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UNITED STATES  
ENVIRONMENTAL PROTECTION AGENCY  
  
PESTICIDE PROGRAM DIALOGUE  
  
COMMITTEE MEETING

April 29, 2010

Conference Center - Lobby Level  
  
2777 Crystal Drive  
  
One Potomac Yard South  
  
Arlington, VA 22202

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

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3 MR. BRADBURY: Good morning, everyone. I want  
4 to welcome you to our Pesticide Program dialogue  
5 committee meeting. I'm Steve Bradbury, the acting office  
6 director for the pesticide program. I want to welcome  
7 you all to Washington. It's sort of a brisk morning, but  
8 that feels good when we think of the summer days to be  
9 coming.

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15 I want to again welcome you all to our meeting.  
16 The next day and I half I think is going to be a pretty  
17 robust meeting and a lot to talk about, which I'll  
18 address a little bit in a few minutes.

19 Before I get started, I'd like to introduce Jim  
20 Jones, who is a deputy assistant administrator for the Office of  
21 Chemical Safety and Pollution Prevention, and ask Jim to  
22 give opening comments for us as we get started.

1 Jim.

2 MR. JONES: Thanks, Steve.

3 I appreciate the opportunity to be here today. A  
4 number of you have come up and said you haven't seen me  
5 in a while, and it has been a while since I've seen many  
6 of you. But it's really good to see so many people who  
7 I've worked with for so many years in my time at EPA.

8 Steve Owens, the assistant administrator, sends  
9 his regrets. He was planning on being here this morning  
10 but he had some travel that he needed to take, so he's  
11 not able to be with you here this morning. But he hopes  
12 to be with you the next time you all get together.  
13 So, he sends his regrets.

14 I wanted to first talk about the name change,  
15 as Steve mentioned. We are now the Office of Chemical  
16 Safety and Pollution Prevention, which I actually have to  
17 say the full name does roll off the tongue. As someone  
18 who has had to say the former name in multiple fora over  
19 the course of my career -- and I butchered it routinely  
20 because it really didn't roll off the tongue very well.  
21 It's not about the ease of senior officials being able to  
22 say the name of the organization, but it is nice when the

1 name of your organization aligns with what you do. That  
2 is what we do, chemical safety and pollution prevention  
3 here in this office.

4 That's the reason why Steve changed the name,  
5 because he wanted to see alignment in what it is that  
6 we're called so that when we're talking about who we are  
7 and who we represent and where we're from, it represents  
8 what we do. Chemical safety and pollution prevention is  
9 what people in this office do. Whether you're in the  
10 toxics program, the pesticides program, or you're doing  
11 science coordination, you're working on chemical safety  
12 or pollution prevention or both. So, that's why we've  
13 changed our name.

14 The acronym isn't exactly -- definitely doesn't  
15 roll off the tongue. As Margie said to me, when you say  
16 it, someone might say God bless you. But chemical safety  
17 and pollution prevention does fit together, so that's generally how I  
18 describe the name of this organization.

19 I'm going to talk to you just a little bit  
20 about the administrator's priorities for which chemical  
21 safety is very high on her list, and then  
22 just a little bit briefly talk about how the agenda of

1 this meeting lines up with that.

2 The administrator has articulated -- when she  
3 first came on board --  
4 five priorities. In the last month or so, actually right  
5 around Earth day, she said, I've thought about it, I've  
6 been listening to both the stakeholders and working with  
7 the people within the agency, and she supplemented her  
8 priorities.

9 But they're fundamentally still the same, the  
10 first being action on climate change, ensuring clean air,  
11 ensuring the safety of chemicals, protecting America's  
12 waters, and cleaning up our communities, which were the  
13 original five that she articulated on Inauguration Day in  
14 January of 2009.

15 After being here for a year, she has  
16 supplemented them with two additional ones, both of which  
17 she has talked about consistently in her 15 months here.  
18 They are expanding the conversation on environmentalism  
19 and environmental justice and building strong state and  
20 Tribal partnerships. So, those are two areas that the  
21 administrator has said are also major priorities for this  
22 agency and for all of us who work here.

1           Your agenda today is a clear reflection  
2 of ensuring chemical safety is reflected  
3 throughout the agenda. When you look through what you  
4 all are going to be talking about, it largely is a  
5 representation of our efforts to ensure chemical safety;  
6 in particular pesticide safety in the United States.

7           It also brings another element of the  
8 administrator's priorities. The conversation you'll be  
9 having later this morning on NPDES brings in the priority  
10 of protecting America's waters. It also is a reflection  
11 of the way in which we've managed that process. It's  
12 about helping to ensure strong state partnerships, the  
13 way in which we've engaged our state partners in the  
14 development of that program. So, if you work through the  
15 agenda as we do our work here, ensuring safety of  
16 chemicals will continue to be a top priority for the  
17 Office of Pesticides Program.

18           The other piece, and I realize this is not an  
19 agenda item for you, but it is a major priority for this  
20 AA and for the administrator. I think it just warrants a  
21 minute or two of my reviewing, and that is around  
22 industrial chemicals in TSCA form. The

1 administration last summer articulated principles for  
2 reforming TSCA.

3 For those of you who have worked in the arena  
4 of pesticide regulation, it will sound somewhat familiar.  
5 That is that we need to have a strong science-based  
6 safety standard for industrial chemicals in the United  
7 States. The EPA needs strong authority to be able to  
8 manage risks associated with industrial chemicals. We  
9 need the ability to get data in a relatively easy way.  
10 Manufacturers have responsibility for demonstrating  
11 through data the safety of their chemicals. Kind of  
12 sounds familiar, doesn't it?

13 We are working right now towards achieving that  
14 through the reform of TSCA. There's a Senate bill that  
15 has been introduced and the House has introduced a  
16 discussion draft. We're actively engaging in discussion  
17 with stakeholders and the House actually on their  
18 discussion draft. We hope to see the reform of that  
19 statute, which I think is widely viewed as not having  
20 succeeded in its objectives of ensuring the safety of  
21 industrial chemicals.

22 So, with that, I will turn it back over to

1 Steve. I'll be able to stay with you through the first  
2 session this morning. I hope you have a really  
3 productive meeting. Thanks.

4 MR. BRADBURY: Thank you. Before we get  
5 started, I wanted to just express my appreciation for all  
6 the folks before me at this point spotting the table and  
7 chairing the PPDC meetings. Actually, Jim was the office  
8 director. And more recently, Debbie Edwards was the  
9 office director, and who you all know retired around the  
10 turn of the year. I greatly appreciated working with  
11 Debbie and all the advice and counsel she gave me and all  
12 my colleagues in OPP, as well as Jim and Marsha Mulkey  
13 before that.

14 So, I'm really honored to be in this spot kind  
15 of with the ghosts of Christmas past wooing around me and  
16 one actually right next to me. I hope I can contribute  
17 as they did to the very constructive relationship this  
18 committee has with the program in terms of giving us  
19 advice and counsel on a lot of challenging efforts that  
20 we have to undertake.

21 We undertake them in the context, as Jim  
22 indicated, of ensuring protection for the environment and

1 human health, but in the context of using these products  
2 to ensure safe food, and an appropriate  
3 safety from the pests in our homes and in our different  
4 settings around our country.

5           So, I want to start off first by again thanking  
6 all of you for the time and effort you've put in to the  
7 work of this committee, not only at these sessions but I  
8 think more importantly in the sessions between these big  
9 meetings where we have different work groups that are  
10 taking on a number of the challenging activities.

11           I think two or three of the work groups who are  
12 meeting this week, or they will be meeting at lunch today  
13 even, will be going over a lot of the work that goes on  
14 that really feeds into the kind of conversations we have  
15 at these sessions. Again, I want to thank you all for  
16 your time and effort.

17           Let me spend a little bit of time just walking  
18 through the agenda. I won't use a lot of time but just  
19 put a little bit of context in the agenda and what we  
20 hope to accomplish over the next day and a half. From  
21 the feedback we got from all of you, there was a lot of  
22 interest in a lot of topics. We had some topics that we

1 wanted to spend some time with you to get some feedback  
2 as well.

3 In part because of a lot of new activities  
4 going on, this agenda is probably a little bit more  
5 towards the information sharing than we typically like to  
6 do just because you all had so many topics you wanted to  
7 get an update on.

8 Having said that, we've also inserted topics  
9 where we do want to have some dialogue and some back and  
10 forth in terms of where we are and where we're heading.  
11 One of those first topics has to do with nanotechnology.  
12 Bill Jordan will be chairing the session.

13 We'll review where we're at in terms of  
14 nanotechnology and pesticides and also some dialogue  
15 around the relationship between what we're doing in the  
16 area of nanotechnology and pesticides and what's going on  
17 in terms of industrial chemicals and looking at  
18 nanotechnology and how to do the risk and risk management  
19 around that.

20 Then we'll take a break and then we'll spend  
21 some time working through where we are with the NPDES  
22 permit process for pesticides that can be applied to

1 water or over water including near water. We've had this  
2 topic periodically over the last, I think, three  
3 sessions, perhaps, with the PPDC. We're reaching an  
4 important milestone in our activities with the Office of  
5 Water. Alison Wiedeman will be joining Bill Jordan and  
6 Susan Lewis to discuss where we are in that process of  
7 developing the general permits.

8           This afternoon we have two update sessions  
9 which will be intense because we have a lot of  
10 information we want to get to. But, having said that,  
11 for most of the topics, you've received background  
12 information or some web sites that you could take a look  
13 at. So, our goal there is to provide some quick  
14 snapshots or key points, try to manage the time so that  
15 there will be some time for clarifying questions during  
16 those sessions. But those updates aren't intended to be  
17 a wide-sweeping dialogue around different perspectives  
18 but just to give you a snapshot of where we are.

19           If we have some time, we'll do some clarifying  
20 questions. We're always open to have other meetings with  
21 the office in terms of more detailed explorations of  
22 topics. So, I hope you'll bear with me if I start to be

1 the ref on the ice at a hockey game. I won't put you in  
2 the penalty box but I am going to watch the clock so that  
3 we can stay on schedule, again in the context of how we  
4 tried to set up the meeting today.

5 We'll also be spending some time this  
6 afternoon, more in-depth time, for some back and forth in  
7 terms of endangered species. We're particularly focusing  
8 on where we are and starting to work through  
9 consultations and how to try to take the best advantage  
10 we can with the time frames we have of getting public  
11 input as we have to move forward with the consultation  
12 packages and responding to biological opinions from the  
13 services.

14 Vicki Dellarco will then give a brief update on  
15 where we are with our PPDC work group looking at 21st  
16 century toxicology and give a report out on some of those  
17 activities.

18 We'll also be looking at the end of the day  
19 getting some update on our -- oh, we'll have a public  
20 comment period, sorry, at the end of the day to kind of  
21 wrap it up. By then, I'm sure we'll be ready for taking  
22 a break as we move into tomorrow where we'll be taking a

1 look at the issue of pollinator protection which is an  
2 area that I'm sure you all are aware of, everything from  
3 colony collapse disorder in honeybees to just sort of  
4 broader issues about native pollinators.

5           What we want to do in that session with our  
6 colleagues at USDA is give you an update of where we are,  
7 in particular get some feedback from you on how we can  
8 enhance our communication, not just in EPA but with EPA  
9 and USDA and others in terms of where we are in receiving  
10 information and how can we do a better job at  
11 communicating what the federal government is trying to  
12 work through with this very challenging topic that we're  
13 dealing with.

14           Lois Rossi will then spend a little time giving  
15 an update from another PPDC work group, a newer work  
16 group looking at public health issues and how to start  
17 tackling some of those issues.

18           Then, we'll also get an update from Rick  
19 Keigwin and Karen Whitby on where we are in issuing test  
20 orders in the endocrine disruptor screening program and  
21 give you sort of a snapshot of how that process is going  
22 and where we're heading.

1           Then, we'll wrap it up tomorrow talking a  
2 little bit about next meeting. Also, Margie will walk  
3 you through the process of getting new members for the  
4 committee as we move forward in the history of this  
5 August body and the great work you all provide to us.

6           So, what I'd like to do before we get started  
7 is spend some time going around the table so everybody  
8 can introduce themselves and your organization. If  
9 you're an alternate for another individual, if you could  
10 clarify that as we go around the table. Why don't we  
11 start on my left and start with Marty.

12           MS. MONELL: Marty Monell, Deputy Director,  
13 OPP.

14           MR. HOUSENGER: Jack Housenger, Director of  
15 BEAD.

16           MR. JORDAN: Bill Jordan, Senior Policy Advisor  
17 in the Pesticide Office.

18           MS. SHIMKIN: Martha Shimkin (phonetic) with  
19 the Office of Pesticides Programs.

20           MR. DWINELL: Steve Dwinell of --

21           (Break in tape.)

22           MS. ROBERTS: Amy Roberts sitting in for Maria

1 Herrero as representative of the Biopesticide Industry  
2 Alliance.

3 MR. VROOM: I'm Jay Vroom, President of  
4 CropLife America representing agricultural crop  
5 protection manufacturers, distributors and formulators.

6 I wanted to take a moment just to say thanks to  
7 all the farm organizations that are represented. Cannon  
8 Michael, I think, is the only active farmer with us here  
9 today. Being away at this time of the year from planting  
10 season is a special commitment, but I think all of us are  
11 well reminded to thank farmers every day but especially  
12 during planting season.

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

15 MS. LAW: Beth Law, Consumer Specialty Product  
16 Association sitting in for Phil Klein today.

17 MR. FRY: I'm Michael Fry from American Bird  
18 Conservancy.

19 MS. RAMSAY: I'm Carol Ramsay from Washington  
20 State University and representing the American  
21 Association of Pesticide and Safety Educators since Amy  
22 Brown was unable to make it today.

1 DR. ROBERTS: I'm Jimmy Roberts. I'm a  
2 pediatrician at the Medical University of South Carolina.

3 MR. SMITH: Steve Smith, S.C. Johnson.

4 MS. BRICKEY: Carolyn Brickey.

5 MR. TAMAYO: Dave Tamayo, County of Sacramento  
6 and California Stormwater Quality Association.

7 MR. WEGMEYER: Tyler Wegmeyer, American Farm  
8 Bureau Federation.

9 MS. KEGLEY: Susan Kegley, consulting scientist  
10 and representing Pesticide Action Network.

11 MR. GUSKE: Marco Guske with the Tribal  
12 Pesticide Program Council.

13 DR. SCHELL: I'm John Schell, a toxicologist  
14 with ENTRIX.

15 MR. SCHERTZ: Scott Schertz, Schertz Aerial  
16 Service, representing the National Agricultural Aviation  
17 Association.

18 MS. SULLIVAN: Kristie Sullivan, Physicians  
19 Committee for Responsible Medicine representing animal  
20 protection and consideration.

21 DR. WHALON: Mark Whalon. Jay, I'm also a  
22 farmer.

1 MS. LIEBMAN: Good morning. I'm Amy Liebman  
2 from the Migrant Clinicians Network.

3 MR. JAMES: Allen James, Responsible Industry  
4 for a Sound Environment. We represent companies that  
5 manufacture and formulate products for urban use.

6 MR. THRIFT: Jim Thrift, Agricultural Retailers  
7 who represent retailers, distributors and applicators.

8 MS. RUIZ: Virginia Ruiz, Farmworker Justice.

9 MR. MICHAEL: Cannon Michael. I am a farmer  
10 also and here representing National Cotton Council,  
11 California Cotton Growers. My friend Tyler across from  
12 me is also a farmer.

13 MS. SPAGNOLI: Julie Spagnoli, FMC.

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

15 MS. BAKER: Cindy Baker representing the Gallon  
16 Group of which one company J.R. Date Growers. We grow  
17 dates.

18 MX. COX: Caroline Cox, Center for  
19 Environmental Health.

20 MR. CONLON: Joe Conlon, American Mosquito  
21 Control Association.

22 DR. FERENC: Sue Ferenc, Chemical Producers and

1 Distributors Association.

2 MR. BOTTS: Dan Botts, Florida Fruit and  
3 Vegetable Association and Monarch Crop Farmer Alliance.

4 MR. ROSENBERG: Bob Rosenberg, National Pest  
5 Management Association and I eat farm products.

6 DR. SHAH: Hasmuckh Shah, American Chemistry  
7 Counsel representing manufacturers and formulators of the  
8 antimicrobial pesticides.

9 MR. BEAVERS: Good morning, everybody. Mark  
10 Beavers. I'm at the Armed Forces Pest Management Board.  
11 I'm representing the Department of Defense.

12 MR. KASHTOCK: Mike Kashtock, Food and Drug  
13 Administration, Office of Food Safety. I'm representing  
14 Dr. Nega Beru.

15 MR. CHIN: Teung Chin, USDA Office of Pest  
16 Management Policy. I have a good crop of dandelions in  
17 my yard.

18 MR. BRADBURY: Thanks. If any members of the  
19 PPDC on the phone, if you could introduce yourself as  
20 well, please.

21 (No verbal response.)

22 MR. BRADBURY: Okay. During the course of the

1 day and a half, I think there will be some members who  
2 will be calling in on the phone, so we'll check in  
3 periodically and make sure when they're on that they  
4 introduce themselves so we know they're there. I can  
5 make sure they can ask a question or get some feedback to  
6 us as they desire.

7           Why don't we start our first session which has  
8 to do with nanotechnology and some of the activities that  
9 we've been undertaking in the pesticide program. I'm  
10 going to turn it over to Bill Jordan who is going to  
11 chair this session. Bill.

12           MR. JORDAN: Thanks, Steve. Thanks, everyone,  
13 for starting your morning with us on nanotechnology. The  
14 agenda indicates that there will be three of us working  
15 together. Joan Harrigan-Farrelly, the director of the  
16 Antimicrobials Division, is unable to be here this  
17 morning. She's attending a funeral. But Joan, along  
18 with Jack and I, work on the interdivisional team of  
19 folks who are trying to make sure that we proceed in an  
20 coordinated fashion with the development of policies and  
21 making particular decisions on products that involve  
22 nanotechnology.

1           So, I'm very grateful for the support of the  
2 other folks on this front. The presentation that I'm  
3 making actually was drafted by folks in Joan's division.  
4 I crib liberally from their work as well as work of folks  
5 in the other parts of EPA.

6           So, the presentation today is the first one  
7 we've had at PPDC since November of 2006. A lot has  
8 happened since then. If you're like me, you probably  
9 didn't know much about nanotechnology and maybe you have  
10 learned a fair amount. Or, if you're like me, you've  
11 probably forgotten a lot of what you might have learned.  
12 So, we're going to start off with a basic review of  
13 nanotechnology and talk a little bit about how we in OPP  
14 are going to define nanoscale materials.

15           Then we'll move on to some brief discussion of  
16 why OPP is concerned about nanoscale materials and then  
17 describe in particular the kinds of products that we are  
18 beginning to see. Because we have a lot of questions and  
19 a lot of places where we need help from the outside, we  
20 convened a meeting of the scientific advisory panel in  
21 November. I'll tell you what we asked them about and the  
22 kind of advice that we got from them.

1           I'll wrap up with a discussion of some notice  
2   that we're going to issue, I hope very soon, on nanoscale  
3   issues and summarize some activities that we're engaged  
4   with across the agency and internationally.

5           So, let me start off by reviewing a little bit  
6   of the basics. Nanotechnology has often been referred to  
7   as the science of the small. We're talking about really  
8   really small, in the range of approximately 1 to 100  
9   nanometers. That may not mean much to you. I'll try to  
10   put that in perspective in the next slide, but working  
11   with materials in that size range is extraordinarily  
12   challenging.

13           The people who are doing it have discovered  
14   that it's just a field that requires new technology and  
15   new skills. They are developing and creating structures  
16   that will have astounding applications potential  
17   benefits. I'll talk a little bit about them.

18           So, it involves the ability to control or  
19   manipulate matter almost at the size of single atoms and  
20   then to understand what that does in terms of the  
21   properties of materials. The field is growing very  
22   rapidly. In 1985, people filed for 125 patents. In

1 2005, the last year I have data for, there were almost  
2 5,000 patents. That represents a growth of about 20  
3 percent a year. There doesn't seem to be any signs that  
4 it's going to stop growing.

5           So, how big is a nanometer? It's one billionth  
6 of a meter. If you lined 10 hydrogen atoms up next to  
7 each other, that would be about a nanometer in length. A  
8 carbon nanotube, which is carbon atoms bound together in  
9 a single layer and then rolled to form a hollow tube, is  
10 about two nanometers in diameter. DNA is about two-and-  
11 a-half nanometers. A virus which is pretty small is 100  
12 nanometers.

13           By contrast, a human hair -- I will digress  
14 here to day that the figures on human hairs ranged  
15 anywhere from 60,000 to 100,000 nanometers. It runs in  
16 the range of about 75,000 nanometers. Shaquille O'Neal,  
17 according to the web site, is about 2.1 billion  
18 nanometers tall. So, we're talking really really small  
19 stuff.

20           Why are people interested in materials like  
21 that? Well, the answer is that they begin to display  
22 novel properties. Almost every field of product that you

1 can imagine is looking into nanotechnology. It's being  
2 applied in semiconductors to make them faster, cheaper,  
3 and smaller for data storage, to process information more  
4 quickly. There are carbon nanotubes which can transmit  
5 electricity with less energy loss. There are sunscreens  
6 that incorporate titanium dioxide. So, instead of being  
7 the messy white goop that you may be familiar with from  
8 years ago, it's now possible to have it transparent and  
9 provide better UV protection.

10           There are sensors that can detect explosives, I  
11 think land mines or IEDs or terrorist bombs in very very  
12 small levels of explosive materials. Quantum dots are  
13 being used in lighting. A quantum dot is a kind of  
14 nanosized crystal that absorbs light and then emits  
15 photons. They can be much more energy efficient.

16           There are nanoapplications that involve self-  
17 cleaning surfaces so that you never have to wash windows  
18 anymore, also capable of repelling dirt on textiles,  
19 structural reinforcement. Adding carbon nanotubes can  
20 produce lighter, stronger car bodies or airplane fuselage  
21 that's making people safer, saving fuel. This is just  
22 the start of some of the kinds of applications that we've

1 run across already.

2           So, people are beginning to think about using  
3 nanoscale materials in pesticides. We are beginning to  
4 see products. This is how we are going to define  
5 nanoscale materials. It's an ingredient that contains  
6 particles that have been intentionally produced to have  
7 at least one dimension that measures between  
8 approximately 1 and 100 nanometers.

9           A couple of comments on that. The first is the  
10 use of the phrase intentionally produced. Nanoscale  
11 particles occur naturally. They may be produced  
12 inadvertently in the course of making materials. What  
13 we're interested in are when people intentionally or  
14 deliberately manufacture a material so that it falls into  
15 the nanoscale range.

16           People don't do that unless they are hoping to  
17 take advantage of some novel property. So, you'll notice  
18 that it does not refer here to novel properties, as some  
19 of the definitions currently do. That's because we want  
20 to have the opportunity to look at the materials and to  
21 evaluate whether or not there are, in fact, novel  
22 properties and how those properties relate to our safety

1 assessment.

2           Finally, you'll see that there is no particular  
3 percentage. We are interested in trying to understand  
4 this field and don't yet have enough knowledge to be able  
5 to predict what level or percentage of nanoscale  
6 materials will be enough to change the characteristics of  
7 a pesticide product. As long as somebody is  
8 intentionally producing nanoscale material, we'd like to  
9 know about that.

10           So, what do we know? Well, lots of research is  
11 going on in the area of nanoscale materials. What it  
12 demonstrates is that nanoscale materials behave  
13 differently from conventionally-sized counterparts. When  
14 materials get smaller, they begin to behave differently.  
15 Gold, for example, in wedding rings such as the one I'm  
16 wearing, is a pretty familiar yellow-colored metallic  
17 substance not particularly harmful. People are intimate  
18 contact with it for long periods of time, one hopes, when  
19 they're wearing their wedding rings.

20           But when it's nanoscale size, gold can have  
21 very different properties. For example, it's no longer  
22 yellow colored. It can vary in color from red to black.

1 It becomes much more highly reactive and more toxic. The  
2 same is true for nanocopper, much more acutely toxic than  
3 the micron-sized particles.

4 The literature is growing fast. It indicates  
5 that not only size is important but so, too, is shape and  
6 coating. The SIP, when they reviewed our consultation  
7 package in November, said that there are just very large  
8 gaps in our understanding and we still need and have a  
9 lot to learn.

10 So, I found this slide particularly  
11 interesting. It helped me understand a little bit better  
12 as a lay person why nanoscale materials are different.  
13 This is a depiction of the relationship between size and  
14 surface area. The smaller a particle is -- this is sort  
15 of intuitively obvious, but the smaller the particle is,  
16 the more atoms appear on the surface of the particle.  
17 The larger the particle is, the smaller the percentage of  
18 atoms that appear on the surface.

19 This chart shows that around 100 nanometers in  
20 diameter, the ratio of surface area to diameter begins to  
21 rise dramatically. In the 1 to 10 nanometer range, it's  
22 dramatically different from a higher range. But once you

1 get above 100 nanometers, the percentage of particles on  
2 the surface goes down. This is important because in a  
3 lot of ways, what determines the reactivity or the rate  
4 at which things happen is related to the availability of  
5 the atoms to interact.

6           So, the more atoms that are available, the  
7 higher percentage of the atoms that are available to  
8 interact, the faster and greater their interaction goes.  
9 This raises the possibility that there are ways of  
10 assessing risk, which historically have been based on  
11 mass, milligrams. Material related to a kilogram of body  
12 weight, for example, which is familiar for most of you, I  
13 hope, in our risk assessment, may not be as important as  
14 considering the surface area phenomenon.

15           On the next slide, I talk a little bit about  
16 why OPP is concerned. The research that's been conducted  
17 suggests that at least for some nanoscale materials,  
18 dermal absorption is more rapid. It can pass into the  
19 body much more readily because of its small size and  
20 actually penetrate into cell membranes.

21           In terms of inhalation, small particles can go  
22 much farther into the respiratory system, deep into the

1 lung, enter into the blood supply, cross the brain  
2 barrier, and reach parts of the body that are not  
3 otherwise expected.

4           Those same properties also are a concern  
5 potentially for environmental effects. These materials  
6 may be more durable and, as I mentioned earlier, more  
7 reactive, raising questions about fate and what  
8 compartments they would enter. We really don't have a  
9 whole lot of information about the toxicity of these  
10 nanoscale materials to nonmammalian species compared to  
11 conventionally-sized materials. So, we have a lot to  
12 learn.

13           Let me shift over now to what's happening here  
14 in the Office of Pesticide Programs. Currently, we know  
15 of at least one product on the market that contains a  
16 nanoscale material; it's nanosilver. This product was  
17 approved by EPA without our knowledge that the product  
18 contained a nanoscale material.

19           The applicant did not identify the presence of  
20 a nanoscale material and simply suggested that it was a  
21 ME 2 (phonetic) version of an already registered product.  
22 In fact, it does have many characteristics that are quite

1 similar to other registered products. It's material is  
2 preservative. There are a number of other silver-based  
3 antimicrobial products that are used as materials  
4 preservative.

5 So, identifying that product has led us to  
6 think that perhaps there are other registered pesticides  
7 that contain nanoscale materials. We are taking steps to  
8 identify them. We sent a letter to the registrants of  
9 all silver-based antimicrobial products informing them  
10 that we would not only like to know but we regard them as  
11 having a legal obligation to identify for us the presence  
12 of nanoscale material.

13 That letter was sent under the auspices of  
14 FIFRA section 6(a)(2). We're currently reviewing their  
15 responses and other information in order to identify any  
16 additional products that may contain nanoscale silver.  
17 When we do, then we'll take appropriate actions under  
18 FIFRA to ensure that all of those products meet FIFRA  
19 standards.

20 Beyond currently registered products, we have  
21 pending before us a number of applications. All of them  
22 at this point are in the antimicrobials division. Most

1 of them involve products that would contain nanoscale  
2 silver. Again, uses as materials, preservatives,  
3 additives to textiles or plastics, coatings or other  
4 substances in order to protect the treated products from  
5 microbial degradation, again very similar to currently  
6 registered products.

7 But there are other products in the works. One  
8 of them that is not a nanosilver-based product uses a  
9 nanotube like clay substance, halloysite, which would be  
10 used as a kind of microencapsulization of the active  
11 ingredient and would provide better delivery in timing  
12 for the active ingredient. I've also heard about another  
13 product that's not the subject of an application as far  
14 as I know, but it could be coming into our registration  
15 division or by pesticides division as a mosquitocide.

16 So, with all of this activity going on, we  
17 decided that we were going to be facing fairly quickly  
18 the need to make our science-based decisions on the  
19 pending applications and the currently registered  
20 products. Because of the newness of this field, we  
21 thought it helpful to consult with the FIFRA scientific  
22 advisory panel.

1           We held that meeting in November of last year.  
2           They have since provided us a report in which they  
3           responded to the questions that we asked them about how  
4           to evaluate the hazard and exposure from nanosilver and  
5           other nanometal-based pesticide products.

6           We wanted to understand whether these products  
7           incorporate nanoscale silver. We're going to pose any  
8           kind of differences from other silver-based products in  
9           terms of silver ion exposure and in terms of the release  
10          of nanosilver particles.

11          The SAP wrote a very extensive report in which  
12          they cited numerous scientific articles. In spite of the  
13          lengthy bibliography, their bottom line conclusion is you  
14          need a lot more data in all the scientific disciplines in  
15          order to be able to have a comprehensive understanding of  
16          the affects of the nanoscale silver.

17          The kinds of data requirements will need to be  
18          defined on a case-by-case basis. For example, looking at  
19          materials preservative, you need to take into account  
20          differences between the kinds of materials that might be  
21          preserved. Are you talking about ceramics or caulks or  
22          insulation or textiles? Also, is it being applied as a

1 coating or is it a constituent of the ingredient. These  
2 will all influence the kind of day requirements.

3 The other sort of broad overreaching idea that  
4 they recommended was life cycle analysis, something that  
5 I think we've been doing intuitively in the pesticide  
6 program. But their recommendation is to make it more  
7 explicit, starting with the initial use of the pesticide.  
8 So, you're talking about a product that's being used as a  
9 fabric treatment in order to extend the life of the  
10 fabric and anything about how the exposure might occur.

11 Well, there's the exposure that workers might  
12 get when they incorporate that material preservative into  
13 a textile product. Then there's the exposure that  
14 workers might get when they're handling the treated  
15 fabric. Then there are exposures that people might get  
16 wearing the fabric.

17 For example, does the product leach out when it  
18 comes in contact with human sweat? Or what about if it's  
19 put into a piece of clothing worn by a child and the  
20 child decides to suck on the clothing. So, that would be  
21 dermal exposure, perhaps an oral exposure.

22 Then you'd need to think also about washing and

1 drying the treated clothing. Does the nanoscale material  
2 come out during the washing or drying process? What  
3 about different kinds of detergents or bleach or  
4 qualities of water? Where does it go? Does it go down  
5 the drain? Does it aggregate, that sort of thing? What  
6 happens when it's dried? Does it go out the exhaust fan  
7 in the form of lint creating a possible exposure by de-  
8 inhalation?

9           Then, finally thinking about eventual disposal  
10 of the treated fabric. Will it be burned? If so, what  
11 combustion products form and what's the potential for  
12 exposure by that route? Or, if it's put in a landfill,  
13 what are the potential exposures there? So, these are  
14 the kinds of things that would go into a life cycle  
15 analysis.

16           Shifting now to some of the upcoming policies,  
17 we are working currently on a Federal Register notice  
18 relating to nanoscale materials and pesticides. My hope  
19 is that we will issue it in June, but I'm happy to use  
20 this time to tell you a little bit about what it's going  
21 to say.

22           It will announce a new interpretation of FIFRA

1 and our 6(a)(2) regulations and propose a new policy.  
2 With regard to the interpretation, it will say that the  
3 presence of a nanoscale material in a pesticide product  
4 is reportable under FIFRA section 6(a)(2). The basic  
5 idea here is pretty straightforward.

