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UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY

PESTICIDE PROGRAM DIALOGUE
COMMITTEE MEETING

May 21-22, 2008

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

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P R O C E E D I N G S

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3 MR. GULLIFORD: Well, good morning. If we can
4 get people to take their seats, there will be
5 opportunities over the course of the day for the type of
6 informal dialogue that is occurring now, which is a very
7 productive dialogue.

8 First of all again, good morning, welcome. My
9 name is Jim Gulliford. I am the assistant administrator
10 for the Office of Prevention, Pesticides, Toxic
11 Substances. It's my pleasure to welcome you here today
12 as the Pesticide Program Dialogue Committee, PPDC as we
13 refer to it.

14 We are very appreciative of the turnout for the
15 meeting, not only in the part of the PPDC members, but
16 also the public. As I've talked to a number of you this
17 morning prior to the meeting starting, there was a number
18 of observations that gee, the group must be growing
19 because the table is getting longer and we're pressing on
20 the space that we've provided to the public.

21 The reality is that no, our numbers aren't
22 going up, but people are participating. So, a turnout of

1 the actual members of the PPDC is greater than it has
2 been for the last couple of meetings. So, that's why the
3 table looks longer.

4 We set for the number that we expect to be
5 here, which really points out, I think, two very positive
6 things. One is that the issues that we are bringing to
7 the PPDC for discussion clearly has your interest, which
8 is why you come and participate.

9 Secondly, the same is true for the public; it
10 has their interest as well and for them to be observers
11 to this process and have an opportunity to participate in
12 the session along for their comments that we have good
13 interest.

14 So, we appreciate the fact that many of you
15 have traveled long distances to be here. We also
16 appreciate that some of you have braved the traffic of
17 Washington, D.C., and made it over here as well for that.

18 The committee itself -- the PPDC itself has
19 just revised its membership. So, we have some people
20 that have left the committee, and we have some new faces.
21 When Debbie has an opportunity, she's going to go around
22 and get some introductions for everybody.

1 But my purpose today really is just again to
2 thank you for your participation and for your role. We
3 as an agency are the beneficiaries of the discussion that
4 takes place at the PPDC. You bring us your comments,
5 your perspectives on a variety of issues. You do it in a
6 way that we find very helpful by, one, being respectful
7 of your colleagues but by not being afraid to or in any
8 way challenged to bring your ideas to the meeting. So,
9 we're very grateful for that.

10 The PPDC has a long history. We think it's
11 becoming now one of the longest FACA committees that EPA
12 has. You've been around for a while. My notes say this
13 is the 24th meeting of the PPDC. I'm not going to ask
14 for a show of hands because I think there are a few of
15 you that have been around almost that long. But again,
16 clearly this is operated under the rules of a FACA. We
17 are looking for your ideas, for your input, for, again,
18 the variety of perspectives that are offered by divergent
19 points of view and divergent interests of this group.

20 You've got a wonderful agenda. Opportunities
21 for you to be briefed on where we are on a number of
22 issues, opportunities for you to give us your input.

1 Also, we want to continue to commit to some of the work
2 groups that allow for the PPDC to conduct business and
3 develop background, develop information to support this
4 meeting between the actual meetings of the PPDC would
5 occur.

6 So, we're going to continue to support those
7 work groups. Historically, there's been work groups
8 would just spray drift, worker risk issues, registration
9 review and others. We have two now that are currently in
10 process, the PRIA process improvement work group and the
11 AZM transition work group. So, those are helpful to us,
12 and we will continue to develop work groups as it's
13 apparent to us and to you that those can be productive.

14 So, again, I think you've got a wonderful
15 agenda, a couple of good days of good work, good
16 discussion. I'm looking forward to getting a report from
17 Debbie when we're done. But for now, I'm going to turn
18 it back over to Debbie Edwards who is the chair of the
19 PPDC but also the office director for our Office of
20 Pesticide programs.

21 Debbie, thank you.

22 MS. EDWARDS: Thank you, Jim. I'd like to echo

1 Jim's welcome to all of you, both the committee members
2 and officially the new committee members to the PPDC, as
3 well as the public who are here today.

4 I'd like to start with just kind of setting the
5 stage by articulating what we view as OPP's three program
6 principles. Those are that we focus on public health and
7 the environment in this program. We base our decisions
8 on sound science. And we run a transparent open process
9 with opportunities for public input and involvement.

10 With respect to public input, we have many
11 opportunities. This is one of them. We have informal
12 public input through the correspondence that we receive
13 and respond to, often making both the incoming and the
14 outgoing very public. We will meet with anyone who asks
15 to meet with us. If you find that you are not being
16 granted a meeting, I would like to know about that. We
17 will meet with anyone who provides us with an agenda and
18 a list of a participants on any topic. Presumably, it
19 would have to do with pesticides.

20 But we have other opportunities for public
21 input that are more formal. Those includes our public
22 comment periods. We have many, many public comment

1 periods. If you look on our web site, you'll see that we
2 always have various policies, procedures, decisions and
3 so on and so forth available for public comment. And
4 there are dockets associated with all of those. So,
5 that's a very formal public participation process.

6 We actually have two FACAs. The first one I
7 will mention is the Scientific Advisory Panel and that's
8 where we take very technical science issues for public
9 review with expert panels of scientists. Those actually
10 also occur in this room, typically.

11 The second is what we're here for today. This
12 is a Pesticide Program Dialogue Committee. The focus
13 here is on policy and process within the Office of
14 Pesticides Program. So, thank you again for
15 participating.

16 The PPDC charter, which I believe you have
17 within your folders, says that we will typically meet
18 twice a year. We can meet more often if need be. We
19 often have, as Jim mentioned, work group meetings that
20 meet more frequently on specific topics of interest.

21 It also says that typically the PPDC will be
22 composed of 35 members. We recognize that there are a

1 lot of diverse stakeholder groups that have an interest
2 and can provide valuable advice to the pesticide program
3 and pesticide regulatory issues.

4 When we solicited interest for this reforming
5 of the PPDC this time, more than 75 people were either
6 nominated or self-nominated to participate. Even though
7 we knew that the cost to the Agency is higher by having
8 more than 35 people involved, we made a decision to have
9 45 people invited to participate. All accepted so we're
10 very happy to have that and that's why you see so many
11 people here today.

12 I'm a little concerned that I won't be able to
13 read the tent cards, but I'll do my best. They're at the
14 end of the table. As you can see from the roster, as I
15 said, there are very diverse stakeholders all with valid
16 viewpoints involved in this committee. They include
17 growers and other users of pesticide products, animal
18 welfare advocates, farm worker representatives, the
19 pesticide chemical industry.

20 In there we have manufacturers, formulator
21 interests, retailers. This is for both agricultural and
22 consumer products and for conventional, antimicrobial,

1 and biopesticides. We have public health educators. We
2 have physicians. We have state, local and tribal
3 governments represented. We have extension and IPM
4 specialists.

5 We have pesticide safety educators,
6 researchers, enforcement and compliance experts. We have
7 our federal partners from USDA, the Food and Drug
8 Administration, the Fish and Wildlife Service, and the
9 Department of Defense. We have EPA regional interests
10 represented. So, that's a very broad stakeholder
11 community that we're working with here.

12 The pesticide program continues to enjoy many
13 challenges and many opportunities in our work. Several
14 of our front burner issues and initiatives will be
15 discussed here in the next day and a half. We're looking
16 forward, as Jim mentioned, to a very constructive
17 dialogue around those issues.

18 I'd like to briefly go over the agenda now and
19 then I'm going to ask each of you to introduce
20 yourselves. So, first let me just review the agenda.
21 After the break, which will occur after the introductions
22 -- and you'll see why -- I'm going to ask you to speak a

1 little bit during your introduction, so that's why we're
2 going to take some time with that.

3 After the break, we're going to start with
4 Session Number 1, which is on our vision and strategy
5 around the National Research Council's Report on
6 toxicity, testing and the 21st century. This is a very
7 exciting area for this program. I think this is an
8 exciting area for toxicologists in general throughout the
9 government and throughout the research community.

10 Our session chairs there are Steve Bradbury,
11 who is the director of the Special Review and Re-
12 registration Division, and Vicki Dellarco, who is now our
13 senior science advisor in the Office of Pesticide
14 Programs.

15 We will then break for lunch after that session
16 and come back at 1:30 for Session Number Two on labeling
17 initiatives. There's a lot going on in this program to
18 revolutionize the way we take in and handle and make
19 public labeling information for pesticides. So, the
20 first session there will be chaired by Anne Lindsay,
21 deputy director for programs.

22 And Session Number Three is related to that and

1 that's Bill Jordan our senior policy advisor in the
2 pesticide program who will run a session on web-
3 distributed labeling. Then, at 3:00 we're going to have
4 a few program updates on issues of interest.

5 Volatilization is an area -- it's an emerging
6 issue in the pesticide area. Charles Smith from our
7 Health Effects Division will give that update, followed
8 by an endocrine disruptor or endocrine disruptor
9 screening program update from Steven Bradbury again. And
10 then the inerts update will be provided by P.V. Shah from
11 the Registration Division.

12 Following another break, short break, we'll
13 have Session Number Five which is a Harmonization/Update
14 on a lot of things that we're very excited about and
15 doing very well with, in my opinion, this year, global
16 registration, workshares, MRL harmonization and some of
17 our international activities, in particular with China.
18 There we're focusing on efficiency, food safety and
19 trade.

20 We'll end the day with our typical registration
21 updates. Actually, we'll talk about where we are with
22 our re-evaluation programs, registration and re-

1 registration -- excuse me, re-registration and
2 registration review and also then registration. Steve
3 Bradbury will handle the part on re-evaluation programs
4 and Janet Andersen will cover the part on registration.

5 Tomorrow morning we'll be here again at 9:00 in
6 the morning. Session Number Seven, Marty Monell, the
7 deputy director for management, will give the
8 presentation she often gives on OPP resource allocation
9 used this year. Then we will follow with a PPDC work
10 group report on PRIA process improvements. That's
11 Session Number 8 by Elizabeth Leovey who chairs that
12 group.

13 Then follow with Session Number Nine after a
14 break will be an endangered species session chaired by
15 Don Brady who is our acting director for the
16 Environmental Fate and Effects Division. Then, finally,
17 we'll close in Session Ten with some planning for our
18 next PPDC meeting which will be in October. I believe it
19 will be the week before Columbus Day. I don't know the
20 exact dates yet, but Margie will know that.

21 So, that's where we are with the agenda. What
22 I'd like to do now is actually ask that each of you go

1 around and introduce yourself and provide your
2 affiliation and then very briefly -- obviously there are
3 many of you -- I wanted to take some time to do this,
4 though, because I think this is a new configuration of
5 the group.

6 There are many new members, as I said, and I
7 think it will be useful to all of us to have you state,
8 just briefly, your key interest in being here and the
9 perspective you believe you're able to offer to the
10 Agency. Also, if you are representing someone else,
11 please state who that is. We do have a few substitutes
12 today.

13 So, let's start.

14 MS. BAKER: I'm Cindy Baker. I'm with the
15 Gallen (phonetic) group of companies. I guess the
16 perspective that I bring to the PPDC is that of a basic
17 registrant that is vertically integrated. So, we have a
18 plant. We have basic manufacturing capabilities. We
19 also have retail operations and a feed business. So, I
20 think we bring kind of a broad perspective that way.

21 MR. BOTTS: Dan Botts with Florida Fruit and
22 Vegetable Association. I represent a grower group that

1 also as a service to its members provides third party
2 registrations, liability limitation registrations for use
3 of our members for products that would otherwise not be
4 available.

5 So, we are a registrant as well albeit the only
6 not-for-profit stock ownership corporation that we know
7 of that's ever been registered anywhere in the world. It
8 was intentionally set up that way.

9 My main role in this process is to provide
10 institutional memories since I've been on the committee
11 since it was -- before it was founded when Dan Borolla
12 (phonetic) was trying to figure out a way to set this
13 process up. I went through the troubled early years when
14 it tried to meet when the government was shut down and
15 wouldn't let us meet because they had no funds to do it.

16 But I'll try to bring a perspective to the
17 table because -- that represents our true grower needs in
18 Florida. Being specialty crop producers, we are totally
19 dependent on the ability to move our products through
20 trade channels fairly rapidly because they're all
21 perishable commodities. And without a strong regulatory
22 program that backs up the health and safety of the

1 products we use, we would be at the mercy of the whims of
2 the buying public in a lot of cases and perceptions
3 rather than reality of whether that food product is safe
4 or not. So, it's critically important to us to have a
5 process that works that allows us to use products in a
6 safe and responsible manner.

7 MS. FERENC: I'm Sue Ferenc with Chemical
8 Producers and Distributors Association. I think what we
9 bring to the table is the perspective of generic
10 producers and also a large part of our membership are
11 adjuvant and inert suppliers. So, we are the association
12 that pretty much represents adjuvant and inert suppliers
13 into the agricultural market. Also, we represent small
14 businesses. So, it's a tri-fold group.

15 MR. ROSENBERG: I'm Bob Rosenberg. I'm with
16 the National Pest Management Association. We're the --
17 well, for those of you who don't know, the association
18 that represents companies that do structural pest
19 control. We have about 5,000 member companies in the
20 United States. A couple of those are big, well-known,
21 publicly trade companies like Orkin and Terminex and
22 probably more than 5,500 of them are very small

1 businesses like Susan's.

2 We're interested, like I expect everybody else
3 is interested, in good public policy and applaud the
4 Agency. You know, I think maybe, you know, Dan is the
5 only older person at the table than me. We remember when
6 this process was not so stakeholder driven or as
7 transparent as it is today. We welcome the opportunity
8 to participate in that.

9 MR. WALLACE: Good morning. My name is Jim
10 Wallace. I am the North American -- or manager of North
11 American Registration Group for SC Johnson. I'm
12 representing the consumer products industry on this
13 panel. Some of the issues of significant interest to our
14 industry at this point in time are labeling issues, inert
15 ingredients, harmonization, and pre-process improvement.
16 So, I'm pleased to see that those issues are on the
17 agenda. I look forward to the discussion.

18 As far as the perspective we bring, I think
19 that you could sum it up by saying that our interest is
20 with how each policy might impact the consumer users and
21 the consumer market.

22 MR. TAMAYO: My name is Dave Tamayo. I'm with

1 the California Stormwater Quality Association. We
2 represent all of the large and medium size cities in the
3 State of California that are subject to NPDS water
4 quality discharge permits.

5 The primary reason that I'm here is that we're
6 finding that we have an ongoing and statewide problem
7 with toxicity in our local waterways that are linked to
8 registered pesticides. We found it in the 90s. We found
9 diazner (phonetic) and chlopirofos (phonetic) and now
10 since those are off the shelves, we're finding widespread
11 pyrethroid (phonetic) and some indications of terpinel
12 (phonetic). So, those things set us up for Clean Water
13 Act liability.

14 We're very concerned about complying with our
15 discharge permits and making sure that our waterways are
16 not consistently toxic. We look at the role of Office of
17 Pesticides as being very crucial in meeting that
18 obligation. We want to make sure that -- we're looking
19 for opportunities to tweak the registration and
20 registration review processes and all the things that
21 feed into that, and improving the ability to keep those
22 toxic events from occurring.

1 In addition to the registration issues, we're
2 also very active in promoting integrated pest management
3 throughout California. We find that the stormwater
4 agencies are often the lead agencies in a given
5 metropolitan area in promoting that sort of thing. We
6 worked a lot with our structural pest control folks and
7 made some significant progress in establishing a new
8 regulation to move for statewide integrated pest
9 management certification programs.

10 So, I have both of those hats, the pesticide
11 regulatory side and then the pest management side.

12 MR. ROBERTS: I'm Jimmy Roberts and I'm from
13 the Medical University of South Carolina in Charleston,
14 South Carolina. I'm a general pediatrician with an
15 academic interest in children's environmental health.

16 Really, I guess I represent two groups. One is
17 pediatricians and other health care providers that take
18 care of children who are often faced with the very
19 difficult task of identifying a child who might have been
20 poisoned, whether it's from a pesticide or something
21 else.

22 And also, from a children's health standpoint,

1 children don't really have much of a voice in government.
2 As a pediatrician, I take care of the children and try to
3 look for policies that can help protect them.

4 MS. BERGER: My name is Lori Berger. I'm with
5 the California Specialty Crops Council. We represent
6 groups varying from root, berry, tree fruit, etc.,
7 vegetable crops, mainly on issues of pest management and
8 environmental stewardship.

9 Our main interest in serving on PPDC -- and
10 I'll also say that in addition to California specialty
11 crops, we work actively with the Minor Crop Farmer
12 Alliance that Dan Fox heads up. That's a national
13 coalition of specialty crops.

14 We are very interested in the minor youth
15 situation, registration of products through IR4 and EPA,
16 and also global regulations and implications with MRLs
17 and regulatory harmonization throughout the world. We're
18 interested in worker protection issues and also in
19 endangered species.

20 This is a great issue for us in California, a
21 lot of the competing interests between environmental
22 issues and land use. We would like to maintain crop

1 protection tools as much as possible and increase the
2 availability of a wide variety of technology for
3 pesticide and pest management.

4 DR. WHALON: Good morning. I'm Mark Whalon.
5 I'm a professor at Michigan State University. I'm an
6 entomologist. I've had a career in integrated pest
7 management both in the applied end and also on the basic
8 end. I've served on a number of FACAs related to the
9 Quality and Protection Act.

10 I think that some of the interest that I have
11 -- in particular, right now, I'm interested in the impact
12 of the FTPA, particularly on ecosystems. We're seeing
13 some interesting changes from basically an OP driven
14 system in tree fruit, for example, to a neonicatenoid
15 (phonetic), oxydiozene (phonetic) and biopesticide
16 system. You'd think that that would be really soft on
17 the environment. It's not necessarily true. So, some of
18 those things are servicing at the IPM international
19 congress next year. There will be a session dealing with
20 that.

21 I'm also involved in a number of research
22 projects. I run a lab called the Pesticide Alternative

1 Lab. We do a lot on biopesticides, particularly fungi
2 and nematodes, as well as natural enemies, parasatoids
3 and predators in ecosystems. I serve on a number of
4 national and international committees that relate to
5 specialty crops. Thank you.

6 DR. WILLETT: I'm Catherine Willett and I'm
7 standing in for Kristie Stoick. I'm representing the
8 animal protection community. Our perspective is
9 primarily to identify and help promote opportunities for
10 the -- for decreasing the reliance on animals in various
11 testing programs.

12 We're particularly interested today in this
13 meeting on the report of the NRC report, the update on
14 the NRC report, and also the endocrine disruptor program.
15 We also work on many other national and international
16 forums to reduce reliance on animals and testing
17 programs.

18 MR. VROOM: Good morning. My name is Jay
19 Vroom. I'm here representing CropLife America. We are
20 the trade association representing the agricultural
21 chemicals industry from basic manufacturer proprietary
22 companies, generics and distributor formulator companies,

1 as well as a range of associate member interests in
2 CropLife America that include law firms, regulatory
3 consultants, contract research firms and other service
4 and product suppliers to the pesticide industry at large.

5 I'm also a member of the EPA's new agricultural
6 advisory committee known as the Farm Ranch and Rural
7 Communities Committee which was just formed earlier this
8 year and has conducted its first meeting in April of this
9 year and will have its second meeting in the fall as
10 well. So, hopefully it can provide some bridge between
11 this advisory committee and that one to the Agency.

