we
 3 say, this is the way we all agree we should go, or the
 4 majority of us should go. Majority is not (inaudible)
 5 when you use consensus, but that's where I'm coming from.
 6 MR. BRADBURY: Thanks. I'm going to turn it
 7 over to Margie and run through some options for the next
 8 meeting, the spring meeting.
 9 MS. FEHRENBACH: We're looking at dates in sort
 10 of late April/early May. I'll send an e-mail to
 11 everybody offering April 18th-19th, 25th-26th, or May
 12 2nd-3rd. If you're aware of any major meetings that
 13 would conflict --
 14 MR. BRADBURY: While we've got everybody
 15 together, I'd like to thank Margie for all her work in
 16 getting this meeting up and running and another great
 17 success. I don't think we'd have a chance to get any of
 18 these meetings without Margie, so I can't thank her
 19 enough.
 20 I think she talked about it last time, but the
 21 work it takes when FACAs have to get reauthorized and the
 22 process Margie had to go through with, she calls them --

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1 I should be careful what she calls them -- but the
 2 bureaucracy to ensure that this FACA could continue and
 3 the documentation and then the work to get all of you on
 4 the panel, it's an incredible amount of work. So, I want
 5 to thank Margie for that as well as this specific
 6 meeting. So, thanks, Margie.
 7 MS. FEHRENBACH: One other thing I forgot to
 8 mention, the charter and the membership are on different
 9 tracks. So, there will be a Federal Register notice soon
 10 to show that the charter to this group is being renewed
 11 starting like October 31st for two more years. It's just
 12 the charter.
 13 The membership process for the next round will
 14 actually have to start, I think, in a few months. They
 15 like you to have six to eight months for the process.
 16 It's a little out there but it's over the next year.
 17 MR. BRADBURY: So, with that insight into the
 18 bureaucracy, let me thank you again and have a good trip
 19 back. Looking forward to seeing you in about six months.
 20 Take care.
 21 (Whereupon, the meeting was
 22 concluded.)

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