6 That is that companies that are seeking to  
7 register product or companies that already have products  
8 in the marketplace need to disclose to EPA the presence  
9 of a nanoscale material and their product, if they  
10 haven't already done so. This isn't a new regulation.  
11 This isn't a policy statement. It is an interpretation  
12 of the statute 6(a)(2) and our existing regulations at 40  
13 CFR part 159.

14 In talking about this with some stakeholders,  
15 I've heard concern raised that this stigmatizes in some  
16 fashion nanoscale materials. That is not what we are  
17 hoping to do. We're simply hoping to get information.  
18 We don't think it is any more of a stigma than the  
19 existing requirement which requires registrants to report  
20 to EPA any newly identified metabolites that might be  
21 formed by their product, something that's been going on  
22 since the 6(a)(2) regulations were promulgated a long

1 time ago. Those metabolites, as far as I know, are not  
2 being stigmatized.

3 We're very clear in the notice and we'll be  
4 clear in any communications that we make that we are not  
5 convinced that all nanoscale materials are automatically  
6 dangerous or harmful. What we do know, though, is that  
7 they behave differently from conventional and sized  
8 materials. That fact, which is common across lots of  
9 different nanoscale materials, is enough to make it  
10 prudent on our part to look for additional information in  
11 order to be able to understand the effects.

12 The application of this -- I should point out  
13 that under our regulations, we also have a provision that  
14 says that any person applying for registration of a  
15 product must also report as part of its application any  
16 information that would be reportable under 6(a)(2). So,  
17 as a consequence of that existing regulation, this  
18 interpretation will apply not only to registered products  
19 but also to products that are submitted for registration.

20 This next slide simply summarizes what I just  
21 said. It places the burden of reporting the presence of  
22 nanoscale materials on registrants and applicants who

1 will continue to be responsible for proving the safety or  
2 continued safety of their products.

3           The other part of the notice will be to  
4 announce a proposed new policy. That policy is that when  
5 an active or an inert ingredient contains a nanoscale  
6 material, it would be presumptively considered a new  
7 active or a new inert ingredient even if there is a  
8 conventionally-sized active ingredient already in a  
9 registered product.

10           So, just to explain, we have registered lots of  
11 products with silver-based active ingredients. A company  
12 seeking to register nanosilver products, we would presume  
13 that that nanosilver would be a new active ingredient and  
14 would process it according with PRIA schedules and data  
15 requirements accordingly.

16           Now, I said that's a presumption. A  
17 presumption is something that isn't binding and can be  
18 overcome by submission of information demonstrating that  
19 the nanoscale material and the conventionally-sized  
20 material behave in comparable fashions.

21           I want to move on to a citizen petition in May  
22 of 2008. The International Center for Technology

1 Assessment filed a petition with us asking EPA to  
2 regulate products containing nanosilver. We have been  
3 looking at that petition in the context of the pending  
4 applications and also in light of the FIFRA SAP review.  
5 Among other things, the ICPA asked us to take regulatory  
6 action on what they estimated was about 600 unregistered  
7 nanosilver products. They claim that we ought to be  
8 regulating them under FIFRA.

9 I will note that the products are pretty  
10 diverse. Some of them clearly do have antimicrobial  
11 claims and would be regarded as pesticides whether they  
12 were nanosilver or any other ingredient, claiming that  
13 they are antibacterial or that they eliminate 99.9  
14 percent of bacteria or providing antimicrobial or  
15 antifungal affect. But there are other products that are  
16 not FIFRA-regulated materials, soaps and personal care  
17 products and that sort of thing, and some that are  
18 clearly within the scope of FDA's jurisdiction.

19 With regard to the regulatory issues, another  
20 aspect of this that makes it challenging is that many of  
21 these are manufactured around the world, not necessarily  
22 in the United States. So, enforcement is facing some

1 pretty interesting and challenging issues here. Our goal  
2 is to answer this response in connection with and  
3 concurrently with issuing that Federal Register notice  
4 hopefully in June.

5 I'll wrap up by talking briefly about how OPP  
6 working with other parts of the agency, other parts of  
7 the Federal Government and international organizations.  
8 We, in OPP, are really not the leaders of this effort.  
9 The Office of Research and Development and the Office of  
10 Pollution Prevention and Toxic have been looking at  
11 issues related to nanotechnology much longer and know a  
12 lot more about the science of this area than we do. They  
13 are leading, appropriately, the efforts for the agency.  
14 We're very happy for their support and help.

15 The Office of Research and Development issued a  
16 nanomaterials research strategy with a lot of emphasis on  
17 understanding sources, fate and transport of  
18 nanomaterials, and understanding the human health and  
19 ecological effects. They are also spending time  
20 developing new testing methods which will be very  
21 valuable when we, in OPP, begin to require data on  
22 nanoscale materials.

1           They are serving another very helpful role in  
2 pulling together the information in the public literature  
3 in case studies on particular chemicals. They have case  
4 studies already available on titanium dioxide and carbon  
5 nanotubes. And very happily and gratuitously they are  
6 developing a case study on nanosilver which they hope to  
7 get out this year.

8           OPPT, our sister organization, in 2008 started  
9 a voluntary program called the Nanoscale Materials  
10 Stewardship Program in which companies that were making  
11 industrial chemicals of nanoscale were invited to provide  
12 information to the agency to assess them. We got  
13 information from 31 companies, 132 unique materials.

14           That's the good news. The bad news is that  
15 that probably didn't come close to capturing even the  
16 majority of nanoscale materials that we think are out  
17 there in the environment. So, we think more needs to be  
18 done. I'll say a little bit about that on the next  
19 slide.

20           In addition, the TSCA New Chemicals Program is  
21 looking at nanoscale materials. In the world of TSCA,  
22 the universe of chemicals is divided into old materials

1 and new materials. Old materials were ones that were  
2 being marketed when TSCA was passed. New materials are  
3 new chemicals that were developed since the passage of  
4 TSCA.

5 Over 100 new chemicals have been developed that  
6 are in the nanoscale range. TSCA requires those  
7 developers to notify EPA and provide us with information  
8 about them so that we can decide whether they should go  
9 ahead. This premanufacturing notice program has led to  
10 requirements on the release of the new nanoscale  
11 materials to minimize human and environmental exposure in  
12 many cases.

13 OPPT's future activities to deal with old  
14 chemicals will include a significant new use rule that  
15 says if you're going to take an existing chemical, an old  
16 chemical, and put it out and start using it in nanoscale  
17 form, you need to notify EPA such that it would go  
18 through the same kind of review process as a notice on a  
19 new chemical.

20 The TSCA section 8(a) rule would get existing  
21 information to characterize the use, production volume,  
22 exposure pathways, existing toxicity data on currently

1 marketed nanoscale materials. A TSCA section 4 test rule  
2 will be issued for certain nanoscale materials, probably  
3 a proposal by the end of this year.

4 With regard to EPA's role through the Federal  
5 Government, there is a national nanotechnology  
6 initiative. It has a complicated organizational chart  
7 that you see here. We play actively along with other  
8 federal agencies that are involved in nanotechnology  
9 research or regulation.

10 Our primary involvement is through NEHI. I  
11 should have printed this in purple or orange, but the  
12 NEHI one is at the bottom there. It's the group that  
13 focuses particularly on environmental and health  
14 implications which is a special concern to us and other  
15 regulatory agencies like CPSC and FDA.

16 EPA is actively working in international  
17 organizations. We took a lead role in the working party  
18 on manufactured nanomaterials established under the  
19 auspices of the OECD about four years ago. There have  
20 been a number of meetings. We've set up a number of  
21 working groups. We chaired the first five and now the  
22 responsibility is passed over to the EU.

1           This group is actually doing a fair number of  
2 interesting things with the overall goal of promoting  
3 international cooperation. This is such a fast growing  
4 field and there are so many countries trying to  
5 understand and take advantage of the important and  
6 exciting opportunities in nanotechnology that this kind  
7 of international cooperation is going to be very  
8 valuable.

9           The next slide and the last slide shows you an  
10 example of that. The working party on manufactured  
11 nanomaterials has decided that one of the gaps that we  
12 need to fill is getting more understanding of the  
13 toxicity of many of the widely used nanomaterials. They  
14 are listed here, single wall carbon nanotubes, multi-wall  
15 carbon nanotubes. The fourth one down is silver  
16 nanoparticles which is of particular interest to us. It  
17 indicates that there will be testing on all of these  
18 materials.

19           Various countries are volunteering to take the  
20 lead and others are participating in various ways to do  
21 parts of the research. The lead sponsors will design the  
22 research programs and the other countries will contribute

1 resources. As a result of this, we should be getting a  
2 lot of additional information in the relatively near  
3 future, next few years, to better understand the toxicity  
4 of these materials. It will be quite helpful, I think,  
5 for all of the regulatory agencies to be able to fill our  
6 responsibilities to evaluate safety.

7 So, that is a fast run through of what's  
8 happened since November 2006 on nanomaterials. I'm going  
9 to stop here and invite comments and questions. Jack and  
10 I will do our best to try and answer. The way we'll do  
11 this is raise your cards if you want to make a comment  
12 and we'll circle around starting --

13 Steve started on his left. Last time he  
14 started on his right. The first card up appears to be  
15 Joe Conlon. So, Joe.

16 MR. CONLON: We don't know what we don't know  
17 in a way with this product and given the fact that  
18 there's different toxicology profiles of nanotechnology  
19 vis a vis regular active ingredients and environmental  
20 fates, et cetera, et cetera, how does all of this fit  
21 into the risk cup?

22 MR. JORDAN: That's a great question and that's

1 one that frankly not only we in OPP are struggling to  
2 make sense of but so, too, are a lot of other regulators  
3 and scientists.

4 The SAP report, which is very dense, very  
5 technical, has suggested a variety of ways of thinking  
6 through those issues. I will tell you I don't yet feel I  
7 have the technical sophistication to be able to explain.  
8 I'm not even sure I come close to understanding some of  
9 their ideas. But they are suggesting qualitative  
10 approaches in conjunction with quantitative approaches  
11 that would be appropriate for assessing these materials.

12 We'll be working with our colleagues in the  
13 Office of Pollution Prevention and Toxics who have had to  
14 come to grips with these questions in the context of the  
15 PMNs on over 100 different nanoscale materials. I think  
16 the short answer is that we'll be using some of the basic  
17 principles of toxicology and using our best professional  
18 judgment, understanding potential sources of exposure and  
19 being careful and being transparent about it as we go  
20 forward, consistent with the notion that these are new  
21 active ingredients or new inert ingredients. They'll be  
22 covered under our transparency policy and we'll take

1 public comment on our assessments.

2 MR. BRADBURY: Caroline Cox.

3 MS. COX: I was speaking with an analytical  
4 chemist who said that nanomaterials are the one clear  
5 category that she flagged as there not being available  
6 analytical techniques to identify, I think, especially  
7 once these materials get out in the environment.

8 So, my question is, is there going to be a  
9 requirement from EPA that registrants of these products  
10 provide an appropriate analytical technique?

11 MR. HOUSENGER: Yes. That's one of the issues  
12 that NIST (phonetic) is looking into and certainly one  
13 that we're concerned about. How do you measure  
14 nanomaterials present out in the environment? How do you  
15 know what form they're in? Are they agglomerated? Are  
16 they individual particles? I wish I had the answer to it  
17 right now, but I think it's one that we're struggling  
18 with along with the other agencies in the government.

19 Certainly, when we're talking about nanosilver  
20 in textiles and other materials, we need a way to  
21 identify how much they leech out and also what's leeching  
22 out. I think we have identified some of the methods to

1 do that but I think it becomes harder as we get into how  
2 these materials get into the environment and in what  
3 form.

4 MR. JORDAN: I'll add that on the slide  
5 indicating ORD's research priorities, about half of their  
6 research funds are going toward identification of sources  
7 and measurement issues.

8 So, Cindy Baker next.

9 MS. BAKER: Thanks, Bill. Nothing like  
10 starting off the morning showing your ignorance. So,  
11 here's my ignorance question. If I think I understood  
12 you right in what you were saying, it sounds like it  
13 might be possible that there is existing products out  
14 there that have nanoscale materials. Even the  
15 registrants might not be aware of that by the nature of  
16 how some of these things could form.

17 So, I mean, your definition is very clear. If  
18 you're intentionally producing something to be a  
19 nanomaterial, then you come in upfront saying that. But,  
20 having this requirement under FIFRA 6(a)(2) is a  
21 different level, I guess, of awareness and responsibility  
22 and all that on the registrant, which I'm not saying is

1 right, wrong, or indifferent.

2 But, does this change the product chemistry  
3 requirement? I mean, how do you go about figuring out if  
4 you have a nanoscale material in something or one is  
5 formed if you weren't intentionally doing that in the  
6 first place?

7 The other is sort of a comment about just  
8 putting this under the umbrella of FIFRA 6(a)(2), because  
9 historically, what information comes in about a  
10 formulation and what's in it, comes in under a  
11 confidential statement of formula, which is, in fact,  
12 confidential information for a proprietary business  
13 reason which FIFRA 6(a)(2) reports are not covered under  
14 that. So, just kind of your thoughts a little bit around  
15 those two issues.

16 MR. JORDAN: One of the sort of bedrock  
17 principles of the 6(a)(2) reporting requirements is that  
18 it doesn't require people to develop new information.  
19 So, to address the first part of your question, if a  
20 company doesn't have knowledge that their product  
21 contains a nanoscale material that was intentionally  
22 produced, this interpretation would not in any way expose

1       them to any kind of failure to report liability.

2               The second part of your question relating to  
3 product chemistry data requirements, we are thinking  
4 about whether we need to change the prior chemistry  
5 information that we routinely ask for in connection with  
6 an application. My hunch is that we probably will ask  
7 for additional prior chemistry information if the  
8 applicant or registrant reports that they have  
9 intentionally put a nanoscale material in their product.

10              At least at this point, I'm thinking that it's  
11 not particularly likely -- but I could be wrong about  
12 this, pardon my ignorance as well. It's not particularly  
13 likely that somebody is going to manufacture something  
14 with a lot of nanoscale material in it by accident. So,  
15 I'm not sure where that goes.

16              The last piece seemed to relate to the CBI  
17 issues. The FIFRA CBI protections, I think, apply to  
18 material, to any kind of information submitted to EPA.  
19 That would include 602 if the claim is appropriate, it  
20 would not be released to the public.

21              Rather than my calling on people and since my  
22 eyesight is not great, I'll just let you all do it. So,

1 Julie, go ahead, please.

2 MS. SPAGNOLI: I wanted to clarify. So, under  
3 your OPP under FIFRA, if it's a nanomaterial of an  
4 existing active ingredient, it's considered a new active  
5 ingredient. But under TSCA, if it's a nanomaterial of an  
6 existing chemical, it's considered a significant new use?  
7 Is that how they're -- little differences in how they're  
8 addressing nano?

9 MR. JORDAN: What you said I think is correct.  
10 I looked over to Jim Jones who gave me a very subtle  
11 understated nod. Having said that, I think the  
12 differences arise from the differences in the definitions  
13 and structure of the two statutes. While they may sound  
14 different, in practice, I think they are really quite  
15 similar.

16 Under both FIFRA and TSCA, what we're saying is  
17 we want to know about new nanoscale materials so that the  
18 agency can assess the safety of these chemicals. I'm not  
19 saying that they're unsafe, but just that we want to know  
20 about them.

21 MS. SPAGNOLI: I just wanted to make sure I was  
22 understanding that.

1           MR. HOUSENGER:  If I can just put a  
2           clarification, we actually aggressively explored, both in  
3           the last administration and again in this one, whether or  
4           not we could under TSCA say that a nanomaterial of an  
5           existing chemical was new, as we are and are allowed to  
6           under FIFRA.  The statute just doesn't allow you to get  
7           there.  So, we came up with the concept, which isn't a  
8           new concept and topic at all, of saying it's a  
9           significant new use and therefore we have to be notified.

10          MR. BRADBURY:  Virginia Ruiz.

11          MS. RUIZ:  I'm just wondering if there's also a  
12          consideration -- if you're looking into tools for  
13          detecting the presence in people, like the tools for  
14          physicians or to help protect health effects?

15          MR. JORDAN:  I can't say that I know about all  
16          the research that's going on in this area.  Measurement  
17          and detection, as I noted earlier, is a significant part  
18          of the research agenda for the Office of Research and  
19          Development.  But I can't answer -- don't know the answer  
20          to that particular question, sorry.

21          MR. JAMES:  Allen James.  My question is a  
22          follow on to Cindy's.

1           If a company now reports a nanoparticle or  
2           whatever it's called, a nanoproduct, a nanoscale item in  
3           their product, and it is considered a new active  
4           ingredient, and they have distributed products nationwide  
5           -- it's in the channels of commerce -- is that company in  
6           violation of FIFRA for having that product on the market?  
7           If so, how will that be handled? Will they be subject to  
8           the extreme fines that are associated with marketing an  
9           unregistered pesticide?

10           MR. JORDAN: Steve, did you want to say  
11           something about the last question while I think about how  
12           I'm going to answer Allen's?

13           MR. BRADBURY: Virginia, we'll get back to you  
14           to confirm, but my understanding in the research programs  
15           and ORD and others that they're looking at a variety of  
16           matrices to the analytical methods, including looking in  
17           biological tissues. So, we'll get back to you, but my  
18           sense is that the research is going in the direction you  
19           were wondering about. There's analytical methods for a  
20           variety of applications and matrices. We'll confirm that  
21           for you.

22           MR. JORDAN: Thanks. The report of information

1 under 6(a)(2) does not change the status of a product's  
2 registration. If the product is registered, it may be  
3 sold and distributed in the United States in accordance  
4 with that registration.

5 I don't want to speculate about -- in the  
6 failure to have provided that or the fact that a person  
7 -- I don't want to say failure -- the fact that a person  
8 hasn't provided information about the presence of a  
9 nanoscale material does not constitute a violation until  
10 the person is on notice that we expect to receive that  
11 information, which we think, among other things, this  
12 Federal Register notice will clearly accomplish.

13 If we at EPA find out that currently registered  
14 products have nanoscale materials in them, that could  
15 lead to our decision to require additional data to assess  
16 the continued safety of those products. That would be  
17 imposed through a (inaudible) notice in all likelihood.

18 Amy.

19 MS. LIEBMAN: Thanks. Steve, you had clarified  
20 some of my question, but I just wanted to -- first of  
21 all, I'm very happy that you guys are taking this  
22 seriously and doing the work that you are to try to

1 understand.

2 I just want to reiterate Jack's answer to  
3 Caroline's, a lot about what's happening in the  
4 environment but the importance of trying to understand  
5 the human health effects even before you're allowing them  
6 to be registered. Then, once they are registered, the  
7 importance of trying to understand the human health  
8 effects and what the exposures are. I mean, I think  
9 that's part of the product registration from my  
10 understanding.

11 So, as we talk about environmental exposures,  
12 we really need to better understand what the human health  
13 effects are, particularly the bonable (phonetic)  
14 populations. You mentioned products that kids are  
15 involved with or baby products and then also worker  
16 populations that might be disproportionately exposed.

17 DR. WHALON: Mark Whalon. Bill, you mentioned  
18 your ring, your gold marriage ring there. One of the  
19 things that that brought to mind is that an old remedy  
20 for sties in the eye were to take a ring off and rub them  
21 on a sty which accelerated return to normalcy in that  
22 way. That suggests that nanotechnology has been around

1 for a long time. But now we know it has been around for  
2 a long time because a lot of Roman era stained glass used  
3 nanotechnology for affecting light transmission through  
4 the glass.

5           So, on the one hand, we don't need to panic.  
6 On the other hand, in the journal Cell a recent article  
7 pointed out that under evolutionary processes,  
8 symmetrical cell division is expected. It turns out that  
9 nanoparticles do create nonsymmetrical cell division. In  
10 other words, one of the daughter cells resulting from a  
11 division dies with all the nanomaterials which are  
12 redistributed after the death of the cell.

13           So, that creates a microevolutionary issue and  
14 one that could lead to mutagenesis and teratogenesis and  
15 opens up a whole new area where probably life cycle  
16 exposure and things like that will have to be addressed  
17 for some of these materials.

18           This article, by the way, is in Cell, 135,  
19 November '08. There's also a summary of it in Nano  
20 Today. That's a new magazine like thing that's come up  
21 around nanotechnology, volume 5, issue 2, April 2010.  
22 So, it's a real thing.

1           In the area of resistance development and in  
2 segregation of genetic material in cells, particularly  
3 microbes, it becomes really really important to look at  
4 short term and long term.

5           MR. BRADBURY: Kristie.

6           MS. SULLIVAN: This is another research  
7 question, I guess. The next slide on research allocation  
8 where there's 30 percent in the nanomaterials research  
9 strategy going to human health and ecological effects,  
10 from what I understand, some experts in nanomaterials  
11 have made statements about current toxicological testing  
12 methods and some of the properties of nanomaterials  
13 making it difficult to test them in, for example, an  
14 inhalation test.

15           So, I was just wondering if you could speak to  
16 what portion of your research strategy relates to  
17 determining the appropriateness of testing methods for  
18 tox testing of nanomaterials.

19           MR. JORDAN: Well, the short answer is I can't  
20 give you much in the way of details or specifics. I  
21 don't know that much about the particular projects that  
22 are being funded under these headings. From that said,

1 the first question that I think needs to be getting  
2 answered in any kind of assessment is to what are people  
3 being exposed.

4 Jack, in his answer earlier, referred to  
5 questions relating to agglomeration, are nanoparticles  
6 coming off of the treated substrate. If so, are they  
7 complexes, which are maybe nanosilver bound to other  
8 chemicals, or is it just nanosilver. Once it gets into  
9 the environment, does the nanosilver or the nanosilver  
10 complex interact with other substances? Do they interact  
11 with each other to form agglomerates?

12 Answering those questions is, in my mind, one  
13 of the first things that needs to happen in order to be  
14 able to figure out from a toxicological point of view,  
15 what are people in the environment, nontarget organisms,  
16 going to be exposed to. That's the reason why I believe  
17 it makes a lot of sense to emphasize sources, fate,  
18 transport, and exposure research as the threshold. Once  
19 that's answered, then I think we could turn attention to  
20 okay, what's the toxicity of those materials.

21 In the SAP, there were discussions about how  
22 difficult it is to maintain exposure to different

1 substances because of those tendencies to agglomerate and  
2 change character. That's a particular challenge that the  
3 methods part of the research is working on. That's about  
4 as far as I can go in terms of being able to give you an  
5 answer.

6 MR. BRADBURY: Susan.

7 SUSAN: I'm curious if any of the inert  
8 ingredients have been turned into nanoscale materials or  
9 nanoscale materials used in inerts? If so, are those  
10 reportable?

11 MR. JORDAN: The reporting requirement would  
12 apply to any nanoscale material, whether it's active or  
13 inert. At this point, I don't have any information on  
14 inerts.

15 MR. BRADBURY: Jennifer.

16 DR. SASS: First of all, thank you, Bill. That  
17 was a really good presentation. That was actually a very  
18 detailed overview. It was also very informative. So,  
19 thank you. There was some new information there.

20 There's one point that I missed and then I  
21 wanted to make a couple points. You said, I think -- I  
22 missed the slide because I was taking notes -- that when

1     you issue the Federal Register notice in June, that that  
2     will be responsive to that petition. Is that right or  
3     no?

4             MR. JORDAN: We are planning to respond to the  
5     petition and issue the Federal Register notice  
6     concurrently.

7             DR. SASS: I see, okay. Then, I'm going to  
8     make my two points first and then ask you a question.  
9     First of all, I actually want to very very strongly  
10    support what some of the other people around the table  
11    have brought up, that you could actually make the  
12    registration conditional upon the registrants providing  
13    you with monitoring or analytical techniques, because --  
14    and this just doesn't apply to FIFRA but this applies to  
15    every statute that regulates any toxic materials -- if  
16    you can't detect it, you can't enforce the statute.

17            So, it's really important to have those  
18    techniques available both in biological media as well as  
19    environmental media. And only under FIFRA could you  
20    require that to be provided. So, I think that you should  
21    and I would strongly recommend that.

22            The other thing is, I'm going to sort of go

1     against the grain here and say actually, I don't think  
2     you need to reinvent toxicology to test these materials;  
3     you just need to test what's actually being used in the  
4     product or in the formulation. It doesn't have to be  
5     fully defined in order to be able to test it in a  
6     toxicological system.

7             I'm not the only one that's saying that.  
8     There's a whole lot of -- a lot of the people that own  
9     the patents for these materials are actually saying the  
10    same things. If they provide you with the actual  
11    material that's being used, not a purified or an  
12    artificial sample but actually what's being used in the  
13    material, in the formulation so that if it's altered in  
14    surface coatings or interactions in the formulation that  
15    you have that, then all you have to do is test it.

16            So, actually, under FIFRA, you have the ability  
17    to require that information. And although it would be  
18    nice to understand the materials and be able to define  
19    them at the molecular level better, like to characterize  
20    them, the fact that they're in products already means  
21    that we shouldn't have to wait. I know those  
22    toxicologists have like a 10-year plan. As an agency

1 that protects environmental health and human health, I  
2 don't think we can wait 10 years because they're already  
3 in products.

4 I wanted to ask you a question. Are you  
5 concerned that with your definition of 1 to 100  
6 nanometers, you're locking yourself in, because everybody  
7 agrees, everybody agrees, scientists and policymakers,  
8 that there's nothing quite magic about the 100. So, if  
9 it's 200 or 150 or 250 nanometers, the important  
10 distinction is that the characteristics are altered in a  
11 size-dependent manner.

12 If the characteristics are altered in a size-  
13 dependent manner, it's very likely that the toxicological  
14 profile is also altered. That's what's needs to be  
15 tested. So, are you concerned about that? FDA didn't  
16 actually lock themselves into a strict size definition.

17 MR. JORDAN: I notice that we've used up the  
18 allocated time and the level of interest is great. I  
19 want to thank folks. We'll take the comments and  
20 questions from the four cards that are up, at least that  
21 I can see.

22 With regard to your question, Jen, the working

1 definition says approximately 1 to 100 nanometers. It  
2 gives us some flexibility to take into account variations  
3 above or below those values to the extent that they  
4 potentially affect the behavior or safety of the product.

5 MR. BRADBURY: Jimmy, I think.

6 JIMMY: One of the nice things about being last  
7 is that a lot of the questions I had were already asked.  
8 Joe Conlon and Virginia Ruiz and Allen James brought up  
9 several concerns that I had.

10 So, I did want to comment as one of the few  
11 health care providers on PPDC that if we've got some  
12 products out there that were registered but not  
13 identified initially as having nanosilver in it, then we  
14 really should consider suspending use of the product  
15 until you can assure that these products are safe.

16 I really echo and really strongly urge that as  
17 a health care provider, again, we don't have much of an  
18 idea of how to identify some of these people who may be  
19 poisoned. This need for analytics and diagnostic testing  
20 is brought to the forefront with this. I think this  
21 really kind of is exactly why some of us on the 21st  
22 century tox committee has been pushing for this.

1           MR. JORDAN: We'll be looking at the products  
2           that are currently in the market. I will note that I  
3           have heard that nanoscale silver is incorporated into  
4           surgical dressings which are used currently. So, at  
5           least, sort of intuitively to me, it suggests that that  
6           particular way of using nanoscale silver involves a  
7           greater level of potential human exposure than putting it  
8           in a piece of clothing. But we'll looking at the safety  
9           and trying to determine whether we need to take any  
10          further regulatory action.

11          MR. BRADBURY: Michael.

12          MICHAEL: I also agree that this has been an  
13          extremely informative session. I would like to reinforce  
14          Jennifer Sass's recommendation of testing the formulation  
15          rather than testing the active ingredient. That's not  
16          normally done in FIFRA. I would like to see that changed  
17          not only for nanomaterials but also for conventional  
18          pesticides and other products.

19          UNIDENTIFIED MALE: I have four questions, and  
20          probably they're all to different degrees and ponderable  
21          but just quick reactions and then maybe further follow up  
22          later.

1           Number one, would most individual pesticide  
2 molecules actually fit within the 1 to 100 definition?  
3 How do you address that?

4           MR. JORDAN: It's my understanding that  
5 molecules are generally smaller than one nanometer. I'll  
6 defer to scientists who can help me on that at some later  
7 point.

8           UNIDENTIFIED MALE: So, by definition, would  
9 then everything that's already registered under FIFRA --

10          MR. JORDAN: The molecules, as I understand it,  
11 are smaller than one nanometer. But, like I say, that's  
12 just my understanding. So, that would not implicate --

13          UNIDENTIFIED MALE: Okay. It's outside the  
14 bounds on the low side, then. I think the question about  
15 the pejorative concerns around the use of 6(a)(2) are  
16 interesting and important and I appreciate the fact that  
17 you acknowledge that and are looking for ways to work  
18 through that. Communications and language are important.

19          I think a parallel, if you remember, and Bill,  
20 I know you remember this very well, in the early days, in  
21 the early 90s, the approach to the regulation of plant  
22 biotechnology, when it was making a pesticidal claim, was

1 the development of a rule then known as the plant  
2 pesticide rule. There were a lot of concerns about that  
3 in the academic community and industry and elsewhere.

4 Eventually, we came around to the notion of  
5 relabeling that rule. It's now the plant incorporated  
6 protectant rule. That was prospective and forward  
7 looking as opposed to the use of 6(a)(2) in this context  
8 which is a little bit of a reaction.

9 Again, I understand the construct of where  
10 you're at but I would just suggest as we go forward that  
11 we think about the PIP rule experience as a way to fit  
12 the language to the regulatory construct and help with  
13 the avoidance of pejorative language. Again, I don't  
14 know that you need to respond to that.

15 Third, Dr. Chin, USDA, I'm curious to know  
16 whether the organic board has looked at these issues and  
17 whether or not, particularly given the fact that Bill had  
18 mentioned in his presentation that as an example, it's a  
19 known scientific fact that copper nanomaterials are much  
20 more active than non-nanoscale copper compounds and then  
21 how the organic certification of copper compounds be  
22 considered. Did that come up at all or do you know?

1 DR. CHIN: Teung Chin, USDA. I'm not aware of  
2 any conversations with the national organic program or  
3 the OMRI (phonetic) on that particular question about  
4 copper. I'll look into it, though. USDA does have  
5 scientists looking at nanotechnology and risk assessment  
6 in an international forum though.

7 UNIDENTIFIED MALE: Great, thank you. The  
8 fourth question is kind of back to at what point does  
9 regulation engage with regard to FIFRA requirements for  
10 the Environmental Protection Agency, and then overlay  
11 that with how does it engage with PRIA, fee authority  
12 (phonetic)?

13 Marty, I don't know. Again, we've got so many  
14 other complicated issues around PRIA right now that this  
15 is probably one for down the road a ways, but it is an  
16 important point of consideration for sure, both in terms  
17 of the allegation -- the burden on the industry, but also  
18 providing the appropriate resources to the agency  
19 eventually, and especially OPP, to be able to manage  
20 these responsibilities.

21 MR. DWINELL: Steve Dwinell, Florida Department  
22 of Agriculture. Will the notice that you're planning

1 address 25(b) products?

2 MR. JORDAN: I think the answer is no.

3 MR. DWINELL: Can I urge the agency to  
4 reconsider that?

5 MR. JORDAN: Okay. I think we'll look at that  
6 and think about that.

7 I want to just wrap up by saying thanks to  
8 everybody for your questions and comments. Feel free to  
9 get in touch with Jack Housenger or John Harrigan-  
10 Farrelly or me if you want to continue the conversation.  
11 We're happy to get feedback from any and all of the  
12 stakeholders here.

13 MR. BRADBURY: I'd like to re-echo Bill's  
14 thanks. It is very helpful to go around the table and  
15 get some of the various perspectives and insights. If  
16 there's some facts we can get to you before we break up  
17 in the next day and a half, we'll do that, especially  
18 with regard to some of the ORD research portfolio.

19 Let's take a 15-minute break. We'll start our  
20 next session at 10:55 instead of 10:45. Thanks.

21 (Whereupon, a brief recess was taken.)