12 MS. BROWN: I'm Amy Brown. I'm a professor at
13 the University of Maryland in the Department of
14 Entomology. I am an entomologist and toxicologist. I
15 coordinate the state outreach and education program for
16 pesticide applicators whether they're growers,
17 occupational applicators or consumers. That takes a
18 large part of my effort.

19 I also have an active research program. My
20 graduate students and I focus on exposure to pesticides,
21 a little bit on the potential effect of pesticides to
22 those exposed, and a lot on identifying effective

1 strategies that education can provide to minimize
2 pesticide exposure.

3 MR. CONLON: Good morning. My name is Joe
4 Conlon and I'm a technical advisor for the American
5 Mosquito Control Association which is a nonprofit
6 organization comprised of about 1,700 public health
7 officials, mosquito control professionals, and
8 academicians from 52 countries.

9 Our reason for being here is to ensure that the
10 rather unique parameters for public health insecticide
11 application are taken into account in the regulatory
12 process. As you may know, our insecticide applications
13 are fundamentally different than agriculture, and we just
14 wanted to make sure that that is taken into account in
15 your deliberation.

16 Thank you.

17 MS. KEGLEY: I'm Susan Kegley, Senior Scientist
18 at Pesticide Action Network out in San Francisco.
19 Pesticide Action Network works both nationally and
20 globally to reduce the use of toxic pesticides and
21 promote the (inaudible) method of pest management. We
22 represent the interest of workers, neighbors to

1 agriculture and others who have been adversely affected
2 by pesticides. We also provide information on pesticides
3 and have the pesticideinfo.org web site as ours that
4 brings together a variety of data sources for pesticides.

5 The things that we're working for is to use --
6 you know, we do a lot of science-based advocacy for
7 thinking about ways to remove the most problematic
8 pesticides from the market and then also work towards
9 mainstream biologically-based pest management as a
10 primary pest management approach. We believe that it's
11 really important for everyone to have full access to
12 information on pesticides so that they can make informed
13 choices about their pest management decisions.

14 Some of the work we've been doing lately is
15 collecting actual air monitoring data in people's homes
16 and yards to see what the actual exposures are to some of
17 the volatile pesticides.

18 Our interest in serving on the PPDC is to
19 really hear about the emerging issues and to hear the
20 different points of view and meet the people. It's a
21 pleasure to be here.

22 MR. BARON: Good morning. My name is Jerry

1 Baron and I'm executive director of the IR-4 project.
2 I'm also associate director of the New Jersey Agriculture
3 Experiment Station which is connected to Rutgers
4 University in New Jersey.

5 The IR-4 project is a national agriculture
6 program for the regulatory clearance of safe and
7 effective biopesticides and conventional products for
8 specialty crops. We've been out there for 45 years doing
9 this task. IR-4 is funded by the United States
10 Department of Agriculture. We're a true partnership with
11 the Land Grant University system, the agriculture
12 chemical companies, as well as the Environmental
13 Protection Agency.

14 Thank you.

15 MS. COX: My name is Caroline Cox and I'm the
16 research director at the Center for Environmental Health
17 in Oakland, California. We work with businesses to
18 reduce their use of toxic chemicals, including
19 pesticides. We use a variety of strategies, some very
20 collaborative and some more litigation-focused. But the
21 end goal is always the same, just to reduce the use of
22 toxic chemicals.

1 My specific interest on the PPDC is that I've
2 worked on the issue of increasing information that's
3 available to the public about inert ingredients and
4 pesticides for the last couple of decades and plan to
5 continue that as long as necessary and think that the
6 PPDC is a useful way to go about that.

7 MR. THRIFT: My name is Jim Thrift. I'm with
8 the Agricultural Retailers Association. Agricultural
9 Retailers Association, ARA, represents virtually all the
10 retailers and distributors that sell the crop protection
11 chemicals to America's farmers. I spent 35 years with
12 two international pesticide registrants in the last five
13 years of ARA.

14 Our basic interest in being here was I served
15 on the spray drift work group, so spray drift mitigation,
16 applicator standards and safety, worker protection and,
17 of course, endangered species. We have a significant
18 interest in a variety of these areas since we work with
19 basic registrants and the communities where we do a good
20 deal of the application of the pesticides besides the
21 sales. I have a long history of interaction with the EPA
22 and know most everybody here at the table.

1 MS. RAMSAY: My name is Carol Ramsay with
2 Washington State University Extension. When we mention
3 extension, that includes all of the county agents, the
4 state specialists, as well as the pesticide safety
5 educators.

6 My interest in this committee is basically
7 looking at policy and process regarding the certification
8 of applicators and also the outreach to consumers and
9 home gardeners. In particular, I've got interest in
10 public health and environmental safety outreach, as well
11 as labeling issues.

12 MR. SCHERTZ: Hello. I'm Scott Schertz. I own
13 and operate Schertz Aerial Service which is an aerial
14 spraying operation in central Illinois. I am
15 representing the National Agricultural Aviation
16 Association here. Currently, I do lead their research
17 and education foundation which handles the safety and
18 education programs for the aerial application industry.

19 My perspective here is as an aerial pilot
20 applicator, also as an operator, which means running an
21 aerial spraying business, but also as an independent
22 retailers that handles the products and works with the

1 handlers and all the other issues.

2 Thank you.

3 MR. KEIFER: My name is Matthew Keifer. I'm a
4 physician at the University of Washington. I'm an
5 academic researcher and teacher in the School of Public
6 Health, in the School of Medicine. I'm clinically active
7 and see farm workers in farm worker clinic in eastern
8 Washington which is a place where there is a lot of
9 agricultural activity.

10 My perspective is principally that of an
11 occupational health specialist with some knowledge of
12 pesticide health effects and particular understanding of
13 the clinical manifestations of pesticide exposure.

14 MS. DAVIS: My name is Shelley Davis. I'm with
15 Farmworker Justice. We're a national advocacy and
16 education center for migrant and seasonal farmworkers.
17 My interest in this committee primarily is to ensure the
18 health and safety of farm workers and persons who apply
19 pesticides in agriculture.

20 So, I'm interested particularly in the
21 registration process which determines the work conditions
22 under which pesticides can be applied and any changes in

1 the work protection stand.

2 DR. GREEN: I'm Tom Green with the IPM
3 Institute based in Madison, Wisconsin. We're an
4 independent non-profit. Our mission is to leverage
5 marketplace power to improve health in the environment
6 through IPM. We work with Cisco, the food distributor,
7 on a program now that includes 4,000 growers and 80 food
8 processors in over 600,000 acres of production that
9 participates in an IPM as a scenable AG program.

10 We also operate the IPM star program which is
11 an on-site verification and certification program for
12 school systems nationally and a new program called Green
13 Shield Certified which also evaluates structural pest
14 management professionals on site and certifies them.

15 We're really interested in strategies that
16 prevent and avoid pest problems and the need to intervene
17 and also strategies to choose least toxic pesticides and
18 reduce potential for exposure when a pesticide is needed.
19 We're a new member and really appreciate the opportunity
20 to participate on the committee.

21 MR. KASS: Hi. My name is Dan Kass. I'm with
22 the New York City Department of Health and Mental

1 Hygiene. I'm an environmental epidemiologist. I run a
2 group at the health department that has been trying to
3 pay increasing attention to pests and pesticides in New
4 York City.

5 Like most of these, I suspect, although we have
6 better data, we have pest and pesticide problems. About
7 30 percent of households in New York City report recent
8 infestations of cockroaches and 25 percent with mice. We
9 have a resurgent bedbug problem.

10 In the midst of all this, we have a significant
11 amount of use of pesticides in the city. For example, a
12 third of New York City households report the regular use
13 of aerosol products indoors. Fewer than 25 percent have
14 regular professional pest control management visiting
15 their homes.

16 About 1,000 people a year report accidental
17 exposures to our poison control center from the use of
18 pesticides, a vast majority of children and a vast
19 majority in the homes. We have hundreds of people every
20 year who report to emergency rooms with exposures and
21 about 60 people are hospitalized in New York City each
22 year from exposure to pesticides. About six to nine

1 apartments explode every year from the use of pesticides.

2 In the midst of all this, we have also
3 completed preliminary analysis of an exposure study that
4 demonstrates that urban exposure, as demonstrated in New
5 York City, are dramatically higher to organophosphates
6 and pyrethroids compared to a national representative
7 population.

8 In the midst of all this, we have pretty
9 dramatic disparities in New York City. Low income
10 families are far more likely to have pests, are far more
11 likely to depend on off-the-shelf products, are far less
12 likely to get professional pest control services.

13 My interest here is to seek help and offer
14 guidance on ways in which we can try to address some of
15 these situations. New York City, like most cities, is
16 ill-equipped in a regulatory perspective to really
17 influence most important aspects of influence over
18 applicators and over product registration and labeling
19 that might help to alleviate the problems.

20 I look forward to participating and thanks very
21 much for the opportunity.

22 MS. LAW: Good morning. My name is Beth Law

1 (phonetic). I'm with the Consumer Specialty Products
2 Association and I'm here this morning sitting in for Phil
3 Klein.

4 The Consumer Specialty Products Association
5 represents consumer pesticide products -- represents the
6 manufacturers and the sellers of consumer specialty
7 products.

8 Our particular interest is in working with the
9 regulatory community on a whole host of issues, including
10 labeling and youth and other issues that would help
11 ensure the proper use of the products, thereby increasing
12 the efficacy.

13 So, we look forward to doing that in this
14 forum. Thank you.

15 MS. LIEBMAN: Good morning. My name is Amy
16 Liebman. I'm from the Migrant Clinicians Network.
17 Migrant Clinicians Network is a national clinical network
18 with about 4,000 clinical constituents that we work with.
19 They, in turn, serve the mobile underserved largely
20 farmworkers and migrant seasonal farmworkers.

21 So, I am here as a member of the PPDC. I'm
22 happy to be a returning member. Thank you. And I think

1 that I represent our clinicians who are working with
2 migrant and seasonal farmworkers. We're interested in
3 their health and safety. Specifically on the PPDC, I'm
4 very interested in the worker protection standard and the
5 registration process and labeling.

6 DR. SHAH: I'm Hasmukh Shah with the American
7 Chemistry Council. I represent the interest of the
8 (inaudible) and the formula to registrants for industry
9 (inaudible) and the consumer uses. Our interests are
10 varied, including research, regulatory and the outreach
11 programs infecting the (inaudible) industry at the
12 federal, state and the international level.

13 MR. FRY: My name is Michael Fry. I represent
14 the American Bird Conservancy. I'm an avian
15 toxicologist. Prior to being at ABC, I was 25 years on
16 the faculty at the University of California at Davis as a
17 toxicologist.

18 My interests are in protecting wildlife from
19 the adverse effects of pesticides and finding safer
20 alternatives for wildlife so that agriculture and
21 wildlife can go peacefully. I represent also a member of
22 the National Pesticide Reform Coalition which is a group

1 of about 20 environmental organizations all interested in
2 protecting wildlife and the effect of pesticides. Thank
3 you.

4 MS. SPAGNOLI: I'm Julie Spagnoli with FMC
5 Corporation. We're a basic registrant of agricultural
6 products, turf and ornamental structural pest control and
7 consumer products which we supply through consumer
8 product marketers.

9 I guess, sort of like Dan Botts, I just bring a
10 lot of institutional knowledge. I've been working with
11 the Agency on a number of initiatives over the years, I
12 guess starting with insect repellent issues back in 1990
13 and working on a PR notice on insect repellents. I've
14 worked with them on the consumer label initiative and
15 termiticide issues.

16 I've been on a number of PPDC workgroups,
17 inerts, inert disclosure, registration review,
18 performance measures. So, as I said, I've been here a
19 while and look forward to continuing to work
20 collaboratively with, you know, other state (inaudible)
21 to come up with the best policies that we can.

22 MR. JAMES: I'm Allen James, president of

1 Responsible Industry for a Sound Environment. We
2 represent manufacturers, formulators and distributors of
3 specialty pesticides and fertilizers that contribute to
4 healthy urban environments. I'm pleased to be
5 reappointed to the committee.

6 MS. KENNEDY: Good morning. My name is
7 Caroline Kennedy. I'm with Defenders of Wildlife.
8 Defenders was established in 1947 and we're a DC-based
9 conservation organization that focuses primarily on large
10 carnivore conservation, but we're also interested in
11 impacts of pesticides on particularly endangered species
12 and migratory birds. We have a million members and
13 supporters across the country.

14 MR. GUSKE: Good morning. My name is Rodney
15 Guske. I work with the Yakama Nation in south central
16 Washington state where I work as a one percent pesticide
17 program. I'm here as a representative of the Tribal
18 Pesticide Program Council listening for items of interest
19 to tribes and reporting back to the TPPC on items of
20 tribal interest.

21 MS. HERRERO: I'm Maria Herrero. I'm with
22 Valent BioSciences. I'm naturally here representing the

1 biopesticide industry alliance which is a trade
2 association with about 32 members, mainly small business.
3 But we look for biologically-based products, microbials
4 and naturally occurring biopesticides that hopefully have
5 a softer impact on human health and the environment. We
6 are basic registrants but look for some products that can
7 be more of an integral part of the sceneable agriculture
8 and public health.

9 MR. HOWARD: Good morning. My name is Dennis
10 Howard. I represent, well, first of all, the Florida
11 Department of Agriculture and Consumer Services and also
12 the state lead agencies for pesticide regulation in the
13 U.S.

14 State lead agencies consider themselves to be
15 in full partnership with EPA. They vary very much in the
16 size of their programs and capabilities and their
17 complexity, so representing a group of that diversity is
18 -- it's important for us to have an association that
19 deals directly with the Agency and that's the American
20 Association of Pest Control officials.

21 A lot of the issues that are of interest to EPA
22 are direct interest to us in the states. In particular,

1 we're responsible for making sure that pesticide use is
2 complied with, so compliance and enforcement is important
3 to us, as well as registration of products.

4 A key part of registration of products and
5 compliance is the label. That turns out to be the dictum
6 that everyone relies on to determine how to use things
7 safely. A lot of labeling issues that have come up in
8 the PPDC as well as in ABCO forms spray drift, endangered
9 species, worker protection, a lot of different issues.

10 We're very interested in maintaining our
11 partnership and look forward to hearing the perspective
12 other stakeholders as well.

13 MR. MICHAEL: Good morning. My name is Cannon
14 Michael. I'm here on behalf of the California Cotton
15 Ginners and Growers and the National Cotton Council. I
16 am also a sixth generation California farmer, so I'm an
17 end user of a lot of the agricultural products.

18 We have a vested interest in the health and
19 safety of our workers, the environment and the crops of
20 our neighbors and our own. And so we have a lot of
21 interest on a lot of the issues that are happening here.
22 It's one thing to sit in DC and make regulations and

1 rules; it's another thing to implement them.

2 So, we just look for the policy to be made in
3 intelligent ways and just look forward to contributing to
4 that.

5 MS. BRICKEY: Hi. I'm Carolyn Brickey and I
6 think I was with Dan, one of the founding members of this
7 group. I've worked on a lot of pesticide policy issues
8 over the years, primarily focusing on ways to reform the
9 process and make it work better.

10 I've been involved in re-registration programs,
11 the Quality Protection Act, the Pesticide Regulatory
12 Improvement Act, PRIA-1 and PRIA-2, and I'm particularly
13 interested in risk assessment, how it's done, risk
14 reduction of course, and impact on the environment and on
15 water quality.

16 Would be very interested in making efforts with
17 some of the members of this group to green the pesticide
18 industry a bit more as we move along. I'm pleased and
19 happy with some of the work that's been accomplished
20 through this process to reduce risk.

21 DR. COPE: Good morning. My name is Stan Cope.
22 I'm a medical entomologist for the United States Navy and

1 I'm here representing the Armed Forces Pest Management
2 Board. If you can't remember that, we just call it the
3 big bug board. We're here in Silver Spring, Maryland.
4 Anything that has to do with pesticides within DOD, we
5 write policy, provide guidance and oversight for that.

6 Our primary interest is to minimize the threat
7 of insect transmitted diseases to our men and women in
8 uniform, because it still has a serious impact on our
9 ability to carry out our mission. We also -- I
10 personally oversee a \$5 million a year research program
11 to find new pesticides, new application equipment, and
12 new methods of personal protection. We're making
13 progress in a lot of those areas, so we're very
14 interested in topics such as registration, etc.

15 DR. KASHTOCK: I'm Mike Kashtock. I'm here for
16 Nega Beru who is the director of FDA's Office of Food
17 Safety in the Center for Food Safety in College Park.
18 FDA is responsible for enforcing the pesticide tolerances
19 created by EPA in the part of the food supply that FDA
20 regulates.

21 A lot of what happens, obviously, in the EPA
22 pesticide realm directly affects FDA and how FDA

1 discharges that part of its mission. I'm here simply to
2 bring an FDA perspective as needed to the discussions in
3 this committee.

4 MR. COLBERT: Good morning. I'm Rick Colbert,
5 director of the Agriculture Division in EPA's Office of
6 Compliance. Among the things we do is we implement the
7 good laboratory practices inspection program for dealing
8 with laboratories (inaudible) studies, part of
9 registration. We also administer the pesticide
10 enforcement grants that go to the state lead agencies,
11 like Dennis Howard's, that enforce FIFRA.

12 I'm here to look at OPP regulations, labels,
13 policies, from the perspective of the ability to assure
14 compliance.

15 MR. SAYERS: Good morning. My name is Rick
16 Sayers and I'm with the US Fish and Wildlife Services
17 Endangered Species Program. That's my primary
18 perspective here, to help inform this group and EPA on
19 both the process and the substance of Endangered Species
20 Act compliance.

21 To the extent that a broader perspective is
22 needed from the Agency, I may have to actually go back

1 and talk to people in our refuge program or our
2 environmental quality program if those kinds of issues
3 are brought up and need our attention.

4 MR. JENNINGS: Hi. I'm Al Jennings. I'm
5 director of the Office of Pest Management Policy with the
6 United States -- or Agriculture. As most of you know,
7 the USDA is a very large department consisting of many,
8 many rather independent agencies. The last time I
9 counted, there were probably at least seven, and maybe
10 eight, of those agencies that had something to do with
11 pesticides and pest control.

12 My job is to try to integrate all of that
13 wonderful information in those independent agencies and
14 put it together in a meaningful way and give it to my
15 friends here at EPA so they can use it in making their
16 decisions.

17 I guess ultimately what we try to do is provide
18 reasonable information on pesticide use, crop production
19 systems, and risk mitigation options, along with the
20 impacts of what those various options might be on
21 agriculture. Basically, we do try to represent the
22 farmer's and rancher's view of pesticide regulation. I

1 work a lot with those people as well as our partners in
2 the land grant system.

3 I suppose my main qualification for the job is
4 working over 20 years here at EPA, so I know the language
5 here and have, after 10 years, learned it in USDA.

6 MS. EDWARDS: I believe we have captured
7 everyone at the table except Jennifer Sass. If that's
8 incorrect, let me know, but Jennifer.

9 DR. SASS: Hi. Thanks for inviting me back to
10 the PPDC. I'm a returning member. I work with the
11 Natural Resources Defense Council, NRDC, which is an
12 environmental nonprofit. I'm based here in Washington
13 and I work in the health program. I'm a senior scientist
14 with the program. My background is all basic medical
15 research. I worked at the lab for 10 years and now I've
16 been at this job for 7. I kind of think I've been on the
17 PPDC about that long.