22 MR. BRADBURY: Okay, thanks all for getting

1 back in time, at least those of you around the table, and  
2 the rest of them will lose out because they won't hear  
3 the beginning of this presentation.

4           What we're going to do now is spend some time  
5 giving you an update on where we are with the NPDES  
6 permit process for pesticide use applied to water or  
7 near, including overwater. Bill Jordan is going to chair  
8 the session and he'll introduce the members of the team  
9 that will be doing the presentation today and answering  
10 questions.

11           I think, as many of you know, this effort,  
12 which is lead by the Office of Water, reflects the area  
13 of close collaboration not only here in headquarters of  
14 the pesticide program and the water program, but also  
15 working closely with our colleagues in the regions and  
16 working closely with our colleagues in the states as this  
17 process has evolved and all the work and development of  
18 the proposed permit has come along. It's a very intense  
19 effort across a lot of organizations in EPA and outside  
20 EPA and a lot of input from the public to help us.

21           So, Bill, I'll turn it over to you.

22           MR. JORDAN: Thanks, Steve. In addition to the

1 folks listed on the agenda, we are fortunate to have with  
2 us today Linda Bernasian (phonetic) who is the director  
3 of the Water Permits Division, part of the Office of  
4 Wastewater Management responsible for the development and  
5 issuance of the NPDES pesticide general permit.

6 She's going to begin with some opening remarks  
7 and then turn it over to Allison Wiedeman who has been  
8 here with the PPDC before. Allison is the chief of the  
9 Rural Branch. It's Allison's day-to-day management  
10 responsibility to deliver the permit for proposal and  
11 final. That is no easy challenge. Fortunately, Allison  
12 has a really good team of folks working with her and led  
13 by Jack Faulk (phonetic) who is sitting behind me, along  
14 with a lot of other folks from the Office of Water and  
15 the Office of Pesticide Programs.

16 OPP's part of the effort is led by Susan Lewis  
17 who is the associate director in the biological and  
18 economic analysis division. This team I think has been  
19 really effective at working together. I'm happy to be a  
20 part of it from time to time.

21 So, let me turn it over to Linda to get  
22 started. We're going to set aside a lot of time for

1 questions, so be thinking about what you'd like to ask or  
2 comments you'd like to make.

3 MS. BERNASIAN: Thank you, Bill. I appreciate  
4 the opportunity to be here. In addition, I think I came  
5 about six months ago when we were only at the prototype  
6 phase. So, obviously, with all of the excellent work  
7 that our two offices have done, as well as we have held  
8 two different sessions with the states.

9 When we say the states, it's both the water,  
10 NPDES regulators, as well as the pesticide folks. So, I  
11 know from the water folks that have participated in  
12 those, they have appreciated so much the states that have  
13 come to those meetings and shared so that we can all  
14 learn in our knowledge as we continue and try to do the  
15 right thing.

16 Overall, the NPDES program has taken the  
17 approach that we're trying to recognize overall there is  
18 already a FIFRA system in place. As we look at it and we  
19 recognize that that's in place, we've been trying to  
20 think about how we can move forward and ensure that the  
21 appropriate pesticides are applied as they need to be  
22 applied to protect public health and the environment. We

1 do recognize that.

2 So, we've also tried to take a very common  
3 sense approach and ask what are the procedures out there  
4 that can really best fit within the water program so that  
5 you don't have to do additional activities to the extent  
6 that that's possible and really just adopt the good  
7 practices that a lot of folks are already doing.

8 So, as we move forward and just share with you  
9 the concept, we've tried to do a very open process. We  
10 have had a meeting with this group. We've had a webcast  
11 before the group. That happened. We're really looking  
12 forward to any thoughts today as we try to move to  
13 propose, hopefully within the next month. So, we are  
14 very close to really sharing in a very public way where  
15 we are. We take our public comment period very  
16 seriously.

17 We are planning to do, I think, four outreach  
18 meetings across the country. We do a lot of webcasts  
19 with those as well. So, there will probably be one  
20 webcast for people that can't travel to those meetings.  
21 Our permit -- and Allison will go into this in a lot more  
22 detail, but the permit that we're going to be proposing

1 is really for EPA.

2 We do have a lot of states that are authorized  
3 to run this program. They will be following by issuing  
4 and proposing their own permit. A lot of them are  
5 looking forward to seeing our version so that they have  
6 something to start with as they move forward.

7 So, overall, we are very happy to be here. We  
8 are still in a very significant listening phase, as we  
9 will be throughout the process. We look forward to  
10 hearing from you today. Thank you.

11 MS. WIEDEMAN: Good morning, folks. I think  
12 the way that we'll run the next hour, then, is that I  
13 will give a brief presentation, about 20 minutes, that  
14 goes over some of the requirements that we have in the  
15 permit right now ready for proposal and talk a little bit  
16 about the kinds of issues that we'd particularly like to  
17 get comment on during the comment period. Then we'll  
18 open it up for a general discussion.

19 Just to start off, the court's decision, which  
20 essentially results in the need for folks to get permits  
21 for discharges of pesticide in U.S. waters, will not take  
22 effect until April 2011. So, we have until then to

1 develop the permit, as most of you know. Until then, the  
2 regulation that we develop that says you don't need a  
3 permit is still in effect. I think that most folks know  
4 that industry asked the Supreme Court to hear the case  
5 and the Supreme Court denied that. So, we are moving  
6 forward with development of the permit.

7           The schedule hasn't changed since the last time  
8 I spoke with you, I believe. We are on course to develop  
9 or issue the proposed permit next month towards the end  
10 of May. Then we plan to have this permit finalized by  
11 December of this year. That's to give four months beyond  
12 that until the court's decision takes effect to provide  
13 outreach and education to the regulated community and  
14 also to get the state regulatory authorities in a  
15 position where they can have their permits final and  
16 begin accepting permit applications.

17           A little bit more about the schedule. We will  
18 be publishing end of May. There will be a short comment  
19 period. So, folks need to be ready as soon as this  
20 permit comes out in the Federal Register to take that  
21 permit and review it and provide us comments within 30  
22 days. It's unfortunate that it has to be that short, but

1 we don't have much choice given the short timeframe of  
2 the court's decision.

3 We will be having three public meetings in June  
4 during the public comment period for the purpose of  
5 helping people to better understand the permit so that  
6 they can provide more knowledgeable comments. Those will  
7 be in Boston, Albuquerque and Boise. Those are the  
8 states for which EPA will actually be developing the  
9 permit. The actual dates for those will be published in  
10 the Federal Register.

11 We will also have one public hearing in  
12 Washington, D.C. As Linda mentioned, we will be having  
13 at least one webcast, probably two, where we can accept  
14 thousands of phone calls at the same time to hear about  
15 and understand the permit better.

16 I think you all are familiar with our efforts  
17 to date. It has been a fairly open process and it has  
18 worked well, particularly with our states. In order for  
19 the states to be able to develop permits pretty much  
20 simultaneously with us, we've had to be more open with  
21 them and have meetings with them, more so than we have in  
22 other permitting or regulatory efforts in the past.

1           They've actually seen the permit in draft and  
2 they have it and they have what they need to be able to  
3 start moving forward with developing their own permit.  
4 Certainly, they're very interested in finding out what  
5 the final permit looks like next month to hopefully begin  
6 finalizing their permit for their proposals.

7           This project has posed several major challenges  
8 to the NPDES program. One of them is indicated here  
9 where the permitted universe up until pesticides became a  
10 necessary permitted entity shows that the increase in  
11 pesticide permittees are those that we expect will need  
12 permits.

13           An increase from about 600,000 to -- increase  
14 by 350,000 permittees, which is almost a 60 percent  
15 increase in the permitted universe to the more  
16 traditional industries and manufacturing plants and then  
17 we went to vessels and stormwater and (inaudible). So,  
18 it has significantly increased the size of the permitting  
19 universe nationally. About 10 percent of that is for  
20 those permits that EPA will be developing.

21           I'm going to skip over state outreach. I think  
22 I covered that already.

1           Speaking of the permits for which EPA will be  
2     developing, the states that we still have NPDES authority  
3     for are New Hampshire, Massachusetts, Idaho, New Mexico.  
4     We will also be developing the permit for Alaska and  
5     Oklahoma because they don't have authority to develop a  
6     permitting program just for pesticides.

7           There are other places in the country, other  
8     regions. We've developed the permits for tribal areas  
9     and for federal facilities, particularly Washington and  
10    Colorado, and also for other regions such as Puerto Rico  
11    and Guam. Those will be the areas that really will be  
12    developing a permit. The permit that's proposed in May  
13    will be one permit that will apply to all of those areas.

14          Folks often ask if the states have flexibility  
15    to write different permits than what EPA develops. They  
16    do to a point. What we are telling folks and what is our  
17    authority is we review the permits that the states  
18    develop and we expect them to have permits at least as  
19    stringent as the EPA develops.

20          The way they go about doing that can be  
21    different. There might be site specific situations in  
22    other states where certain requirements can vary as long

1 as the overall environmental protection is the same. So,  
2 we are working with them to make sure that they are at  
3 least as stringent as ours. Many states also have the  
4 ability to be more stringent if they would like to.

5 A little bit about the actual contents of the  
6 permits. I'll talk first about the scope. In developing  
7 the permit, EPA has strived to maintain the coverage of  
8 the same (inaudible) situations that we envision covering  
9 in the 2006 rule. Those are for pesticide applications  
10 to or over near waters of the U.S.

11 Through research and talking with industry and  
12 other stakeholders, we've determined that these four uses  
13 are those that were primarily covered in the previous  
14 rule and are now uses that need to have permits. That  
15 would be mosquito and other flying insect pest control,  
16 aquatic weed and algae control. That also includes  
17 irrigation ditches and irrigation canals, aquatic  
18 nuisance animal control, and that use would also include  
19 invasive species, and forest canopy pest control for  
20 other pests than mosquitos.

21 There are certain things that this permit will  
22 not cover. We want to make clear that the exemption

1 that's in the Clean Water Act that says that irrigation  
2 return flow and agricultural stormwater runoff are not  
3 point sources subject to NPDES permits is still intact.  
4 The 6th Circuit Court decision did not affect that in any  
5 way. So, obviously the permit would not cover those  
6 situations.

7 We're also not covering in this general permit  
8 discharges to tier 3 waterbodies -- those are natural  
9 resource waterbodies, pristine water -- or discharges to  
10 impaired waterbodies for a particular pesticide that is  
11 being applied. What we mean by that is, for example, if  
12 malathion is a pesticide being applied but there is an  
13 impaired waterbody for malathion, we would say  
14 (inaudible) cover that particular situation.

15 We're also not covering terrestrial  
16 applications to row crops or agricultural crops or  
17 terrestrial applications to forest floors. We are also  
18 not covering under this permit spray drift. For the  
19 discharges to tier 3 waterbodies and for the discharges  
20 to impaired waters for particular pesticides, it may be  
21 that an individual permit would be necessary. Certainly,  
22 there still is an option to get individual permits. Just

1 because it's not being covered under a general permit  
2 does not mean that a permit is not available or a permit  
3 is not necessary.

4 The next huge challenge in regulating this  
5 industry is who should actually file for what we call a  
6 notice of intent to be covered under a general permit.  
7 In the general permit realm, the regulated entities would  
8 submit an NOI. It will be an electronic document about  
9 one or two pages that asks information on who they are  
10 and where they intend to be applying pesticides.

11 The Clean Water Act allows EPA to, under  
12 certain circumstances, not require NOI (inaudible) of the  
13 industry, although the industry would still need to be in  
14 compliance with the permit requirements. But because  
15 this industry is potentially so large, the number of  
16 permittees so large, and for a host of other reasons,  
17 we've decided that NOIs will only be required for the  
18 largest of the large applicators.

19 So, we are including a threshold in the permit  
20 that says for entities above this threshold. The  
21 threshold would be in terms of acres of areas, a  
22 treatment area, that they would be required to submit a

1 notice of intent. Other that don't again still have to  
2 meet the terms of the permit. So, in terms of the  
3 threshold, we will definitely be seeking public comment  
4 on the thresholds and its appropriateness in size and  
5 appropriateness to have such a threshold in this permit.

6 In terms of the technology-based effluent  
7 limitations, there's technology-based effluent  
8 limitations and there's also water quality-based effluent  
9 limitations. For the technology-based effluent  
10 limitations, we have determined that in addition to  
11 meeting the FIFRA label, which is not a part of the  
12 permit -- I want to note that the FIFRA label is required  
13 under FIFRA. We're assuming compliance with that label  
14 is already occurring. We're not requiring that to be met  
15 again in this permit.

16 Beyond the FIFRA label, we are requiring that  
17 all permittees should minimize their discharges. What we  
18 mean by that is that we recognize that a FIFRA label says  
19 that you -- many of them say that a certain maximum  
20 amount of pesticide may be applied. That's fine. We're  
21 not arguing with that, but we are asking folks to use the  
22 lowest amount of pesticide possible, to make sure that

1 leaks and spills are prevented, and to calibrate and  
2 maintain equipment. This is something that most folks do  
3 anyway, but we want to make sure that all folks do this  
4 now.

5 We're also concerned, though, and have heard  
6 many comments about the fact that if you don't use a  
7 certain amount of pesticide, that there will be a buildup  
8 or resistance. We don't want to interfere with the  
9 resistant phenomenon at all either, so that, of course,  
10 would be taken into account when you're using a certain  
11 amount of pesticide.

12 Then, for all permittees that are above a  
13 threshold or for the largest of the large applicators or  
14 those that have to submit a notice of intent, we're  
15 asking them to implement some additional IPM practices.  
16 The first is identify and assess the pest problem. This  
17 is where an action threshold is determined above which  
18 you would need to apply a pesticide, below which you  
19 would not.

20 The next one is to assess pest management  
21 alternatives. There could be mechanical alternatives to  
22 using a pesticide. There could be removal of the sources

1 of the pesticide, such as standing waterbodies for  
2 mosquitos. So, we're asking folks to look at the  
3 alternatives to pest management.

4 Then, follow appropriate procedures for  
5 pesticide use. This means that once this pest threshold  
6 is determined, make sure that a surveillance prior to  
7 pesticide application is done to make sure that the  
8 threshold has in fact been met.

9 Then, also ensure that the use of pesticides  
10 are done in appropriate environmental conditions, such as  
11 make sure that the winds are proper, that it's not too  
12 hot that the pesticides will volatize, and that kind of  
13 thing. So, we've laid out those kind of considerations  
14 in the permit itself.

15 The second effluent limit is water quality-  
16 based effluent limits. This would mean if your  
17 technology-based effluent limit did not meet water  
18 quality, then you may need to have additional effluent  
19 limits to meet water quality. We believe that because  
20 the requirements in the permit go beyond the FIFRA label,  
21 that they are IPM measures.

22 The data that we have seen so far does not show

1 significant water quality standard violations even  
2 without additional IPM measures. Following the  
3 requirements in this permit will allow the applicator to  
4 meet water quality standards. The fact sheets or the  
5 accompanying documentation to the permit will say your  
6 discharge must be controlled as necessary to meet  
7 applicable water quality standards.

8 We will then go on to explain in detail the  
9 reasons why we expect that compliance with FIFRA plus  
10 compliance with permit conditions would generally control  
11 discharges to meet those water quality standards. We  
12 certainly are interested in comments in this area.

13 The last few parts of the permit are  
14 monitoring. Then, after this is record keeping and  
15 reporting. For monitoring, we looked at several  
16 alternatives, including ambient water quality monitoring,  
17 visual monitoring that we have selected here, and also  
18 monitoring to make sure the practices that are required  
19 are actually being implemented in the permit.

20 The visual monitoring that we're requiring in  
21 this permit is monitoring that we're asking to be done  
22 while the pesticide is being applied. Also, if post

1 application surveillance is done by an applicator as a  
2 regular course of doing business, we would ask them to  
3 also visually monitor for purposes of the permit.

4           What we're asking for them to look for is in  
5 the adverse effects that may have occurred because of  
6 pesticide application, fish kills, unexpected vegetation,  
7 impairment and those kinds of things. If there is an  
8 adverse effect, we are asking that this be reported.  
9 This will be a good opportunity for regulatory  
10 authorities to know if and when adverse effects are  
11 caught.

12           In terms of reporting and recordkeeping, we're  
13 asking that for those that are submitting a notice of  
14 intent or those that are again above the threshold, that  
15 annual reports be submitted. Those annual reports will  
16 provide information to the regulatory authority that says  
17 where spraying actually occurred.

18           So, the notice of intent will say where the  
19 permittee is planning to apply a pesticide, but the annual  
20 report will say where they actually did apply pesticides,  
21 what kind of pesticide was used, and over what area it  
22 was applied.

1           We will also, as I indicated, ask for adverse  
2 incident reporting as any adverse incidents occur. The  
3 records that we're asking for for those that are again  
4 above the threshold or have to submit NOIs are that they  
5 develop and implement a pesticide discharge management  
6 plan which essentially implements the technology based  
7 effluent limits or the IPM requirements.

8           We're asking them to keep this plan on site.  
9 It does not have to be something that is submitted to the  
10 permit authority for review or to the public for review.  
11 We're also asking them to keep records of any other  
12 adverse incidents and corrective action documentation  
13 that may have been required as a result of adverse  
14 incident records that they would keep on site as well.

15           I wanted to talk just briefly about the  
16 particular areas where we would like to have public  
17 comment. The whole permit is certainly available for  
18 public comment and we want comments on the whole permit.  
19 But, in particular, there are some places where we have  
20 actually specified in the Federal Register notice that we  
21 would like to get comments.

22           I also wanted to point out that it can be kind

1 of confusing where these documents are. The thing that  
2 actually gets published in the Federal Register is the  
3 Federal Register notice that says that the permit is  
4 available for public review. It's not the permit itself  
5 that's published in the Federal Register, but it tells  
6 you where it is on our web site. The Federal Register  
7 notice has the actual specific questions that we want  
8 folks to particularly respond to. I'll just describe  
9 those briefly in the next overhead.

10 The pesticide general permit and its  
11 accompanying fact sheets will be on our web site. That's  
12 what we need to have reviewed and provide comments. The  
13 fact sheet is a document that explains our rationale for  
14 the permit requirements.

15 So, the kinds of questions that we're  
16 soliciting input from are the type, size and number of  
17 entities that are applying pesticides to US waters. That  
18 350,000 permittees is an estimate by us, but we could use  
19 some more specific data. The appropriateness of entities  
20 not submitting an NOI is that threshold appropriate, is  
21 that site threshold appropriate, does that cover most of  
22 the largest of the large facilities, or are there other

1 types of thresholds that would be more appropriate.

2 The best way to cover entities where each are  
3 partially responsible for meeting permit requirements,  
4 this is a tough one because in this industry, you have  
5 folks that are making the decision to apply a pesticide.  
6 Many of them would be responsible for conducting IPMs.  
7 Then they would hire an applicator to apply the  
8 pesticide.

9 So, the types of requirements in the permit  
10 could easily apply to the pesticide applicator as well as  
11 the decision maker or the land owner. So, who should be  
12 responsible for what requirements in permit? We have  
13 developed a methodology in this permit and we'd like to  
14 see if folks could think of any other better way or what  
15 they think of the way that we are proposing.

16 We'd also like confirmation that folks are  
17 doing IPM out there. We think they are doing IPM. How  
18 small of an entity is actually capable of conducting IPM.  
19 Very small applicators or very small government agencies,  
20 can they conduct IPM as well as other larger  
21 organizations?

22 Other pesticide use patterns that should be

1 covered under this permit, are we missing some? I talked  
2 about the appropriateness of threshold sizes. The  
3 appropriateness of ambient water quality sampling, who  
4 should be required if we were to require that? What  
5 types of methodologies would make ambient water quality  
6 sampling, provide valuable data, and would be affordable?

7 MR. JORDAN: Thanks, Allison. This time around  
8 I'm going to work it slightly differently. We have about  
9 35 to 40 minutes. I'd like to end close to noon so that  
10 those people who are planning to participate in a work  
11 group can have full time to do their work group work.  
12 The rest of us can enjoy a leisurely lunch.

13 This time again raise your cards if you're  
14 interested in making a comment. I will try as best I can  
15 to keep track of the order in which the cards went up.  
16 There are so many that I'm clearly not going to get that  
17 right. Steve is whispering in my ear that Bob is first.  
18 I'll just sort of call randomly on other people.

19 Because our Office of Water folks don't know  
20 everybody around the table as well as we do, please  
21 identify your organization when you introduce yourself,  
22 as well as your name.

1           MR. ROSENBERG: I'm Bob Rosenberg. I represent  
2 the National Pest Management Association. Our membership  
3 is pest management companies. Most of what they do is  
4 structural pest control inside of houses but they also do  
5 things outside. I have two questions.

6           One just really quickly, in answer to the  
7 question of what constitutes near water, is that some  
8 number of feet? Then I have a second one.

9           MS. WIEDEMAN: Actually, how near isn't as  
10 important as whether or not it contacts the water. So,  
11 now that permits are required, if there is an application  
12 of a pesticide that is say along a ditch tank for example  
13 and it actually hits the water, that direct contact means  
14 it needs a permit. If there is no direct contact, then a  
15 permit would not be needed. So, we're not really  
16 focusing too much anymore on the distance. It's whether  
17 it actually contacts water or not.

18          MR. ROSENBERG: In the initial application.

19          MS. WIEDEMAN: Yes, right.

20          MR. ROSENBERG: Okay. That solves a lot of my  
21 issues. Secondly, it seems to me from a small applicator  
22 point of view, there are advantages to not being in the

1 general permit and advantages to being in it. It  
2 provides something of a safe harbor from liability and  
3 litigation. What advice do you give to someone that  
4 thinks they may cross the threshold that require a permit  
5 but aren't included in the general permit?

6 MS. WIEDEMAN: First, let me just make sure  
7 that even if you don't submit a notice of intent, you're  
8 still covered. I wanted to make sure we're clear on  
9 that. So, now you're talking about something that is not  
10 covered in the general permit.

11 MR. ROSENBERG: Yeah. If there is a pest  
12 control operator that makes applications to pesticides  
13 for leads adjacent to river banks, for instance, but it's  
14 not for any one of the covered purposes and they don't  
15 want to run the risk of citizens or having to themselves  
16 get their own permit, what do you ask them to do?

17 MS. WIEDEMAN: At this point, they have the  
18 option to get coverage under an individual permit so they  
19 can go to their regulatory authority and be covered under  
20 individual permits. But we would also recommend that you  
21 submit comments letting us know if you think that is  
22 something else that we should cover.

1 MS. BERNASIAN: If you discharge a pollutant  
2 into the water of the United States from a point source,  
3 you do need coverage under the Clean Water Act. If a  
4 citizen or the government files suit, the penalties, I  
5 think, are \$32,000 a day.

6 So, my advice, if you are above the threshold,  
7 you are required to file a notice of intent if you're in  
8 those categories. If you're not in those categories,  
9 then you should really seek coverage from the regulatory  
10 agency, whether they can do a different general permit,  
11 we could amend the scope of this general permit, or you  
12 do individual permits.

13 But the purpose of public comment is to figure  
14 out if we've missed people. So, if you're saying yeah,  
15 you've already missed people, could you talk to Jack  
16 afterwards and we can sort it out a little bit.

17 MR. JORDAN: Joe Conlon.

18 MR. CONLON: Joe Conlon from the American  
19 Mosquito Control Association. We've talked on a number  
20 of occasions. I'd like to express my thanks to the EPA  
21 for handling what is, at best, a sticky wicket for us. A  
22 few things.

1           The time line, I know you've spoken to the time  
2 lines but the time lines are really putting some people  
3 in a world of hurt, particularly the states, because even  
4 though it's been transparent to a degree, a lot of things  
5 have been kept close to the vest. There was only, I  
6 believe, what, 27 or 23 states involved as stakeholders,  
7 so the other folks are generally --

8           I don't know how they're getting their  
9 information unless it's being purloined from someone.  
10 Once it is published, then they've got to go into some  
11 serious resource spinning up mode. Colorado has already  
12 said that they don't have the resources and they don't  
13 intend to put the resources towards it. So, they're  
14 putting themselves in a liability situation.

15           So, the time lines are really going to be  
16 difficult to deal with, particularly a 30-day comment  
17 period on something of this magnitude. I mean, we're  
18 really going to have to spin up some comments.

19           I notice that services, US Fish and Wildlife  
20 Services and NOAA fisheries, when are we going to hear  
21 from them, because they're going to have some significant  
22 input into this. Is that going to be when it's published

1 afterwards because that could change a whole lot of  
2 things with regard to the permit?

3 MS. BERNASIAN: I didn't mean to cut you off.  
4 It's just that I'll forget what the questions are.

5 MS. WIEDEMAN: In terms of working with the  
6 states -- actually, all of the states, we've been working  
7 with all 45 states, actually all 50 states. We're even  
8 working with those for which we'll be developing permits.  
9 They have been sent a permit. We have conference calls  
10 every two weeks where we talk to them.

11 So, I think you were referring to the number of  
12 states that attended our meeting. There was, I think,  
13 about 23 there. They're always included in the loop with  
14 our conference calls and all the information that was  
15 sent. The time line is tough. That's why we have  
16 actually developed a permit in record time, if I say so  
17 myself, and will be finalizing it by December.

18 The main reason we're finalizing it by December  
19 and not by April is to give the regulated community time  
20 to know what the requirements are and also to give the  
21 states time to finalize their permit. But, you're right,  
22 we have heard about those states that aren't moving

1 forward. Our focus from now through the comment period  
2 will be to work with those states to make sure that they  
3 are gearing up for this.

4 MS. BERNASIAN: Two more things. The 30-day  
5 comment period, if you extend it, then you get less time  
6 on the end. So, there's really a balance between trying  
7 to get our permit out as fast as we can so the states can  
8 follow. So, that will be a balance. I'm sure we'll get  
9 a request for more time, but we're really balancing here  
10 so we want to try for the 30 days. If people absolutely  
11 can't make it, they can always ask us for an extension.  
12 We may or may not grant it.

13 So, I do suggest -- we're trying to give  
14 everybody as much advance notice and be as open as  
15 possible through the process so that people shouldn't be  
16 surprised when the permit comes out what it may say.

17 The other thing I do want to say is this permit  
18 is not final yet. So, all the words that Allison shared  
19 with you are tentative at this point because we haven't  
20 gone through all of our different cycles yet.

21 So, while we're heading in this direction,  
22 there might be some differences when it's actually

1 published. So, I do suggest you read it as you go  
2 through.

3 Did we cover all your --

4 MR. ROSENBERG: Just one more. You did fine on  
5 that. With regard to the adequacy of the best management  
6 practices for integrated pest management, with the EPA's  
7 draft permit, who at the EPA is going to evaluate the  
8 adequacy of the pesticide discharge management plan? I  
9 mean, who there has the expertise to actually say, well,  
10 these are good, these are bad, you should do something  
11 else?

12 MS. WIEDEMAN: The pesticide discharge  
13 management plan will be something that the permittee  
14 develops, kept on site. This is not something that would  
15 have to be submitted to a permit authority for review.

16 MR. ROSENBERG: Okay, thank you.

17 MS. BERNASIAN: But we will, one, have to  
18 develop, obviously, training sessions. We do have EPA  
19 inspectors that go out to -- we are very fortunate to  
20 have pesticide agencies in each state that we were and  
21 are heavily relying on helping us best understand the  
22 practice. So, there's got to be some capacity built

1       there for us to be able to look at it when we do a site  
2       visit if we do a site visit. EPA can also request a copy  
3       be sent to them. Then we could also hire contractors  
4       that are trained in this area to help give us that  
5       expertise.

6                So, every state is going to have to deal with  
7       the capacity issue as they move forward. So, our job,  
8       once we issue a permit, is to make sure it's complied  
9       with.

10               MR. JORDAN: Tyler Wagmeyer is next. After  
11       Tyler is Susan Kegley.

12               MR. WAGMEYER: Thank you. Tyler Wagmeyer, Farm  
13       Bureau. This is a big deal for farmers. The end of May  
14       is an extremely busy time, if not the busiest time on the  
15       farm, whether you're a vegetable grower, harvesting  
16       strawberries, a row crop farmer trying to get soybeans in  
17       the ground, livestock producer trying to get your hay  
18       made.

19               Thirty days -- and I know it's been talked  
20       about. Joe took my question, essentially, but I just  
21       need to reiterate we need more time. I mean, that's  
22       almost impossible to expect a farmer to look this over

1 and to make substantive comments back to you.

2 MS. BERNASIAN: We appreciate that. I think  
3 what we're trying to share with you here is we've met  
4 with a lot of farming groups. What they have told us is  
5 that they believe they can avoid a line directly into  
6 water. So, we do not have the farming group as one of  
7 the sectors we're trying to cover in this permit.

8 MR. WAGMEYER: Well, to follow that up, what I  
9 was going to say is, has EPA -- do you think it's  
10 necessary or even possible to go to the court and ask for  
11 an extension? I will say that we have thousands of  
12 farmers that come to Washington, D.C. that care about  
13 what their government does every year.

14 This has been one of the top issues that  
15 they're looking at and paying attention to. They are  
16 looking at okay, let's put this into my operation. Do I  
17 need a permit or do I not? There's a lot of questions  
18 out there. It's not an easy answer. I mean, there's not  
19 really an answer for a lot of their questions that they  
20 have.

21 MS. BERNASIAN: Would it be helpful if we did a  
22 webcast just for farmers so that we can actually share

1 with them they have the two exemptions? If they are  
2 irrigating their crops and it runs off from that  
3 irrigation flow, that's exempt, and also stormwater?

4 MR. WAGMEYER: Only about 50 percent of farmers  
5 have access to high speed internet right now. So, web  
6 access is going to be hard. Like I said, they're in the  
7 field. So, maybe Cannon in his tractor has GPS enabled  
8 satellite systems that he can connect to the internet  
9 while he's driving, but the majority of farmers don't  
10 have that ability to do it. So, yes, theoretically, if  
11 you can get all farmers on the internet to do it, great,  
12 but I just don't think that's going to be a possibility.

13 MR. JORDAN: Tyler, thanks. We'll think about  
14 the comment period and what we can do there.

15 Susan Kegley is next and then Scott Schertz.

16 DR. KEGLEY: I'm more than a little bit worried  
17 about enforcement. You have the people who are doing the  
18 applications responsible for the monitoring and  
19 reporting. Then they're to report fish kills or some  
20 environmental damage or whatever and then they're going  
21 to get punished for it. That doesn't encourage  
22 reporting, really. So, I just wonder how the enforcement

1 is actually going to work.

2           Then, I'm also -- and maybe this doesn't fall  
3 under the -- maybe the labels preempt this concern, but  
4 herbicide applications to clear cuts, you have forested  
5 canopies in there but I know that some of the labels on  
6 the herbicides that are used in forestry say do not apply  
7 directly to water. But I'm not sure that that is true of  
8 every single pesticide that is used in that situation.  
9 So, I'm curious about what's going on there.

10           Three, the threshold limit doesn't deal with  
11 multiple applicators who might be applying at the same  
12 time. So, you've got the Alameda County mosquito control  
13 district and the Solano County mosquito control  
14 districts. Are they coordinating with each other so that  
15 the net treatment area is not exceeding that threshold if  
16 they're not going to get a permit? Maybe those are bad  
17 examples because those will be huge areas.

18           But farmers applying weed control in irrigation  
19 ditches, there's probably a season to that. When things  
20 start to really go in the spring, you might have all of  
21 your growers applying herbicide at the same time. So, I  
22 wonder how that's going to be handled.

1           MS. WIEDEMAN: Thanks, Susan. The first one,  
2 and I'm glad you asked it, about adverse incidents and  
3 recording them, having an adverse incident does not  
4 necessarily mean that a violation has occurred. We want  
5 the information. You're right, we don't want to punish  
6 them from reporting it to us.

7           We want to know so that if there's any  
8 corrective actions that need to be taken for that  
9 permittee, that there's an opportunity for the regulatory  
10 authority and the permittee to discuss that. We talk  
11 about how there needs to be communication between the two  
12 and the fact sheet to develop corrective action.

13           The second one about herbicide application to  
14 the forest floor, this is a situation very similar to  
15 application of pesticides to crops. The terrestrial  
16 applications are meant to be applied terrestrially for  
17 the purpose of eradicating either herbicides in forest  
18 floors or pests and other plants and crops.

19           Our policy on this right now, at least just for  
20 the proposal, is that these are terrestrial applications  
21 that were not covered in the original 2006 regulations  
22 and they wouldn't be covered in this permit. But that is

1 definitely an area that we are seeking public comment on.

2 MR. JORDAN: Scott Schertz and then John  
3 Schell.

4 UNIDENTIFIED FEMALE: Quickly on the third  
5 question that had to do with maybe multiple applications  
6 to the same maybe water body, the way we have it  
7 currently structured is that the decision for a threshold  
8 is by the decision body. So, if you had two different  
9 counties making different decisions, the way it's  
10 written, there would be no coordination. Their threshold  
11 would be based on their application. So, I'd encourage  
12 you to look at how we set the thresholds and describe it  
13 and in your comments address that.

14 MS. WIEDEMAN: The other thing I'd like to add  
15 to that is if there is already a water that is impaired  
16 for that pollutant, it's not covered by this permit and  
17 we'll be asking folks to do more reasonable potential  
18 type analysis. Then you do figure out what the  
19 background is in the water and things like that. So,  
20 where it's already on what we call the 303(d) list, d is  
21 for dirty, then you do need to do more analysis.

22 MR. JORDAN: At the rate we're going, we'll use

1 up all available time with cards that are up. If we  
2 somehow finish early, then we'll entertain more cards.

3 Scott Schertz is next.

4 MR. SCHERTZ: Thank you. Just to repeat, there  
5 are a lot of concerns as far as the states being up to  
6 speed. I don't think that's new. It's just a  
7 reinforcement of some of the other comments. Also, the  
8 30-day comment period that Tyler very adequately  
9 described.

10 The other issue, though, has to do with who  
11 falls underneath the permit the and notice of intent.  
12 When you look at a lot of the activities required by  
13 that, it really does need to stay with the party that has  
14 control over it, the land, of deciding it.

15 There is a subissue there of if an applicator  
16 does end up going over that threshold, how much, so to  
17 speak, retroactive activities would be required of the  
18 IPM, the monitoring, et cetera, and reporting? So,  
19 there's some real concerns. The impetus really does need  
20 to be on who has control over the initial operation.

21 MR. JORDAN: Thanks, Scott. John Schell and  
22 then Jay Vroom. Sorry, I misread the car. Jay, you're

1 next and then Amy Roberts.

2 MR. VROOM: Jay Vroom with CropLife America.  
3 First, I'd like to compliment Susan and Allison and the  
4 teams that have been working on this from both the Office  
5 of Water and the Office of Pesticides. I don't think any  
6 of us were really ready for this a year ago January, and  
7 while it's been a long time, it probably seems like it's  
8 been longer than it has been. But you guys have done a  
9 tremendous amount of collaborative work. We definitely  
10 appreciate that.

11 So, I'd like to ask questions related to slides  
12 12, 14, and 16, and 17. But separately, I wonder if you  
13 could speak to whether or not this is a federal action  
14 subject to the provisions of Endangered Species Act  
15 consultation?

16 MS. BERNASIAN: Yes. We have initiated  
17 consultation with the services and they are really trying  
18 to work with us to come up with the actual scope for the  
19 biological assessment. We are hoping to work through it  
20 because they spray pesticides, too, and need coverage.  
21 That did help us in vessels when they actually had boats.

22 MR. VROOM: Yes. So, will that information

1 regarding work dealing with the services be part of the  
2 May Federal Register information or will that come later?  
3 If you don't know, that's fine.

4 MS. Bernasian: It's really a work in progress.

5 MR. VROOM: Okay.

6 MS. BERNASIAN: So, we might not have much in  
7 the proposal, but it is being worked on. What I want to  
8 do is try to see if I can really get buy in before we  
9 actually do the work so that at the end, they'll be happy  
10 with the work.

11 MR. VROOM: Great idea.

12 MS. BERNASIAN: So, we're spending more time up  
13 front there. So, I'm sorry if you might not get as much  
14 as you want in the proposal, but we will be sharing the  
15 information.

16 MR. VROOM: Good, thanks. On slide 12,  
17 Allison, you mentioned activities exempt. So, will the  
18 information in the May Federal Register announcement and  
19 web site have explicit language with regard to explicit  
20 exemptions or are the exemptions going to be sort of just  
21 silent, or have you thought about that?

22 MS. WIEDEMAN: We have been as explicit as we

1 can in the fact sheets to describe what I've just  
2 described to you today about what is in and what isn't.  
3 I think that it would be clear.

4 MS. BERNASIAN: The other thing that I want to  
5 highlight that wasn't on one of the slides is we did also  
6 consider an emergency provision that all of a sudden if  
7 you get something totally unexpected, then you can  
8 actually do the spraying and then file within a certain  
9 number of days.

10 MR. VROOM: I appreciate the fact that you've  
11 given thought to exemptions. This has more to do with  
12 applicators and growers where they may be involved having  
13 explicit legal protections if there are explicit  
14 exemption examples out there.

15 MS. BERNASIAN: Well, we are not allowed to  
16 exempt anybody -- we learned that in vessel -- by  
17 regulation. So, it has to be a statutory exemption. The  
18 two that we described here are the ones that we believe  
19 apply. So, those will be definitely discussed in the  
20 fact sheet in detail.

21 MR. VROOM: Okay, good. On slide 14, and I  
22 don't think this requires a response from you, but I just

1 wanted to reinforce that in referencing using lowest  
2 amount possible for avoidance of resistance management,  
3 et cetera, is a really important thought and I'm glad  
4 that you already caught that and expressed it.

5 On slide 16 and 17, with respect to visual  
6 monitoring, obviously, you know it when you see it, comes  
7 to mind, but -- so, it will obviously be important for as  
8 much definition for what applicators need to be looking  
9 for be conveyed in explicit writing as possible.

10 Adverse effects, I guess maybe, Susan, this  
11 comes back to OPP, how much convergence is there with  
12 adverse effects in this context and the 6(a)(2)  
13 requirements under FIFRA that you currently apply or will  
14 it be the same? Does this have to go into 6(a)(2) if  
15 it's separate?

16 MS. LEWIS: I think when you see the permit,  
17 you'll see how we define what we believe is an adverse  
18 effect in a report. We haven't worked out all the  
19 nuances of whether it comes under 6(a)(2) or the clean  
20 water.

21 MR. VROOM: But this will be a report that will  
22 come to the Office of Water, though?

1 MS. LEWIS: It will be the regional office.

2 MR. VROOM: Okay. I'm cognizant of the fact  
3 that 6(a)(2) reporting for OPP at times can be a  
4 significant burden for both the government as well as  
5 registrants. Now we're extending that responsibility to  
6 applicators. Presumably, you've already talked with  
7 regional offices about how to design systems to receive  
8 this information and manage it, et cetera.

9 MS. LEWIS: We have a national what we call our  
10 NOI database. So, it's electronic. It can receive  
11 annual reports and quarterly monitoring data. The one  
12 thing I want to share with you is we normally in the  
13 NPDES program do end of pipe discharge monitoring. There  
14 are costs associated. Sometimes we have people do them  
15 monthly, sometimes we have them do them quarterly and  
16 sometimes annually. They have to scan for priority  
17 pollutants and do all of this.

18 This is a unique universe. There might be some  
19 in public comment period that might want more ambient  
20 monitoring. We really are wrestling with that concept.  
21 We do need to have a whole cycle of feedback because we  
22 are responsible for making sure our permits achieve water

1 quality.

2           So, what we're describing here is that we have  
3 states doing monitoring. I really want to thank the  
4 states that have submitted the data to us from the  
5 pesticide folks, particularly Delaware and Florida have  
6 been so wonderful in all of their knowledge and sharing  
7 with us. I do want to recognize that. But we need to be  
8 able to show overall that our permit is protected.

9           So, one of the other things we're asking for is  
10 the cycle that we're creating, whether it's the state  
11 pesticide folks that are doing the sampling or whether we  
12 have the largest of the large do some ambient sampling,  
13 we need somehow to verify overall that the system is  
14 effective, or if the registrants are giving us ambient  
15 data.

16           So, this is our (inaudible) permit. As we move  
17 forward and try to really make sure that our system is  
18 effective, we do need to be careful of those things as we  
19 move forward.

20           MR. VROOM: So, it sounds like you're on a much  
21 different kind of time horizon for this reporting as  
22 opposed to FIFRA 6(a)(2) reporting. So, that's helpful.

1 Thank you.

2 MR. JORDAN: Jay, we'll look at that. Next  
3 person on my list is Amy and then Steve Dwinell.

4 MS. ROBERTS: Amy Roberts with (inaudible). I  
5 understand the scope of the pesticide uses that are  
6 covered. But if there's still any opportunity to talk  
7 about the scope of the pesticides, specifically  
8 pesticides that are exempt from (inaudible) residues,  
9 looking at them being exempt from the permit or --

10 MS. LEWIS: I would encourage you to make that  
11 comment. Right now it includes are registered and  
12 nonregistered 25 (inaudible).

13 MR. JORDAN: Steve and then Cannon Michael.

14 MR. DWINELL: Thank you. Steve Dwinell,  
15 Florida Department of Agriculture. First of all, I want  
16 to echo what several people have said and congratulate,  
17 thank, and whatever other good words I could use, the  
18 agency for engaging in the process they've engaged to in  
19 this. This has been really very productive.

20 I mean, when we first saw this thing coming  
21 down the pike, we were terrified. It's been very  
22 gratifying to work with the agency the way they've been

1 working on this. We've been actively involved right from  
2 the get go.

3 The other thing is that what this is doing --  
4 and I don't know if it's fully sunk into everybody yet,  
5 but this is a really really major change in the way  
6 pesticides are regulated. What it has forced us to do at  
7 the state level and I think is going to continue for the  
8 foreseeable future is the water agencies and the  
9 pesticide agencies have to work together very closely.

10 Obviously, it's forced OPP and the Office of  
11 Water to work very closely together. That's been good.  
12 But it's forced us at the state level to do the same  
13 thing. We've been meeting with our water agency folks  
14 every two weeks on this since January of 2009 and have  
15 developed some pretty close relationships on this.  
16 States that are not doing that are going to be in a lot  
17 of trouble. It's just not going to work. So, we have to  
18 keep that in mind.

19 The last comment is on the enforcement issue.  
20 People have to keep in mind when you talk about  
21 enforcement of the objectives of the Clean Water Act  
22 relative to the pesticides applied to water, we already

1 have an inspection enforcement mechanism in FIFRA that's  
2 well developed and used daily when it comes to pesticide  
3 applications and water. We already do it. We do it  
4 every day. We have to keep that in mind.

5 We don't need to invent an entirely new  
6 regulatory structure and impose it on people who are  
7 applying pesticides in water. We just need to map it to  
8 the goals of the Clean Water Act, which I think is very  
9 doable. There may be some changes we need to make, but  
10 it is already a violation to violate water quality  
11 standards due to the application of pesticides in water.  
12 You can't do that, although it's pursued under FIFRA as  
13 opposed to the Clean Water Act. So, that's something to  
14 always keep in mind. Thanks.

15 MR. JORDAN: Thanks. Cannon Michael and then  
16 Caroline Cox.

17 MR. MICHAEL: Cannon Michael, National Cotton  
18 Council. Just had a quick clarification question. In  
19 some of the initial documentation about pesticide uses to  
20 be covered, there was an area wide category. I don't see  
21 that here. Was that replaced with the forest canopy pest  
22 control category?

1 MS. WIEDEMAN: Yes, that's correct.

2 MR. JORDAN: Thanks. Caroline.

3 MS. COX: The definition of IPM has been pretty  
4 controversial over the years. I wonder if the permit  
5 will actually have a definition of IPM. If so, what  
6 definition is it going to use?

7 MS. LEWIS: It's more concept. It's IPM  
8 principles. But an exact definition? Not at this  
9 moment, but it will give her guidelines of different  
10 areas we would like addressed.

11 MR. JORDAN: Speaking of IPM, Tom, you're next.

12 TOM: Carol asked my question. I told her not  
13 to but she went ahead anyway. I'm wondering what kind of  
14 work is being done to specifically look at these  
15 particular applications of concern to really define IPM  
16 for those applications more specifically rather than  
17 conceptually, so the permittee is going to put in there  
18 documentation what they consider to be the specifics for  
19 IPM that correspond to the general concept and then they  
20 may get that audited?

21 MS. LEWIS: We have outlined in great detail in  
22 the fact sheet as well as in the permit the four

1 different sort of areas and what needs to be covered in a  
2 draft. But we also wanted to leave enough flexibility so  
3 that not everyone is treated the exact same because  
4 situations change.

5 TOM: Okay, great. I'll take a look at that.  
6 Also, I hope to be able to contribute some information in  
7 terms of your question about how much IPM is already  
8 being implemented.

9 MR. JORDAN: That would be helpful. I have  
10 next on my list Dave Tamayo and then Jen Sass.

11 MR. TAMAYO: I really think it's important that  
12 you have pretty clear standards. I appreciate the need  
13 for flexibility with the IPM but it needs to be really  
14 clear to the people who are supposed to be enforcing it.  
15 Also, I'm assuming, since this is the Clean Water Act,  
16 that these things are subject to citizen's suit. So, if  
17 you don't have that clarity, then you don't have very  
18 much protection if you're the discharger in that case.

19 I'm sorry, I didn't introduce my organization.  
20 It's California Stormwater Quality Association. We  
21 represent a lot of stormwater permit holders, primarily  
22 municipalities.

1           My other question is, what sort of interaction  
2           is there between the urban permittees under this system  
3           and then the municipal stormwater permit holders that are  
4           responsible? We do, actually, a much more rigorous level  
5           of monitoring. So, if we find something that now we're  
6           kind of stuck with, you don't have monitoring of the  
7           discharges that are discharging into our system.

8           What's our recourse? Are we responsible, then,  
9           for their discharge that was supposedly covered under  
10          their permit. But now we don't even have the information  
11          because the monitoring won't -- they won't have a level  
12          of monitoring that we do to reveal problems that could  
13          very well have been caused by their applications?

14          MS. BERNASIAN: Thank you. That was a great  
15          question. The stormwater program is also an NPDES  
16          program. In the stormwater program safe for construction  
17          sites under one acre, you're not required to do anything.  
18          So, stormwater is a little different. The way that  
19          they've written the law is it gave EPA discretion how to  
20          create that program.

21          What we've done is we've picked some thresholds  
22          in that program that said under those thresholds, unless

1 we've designated you, you do not need a permit. So, the  
2 example that you're mentioning -- say if you had these  
3 terrestrial applications and then it washed off into the  
4 river, we consider those nonpoint source because it's  
5 stormwater and it's not designated.

6           So, that is not something that needs a permit.  
7 Nonpoint source pesticide application does not need a  
8 permit unless it's designated under the stormwater  
9 program or already captured. So, if somebody is spraying  
10 some pesticides on their lawn and it doesn't hit the  
11 water but then it rains and flows in, under stormwater  
12 that's a nonpoint source and you do not need a permit.

13           Now, if it's going into a municipality, again  
14 that is not something that is directly being applied to  
15 water. It's handled under the MS-4 regulations which is  
16 the stormwater regulations. We are looking at that  
17 question because we're also doing MS-4 regulations.

18           MR. JORDAN: Dave, why don't you and Linda talk  
19 at the lunch break which I hope will be coming up soon.

20           MR. TAMAYO: Well, okay. I'm going to be in  
21 the Tox 21 (phonetic) but --

22           MR. JORDAN: Okay. Jen and then Carolyn

1 Brickey.

2 DR. SASS: Mine is a fast one. The slides  
3 itself, I just wondered if some of those things will be  
4 publicly accessible like the pesticide discharge  
5 management plan?

6 MS. WIEDEMAN: As explained in the fact sheet  
7 and the permit, if the public asks for these documents,  
8 EPA will make them available.

9 MR. JORDAN: Carolyn and then Mark Whalon.

10 MS. BRICKEY: Question and then observation.  
11 Question, on slide 13 you talk about the pesticide  
12 application threshold. Will some options for what those  
13 thresholds should be be discussed as part of this  
14 document?

15 MS. LEWIS: We're going to be providing what we  
16 think are the best thresholds that we have been able to  
17 determine. So, it won't be options but they will be a  
18 different threshold for each of the four uses.

19 MS. BRICKEY: So, they'll be suggested for each  
20 of the four?

21 MS. LEWIS: Yes.

22 MS. BRICKEY: Okay. Observation, Linda

1 mentioned that there might be some options for emergency  
2 applications before the fact of having a permit. I just  
3 caution you about that because the pesticide program has  
4 a Section 18 program for emergency applications before  
5 pesticides are used. So, I would think long and hard  
6 about allowing people to use the materials before they  
7 have any notification or information into you.

8 MR. JORDAN: The Section 18 program will still  
9 apply, Carolyn. This isn't authorizing something that  
10 isn't --

11 MS. BRICKEY: To these uses?

12 MR. JORDAN: To these uses.

13 MS. BRICKEY: Okay.

14 MR. JORDAN: Or registration. They'll need to  
15 have either a registration or a Section 18-24©) external  
16 use permit.

17 Okay, Mark Whalon and then Allen James.

18 DR. WHALON: I just want to thank EPA for the  
19 general permit process because I think it's a big burden  
20 lifter for a lot of indirect users. It's a good  
21 strategy. I'd like to come back to this IPM thing,  
22 though. In terms of state lead agencies and the kind of

1 response that Colorado had, I can see a number of other  
2 states doing the same thing because a lot of these states  
3 in the recent economic times have been gutted.

4 So, if you look at a state like Michigan, look  
5 at MDA, Department of Environmental Quality, who would  
6 have a state lead agency responsibility, there's three  
7 people left. In terms of extension, cooperative  
8 extension in extending this information to growers, we're  
9 looking at a RIF of 50 to 70 percent in the state of  
10 Michigan.

11 So, some of these getting the word out, getting  
12 the response back, you're going to have kind of a no  
13 response deaf kind of thing in a lot of states given the  
14 time frame and also given the structure as good as it is.

15 MS. BERNASIAN: Well, we have 10 regions. I,  
16 in the next two weeks, am visiting three of them. This  
17 is on the agenda for each state for me to sit and talk  
18 with them exactly about where their states are and are  
19 they planning to use our permit or some iteration and  
20 when are they proposing it. So, what we'll do is we'll  
21 have a hot list of the ones that aren't moving forward  
22 and then we'll have to have a strategy for that.

1           MR. JAMES: Allen James with Responsible  
2           Industry for a Sound Environment. I'll make mine very  
3           quick.

4           On slide 14, you emphasized that permittees must  
5           use the lowest amount possible of pesticides in their  
6           application. I hope you will consider including in that  
7           statement using their best professional judgment, because  
8           if you don't allow them to use their best professional  
9           judgment, someone else's best professional judgment will  
10          be used. So, I hope you'll include that specifically,  
11          and I urge you to do that.

12          Secondly, I've been asked to express a concern  
13          for representation of some of our members which are  
14          utility rights of way. A number of them across the  
15          country are so large that they will certainly fall into  
16          the classification of the general permit. It has been  
17          the experience of a number of these that when pressure  
18          has been applied to them to move away from pesticides,  
19          they often do initially. That will happen under this  
20          program, I'm certain.

21          The problem with that is that the alternative  
22          methods of mechanical control have been proven to be far

1 more environmentally damaging through machine oil, other  
2 discharges, that would not be covered under a pesticide  
3 permit but would have a lot more negative impact upon the  
4 environment. So, the utilities are very concerned. The  
5 applicators particularly that do the work under contract  
6 for the utilities are very concerned about what this  
7 impact will be to them if they're required to do more  
8 mechanical use.

9 I have with me, who can't stay through the  
10 afternoon and give public comment, one of our leading  
11 experts in the nation on utility rights of way. He's  
12 done a marvelous job with protecting endangered species  
13 and bringing back endangered species where they have not  
14 been known to exist for some time. He's done it with the  
15 proper use of chemicals, to some degree mechanical but  
16 primarily through chemical. That program will be  
17 entirely lost on some of these utility rights of way  
18 under these permits.

19 The final thing is the question, although I  
20 know you're operating under a court order, the impact of  
21 this decision or your program is going to impact small  
22 business without question. It will be a large impact.

1 Are you required to meet the terms of the analysis of the  
2 impact on small business, the financial analysis, as part  
3 of your decisionmaking process?

4 MR. JORDAN: I think that the Federal Register  
5 notice and fact sheet will discuss our assessment on the  
6 small business impacts. My recollection is that it does  
7 not -- our assessment is that it will not trigger any  
8 additional requirements beyond the service threshold  
9 evaluation.

10 MS. BERNASIAN: First of all, they're already  
11 required to be covered, so I'm not doing anything other  
12 than trying to get them protected. So, right now, if  
13 they discharge without a permit, they could be charged  
14 \$32,000 a day. So, in our permit, we don't have a  
15 regulation. This isn't a regulation so we don't have to  
16 go through some of those things. But we have really  
17 factored in and tried to pick things that are common  
18 sense.

19 So, you saw for the smallest applicators we're  
20 telling them they've got to minimize. We're telling them  
21 they've got to calibrate their equipment if they tell us  
22 if there's some adverse incident. That's what we're

1 going out with. So, we don't think that's a big burden  
2 on small business.

3 MR. JAMES: I'm not debating you on that part  
4 of it. But I will say that we're operating at this point  
5 in time and until the court order goes into effect under  
6 your rule that says these companies do not have to have a  
7 permit. They're not in violation if they do not have a  
8 permit today.

9 MR. JORDAN: Carol Ramsay and then I can't read  
10 the other three, so I'm going to ask you all to figure  
11 out amongst yourselves who goes next.

12 MS. RAMSAY: Mine is just a simple observation  
13 back to the ag impacts. If you look at slide number 12  
14 and then the handout that you had, I think one of the  
15 concerns is the clarity issue that's already been brought  
16 up.

17 Slide number 12 up there says terrestrial  
18 applications on row crops and in your fact sheet it says  
19 agricultural crops. There's lots of crops that aren't  
20 row crops. So, I think that's a lot of the confusion of  
21 what's going on with people reading. What they're seeing  
22 is that the message is not coming across clearly.

1           So, I do encourage you to engage the  
2           agricultural commodities again before this May release to  
3           best define what crops may or may not fall under this.  
4           If it's going to be all agricultural crops are out,  
5           that's something. But if there are some agricultural  
6           crops that will be in, I think you want to define that.

7           MR. JORDAN: Thanks for adjusting the angle on  
8           the cards. Julie, I think you're next, and then Jerry  
9           has the last word.

10          MS. SPAGNOLI: This is with regard to the  
11          request and comments to if there are other uses that need  
12          to be a subject. Are you going to have time? I mean, if  
13          they identify four or five additional uses that they feel  
14          need to be under permit, how is there going to be enough  
15          time to develop thresholds and all the parameters around  
16          those permits?

17          I guess this goes to what Tyler said. If they  
18          determine there's that many more uses that need to be  
19          subject, would the agency consider asking for a further  
20          stay in order to have the time to develop those?

21          Then, I guess my second question is, and I  
22          think this had to do with what Bob said about individuals

1 getting permits. If people feel the need to get an  
2 individual permit because they're not covered under  
3 general permits and they're concerned about their  
4 liability, do the states have anywhere near the resources  
5 to issue those permits if thousands of applicators come  
6 in looking for individual permits?

7 MS. BERNASIAN: I really appreciate your  
8 question. Like say for a different state that has a  
9 whole lot of water throughout their state, they may  
10 decide that it's really not avoidable and they may  
11 include more categories. So, they're not restricted to  
12 what we do. We've just looked at the areas in which  
13 we're regulating.

14 The other thing is when we issue a draft  
15 permit, we could also do a supplemental permit  
16 modification a couple months later or things like that.  
17 So, we're not restricted to that. Or we could just start  
18 another general permit and that one may hit and not  
19 finish until four months. So, we wanted to really try to  
20 get this one to finish in case we've missed something so  
21 that we could have some amount of time to amend it if we  
22 needed to.

1           MR. BARON: It's always tough to be the person  
2 between lunch and asking one more question. In fact,  
3 Julie said a lot of my question. I thought I was going  
4 to make it through with all these cards there and no one  
5 coming up. It didn't happen.

6           Anyway, I applaud you for what you've done in  
7 very short order and tough conditions. The four areas  
8 are pretty clear cut. But what concerns me is the  
9 nebulous areas of those other crops. It was even implied  
10 before that people if they feel it's necessary -- and  
11 that's going to trigger in the time factor which I think  
12 our diminishing infrastructure at the state level will  
13 not have a chance to do it.

14           Two of the crops in my program -- I neglected  
15 to mention the IR-4 program -- that we deal with on a  
16 routine basis are watercress and cranberries. My guess  
17 is those two crops, if a grower was out there, they would  
18 probably want to think very strongly of submitting  
19 permits because they will likely require one.

20           That leads to the question. I feel that in  
21 some cases this is opening growers by not including them  
22 as part of this general permit to lawsuits. Again, I

1     applaud you for what you've done, but I think that you're  
2     giving some people a false sense of security that they're  
3     going to make it through 2012 after April 11th without  
4     having a lawsuit coming back to them. Thank you.

5             MR. JORDAN: Well, the scope question is  
6     definitely on the table, as Allison explained, in the  
7     Federal Register notice and a lot of other questions.  
8     So, thank you all for your comments. We will consider  
9     them carefully and we'll also be open to continued  
10    conversations outside this forum.

11            Steve.

12            MR. BRADBURY: I just want to repeat Bill's  
13    comments. I appreciate all the very insightful  
14    observations and questions. Some of that feedback  
15    already I think will have an impact for shaping aspects  
16    of the proposed permit going out.

17            The many other concepts and issues you brought  
18    up are actually part of what we want to get comment on  
19    once that proposal gets out there. So, again, I  
20    appreciate the thoughts now because it gives us some  
21    insight as to the stage we're at now. Also, if you  
22    didn't get an answer to your question, it's because, in

1 fact, we're asking for all of the public to consider  
2 these certain critical issues and get us some feedback as  
3 we go forward. So, I appreciate the very thoughtful  
4 input.

5 So, we're not doing too bad. Nobody is in the  
6 penalty box yet, no 10-minute majors or anything. So,  
7 why don't we shoot for a 1:30 start so we're only about  
8 15 minutes off schedule. I'll work with our folks to see  
9 if we can pick up some of that 15 minutes after lunch.  
10 So, thanks, all. We'll see you at 1:30.

11 (Whereupon, a luncheon recess was taken.)

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## 1 CERTIFICATE OF TRANSCRIPTIONIST

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PESTICIDE PROGRAM DIALOGUE  
COMMITTEE MEETING

April 30, 2010

Conference Center - Lobby Level  
2777 Crystal Drive  
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Arlington, VA 22202

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

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3 MR. BRADBURY: Good morning, everyone. If you  
4 all could take your seats, we'll get started. Before we  
5 get started, I know there are a few folks that are  
6 serving as alternates for standing members of the  
7 committee. Those folks can introduce themselves, Pat,  
8 for example.

9 MR. DONNELLY: Hi, I'm Pat Donnelly (phonetic),  
10 representing Gallon Companies, sitting in for Cindy  
11 Baker.

12 MR. BRADBURY: Thanks. Also, introduce  
13 yourselves. I'm just asking people that are sitting in  
14 as alternates today if you just introduce yourselves to  
15 the group.

16 MR. BETZ: Fred Betz standing in for Maria  
17 Herrero, representing the Biopesticide Industry Alliance.

18 MR. BRADBURY: Thanks. So, we'll get started  
19 with this morning's discussion. We're going to start  
20 with the discussion on our pollinator protection  
21 activities not only here in the pesticide program in EPA  
22 but also in the context of our collaborative efforts with

1 the U.S. Department of Agriculture. I'll turn it over to  
2 the team in just a minute.

3 The goal of this session is to provide you some  
4 information. The team will be efficient in their  
5 presentation so we can get some dialogue. What we want  
6 to do is get some feedback on communication strategies.  
7 I'm sort of curious during the discussion what you all  
8 hear out there across the country.

9 Is the information getting out to you clearly  
10 about what the status of pollinators are, what some of  
11 the issues are, and to let you know that we're sensing  
12 that we could probably do a better job of communicating  
13 what we're doing, what's going on, just based on the  
14 kinds of questions we get or e-mails we get. So, that's  
15 the real focus of the discussion, get some feedback, some  
16 ideas going on how to improve communication.

17 Then we'll take a break. Then Lois Rossi will  
18 come in and do a snapshot on work she's been doing with a  
19 subset of you all on public health. Then we'll have a  
20 session giving an update on where we are in the endocrine  
21 disruptor screening program. Then we'll talk about next  
22 steps for the committee.

1           So, with that, I'm going to turn it over to Don  
2 Brady who will introduce the pollinator protection  
3 session.

4           MR. BRADY: We welcome you to this session. We  
5 think we have an interesting presentation. We hope to  
6 get some good feedback, as Steve indicated. So, the  
7 first presenter will be Dr. Mary Purcell-Miramontes who  
8 is with USDA and she will present on USDA's role in  
9 monitoring and research of pollinators. And then, Tom  
10 Steeger from EFED (phonetic) and Tom Moriarty from PRD  
11 (phonetic) will team up for a second presentation on  
12 pollinators in OPP. So, we'll get started.

13           DR. PURCELL-MIRAMONTES: Everybody hear me  
14 okay? Smiling faces. So, it looks like you heard me,  
15 okay. So, thanks, everyone, for the opportunity to come  
16 speak with you today. I work for the USDA National  
17 Institute of Food and Agriculture. I'm national program  
18 leader in Arthropoda nematode biology.

19           Part of this presentation and who are  
20 responsible for the material I'm going to present are Dr.  
21 Hackett (phonetic), also national program leader with the  
22 intramural research arm of the USDA and of course Dr.

1 Jeffrey Peduct (phonetic) who is the research leader  
2 (inaudible) Agriculture Research Service.

3 Just by way of introduction, the agency I work  
4 for in USDA, the National Institute of Food and  
5 Agriculture, is the extramural funding agency which funds  
6 competitive grant research, formula fund research,  
7 educational programs, and extension programs, issues of  
8 national agricultural interest.

9 So, I became intimately linked with Jeff Pettis  
10 and Kevin Hackett and Rick Meyer, also at NIFA, when the  
11 news about pollinator decline and colony collapse  
12 disorder hit the press in early 2007. We just beat the  
13 pavement continuously in the spring of 2007 going to  
14 congress to give briefings about it. So, we learned in a  
15 hurry what the issues were.

16 What is pollinator decline? Pollinator decline  
17 is a major issue impacting several kinds of organisms  
18 that pollinate plants in the environment as well as an  
19 agri-eco system. In January 2007, the National Academy  
20 of Sciences produced a report entitled, "The Status of  
21 Pollinators in North America."

22 This reviewed the literature to date on

1 population declines of several species of pollinators,  
2 which includes bees, wasps, butterflies, bats,  
3 hummingbirds. The report also charged the USDA to  
4 enhance research efforts for this urgent problem.

5           Several factors are implicated in pollinator  
6 decline. The top lab European honeybee is a main  
7 pollinator but there are several species of native and  
8 wild bees that are also suffering significant decline.  
9 Several of these wild bee species are extremely rare and  
10 possibly extinct.

11           Several factors have been implicated in these  
12 losses such as the use of pesticides in large scale  
13 agriculture. Pesticides are known to kill bees and cause  
14 serious chronic effects on bee health. It reduces  
15 longevity, it reduces feeding, affects behavior, mating,  
16 and so forth.

17           The wide-scale planting of single crop types,  
18 called monocultures, could have questionable value to  
19 pollinators as a sole dietary source of pollen and  
20 nectar. Monocultures provide fewer field margins which  
21 make it difficult for bees to move in and out of the crop  
22 to find other sources of pollen and nectar to supplement

1 their diet.