18 But anyway, NRDC and my program interacts in
19 the world of pesticides of EPA on a daily basis. We have
20 scientists. We don't generate our own research but we
21 review and submit research. I participate in several
22 opportunities on (inaudible) advisory committees like

1 this. As well, we have litigators, science and policy
2 people.

3 Mostly, I just want to say welcome to all the
4 new members and also members returning. It's really
5 exciting to hear people around the table with all this
6 new experience and new perspectives. I'm most especially
7 excited to see that nobody is going to be quiet, so it
8 should be a really fun and interesting two days.

9 MS. EDWARDS: Thank you. I believe we also
10 have a couple of members on the phone. So, at this point
11 I will ask that you step in and introduce yourselves as
12 well.

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

14 MS. EDWARDS: Maybe we don't have anyone on the
15 phone.

16 MR. LEAHY: Hi. I'm Richard Leahy from Wal
17 Mart Corporation. I'm the senior director of
18 environmental compliance. We're new to the group. We're
19 very pleased to be here. So, thank you.

20 Our particular interest is in reducing
21 pesticide waste at the retail level and promoting
22 pesticide recycling at the retail level. We see -- we

1 have millions, literally millions of pounds of product
2 that become cosmetically damaged at stores that wind up
3 as waste.

4 We're very interested as part of our overall
5 environmental sustainability push in finding out ways to
6 deal with that so the product can be used for its
7 intended purpose and not be waste. And that's our
8 interest.

9 UNIDENTIFIED FEMALE: I just want to echo what
10 Jennifer said about the amazing diversity of this group.
11 I really want to congratulate you and your staff, I
12 presume principally Margie Fehrenbach, in putting this
13 array of divergent interests together. I'm very
14 impressed.

15 MS. EDWARDS: Well, thank you very much. That
16 was the intent. Margie worked very, very hard on this
17 and spent weeks getting this together and doing all the
18 leg work. She is our designated federal official. For
19 those of you who don't know her, please come out here,
20 Margie, so they can see who you are. I should have
21 introduced you before. Margie takes care of an enormous
22 amount of work to keep this being, I think, one of the

1 better run FACAs that we know of.

2 I'd also like to introduce Anne Lindsay at this
3 time. She is our deputy director for programs. I didn't
4 have her introduce herself. I think most of you know
5 her, Anne Lindsay.

6 So, I think at this time I would like to --
7 we're actually running ahead of time, which is a good
8 thing. That means we'll have more time for discussion as
9 we move through the topics today. So, what we'll do is
10 have a break until, let's say, 10:25, and then start in
11 with our session. Thank you.

12 **(Whereupon, a brief recess was taken.)**

13 MS. EDWARDS: Welcome back. If you would,
14 please, take your seats. We have a very jam-packed
15 afternoon, so I wanted to talk just a little bit about
16 how we're planning to run this.

17 We have coming up two sessions on labeling
18 issues. The first one is an overview of many things
19 we're doing in the labeling improvement area, everything
20 from public access to information, efficiencies, labeling
21 quality, and so forth. Anne Lindsay is going to make
22 that presentation.

1 There will be in this particular session very
2 little time for comment because what we want to do is get
3 to the longer session that Bill Jordan will chair, which
4 is a full hour, to talk about our new initiative on web-
5 distributed labeling. There again, we're going to ask
6 this group if you would be interested in having a
7 workgroup formed to begin to work the issues around web-
8 based labeling.

9 So, I guess I'm going to ask that you just
10 recognize up front here that we're not going to have much
11 comment at this point. But what we can do, again
12 tomorrow -- and I'll say this later on in a couple of
13 other topics -- is as we begin to develop the agenda for
14 October's meeting, some of these topics that you're
15 getting previews on or updates on this time, you can let
16 us know if you think that you'd like to have some more
17 significant input in this forum at a future meeting.

18 So, with that, I'll hand it over to Anne.

19 MS. LINDSAY: Okay. This is actually
20 reflecting on the morning's discussion and I think one or
21 more people used the word transformation or
22 transformational, something like that. It occurred to me

1 that OPP has been very fortunate in its advisory
2 committees. This is I think the advisory committee with
3 the greatest longevity at this point in time. It's
4 looked at the widest array of issues.

5 We've had some other advisory committees as
6 well, track and carrot, that were very focused on FQPA
7 implementation. Those early FQPA committees I think
8 really did transform the way we do public participation
9 and in part I think help make this the very robust
10 advisory committee group that it is. So, that's one
11 piece of our regulatory program that advisory committees
12 have really helped us to change.

13 It's like my point of view is like night and
14 day, the old things we used to do, calling them public
15 participation, versus what we do nowadays and not just
16 the mechanisms but what we open to public participation
17 and kind of the depth and breadth of it.

18 We've had this committee in particular in some
19 earlier years help us really transform how we reevaluate
20 chemicals that have been on the marketplace, implementing
21 another provision of the Food Quality Protection Act, one
22 that I think in some ways is kind of a sleeper provision.

1 It's just a little tiny line, but I think it's very
2 transformative because what it says is you need to have a
3 continuous evaluation process in place. It's not once
4 and done.

5 And again, I think we would not have this sort
6 of registration review program that you'll hear about
7 later this afternoon if it were not for the deep and
8 extensive involvement of a number of members of this
9 committee.

10 You have an opportunity for the future on the
11 science side, which is obviously a very important piece
12 of our regulatory program, to help us transform the
13 science and the way we do our evaluations in some very,
14 very substantial ways, even if it does take more than a
15 year or two to actually get there.

16 I think there is actually another area where
17 you've already begun to have a transformational effect
18 and I think that -- I hope that it will actually grow and
19 bear extraordinary fruit, and that's the label. For me,
20 the importance of good labeling is paramount.

21 Labeling in many ways is the distillation of
22 everything that we do. It's the distillation of the

1 science development, the science evaluation, the risk
2 mitigation, what we know about good agricultural
3 practices or, if it's not an agricultural product, good
4 practices in the context in which the product is to be
5 used. It's the one clear document we have to tell the
6 user of the pesticide everything they need to know about
7 the right way to be using that pesticide product. So, a
8 lot less on the label.

9 And when the label doesn't work right, when
10 it's not as effective as it could be, then we actually
11 don't prevent the sort of adverse effects that we are
12 expecting to prevent through our evaluation and our risk
13 mitigation decisions. We actually don't get our job done
14 if this doesn't happen, if the label isn't effective.

15 So, in all of the transformation that's going
16 on, what I want to put the idea in your head is there's a
17 real opportunity here to transform labeling in some
18 fairly substantial ways. We actually have a lot of work
19 underway of some very different types. I think when you
20 put it all together, you can see that that transformation
21 process is already underway.

22 This is just what I'm going to go through

1 quickly in the presentation. We probably can move on to
2 the next slide.

3 This was actually a hard slide for me to want
4 to put up here because for as long as I've worked at EPA,
5 we've put a lot of resources into label review. The very
6 first people I met when I was new to the program were
7 label reviewers. They were kind of like gods to me at
8 that point in time. They were the ones who could explain
9 everything, or at least that's what I thought. In fact,
10 they are very good people and they always have been. They
11 do an extraordinary and remarkable amount of good work.

12 Nevertheless, this kind of lists what we have
13 come to realize for our own selves with regard to
14 labeling. I think it is the whole labeling system at
15 whose feet I would lay these sorts of problems that the
16 current system we've got is antiquated, it's conflicted
17 to a certain extent.

18 You have multiple goals. One goal is to make
19 labeling enforceable. Another goal is to actually make
20 it easy for the user to understand what they should be
21 doing. As it turns out, enforcement and use are not
22 always easily compatible. What makes sense from a user

1 context may actually not be very enforceable.

2 The label is supposed to carry out both of
3 those roles. It's a paper-based system. It's an
4 incredible paper-based system. It's product by product,
5 so it's hard to actually get out of the details of it and
6 get up on top of it to perhaps see what are the generic
7 issues, the generic solutions, the generic approaches
8 that could help with quality control.

9 We have changing standards of acceptability. I
10 was looking at an older label and for -- it was actually
11 an OP and it said "use as needed." Well, so you could
12 use it as needed and you wouldn't be violating the law
13 probably, but you might be actually overapplying.

14 One term somebody used was inappropriate use.
15 I think that's an example, you know, of a changing
16 standard of acceptability. I imagine at the time that
17 that product was approved and that language was graded,
18 that's what people thought was really appropriate and all
19 that was needed at that point.

20 Nowadays, I think we all know -- and I can tell
21 by your nodding of heads and smiles and so forth --
22 that's really not what you want to see on a pesticide

1 label. So, we have definitely had a change in standards
2 of acceptability for important labeling statements over
3 time.

4 Then there are major resources that are needed
5 and not just agency resources but industry resources,
6 state resources, all kind of training resources, to
7 effect label changes, especially if you want to make big
8 changes over lots of products. There can be a very long
9 implementation time for those changes which can frustrate
10 everybody, especially if there's a risk safe reason for
11 wanting to make the label changes.

12 This is just some more about existing problems
13 we have, in some cases long labels. I remember my father
14 telling me about the label encyclopedia he watched a
15 farmer throw on the riverbank. He brought it home and
16 showed it to me and asked if this was what my job had to
17 do with. He wanted to let me know it wasn't very useful
18 because it was left on the riverbank.

19 Unenforceable and ambiguous language, language
20 that's internally not consistent. So, one place it tells
21 you to do one thing. If you go to another part of the
22 label, it seems to be telling you just the opposite of

1 that.

2 So, all of these areas are problems that I
3 think this group over time has brought to us in the
4 context of different work that you've done. We've also
5 heard these kinds of issues from states and tribes. I
6 think as we ourselves have gone through the reevaluation
7 process and tried to change labeling on pesticides, we've
8 spotted them as well.

9 So, that's why I think we have kind of an
10 opportunity for real change, because even though it's
11 hard to look at your work which you invest a lot of
12 resources in and you know how hard you work at it, you
13 can also see that it's time for a change.

14 Our overall approach to labeling, the way I'm
15 looking at it currently, we've got three major areas that
16 we're focusing on. I'm just going to touch on each of
17 them very briefly. One is electronic submission and
18 review. One set of changes that we're looking at is how
19 do you actually improve the content of the label. Then,
20 finally, and this is the topic in particular that you're
21 going to hear a lot more about when Bill does his
22 presentation, is the electronic dissemination or

1 distribution of pesticide labeling.

2 Basically, we think if you want a different
3 outcome, if we don't want to continue to have this sort
4 of historical problems that I've tried to characterize
5 for you, then you actually really do have to change the
6 underlying system by which you do the labeling. When I
7 say the we, I'm actually probably using the very large
8 we, not completely (inaudible), but all of you and many
9 others.

10 So, we need to change how we obtain labeling.
11 That is, how do we actually get the labeling for approval
12 from the registrant. How do we capture that labeling
13 information into our internal system in useful ways? How
14 do we review the labeling? How do we process the
15 labeling? How do we make decisions on it? And how do we
16 communicate about labeling to users both through the
17 label and through other mechanisms?

18 The electronic submission and review of the
19 label is actually part of a much larger transformational
20 activity that we have going on where we're ultimately
21 looking at the sort of full electronic submission of all
22 elements of a pesticide application into our system, and

1 I think as much as possible then to actually use it
2 electronically and document the results and be able to
3 share the results of our reviews, whether it's a label or
4 a piece of data, electronically and be able to store it
5 in such a way that it's manipulable and useable in a
6 variety of different ways, both by EPA staff as well as
7 by others.

8 We're doing this in a way that we're going to
9 be trying to harmonize with other major regulatory
10 agencies through the OECD, and we believe that we'll
11 actually see some extraordinary efficiencies as well as I
12 think quality control improvements in our review
13 processing.

14 XML, I can actually say what it is, extensible
15 markup language. I'm not going to talk about it for
16 those of you who are not IT experts for the course. It's
17 actually a very important tool for us in it's going to
18 allow us to capture labeling elements in ways that are
19 useful, that are sort of tagged so that your internal
20 systems actually know what piece of information it's
21 getting and it knows where to sort of put it so that it
22 becomes useful to us.

1 We have begun the process internally of
2 developing requirements for the next generation of
3 electronic label submission. We're asking ourselves what
4 information do we need the system to capture and what do
5 we need to do with it. Ultimately, what we want to have
6 is this sort of labeling builder software which would be
7 sort of like Turbo Tax. If you were an applicant, you
8 could sit there and build your label using labeling
9 builder.

10 We think that this e-submission process would
11 really replace the relatively cumbersome by hand process
12 that we've got. Although we've started that and we have
13 sort of a PDF electronic submission process now available
14 to labels, the label builder concept using XML will
15 actually really represent an advance over the current
16 state of affairs.

17 It will allow us to install information into
18 our label use and information system in an automated way
19 quicker, cheaper and error free. Obviously, we think it
20 will allow us to actually complete our product
21 application reviews much quicker and more efficiently.

22 So, that's one stream of activity that's

1 ongoing. The second is actually a set of activities
2 designed to improve labeling content. A lot of this is
3 actually driven from groups like this, advisory
4 committees, looking at particular types of labeling,
5 giving us feedback about problems and opportunities for
6 improvement that you saw.

7 I will also -- the spray drift working group,
8 in particular, spent a lot of time on labeling and had
9 recommendations not just for spray drift but more broadly
10 for improving labeling. Our state partners and our
11 tribal partners have for a very long time been telling us
12 that we needed to take a rigorous look at the quality of
13 our labeling and think about opportunities for change.

14 Then we've also heard from all kinds of
15 advocacy groups. We've heard from individual companies.
16 It's pretty uniform that there were real problems with
17 labeling content. So, we're instituting both some
18 procedural internal changes as well as we're making some
19 substantive changes to the content of labeling.

20 On the procedural side, we've established an
21 internal workgroup which we'll call label accountability
22 workgroups since the label is the law. That group

1 actually spent a number of months last year doing a
2 diagnosis of what really did seem to be the problem and
3 came up with a set of recommendations, which were
4 presented to Debbie, and she actually decided that it
5 would be good for the program to move forward on the
6 implementation of those recommendations.

7 The first piece was actually pretty critical,
8 which was to put out as guidance to everybody in the
9 program some basic principles for the review of labeling.
10 They're also pretty simple. It includes things like use
11 the label review manual that we developed when you're
12 reviewing labeling.

13 Try to maintain as you're reviewing a label a
14 clear distinction between language that needs to be
15 mandatory because it needs to be enforceable versus
16 language that is purely advisory in nature. Choose the
17 right words. If you mean must, if you want it to be
18 mandatory, then use must, not may, not should, must.

19 The importance of also looking at the format
20 and layout of a label so you're looking at not just the
21 specific words but in what section do those words fall
22 and what does the section heading actually say? If the

1 section heading says one thing and then the interior
2 content of that section seem to say something else,
3 you're already setting up problems, I think, both for the
4 user potentially as well as for enforcement when
5 enforcement is important.

6 Then as much as possible actually use terms
7 that are understood, that have clear meaning, and to stay
8 away from undefined and unclear and jargony terms that
9 people will not understand.

10 But the other recommendations beyond trying to
11 have us all use those principles as we're evaluating
12 labels have to do with updating, training and making sure
13 that that training is comprehensive and routinely
14 available within our program on how to review labeling,
15 having, I think, more frequent updates for the label
16 review manual and where it's appropriate for certain
17 kinds of changes to incorporate processes for stakeholder
18 input into changes for the label review manual, not every
19 change necessarily but for some where it would be very
20 valuable.

21 We're also looking at establishing what I'll
22 call quality assurance programs within our registering

1 division where it might be some kind of an audit
2 approach. I think each of the divisions may ultimately
3 come up with slightly different approaches to it. But
4 the end goal is to have some way ourselves to be able to
5 actually monitor overall the quality of our label review
6 and thus of our labeling.

7 Look at priorities. Which are the labeling
8 problems that merit the earliest attention because they
9 seem to be most widespread and most significant? Then
10 finally looking at new ways for stakeholder involvement.
11 We've already begun that process working with our state
12 officials through the state -- issues, research and
13 evaluation groups. So, we have a mechanism now to
14 actually bring in some direct state participation on key
15 labeling issues.

16 I'm not going to go through all of these things
17 on the list, but these are just a listing of some of the
18 areas where we either have recently completed work or we
19 have significant work underway that will lead to
20 substantive labeling change. I will talk about a few of
21 them.

22 Spray drift, obviously we're very much at work

1 internally in developing draft PR notes for spray drift
2 labeling which I would expect to be out for public
3 comment this summer. We're working with the work of --
4 this committee spray drift workgroup is proving very,
5 very useful. I have very close working relationship with
6 our states in developing the concept and I think it will
7 be actually a very good draft for people to comment on.

8 The mosquito adultsize is actually the first
9 time I remember taking a major labeling issue to this
10 advisory group and I think it led to some substantial
11 improvement in the final PR notice we issued and then
12 some substantial improvements on the labels of these
13 kinds of products.

14 Cause marketing I wanted to mention just very
15 briefly. We took this issue, this -- for those of you
16 who are new, cause marketing essentially means can we
17 permit on a pesticide label the use, say, of a logo from
18 a charitable organization perhaps to raise funds for that
19 charitable organization and whether or not those
20 statements would be false or misleading. False or
21 misleading is the essential set of criteria we have to
22 use to judge labeling statements.

1 We had a discussion about a year ago, as I
2 recollect, at this advisory committee meeting. Heard
3 everybody's views. We put a draft PR notice out for
4 comment. That comment period closed at the end of March
5 this year. I will say that we got 100-plus comments and
6 I would say almost all of them, except for less than a
7 handful, were unanimously, I would say, opposed to cause
8 market type statements on pesticide products for a
9 variety of reasons, most of which we actually heard at
10 least in summary form at the PVDC meeting.

11 So, as you know, we take very seriously the
12 comments that we get from a process like the advisory
13 committee as well as the public process. I think that
14 the nature of the comments that we got are such that it's
15 going to have a significant impact on the final outcome.
16 I would expect that we'll be publishing a document that
17 will sort of bring to closure at least this round of
18 discussions on cause marketing. Again, I would look for
19 that later this summer.

20 The last thing I'll just mention is a recent
21 completion -- it's the second from the bottom -- the
22 environmental hazard statements on consumer products.

1 There was a PPDC workgroup that looked at consumer
2 labeling. Came back, actually, with some advice that
3 consumer labeling could use some improvement and
4 identified in particular environmental hazard statements
5 like consumer products as an area of needing improvement.
6 So, we've issued a final PR notice just this week, I
7 think, and we hope that people who manufacture and sell
8 consumer products will actually use it.

9 The last element is really just a preview of
10 Bill's presentation and the discussions that we hope
11 we'll be able to have at least a bit of here. This is on
12 web-based distribution and labeling. It is a system
13 which would make the most current version of the
14 pesticide label available to purchasers and users
15 electronically on an EPA-maintained web site.

16 Those of you who are familiar with endangered
17 species and our efforts in that arena will maybe notice
18 this is somewhat similar to the endangered species
19 bulletin and what we've done there to make the bulletins,
20 once we actually have bulletins available, part of the
21 labeling and available from the web site.

22 But this would be more broad than just the

1 endangered species bulletin. We think it would allow
2 simplifying the container label and it would also allow
3 for much more rapid updating of pesticide labeling than
4 we're able to do currently.

5 A URL would actually be placed on the pesticide
6 label, on the container, that would direct users to the
7 web site. As we're currently envisioning this, we think
8 it would probably, most likely, replace the directions
9 for use that are currently on the physical container.
10 The label that would be on the physical container would
11 still have all of the FIFRA-mandated elements, so things
12 like the product name, the registration number, the net
13 contents, the ingredient statement.

14 So, there would still be useful information on
15 the container itself, but it would be much more limited
16 and more focused. You would direct the user then through
17 the URL to the web site to get more detailed instructions
18 that would be pertinent, for example, for the use that
19 they wanted to put the product to.

20 Distributors, purchasers and users could go to
21 EPA's pesticide labeling web site, enter the product
22 registration number, and they would then get the product

1 label in a printable format. Dealers could actually
2 distribute the printed labeling as a service to their
3 customers, although, obviously, users could do it
4 themselves as well.

5 For those who don't have access to the web or
6 don't have I guess what they call rapid access to the
7 web, we would also envision having a toll free telephone
8 number that would be available for folks to get their
9 labeling through the toll free telephone number. Again,
10 that was actually something that we piloted quite a long
11 time ago with endangered species as an alternate way of
12 getting it.

13 Users would need to actually have a copy of the
14 labeling from the web site at the time they applied the
15 product. Labeling would be good for a specified duration
16 of time from the date of printing. We think this
17 expiration date is kind of critical to making things
18 enforceable and making sure that a user isn't, in effect,
19 using an old label when in fact there's a new label
20 available.

21 They need to be following the new labeling
22 instructions. This again is similar to endangered

1 species where there's an expiration date, as it were.
2 Then there would be an archival system that would allow
3 verification of the version of the labeling posted on any
4 date.

5 So, if you had someone, a state official, who
6 is trying to conduct an enforcement investigation, they
7 needed to know what the label was that was in place at
8 the time of application, that archival system would allow
9 them to actually be able to check and see what that was.

10 This is really kind of a summation. We think
11 that while we've got three what seem like somewhat
12 distinct excessive activities or initiatives underway,
13 the e-submission, content changes, and then the web
14 distribution, that there are synergies across these three
15 initiatives.

16 The label builder, for example, as we're
17 envisioning it, is really going to take the label review
18 manual and make that sort of the first choice for
19 labeling. It doesn't mean that an applicant developing
20 their label couldn't do something different, but your
21 default option would be to stick with whatever the
22 standard recommendation was in the label review manual,

1 say for spray drift, when we have our spray drift PR
2 notice finalized.

3 We think through that you would probably start
4 eliminating a number of just accidental changes and
5 consistencies and errors that now crop up. Obviously,
6 this also then becomes a flag for our own label
7 reviewers. It helps improve the quality of our label
8 review process.

9 If we see something flagged, oh, this is
10 different from the label review manual. It allows us to
11 hone in and ask questions of the applicant, why have they
12 made that different. Is there actually a very good valid
13 reason for being different? Was it accidental or
14 something else?

15 We could also be able to be identify all
16 products that had an element that was not consistent with
17 the label review manual if we wanted to look across a
18 group of products for a particular reason. E-submission
19 and web distribution, you could customize labeling by use
20 of sight.

21 So, if I go to the web site to get the label, I
22 don't necessarily in this world of the future have to get

1 the whole label. If I know that I'm growing cumquats and
2 I wanted to see the cumquat instructions, I could just
3 get the cumquat instructions and nothing more, which,
4 again, from my point of view, I think would make it more
5 likely that a user would actually see all those things
6 which were critical for their situation and not be left
7 with the encyclopedia perhaps that got left on the river
8 bank 20 years ago when my dad was out there looking.

9 This might also enable labeling in different
10 languages. We've had a lot of requests to think about
11 doing that more broadly. While we permit labeling in
12 other languages, we have not done a lot to sort of
13 actively encourage it across the board. But this kind of
14 electronic system between submission and web distribution
15 might make it very easy to do that more broadly.

16 And then some of the coordination or synergies
17 content and web distribution, you can implement labeling
18 changes for all products more quickly and concurrently.
19 So, you can have a level playing field. You don't have
20 to do one product by one product by one product. You
21 have searchable databases and you can get user feedback.
22 So, we think there are a lot of potential advantages and

1 synergies between these initiatives.

2 We've had a lot of stakeholder involvement to
3 date on electronic submission and review. We've had
4 involvement at the OECD international level. We've had
5 the PPDC PRIA process improvement workgroup. We're here
6 developing the existing efforts in this arena. We've
7 been working with our state folks through the LAW, the
8 Labeling Accountability Workgroup.

9 We've created the recent new process with our
10 state to review labeling issues that are generic in
11 nature. Obviously, we have kind of a standard public
12 comment process in all manner of PR notices and several
13 register notices and REDS and eventually registration
14 review documents if they go to labeling issues.

15 We've been doing a lot -- and Bill and his team
16 -- on reb distribution, a lot of, I guess, early
17 communication as a way to build, refine, sharpen our
18 ideas, understand what are the issues and the problems
19 that would have to be solved. We've had several PPDC
20 presentations. We're anticipating future federal
21 register notice and actually future work with this group.

22 Timelines, finally. On electronic submission

1 and review, we already have a simple form underway using
2 PDF files of labels. We would hope to have this more
3 sophisticated label builder approach available for use in
4 the next two to three years.

5 Improving content systematically -- well, it's
6 underway. Some things like the environmental hazard
7 statement for consumer products is just out there.
8 Future things are coming. I think there will always be
9 plenty of opportunities for other content improvement.

10 Web distribution of labeling, some
11 possibilities, we're looking at a small scale pilot in
12 the next year, 2009 -- Federal Register notice about this
13 -- and an expanded pilot in 2010 and 11.

14 I think with that, I should probably turn
15 things over to Bill and let him go on in some more detail
16 on the web-distributed labeling.

17 MR. JORDAN: Thanks, Anne. Many of you have
18 heard the presentations that I've given about web-
19 distributed labeling or that other folks who have been
20 working on this project with me have given. The heart of
21 it was extracted and appears in the materials that Anne
22 just covered. So, I won't go back over that, except to

1 pull out one of the slides that Anne used in her
2 presentation to talk about what our goal is for web-
3 distributed labeling.

4 The idea is to improve public health and
5 environmental protection, like giving the users the
6 information they need that will help them use the
7 products effectively and safely. We think that the
8 current paper-based model of giving them all of the
9 instructions that are approved for a particular product
10 doesn't work as well as it could. We can do better.

11 The idea is, first of all, to simplify the
12 information that's on the container by giving the user
13 the specific information about how to handle that
14 container safely and to give them information about what
15 to do in case of an accident or a problem, first aid
16 statements, telephone numbers to call for getting
17 assistance, medical assistance, and that sort of thing.
18 Also, this web-based system will allow us to update the
19 content of labeling more quickly than the current paper-
20 based system.

21 I'll be talking about two broad things that we
22 have been doing since we had the last PPDC meeting. The

1 first is that we've been talking to a lot of stakeholder
2 groups. I want to say for those of you who have had the
3 patience and willingness to let us come over and meet
4 with you, thank you. We've learned a lot through that
5 process and we hope that you found it useful as well.

6 For those of you who haven't had the chance to
7 sit down and talk with us about this project, if you are
8 interested in doing so, we will find a way to make that
9 happen. We are eager to get input from individuals and
10 to do it in a way that will suit your interest. As
11 Debbie says, one of our principles is transparency and
12 openness to participation.

13 The second thing that we've done is we've
14 formed an internal EPA workgroup. Saying it's internal
15 means that our focus and primary composition is people
16 within EPA, but we do have two state representatives.
17 I'll say a little more about that in a moment.

18 On the stakeholder engagement front, I've lost
19 track of how many meetings we've had. Here you see a
20 list of all of the different stakeholder groups that have
21 met with us in probably over two dozen different
22 meetings. Some organizations will meet with us once and

1 then say come back again because we've had some ideas
2 that we want to talk to you about. We're happy to do
3 that sort of thing.

4 The process of talking to stakeholders has
5 raised a lot of issues. I've said in these meetings that
6 almost every session that I've had somebody has asked a
7 question or made a point that has brought up a new idea
8 that nobody else had raised until that time. That is the
9 reason why we're doing this.

10 Very recently, one of the state folks, Jim
11 Gray, who is participating in our internal workgroup,
12 said, you know, I think I'm beginning to hear the same
13 types of comments. So, maybe we have done what we needed
14 to do through the stakeholder process of identifying most
15 of the major issues. I've listed here some of the points
16 that have come up, by no means all of them.

17 Web site content, that has to do with the
18 question of what goes on the container versus what goes
19 on the web and also relates to that, what about providing
20 additional information that might enhance the user's
21 understanding and ability to use the product safely and
22 effectively.

1 Web site location is a question of who owns the
2 web site. It is run by EPA? Is it hosted by a
3 registrant? Is it hosted by some sort of third party,
4 mutual third party, like Perdue. The Inpair (phonetic)
5 system already exists and has something like that. It's
6 an important issue and we're still working through that.

7 Enforcement issues, labeling life span, Anne
8 mentioned that the operating notion that we've been
9 talking about is if labeling will have a fixed life span.
10 We haven't made a decision about that, but that certainly
11 is an important question to sort out.

12 State synchronicity is a fancy way of saying we
13 need to recognize in this system the role, the very
14 important role, that states play in reviewing and
15 registering pesticide products for use within their
16 state. States sometimes don't approve a product that EPA
17 has said is acceptable or at least will want to have
18 different kind of labeling on it if they approve that.

19 Now, since states can't change labeling, their
20 registration decision actually operates to force the
21 federal registrant to go back and try to get a change at
22 the federal label. But we need to take into account that

1 independent role that the states have so that EPA's
2 system doesn't inadvertently make product labeling
3 available for use in the state which the state has not
4 yet approved.

5 You'll see here some of the other issues that
6 I've listed. One more that I'll mention -- and it came
7 up on a blog recently by Deon (phonetic) pesticides, an
8 environmental advocacy group -- that set of comments is
9 that it's not appropriate for all kind of products. In
10 fact, Jim Wallace said as much when we had the last
11 meeting of the PPDC.

12 In our internal discussions, I think we are
13 pretty much in agreement, that for consumer products,
14 this kind of web-distributed labeling system is probably
15 not going to be a very workable thing. If you've got a
16 can that you want to use to spray for cockroaches or
17 something like that, you're not going to go to the
18 computer and download a bunch of labeling.

19 But for products that are used in the course of
20 a business enterprise, say agricultural use or something
21 that might be used by a professional in a paper mill or
22 cooling tower or treatment facility or something like

1 that, it seems a lot more feasible.

2 Generally, when we've been talking to
3 stakeholders, the reactions across the board have been
4 enthusiastic. People say, this is a good idea. This
5 really will take advantage of labeling and should -- of
6 new technology and should help us put in the hands of
7 users labeling that they will find a lot more useful.

8 However, and almost everybody has a however,
9 and then they'll go on and talk about some issue or
10 concern about how to make it work. Certainly, there are
11 tons of important details that need to get sorted out,
12 need to be further developed and refined before we have a
13 system that will deliver on its promise without creating
14 additional problems.

15 So, in our view, we need to have continued
16 stakeholder engagement to ensure that the system will
17 really meet the needs of everybody who is likely to use
18 it, which includes not only the people who are applying
19 pesticides but also advocacy groups, public health
20 professionals and, say, people in the migrant clinicians
21 program or in academia or in other places who might be
22 using it, as well as the chemical companies who make

1 these products and sell these products in the states who
2 have the responsibility of enforcing them.

3 So, that's our stakeholder engagement process.
4 It's been very, very rich in activity for us. We're
5 grateful for it. We want to continue that.

6 At the same time, and in parallel to the
7 meetings that we've been having, we've formed a work
8 group. This being government, we've got to have a
9 workgroup and we've got participation from all across
10 EPA. The Office of Pesticide Programs have a number of
11 different divisions, including our IT experts that are
12 the folks who work with the states from (inaudible), our
13 registration division.

14 We also have participation from General
15 Counsel, Enforcement, our regional offices and
16 representatives from two states. Jim Gray, who is the
17 chair of the SFIREG committee on program operations and
18 management, participates in this, as does Carol Ramsay,
19 who is part of the PPDC. They both bring valuable
20 perspectives from the front lines of educating any users
21 about, say, pesticide use practices and interacting with
22 users in enforcement context.

1 We have been using the stakeholder process as
2 well as our own dialogue to develop a list of issues. We
3 are slowly beginning to work through those issues
4 developing internal issue papers and discussing them. At
5 this point, I'll say we have some positions that are
6 tentative but nothing has yet been made in final form.

7 Here's some of the topics that we're talking
8 about. For those of you who are interested in inside
9 baseball, the establishment regulations bare on this and
10 when and under what circumstances web distribution of
11 labeling triggers the registration establishment
12 requirements in those regs, working through what content
13 should be on the label versus put in the website, if
14 there is a life span, how long should it be, where should
15 the web site be hosted, what additional content,
16 educational materials like MSDS sheets or reg calculators
17 or demonstration videos or other things might be included
18 on the web site. How does that affect enforcement
19 questions? How are they to be formatted, so on and so
20 forth.

21 We're talking a lot about logistics of a pilot.
22 So, let me turn to that one for a second. We are working

1 on communications materials. I see here we've done a
2 variety of Power Point presentations. The Ag retailers
3 have invited us to prepare an editorial for inclusion in
4 their monthly magazine for which we are working on that
5 and we'll use the feedback from this group to refine and
6 improve.

7 We have an informational web site that has sort
8 of the basic information about it, and we'll be using
9 that web site to improve and communicate as we develop
10 answers on some of the interesting issues. And then we
11 have been compiling and updating periodically a list of
12 issues that we've seen.

13 In regard to the pilot, lots of people are
14 interested in trying to test drive the idea of web-
15 distributed labeling next year -- for next year's growing
16 season primarily, probably, in the agricultural arena.
17 That seems to us like it's a good idea to have some sort
18 of pilot test of it on a small scale to find out what
19 works and what doesn't work, what we need to do in order
20 to be successful in this area. But there are tons of
21 questions that we think need to get sorted out before we
22 actually put that in place.

1 You'll see some of these things, what scope of
2 products -- uses are we going to cover, how do we
3 reconcile the timing of state decisionmaking about
4 registrations and EPA's decisionmaking. Very important
5 piece in my mind that we still need a lot of discussion
6 about is how to make sure that the culture change
7 happens.

8 People who had been buying and using pesticides
9 for their -- over the course of their life, career, have
10 been accustomed to going into a place, picking up the
11 container and getting with that all of the paper that
12 tells them how to use the pesticide safely. We're going
13 to change that.

14 We're going to say, at least in some cases,
15 that those people need to go through an extra step of
16 going to a web site or calling a toll free telephone
17 number to get the information that they previously would
18 have found with the container. That's a very different
19 way of doing business.

20 If they don't do it, then we have actually made
21 things worse. We don't want to make things worse. We
22 want to improve the situation. So, how do we bring about

1 the understanding and culture change so that people will
2 actually do that, which we are going to make possible
3 through this web-distributed labeling.

4 We'll need to work out the container language.
5 We'll need to work out the mechanics of the web site and
6 the toll free telephone number. We'll need to figure out
7 what to do about the life span so that we don't have a
8 whole bunch of labels 20 years from now that we're
9 creating in 2009 that are still somehow valid.

10 We're working on the database structure issues
11 that will need to happen to make this possible. Then
12 we'll need to have appropriate quality assurance to make
13 sure that we don't somehow jump the gun and put the wrong
14 label up or something like that.

15 These are things that we need feedback on, not
16 just from folks within EPA but likely from folks like
17 you. So, that's another reason why we are interested in
18 having a PPDC workgroup.

19 Next steps, we're going to continue stakeholder
20 engagement. This is an invitation to all of you, any of
21 you. If you want to have somebody from us come and talk
22 with you about this in greater depth, we'd be delighted

1 to do that. We're talking about forming a workgroup, as
2 I mentioned.

3 We're trying to figure out whether we can get a
4 pilot off the ground next year. We're looking to have a
5 Federal Register Notice that describes in much greater
6 detail how we're approaching this. We're going to keep
7 coordinating this across the other labeling initiatives
8 that Debbie had mentioned.

9 So, with that, let's open it up for discussion.
10 Since we heard from the other side last time, I'll begin
11 here with Cindy.

12 MS. BAKER: Well, thanks to both of you for
13 your presentations. There's certainly a number of things
14 in both of your talks that I think are very positive that
15 you would see registrants supporting upbeat, specifically
16 to this lead-based labeling distribution.

17 I think there's some positives that come out of
18 that for sure in the area of stewardship, you know, in
19 readability and sortability, some of the things that
20 you've already talked about, in timeliness in getting out
21 new uses and other changes to labels, and ability to get
22 state-approved labels that people can go and get them and

1 know what to prove.

2 And certainly in cost. As a registrant, if
3 you're looking at the cost of doing this, there's a
4 definite cost savings there. I would think there's a
5 cost savings at the Agency too if all of this is done
6 electronically instead of paper.

7 As you said, though, when you give this talk,
8 you hear the good things and then you hear the concerns.
9 The hosting is a big concern. Who hosts it? I guess
10 what I would like to go out for your consideration is
11 that it not have to be only EPA, or only a third party,
12 or only a registrant. That there be some consideration
13 to, you know, registrants who have a strong feeling that
14 they should host because they have control of that
15 function now.

16 I mean, it's our responsibility to print the
17 final printed label. You have to prove it but we have
18 the responsibility to carry that out in implementation
19 now. There are reasons why we have that. I mean, some
20 of these labels are copyrighted, some of them have
21 trademarks, some of them have alternate brand names, some
22 of them get changed by notification. I mean, there's a

1 number of things that happen there that keeping control
2 of that label I think is important to registrants.

3 There are concerns about liability, concerns
4 from the registrant's perspective, concerns from the
5 retailer/dealer perspective, concern from the user
6 perspective about what happens to liability in a system
7 like this.

8 An accessibility issue, as you pointed out, not
9 everybody will have access to the web or be able to use
10 it that way. So, where does it go? A phone number is
11 one way. Distribution at a point of sale is one way.
12 Going to a registrant is one way. I mean, there's a
13 whole host again of possibilities that come up for people
14 to get it.

15 Resources, resources on the Agency. I mean,
16 right now, let's say you approve a master label of mine.
17 That takes a set of resources. If now I market that
18 under three different brand names and subsets of that
19 label, now do all of those have to be approved and on
20 your site? I mean, there's a whole set of questions that
21 come up with that around resources, resources on the
22 registrant side, resources on the end users side.

1 One of the other points you talked about, what
2 goes on a container label. I would say let's capture
3 some of the work that's taking place and some of these
4 other initiatives, the NASA label for example. We spent
5 a lot of time talking about what needs to be on the
6 container label. In fact, I think there's a paper that
7 we've done that spells that out.

8 This issue of state labels, one is the timing
9 of when they approve them, but the other is frequently
10 you can get from a state like California a requirement
11 that says, you know, if you don't provide efficacy data
12 for this crop, you can't have it in California.

13 Well, it might be a crop that's not growing in
14 California. So, as a registrant, you're just going to
15 put except California on your label. Well, that doesn't
16 necessarily require any review at EPA. You just -- or
17 choosing not to market in California for a specific
18 efficacy requirement. Those things vary among the
19 states.