2 In that National Academy of Science report, the  
3 report studied or collated the data on colony numbers in  
4 the United States. This is data provided by the National  
5 Agricultural Statistic Service which is a USDA agency.  
6 This slide shows data collected by NASS on honeybee  
7 colonies between 1945 and 2006.

8 Colonies began to take a precipitous decline  
9 from five million colonies in the 1940s to two-and-a-half  
10 million in 2005. In the 1970s when the varroa mite  
11 invaded the U.S. and infested beehives, this was  
12 responsible for the precipitous decline.

13 So, what is colony collapse disorder? Colony  
14 collapse disorder is a phenomenon which may or may not be  
15 a new thing. The symptoms of colony collapse disorder  
16 include the rapid loss of adult worker bees. Few or no  
17 dead bees left in the colony is pretty unusual in that  
18 bees that suffer pesticide exposure have a collection of  
19 dead bees just outside the hive. This is not the case in  
20 colony collapse disorder.

21 Another symptom of colony collapse disorder is  
22 that the colonies die and they have an excessive number

1 of immature larvae. But the reason they die is that the  
2 larvae are unable to feed themselves and quickly the  
3 colony becomes what they call dead. There is a small  
4 cluster of nurse bees that remain with the queen, but  
5 typically within a week or so the queen will die.

6 So, the USDA, in conjunction with the APRA  
7 inspectors of America have conducted surveys since 2007.  
8 The losses are ranging from 32 percent in 2007 to what  
9 most recently was reported by Jeff Pettis and Van  
10 Englestop (phonetic), 34 percent in 2010. So, things  
11 clearly aren't getting better. Several beekeeping  
12 industries are seriously struggling.

13 So, the working hypothesis based on researchers  
14 that have been gathered to discuss and study the problem  
15 is that several factors are working in combination or  
16 synergistically to lead to colony collapse disorder. For  
17 example, some primary stress is imposed on bees to weaken  
18 them.

19 This kind of stress could be transporting bees  
20 long distances with adequate food or shelter. This leads  
21 to lowered immunity to secondary pathogens. Normally,  
22 they don't have a problem with these pathogens, but when

1 they're stressed, their immune response if hypothesized  
2 is compromised.

3 Secondly, the varroa mite, which I told you  
4 about, is a major stressor. Research is showing that the  
5 mite vector viruses to honeybee colonies and high levels  
6 of these viruses have been associated with bees that are  
7 unhealthy and have the CCD symptoms.

8 The ways bees are managed, their level of  
9 nutritional needs could be very inadequate. In addition,  
10 exposure to pesticides used to kill varroa mite and other  
11 diseases attacking bees are also important. It seems to  
12 be important that these management and nutritional  
13 factors and pesticides are associated with an increased  
14 susceptibility to a Nosema (phonetic) disease and various  
15 fungal diseases.

16 So, why do we care? Well, this is a problem of  
17 real concern to ensuring an adequate food supply in this  
18 country and perhaps the world. We have an ever-expanding  
19 population and increasing acreages of crops are needed to  
20 feed more people. A third of the fruit, vegetables and  
21 nut crops depend on pollinators for seeds and fruit  
22 production. So, bee shortages are linked with CCD and

1 other issues.

2           Consequently, growers are demanding ever more  
3 attention from beekeepers to provide pollinator services.  
4 Beekeepers are not keeping pace with the demand.  
5 Consequently, there could be food shortages. Certainly,  
6 it's not been well studied and there's a pressing  
7 research need to do that, to document whether yields are  
8 impacted by shortages and declines of pollinators and due  
9 to CCD.

10           So, what has the USDA's role been since the  
11 advent of these issues? So, the National Institute of  
12 Food and Agriculture has developed a coordinated  
13 agricultural project on colony collapse disorder. They  
14 provided \$4.1 million to the University of Georgia and 14  
15 other institutions to focus on research and mitigating  
16 the problem.

17           Secondly, ARS has an area-wide project to  
18 promote bee health. They're focusing on best management  
19 practices for beekeeping as well as basic and applied  
20 research on CCD and bee health in general. The research  
21 is highly complementary with the bee cap study being  
22 funded by NEFA (phonetic).

1           Thirdly, the animal plant health inspection  
2 service is initiating a bee health survey on the national  
3 scale. Federal, state and (inaudible) will collect  
4 samples and the ARS bees research lab will analyze them  
5 for pathogens and pests. Dr. Robin Rose and Jeff Pettis  
6 are the key contacts if you want more information about  
7 the national bee health survey.

8           AFIS (phonetic) is secondly providing funding  
9 for the problem of varroa mite which has invaded the big  
10 island of Hawaii and is threatening cona queen (phonetic)  
11 production on the west side of the big island. A control  
12 program is underway to limit expansion of the varroa mite  
13 from the east side of the island to the west side.

14           So, the Natural Resource Conservation Service  
15 has developed a conservation practice standard for  
16 pollinator species in conjunction with individual states  
17 and counties. They've developed planting guides which  
18 select plants can serve pollinators in natural  
19 landscapes. Doug Collee (phonetic) is the person that we  
20 work with the most and he's on the colony collapse  
21 disorder steering committee, along with EPA, Department  
22 of Defense, and two land grant universities. EPA is

1 developing new pesticide tests and protocols to better  
2 understand the risk of pesticides on honeybees.

3           So, I just want to give you some feeling for  
4 what's being done on these fronts of the managed  
5 pollinator cap and ARS area-wide study. So, as I said  
6 before, these two projects are developing basic and  
7 applied research on the causal factors. They're  
8 conducting monitoring surveys such as using sentinel  
9 beehives. They're surveying beekeepers and asking them  
10 what their losses are. There's a fair bit of extension  
11 and outreach being conducted that I'll talk about in the  
12 subsequent slides, and providing information to  
13 communities.

14           So, proceedings of the National Academy of  
15 Sciences paper written by Reed Johnson (phonetic) and May  
16 Berenbaum (phonetic) of the University of Illinois. They  
17 studied the genetics of bees in CCD colonies or colonies  
18 reporting CCD-like symptoms and colonies that were  
19 healthy and did not have the symptoms.

20           What they observed was there was a lot of  
21 variation in the genes that were expressed in CCD  
22 colonies. It leads to a question about whether different

1 stressors may be occurring on the eastern side of the  
2 U.S. versus the western side. So, there's no sort of set  
3 number of genes that are expressed across all regions.

4 Sixty-five gene transcripts were identified,  
5 however, as potential markers for CCD status. They also  
6 found that within the genes that damaged ribosomal RNA  
7 fragments were occurring much more frequently in the CCD  
8 affected bees.

9 So, again, these are very interesting phenomena  
10 and maybe ways we don't know what causes CCD but we at  
11 least can have a good handle on a marker for CCD. So,  
12 future research is going to be conducted to see if this  
13 is something that can be repeated over several regions.  
14 In this study, a final conclusion was that two viral  
15 diseases were associated with CCD. Those were Israeli  
16 Acute Paralysis Virus and Deformed Wing Virus.

17 Some more highlights were pesticide studies.  
18 University of Georgia did some testing of chemicals in  
19 the hives, for example, wood preservatives and various  
20 miticides used to control varroa mites. They found that  
21 it led to decreased feeding by the bees on supplemental  
22 sugar. So, as you know, to overwinter successfully,

1 honeybees need to feed on supplemental food and that  
2 seems to indicate that they just lose their appetite.  
3 So, these sorts of things are measures of strength of a  
4 colony and that beehives are incurring severe winter  
5 losses. So, that's an interesting finding.

6           Studies also at the University of Illinois and  
7 Nebraska have documented synergistic effects of  
8 pesticides when they are combined. So, when the  
9 pesticides Cumifa (phonetic) and fungicides are applied  
10 separately, they didn't find lethal effects. But when  
11 they applied them together, they observed synergistic  
12 acute effects or mortality effects on honeybees.

13           Then, most recently, a study by Chris Mullen  
14 (phonetic) and others at Penn State -- Jeff Pettis at  
15 ARS, a co-author, published the PLOS-1 that high levels  
16 of 121 pesticides and metabolite residues were observed  
17 in wax, pollen and bees from colonies which were termed  
18 unhealthy. So, these could be beehives that had both CCD  
19 and just heavy heavy losses. So, that's not defined.

20           What they observed were mainly miticides and  
21 fungicides in this group of pesticides. The highest  
22 residues they observed were in wax; the lowest were in

1 bees. What we need now are controlled studies to  
2 understand the biological effects of bees on materials  
3 and in particular in combination -- applied in  
4 combination and their association with CCD and other  
5 stressors.

6 I wanted to also mention another study  
7 conducted by Jeff Pettis and a French researcher, Aloe  
8 Ettal (phonetic). Sublethal exposure of several  
9 pesticides indicated an increased level of pathogenicity  
10 in bees. They were able to document that. Nosema levels  
11 increased after exposure, for example, to Imiticoprid  
12 (phonetic).

13 So, outside the research front, there is a  
14 heavy component of mitigation and outreach. There is a  
15 community, a practice web site that is funded by the  
16 BECAP (phonetic) and ARS. It was publicly released in  
17 2009. Here's the web site for any of you that are  
18 interested.

19 A big part of the mitigation and outreach part  
20 of what USDA is doing is to do beekeeper surveys before  
21 best management practices are adopted and after adoption  
22 of these practices. Members of the public can get on

1 this web site and put a question on and ask the expert.  
2 I'm observing bees in my yard much less commonly. What's  
3 going on? Any question and somebody within 24 hours will  
4 give you an answer.

5 Another part of this outreach is conducting  
6 workshops such as queen rearing studies or courses to  
7 show the public or beekeepers how to incorporate disease  
8 resistance trace in their bees.

9 In conclusion, what I hope I've gotten across  
10 to you is that all pollinators are threatened. That's  
11 what's meant by pollinator decline. The issue of  
12 honeybee health is a complicated one. It's not one  
13 that's going to be solved overnight. As you saw, there  
14 are several factors that are suspected as causing CCD or  
15 being associated with CCD. It's going to take careful  
16 research and good coordination between USDA and other  
17 research entities to really get a handle on it.

18 So, we've seen research that documents affects  
19 on bees with the miticides and other agricultural  
20 chemicals. There seems to be a very interesting  
21 interaction going on between pesticides perhaps enhancing  
22 susceptibility to pathogens that they normally would be

1 able to fend off.

2 With that, I'm going to close.

3 MR. STEEGER: Thank you very much. My name is  
4 Tom Steeger and I'd ask our slide presentation come up  
5 and we'll move right to slide 3. As we get set up, my  
6 presentation is going to include a brief overview, sort  
7 of touching on what Mary just talked about. We'll also  
8 describe how the agency is engaged in a number of fronts  
9 including monitoring research, enhancing the regulatory  
10 programs, and communication and outreach. Finally, we  
11 will present specific questions to the PPDC. So, I'm  
12 going to continue to go on here.

13 As mentioned by Dr. Purcell, the National  
14 Academy of Science did publish a report in 2006  
15 discussing the status of pollinators in North America.  
16 That report concluded that there was sufficient direct  
17 evidence that indicated declines in North American  
18 pollinators, including America's most important managed  
19 pollinator, the European honeybee. The report also  
20 concluded, though, that species of insects, birds, and  
21 mammals associated with pollination are in decline but  
22 that there was insufficient information to determine the

1 causes of those declines.

2 Also, the NAS survey that Dr. Purcell presented  
3 on indicates that managed honeybee colonies have been in  
4 decline from a peak of approximately six million colonies  
5 in 1947 to roughly 2.8 million colonies in 2006. Some of  
6 the marked declines in managed honeybee colonies in the  
7 mid-1980s, though, were attributed to the introduction of  
8 parasitic mites which is the tracheal mite and the  
9 ecoparasitic mite, the varroa.

10 Historical trends monitored by USDA indicate a  
11 steady decline in managed pollinator colonies in the  
12 United States, a typical loss of 15 to 20 percent since  
13 the introduction of the two mites. The marked colony  
14 losses, though, have increased roughly 30 to 36 percent  
15 since 2007 and present.

16 While USDA has been tasked with monitoring and  
17 reporting the number of managed honeybee colonies in the  
18 United States, beekeepers have voluntarily reported their  
19 experiences directly to EPA as well. The majority of the  
20 losses described in two EPAs had CCD-like characteristics  
21 and in some cases involved what could only be described  
22 as a staggering number of managed bee colonies abandoned

1 by their once resident bee population.

2 Beekeepers have reported increased difficulty  
3 in finding replacement bees and increased costs  
4 associated with reestablishing colonies through the  
5 purchase of new queens, packaged bees and nucleus  
6 colonies. Although a number of factors and agents have  
7 hypotheses as potential contributors to pollinator  
8 declines, at this time no factor has been identified as a  
9 single cause. Rather, the available science suggests  
10 that pollinator declines are a result of multiple factors  
11 which may be acting in various combinations.

12 Research is being directed at identifying  
13 individual and combinations of stressors that are most  
14 strongly associated with pollinator decline. While the  
15 exact causes of the general declines in pollinator  
16 species and in the phenomena characterized as CCD have  
17 not been determined, potential contributing factors such  
18 as those identified by Dr. Purcell include diseases,  
19 habitat destruction organization, agricultural practices,  
20 monocultures, pesticides, nutrition and demanagement  
21 practices have to be considered.

22 Researchers at the USDA have (inaudible) CCD

1     may be caused by a primary stressor such as a parasitic  
2     mite or poor bee management, nutrition, or pesticides  
3     that may in turn cause honeybees to become more  
4     susceptible to the disease.

5             In 2007, the director of the Office of  
6     Pesticide Program, Debbie Edwards at that time,  
7     established a multidisciplinary Office of Pesticides  
8     Programs pollinator protection team which included staff  
9     from various scientific and regulatory divisions within  
10    OPP. Since that time, staff participation in the team  
11    has expanded to include other offices within EPA and  
12    across EPA regions.

13            The multidisciplinary team is tasked with  
14    exploring possible approaches, tools, and resources for  
15    reducing the potential risks of pesticides to  
16    pollinators. To that end, the team has also been tasked  
17    with developing a strategic plan to guide its future work  
18    and direction.

19            The strategic plan, which is available on the  
20    EPA web site, identified three major goals. Goal one was  
21    to advance the agency's scientific knowledge and  
22    assessment of pesticide risks to pollinators. Goal two

1 was to improve risk management tools for mitigating  
2 potential risks to pollinators. Goal three was to  
3 increase and broaden collaboration and communication with  
4 governmental and nongovernmental organizations and the  
5 public in addressing pollinator issues. Over the  
6 remainder of the presentation, we'll discuss progress  
7 being made on achieving these goals.

8 As indicated by Dr. Purcell, USDA has taken the  
9 lead in the effort to determine causes contributing to  
10 CCD and serves as the lead on CCD steering committee.  
11 The committee developed an action plan which is available  
12 through the USDA ARS web site. The action plan outlines  
13 a strategy for addressing CCD and involves four main  
14 components, survey and data collection, analysis of  
15 samples, hypothesis driven research, and four, mitigation  
16 and preventive action.

17 EPA is a member of the CCD steering committee  
18 and is working with USDA to understand the factors  
19 associated with CCD and pollinator declines. As  
20 indicated earlier, pesticides have been identified as one  
21 of the factors that may be associated with the incidents  
22 of CCD and with pollinator declines in general.

1           Through its membership on the CCD steering  
2           committee, EPA is providing technical expertise in  
3           reviewing study protocols submitted to USDA for funding.  
4           It's examining the potential role of pesticides in CCD.  
5           The reviews provide EPA science staff an opportunity to  
6           learn more about the proposed research efforts, and the  
7           reviews provide researchers with an understanding of  
8           EPA's perspective on study designs and potential  
9           confounding effects on efforts to document the potential  
10          cause/effect relationship.

11           OPP science staff have participated in site  
12          visits to some of the facilities conducting research on  
13          the potential effects of pesticides and pollinators. OPP  
14          labs are assisting in pesticide residue analyses to  
15          support some of these research efforts and to potentially  
16          increase the utility of these data in a regulatory  
17          context.

18           In a cooperative study between USDA and the  
19          University of Maryland examining the effects of  
20          neonicatenoid insecticides on honeybees following a long  
21          term exposure, OPP labs have been conducting pesticide  
22          residue analyses on bees and bee products from that

1 study.

2 OPP labs have refined the messages in these  
3 analyses and have increased the capacity to detect both  
4 the parent compound and all of its major degradation products in  
5 biological matrices and have historically limited  
6 detection on them. These refined methods have recently  
7 been published in the Journal of Agricultural and Food  
8 Chemistry.

9 Over the past several years, OPP has supported  
10 opportunities for EPA science and management staff to  
11 increase their familiarity with honeybee biology and  
12 ongoing research to examine the potential factors  
13 associated with pollinator decline.

14 For the past two years, USDA, in cooperation  
15 with land grant universities, have provided day-long  
16 training on beekeeping. These workshops not only  
17 increase staff awareness of bee biology but have also  
18 provided an opportunity to learn about the most recent  
19 research examining the potential factors, including  
20 pesticides, associated with pollinator declines.

21 In response to the uncertainty regarding the  
22 potential role of pesticides and pollinator declines, and

1 in CCD in particular, EPA is a member of a committee with  
2 representation from government, industry and academia  
3 that has written a proposal to the Society of  
4 Environmental Toxicology and Chemistry, or SETAC, for a  
5 global Pellston SETAC conference on estimating the  
6 potential role of pesticide or potential risks from  
7 pesticides to insect pollinators.

8 We are very pleased to announce that on  
9 Wednesday of this week the steering committee received  
10 notice that the conference will occur. The conference is  
11 intended to bring together the best available science  
12 regarding exposure and effects assessment methodologies  
13 for honeybees and native bee species.

14 The conference would provide specific  
15 recommendations for determining potential risks to insect  
16 pollinators from pesticides in a cost effective way. To  
17 these end, the conference has four focus areas. First,  
18 it is intended to produce tiered standardized test  
19 methods to assess exposure from systemic and non-systemic  
20 pesticide products.

21 Second, the conference will identify hazard  
22 endpoints applicable to risk assessment for the honeybee

1 and a tiered standardized test method to consistently  
2 identify and measure hazard endpoints.

3 Third, the conference is intended to identify a  
4 risk assessment process that can serve as both a screen  
5 level and as a basis for more refined assessments where  
6 needed.

7 The fourth objective of the conference will be  
8 to evaluate information on risk of pesticides to  
9 nonnative pollinators.

10 To further increase our understanding in  
11 advancing the science of assessing potential risks, last  
12 summer EPA hosted a USDA sponsored meeting on acute and  
13 chronic laboratory and field toxicity study designs with  
14 honeybees. The conference included representatives from  
15 government and academia, and the conference proceedings  
16 will both inform the SETAC Pellston and will be part of  
17 the CCD steering committee annual report.

18 Over the past year, EPA has been coordinating  
19 with the California Department of Pesticide Regulation  
20 and the Canadian Pest Management Regulatory Agency on  
21 data needed to support respective efforts to evaluate the  
22 nitrochlonodine class of the neonicatenoid pesticides.

1           Also, in response to beekeeper concerns, the  
2   bee kill incidents were not being consistently reported  
3   to OPP's ecological incident information system under  
4   FIFRA 6(a)(2) adverse effect recording requirements. EPA  
5   has expanded the mechanisms to which beekeepers can  
6   report bee kill incidents.

7           At this time, bee kill incidents can follow a  
8   typical process whereby states enter a registrants file  
9   6(a)(2) incident reports. However, beekeepers can also  
10  report incidents directly to EFED through contacts  
11  provided to the two largest beekeeping organizations.  
12  Beekeepers can also make use of newly expanded capacity  
13  of the National Pesticide Information Center portal, the  
14  NPIC portal, to report bee kill incidents.

15           Beekeepers, though, are encouraged to report  
16  bee kill incidents to their respective state agencies  
17  and/or registrants to better ensure that incidents can be  
18  properly documented.

19           My colleague, Tom Moriarty, will follow up on  
20  that. Tom is the chair of the pollinator protection  
21  team.

22           MR. MORIARTY: Hi. OPP has developed efforts

1 to develop the risk management. It can't be done in  
2 advance of a separate to develop the science. However,  
3 OPP is doing what it can now and is considering the best  
4 way to develop a tool to protect pollinators.

5 Current risk management is captured by honeybee  
6 warning statements on product labels which are based on  
7 acute contact toxicity data, not on the consideration of  
8 both hazard and exposure. Over time, the language has  
9 proven difficult to enforce and therefore perhaps not  
10 very effective.

11 Development of risk assessment methodology, as  
12 well as risk management strategies, is the focus of the  
13 pollinator protection team. Risk management for  
14 pollinators may turn out to be different than risk  
15 management for other taxa (phonetic) as pollinators,  
16 particularly managed pollinators, are different, say,  
17 than fish in a static water body.

18 So, approaching risk management for pollinators  
19 may present OPP with new challenges. To meet these  
20 challenges, the first and foremost step is the  
21 development of a sound risk assessment methodology.  
22 Second, OPP plans to engage its partners such as state-

1 lead agencies, beekeeper industries, applicators, and  
2 growers, and the like to understand what measures may or  
3 may not be effective to protect pollinators as well as  
4 the interest of growers.

5 Through dialogue with these stakeholders, OPP  
6 hopes to gain a sense of what management practices would  
7 be protective, feasible, and cost effective. Thirdly,  
8 OPP will share management approaches through its  
9 cooperative efforts with its international partners.  
10 While EPA knows that policy and management practices  
11 reflect numerous contextual variables, sharing measures  
12 and actions with the global partners may provide new  
13 ideas that may be adaptable here in the U.S.

14 Finally, possible changes to the spray drift  
15 language currently being explored through PR notice 2009X  
16 may also serve to provide a framework for protective  
17 language pollinators.

18 In the meantime, while it develops the science,  
19 OPP is being proactive to adopt risk management  
20 approaches where possible, such as reducing potential  
21 exposure from dust drift. Based upon events that  
22 occurred in Germany in 2008 where a large number of hives

1 were lost during the process of planting seeded tree and  
2 seeds, OPP engaged feed treatment manufacturers to adopt  
3 label language that would help reduce potential of a  
4 similar event occurring here in the U.S.

5 That event, pesticide dust drift to hives that  
6 are adjacent to a field that resulted from an  
7 environmental condition as well as failure of a sticking  
8 agent to prevent the pesticide from dislodging from the  
9 seed coat (phonetic).

10 Over the past year, OPP has met with technical  
11 registrants to discuss label language that would require  
12 appropriate sticking agents for certain types of seed.  
13 In addition to language regarding sticking agents, OPP  
14 has also met with equipment manufacturers to discuss  
15 engineering approaches that would further reduce  
16 potential dust drift.

17 In its registration review program, OPP is  
18 coordinating schedules in order to consider classes of  
19 compounds together. One class of insecticides that has  
20 received a lot of attention is that of the  
21 neonicotinoids.

22 The (inaudible) registration review was the

1 first to open in late 2008, and the rest of the  
2 neonicotinoids are scheduled to begin registration  
3 together in 2012. As was mentioned by Tom earlier, OPP  
4 is coordinating its review of Imidacoprid with Canada's  
5 PMRA and California's PPR. OPP will coordinate with PMRA  
6 on the other neonicotinoid compounds if the schedule of  
7 the two agencies align.

8 On a longer time line, OPP plans to revise the  
9 Code of Federal Regulations Part 171 which deals with  
10 certification of pesticide applicators. Updating Part  
11 171 is a lengthy rulemaking process. Once complete, it  
12 requires additional time for adoption by an individual  
13 state.

14 Applicators, we know, are critical players in  
15 the safe use of pesticides. The originator of 171, which  
16 provides for public participation, will add requirements  
17 to the applicator and handlers certification program that  
18 deal specifically with pollinators.

19 The agency is also considering revising the  
20 core training manual which is a document that provides  
21 information to applicators on the safe use and handling  
22 of pesticides in accordance with the requirements of 171.

1 This again is (inaudible) potential cooperation and  
2 collaboration between OPP and stakeholders to provide  
3 guidance on protective practices for pollinators.

4           Communication and cooperation are key in the  
5 challenge that we all face. Need for good communication  
6 to bring about protection to pollinator species is  
7 apparent at different levels between agencies, between  
8 agencies and stakeholders, between growers and  
9 beekeepers, and so on.

10           The agency encourages and has gone so far as to  
11 stipulate the need for effective communication through  
12 labels. The pollinator protection team in OPP has  
13 strived to be open and available for stakeholders to  
14 request meetings who want to provide information to or  
15 who may be seeking information from the agency.

16           OPP believes that this committee serves an  
17 important role here as it seeks to develop consensus-  
18 based actions that rely upon bringing different parties  
19 together to exchange perspectives. As an example, during  
20 last year's North American Pollinator Protection  
21 Campaign's annual conference, which OPP hosted, OPP  
22 signed a memorandum of understanding with NAPPCC to

1 further its relationship with the pollinator advocacy  
2 group.

3 OPP, like many, sees this issue as a global  
4 one. Part of OPP's global efforts is the SETAC  
5 conference. In addition to that, it has engaged with  
6 partners from the Organization of Economic Cooperation  
7 Development to find further areas where cooperation would  
8 advance the science and the management around protecting  
9 pollinators.

10 Specific recommendations from that survey  
11 include advancing the harmonization of science and risk  
12 assessment, which of course is the primary focus of SETAC  
13 conference; two, sharing risk management approaches where  
14 risk managers in North America, Europe and beyond  
15 understand the policy specific statutory requirements;  
16 and specific commercial agricultural profiles sharing  
17 information on risk management approaches could be  
18 helpful to spread ideas and continue to find creative  
19 ways to meet our respected demands.

20 Developing tools to share infinite information,  
21 timely and efficient sharing of information on causes,  
22 circumstances, effects and responses around incidents

1 that occurs in one country can potentially help other  
2 countries be proactive, evidenced by OPP's efforts to  
3 reduce dust drift. Finally, the survey indicated a need  
4 for index research relevant to pollinator health and  
5 protection.

6 As mentioned earlier, OPP is open to meeting  
7 and interaction with all stakeholders but it is also  
8 planning several presentations on its pollinator  
9 protection efforts to reach out and build bridges. Next  
10 month, OPP will present, in conjunction with the French  
11 Minister of Agriculture, at the SETAC European meeting  
12 and is also presenting at the Penn State International  
13 Conference on Pollinator Biology in July.

14 Finally, we encourage you to visit both the EPA  
15 and the USDA web sites which we and our federal partners  
16 here use to communicate with the general public on  
17 actions taken either respectively or together to protect  
18 pollinators.

19 Thank you for your attention. I'd like to ask  
20 if there are any clarifying questions before we move on  
21 to the charge questions.

22 UNIDENTIFIED MALE: You said that pretty fast.

1       What did you say that last part?

2                   MR. MORIARTY:  The slide regarding  
3       communication, the last slide, I mentioned that OPP is  
4       going to make a couple presentations, one in combination  
5       with the French agricultural ministry at the SETAC  
6       European Conference, and then we're also presenting at a  
7       Penn State conference in July.

8                   UNIDENTIFIED MALE:  You asked for feedback and  
9       if there are any clarifying questions.  Then you said?

10                  MR. BRADY:  Let's start first and see if anyone  
11       on the panel has any clarifying questions from what Dr.  
12       Purcell, Dr. Steeger and Tom already mentioned.  Then  
13       we'll go on to questions.  Are cards up for clarifying  
14       questions first?  I see Steve, Michael and John.

15                  MR. SMITH:  I see this all the time.  
16       Obviously, in Florida we've been dealing with this issue  
17       for a while.  It's consistently reported that you lose  
18       about a third of your colonies every year.  But it's  
19       impossible to lose a third of your colonies every year  
20       for four years running.  Otherwise, you wouldn't have any  
21       colonies left.

22                  So, there's an increase in colony procedure

1 that occurs in the spring or after the overwintering  
2 period. That's usually not explained to people. So, I  
3 think it's important when you're communicating with the  
4 public when you say you've lost a third of your bee  
5 colonies. What you've lost is a third of the colonies  
6 that you ended the season with. Then, at the beginning  
7 of the season, you've increased your colonies again.

8           So, obviously, whatever is causing the colony  
9 collapse or the loss isn't affecting the ability of the  
10 colonies to be increased. So, something is going on  
11 there. I mean, they're increasing the size of their  
12 colonies, the number of their colonies enough to continue  
13 to function and produce honey and provide pollination  
14 services. So, there's something going on there.

15           You just have to be careful how you describe  
16 that to people because I get calls from people -- this is  
17 a little off the clarifying question, but it's part of  
18 the problem. We get calls from people who have bees,  
19 Africanized bees, who have invaded their homes who are  
20 afraid to do anything with them because they don't want  
21 to kill any more bees. They're afraid all the bees are  
22 gone. So, they won't do anything to protect their

1 structures or themselves because all they've heard about  
2 from the media is the fact that there are no bees left  
3 anymore; they're all dying out.

4 So, we have to be real careful how we describe  
5 this. It's real easy for the media to take what you're  
6 saying and misinterpret it and run with it. So, when you  
7 say you've lost a third of your colonies, you need to  
8 clarify what you're saying, that you've lost a third of  
9 the colonies you started the dormant period with.

10 MR. BRADY: Thanks, Steve. Michael.

11 MICHAEL: Thanks. I think that was a really  
12 good update as to what's going on and a nice description  
13 of the problems.

14 I've got three questions, basically, clarifying  
15 questions. The first one is, is there a problem like the  
16 problem in the U.S. in other OECD countries? In Europe,  
17 is it the same kinds of colony collapse? If not, what  
18 are the differences?

19 MR. SEEGER: I think in our discussions with  
20 the OECD, it's become clear -- and with publications that  
21 are coming out of the group Co-Lost, which is Colony  
22 Lost, and out of the ICPBR group that researchers and

1 government officials in Europe that they are experiencing  
2 significant losses similar to those in the United States.  
3 Characterization of those losses, whether they completely  
4 overlap with CCD, is an uncertainty.

5 It was identified in the OCD survey that EPA  
6 participated in that there is a greater need to collect  
7 information to sort of standardize how these types of  
8 losses are characterized and potential ways of monitoring  
9 them and actually mitigating effects once causes are  
10 determined.

11 MICHAEL: So, there are losses similar to the  
12 CCD in Europe. Are the pesticide residues and residues  
13 in wax, that kind of stuff, similar as well? How many  
14 parallels have been looked at?

15 MR. SEEGER: First of all, let me reiterate  
16 what I presented in my slides. At this time, that I am  
17 aware of, there has been no correlation established  
18 between particular pesticides and the loss of honeybees  
19 as has been characterized as CCD. I'm not aware of any  
20 correlation there. The pesticides that are being  
21 detected in hives by various researchers, while there are  
22 many, the level of detection and the frequency of

1 detection have to be taken into consideration.

2 We need to have some ability to put it into  
3 context of how that spectrum has changed relative to the  
4 occurrence of these rapid losses. So, the type of  
5 pesticides that are being seen in Europe probably reflect  
6 the use pattern of chemicals and the extent to which  
7 chemicals are used specifically in bee colonies. But, at  
8 this time, the correlation between the losses and  
9 particular pesticides or even the presence of pesticides  
10 has not been established.

11 MICHAEL: It's not the primary cause I'm  
12 looking for, synergistic effects or other kinds of  
13 things. I'm just trying to find out what has been done.

14 I'm interested in the status of the reporting  
15 to the National Pesticide Information Center. Do you  
16 guys get feedback from the University of Oregon or Oregon  
17 State as to whether or not there have been incidents  
18 where honeybees reported to NPIC or what's the status  
19 now?

20 MR. SEEGER: The availability of the NPIC to  
21 reporting bee kill incidents has only just been made  
22 available. We will be monitoring that once some of the

1 initial difficulties have been worked out. I think  
2 beekeepers have tried to move through that system and  
3 have experienced some difficulty through the initial data  
4 testing of the portal as it relates to bee kill incident  
5 reporting.