20 But I would say definitely form a workgroup. I
21 mean, I think it's great that you guys have an internal
22 workgroup going. But the obvious key piece missing is

1 the stakeholders in there, the registrants, the end
2 users, the retailer and dealer side. So, I think it
3 would be really wise before too much effort gets underway
4 on both sides --

5 If you come around and have talked to everybody
6 about it, you might imagine we're thinking about position
7 papers and issues and all that and pretty soon we'll be
8 wasting each other's time if we don't quickly get
9 together and start talking about transition and cost and
10 implementation and pilots. I mean, we're all having the
11 same kinds of thoughts.

12 So, I think it would be very beneficial to form
13 a workgroup sooner rather than later and start talking
14 about it.

15 MR. BOTTS: I don't know what else I can say.
16 Cindy covered all the issues. Bill and I had a long
17 conversation, as you can see from the list of parties
18 that he identified in the stakeholders that he's met
19 with. That was an initial meeting to identify a series
20 of issues that we see at least from the way our role or
21 membership purchasing these pesticides in Florida from
22 both a -- not only from how they use the products, but

1 how they purchase it and the fact that a lot of them
2 purchase products for a period of time and might end up
3 in the storage shed with the intention of being used
4 within six to 12 months.

5 It might end up there for two or three years
6 and it creates some issues down the road of what happens
7 if in the process of label they're using has subsequently
8 changed through this process and have a notification
9 process to ensure that they can still legitimately and
10 legally use those products in the first place.

11 It creates in my mind a significant enforcement
12 issue as well as a tremendous burden on education that
13 needs to take place as this process is rolled out,
14 because since we've changed the whole structure and
15 function of the process -- because we've been telling
16 everybody for the last 35 years since I've been involved
17 in this that you're bound by the label that's on the
18 container when you purchase it. Now, all of a sudden,
19 you're modifying that position and it's going to be a
20 tremendous shift in just attitude and process at the
21 grower level.

22 Having said that, I don't know that I would

1 necessarily say I enthusiastically endorse the concept.
2 I recognize the value of this process and what it brings
3 to the table and the ability to make everybody's life
4 simpler and easier, but it's going to be a real
5 significant process with a lot of time involved to work
6 through the details to make it work, I think, the way
7 it's going to need to work for everybody to get the
8 benefit out of it that at least is perceived out there in
9 the future.

10 Having said that, I endorse the concept of the
11 workgroup. I don't know that it's ready for prime time
12 pilot in the time frames that you're talking about yet
13 because there's still a tremendous amount of issues,
14 development and discussion that needs to take place to
15 capture some of the issues that even we haven't thought
16 about or looked at from the user's side of this process
17 at this point.

18 MR. JORDAN: For the benefit of those folks who
19 might want to listen to an audiotape of this or read a
20 transcript, I'd appreciate it if each person would
21 introduce yourselves, say your name. It will also help
22 those folks who are new to put people like me who are

1 getting increasingly nearsighted to put names with faces.

2 That was Dan Botts for the insurance groups
3 benefit.

4 MS. BAKER: This is Cindy Baker. One last
5 thing I wanted to ask on yours, Anne, and I'm sorry I
6 forgot, your slide about procedure changes to improve
7 labeling content and the internal work that's going on
8 within EPA, I think you'll find strong support for that
9 from people who like to see consistency and reviews and
10 understand what's going on.

11 Is there any way that people who are writing
12 labels, like registrants, can we get a copy of this
13 labeling principle so that we follow that stuff up front
14 and we're not sending in stuff that we know is just going
15 to get turned right back out?

16 MS. LINDSAY: One of the things that I think
17 the group has actually also talked about is a lot of the
18 stuff that we think we may need to do for ourselves may
19 also be suitable -- not just the principles but for the
20 registrant. So, I think there is actually a larger plan
21 as we do things that we think would be useful to figure
22 out how best to share them with the registrant community.

1 DR. FERENC: Sue Ferenc. I echo what Dan and
2 Cindy already said about some of the concerns, liability,
3 notification, enforcement, those types of things, and
4 just the changing culture in education to implement
5 something like this. When would be the expectation that
6 we replace labels? When does that finally happen?

7 But it's never really a simple question,
8 though. I think if the well label builder software that
9 you're talking about, if you've got a label that's a
10 hundred pages long, does that mean you have to recreate
11 it in a structured format or is it like cut and paste
12 that you could simply take everything you've already got
13 on the label and put it in there? Is that the same
14 mechanism you'd use for going in and making label
15 changes? And would it be the same?

16 In other words, are these all integrated -- is
17 this an integrated system for taking information you're
18 putting in for the first time for your electronic
19 labeling all the way through to when you go through
20 changes in the label?

21 MR. JORDAN: I'll take a shot at answering
22 this. Basically, those are some of the questions on

1 which we haven't made any final decisions. To get the
2 greatest benefit for EPA, it would help us to have all of
3 the labeling information coming in on a new product in
4 this structured format so that we can immediately do
5 comparisons to old labels, so that we can compare it to
6 label review manual, so that we can populate the Luis
7 (phonetic) information system.

8 Not everybody is necessarily going to want to
9 do that or -- so, one of the questions that you'll have
10 to think about is how to apply it. Will it be voluntary
11 or will it be mandatory or will it be something that gets
12 a faster review? What kind of set of incentives will we
13 use?

14 If the information comes in that form, however,
15 it will be a huge benefit to us. That's the reason why
16 we're trying to figure out ways to make it more
17 widespread.

18 DR. FERENC: Is the label builder now
19 consistent with what we are looking for for electronic
20 submission of labels?

21 MR. JORDAN: Label builder does not now exist.

22 DR. FERENC: Okay.

1 MR. JORDAN: This is sort of -- once we figure
2 out the feel of the label, then we will try to create a
3 software program for those of you who are familiar with
4 Turbo Tax. It conducts "an interview" with the user,
5 asks questions.

6 So, it might ask, what is the name of your
7 product. You type in name of the product and that would
8 then go into a field that would be tagged label name and
9 we'd know that is the name of the product. Then, will
10 you have alternate brand names? Well, if the answer is
11 yes, then you get a number of fields for that. If the
12 answer is no, then you go on to the next step of the
13 interview process.

14 But that's kind of the way that the label
15 builder would work. What crops are you going to use?
16 You'd get a menu of approved crop names and you'd check
17 off those crops that would be of interest, for example.

18 MS. LINDSAY: I also commend the formation of a
19 workgroup.

20 MR. TAMAYO: Dave Tamayo. As long as things
21 are going to be submitted electronically and in hopefully
22 a standard sort of format, it would be very useful for

1 agencies like mine to be able to search that in some sort
2 of a database format so that if we have a particular
3 concern about some sort of whatever -- we wanted to find
4 out what universe of chemicals is used for Argentine air
5 control or broccoli or whatever we happen to be
6 interested in, it would be very helpful to be able to
7 have a database built from this that we could search and
8 do that.

9 It would also probably be helpful in things
10 like looking at what's on retail shelves. I know that
11 even if we continue to have retail or consumer type
12 products where they're not only available on the web, it
13 would still be incredibly helpful to have that available
14 through a database type search.

15 MR. JORDAN: The search functionality is one of
16 the features that we hope to build into such a future
17 system. Trying to understand better what features of
18 that search capability would be of interest is something
19 that I think would benefit from further conversations.

20 UNIDENTIFIED MALE: One thing that would be
21 really helpful would be not to -- it would be nice to
22 have sort of an application that would make it really

1 simple, but also have the data available so that if we
2 wanted to do something more sophisticated or just
3 something you hadn't thought of, that we could just go
4 ahead and do it, we wouldn't have to go through your
5 group to ask for a specific kind of project. I would
6 imagine it would be cumbersome things. Thanks.

7 DR. ROBERTS: This is Jimmy Roberts. My
8 questions start off with Anne's presentation when you
9 said the URL might replace directions of use on a
10 physical container. Actually, when Bill had done his
11 presentation, it partly answered my question because I
12 was thinking about consumer products. So, it's really
13 more of a clarification question.

14 If I understood Bill correctly in saying that
15 some of the consumer products would not be a good
16 candidate for the web-based labeling, I'd just kind of
17 throw this out as that if for consumer products, I think
18 it's reasonable to have the web-based labeling as one
19 way, but this would be one situation where you do want to
20 have the directions of use on the container and then
21 consumers could still go to the web for further
22 information.

1 MR. VROOM: Jay Vroom, CropLife. Anne, I
2 remember at one point, probably starting 15 years ago,
3 that there was an electronic submission. There was a
4 fundamental disconnect between the way the United States
5 was approaching this and the EU. Has there been any
6 consolidation or closure between those differences?

7 MS. LINDSAY: There's been lots of progress.
8 We actually just in the month of April hosted a OECD
9 workshop that was focused on IT issues. It has gone
10 through and identified a whole series of recommended
11 areas of work which I'm actually not competent to discuss
12 because I'm not an IT expert and I would undoubtedly
13 miscommunicate to anybody. But we thought it was a very
14 successful workshop.

15 One of the things that was said about it was
16 that we had not only IT people from other countries,
17 which is the UK, here meeting with our folks, but we also
18 had reviewers who are going to actually be the ones who
19 are using the IT systems that are being built. So, we
20 think that we're actually making a lot of progress on
21 harmonizing the approaches.

22 I don't believe we're going to see what I would

1 call major disconnects. I think there's going to be
2 plenty of opportunity for further work to bring things
3 together, but not us going like in totally opposite
4 directions.

5 UNIDENTIFIED MALE: Bill, we talked at an
6 earlier conference about the need to do more outreach
7 with major distributor agricultural companies that also
8 control a significant percent of the overall retail
9 capacity in the United States.

10 It's my sense that they all have very
11 sophisticated internal intra-company electronic
12 communication systems that all or to one degree or
13 another capable of handling the web-based labeling
14 approach that you're describing for us today, but they
15 probably are different in degrees as well.

16 All those companies, along with the
17 manufacturer companies, are members of parallel
18 organization to CropLife called Rapid, Incorporated.
19 We'd like to be sure that Rapid and all those
20 distribution companies are part of this next phase of
21 stakeholder involvement on this.

22 But I think just like the topics around

1 transformational science that we've discussed at the
2 outset this morning, this is transformational and there
3 will be opportunities and risks. But the opportunities
4 are certainly well worth the continuing pursuit.

5 MR. CONLON: Joe Conlon, AMCA. I think you've
6 anticipated quite correctly that forcing a consumer who
7 is just now trying to find something to kill a cockroach
8 in his house to go to the web in order to find directions
9 for use is going to be rather problematic. So, if I'm
10 hearing you correctly, you're going to leave some labels
11 on the container as is but the directions for use in some
12 are going to be on the web.

13 My question, if I'm understanding it correctly,
14 is what criteria is going to determine which ones are
15 going to be on the web and which ones are going to be on
16 the container?

17 MR. JORDAN: Well, a couple of things. One is
18 that we are still thinking about it. There are both
19 criteria -- question about whether this should be
20 mandatory or voluntary. I'm inclined at least at the
21 initial stage to say it ought to be voluntary, that no
22 company should be forced to do this.

1 Secondly, are there some categories of products
2 that ought to be ruled out? As I suggested in my
3 comments, at least internally, we're thinking that it
4 doesn't work for consumer products. One of the questions
5 then becomes how do you define that. I have had -- I've
6 seen a paper that suggested some good thoughts on that,
7 but I don't want to rule out the possibility that we
8 might use different criteria. So, I don't want to toss
9 out any criteria at this point.

10 The suggestions I got were from Jim Wallace
11 whose card went up when you asked that question. So,
12 maybe, Jim, you want to say a word or two about that?

13 MR. WALLACE: Sure, thanks. I was pleased to
14 hear, first of all, that the Agency agrees that consumer
15 products probably aren't appropriate for this program for
16 obvious reasons. So, then, you're right, the question
17 then becomes how do you define a consumer product.

18 I believe that the best way to do it is to
19 define it by the channel of trade in which it's sold.
20 So, for example, perhaps anything that's offered for sale
21 in food, drug mass, hardware, DIY, would not participate
22 in this program. There are probably other channels of

1 trade as well.

2 The point being that if it's available to a
3 consumer and outside a professional area of expertise,
4 someone who does not have the expertise or perhaps might
5 not have access to the web-based labeling, if it's a
6 product that's sold in that channel of trade where that
7 type of individual might be able to acquire the product,
8 then the product should not be part of this program.
9 That was my suggestion.

10 MR. JORDAN: Thanks. So, let's continue
11 working around the table. I'm not sure whose card is up
12 next.

13 MR. BARON: Jerry Baron, IR-4 project. Bill, I
14 applaud you for your efforts on this one. A question is,
15 have you considered during your discussions with other
16 stakeholders the nuances involved in crop groups and the
17 registration limitations of putting some crops and crop
18 groups on master labels and some on marketing labels?

19 MR. JORDAN: That has come up and it's going to
20 make things harder. We'll have to figure out how to make
21 it work. I think it will be pretty tricky.

22 MS. BAKER: That's actually, Jerry, one of the

1 reasons why we talked about the registrant wanting having
2 control because that's exactly the situation that we'll
3 come up against in a leaky vegetable, for example, or
4 whatever. You might have safety with all but two. So,
5 you get them all approved because you get a crop group
6 registration but on your marketing label you take them
7 off. That's why I believe that a registrant has to have
8 control there.

9 MR. BARON: With that, I wrote a dialogue with
10 the stakeholders for the --

11 MR. JORDAN: Thanks. That was Cindy Baker's
12 comment. Thanks. Who's next? Jim Thrift.

13 MR. THRIFT: Thanks, Bill. First of all, we
14 believe that the Agency is on the right track with this
15 program. We believe that a label that is approaching the
16 length of War and Peace has no benefit for any of the
17 parties. If the label is web-based, there are
18 significant benefits.

19 One of the benefits is, of course, it could be
20 sorted by a variety of key words. In that vain, I would
21 add a caution, that right now it looks as though,
22 according to the presentation, that the key word for

1 finding a label is entering the pesticide registration
2 number. I'm a little familiar and some of the people in
3 the audience may have heard of RoundUp. I'm not familiar
4 with their pesticide registration number. So, I realize
5 that's a detail.

6 We are very supportive of the Agency's efforts
7 in having Bill and his team reach out to stakeholders.
8 However, we are also concerned conversely that the Agency
9 may use what we sometimes call the trickle down effect.
10 We understand that the label is, in fact, the property of
11 the registrant.

12 The registrant sells to the retailers and
13 distributors. They give us information. We are then
14 usually required to transfer that information to growers
15 and users and other independent applicators that we sell
16 the materials to.

17 We would like to have the Agency make sure they
18 have a broad coalition that they are explaining the
19 ramifications, because, as Cindy Baker said a few minutes
20 ago, this thing has dramatic liabilities. Then Mr. Botts
21 mentioned it. We are concerned that the trickle down
22 effect on information could be a real drawback.

1 We also believe that there are a number of
2 existing systems. Jay Vroom mentioned it a minute ago.
3 As the Agency develops the actual host and the site for
4 this information, there are several databases already
5 commonly used in agriculture. If it can be incorporated
6 into one of these, it will be far more efficient than a
7 stand-alone. You'll have far more people accessing the
8 system.

9 The other thing that I thought was particularly
10 entertaining was over here in one of the places it says
11 dealers could then distribute printed label information.
12 Okay. Well, that sounds like the registrant no longer
13 prints the 100-page label and now the dealer prints the
14 100-page label.

15 I really think you might want to look at this
16 -- I know Bill is already aware of this one -- that maybe
17 if the user has a computer in his pickup truck or his
18 spray rig, that will suffice for the label information if
19 he has some sort of card.

20 We believe -- again, I want to reiterate, we
21 believe you're going in the right direction. The problem
22 is the devil is in the details and not having a broad

1 coalition not just that the Agency is talking with but
2 that we are talking with each other would not be in the
3 best interest of all parties.

4 Now, the trickle down thing really concerns me.
5 The brand new web site that we have to go to and my
6 members have to go to is probably second. With that,
7 again, we think the Agency is on the right track.
8 Obviously, we have been very proactive in offering any
9 kind of communication assistance that we can. However,
10 we do not want to be left with the impression that we are
11 going to handle all of the communications to all of the
12 users that we sell to.

13 MR. SCHERTZ: Well, I'm Scott Schertz. I'd
14 like to just sort of reinforce and expand a bit on Dan's
15 earlier comment that the duration is a big concern,
16 particularly when you start getting into bulk products
17 that you may have had a ship date and they may be used
18 over the next year or two. I suspect to handle it
19 correctly, since there's going to be some sort of an
20 archive, that the product number will end up needing to
21 be tracked or referenced to some sort of a release date
22 or lot number to actually be accurate. The bulk products

1 will probably complicate this and it should be followed
2 through and approached, is my suggestion.

3 DR. GREEN: Tom Green with the IPM Institute.
4 I really think this has a lot of potential. I really
5 fear not having the printed information on the label.
6 But as a supplement, it would be great, I think, to
7 integrate the system with access to MSDS sheets because
8 those suffer a lot of the same issues as pesticide labels
9 in terms of trying to identify the most current version
10 of the label that's out there.

11 Second, it would be great to Jim's point to
12 allow some seamless integration with third party systems.
13 If I'm a dealer and I offer a scouting service, for
14 example, and someone is using a label builder to buy a
15 product from me, to be able to communicate that
16 information to that customer in the same process -- or if
17 I'm a food processor, I might want certain mitigation
18 techniques or IPM techniques used along with that product
19 and be able to integrate that into the label builder
20 system would really be ideal, I think.

21 MR. KASS: Dan Kass from the New York City
22 Department of Health. I also think this has a lot of

1 potential. I was relieved to hear that you are
2 considering off the bat excluding consumer products. I
3 would encourage you to think about going a step further
4 for many structural pest control products that are
5 registered for use by applicators, by licensed
6 applicators.

7 In our experience, dealing with that group of
8 people in New York City is that very few have web access.
9 We've been trying to encourage electronic pesticide use
10 reporting and are coming up really short based on
11 computer knowledge, expertise and access. So, I wouldn't
12 assume that just excluding consumer products is
13 sufficient in this application.

14 I also just want to comment. I'm new to the
15 PPDC so I don't know the whole history of the role this
16 group has played around label review generally. But the
17 fact that you're excluding consumer products from this
18 shouldn't be a reason to exclude a broad look again at
19 consumer product labeling.

20 Our experience in New York City is that people
21 don't do labels. We run focus groups, we do interviews.
22 For the most part, labels are utterly unread. For those

1 that do, many don't understand them. For many that do
2 attempt to read them, they're not in their native
3 languages.

4 For many, our experience has been that all of
5 the sort of details on a label in fine print are treated
6 the same way that the ingredient list on a Twinkie is
7 treated. The decisions are to be made to buy it so that
8 it's kind of extraneous information.

9 So, I was hoping that the PPDC would, you know,
10 continue to look deeper at the quality of labels, their
11 understandability, their readability in their utility for
12 consumer product.

13 MS. LIEBMAN: Hi, this is Amy Liebman from
14 Migrant Clinician Network. First of all, I really have
15 to say that the stakeholder involvement in your process
16 here has been fabulous. I really want to commend you for
17 the effort that you took to get the different number of
18 stakeholders to come on this prior to this PPDC meeting.

19 I want to reiterate some points that my
20 colleagues have made here and also just some of the
21 concerns, real briefly, that we brought up in our meeting
22 with you.

1 First of all, you know, the idea of having web-
2 based labeling is wonderful, and the direction that
3 you're going into offers a lot of important opportunities
4 for enhancements that are not there. But really, until
5 we have a perfect world and our farmers and growers have
6 access to the web, we really need some kind of
7 simultaneous rule system. I think that as you start
8 piloting it, you still have to have your old system of
9 having the user have access to the labels.

10 Another point that I want to bring up -- this
11 is outside of the web labeling but web labeling does
12 allow enhancement -- is the importance of labeling. I
13 find it incredible that we don't have easy access to
14 Spanish language labels. It's 2008.

15 I actually am sitting here today with a list of
16 34 pesticides that a group that I'm working with in
17 Puerto Rico uses regularly on their crops. They did some
18 worker training and they said, well, gee, all this worker
19 protection stuff, how can we read the label.

20 So, I need to go through every single
21 pesticide, look up every single company that produces
22 each of these pesticides and contact these companies

1 because I know that they probably sell the same product
2 overseas and can use this and already have a Spanish
3 language label. But it's not easily accessible at all
4 right now. The roundabout way to do it is kind of crazy.
5 And that's in the United States.

6 So, the other issue, Puerto Rico, one of the
7 reasons I'm working so hard to get the Spanish language
8 label for our colleagues in Puerto Rico is that the
9 education level of the workgroup is a little bit
10 different -- a little bit higher than the education level
11 of our general users when we look at the farm worker
12 population.

13 So, as we look at enhances and changes, we
14 really need to look at not just language but the literacy
15 level. That's very, very important if you want anyone to
16 take the safety precautions, understand the health
17 effects and the risks. We need to have it in a format
18 that they can actually understand.

19 So, I think it's very exciting what you're
20 proposing to do, the thought that you've put into it.
21 But we really need to remember who some of the end users
22 and end people that are openly affected by the

1 pesticides.

2 MR. FRY: Michael Fry from American Bird
3 Conservancy. First, I really think your process has been
4 quite superior. I offer my admiration and condolence for
5 sympathy for having to deal with stakeholders that are
6 even represented in this room.

7 Registrant control of the label I think, you
8 know, there have been some very important points brought
9 up. But you've got to have a centralized URL because you
10 can't have 100 different URLs. Nobody would be able to
11 find the information. So, whether that is at EPA or
12 whether, as Jim Thrift has suggested, through another
13 organization, I think is good. I think the registrants
14 need to have some sort of control or rapid access or
15 something. But there still has to be one central
16 location.

17 In terms of consumer products, I'm very
18 disturbed by the comments here because in many states,
19 consumer sales represent more than 50 percent of all the
20 pesticide sales in the state. You either have to have
21 profound improvements in the labels in two different kind
22 of processes or include consumer labeling in this.

1 I mean, you could simplify the labels greatly
2 if your database had access to zip codes and at the
3 retailer level the zip code of the retailer goes in
4 automatically with a bar code reader off the product.
5 What gets printed out, just like it's stapled, when you
6 get a product, you get a register tape that's about four
7 feet long anyway. Single column printout of the
8 pertinent label information for that zip code I think
9 would be phenomenal. You wouldn't have to have 100 pages
10 printed out.

11 You mentioned, I think, maybe I got it wrong,
12 that no company would be forced to participate in this.
13 That's absurd. I think everybody -- registrants already
14 have a great deal of requirements that they have to go
15 through to register a product and comply with FIFRA.
16 This is not going to be Draconian in terms of that kind
17 of thing.

18 I certainly hope that this generation of people
19 in this room don't have to all retire before we get a web
20 sympathetic group of people that would prove this.
21 Thanks.

22 UNIDENTIFIED MALE: Jenn Sass has a question.

1 DR. SASS: I didn't understand when you said,
2 Amy, about the Spanish language and then the labeling. I
3 didn't understand if you thought that this web-based
4 program would actually address the issue of needing
5 Spanish language.

6 MS. LIEBMAN: From my understanding, one of the
7 enhancements that a web-based labeling system would offer
8 is the potential to have easy access to the same label in
9 multiple languages.

10 DR. SASS: On the web?

11 MS. LIEBMAN: On the web, but that's a
12 potential enhancement and we're not seeing that right now
13 in the system that we currently use. So, regardless of
14 what happens, whether we use the web or not, we need to
15 look at that language issue.

16 UNIDENTIFIED MALE: Right now it would be
17 impractical to have the full labeling language that
18 appears in an 80-page English version than appear in a
19 100-page Spanish version and also capture some of the
20 other languages that users might want.

21 Whereas, if you go to a web site, something
22 like my experience at ATM I use, the first screen that

1 pops up is what language would you like to have your
2 information delivered. Then you click that and that's
3 what you get. So, we could deliver it in Spanish, or
4 Creole, or Haman, or French, or whatever.

5 UNIDENTIFIED FEMALE: I really have to say that
6 word impractical about it being in another language is --
7 we shouldn't be talking about that. I mean, this is
8 really a serious issue. There are people who do not
9 speak English who need to know what's in that label.
10 It's something that we should look at as a very practical
11 solution to a very real problem.

12 MS. SPAGNOLI: Julie Spagnoli, FMC. First, I
13 just want to reiterate what Cindy had said as far as the
14 host of the web site -- or of the labels. Right now
15 there already is an EPA, you know, database of labeling
16 that EPA approved labels are available through PPLS. But
17 what the registrant wants to market may be actually a
18 different subset for various reasons, market reasons, you
19 know, if we have a concern for phytotoxicity for
20 something in a particular region.

21 There's a lot of different reasons that we may
22 want to subset labeling. I think the only way to keep it

1 up to date and to what the marketing aspects are is for
2 the registrant to own it.

3 The other issues with consumer labels,
4 essentially, anything that's not a restricted use product
5 is a potential consumer product. However, we all know
6 that that's not really the case from a practical
7 standpoint. But I think it really has to be up to the
8 registrant from a voluntary standpoint whether, you know
9 -- depending on how they intend to market their product,
10 whether they want to have web-based labeling or not.

11 You may have, like I said, a product that's for
12 a vegetable garden, it's a shudo (phonetic) egg label,
13 but it's intended for homeowner use. You have products
14 like cattle ear tags. It doesn't really make sense to
15 put a web-based label, you know, on how to use a cattle
16 ear tag. But, you know, that's technically a consumer
17 product.

18 So, the counter to that, and this is an issue
19 we've been struggling with from a stewardship standpoint,
20 is how do you -- if you do want distribution of a product
21 to a professional user, how that's done. This is
22 something that -- you know, one of our labels is put up

1 as an example of the bad label by ABCO because it says
2 for professional use only. Well, it's not enforceable.
3 It doesn't mean anything. Therefore, it's a bad label.

4 You know, obviously, if we've got a
5 concentrated product that's intended for use by Bob's
6 members, we don't want that product going to homeowner
7 use. That's not its intent. But right now we're
8 struggling from a product stewardship saying in how do we
9 label the product such that we can -- you know, there is
10 some limitation.

11 So, I think as we go forward in this both from
12 the label accountability, you know, workgroup, what
13 they're doing as far as enforceability and intended users
14 and we move forward on this web-based labeling, I think
15 we're going to have to figure out, you know, kind of how
16 we want to be able to categorize products.

17 MR. JAMES: Allen James with Rise. I hope I
18 have a very simple question. Have all the legal hurdles
19 within EPA and those agencies that sometimes impact
20 decisions at EPA been cleared to do something like this?
21 In other words, is there anything within the Agency or
22 related agencies that could hamper this progress over

1 time because of legal words?

2 MR. JORDAN: We have a very talented lawyer
3 working with us from the Office of General Counsel who
4 regularly reminds us of our responsibilities to follow
5 the applicable statutory provisions. So far, her answer
6 has been -- and so my answer to you is it depends on the
7 shape of the program. I don't think there are many
8 things that we have been discussing that will be a
9 problem but I'm sure as the details get nailed down,
10 we'll have to take another look at that.

11 Two more comments. Three more comments, I'm
12 sorry. I'll be happy to talk on the break.

13 MS. HERRERO: This is Maria Herrero. As to
14 registrant, I can see definite values to what EPA is
15 trying to do. If nothing else, my label printing costs
16 should significantly be reduced. I do have an issue that
17 has already been voiced in some (inaudible).

18 The other one I would like to point out to EPA
19 is the onerous right now is (inaudible). I can see this
20 shift beyond risk to the end user and there's been
21 nothing talked about education and how you educate the
22 end user as to their responsibilities now to have access

1 to these labels.

2 Also, as I put on new uses on to my labels, I
3 may change the safety requirements that are needed for
4 that. My products out in the field may have a different
5 set of safety requirements, standard use that the
6 consumer now wants to have.

7 I just see this as navigating web sites within
8 people within my organization outside of regulatory have
9 a difficult time navigating to EPA's web site. If we're
10 going to make end users go this route, we better have a
11 very easy web site to navigate.

12 MR. JORDAN: Thanks. I couldn't agree more. I
13 think the culture change piece has not gotten nearly as
14 much attention as it needs.

15 MR. HOWARD: Dennis Howard, Florida Department
16 of Agriculture. ABCO and the states are very supportive
17 of the efforts that the Agency has been undertaking to
18 work towards this web-based distribution of labels. We
19 realize that there's going to be a lot of issues that
20 need to be tended to and the details will probably make a
21 big difference in whether this is a success or something
22 that we'll talk about somebody and reminisce about how it

1 could have been.

2 If the pilot is planned for 2009, just based on
3 what I'm hearing here today -- I'm not speaking for ABCO
4 now; I guess I'm speaking for myself -- it just seems
5 (inaudible) optimistic. Unless the pilot is going to be
6 of a very narrow scope that allows you to not only get it
7 implemented, but to provide the kind of education that
8 Maria just alluded to to the people who would be using it
9 as well.

10 So, maybe that's something that a working group
11 could help the Agency out in thinking about timing. In
12 conclusion, we're very supportive of the effort.

13 MR. MICHAEL: Cannon Michael. I think I see a
14 lot of positives for this program, but you are targeting
15 users who are A, in rural areas and who B, are generally
16 -- at least a lot of the ones I know are not necessarily
17 very technically savvy. We're talking about an older --
18 generally an older population of agriculturalists rather
19 than a younger one. So, you're obviously going to have
20 issues there.

21 The dealers being responsible for taking the
22 labels to growers, I see that as another issue. This

1 pilot program and transitional period will need to be a
2 time of major outreach. I don't know how you bridge some
3 of those hurdles as far as internet saviness and internet
4 access. I mean, our internet connections are back in the
5 stone age really.

6 So, for some of our areas, at least where I am,
7 other things -- having no label on the container, just
8 having the basic, hardly any information, that does
9 concern me. We also sometimes will purchase in large
10 quantities just in terms of actual container size and
11 have it around for a significant amount of time to deter
12 theft. So, I don't know.

13 Sometimes those chemicals are around for a year
14 length of time or more. So, is it the time of purchase
15 the label or the time of use, or how do you -- so,
16 anyway, the education part of that is going to be a big
17 issue.

18 To Amy's point about the multi-language labels,
19 we've tried very hard to get out lots of educational
20 materials in our business and get them printed into
21 Spanish, obviously, mainly the one that we use. Often we
22 run into the problem where some of the workers can't even

1 read it in their own native language. So, I mean, a lot
2 of times that's an issue that we face.

3 We found a lot of times like picture diagrams,
4 things like that work better. But obviously, you can't
5 do that with a label. But I don't know that just having
6 it in Spanish is necessarily going to solve the problem.

7 But anyway, I think it is a good program and I
8 look forward to seeing it go forward.

9 MS. EDWARDS: All right, thank you. Once
10 again, I think this is obviously a topic that there's a
11 lot of interest in, a lot of optimism, but a lot of
12 concern that we have to take the time and involve
13 everyone to do it right. Does anyone disagree that we
14 should have a workgroup? Okay, once again, name --
15 Margie, within a couple weeks -- what I'm guessing is
16 after this meeting she'll send out a call actually for
17 both of these workgroups that we've identified.

18 I wanted to give you -- actually, we're going
19 to take a short break now. I wanted to give you a little
20 bit of a preview, though, of what we're going to do
21 afterwards. You'll see on your agenda that there are
22 three topics that I'm guessing are topics that each and

1 every one of you would have something you'd like to say
2 about at some point.

3 What we have is 10 minutes for each topic, so
4 what these are intended is to give you an update of what
5 we're doing on these topics and to determine -- to give
6 you something to think about and as to whether or not you
7 might want it to be a more broad topic with more
8 conversation in this venue in the October meeting and
9 also the possibility that you might want to come in and
10 meet with us on your own to discuss what gets discussed
11 here today. As I mentioned earlier, we'll take those
12 meetings as well.

13 And then we'll go on so we won't be taking
14 comments on that. But then, after that, Lois Rossi will
15 be here and we should have some time to talk about the
16 global registration MRL international work with some
17 dialogue here today. Then, we may actually skip the
18 registration update because you have the material in your
19 folders and those are just fairly routine updates that we
20 provide. But we'll see how that goes. If there's time,
21 we'll go ahead and do that.

22 So, I don't know if -- I also would like to

1 apologize for the heater. I don't know if I'm just in
2 the hot seat up here, but I feel kind of warm. Anyway, I
3 apologize about that.

4 I would like for everyone to be back at 3:25
5 sharp because that's when we're going to start.

6 (A brief recess was taken.)

7 MS. EDWARDS: All right. We're going to begin
8 now. But just before we begin, it's my understanding
9 that Jennifer Sass would like to say something. So,
10 please, Jennifer.

11 DS. SASS: Yeah, really quick. I just wanted
12 to say really quickly thank you to EPA for the amazing
13 snack, the healthy snacks and the cookie snacks. But
14 also to remind everybody, because I know nobody reads
15 labels and nobody reads signs, that she had no budget to
16 put out coffee or tea or cookies or fruit or all the
17 yummy things they do. So, it's really important that
18 people put some money in that little basket with that
19 (inaudible).

20 MS. EDWARDS: Thanks, Jennifer. We appreciate
21 that. Thanks very much.

22 Well, our next presentation will be a 10-minute

1 presentation, as I mentioned. Hopefully, we'll bring you
2 just up to speed on what we're doing with volatilization,
3 an emerging issue in the pesticide regulatory world. So,
4 Charles Smith, or Billy Smith, will give this
5 presentation.

6 MR. OUDENGER: Actually, I'm going to introduce
7 Bill.

8 MS. EDWARDS: Jack Oudenger (phonetic).

9 MR. OUDENGER: Last October we briefed this
10 group on field volatilization and kind of what we were
11 doing and our approach to it. Since the membership had
12 changed significantly, we thought it was time for -- to
13 revisit it and also tell you kind of what our thoughts
14 are today and what challenges we have facing us in
15 addressing this issue.

16 Currently, we're looking at the fumigants and
17 those are very volatile chemicals that move off the
18 field. We think we have an approach for them that should
19 come out soon. These are semi-volatile chemicals that
20 caught us a little bit by surprise. PANNA has done a lot
21 of looking for off-field volatilization of these and
22 we've used some of the PANNA data and we're going to talk

1 a little bit about that today.

2 Since we only have 10 minutes, I'm going to
3 introduce Bill Smith who is on a workgroup on EPA that's
4 looking into this issue and will talk about some of the
5 approaches and stuff that we're doing.

6 MR. SMITH: Thanks, Jack. For those of you who
7 were here last October, some of these slides may be a
8 little bit of a redo but we're going to go through them
9 anyway for everyone.

10 So, volatilization, as Jack said, what is it?
11 It's vapors of a pesticide leaving an application site
12 after sprays settle. We're not talking about spray drift
13 or overspray or even wind-blown soil here. Right now
14 we're focusing on possible risk to humans, but
15 volatilization of pesticides could also effect wildlife
16 exposures, drinking water exposures, or even cause off-
17 site crop damage.

18 Previously, in the outdoor setting, as Jack
19 said, we mainly focused on the fumigants which are highly
20 volatile. With these semi-volatile chemicals, for the
21 most part, we believe that there's infinite dilution
22 outdoors, so this really wouldn't be a risk of concern.

1 But as he said, looking at the PANNA data has caused us
2 to look into this issue further.

3 As far as our framework for assessing these
4 types of exposures, the first question we've kind of
5 asked is what do we know about the potential for exposure
6 and risk from pesticides that volatilize. Residential or
7 bi-standard exposures, as we've called them in the
8 fumigant assessments, the pesticides can occur through
9 inhalation from volatile pesticides that are applied to
10 fields. As we've said again, the recent data from PANNA
11 indicates that exposures can occur similar to the
12 fumigants from the semi-volatile pesticides.

13 The second question we've kind of examined is
14 the criteria for determining when to conduct a
15 quantitative risk assessment for these types of
16 exposures. The fumigants have really shaped the
17 assessments that we've done, the methods that we've
18 utilized from a toxic side, from an exposure side. We're
19 looking at different air monitoring data, including PANNA
20 data, California Air Resource Board data, and tox data
21 with acute and short term inhalation studies.

22 Finally, what are the methods that are actually

1 used in assessing exposure and risk? This presentation
2 is going to take us through our methods thus far.

3 So, currently we're working on -- as you can
4 see on the next slide -- these sort of four main factors,
5 the first being how do we determine what pesticides may
6 be a volatilization risk, the factors that are actually
7 affecting the volatilization.

8 In looking at tox issues as far as the RfC
9 methodology, inhalation versus oral studies in
10 assessments, as I said, we're looking at various
11 monitoring data, PANNA, CARB, as well as looking into
12 what the European guidelines are for these types of
13 exposures, as well as looking at air dispersion modeling
14 from one field, one application, compared to air shed
15 modeling, high seasons of use -- high areas of use.
16 Then, we're trying to put together some example
17 assessments using these different methodologies.

18 From what we've looked at thus far in the
19 literature, the main factor that's affecting the field
20 volatilization is vapor pressure, which isn't surprising.
21 Again, you can see here I've listed a number of resources
22 that we've examined. This is true for both

1 volatilization off of soils and plant surfaces.

2 But we also believe there's other factors that
3 impact volatilization to varying degrees, including the
4 pesticide properties such as water solubility, the
5 Henry's Law constant, agricultural practices, you know,
6 area of use, application methods, things like that,
7 meteorological conditions such as air temperature, wind
8 speed, inversion conditions, precipitation, persistence
9 on the plant surface including photo degradation and
10 plant uptake and soil physical properties such as soil
11 temperature, you know, the moisture content of the soil.

12 Some uncertainties around these factors include
13 -- volatilization, we believe, may be product specific in
14 that inert ingredients could actually have an impact
15 depending on the formulation of the pesticide, as well as
16 the fact that it's hard to pinpoint the magnitude that
17 the other factors may play into it on top of vapor
18 pressure.

19 When it comes to actually trying to evaluate
20 the risk from volatilization, focusing on the hazard,
21 we've preferred thus far to have inhalation toxicity data
22 of the duration matching exposure to assess risk. So, if

1 we want to look at acute risk, we would want an acute
2 study. If we want to look at short term risk, we would
3 want a short term tox study. If those aren't available,
4 we've typically used oral studies in the place of those
5 inhalation studies.

6 If an inhalation study is available, we've used
7 the RfC methodology. The RfC methodology has been
8 developed by the EPA's Office of Research and
9 Development. It's gone through extensive peer review,
10 both within and outside the Agency, including the Science
11 Advisory Board. We've repeatedly used this methodology
12 throughout the fumigant risk assessments.