6 So, it will be a tool, as our ecological  
7 incident information system is a tool from 6(a)(2)  
8 reports and as direct reporting of beekeepers themselves  
9 to the agency. All those are information that inform our  
10 risk assessment process.

11 MICHAEL: Have the beekeepers been using the  
12 EIS reporting directly?

13 MR. SEEGER: We have had a very limited number  
14 of beekeepers report directly to the agency on bee kill  
15 incidents, a much lower number than I would have  
16 suspected given the concerns that were expressed that  
17 beekeepers felt that their losses were underreported.

18 MICHAEL: Okay. The last question I've got is,  
19 what are current tests that are being done to look at in  
20 registration and registration review of conventional and  
21 other pesticides for honeybees? Do you do acute LD 50s  
22 or chronic or does anybody look at transfer of compounds

1 to brood? Are there any developmental studies done or  
2 disease resistant studies, this kind of stuff?

3 MR. SEEGER: For all outdoor use pesticides,  
4 the 850 guidelines, 40 CFR, define the studies that have  
5 to be conducted. They are tiered studies. The first  
6 tier study is looking at acute contact, toxicity to young  
7 adult bees. The endpoint is a 96-hour LD 50 value.  
8 Depending on the outcome of that test, if the study  
9 results in an LD 50 that is more toxic than 11 micrograms  
10 per bee, they are then required to conduct toxicity of  
11 residues on foliage.

12 Depending on the outcome of that study and if  
13 there's information that's indicating that there are  
14 actually field effects going on, field pollinator studies  
15 would be required. The studies we would acknowledge that  
16 a contact toxicity study is not that informative for a  
17 systemic pesticides where bees might be consuming pollen  
18 and nectar. That is a limitation of our current study  
19 design or testing paradigm and we hope to and expect to  
20 address those limitations in the SETAC health. That will  
21 occur either late this year or in January 2011.

22 MICHAEL: Thank you.

1           MR. BRADY: We've got a bunch of other -- we  
2 haven't even gotten to the charge questions yet.

3           DR. SASS: This is Jennifer Sass on the  
4 telephone. Can I be put on the cue somewhere and then  
5 you call my name when it's my time to speak?

6           MR. BRADY: I will, Jen. Dr. Schell.

7           DR. SCHELL: Just a couple of real quick  
8 questions. Mary, you gave the graph on managed  
9 honeybees. Is this collapse? Are we seeing it just in  
10 the managed colonies or are the wild populations seeing a  
11 collapse as well? Is there any regional aspect to this?  
12 Michael touched on it a little bit, but are we seeing  
13 this across the country or is it peculiar to certain  
14 areas of the U.S.?

15          DR. PURCELL: Colony collapse disorder is a  
16 phenomenon that is unique to European honeybees. The  
17 native bees, bumblebees for example, are experiencing  
18 declines but it's not a colony collapse disorder  
19 syndrome. And the second question?

20          DR. SCHELL: Is there a regional component to  
21 it?

22          DR. PURCELL: Well, it's been reported in over

1 35 different states. I mean, it may be overreported and  
2 a lot more careful analysis needs to be done. At least  
3 at this point we can say it doesn't appear to be  
4 regional.

5 MR. BRADY: I see another round of cards came  
6 up. Are we still in the clarifying question realm?

7 DR. PURCELL: Yes.

8 MR. BRADY: Okay. So, I see Virginia, Susan  
9 Kegley and then Jennifer Sass on the phone. So,  
10 Virginia.

11 MS. RUIZ: You answered part of my question in  
12 response to one of Michael's questions. I'm just curious  
13 about the expanded reporting mechanisms directly to EPA  
14 and to NPIC. Can you just explain that process a little  
15 bit better?

16 MR. BRADY: The National Pesticide Information  
17 Center has historically had the capability to report pet  
18 incidents that have occurred. That has typically been  
19 limited to people that are classified as professionals in  
20 that field. Like veterinarians would only be able to  
21 access the reporting mechanism of the NPIC. Now that has  
22 been expanded that beekeepers themselves can actually

1 report the loss of their hives through the portal system.

2 The other mechanism is where beekeepers -- we  
3 have people identified in the environmental fate and  
4 effects division that you can either send an e-mail to or  
5 call and report a bee kill incident. That information  
6 would be captured, then, in our ecological incident  
7 information system database.

8 Susan?

9 DR. KEGLEY: I have two kind of clarifying  
10 questions. You mentioned best management practices that  
11 are being promulgated to pesticide users. So, question  
12 one is, what are those BMPs?

13 DR. PURCELL: Good question that I probably am  
14 not equipped to answer that. It's something that the  
15 researchers themselves could provide answers to.

16 DR. KEGLEY: The second question is, this  
17 grasp, the thought of managed bee colonies in the U.S.  
18 over time, the source is NASS data, but how is that data  
19 collected?

20 DR. PURCELL: They're from honey-producing  
21 hives. So, NASS has collected data over the years, is  
22 tasked with collecting the data over the years about the

1 number of hives that are used to produce honey.

2 DR. KEGLEY: So, it's only commercial bees?

3 DR. PURCELL: It's just commercial bees, yes.

4 MR. BRADY: Then, Jennifer Sass on the phone.

5 DR. SASS: Thank you. Can you hear me?

6 MR. BRADY: Go ahead.

7 DR. SASS: Well, first of all, thank you for  
8 the very informative presentation. You covered a lot of  
9 information and also a lot of time. But I know you guys  
10 have been working on this issue. So, thank you.

11 I have one clarifying question and then one  
12 sort of more deeper question. The clarifying question  
13 is, is it true -- the way I understand it is once you  
14 determine that a pesticide is actually toxic or highly  
15 toxic or hazardous or whatever to honeybees, you don't  
16 actually regulate it differently.

17 The only thing it triggers is a bee caution  
18 statement on the pesticide. Is that right? You can't  
19 actually change the way the pesticide is used or cancel  
20 certain tolerances or uses knowing that information.

21 Then, my second question is, I'm really glad  
22 you guys are putting together a reporting database. I

1 want to ask if that's going to be a national reporting  
2 database and if it's going to be publicly accessible and  
3 searchable so that someone like me could go in and see  
4 how many reports there might have been associated with a  
5 particular exposure or set of circumstances?

6 MR. SEEGER: In response to your first question  
7 regarding the type of language that makes it on the  
8 label, we indicated the battery of tests that are used to  
9 look at the hazards that are associated with pesticides  
10 is used to inform the hazard statements on labels.

11 There can be, depending on what is available  
12 from a weight of evidence approach in terms of open  
13 literature and our toxicity studies that would include  
14 not only the laboratory studies but field pollinator  
15 studies as well, additional label language may be  
16 captured indicating potential risks to bees and  
17 mitigation to reduce those risks.

18 Regarding the question on the NPIC, I'm not  
19 familiar enough to know whether the NPIC results can be  
20 accessed. It's currently operated by a contractor. In  
21 this case, it would be Oregon State. But the  
22 accessibility of the data for analysis outside of the

1 operator, I'm not familiar enough with it.

2 MS. MONELL: Let me jump in here. It's Marty  
3 Monell. Part of our plan, if you recall, where we're  
4 dealing with the handling of incident reports  
5 holistically -- and part of the plan is to improve our  
6 reporting database so that we will have all of the  
7 incidents, human health, eco, and including the bee  
8 incidents reported funneled into our internal system --  
9 ultimately, the plan is to have it available and  
10 searchable by the public.

11 So, it's a project in the works. We're not  
12 there yet, but that is the ultimate goal. Oh, gee,  
13 probably a year. It's resource dependent on a major IT  
14 project. So, those things take some time to develop the  
15 requirement, build it and then build the pieces that  
16 allow the external information to be fed into it. So,  
17 it's a good year.

18 DR. SASS: Thank you very much. I appreciate  
19 that.

20 MR. BRADY: We're very close to the end of our  
21 time limit, so I think what we'll do is -- Susan, did you  
22 have another set of questions?

1 DR. KEGLEY: Yes.

2 MR. BRADY: Wait. I was just clarifying  
3 whether or not your card was still up. I think we can  
4 take the ones that are up, so I see Jay, Susan, Mark and  
5 Lori. Then I think we're going to have to cut it off  
6 there for time reasons, but we can look for ways outside  
7 of the meeting, either through a teleconference or a  
8 webinar, to get at some of the other issues that have  
9 been coming up and circle back to the charge questions  
10 that we had.

11 So, why don't we -- Jay?

12 MR. VROOM: Thanks a lot. My guess is there's  
13 not time or available information to get into this, but I  
14 think it would be helpful for us in another setting to  
15 have a greater dialogue about Mary's third slide, the  
16 chart that Susan was asking about, the managed bee  
17 colonies. It's my understanding that many, if not most,  
18 of the colonies that are managed for pollination don't  
19 harvest much honey. So, I think we need to drill into a  
20 greater understanding of what's the available data, et  
21 cetera, but probably not for today.

22 Mary, I would just make a completely unrelated

1 plea. That is, the fifth slide that you showed which has  
2 the two photographs of a pesticide application and  
3 habitat destruction -- and the pesticide application is  
4 labeled pesticides and large scale agriculture. The  
5 accompanying photograph is a couple of people in a golf  
6 cart or an ATV spraying out of the passenger seat.

7 My guess is that that's a worker protection  
8 safety violation. So, I'd make that picture go away and  
9 find the people that were doing that. If they're USDA  
10 employees, then fix that. Thank you.

11 MR. BRADY: Okay. Let me go to the other side,  
12 Susan, and then I'll come back. Mark.

13 DR. WHALON: Thanks. A couple comments. From  
14 an ecological sustainability point of view, importing a  
15 species, propagating that species, and then becoming  
16 absolutely reliant on a foreign species to pollinate  
17 native as well as imported plants is probably  
18 ecologically speaking the height of (inaudible).

19 So, one of the things that is happening, at  
20 least in Michigan, is that we're trying to diversify our  
21 reliance on native pollinators and we know that there are  
22 a lot of problems in the genetic inbreeding, et cetera,

1 with domestic bees, parasite diseases, and things that we  
2 went over today.

3           When we look at native pollinators, there's a  
4 real challenge there because they're known but they're  
5 known obliquely, hardly known at all, hardly manipulated  
6 at all. So, an integrated approach to pollination is, I  
7 think, the future of pollination. We need some kind of  
8 focus on that.

9           We have an NRCS supported trial in Michigan  
10 that has a subscription up to 5,000 acres. It's designed  
11 to go with deciduous tree fruits. The whole approach is  
12 a companion planting approach. Historically, in  
13 orchards, you try to eliminate all pollinating plants in  
14 the ground cover and in the surrounding area so that you  
15 wouldn't have competition with bees to pollinate the  
16 crops. That may be an erroneous way of approaching  
17 pollination today, especially if you want to integrate  
18 native pollinators.

19           So, our approach has been to design a series of  
20 native plants that provide pollen and nectar reward at  
21 times that the deciduous tree groups are not in need of  
22 pollination. So, essentially, you feed them early and

1 you feed them after pollination but not during  
2 pollination, and you do companion planting.

3           It seems like a logical idea. We've done quite  
4 a few studies on what natives are available and what  
5 natives work, apples, cherries, peaches, plums, et  
6 cetera. There's an array of them. We don't know very  
7 much about a lot of them. So, the challenge is much the  
8 same way as integrated pest management.

9           I believe we should have an integrated  
10 pollination management system that tries to exploit  
11 native plants to feed native pollinators so that we can  
12 augment our weak European sister bees that we imported  
13 years ago with native bees.

14           So, the problem with this whole approach is  
15 NRCS, we got this through NRCS but the evaluation piece  
16 of it, does it work or not, is not funded. So, it's kind  
17 of typical of the way NRCS does things. They will fund a  
18 project to get it on the land, but they won't fund the  
19 companion evaluation stuff. So, we're trying to limp  
20 along and get that evaluated.

21           But it's a novel approach and it reflects what  
22 can be done in systems like tree (inaudible).

1 MR. BRADY: Lori.

2 DR. BERGER: I've just got a few points I'd  
3 like to make here. First to answer Susan's question  
4 about best management practices, those are being  
5 developed now. There's a big project in California. I  
6 know that the pollinator question and issue oftentimes  
7 does tend to be California centric because we have so  
8 many nut crops and tree fruit crops that are dependent  
9 upon this issue.

10 I can say, representing an organization that  
11 includes both growers as well as beekeepers, that these  
12 issues are very very important and we really need and  
13 request, as you guys develop all of this information,  
14 increased outreach at increasing intervals of time  
15 because it sounds like there's a lot of information being  
16 generated and people at many levels are extremely hungry  
17 for it, both from pollinator protection and crop  
18 protection.

19 We've had a very (inaudible) product that's  
20 been implicated in pollinator demise. I can guarantee  
21 you that growers and pest control advisors and beekeepers  
22 are all interested in drilling down into the real science

1 of this issue. So, increased outreach on your expanded  
2 research components. Webinars are a great way to meet  
3 with a diversity of people.

4 Also, question, is the NAS support as listed at  
5 200,000, is that enough support to be monitoring the real  
6 picture with bee health? So, that's a concern.

7 And, let's see, something that Mark was just  
8 referring to, the NRCS support, as you all move through  
9 the process in learning practices and so forth, if you  
10 could increase the interaction with NRCS to get some of  
11 this information out into the field and practices, that  
12 would be very helpful. It does seem like that program  
13 has a lot of resource that could benefit pollinators and  
14 growers.

15 Finally, I just want to say that this is a  
16 really important issue. I was disappointed, even this  
17 morning, talking to one of my colleagues on the PPDC.  
18 There's really not recognition a lot of times for the  
19 importance of pollinators, not just to fruit and nut  
20 crops but to seed crops and to forage crops.

21 So, I think just your ongoing messages on the  
22 importance of pollinators to agriculture and the

1 environment are needed and important.

2 DR. PURCELL: I just wanted to respond to your  
3 comment about the NAS report of \$200,000. That was  
4 funding that was provided by ARS to do the National  
5 Academy of Sciences report, not to be confused with the  
6 National Agricultural Statistics Survey.

7 DR. BERGER: Right. One of the things that we  
8 discussed in this committee is that report not having  
9 funding. That provides very important information for  
10 all of agriculture and environmental concerns. So, when  
11 I saw that number, it was a little bit of a red flag in  
12 reference to other discussions we've had about our  
13 concerns about that database.

14 MR. BRADY: Susan.

15 DR. KEGLEY: Pollinators, like many others,  
16 have been on our agenda for the PPDC meetings for several  
17 meetings now in the past. There is certainly a need for  
18 collecting more data, knowing more. We just don't know  
19 what's going on here exactly, it seems.

20 But I guess I'm wondering how far do  
21 populations have to decline before we call it an  
22 emergency and start to actually take action of -- make

1 our best guesses and take action rather than continuing  
2 to study it for year after year after year.

3 MR. BRADY: Nice way to end the conversation,  
4 Susan, in terms of some of the challenges. Clearly, I'm  
5 not going to give you the answer because I don't have the  
6 answer.

7 I think, because we've talked about the  
8 numerous stresses that are out there, everything from  
9 nutrition to habitat quality to the pesticide role, what  
10 I'd like to do as we wrap up this session is I've got two  
11 thoughts as I've heard the conversation.

12 One thought I have is that we and our  
13 colleagues in USDA need to do a better job of  
14 communicating what we're doing, what we're not doing, and  
15 making sure we've got incoming information, which was the  
16 idea behind the charge questions. But the fact that  
17 there were so many clarifying questions I think  
18 reinforces why I wanted to have some discussion about how  
19 information is flowing in and out of the Federal  
20 Government.

21 So, with that in mind, think about these ideas  
22 as we get to the last part of the morning when we talk

1 about actions for the future. One thought I have is  
2 through the PPDC setting up a webinar, telephone  
3 conference, or something with the pollinator protection  
4 team and the USDA colleagues and spend some detailed time  
5 exploring where we are in getting the word out, where we  
6 are in having -- a good receiving mode to get in  
7 information and give us some feedback. Then we can  
8 report that out in the fall so everybody knows what's  
9 going on, and/or thinking about what we might want to do  
10 in the fall.

11 So, I think we need to tackle the communication  
12 issue. We scrape the surface and just reinforce the  
13 challenge I think we have. So, think about something we  
14 might do in the course of the summer through the PPDC to  
15 get that feedback for us.

16 Now, I'd like to stop this session and move on  
17 to our next session. I know we had a break for 10  
18 minutes, but we've only been sitting down for about an  
19 hour. So, I know you had your card up but I'm kind of  
20 doing a little bit of a Roberts Rule and we've got to cut  
21 off the conversation. Maybe we can catch up during the  
22 break and loop it back into the system.

1           Okay, go ahead, real quick.

2           UNIDENTIFIED MALE: Just to clarify, NRCS is  
3   developing a 799 monitoring evaluation standard that  
4   might be very appropriate. Now would be the time to get  
5   with them to make sure that that's incorporated next  
6   year.

7           MR. BRADY: Thanks. Okay, so let's move on to  
8   the next session which will be a report out of our new  
9   work group on public health pesticides and issues. Lois,  
10   thanks.

11          MS. ROSSI: I'm going to give an update on some  
12   public health initiatives. Then, also, on Wednesday  
13   afternoon we had the first meeting of the public health  
14   work group, PPDC public health work group, which was set  
15   up and blessed by this group at the last PPDC meeting.

16          Basically, I'm going to cover some background  
17   in public health initiatives at OPP, some current and  
18   recent public health projects, some collaboration that  
19   we're doing with other federal agencies. Then, last but  
20   not least, to give the results, a report out of the work  
21   group meeting we had and next steps for that.

22          By the way, sitting to my immediate left is our

1 OPP public health coordinator, Susan Jennings.

2 Very brief, as many of you know, in 1996, FTPA  
3 required EPA to develop a list of pests of public health  
4 significance, which we accomplished, and also to consult  
5 with HHS and the Center for Disease Control before taking  
6 any regulatory action on any public health pesticides.

7 By law, the law requires that public health  
8 pesticides are registered according to the same safety  
9 standards as agricultural pesticides. This is the one  
10 set of products that efficacy data is required for  
11 products used to control pests of public health concern.  
12 We also can take into consideration the benefits of the  
13 pesticide in controlling of public health pests before  
14 taking any regulatory action.

15 In dealing with the benefits, it can be quite  
16 an extensive process. A lot of consultation is routinely  
17 done with our federal partners and user communities. We  
18 definitely look at the availability of alternatives and  
19 looking also of whether any replacements in these  
20 alternatives is of concern.

21 CDC is the primary contact that we use to get  
22 information, but other sources are frequently used and we

1     involve our own biological and economic analysis  
2     division. Many of the projects, and you'll see it in a  
3     couple of slides, do not necessarily arise from risk  
4     concerns, but they focus on improving the use of these  
5     pesticides to maximize the public health benefits.

6             They tend to focus on application and  
7     encouraging appropriate use to improve exposure,  
8     obviously the pest control with IPM and efficacy and  
9     communicating and clarifying a lot of the policy issues  
10    and guidelines that we have for efficacy review, for  
11    example.

12            Some of these projects have a lot of components  
13    to them, namely, education and outreach, regulatory  
14    improvements, scientific updates, and label improvement.  
15    I think potentially more than any other of our group of  
16    projects, the collaboration is a very key factor in all  
17    of these public health projects.

18            Some examples of application specific projects  
19    include our currently ongoing repellent strategy,  
20    mosquito adulticidal initiatives including blanket  
21    tolerances and labeling for mosquito adulticides, the  
22    foggers initiative, and misting systems.

1           Some of our pest-specific projects to encourage  
2 appropriate pest control to improve public health include  
3 our extensive right now and very focused bed bug  
4 initiative, our PESP outreach and IPM projects,  
5 communicating the efficacy and the product performance  
6 rules, regulating prions and, of course, the rodenticides  
7 risk mitigation project.

8           Collaborating with federal partners, Susan  
9 actually has been very much involved in not only  
10 participating in the public health pesticide consortium  
11 but contributing a lot of energy to it. It's a common  
12 forum for federal agencies with different missions that  
13 are involved with public health.

14           There's a lot of acronyms there. But it's  
15 representatives from the Center for Disease Control, CDC,  
16 Department of Defense, DoD, EPA, HUD, Housing and Urban  
17 Development, NIH, National Institute of Health, USAID,  
18 USDA, the Agricultural Research Service, the IR-4  
19 program.

20           This forum has been a very productive venue for  
21 partners to discuss problems and look at common  
22 approaches to solving these problems and just

1 coordinating the federal effort on public health disease  
2 control.

3 All of those federal agencies are definitely  
4 involved in public health. Many are involved in the  
5 pesticide use overseas. I think it's pretty obvious to  
6 say the impact of infectious diseases on people's lives  
7 and resources and that new diseases can spread very  
8 quickly, as we saw last year with the H1N1. Of course,  
9 we are currently engaged in working with DoD for their  
10 unique needs for protecting the troops serving overseas  
11 and the pesticides, the pests that need to be controlled  
12 and what's available to control them.

13 We also expanded recently our international  
14 work on public health to sort of parallel the work that  
15 we've done in agricultural international coordination. I  
16 think EPA, as definitely a leader in the regulation of  
17 pesticides, has a key role to play in this. Last year we  
18 had two workshops that were focused on looking at ways to  
19 increase the accessibility and encourage development of  
20 newer public health pesticides both here and for use in  
21 other nations.

22 I think we've had very successful harmonization

1 and global joint review processes for the agricultural  
2 chemicals. I think the work done there can jump start  
3 the work on public health pesticides and not reinvent the  
4 wheel in many of the building blocks that we used and had  
5 to develop over the course of 15 years in global joint  
6 reviews. Certainly, that work can be applied to this and  
7 not concentrate on that, although there are other issues,  
8 obviously, unique issues, that public health pesticides  
9 bring to the table.

10 With those two workshops we did last year, we  
11 worked with WHO and the WHO pesticide evaluation group  
12 there and the secretary of the Stockholm convention whose  
13 main objective certainly is to find alternatives to DDT.  
14 So, we have been including them in a lot of our work. We  
15 look forward to working with them as they develop a  
16 framework in which we can play some role.

17 I think the results of the both workshops  
18 agreed that the harmonization of requirements for public  
19 health pesticides and coordination of reviews could  
20 potentially lead to a greater availability of tools to  
21 the user community and certainly save resources and make  
22 potentially the development of a public health pesticide

1 easier and more profitable for the industry so that we  
2 would have some newer potentially safer tools.

3           The public health workgroup under the pesticide  
4 program dialogue committee, it will provide us with a  
5 forum with some specialized skills that would allow us to  
6 come to stakeholders to seek guidance and advice on some  
7 of our initiatives not only in creating some of the  
8 initiatives, but once the initiatives get going, some  
9 advice on pathways forward. Some of these public health  
10 problems really present quite a challenge to all people  
11 involved. It will assist in the collaboration.

12           The purpose of the work group was to focus on  
13 issues specific to pesticides use to control pests of  
14 public health significance. We see that the issues may  
15 be regulatory, policy, programmatic. It can be a full  
16 range of things, as I think you'll see when I give the  
17 report.

18           We thought that having a work group that we  
19 presented I think at the last PPDC meeting, we thought  
20 that having a work group would be more efficient and  
21 effective. We could get participation from a broader  
22 group of public health stakeholders who we may not

1 normally deal with on a regular basis for most of the  
2 work we do, and increase representation of public health  
3 departments, communities. We did have some  
4 representation from communities and the environmental  
5 justice organizations and also proponents of children's  
6 health.

7           So, the work group will be ongoing. We'll  
8 probably meet regularly mostly by teleconference,  
9 although we probably will have -- and I'll get to that in  
10 a second -- a kick off session. Then, of course, we  
11 would take recommendations through the PPDC.

12           As I said, the kickoff meeting was held this  
13 past Wednesday afternoon. We presented our overview of  
14 public health activities. The public health activities  
15 pretty much involves most divisions in OPP and certainly  
16 impacts a lot of our regulatory decisions. The meeting  
17 was very well attended and we did have quite a cross  
18 section of representatives at the meeting.

19           We discussed areas of interest and priorities.  
20 The bed bug initiative was definitely surfaced to the  
21 top, which is an issue that a lot of people not only in  
22 this country but in the world are struggling with these

1 days. Of course, the concerns and the challenges are the  
2 lack of tools, the potential for misuse of existing  
3 pesticides, the need for education and outreach so that  
4 people who have this problem have a place to go to get  
5 good information. Then we also talked about further  
6 education on the OPP process for determining public  
7 health benefits.

8 Other areas we talked about was the 25(b) and  
9 public health pesticides. The workgroup expressed  
10 concern about projects that are proliferating during  
11 times of pest and disease pressure that may not work,  
12 that may not be efficacious. We talked about also the  
13 international efforts towards the global harmonization  
14 for public health registrations. The work group  
15 suggested that it could offer some help to locate some  
16 potential pilot projects that we could take forward.

17 Further, efficacy and communication for the  
18 products, developing a performance measure for public  
19 health, which is something we've talked about internally  
20 for many years now. This work group, I think, could  
21 provide some very valuable input into getting to a  
22 performance measure for public health.

1           There were concerns expressed about the new  
2 NPDES permitting process and its effect on the use of  
3 pesticides to control public health pests, vector borne  
4 pests. Coordination with EPA about an urban IPM, the  
5 misting systems and resistance concerns. I think that  
6 pretty much summarizes the main issues that people did in  
7 a little brainstorming session we had.

8           The work group is eager to work on these  
9 issues, provide advice and recommendation. We will  
10 develop a paper on the activities that were suggested.  
11 The bed bugs is very likely to be one of the first things  
12 we address. It was suggested that we try and have a one-  
13 day session in late June to put some concentrated effort  
14 into kicking off the initiative.

15           That's it. Thank you.

16           MR. BRADBURY: We'll take some questions.  
17 Dave.

18           MR. TAMAYO: At this point, can we do more than  
19 clarifying questions?

20           MR. BRADBURY: Sure. We can explore a bit.  
21 And then Amy.

22           MR. TAMAYO: Well, I've got a couple of hats

1 here. I'm on the board of our local mosquito and vector  
2 control district and then also I'm speaking from the  
3 stormwater quality perspective. One thing that I didn't  
4 really see up there is really sort of preserving the use  
5 of public health pesticides.

6 One of the things that we see, at least in the  
7 Sacramento area, is that there's a conflict between other  
8 urban uses of various pesticides and with the public  
9 health pesticides that are available. That happens in a  
10 couple of ways.

11 One is, I think because there's very extensive  
12 use of pyrethroids in the urban areas, that that's not  
13 really taken into account in resistance management. The  
14 district can do its own resistance management but you  
15 can't really do that in a vacuum. Because there's such  
16 extensive use of pyrethroids, for instance, in urban  
17 areas, at least in California, I think there's an  
18 expectation that that's going to lead to early  
19 development of resistance to pyrethroids.

20 We don't use pyrethroids at this point, but I  
21 think what we do use is pyrethrins. The mosquito  
22 district uses pyrethrins. I would suspect that there may

1 be some resistance crossover. Forgive me if I'm wrong on  
2 that, but I'm guessing that there's a very good potential  
3 for that.

4           So, I think I would expect that that's  
5 something that really needs to be looked at. How does  
6 the registration of pesticides in general throughout the  
7 country, how does that affect the ability to maintain or  
8 to reduce resistance or development of resistance for  
9 public health pesticides. I think a lot of the uses of  
10 these pesticides are basically either unnecessary or  
11 frivolous. I'm talking about some of the urban uses.

12           There really needs to be a look at how those  
13 certain uses are being allowed that really aren't that  
14 necessary and that will take tools out of the hands of  
15 the public health professionals where I think that's a  
16 higher use than certain other uses.

17           So, the other way that we've seen an impact is  
18 from -- there's ongoing toxicity in urban waterways.  
19 That's actually affected the ability -- you can even see  
20 it. We've created 303(d) listings under the Clean Water  
21 Act. So, those are impaired water bodies that now those  
22 types of water bodies, if the mosquito district needs to

1 do a public health application, they're not going to be  
2 able to get the general permit coverage.

3 Now, that may not be the case in California,  
4 but in the other parts of the country, if there's an  
5 existing impairment that's caused by other types of uses,  
6 then that takes, once again, a tool out of the hand or it  
7 makes it much more difficult to use those pesticides for  
8 public health because there's already an impairment  
9 either through synergists -- and there's also an observed  
10 problem with a synergist because there was already  
11 toxicity or there were already toxic levels of pesticides  
12 in the sediments in the creek.

13 A very small amount of synergists that was  
14 applied by our district actually caused the existing  
15 pollution in the sediments to become toxic. That's yet  
16 another way. So, that sort of interaction between very  
17 different types of uses that are in the same geographic  
18 area, I think that's something that needs to be looked  
19 at. I think in general, EPA needs to be able to look at  
20 the whole system rather than just use by use and chemical  
21 by chemical. Otherwise, you're going to run into  
22 conflicts like that.

1           MR. BRADBURY: Thanks, David, for the comments.  
2     Amy.

3           MS. LIEBMAN: Thank you for explaining what the  
4     public health work group was going to do. That was  
5     really interesting.

6           I'm just curious, given -- when we started off  
7     our PPDC meeting yesterday, we sort of heard about the  
8     administrator's priorities. I see that there's a very  
9     broad group of stakeholders involved in the committee.  
10    That's great. But what I'm not seeing, and maybe you can  
11    speak to this, is when we look at public health use of  
12    pesticides, where is the analysis or where is the input  
13    or concern for forebordable populations?

14           Let's take the example of substandard housing.  
15    You have poor low income people living in substandard  
16    housing. There's a lot of vector issues. There's an  
17    extensive use of pesticides to try and control that. So,  
18    I would love for you guys to address that and make sure  
19    that when you're looking at more efficient use of  
20    pesticides, regulatory issues, your outreach and  
21    education, that that rises to the top in terms of exposed  
22    populations that might be more vulnerable in your public

1 health effort.

2 MR. BRADBURY: Thanks, Amy. Let's see,  
3 Carolyn, Mark and then Pat. Pat, do you have yours up?  
4 Okay. We'll take those three and then we'll check the  
5 clock and see how we're doing.

6 MS. BRICKEY: I think the comments that both  
7 Dave and Amy made really bring out for me the importance  
8 of looking at public health pest management as pest  
9 management and not just focusing on the use of chemicals  
10 for public health pest management but also looking at all  
11 the innovative practices that have been developed to  
12 manage public health pests without or with reduced  
13 chemical use.

14 I really hope this work group can figure out  
15 what steps EPA can take to make sure that those pest  
16 management practices are developed and widely implemented  
17 and are as successful as they can be.

18 MR. BRADBURY: Mark.

19 DR. WHALON: Thank, Lois. Great presentation.  
20 Great summation from our meeting on Wednesday. I think  
21 it's also nice that we have the work group. I think it's  
22 long been needed.

1           My comment is more of a request than anything  
2 else. As you captured, we talked a lot about bed bugs.  
3 I don't want to minimize the importance of bed bugs or  
4 the rising importance of bed bugs, but we shouldn't lose  
5 focus on vector borne diseases.

6           There's another hot topic, dingo fever, also  
7 known as breakbone fever. It's named breakbone for a  
8 reason. Last year, there were 22 cases in Key West.  
9 Just last week there was another case, first case for  
10 this year. CDC just put out a health advisory this week  
11 talking about relief workers coming back from Haiti.  
12 Look out. And your differential diagnostic doctors for  
13 dingo. That is a rising issue.

14           We need to ensure that our professionals that  
15 are responsible for either controlling disease outbreaks  
16 or maintaining the minimal risk of vector borne diseases  
17 in general, that they have their adequate tools to be  
18 able to do their job and then taking into resistance as  
19 well. I think that's a very important point.

20           MR. BRADBURY: Thank you. Pat.

21           MR. DONNELLY: Thanks for taking on this topic  
22 and getting the work group up. I think it's really

1       incredibly important that that take place.

2               Lois, I was curious. I know you've been doing  
3 a lot of work and discussion with CDC and even DoD. Are  
4 they participating on the work group as well? Great.  
5 I'm glad to hear that.