13 It's used to assess non-cancer risks from
14 inhalation, and it treats vapors and gases differently
15 than aerosols and droplets, which will be important here
16 as I go through the rest of the slides.

17 The final point is that it's used to
18 extrapolate from animals to humans, so it uses the known
19 physiological and anatomical differences between animals
20 and humans, which we believe allows us to better reflect
21 the actual exposure that the human is getting. If you
22 would like more information on this methodology, you can

1 go to the link here that we've provided.

2 Currently, we've used this RfC methodology to
3 calculate the human equivalent concentrations for
4 chlorpyrifos, diazinon and then endosulfan. We focused
5 on these three chemicals because we believe that PANNA
6 has provided valid monitoring data thus far. So, we
7 focused on these chemicals as an example assessment
8 within the Agency.

9 We're also working on developing a database, as
10 I said earlier, that compares the HECs using these
11 inhalation tox studies from NOAELS selected from oral tox
12 studies. So, we're trying to focus on what are the
13 possible uncertainties there if we use an oral study
14 compared to an inhalation study.

15 The uncertainties around the toxicity part of
16 the field volatilization is again the vapors and
17 aerosols, as I mentioned before. Typically, we get
18 inhalation toxicity studies for aerosols, but the
19 volatilization, we believe, is mostly vapors. The
20 fumigant assessment type showed that vapors can have a
21 different effect as far as how they get into the system
22 and what they do when they get into the system.

1 The other uncertainty is oral versus inhalation
2 kinetics, again the inhalation study, how the dose gets
3 into the body. It can impact different regions of the
4 respiratory tract and portal of entry effects as well.

5 The next two slides kind of focus on the
6 exposure data that we've looked at. The first is the
7 PANNA drift catcher data. They have right now publicly
8 available data on four pesticides. There's also
9 chlorothalonil data that we're aware of but we don't
10 believe that it's publicly available yet.

11 Continuous 24-hour samples are taken. Samples
12 thus far for these chemicals in the studies have been
13 taken over one to three weeks, consecutive days, and the
14 samples have been taken at various field edges, homes,
15 schools, places like that.

16 The other factor is we rarely know when an
17 application occurs, so we feel that's a possible
18 uncertainty with the data. If you look at the California
19 Air Resource Board data, many of the similar
20 methodologies have been done there as well.

21 One big difference is that typically with the
22 CARB data, the samples are taken over a longer period of

1 time, two to three months instead of one to three weeks.
2 Samples were taken at similar places. They typically
3 have done about 40 chemicals. They have data for about
4 40 chemicals over the last 20 years.

5 One other key difference as well, they
6 generically know how much of the pesticide that they're
7 looking at was applied from a historical aspect. So, if
8 they did data in 2000, they would typically, you know,
9 know how much was applied maybe '96-'98 which gives us
10 something to speak to as to what was applied and how
11 much.

12 The uncertainties around the exposure data,
13 again as I said, is that we typically don't know when
14 applications occurred. If we know, we typically don't
15 know what product was applied or where it was applied
16 with respect to the sampler.

17 Most samples are 24 hours in length, and we
18 believe that this really has two uncertainties within it.
19 One is that it could be capturing both drift and
20 volatilization if there was an application nearby the
21 sampler. This causes an impact because of respirable
22 particles versus inhalable particles.

1 The 24-hour sample might also confound the data
2 a little bit in that it can't focus between the daytime
3 and nighttime volatilization rate. What we've seen with
4 the fumigants is that it's possible that during calm
5 conditions at night, the volatilization rates could be
6 higher.

7 The final uncertainty is that where the
8 California data differs with PANNA is that they do a
9 continuous weather monitoring over the length of the
10 study. PANNA does not. They kind of just look at the
11 one particular point during the day.

12 Another aspect that we've been looking into is
13 possibly using the same models that we've used for the
14 fumigant assessments to try and model the semi-volatile
15 pesticides. There's a number of models and approaches
16 that we could possibly use here. At this point in time
17 we feel that it would be very detailed and complicated,
18 so we're looking into the number of assumptions that
19 would need to be made to do these types of assessments.

20 This slide we just wanted to kind of go over
21 what we believe is at this point in time our approach
22 compared to how PANNA has interpreted the data.

1 Generally, we started with the same toxicological
2 endpoints. PANNA is utilizing what is called a REL
3 approach, whereas, again, we're the RfC methodology.

4 They use the full uncertainty factors; whereas,
5 the RfC methodology allows us to reduce the uncertainty
6 factor, again because we feel, you know, the methodology
7 allows us to get more accurate with the tox data for
8 humans when we're converting from rats to humans.

9 PANNA's risk is based on an accedence, so they
10 will take the REL that they calculate and they calculate
11 the REL by adjusting from rats to humans using body
12 weight and a breathing rate. They take each sampling
13 day, each 24-hour sample, the concentration that they
14 collected, and compare it to that REL and then
15 essentially say that if they had 21 days of samples,
16 seven of those days exceeded the REL.

17 It's not exactly the way we are looking at it.
18 We're looking at it based on an MOE approach where we
19 would take the average from the study and compare it to
20 our HEC calculated from the RfC methodology. The
21 difference is that it's kind of conservative when you're
22 using say a 21-day study to say that you were exposed to

1 that one single day level which may be a max level for
2 all 21 days. So, we believe the way PANNA is going, it
3 will be more appropriate if you had an acute endpoint.

4 Again, both of us are assuming 24-hour
5 exposures. This is conservative as well for a number of
6 reasons, including that it's not likely that an
7 individual will be stationary for an entire 24-hour
8 period. It doesn't take into account indoor versus
9 outdoor air concentration. Typically, we believe that
10 exposures would be more likely kind of a low-level
11 background with occasional high spikes when there's
12 applications nearby.

13 Finally, we just have two slides as kind of
14 what we're focusing on going forward. We're
15 reconsidering the criteria for triggering an assessment
16 of exposure from volatilized pesticides. Again, that
17 goes back to all the factors that affect it.

18 We're trying to further mine CARB data, PANNA
19 data and any other data sources, as I mentioned, like
20 European guideline, to help us better understand field
21 volatilization.

22 We're trying to determine the best way to

1 evaluate these exposures, whether that's modeling, using
2 the monitoring data, or a combination of both, as well as
3 determining if aggregation of these exposures is
4 necessary.

5 Finally, we're encouraging stakeholders and
6 states to produce data looking at pesticides that do
7 volatilize, as well as encouraging them to initiate
8 programs to better coordinate and cooperate between
9 growers and the public.

10 MS. EDWARDS: Thank you, Bill. Obviously, like
11 I said, we're going to be moving on now, but I wanted to
12 just say a couple things about this. First of all, part
13 of our objective today was to show you that we recognize
14 this as an emerging issue. It's one the public cares
15 about. You see it in the news, probably again this
16 summer, and we're taking it seriously.

17 Right now we're looking at it from a very
18 scientific perspective to try to figure out the
19 appropriate way to do these risk assessments and when we
20 should do them and if so, how we should do them. When we
21 are ready to do so, which shouldn't be too much longer,
22 we'll probably have an SAP meeting. I think that's the

1 appropriate venue for vetting the science and getting
2 some feedback from experts on the way in which we're
3 going to propose to have a framework for the assessment
4 of these kinds of volatile pesticides.

5 So, anyway, at this point, thank you again,
6 Bill. We're going to move on to our endocrine disruptor
7 presentation with Steve Bradbury.

8 MR. BRADBURY: Thanks, Debbie. I'll try to
9 move quickly and keep us on schedule, but I just wanted
10 to give you an update on where we are with the endocrine
11 disruptor screening program. Over the last several
12 meetings, we've been trying to give you at least a short
13 summary of where we're at, and that's what I'll do today.
14 Some of this will be a repeat from some previous meetings
15 with some new folks on the panel. So, we'll just do a
16 little review of how we got here.

17 Under the Food Quality Protection Act and the
18 Safe Drinking Water Act amendments of 1996, there was a
19 mandate under both those acts to take a look at this
20 issue of endocrine disruption and to ask the Agency to
21 move forward in developing a process to do screening for
22 endocrine effects, looking at pesticides, pesticidal

1 inerts and other chemicals that could be found in water
2 and with the focus initially on looking at the potential
3 for estrogenic effects in the context of these chemicals
4 and develop an approach to screen and test for that
5 effect in that group of chemicals.

6 In 1998, the Agency created a Federal Advisory
7 Committee to provide some input on how to move forward
8 with this charge from Congress. Through that FACA, the
9 scope of the effort expanded. It expanded from focusing
10 on estrogen-related effects to also include looking at
11 androgen related effects and thyroid-related effects.

12 Another aspect of the dialogue with the input
13 from that Federal Advisory Committee was in addition to
14 looking at potential human health effects, to also take a
15 look at wildlife and aquatic life, as well as human
16 health. The Agency accepted those recommendations from
17 the FACA.

18 The FACA also provided some approaches on
19 priority settings for chemicals. We talked about that a
20 little bit earlier this morning when we were talking a
21 little bit about high throughput testing and USAR. That
22 was one aspect of some of the recommendations near the

1 end of the EDSTAC process. There was also some
2 discussion on other methods that could be used to
3 prioritize them.

4 The major focus of the factor was to look at
5 how to go from screening to testing. The jargon of that
6 dialogue and that public process was first to describe a
7 Tier 1 process which was a screening process that can be
8 used in in vitro or in vivo tests to detect the potential
9 of a chemical to interact with an endocrine system. That
10 was used to answer the question, could this chemical have
11 a reasonable probability of interacting with the
12 endocrine system. It wouldn't be making any statement
13 about potential risk or whether or not that effect would
14 really play out.

15 The way to answer that question would be then
16 to move into a Tier 2 testing where you would actually
17 take a look at whether or not that effect was playing out
18 in the attacked organism and get a sense of the dose
19 response relationship for any effect that would be
20 detected. Then you can use that information as
21 appropriate in the risk assessment process.

22 So, over the many years, because it was a

1 challenging charge that the EDSTAC provided in terms of
2 the kinds of science that would have to be created to go
3 through that process -- through that process, then, there
4 were Tier 1 assays that were proposed and research was
5 done and validation was done. In the context of the Tier
6 1 assays, we're now at a point in this work where a
7 number of these Tier 1 screening assays have completed
8 the validation process.

9 There's an error on this slide and I'll just
10 explain it. So, everything has been through the
11 validation process, through the steroidogenesis assay.
12 There's an estrogen receptor binding assay and there's
13 also a gene expression assay for estrogen effects.
14 That's an assay that says if the chemical has an
15 estrogen-like activity that actually starts the signaling
16 process in the cell, that would be associated with an
17 estrogen-like chemical.

18 Those two assays are still going through
19 validation right now. So, everything on that list
20 through the steroidogenesis has been through the
21 validation process. Estrogen receptor binding assay and
22 the transcriptional assays are still going through

1 validation now.

2 We also went to the SAP in March of 2008 to ask
3 the SAP to take a look at this battery of Tier 1 assays
4 and get some feedback on the process that had been going
5 on with all those assays and also to hang together in
6 terms of the signs, and again some feedback on the
7 initial approach and trying to integrate this kind of
8 information in the screening assay. We're hoping to get
9 report back from the SAP in late June.

10 The Tier 2 assays are still going through
11 various stages of validation. So, 2010 to 2011 is the
12 projected time that those assays would complete their
13 validation process.

14 In addition to all the work that's going on to
15 get these assays developed and validated, there's also
16 been work going on in preparation for the first round of
17 screening that will be undertaken. Part of the process
18 of getting the screening started -- in previous Science
19 Advisory Panel reviews that the Agency took advantage of
20 over the last several years, was some advice from the SAP
21 on how to get started.

22 It was their recommendation that the Agency

1 should take a look at 50 to 100 chemicals and get started
2 with a data -- a group of chemicals of about that size to
3 go through the first round of screening so that they
4 could sort of see how all of this is going to work.
5 Then, with that information in hand, see if there's any
6 adjustments that should be done rather than just starting
7 off right through all these inventories without doing
8 that first step.

9 So, we've been going through various Federal
10 Register notices on the methodology to identify those 50
11 to 100, which is all based on exposure potential not
12 based on any potential to interact with (inaudible)
13 systems. We've had a lot of public comment and process
14 in developing that approach for identifying the 50 to
15 100. The proposed group of 73 compounds went out for
16 public comment back in June of '07.

17 There's also been public process and comments
18 on the process and the procedures that would be used by
19 the Agency to issue the test orders to get the testing
20 started. That's been going on over the last year or so.

21 With all that work, the where are we now and
22 what's coming up in the next several months. So, as we

1 get near the end of June, the more milestones will be
2 hit. We'll be going out with an FR notice to publish
3 sort of the information collection request so that that
4 process gets done and we get public comment on that,
5 which is part of the processes, the information that
6 we're going to be requesting, you go through a process of
7 getting some public comment on that.

8 As I mentioned before, at the end of June, the
9 Science Advisory Panel report should come out on that
10 March peer review which will give us some feedback on how
11 we're integrating different assays.

12 As we get into August, we'll then be finalizing
13 the policy for how we're going to be going through the
14 procedures of issuing test orders and the whole process
15 of dealing with the test orders as we go out and how
16 people can respond to the test orders when we get them.
17 At the same time, we'll be publishing the final list of
18 50 to 100 that will be the chemicals for which the test
19 orders will be issued.

20 On that same time frame will be when we'll be
21 finalizing what those Tier 1 screening assays will be.
22 With all that, a few weeks later we're targeting the

1 beginning of issuing the test orders. I'm assuming all
2 this stuff comes together in that time frame.

3 The snapshot is that as we go from the end of
4 June to August, all the different components start to
5 come together with the target of starting to issue the
6 test orders in August time frame.

7 MS. EDWARDS: Thanks very much, Steve. It's
8 going to be a busy summer. Next we have P.V. Shah, our
9 acting branch chief for the Inert Ingredient Assessment
10 Branch in the Registration Division to give you an update
11 on our inert activities.

12 MR. SHAH: Thank you, Debbie. We have been
13 quite busy this year with several measurable (inaudible)
14 improvements and have made significant progress on
15 approving inerts.

16 We have made significant progress in managing
17 our workload. So far, in 2008, we have granted 10 food-
18 use petitions, approved 11 non-food use inerts and we are
19 currently working on about 35 petitions under various
20 stages of review.

21 In working with the submitters of the old
22 petitions, we received requests to voluntarily withdraw

1 14 petitions. The FR rule is going to be published
2 today. I'm also happy to report today that we do not
3 have any backlog of old petitions. They are all under
4 review.

5 As you may be aware, inert ingredients are now
6 eligible for PR under certain conditions. For new
7 conventional pesticide products, you may now apply for a
8 new food use inert or a new -- an amended inert tolerance
9 exemption. (Inaudible) incorporated materials are also
10 eligible under PRIA-2. So far, we have received three
11 inert PRIA petitions. All inert PRIA petitions undergo
12 the same completeness screens as conventional pesticides
13 via submission.

14 One petition that we received this year had
15 several previous deficiencies. The petitioner did
16 correct the deficiencies but the product PRIA schedule
17 was infected. So, I want to emphasize the importance in
18 the PRIA of submitting complete and accurate petitions.

19 Besides PRIA, we are also screening food use
20 and non-food use inert petition requests. There are
21 problems we are -- if there are problems with the
22 petition, then we are contacting the submitters within

1 three to four weeks. If the submitters can correct it
2 quickly, then the submission goes on our review plan
3 without any further delay.

4 We are reviewing all CSFs to ensure that the
5 inerts are approved for the label uses. We are
6 conducting registrant with the CSF problems. I want to
7 emphasize here that registration action will not go
8 forward without an approved inert.

9 As I mentioned previously, we will (inaudible)
10 only complete petitions or requests in our work plan. We
11 are also revising the guidance to our (inaudible)
12 submitters with understanding the basic information and
13 data needed for inert ingredient requests. We are
14 encouraging the petitioner to contact inert branch for
15 assistance in planning their petitions. We have also
16 provided guidance on the (inaudible) side and have a
17 mailbox there. We continuously check that and respond to
18 the questions that somebody might have on the inert
19 issue.

20 In December 2007, we updated the web site to
21 include all the non-food use inerts. We also have a link
22 to e-CFR for locating food-use tolerance exemptions. We

1 have also consolidated 25(b) inert ingredient lists. We
2 also have provided link to USDA's the organic program
3 listing.

4 Now I would like to update you on the inert
5 tolerance exemption that was revoked in August 2006 at
6 the end of the EPA tolerance reassessment. A hundred and
7 23 inerts were revoked because they lacked sufficient
8 data to make this FQPA safety finding. The revoked
9 exemptions were given two-year expiration date and are
10 due to expire this August.

11 In November 2007, we also published in the
12 Federal Register a list of exemptions that industry is
13 willing to support, and we'll be submitting the data. As
14 of today, we have 64 inerts that have been supported,
15 meaning that the industry is willing to conduct the study
16 and EPA has agreed to review those studies. There are 59
17 inerts that have not been supported by the industry.

18 We are working with the joint inert task force
19 in the data development plan for supporting certain
20 tolerance exemptions revoked due to insufficient data.
21 The Task Force has provided EPA with their data
22 development plan and submission schedules. We'll be

1 reviewing the data activities and we have made plans for
2 data review based on expected data of submission.

3 After careful consideration of the issues
4 surrounding study development for the (inaudible), we
5 have decided to provide several more months for data
6 submission. We will be extending the tolerance exemption
7 expiration date by one year from August 2008 to August
8 2009.

9 We'll soon put out a Federal Register notice
10 extending the expiration date of the supported tolerance
11 exemptions. By August 9, 2009, EPA will establish new
12 tolerance exemptions for the supported (inaudible) that
13 meet the FQPA standard.

14 For those inerts that are not being supported,
15 their tolerance exemption will expire on August 9, 2008,
16 this year. We believe that most of the products have
17 already been reformulated based on our advance notice.
18 We will be checking our internal database to identify
19 products that contain these unsupported inerts.

20 Based on the results of our check, we will be
21 communicating with affected registrants about options,
22 including reformulations and cancellations. After August

1 9th, this year, we will not be able to grant registration
2 actions of products that contain the revoked inerts.

3 Also, we continue to work on the data
4 compensation issue. According to FQPA, there is a
5 provision for the data compensation. We are hoping to
6 publish advanced notice of proposed rulemaking in this
7 fall. We are currently developing the list of data
8 submitters who are eligible for compensation. The list
9 will be made available for review and comments to the
10 public.

11 Often we have been asked if our data
12 compensation is similar to the Agency's endocrine
13 disruption program data compensation policy. OPP has
14 coordinated with the Agency's endocrine disruption
15 program to ensure that our data compensation provisions
16 are compatible. In the meanwhile, internal procedures
17 for implementation of data compensation have been
18 established.

19 In August 2006, separate petitions were
20 submitted to EPA by 14 states and 22 environmental and
21 health groups asking EPA to require that pesticide levels
22 identify certain inert ingredients that have been listed

1 as hazardous under various authorities. In response to
2 this petition, OPP has been working with EPA's Office of
3 General Counsel and other program offices to investigate
4 the cited environmental statutes and standards used for
5 listing.

6 OPP will next consider the relevance of those
7 classification standards to making inert ingredient
8 leveling disclosure determination under the FIFRA
9 authorities.