6               Just to align some comments with Mark, I hope  
7 that the work group does spend time dealing with not only  
8 sort of the existing problems right in front of us but  
9 sort of the future and emerging problems. I mean, we  
10 certainly can predict that if all the modelers are  
11 correct about climate change that we're going to see,  
12 increasing disease pressure from south to north, we're  
13 going to need to be prepared to deal with that.

14              So, I think taking the time to do some  
15 forecasting and scenario planning and understanding the  
16 what if scenarios, what if dingy really takes hold and  
17 moves quickly up north, are we prepared to deal with  
18 that? Do we have the tools? What are the regulatory  
19 constraints to make decisions and putting stuff out there  
20 that we need to deal with.

21              You may go so far into it thinking about what  
22 are deliverables from this work group. What most

1 companies have to do is emergency planning guides. So,  
2 they do the disaster scenario planning and then they sort  
3 of think through, if this happened, what would be our  
4 steps. They lay them out directly.

5 So, when stuff happens, they can read a book  
6 and say these are the authorities I have to do this  
7 under, this is what I need to do. Lay it out so all the  
8 future generations and all the people can sort of  
9 understand what the process is. That may be something  
10 that's warranted given the severity and seriousness of  
11 public health disease problems.

12 MR. BRADBURY: Bob and then Dave.

13 BOB: Is it all right to make a gratuitous  
14 self-serving comment? Everyone else does.

15 I just wanted to say, having been here for a  
16 long time -- and I understand the importance of  
17 agriculture. Yet, public health has always been a little  
18 bit of a back water. It's understandable. I just wanted  
19 to say that I appreciate the agency committing resources  
20 and shining light on something that's very important to a  
21 lot of us. That's all I wanted to say.

22 MR. BRADBURY: David, and that will be our

1 last.

2 MR. TAMAYO: I wanted to add that I appreciate  
3 that there's a recognition of the need to coordinate this  
4 effort with the NPDES. I realize that it may have met  
5 more coordinating with the NPDES aquatic pesticide permit  
6 stuff. I also think looking at the needs of the MS-4 and  
7 PDS permit holders and the potential impact of public  
8 health pesticides on our discharges -- and I already  
9 touched on that. I think if we remove some of the  
10 existing problems that public health pesticides are  
11 likely to be a lesser impact but they still could have an  
12 impact.

13 One of the things that we would greatly  
14 encourage is that EPA be involved in not just the  
15 chemical aspects of it but really supporting the  
16 development of a more integrated vector management  
17 program. I know that some districts are really great at  
18 it and some of them need some assistance. I think that  
19 the chemical part of it needs to be done as part of a  
20 broader program. Thank you.

21 MR. BRADBURY: Thanks. Lois, any closing  
22 comments?

1           MS. ROSSI: Just one thing that we didn't  
2 mention. We were able to get some funding and the  
3 request for proposal should go out very shortly. That is  
4 directed to developing educational materials particularly  
5 for EJ communities and addressing bed bugs. So, I just  
6 wanted to let everybody know that that request for  
7 proposals will be going out shortly.

8           MR. BRADBURY: Thanks, Lois, Susan, and members  
9 of the work group. I think it's a good effort that we've  
10 got started.

11           The next agenda item is an update on the  
12 endocrine disruptor screening program. Let me check in.  
13 Do people just need to stand up and stretch or sort of  
14 take a break on the slide. Is that working okay? Keep  
15 going. Take a break if you need it. Let's go that  
16 route, then.

17           So, Rick Keigwin and Karen Whitby are going to  
18 come up and give you a snapshot of sort of where we are  
19 in implementing the program and sort of manage the time  
20 so we can at least do a few clarifying questions.

21           We better not get into a debate about some of  
22 the science and other issues associated with the program,

1 but we certainly can clarify any questions about the  
2 processes that we're in right now.

3 I'll turn it over to Rick.

4 MR. KEIGWIN: I'll be joined by Dr. Karen  
5 Whitby to help with this presentation. We thought we  
6 would give you all a quick update on where we are with  
7 the endocrine disruptor screening program, focusing more  
8 on the process and much less so on the science that's  
9 developed to get us to this point.

10 Just by means of refresher, as part of the Food  
11 Quality Protection Act of 1996, we were directed by  
12 congress to develop a screening program to identify  
13 chemicals that may have estrogenic effects in humans, and  
14 that we were to test all pesticide chemicals. The  
15 statute also provided us with the authority to go beyond  
16 estrogen to look at other endocrine effects.

17 About the same time, congress also passed  
18 amendments to the Safe Drinking Water Act that also  
19 provided for testing of chemical substances found in  
20 drinking water, provided that a substantial human  
21 population may be exposed to the substance.

22 As we've gone about developing and validating

1 various screening assays, we've focused on two tiers of  
2 studies. Tier 1, which is the focus of the orders that  
3 went out starting late last year looking at in vitro and  
4 in vivo screens, focus exclusively on trying to determine  
5 whether there's a potential for that particular substance  
6 to interact with the endocrine system. Whereas, the Tier  
7 2 studies, which we would subsequently call in through a  
8 test order process, would focus on providing data for  
9 (inaudible) response and hazard assessment.

10 I think in the past you received an update.  
11 There are basically five in vitro assays and six in vivo  
12 assays that are subject to this initial tier 1 screening  
13 battery. Those are listed here. I'll leave it to Karen  
14 to actually pronounce some of those names because I  
15 can't. Then, some of the tier 2 studies that had been  
16 validated are here. You'll see at least one of those is  
17 a core 158 data requirement instead of mammalian two gen.

18 So, 2009 was a rather busy year for us in OCSPP  
19 getting the endocrine program ready to launch. In April  
20 of last year, we issued the final list of 67 chemicals  
21 after a fairly extensive public comment process. The  
22 list contains 58 pesticide active ingredients and 9 high

1 production volume inert ingredients. None of these  
2 chemicals were selected based upon their endocrine  
3 disruption potential, but reflected solely based upon  
4 what their exposure was, either through drinking water or  
5 food or residential.

6 At that same time, we also published the final  
7 policies and procedures that we'd be following for  
8 issuing the initial test orders and how we would be  
9 screening those responses. We completed the Information  
10 Collection Act request requirements under the Paperwork  
11 Reduction Act in the fall of 2009. We published the  
12 final batteries the following week. Then, we promptly  
13 started issuing test orders. For one person on my staff,  
14 this is all she has been doing for the past seven months.

15 So, to date we have issued a total of 757 test  
16 orders requiring all of the 11 assays across the 67  
17 chemicals. We issued the orders to the registrants for  
18 the pesticide actives and the known manufacturers and  
19 importers of the high production volume inert ingredient.  
20 The vast majority of the test orders actually were issued  
21 to manufacturers or suspected manufacturers of the nine  
22 inert ingredients.

1           The way it works is sort of similar to a data  
2 call in. In response to receiving the test order, the  
3 recipient has 90 days to let us know how they intend to  
4 respond to the order and if they are committing to do the  
5 studies or if they're joining a consortium. With the  
6 issuance of the initial test orders beginning in October,  
7 the first round of responses was due in early February.  
8 If they were responding individually or if they were  
9 responding as a consortium or they were intending to form  
10 a consortium, their responses were due in early April.

11           Then, subsequently, as they're progressing  
12 through developing the data, the test order recipient  
13 needs to provide us with a progress report at each one  
14 year interval. The orders themselves required the  
15 submission of the studies within 24 months of the  
16 issuance of the test order.

17           This is regardless of whether or not they  
18 submitted what we'll talk about in a few minutes, other  
19 scientifically relevant information and our progress in  
20 reviewing that information. Studies, as a result, are  
21 due beginning in late 2011 and then would go into 2012,  
22 depending on when the order was actually issued.

1           Order recipients had nine different options  
2           that they could choose in responding to the order. There  
3           were two options that were specific to inert ingredients  
4           only and three that were specific to pesticide active  
5           ingredients only. Basically, generate the data, site or  
6           submit existing data, form a consortia which then could  
7           result in either generating the data or citing existing  
8           data or claiming not to be subject to the order.

9           For pesticide active ingredients, an order  
10          recipient could also choose to voluntarily cancel their  
11          registration or to reformulate the product to exclude  
12          that chemical from the formulation or claim a formulated  
13          exemption, basically saying that they purchased the  
14          active ingredient from an already registered source.  
15          Then, for the inert ingredients, there were two other  
16          options. One was to discontinue the manufacture of those  
17          substances and/or commit to not sell that chemical for  
18          use in pesticide formulation.

19          As part of our policies and procedures, we  
20          provided for the ability to submit or cite existing data,  
21          along with a rationale as to how those data satisfy the  
22          order. This is what we call OSRI or other scientifically

1 relevant information. In a couple minutes, Karen will  
2 give us an update on where we are with the review of that  
3 type of information.

4           So, through the middle of the month, we have  
5 received responses for 24 pesticides. The heartening  
6 things in this is that a lot of consortia are being  
7 formed. To date, at least, many of the order recipients  
8 believe that a large of data that they had already  
9 submitted to the agency or may have generated on their  
10 own or they have found in public literature may satisfy a  
11 number of these testing requirements. The result likely  
12 could be significantly less testing, fewer animals being  
13 subjected to testing, and a much declined duplication of  
14 effort.

15           So, in terms of the total number of orders for  
16 the inert ingredients, there were 524 orders issued. A  
17 lot of these responses aren't yet due, so the numbers  
18 aren't going to completely add up yet. But for the inert  
19 ingredients, virtually everyone has either said that  
20 they're not subject to the order, meaning they haven't  
21 manufactured the substance in quite some time, they  
22 haven't imported the substance, or that they will be

1 committing to no longer sell that inert ingredient for  
2 use in pesticide formulation.

3 Then, for the pesticide active ingredients, we  
4 have had a total of six active ingredients or  
5 manufacturers of active ingredients. It indicates that  
6 they will be voluntarily cancelling that active  
7 ingredient. The six active ingredients are diselfaton,  
8 methamidifos, methidifion, methyl parathion, resimethrin,  
9 and propocor (phonetic).

10 Then, for some of the other active ingredients,  
11 individual registrants have indicated that they will be  
12 voluntarily cancelling their products. As I said, for  
13 every active ingredient that received an order for which  
14 there are multiple sources of that active ingredient,  
15 those registrants have been joining together in task  
16 forces.

17 I wanted to add here that just like with data  
18 call ins for the registrants, if they have questions  
19 about the process or how to conduct an assay or where we  
20 are with the review of their test order response, they  
21 should be contacting the chemical review manager.

22 About every week, if not every week, every

1 other week, we post an update on the test order responses  
2 on the endocrine disruptor screening program web site.  
3 We'll be including the names of the chemical review  
4 managers there as well for folks in the future.

5 With that, I'll turn things over to Karen.

6 MS. WHITBY: The agency will review the OSRI  
7 submission and cited existing data to confirm that the  
8 cited data support the rationale and that it is  
9 functionally equivalent to the tier 1 assay it is  
10 intended to replace. Test order recipients may also  
11 request that the agency consider an alternate test  
12 protocol or methodology for the conduct of the tier 1  
13 assay that will require a science review.

14 The goal of the agency is to develop and  
15 provide a consistent transparent and defensible responses  
16 to cite existing data and OSRI rationale submitted by the  
17 test order recipients and the public. Evaluations of  
18 OSRI will be performed on the chemical basis rather than  
19 on the basis of individual responses or submissions.

20 Questions on the conduct of the EDSP guideline  
21 studies or requests for approvals of alternate test  
22 protocols should be submitted in writing to the chemical

1 review manager and the pesticide reevaluation division.  
2 OSCPP scientists will review these requests and provide a  
3 written response. Evaluations of OSRI will be very  
4 challenging in light of the diversity of approaches that  
5 may be used, as well as the volume and frequency of the  
6 responses that we've received to date.

7 MR. KEIGWIN: So, our next steps with the  
8 current orders, we expect for the next several months  
9 they'll be continuing to receive responses and will be  
10 processing those. Our goal is to get the other  
11 scientific relevant information packages into the review  
12 process as quickly as possible so that we can get those  
13 through the process so that if companies do not have to  
14 initiate studies, we can alert them of that promptly.

15 One question that we've been getting is when  
16 registrants will start to learn about the fate of their  
17 OSRI submissions. Optimistically, we're looking at  
18 probably the end of the May or early June when those  
19 responses will start to come out. Our intention is to  
20 publish the agency's responses as well as what the order  
21 recipients submitted for everyone in the public to see so  
22 that all can learn from how the agency has responded to

1 the OSRI submissions.

2 One other pieces that we're working on is that  
3 as part of the agency's appropriations for 2010, congress  
4 has required the agency to issue orders for a second list  
5 of substances of no less than 100 chemicals and to begin  
6 to issue those orders by the end of October of this year.  
7 The appropriations language talks specifically about  
8 including water contaminants and that we are to issue 25  
9 orders, although we're interpreting that to be  
10 substances, per year for the chemicals that are on this  
11 list.

12 This list will likely be composed of substances  
13 that are either existing, drinking water standards,  
14 chemicals that are on the CPL-3 list that Pam Barr talked  
15 about yesterday, or chemicals that started registration  
16 review in 2007 and 2008.

17 We're working jointly with the Office of Water  
18 as well as our sister office, the Office of Pollution  
19 Prevention and Toxics, to develop a process. As I said,  
20 our goal is to meet the congressional mandate and to  
21 begin issuing orders later in 2010. We would expect that  
22 with the issuance of those orders, those data would start

1 to be received by the agency in late 2012 and into 2013.

2 So, I'll just end with a really helpful, I  
3 think, resource slide with a number of web sites to  
4 information on the program and where you can get regular  
5 updates as the order responses are progressing through  
6 the process. Thank you very much.

7 MR. BRADBURY: I'll take some questions.

8 MS. BRICKEY: As we all know, Rick, the  
9 legislation that authorized this program was passed in  
10 1996 and it's now 2010, last time I checked. So, give me  
11 some feeling about where this program is in the scheme of  
12 life. Given that it's been this long and this is where  
13 we are, give us some feel for that. Are we playing catch  
14 up in some significant way to make up all those years  
15 when this program just kind of drifted?

16 MR. KEIGWIN: Well, I think it's important that  
17 we have started to issue the orders. There was a  
18 process, a scientific-based process that we had to go  
19 through to develop these assays and get them to the point  
20 that they are. Did it take longer than people had  
21 anticipated? I think the answer is yes. But it's  
22 progressed to the point enough that we have enough

1 confidence in these studies that we could begin to issue  
2 the orders. So, we're at that point.

3 The plan had always been for us to integrate  
4 this into the registration review program. That's what  
5 we're starting to do, particularly with the second list  
6 that will come out, to begin to fold in the chemicals  
7 that are in registration review and then as we progress,  
8 there may have to be a little bit of catch up to progress  
9 this to align this with the other substances that are  
10 going through the registration review.

11 MS. BRICKEY: Could you say a little more about  
12 the catch up and when you talk about the integration of  
13 this into that program? Talk a little more about that.

14 MR. KEIGWIN: Sure. So, this initial set of  
15 orders that were issued only covered 67 chemicals. So,  
16 our clearance under the Paperwork Reduction Act only  
17 covers those 67 chemicals. The next list will cover  
18 probably a little over 100 chemicals. It has to include  
19 both pesticides and nonpesticides. Then we'll have to  
20 get a clearance for that.

21 So, we're beginning to integrate with  
22 registration review to bring the chemicals that went into

1 registration review in the first couple of years in. At  
2 some point, there will probably have to be a third  
3 clearance through the Office of Management and Budget to  
4 factor in the other chemicals. At some point, we'll get  
5 to a point where this is happening in real time.

6 MS. BRICKEY: I know this is not your  
7 department, but as far as registration goes, how is this  
8 process being integrated into registration?

9 MR. BRADBURY: Well, with the first 67 inert  
10 ingredients, that's our first entre into that aspect of  
11 the registration division. What we're looking at right  
12 now is focusing on the registration review program as  
13 that progresses.

14 When some of the information comes in -- I  
15 think that was in the OSRI topic that Karen Whitby talked  
16 about -- I think that will give us some insight as we  
17 take a look at information requirements as you move  
18 forward with the new products. Right now our focus is to  
19 try to take a look at the existing chemicals and get  
20 started, invest the science and the resources to get that  
21 moving forward.

22 Susan.

1           SUSAN: I just have a couple of questions,  
2 clarifying questions. You're going to publish your  
3 determination of the OSRI material, but are you going to  
4 put out for public review or even be able to look at what  
5 your weight of evidence approach is going to be for  
6 evaluating all that material?

7           MR. KEIGWIN: We'll be publishing what our  
8 responses are. As part of our responses, it will be  
9 going through our reasoning for why we reached the  
10 conclusions that we did.

11           SUSAN: I think that would be very helpful  
12 obviously for industry because it would make it easier  
13 for you to do your evaluation if we knew what it was you  
14 were putting the weights on. We could present the  
15 material better for you that way. So, if you do at some  
16 point generate something that would appear to be the  
17 weight of evidence that you use, that would really be  
18 very helpful.

19           Looking at the time line for when you want to  
20 get your next set of orders out at the end of the year  
21 and sort of backing up through what that means for  
22 documents that are out for public comment and draft,

1       whatever, obviously, one of the things that comes to mind  
2       is the ICR for the first round of chemicals.

3               There was a fairly tightly written terms of  
4       clearance associated with the approval for that first  
5       ICR, including that a second ICR couldn't be approved  
6       until some questions that OMB had were answered. It's  
7       based on this, how are you evaluating other  
8       scientifically relevant information such that, for this  
9       question of yes or no, that these assays are pretty much  
10      telling you, do you have data already sufficiently  
11      available to do that.

12              Of course, part of that process then informs  
13      your next ICR whether or not it's mandatory doing all 11  
14      assays or in fact you now would have a process for saying  
15      here's the other scientifically relevant information or  
16      here are other tests that give us the same information we  
17      need to make the appropriate decision on whether or not  
18      you do or do not have the potential to interact  
19      (inaudible).

20              So, I guess my question is, how are you  
21      intending to meet the terms of clearance when you won't  
22      have gone through all of the OSRI compared to all of the

1 data that you'll be getting in that's generated, which  
2 obviously there's much more OSRI being submitted than  
3 there are people looking to generate the tests. So, how  
4 are you going to respond to that?

5 MR. KEIGWIN: Well, obviously, we have a little  
6 bit of a competing mandate. We've got a directive from  
7 congress that says you shall do this as part of our 2010  
8 appropriations language. Then we have the terms of  
9 clearance for the information collection request that  
10 says as part of either renewal or a new ICR, you need to  
11 report back on your experiences to date on reviewing  
12 OSRI.

13 Our plan is that as we gain experience with  
14 developing responses to the OSRI, we would integrate what  
15 we've learned to date and fold that into the ICR. These  
16 will progress through. I don't think the terms of  
17 clearance say you have to have reviewed all of the OSRI  
18 that's come in for all 67 chemicals before you go  
19 forward. I think it says tell us what your experience  
20 has been to date and include that in your report to us.

21 SUSAN: So, you're not going to write a report,  
22 then. You're just going to -- your response to the

1 writing report part that's written in the terms of  
2 clearance would be what you put in your next draft ICR.

3 MR. BRADBURY: I think, Susan, you raised and  
4 Rick summed it up, the beauty of our government. We have  
5 the executive branch and the legislative branch working  
6 through some issues. One of our challenges will be to  
7 work through these perspectives that the two parts of the  
8 government have raised for us. We've got to thread the  
9 needle to provide the information OMB is interested in  
10 but also the responses to the legislative branch that's  
11 handling our appropriations.

12 Kristie and then Scott. And then, after  
13 Patrick, that will be the last person.

14 MS. SULLIVAN: First, I wanted to ask a  
15 clarifying question on slide 15 where it talks about the  
16 orders. It says 100 chemicals by the end of this year.  
17 Does that mean then after that 25 substances per year?  
18 I'm a little confused about that.

19 MR. KEIGWIN: Well, we have a little bit of  
20 confusion, too. This is the congressional language,  
21 though. The congressional language says that you develop  
22 a second list of chemicals to be tested through the

1 program and it needs to contain at least 100 chemicals.  
2 Then it goes on to say that -- which we don't have on the  
3 slide -- that it has to include things beyond pesticides,  
4 so other water contaminants, substances that may be in  
5 personal care products, and the like.

6 Then it says once you've developed that list,  
7 the appropriations language says then for each of the  
8 next several years, issue 25 orders. Well, as you've  
9 seen, for 67 chemicals, we've issued 757 orders. So, we  
10 really don't think that what congress intended was 25  
11 orders per year. We think for a list of 100 chemicals,  
12 that it would be at least 25 chemicals per year.

13 MS. SULLIVAN: So, it actually requires EPA to  
14 develop a list of 100 chemicals.

15 MR. KEIGWIN: Right.

16 MS. SULLIVAN: Okay, because the slide says  
17 issue orders.

18 MR. KEIGWIN: Yes. We first develop a list and  
19 then we issue orders.

20 MS. SULLIVAN: Okay, got it. Actually, I think  
21 part of the discussion was sort of answering my question  
22 anyway, but just wondering how the agency is going to be

1 able to review the battery itself based on your  
2 experience with the first stage, which was your plan, I  
3 think, a couple years ago when we've had briefings, but  
4 having to send out more tox orders at the same time. Is  
5 there still a plan to review the battery itself and the  
6 information you've gotten from that?

7 MS. WHITBY: There is a plan to go back to the  
8 scientific advisory panel with a rereview of the battery,  
9 but that won't be, obviously, until we get the data in  
10 from list 1 and get a chance to review it.

11 MS. SULLIVAN: Okay. Do you have any specific  
12 time frame when you foresee working in some of the work  
13 and techniques and information coming out of the  
14 (inaudible) ecology program?

15 MR. BRADBURY: I can't give you the exact year,  
16 but clearly that's part of the overall computational  
17 toxicology program. One of the things I was going to  
18 mention yesterday is that in fact ORD is thinking through  
19 some ways to consolidate a lot of the research program  
20 with computational toxicology as an umbrella with the  
21 endocrine disruptor program being part of it. There's  
22 appropriation language that also ask the agency to

1 continue pursuing new technologies, new assays, that can  
2 go faster, smarter.

3 So, I think in a way, getting back to Carolyn  
4 Brickey's point, how could you start to accelerate  
5 evaluating these chemicals and sorting out where you need  
6 to focus and get that done efficiently and effectively.  
7 So, it's part of an active effort.

8 Scott and then Caroline Cox.

9 MR. SCHERTZ: I have one clarification  
10 question. You had mentioned, I believe it was, six  
11 actives that essentially were not being supported. Is  
12 that correct? The question is, are those all of the uses  
13 of those products?

14 MR. KEIGWIN: Yes.

15 MR. SCHERTZ: Even with multiple registrants  
16 possibly?

17 MR. KEIGWIN: That's correct. In fact, for  
18 four of those chemicals, we've either already announced  
19 in the Federal Register that voluntary cancellation -- in  
20 the case of diselfaton and methamidifos, we've actually  
21 already issued the cancellation orders.

22 MR. SCHERTZ: Okay, thank you.

1 MR. BRADBURY: Caroline and then Jay.

2 MS. COX: I am also interested in the long term  
3 schedule for this testing. I was just doing some back of  
4 the envelope scribbles and I think if there's about 1200  
5 pesticide active ingredients and maybe 3,000 inert  
6 ingredients, that's over 4,000 chemicals that need to go  
7 through the screening program, not counting the drinking  
8 water contaminants which would add something. If we're  
9 talking about 100 chemicals a year, that's 40 years. If  
10 we're talking 25 chemicals a year, that's 160 years or  
11 something.

12 I think both of those numbers are clearly to me  
13 much bigger than what the intent of the Food Quality  
14 Protection Act was. I mean, I don't think that anybody  
15 expected that that mandate was going to take centuries or  
16 something. So, do you have a plan for how to make this  
17 happen more expeditiously?

18 MR. KEIGWIN: Well, at least for the active  
19 ingredients, the plan is registration review. So, that's  
20 15 years, I realize, but it's much shorter than the 100  
21 that you mentioned. We do need to think about a plan for  
22 the inerts. Steve also mentioned the essential role of

1 (inaudible) as a way to help accelerate us through this  
2 process a little bit more quickly. But we're just not at  
3 that point yet.

4 MR. BRADBURY: If I can insert myself a bit, I  
5 think, Caroline, you captured the conundrum. The fuel  
6 and battery, if you do the whole fuel and battery, it  
7 takes two years because (inaudible) assays take  
8 essentially a year and a half to do. So, as you start to  
9 run the mathematics, you can start to see that you get  
10 sort of a disconnect.

11 That's part of the reason we have the 21st  
12 century toxicology work group as a piece of this puzzle.  
13 If on the one hand you're mandated to look through  
14 potentially 30,000 or 20,000 discreet chemicals and untypical  
15 inert and 800 some active ingredients, there aren't  
16 enough labs in the country to run all those chemicals  
17 through in a short time.

18 But if we can develop some other technology to  
19 help us figure out where to focus, we probably could  
20 start screening through lots of chemicals in a relatively  
21 short period of time to figure out where to focus  
22 resources to tackle the most risky situations that need

1 to be tackled.

2 I think you've captured the challenge, which is  
3 part of the (inaudible) program. A lot of the efforts  
4 we're trying to do here with you all is to figure out if  
5 we can build a science, how do you use the science  
6 appropriately to make long protective decisions.

7 Sorry to soapbox a little bit, but I thought  
8 I'd take it up. Jay.

9 MR. VROOM: Staying on the mathematics theme  
10 and resource challenges, I've asked CropLife members that  
11 are working on this to try to come up with a standardized  
12 way that our members can keep track of resources they're  
13 putting in to interfacing and compliance. I think that's  
14 just as important as keeping track of the government  
15 side, which is very important as well.

16 So, one of my question is maybe for Marty.  
17 Have you put a GPRA kind of a matrix around this to be  
18 able to track resources that are being consumed in OPP  
19 and elsewhere? One of our member companies told me that  
20 their OSRI submission for getting out of the penalty box  
21 on all 11 tier 1 assays took him 250 pages to submit.  
22 That has to be a huge resource commitment to evaluate

1 that, just as an example.

2 MS. MONELL: We actually have. We've gone  
3 through an exhaustive ongoing process to evaluate our  
4 resources that we've expended thus far, as well as those  
5 anticipated for the future in terms of multiple fiscal  
6 years.

7 As you probably are aware, the bulk of the  
8 endocrine disruption resources that are given to the  
9 agency are given to OSCP for their testing and  
10 development. We're now hopefully at the end of that  
11 process for the time being so that more of those  
12 resources will come to the program office. It will be  
13 pesticide programs first but eventually it will be toxics  
14 and the water programs.

15 So, there's a huge resource need by the agency  
16 for this. I think congress is aware of it. We're  
17 spending a great deal of time, not only the planning  
18 efforts but also the (inaudible) resource needs.

19 MR. VROOM: So, that also applies to folks in  
20 HED and elsewhere in OPP?

21 MS. MONELL: HED, EFED, the managers, Karen,  
22 Rick. To the extent they spend time on this effort and

1 energy on this effort, it is tracked through the TIS  
2 system. That's our accounting system for accounting for  
3 people's time, what they're working on here in the  
4 program. So, we have a lot of details and data from all  
5 of the effected program areas.

6 MR. VROOM: I apologize. Maybe you dove into  
7 this when I wasn't in attendance on Wednesday, the PRIA  
8 work group. But did you go into that or can we get back  
9 together at some point to get a better understanding of  
10 what your measures are so far?

11 MS. MONELL: At the PRIA coalition meeting that  
12 was held on I guess it was Wednesday morning, we went  
13 into extensive detail about how PRIA resources are  
14 allocated across the program. What we agreed to do was  
15 follow up with that to put it in the context of --  
16 because PRIA pays for about 33 percent of the cost of  
17 wanting the whole pesticide program. It pays for about  
18 28 percent of the cost of just the registration program.

19 So, appropriated dollars, maintenance fees and  
20 so forth pay for the rest of it. So, we're going to  
21 provide the data that shows it in context. But to answer  
22 your immediate question, yes, we did drill down on the

1 PRIA expenditures.

2 MR. VROOM: Good. We'll look forward to  
3 staying connected on that. The last point relates back  
4 to potential duplication or redundant resources and  
5 trying to avoid having to do things over again. That has  
6 to do with the fact that while I think we understand on  
7 the industry side that the specific test guidelines are  
8 coming and the assays are described, one important piece  
9 that, as I understand it, is not articulated yet and  
10 needs to come from OPPT is the standardized evaluation  
11 protocols.

12 So, as companies design and execute the tier 1  
13 tests, that they understand how the agency intends to  
14 evaluate so that when we get to the end and finish the  
15 test and discover that the test wasn't executed in a way  
16 to address the evaluation point. So, I know that's on  
17 the radar but I just wanted to reiterate that that's very  
18 important and something we think will help avoid a lot of  
19 wasted time at the end.

20 MR. BRADBURY: Pat and then I guess Steve.  
21 We'll sneak it under the wire and then we'll cut off this  
22 topic.

1           MR. DONNELLY: I just had a quick question.  
2       Looking at the timing, particularly that it's sort of  
3       first year, with test orders going out and people having  
4       to get responses and get the consortia together, et  
5       cetera, progress reports are due a year after issuance of  
6       the test order. So, when you add it all together, it  
7       doesn't leave much time for a progress report. So, what  
8       are the requirements or expectations of the progress  
9       report?

10           MR. KEIGWIN: I think it's just where are you  
11       in the development of the study, has the study  
12       progressed, have you contracted with a lab, those sorts  
13       of things. But we can be getting some guidance on what  
14       would be contained in that actual report.

15           MR. DONNELLY: Thank you.

16           MR. BRADBURY: Steve.

17           MR. SMITH: You mentioned that there were six  
18       actives that were going to respond with voluntary  
19       cancellations?

20           MR. KEIGWIN: There are six active ingredients  
21       for which all of the test order recipients have indicated  
22       they will no longer be supporting those chemicals.

1           MR. SMITH: So, would that be all the  
2 registrants?

3           MR. KEIGWIN: Those are all the technical  
4 manufacturers.

5           MR. SMITH: So, essentially all the uses for  
6 those things?

7           MR. KEIGWIN: Right.

8           MR. SMITH: I was just looking through the  
9 table and I'm counting seven. So, if you could just tell  
10 me which?

11          MR. KEIGWIN: The six are diselfaton,  
12 methamidifos, methidifion, methyl parathion, resimethrin,  
13 and propocor. What was the seventh one you saw?

14          MR. SMITH: Well, I got propargide but there  
15 might be another --

16          MR. KEIGWIN: There is an individual  
17 manufacturer who has indicated that they're not going to  
18 support it. In fact, we have an OSRI submission on  
19 propargide now.

20          MR. SMITH: From somebody else?

21          MR. KEIGWIN: From somebody else.

22          MR. SMITH: Okay, thank you.

1           MR. BRADBURY: Thanks, Rick and Karen, and  
2 thanks for the questions and the discussion as well.

3           The next part of our agenda is sort of twofold.  
4 I think I'll have Margie just spend a little bit of time  
5 giving you an update on the process about the membership  
6 renewal. When we do that, we'll ask (inaudible).

7           Then, the other topic to spend some time in  
8 discussion is opportunities for topics for our next  
9 meeting, start some of that planning discussion. I  
10 realize this typically goes on over the course of the  
11 next several months but at least we use this session to  
12 start to tee up some concepts or ideas that we can then  
13 adjust and tune as we go through the coming months. I've  
14 got some ideas but I'm going to hold my ideas to myself  
15 for a while and open it up to the group.

16           Julie.

17           MS. SPAGNOLI: I think it might be of interest  
18 now that the topic got the public health work group and  
19 just to maybe explore a little more of public health and  
20 what are the public health issues that we face. What are  
21 some of the vector borne diseases? How prevalent are  
22 they? I think just to get a little more wider grasp of

1 that whole public health area and what the implications  
2 are. I think we've touched upon it.

3 We've talked a little bit about bed bugs. We  
4 heard there's an outbreak of dingy. There's still lyme  
5 disease. There's still the Hanta (phonetic) virus and  
6 some of these other things. I think just to kind of get  
7 an idea of what are all those potential public health and  
8 vector borne diseases and how prevalent are they.

9 MR. BRADBURY: Caroline Cox.

10 MS. COX: As you all start to evaluate the  
11 public comments that you received on the AMPR about  
12 annotes (phonetic) disclosure and then take the next  
13 steps, I would really like there to be an update and  
14 discussion in this group about that.

15 MR. BRADBURY: David, do you have yours up?

16 No, okay. Susan.

17 DR. KEGLEY: I wasn't actually going to put a  
18 topic for it, but this is sort of the first time. I know  
19 that we've been talking about how the structure of the  
20 meetings are for the day and a half, whether it's lots of  
21 topics for 20 minutes each or this kind of approach. I  
22 just want to say I think that this -- obviously, it took

1 a lot of work to put this program together, to figure out  
2 which topics you were going to have sort of be front and  
3 center and a longer and more comprehensive report on.

4 Personally, I think it went very well.

5 Obviously, you chose issues that everybody was  
6 engaged in and wanted to know about. You got good  
7 discussion on it and kept the updates to, you know, a  
8 pretty straightforward brief and still got everybody a  
9 chance to say something if they wanted to say something  
10 about it.

11 So, I just want to say I think, at least  
12 personally, I'm interested in what everybody else thinks  
13 too, but I think this particular meeting went very well  
14 given that you balanced those things, a couple of big  
15 issues that you spent a lot of time on and let everybody  
16 engage in and then the quick update.

17 MR. BRADBURY: Carolyn Brickey.

18 MS. BRICKEY: My reaction to the agenda for  
19 this time and the way that it went is that I think there  
20 were a lot of really interesting and important topics on  
21 the agenda. I thought they were jumping off the page.  
22 But I thought we had too many topics. I don't think we

1 had enough time to talk about them. I also didn't like  
2 some of the focus of the topics in that I wanted to get  
3 more to some options that you're considering on some  
4 problems that you're trying to solve.

5 I think this group can be a little more helpful  
6 in the problem solving mode than it has been. I'd like  
7 to be able to use all the work that the work groups have  
8 been doing to kind of bring it back to this group and  
9 give us more of an involvement and a sense of what's  
10 going on there.

11 I'm thinking as an example of the toxicology  
12 and the 21st century group. I'm not in that group but I  
13 don't from the presentation have a whole lot of  
14 understanding of what that group is doing and how it's  
15 going to feed back into us and how we can be more  
16 helpful.

17 Finally, I thought that the introduction of  
18 that topic yesterday, looking at non-FQPA protection  
19 policies was a big topic. Bob flagged it as something  
20 that he certainly wanted to spend some more time on and  
21 suggested having kind of an interim meeting to talk about  
22 that, which I think is fine.

1           But I think it ought to be a major topic  
2 perhaps on the next agenda. I think there ought to be  
3 time to really talk about some of the issues and really  
4 get into that, because that's a huge thing and could be  
5 very important and valuable for this program.

6           MR. BRADBURY: Bob.

7           MR. ROSENBERG: At the risk of sounding like a  
8 mutual admiration society, I was going to say, Carolyn,  
9 your plea to not drop drift, you and Jim Thrift, I'd say  
10 try to somehow revive that discussion would be a good use  
11 of time. I was going to talk about 10X. You've already  
12 said it.

13           Third, just playing on what Julie said, I think  
14 it's true in the world of pest control that we used to  
15 make broadcast applications of broad spectrum  
16 insecticides. We don't do that anymore as a matter of  
17 practice, and they're not so available. What's happening  
18 is things like bed bugs. We sort of didn't actually go  
19 out and try to kill bed bugs. We killed other things.  
20 Bed bugs were collateral damage. Now we're having  
21 problems.

22           I think one of the things Lois was trying to

1 say in her discussion is there's not any really good  
2 answers as to what the agency can do to encourage the  
3 development of products or strategies to deal with bed  
4 bugs. I think having an in-depth discussion about bed  
5 bugs would actually be a valuable discussion because it  
6 has implications for a lot of other things.

7 MR. BRADBURY: Carol Ramsay and then Susan  
8 Kegley.

9 MS. RAMSAY: I'll be brief. I agree with  
10 Susan. I kind of like the mix of topics and the  
11 allocation of time. When you've got a day and a half  
12 maybe, it's a real challenge to be able to give enough  
13 updates, get into some detail. So, it's always a  
14 challenge and I think the last five meetings have gone  
15 pretty well on target. You've kept things well in frame  
16 with sending people to the penalty box. I agree with  
17 four other individuals. Spray drift needs to be back on  
18 there.

19 You'll have your 700 comments you'll have  
20 chewed through and hopefully we'll be able to come up  
21 with some plans for some consistency, if not necessarily  
22 all the clarity and then probably with fumigants rolling

1 out, probably should have another update on that and an  
2 update is probably sufficient.

3 DR. KEGLEY: Along the lines of what Carolyn  
4 Brickey was talking about, by next October or this coming  
5 October, it will be almost a year since the scientific  
6 advisory panel meeting on volatilization drifts. So, it  
7 would be nice to have an update on what the agency has  
8 accomplished in that interim period. There were a lot of  
9 science issues to be thought about and dealt with. So,  
10 it would be good to hear what you've done on that.

11 Then, maybe this is too specific, but I would  
12 like to know a little more about the registration review  
13 process. We're just getting some chemicals into there.  
14 There's not been too many finalized yet but kind of  
15 knowing what the process is, where the avenue is for  
16 public input, generally how that works, would be useful.

17 Then, finally, one thing that keeps coming up  
18 is what can we do about bed bugs besides broadcast  
19 spraying of broad spectrum insecticides? I guess the  
20 broader rubric here is what is EPA's role -- where does  
21 EPA tap into promotion of integrated pest management that  
22 may not involve using pesticides? How do you interface

1 with USDA on that? Is there such a program? Is there a  
2 broad way of looking at that throughout the agency?

3 MR. BRADBURY: Thanks, Susan. Amy, Mark and  
4 Kristie. Bob, I did try to keep things mixed up but I  
5 think they all came up pretty close together.

6 MS. LIEBMAN: I thought the agenda worked  
7 really well this time as well. I know that you can't go  
8 into detail about every single topic that we discussed,  
9 but I do think that the brief updates are still needed.  
10 I think perhaps what can happen is as you see the  
11 interest or the questions that arise from some of the  
12 brief updates, the next meeting can follow them up. But  
13 if we don't get some of those brief updates, we're not  
14 quite sure what's happening or if there is a need for  
15 more discussion on them. So, it's a balance that you  
16 guys worked out really well this time.

17 I really particularly like the discussion on  
18 the nanotechnology because for some of us who aren't as  
19 intimately involved on a daily basis with EPA, it's very  
20 important to also look to you for just a little bit of  
21 education. I think the request for more on the public  
22 health involvement is an example of us needing more

1 information. So, I do like that you are able to take  
2 some topics and delve down into them.

3 So, I just second that because there was such  
4 discussion on some of the brief updates that we follow up  
5 with that. Also, I agree with Carolyn that in terms of  
6 what can we do to improve understanding what the work  
7 groups are doing. So that, as they report back, we can  
8 be involved with some of the discussions and decisions  
9 that they're making.

10 MR. BRADBURY: Mark and Kristie.

11 DR. WHALON: Thanks for the opportunity. I  
12 just took kind of a rough poll on the number of issues  
13 that we had that the agency relies either directly or  
14 indirectly on IPM information. So, the MP issue I  
15 thought we talked quite a bit.

16 The endangered species issue obviously we had  
17 in the breakout of issues there, certainly, spray drift  
18 and some of the other worker issues. Pollinator  
19 protection we talked about a little bit and the IPM link  
20 there is key, really. Certainly, with public health,  
21 it's front and center and needs more development and  
22 needs more implementation and needs some new tools.

1           So, I think that EPA, when you look at the  
2 history of EPA and its role in the development of IPM, I  
3 just remind the group that the Huffacre Project  
4 (phonetic) which transitioned into the Adkisson Project  
5 (phonetic) were the origins of IPM in this country. EPA  
6 was the one that funded a large part of the last end of  
7 Huffacre and the start of Adkisson and has facilitated a  
8 lot of that. So, I don't know where the star grant  
9 process is relative to IPM but I think it's nowhere,  
10 personally.

11           I think that PRIA 2 is doing some good things  
12 but not necessarily really focused on specific  
13 developments in IPM. So, if we look at EPA's role in IPM  
14 and creating programs and creating new tools and  
15 developing a transition matrix at a time when the public  
16 sector is beginning to back away from IPM -- if you look  
17 at land grant universities and you look at the erosion of  
18 IPM, it's very startling.

19           Right now the IPM centers are on the chopping  
20 block in USDA. Where's the commitment there? So, it may  
21 be a time when the USEPA steps back in a leadership role  
22 where integrated pest management is concerned and you

1       retake the mantle that you had under Heffacre and  
2       Adkisson and step out and maybe lead the USDA by its  
3       nose.

4               I hate to say that but that's where we're  
5       going. I mean, we're not funding IPM in the public  
6       sector today and who is going to train the trainers in  
7       the future when you look at your depending on IPM into  
8       the future where your partners and what's happening with  
9       them.

10              So, I think that we need to counter some of  
11       that. We need to look at and measure the erosion of  
12       public sector IPM and the transition to private sector  
13       IPM. We need to look at the interface so NASS, NRCS and  
14       USEPA as well as broader research agendas in USDA. Hey,  
15       how about that? Thanks.

16              MR. BRADBURY: Thanks, Mark. Kristie and then  
17       Tom.

18              MS. SULLIVAN: Well, the first thing is that I  
19       forgot to say during the endocrine program updates that I  
20       really appreciated the presentation. I'm sorry they're  
21       not here to hear it but there was a lot of specific  
22       information about the responses that you've been getting

1 which is really really helpful. So, thanks for that.

2 I was also wondering -- and maybe I've totally  
3 missed it -- but have you guys come out with a new part  
4 158W testing regulation and I just didn't see it?

5 MR. BRADBURY: It's still in the works.

6 DR. GREEN: I had a couple things. In terms of  
7 the next agenda and also on an ongoing basis, I think it  
8 would be great to have NRCF participation. For the next  
9 agenda, a couple items that I think would be of interest  
10 to the group are the new conservation activity plan  
11 program that has \$700 million in it this farm bill  
12 period. It includes an IPM conservation activity plan of  
13 cost share available to growers to hire a consultant to  
14 prepare a comprehensive IPM plan for their operation that  
15 could, I think, help with things like the drift issue.

16 Then, the other new element that they're  
17 developing that I mentioned before is the 799 standard  
18 which will be a broad evaluation and monitoring standard  
19 that could be applied to a number of different purposes.  
20 It's being developed initially for doing water quality  
21 monitoring in the upper Mississippi River base and around  
22 nutrients and sediments.

1           So, the NRCF would actually cost share growers  
2     to monitor water quality under operation. That would  
3     seem to have potential applications for the drift work  
4     and the pollinator work and the worker protection work  
5     that we're talking about here. So, I think the group  
6     might benefit from a presentation on those two  
7     developments.

8           Number two, I'm wondering in terms of input on  
9     worker protection poster. Bob had mentioned maybe  
10    organizing a couple hour conference calls with those who  
11    are interested in giving input on another issue. Looking  
12    at that poster, I'm thinking that it might benefit from  
13    input from those interested in a group and talking about  
14    audience and messaging and so forth.

15          Finally, I just wanted to echo Mark's comment  
16    about IPM and looking at more integrated and systems  
17    approaches in all the work that we do. I think we had a  
18    number of topics that should have benefitted from that  
19    perspective during the meeting here, including the worker  
20    protection and the pollinator protection. It would be  
21    great if we do a bed bug discussion to make sure that the  
22    integrated systems approach and IPM are included in that

1 discussion and not strictly pesticide management.

2 MR. BRADBURY: Thank you. David and then Pat.

3 MR. TAMAYO: I'm not usually referred to as  
4 David unless somebody is mad at me, so I'm sorry if I  
5 stepped on your toes in some way.

6 I think that the agency has done a lot of  
7 things recently in response to -- the stormwater  
8 agencies, at least in California, are concerned about the  
9 impacts of pesticides on our urban receiving waters. It  
10 kind of touches on what Susan brought up with the  
11 registration review.

12 I know there's been some significant changes in  
13 how you're approaching the pyrethroids. It actually  
14 would be kind of a good case study of how there is some  
15 information brought to the front. We've got a  
16 significant issue here. This is how we're responding to  
17 it, not just to the registration review process but  
18 looking at labels and early sort of mitigation measures,  
19 just different types of tools that you have to respond to  
20 things like that.

21 But the registration review thing is actually  
22 really important in how mitigation measures get brought

1 into that, how IPM and reasonable alternatives relate to  
2 product registrations and continuing registration,  
3 whatever you want to call it. So, it would be great to  
4 look at that.

5 Then also, how can EPA improve or what is it  
6 already doing to identify or least screen for potential  
7 problems or actual problems of urban water quality  
8 throughout the nation because there is a growing body of  
9 evidence that it's not just a California problem.

10 We're starting to see it in Texas, Illinois,  
11 and Atlanta. It would be really good to see what more  
12 EPA could do to more proactively identify those problems  
13 and forestall them in the future.

14 MR. BRADBURY: Thanks, Dave. Pat and then  
15 Steve.

16 MR. DONNELLY: Thank you. Just a quick comment  
17 on the agenda. All the topics, of course, are very  
18 interesting. I realize and can sort of sympathize how  
19 difficult it is to put one of these meetings together  
20 with so many potential topics and the diversity of  
21 stakeholder interests.

22 I just wanted to share with you some comments

1 that Cindy made to me yesterday about the agenda. I  
2 think she expressed some frustration that there were too  
3 many topics on there and she would prefer to have seen  
4 less topics and more time to get into them, less topics  
5 and more time to discuss them.

6 Specifically, since October, the agency has put  
7 out a number of policies, some of which seem to fall out  
8 of the sky. When those get relegated to brief updates, I  
9 think that would be an obvious source of frustration.  
10 This is new and important and we should be spending more  
11 time talking about it, particularly the implementation  
12 plan is pretty short.

13 MR. BRADBURY: Steve.

14 MR. SMITH: Thanks. One of the priorities that  
15 we talked about yesterday was the agency priority, to  
16 strengthen partnership with state lead agencies. That's  
17 a topic, obviously, that's important to us as the state  
18 lead agencies. We're under a lot of pressure these days  
19 and there's a lot of things that EPA is doing that have  
20 direct impact on our programs and our activities.

21 I think it would be useful for the other  
22 stakeholders to get a sense of how these initiatives are

1 impacting state lead agencies because a lot of the  
2 initiatives we're talking about today, unless they  
3 translate into activities at the state lead agency level,  
4 they're just ideas.

5 We're the ones on the front line doing these  
6 things. It just seems like there would be some useful  
7 information for the stakeholders that we could  
8 incorporate in and give some perspective to some of the  
9 ideas that are tossed around and the things people want  
10 to accomplish, how they actually get accomplished.

11 MR. BRADBURY: So, we'll go Beth, Lori and  
12 Virginia. I think that will be it.

13 MS. LAW: In the discussions yesterday  
14 afternoon about public health pests, one of the topics  
15 that came up was what is sort of the current status of  
16 the NAFTA labels and international labeling issues. How  
17 is that problem being handled in other countries? Is  
18 there anything in those countries that could inform our  
19 debate about the issue?

20 So, I think maybe if this is kind of two  
21 requests, one would be when we do bring the public health  
22 issues here -- and for this forum for the next

1 discussion, I think it would be great to be sure to  
2 include that international component because as we  
3 discussed yesterday, there may be some products or  
4 approaches used in other countries that could help us as  
5 we try to decide what to do here.

6 Then, secondly, I think having a discussion  
7 about the current status of harmonization would be good,  
8 again, not just limited to NAFTA labeling but labeling  
9 and also data requirements. Where do we stand with that?  
10 I know there have been some discussions with PMRA in  
11 Canada. If some of those discussions have been going on  
12 with the EU or you contemplate doing that with the EU, I  
13 think that would be very interesting and very helpful to  
14 know. Thanks.

15 DR. BERGER: Just to underline some of the  
16 comments of other people regarding the need for more  
17 discussion. I think that we had too many topics and the  
18 goal of this group, as I understand it, is to have more  
19 exchange from the stakeholders and the agency. So, I  
20 would encourage more discussion.

21 Also, the work group model has worked very well  
22 and we encourage you to continue that. We need to

1 continue the updates on ESA, drift, pollinators,  
2 endocrine disruptions of our core programs and  
3 initiatives that impact agriculture, something that I  
4 think would be very helpful on fumigants now that we've  
5 moved into a new area with the red. If you could give us  
6 a status report on how your outreach efforts are going,  
7 how the regional offices at EPA, how that's working as  
8 far as taking these programs out to the field.

9           With regard to fumigants, I believe it would be  
10 very interesting if we had someone from AFIS come and  
11 present some of the implications of the fumigants both on  
12 intrastate and international trade issues. I think that  
13 there's some things bubbling to the top on invasive  
14 pests, on international trade, that need to be discussed  
15 in terms of the fumigants.

16           Then, something that was just brought up by the  
17 last speaker was the topic of international harmonization  
18 and the many efforts that are going on at EPA and other  
19 regions of the world to bring about similar regulations  
20 or shared data, that type of thing.

21           MR. BRADBURY: Thanks. Virginia.

22           MS. RUIZ: One thing that I appreciated from

1 this meeting's agenda was the opportunity to learn more  
2 about some of EPA's upcoming regulatory activity or areas  
3 where you are going to be seeking public comment and  
4 participation, the nanotechnology and NPDES. So, I would  
5 encourage you to include similar topics in future  
6 meetings to sort of giving us a heads up and educating us  
7 about issues that you're going to be seeking public  
8 comment on.

9 MR. BRADBURY: Thanks. That's very helpful.  
10 The challenge of finding time to bore into a detail,  
11 finding time to give you some updates is always a  
12 constant set of recommendations to get from you and what  
13 we struggle with back home or here in this home. We'll  
14 continue to try to find that balance.

15 I agree this one might have been a little bit  
16 more information flow than dialogue. Sometimes it will  
17 be oscillating from spring to fall. I take that set of  
18 comments and diversity of comments very seriously and try  
19 to find the right balance.

20 Some of the topics I had on my list, which I'm  
21 having a fun time trying to integrate some of the  
22 thoughts I had. Of course, we're all going to talk about

1     it and we'll have some feedback as we go forward. I  
2     heard some of the conversations around, for example,  
3     registration review and how it interfaces with ESA and  
4     with water quality and with a number of issues, and how  
5     does that process work.

6             I think there might be something there in terms  
7     of getting feedback from you all in terms of is it  
8     working, is it not working, how to make it better, and  
9     how it might plug into a number of topics. We talked  
10    about something in my notes and we're quickly gathering  
11    that aspect about the worker risk policy which is very  
12    new and just beginning to get comments, hearing that --  
13    and I'm not giving an exhaustive list, but seeing some of  
14    the threads that are starting to come out of the  
15    discussions here and some of the notes.

16            The other thing I want to explore with our  
17    group and then we'll get it back out to you is seeing  
18    about the idea of some webinars or some relatively short  
19    meetings on the phone, hopefully webinars, where we might  
20    be able to talk about some topics in between meetings.  
21    Of course, they'd be open to the public to listen in as  
22    well so that we could be very efficient then at these

1 meetings to be having the wider discussions.

2           Maybe we can use the work groups and maybe some  
3 interim webinars to get information flow going so that  
4 when we hit the spring meeting or the fall meeting,  
5 information flow has happened and we can focus more on  
6 how can you do it better, EPA, or EPA, how that I thought  
7 about it, I didn't realize blah, blah, blah. Here is  
8 something you should be working on.

9           I always try to think about some ways to do  
10 that. I know it takes time for you to do that, but that  
11 might be a way to try to strike some of that balance  
12 between dialogue here and information flow.

13           IPM came up and kind of bumped me back to some  
14 of the topics I heard. So, I think we've got a fairly  
15 robust set of ideas. I think there's some integration  
16 among many of these ideas which I'd like to spend some  
17 time contemplating with my colleagues. We'll get back to  
18 you, like we always do, to get feedback.

19           I'd also like you to be seriously thinking  
20 about topics that you think would be useful to have a one  
21 hour or two hour webinar or something in between as we  
22 kind of gel some ideas. I'd like to get some feedback.

1 Is there real commitment, significant commitment among  
2 the group that you'd make that investment to do something  
3 like that in between the meetings.

4 I think it could help balance information flow  
5 with in-depth discussion while we're here. Clearly,  
6 they'd all be public so everybody could listen in on  
7 those discussions as well. But it means some extra time  
8 for you to do that. So, you don't have to give me an  
9 answer now but be thinking about that.

10 What I'd like to do now is give Margie just a  
11 chance to let you know where we are in this process of  
12 the renewal, just in case there's any questions that you  
13 have for Margie on that.

14 MS. FEHRENBACH: I think I've talked to almost  
15 everybody individually, but I'll just review where we  
16 are. The deadline for submitting your applications was  
17 extended through this week. So, if there are any folks  
18 who have not yet submitted their renomination, please let  
19 me know. I know there's been problems with the regular  
20 mail. In fact, I received one the other day. The resume  
21 of the person was glued to the envelope. So, try to  
22 e-mail it if you can. It still goes through that process

1 where things are x-rayed.

2 The process will be, once we have all of the  
3 nominations, our program, the Office of Pesticide  
4 Programs, will put together a proposal. We will share  
5 that with our assistant administrator. Then, the package  
6 will go to the Office of Cooperative Environmental  
7 Management. They will review and make recommendations.  
8 Then it will go to our administrator's office and they  
9 actually have to approve and sign off on it.

10 So, our hope is to have a new committee  
11 sometime later this summer. We'll keep you informed of  
12 what's going on so that we can have our next meeting in  
13 November. That's about it. If you have any other  
14 questions, let me know.

15 Just one point, there's another meeting in this  
16 room at 12:30, so we need to ask everybody to please be  
17 able to leave by then.

18 UNIDENTIFIED FEMALE: What's the date for the  
19 next meeting, Margie?

20 MS. FEHRENBACH: We're tentatively looking at  
21 November 16th and 17th which is in conjunction with the  
22 one-day even that -- the work group on toxicology, 21st

1 century toxicology is going to have a meeting. I will  
2 send that out electronically.

3 MR. BRADBURY: Jay, Beth, and Carol.

4 MR. VROOM: So, I wasn't aware that you had  
5 extended the deadline. Obviously, as a PPDC member, I  
6 overlooked that. Do other members of the public know  
7 that also? If not, could it be extended another couple  
8 weeks so that we could get that message out to a broader  
9 community?

10 MS. FEHRENBACH: It will just delay the whole  
11 process. We have let people know informally that we were  
12 continuing to receive applications because some of the  
13 problems with information being sent to us. I'll let you  
14 know.

15 MR. VROOM: Okay. Then, I'm not aware whether  
16 you post on the web site the nominations that have been  
17 received.

18 MS. FEHRENBACH: You mean the individuals  
19 who --

20 MR. VROOM: Right. So, can we see who has been  
21 nominated in total?

22 MS. FEHRENBACH: We've not done that. I don't

1 know that that's -- I'll have to look into that.

2 MR. VROOM: This is the most open government in  
3 the history of civilization.

4 UNIDENTIFIED FEMALE: There's some privacy act  
5 considerations that we'd have to take into account with  
6 that. So, that's historically why we've not done it.

7 MR. VROOM: Okay. I'd still be interested in  
8 exploring that question, again, just from the overall  
9 context of how do you achieve balance, representation,  
10 and all the rest.

11 Obviously, the other question is, we've talked  
12 a little bit in the past about the six-year rule that  
13 apparently was overlooked for a long time and then also  
14 the various informal representations out of the White  
15 House Office of Ethics about the prohibition of people  
16 who are registered legitimately to lobby the congress of  
17 the United States being discriminated against in terms of  
18 participation and Federal Advisory Committee. So, do you  
19 have any information on either of those points?

20 MS. FEHRENBACH: Well, any questions you have  
21 about the lobbyist issue, we're being asked to refer you  
22 to our Office of Cooperative Environmental Management.

1 They've not yet put anything out in writing. I do know  
2 there's a lot of controversy over the government having  
3 that policy. But it has not been put out in writing yet.

4 The six-year policy, in the past six or eight  
5 years, we've had to justify any members who have been  
6 kept on. So, it is an agency policy and they're  
7 highlighting it this round as something that we're trying  
8 to encourage more new membership. But it's an agency  
9 policy. So, we still have the opportunity to maybe make  
10 justification.

11 MR. BRADBURY: Two things. We're passing  
12 around some information related to the questions around  
13 nanotech and ORDs, Office of Research and Development  
14 investments. So, that came around.

15 Also, there were related questions about what  
16 specific research is being done. The easiest way to  
17 probably do that is to give the web site and you can so  
18 see what's going on. It's [www.epa.gov/nanotimes](http://www.epa.gov/nanotimes). You  
19 can see the specific projects that are going in the  
20 context of that budget.

21 We have one public commentor, so I want  
22 everyone to stay put. Our public commentor is Donna

1 Heppert (phonetic) from Oregon Toxics Alliance.

2 MS. HEPPERT: As Steven said, I'm Donna Heppert  
3 from Oregon Toxics Alliance. I'm here from Portland,  
4 Oregon. Also, I'm the board chair of Oregon Toxics  
5 Alliance. I also sit on the board of Northwest  
6 Environmental Defense Center there. I'm very thankful to  
7 be here today to have observed the proceedings and to be  
8 able to give this public comment.

9 To give you a little background about myself, I  
10 graduated in 1980 with a degree in botany and worked for  
11 10 to 15 years as an ornamental gardener both with the  
12 Austin Parks and Rec Department and I was the head  
13 horticulturist at the Texas Governor's Mansion and also  
14 worked at several private estates in LA. All these times  
15 I worked using organic methods and found them to be  
16 extremely effective.

17 So, it was just natural that when I recently  
18 went to law school and became an attorney -- I'm also a  
19 public interest attorney. I should have disclosed that.  
20 When I went to law school, it was natural that I'd have  
21 an interest in working on pesticide policies. I get to  
22 have the last word today. My mom always used to accuse

1 me of wanting to do that, and maybe she was right. I'm  
2 sure she'd be glad if I told her that.

3           When I did go to law school, coincidentally, I  
4 was actually in the process -- we had been looking for  
5 two years for a piece of land suitable to become a  
6 commercial organic farmer. So, I was trying to be a  
7 farmer, at least. Maybe one of these days I will be able  
8 to stop being a bottom feeding attorney and go back to  
9 the exulted profession of farmer.

10           Anyway, I was also recently fortunate to attend  
11 Beyond Pesticides national conference in Cleveland, Ohio.  
12 At that time, we had a two-day meeting before that of the  
13 pesticide work group, which is a coalition of lots of  
14 groups that are working nationally on pesticide issues.

15           The sentiments of the group, folks are very  
16 encouraged by the progress we're seeing. A lot of that  
17 was gone over at this meeting with the risk assessment  
18 and the worker protection standards. There's also  
19 concerns and frustrations.

20           Part of the concern is about the rate of past  
21 progress, and some of that was brought up today, about  
22 the endocrine disruptor screening and how long it's taken

1 to get around to doing that. Now that we've got the  
2 momentum and the risk assessment and the worker  
3 protection standards, we hope that that momentum will  
4 keep going until we cross the finish line and actually  
5 put those protections into place.

6 The other reason for frustration is because we  
7 really feel that there are viable alternatives available  
8 that could be put into place instead of some of these  
9 pesticides. I overheard a conversation yesterday from  
10 some folks talking about us characters and how it was  
11 crazy for us to think that organic farming could feed the  
12 world. I won't point any fingers; you know who you are.

13 But the coincidence was that I was planning on  
14 bringing up an article that I read recently that talked  
15 about the U.S. Farm Bureau declares war on sustainable  
16 agriculture. This was on the Rodell Institute web site.  
17 But the interesting part of that article is that in there  
18 are two studies that are mentioned.

19 One of them is a UN study from 2008, a UN  
20 report, talking about how in Africa -- and I'm going to  
21 read to you some from there -- a 2008 UN report on  
22 organic farming and how it can feed Africa and bring

1 higher income to the poor. They found that food  
2 production rose and sometimes even doubled when farmers  
3 traded in chemical methods for more sustainable organic  
4 ones.

5 Then there was also a recent USDA 2008 organic  
6 survey that came out. It was the first major look at  
7 certified organic farmers and ranchers. It found that  
8 organic farmers who don't buy into agri-chemicals get a  
9 much higher return on their investment than chemical  
10 farmers do. So, I believe it is possible and I believe  
11 that we ought to look into promoting this more. That's  
12 one of the things that we like to ask for, is training.

13 There was the IPM center comment today, let's  
14 make sure those keep on getting funded. Let's see if we  
15 can get some training for organic farmers. One of the  
16 comments at this pesticide work group meeting is that  
17 there are farmers out there that would like to try  
18 organic methods, but they've been doing chemical methods  
19 for so long, they just don't know how to switch. So,  
20 some sort of program helping those farmers that want to  
21 try and make the switch would be very helpful.

22 Another thing is that organic farmers shouldn't

1 have to bear the burden of chemical drift and potential  
2 chemical drift. There seems to be a sentiment that if  
3 you want to farm organically and you're afraid of losing  
4 your certification with other people's residues drifting  
5 onto your crop, then you should leave a buffer on your  
6 land. Well, really, that doesn't sound too fair. So,  
7 the buffer maybe needs to go across the other side of the  
8 fence.

9 A couple of other majors asks and then I'll let  
10 everybody get out of here. I won't keep you here until  
11 12:30 myself. One thing that would be great would be  
12 independent testing and research. It seems like we get  
13 into the war of the science and study results. You have  
14 to ask yourself if it's the chemical producers that are  
15 putting forward a lot of these research results. You  
16 have to ask where is the bias and which results might be  
17 more credible.

18 So, one way to do this might be to get the  
19 funding from the chemical companies but divorce them from  
20 the process of actually performing the studies and  
21 bringing forth the results. Let the chemical companies  
22 fund the testing but find an independent, the

1       universities, any kind of institution that's capable of  
2       doing that sort of research without the bias.

3               Today was brought up the national reporting  
4       database. That was something that we were very  
5       interested in seeing. It's good to hear that that's  
6       imminent, that that sort of thing -- the reporting, the  
7       usage and the incidence database where it would be  
8       possible for the public to even use that and find out  
9       what's going on.

10              Finally, the last thing I'd like to ask and  
11       comment on is oversight. The state programs are out  
12       there but a lot of times they're nonfunctional. In  
13       Oregon, for instance, we have folks calling in to the  
14       Pesticide Analytic Response Center and they'll say  
15       they've been sprayed and they're getting sick. The  
16       response often is well, you just have the flu. They just  
17       get brushed off. It never gets reported and goes up.

18              So, we need some sort of oversight from the  
19       federal agencies that these state agencies are actually  
20       doing the job that they're supposed to. Thank you very  
21       much.

22              MR. BRADBURY: Thank you. I want to adjourn

1 the meeting. Before I do so, I just want to again thank  
2 you all for your preparation before the meeting and  
3 during the meeting and in between sessions. I appreciate  
4 the dialogue and the information flow. I also really  
5 appreciate the comments at the end here, taking a look at  
6 the future and some approaches for topics in how to  
7 manage the meetings as we go forward. I appreciate that  
8 greatly.

9 I wish you all safe travels for those who are  
10 traveling short or long distances. Take care and thank  
11 you very much.

12 MS. MONELL: Just to reiterate what Margie  
13 said, we have to clear this room. There's another  
14 meeting here at 12:30. Thanks.

15 (Whereupon, the meeting was  
16 adjourned.)

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