10 We are also working in correcting the error in
11 the CFR. We will also be adding CAS number to the
12 tolerance exemptions in the CFR to help us identifying
13 which chemicals are approved for use. We continue to get
14 requests for CAS number in the CFR and know this will be
15 a -- a we know that this will be a different feature of
16 adding a CAS number would be benefit to all of us.

17 We envision a very short process for adding a
18 CAS number in the future that is a direct final rule to
19 update the CFR. We will be (inaudible) the CAS number
20 addition process when we will publish the Federal
21 Register correcting the CFR error that has been in the
22 CFR. We hope to publish this FR in the summer.

1 Lastly, we are also expanding the functionality
2 of our database system, OPPIN, for inert (inaudible).
3 This upgrade will help us serve you better and faster.
4 Thank you very much for your time.

5 MS. EDWARDS: Thanks, P.V. So now we will move
6 on to the last major session of the day and that is
7 harmonization update on our global registrations,
8 workshares, MRLs, and activities with China and so forth
9 with Lois Rossi leading the discussion, director of the
10 Registration Division.

11 MS. ROSSI: This afternoon I'm going to present
12 a brief overview of some of the international
13 registration activities and initiatives involving mostly
14 conventional chemicals. By no means is this an attempt
15 to cover all the international initiatives OPP is
16 involved with. It's very narrowly focused, actually, and
17 geared towards group safety.

18 I always like to begin these presentations by
19 starting off with the principle business of the pesticide
20 programs which gives us the reason why we do what we do,
21 which is to protect public health in the environment as
22 well as ensure that society has access to pesticides and

1 the associated benefits.

2 Our international efforts are linked to these
3 goals. In particular, we have had an emphasis on getting
4 reduced risk pesticides registered in multiple global
5 markets and getting international standards such as Codex
6 established in a timely fashion.

7 Our engagement basically I would characterize
8 as being under three major headings, leadership, advocacy
9 and championship, and fostering communication. With
10 regard to leadership, we have been promoting joint
11 reviews and harmonization both internally in our
12 organization as well as internationally with our global
13 partners, continually identifying opportunities for
14 collaboration and cooperation. There are new ones being
15 discovered every day, some of which I'll touch upon, and
16 fostering communication among regulatory authorities
17 throughout the world and among various stakeholders.

18 These are opportunities that allow us the
19 opportunity to engage and promote collaboration and
20 harmonization. I'll go through some of the activities
21 we're doing under each of these headings. The first one,
22 obviously, is NAFTA, OECD, joint reviews for new active

1 ingredients, new use expansions, and even a program for
2 registration review.

3 Some bilateral collaboration, the Codex, the
4 Joint Committee on Pesticide Residues as well as the
5 Codex Committee on Pesticide Residues which is the risk
6 assessment and the risk management committees on Codex.
7 And a newer initiative on public health pesticides,
8 particularly vector control.

9 First of all, under NAFTA, the joint review
10 program for new active ingredients has been going on
11 since 1997. Actually, I think most of the new active
12 ingredients that are coming in these days are no longer
13 just NAFTA. A lot of them are beyond NAFTA. But we do
14 have a pretty strong minor use joint review program that
15 is continuing between Canada and the United States
16 primarily. Actually, this has been a model program that
17 other national authorities throughout the world are
18 looking at.

19 Also, under NAFTA, we have been pursuing a
20 major trade irritant initiative. Most recently, this
21 past April, we were very pleased to launch a trade
22 irritant database that was grower initiated. Dan Botts

1 of the Florida Fruit and Vegetable Association headed up
2 that initiative with the help of some funding from our
3 colleagues, (inaudible) Service, USDA, to put in one
4 place various potential trade barriers right now confined
5 to NASA that would assist the government to resolve some
6 of these trade irritants in a resource conservative
7 efficient effective manner and resolve them.

8 We have some pretty high hopes for that
9 database. It has a lot of potential to be used by
10 multiple stakeholders and certainly by government, and
11 could even be expanded, if you think really big, to being
12 the trade irritant database of the world.

13 Also, under NAFTA, we have had some commodity
14 specific projects in the last few years to eliminate
15 trade barriers. These have been pretty resource
16 intensive and have kind of led to doing the database
17 which will allow us to use a lot of our regular processes
18 of registration, registration review, adding new uses,
19 those processes to resolve some. But a couple of the
20 ones that have come to conclusion are the commodity-based
21 projects on potatoes, tomatoes and pulse crops. There's
22 a web site where you can see the resolution of those.

1 Recently, at the NAFTA technical working group
2 meeting that was held in Niagra in the lakes a couple
3 weeks ago, we had a presentation on concluding some
4 chemical commodity characteristics that looked like they
5 presented trade irritants but actually resulted in not
6 really creating a trade irritant. That conclusion is
7 soon to be posted. Then there's an ongoing project
8 between Mexico and the United States on avocados.

9 Another huge initiative that we've been doing
10 for the last couple of years is with the national label.
11 I think many of you are probably aware of that. Last
12 year, last January, we had the approval of our first
13 NAFTA label which is the first pesticide listed on your
14 slide. Since then, we've had three other ones approved.
15 You know, even though these represent approvals of
16 labels, the work that went into resolving the
17 difficulties to provide a NAFTA label was substantial.

18 Particularly, we're pleased with the last entry
19 on this slide which is a new active ingredient.
20 Hopefully, there is a lot of potential for new active
21 ingredients being jointly reviewed to result in NAFTA
22 labels.

1 These are the ones that are in progress and
2 there's a couple of brand new pesticides, one definitely,
3 which Mandipropamid is a reduced-risk pesticide. Again,
4 the purpose of the NAFTA label is to allow the pesticide
5 to be purchased in either country and used in either
6 country.

7 With regard to OECD, we do have -- the
8 pesticide program participates very actively and heavily
9 in the working group on pesticides as well as the
10 registration steering group in OECD. We have
11 concentrated on -- actually, I think the registration
12 steering group was created in 1991.

13 Since that time, I think the work that OECD has
14 done with member countries has certainly provided the
15 foundation and building block to allow us to have our
16 program today of global joint reviews and see the
17 exponential growth of this program over the last couple
18 of years.

19 They have champion data requirement
20 harmonization, data review, template harmonization, and a
21 host of other issues. It still provides us the forum to
22 talk about lessons learned as well as harmonization

1 issues. Every time we finish a global review, we do a
2 lessons learned.

3 I refuse to call it a post mortem because that
4 implies death, as many people have called post mortem,
5 but I don't think that's what it should be called. It's
6 a lesson learned and it points out issues that you
7 probably never would have thought were harmonization
8 issues until you actually go through and do an actual
9 example.

10 We also have an experts group on minor uses
11 called EGMU and that group is exploring ways to deal with
12 the minor issues that many countries throughout the globe
13 experience. We had a minor use summit back in December
14 of last year and it was very well attended. It certainly
15 pointed out the universal problem of minor uses in
16 developed countries as well as developing countries.

17 There's also a residue chemistry expert group
18 that's working on data requirements and guidelines.
19 Recently, in this room I believe, in April we held an IT
20 workshop with the focus of dealing with the IT problems
21 of submitting one docier that can go around the world and
22 the reviews associated with that docier.

1 Also being discussed at OECD are chemicals,
2 some of the new active ingredients that are showing PBT
3 type characteristics and how different countries are
4 dealing with that and how we're dealing with it in
5 general. Then also, we've been analyzing and trying to
6 connotate the benefits of work sharing and joint review.

7 On this next slide, for your information, are
8 some recent decisions. Some are joint review, some are
9 work shares, the difference being with work shares a
10 sequential review of where one country completes a review
11 and provides the next country that the submission is
12 going into with the reviews.

13 But on there we've had some reduced risk
14 pesticides which we're very pleased with. The last one,
15 we've had some trilaterals which are the first -- the
16 very first one, pyrasulfotole, a new herbicide, was a
17 trilateral in Australia, (inaudible) in the US. That was
18 the very first one that we did beyond NAFTA. The next to
19 the last one, pyroxsulam, was also a trilateral, a new
20 herbicide. That was our first new active ingredient
21 NAFTA label.

22 Then, the last one, chlorantranillprole, which

1 the biggest challenge on that one is pronouncing it, is a
2 new insecticide, a reduced insecticide, and it was what
3 we were calling our first global joint review because it
4 had Australia, Canada, EU and within the EU we had
5 Ireland and UK as lead reviewers, but also we had quite a
6 few countries peer reviewing in the EU, New Zealand and
7 the U.S. The U.S. registered it just a couple weeks ago.

8 We're most pleased with this one because it was
9 difficult to find endpoints on this one, actually, and it
10 is the best one right now that we see as taking some of
11 the replacements for some of the chemicals such as AZM
12 where we have done restrictions and phase-outs.

13 We have four that are currently in progress,
14 another reduced risk insecticide, spirotetramat, and then
15 three other compounds. One is work share metaflumizone,
16 and thiencarbazon/cyprosulfamide and saflufenacil are
17 two that are trilaterals with the UK and with Australia.

18 We are in presubmission discussions on over 14
19 projects at this time, and also there are additionally
20 four biologicals that are being discussed. I think
21 there's also one antimicrobial. So, there's a huge
22 amount of work being done in the presubmission stages to

1 prepare for these projects.

2 This is just a brief slide on the cooperative
3 effort that is currently being initiated on reevaluation
4 or registration review, what used to be re-registration.
5 A lot of countries' national authorities are at the
6 beginning stages of their next review program. We have a
7 pilot that is being coordinated through the OECD
8 registration steering group and working group on
9 pesticides as a partial workshare. We also have two
10 pilot chemicals that we will pursue under NAFTA.

11 Some lessons learned, I think we all agree,
12 actually, in the room on the fourth floor right now all
13 day the managers and people who have worked on -- staff
14 who have worked on the joint reviews that we've completed
15 today have been meeting in a retreat and talking about
16 lessons learned and ways to go forward. It was really
17 actually amazing.

18 This morning I opened up the meeting and there
19 were like 70 people in the room from the three divisions,
20 the two risk assessment divisions and the registration
21 division. I commented after the first part of the
22 morning that if we had done this a year and a half ago,

1 we would have had maybe three people in the room. So, it
2 has really taken off and the challenge for us managers
3 has been to increase the number of staff that are working
4 on these projects and encouraging them to constantly
5 improve but also encouraging them to communicate with
6 their colleagues around the globe.

7 We heard some success stories this morning of
8 e-mail groups and conference calls and all kinds of
9 approaches to communicate with clients that might be half
10 a world away. They're complex because we're obviously at
11 the infancy stage of these projects, so there's lots of
12 learning curve; the learning curve's steep. We're doing
13 as we're learning. But the benefits potentially I think
14 are huge and make the effort worthwhile.

15 We have the opportunity to take advantage of
16 scientists throughout the world and the various expertise
17 that they bring to the table, which certainly increases
18 the strength of our positions and the quality of our
19 clients. It's subject to a peer review that is quite
20 extensive.

21 It certainly has an incentive for industry to
22 create one single data package that is consistent with

1 the needs of all the regulators and all the regulators
2 see one package. So, you get to see all the data even
3 though it may not be a data requirement for your
4 particular country.

5 We have lessons learned, as I said, routinely
6 scheduled among evaluators. We have them at various
7 places, usually in the margins of the OECD meeting. We
8 do a step-by-step analysis of what went right and what
9 areas to improve on the various joint review.

10 Communication coordination can't be
11 overemphasized, as just about with any endeavor that you
12 try to do, and to become more efficient in the planning
13 stages. We're continually revising a project plan. I
14 think the first project plan we had for one of these was
15 150 pages long which is a little daunting to try and
16 follow on a daily basis.

17 The quality of the global submissions
18 definitely are improving. Then, we do have client issues
19 which are challenges and we're documenting them to try
20 and find the right forum to resolve these.

21 Codex Committee on Pesticide Residues has
22 probably been one of the biggest challenges I've worked

1 with in my career at OPT. We had a recent meeting in
2 Hangzhou, China in April. We have been concentrating
3 over the last few years on accelerating this process and
4 particularly loading up the priorities with the newer
5 reduced risk pesticides.

6 We have sponsored -- by doing a lot of the
7 paper presentations as well as promotions of a process
8 where if the JMPR identifies no intake concern for a
9 commodity, chemical commodity combination, that this
10 could go through an approval process from nomination to
11 adoption of a MRL in two years.

12 Those of you who are familiar with this process
13 know that it was anywhere from 7 to 10 years. We were
14 very pleased to have the support of the previous chairman
15 who is from the Netherlands, as well as the current
16 chairman from China on supporting this process. This
17 year we saw 261 pesticide commodity MRLs advance to
18 adoption. They'll be considered by the Codex
19 Alimentarius (phonetic) Commission at their meeting in
20 July.

21 And again, heavily into the reduced risk
22 chemicals. This is important for our growers to

1 accelerate market penetration of some of these newer
2 pesticides because a lot of countries depend on Codex
3 MRLs before they'll accept a commodity into their
4 country.

5 We're working on -- we are revising in EPA with
6 IF-4 the crop grouping classification. We have presented
7 that to Codex and it's our intention to keep working on
8 that with Codex so that the Codex -- we have one crop
9 classification that's used by national authorities as
10 well as Codex.

11 Then, this year, as a result of a
12 recommendation from the minor use summit that we did have
13 in Rome, there was a working group on minor uses and
14 specialty crops established in Codex. The representation
15 in Codex is very widespread with a lot of developing
16 countries participating in Codex. The U.S. will chair
17 this group, but we have co-chairs from Australia and
18 Kenya.

19 I sat through these Codex committee meetings
20 now for four years, and I have never seen more people
21 raise their flags to participate in anything as they did
22 to participate in this minor use and specialty crop

1 working group. I think it just goes to show you that
2 this is a universal problem that all countries face.

3 Some bilateral initiatives, we've been
4 continually working with Japan over the last couple years
5 as they've been going through their positive lists of
6 MRLs and reevaluation. They have a daunting task in
7 front of them. Every time I talk to them it reminds me
8 of 1996. They have some I think it's like 600 or 700
9 MRLs that they have to review in five years, the Food
10 Safety Commission being the body newly created body;
11 they're celebrating their fifth anniversary this
12 September, responsible for establishing the ADI in Japan
13 and then three other ministries -- one other ministry is
14 involved in the MRLs and two other ministries are
15 involved in the registration of pesticides.

16 We very much would -- or have been encouraging
17 them to participate in the global joint review, again to
18 how to reduce pesticide registered at the same time as
19 one is registered in the United States and Japan
20 certainly allows the pesticide to be used on exported
21 commodities. Japan imports a lot of their food and a lot
22 of food is exported from the United States.

1 We were pleased to just learn that they will
2 actually participate in one of the upcoming joint reviews
3 -- that's a huge step -- in a couple of years. Brazil
4 also is another huge trading partner, and we are very
5 interested in seeing that reduced pesticides are
6 registered in Brazil. We are pleased to say that they
7 also have indicated an interest now in participating in
8 the global reviews.

9 Initiatives with China with ICAMA, which is the
10 Institute for the Control of Agri-chemicals, and the
11 Ministry of Agriculture. We had planned, actually, to
12 begin next week a study to work with representatives.
13 We've had some very successful meetings.

14 Last year, our assistant administrator, Jim
15 Gulliford, signed a letter of intent, or a memorandum of
16 intent, with China for cooperation. We spent a couple of
17 days after the CCPR meeting with ICAMA officials in
18 Beijing. They are very interested in learning our risk
19 assessment processes about our inerts, about impurities.
20 We had set up this study tour, but unfortunately, they
21 had to cancel due to the recent earthquake. So,
22 hopefully in the next year we will be advancing that

1 initiative quite a bit. There are initiatives already
2 planned.

3 Then, most recently, we've had some
4 collaboration with our colleagues in the foreign AG
5 service, USDA, on Taiwan's initiative to establish MRLs.
6 They recently sent around their top priority of 200 MRLs,
7 which we were able to participate with FAS in commenting
8 on. I was very pleased in my analysis to see that they
9 had a heavy emphasis on reduced pesticides as their top
10 200 MRLs.

11 There are some -- there's an initiative
12 starting with CAFTA, with USDA and FDA and the University
13 of Maryland Joint Institute for Food Safety and Applied
14 Nutrition to expand the pesticide work on Central
15 American countries and the Dominican Republic, in
16 addition to some worker safety projects that have been
17 going on in OPT with focuses on food safety. So, that's
18 kind of the newest opportunity that we will have.

19 Lastly, this is actually a very new idea that
20 the U.S. did promote in CCPR. This slide is a little out
21 of order. It should have come right after the CCPR, but
22 anyway, it's a new initiative that was introduced but it

1 came out of the minor use summit, which is the concept of
2 having the benefit in these global joint reviews, having
3 the benefit of knowing what the JMPR is going to
4 recommend for MRLs before national authorities go and
5 assess them.

6 If you think about it, there's so much work
7 these days being done by national authorities to try to
8 harmonize with one another. And then, even FQPA requires
9 us to harmonize with Codex. Yet, in the beginning, Codex
10 is an international body that is setting MRLs. So, if
11 you had the benefit of knowing what their MRLs'
12 recommendations would be, then you could at least
13 consciously know whether you were going to set something
14 that harmonized or did not.

15 This is totally different than the way they've
16 been doing business for 40 years. So, you can imagine
17 the discussion that took place. But we did get approval
18 to go ahead, and we got a work group, and we have a pilot
19 that we'd very much like to see go through that system to
20 see how that works in 2009.

21 Lastly, we've recently become -- we've begun
22 discussions with other federal government agencies as

1 well as such initiatives like the Melinda and Bill Gates
2 Foundation to collaborate with regard to public health
3 pesticides and vector control. We're in the very early
4 stages of doing an organizing committee to have a summit
5 that addresses public health pesticides with a particular
6 emphasis on vector control and see if there can be some
7 safer alternatives that are globally developed and then
8 ultimately registered.

9 So, I guess, just in summary, a significant
10 increase in the last couple of years in the new active
11 ingredients that are coming through the global joint
12 review process. We're starting to see youth expansion.
13 We'll have some youth expansions for a couple of the
14 reduced risk pesticides we've registered just in the last
15 year.

16 Lots of initiatives directed towards trade
17 irritants, minor use initiatives, Codex initiatives and
18 increased bilateral collaboration and cooperation. Thank
19 you. I'll take any questions or comments.

20 MS. EDWARDS: Is everyone stunned or -- okay,
21 you have one.

22 UNIDENTIFIED FEMALE: First I want to say thank

1 you for that update, Lois. That was very, very helpful.
2 I haven't been directly involved, so it's just nice to
3 know what's all been going on.

4 I just wanted to ask one question about the
5 public health. Kind of what is the scope that they're
6 looking at? Is it just domestic use or is this for also
7 like the president's malaria initiative? What's the
8 breadth of what they're going to be looking at from a
9 vector's control?

10 MS. ROSSI: Well, it's a very new idea. We're
11 just basically getting -- Kevin Sweeney I know presented
12 it at the American Mosquito Control Association annual
13 meeting. It's very new. Like I said, the organizing
14 committee is just forming. So, I think a big emphasis
15 will be on the mosquito control and looking at what's in
16 pipelines and from researchers and ways to advance some
17 of these things. So, we haven't totally scoped it out,
18 but that's where we're going with it.

19 MS. WILUSAMET: Hi, this is Kate Wilusamet
20 (phonetic) and I'm a protection community. I would like
21 to hear a little more about your work with Japan and
22 China. Just basically, my concerns come from our

1 discussions we've had with chemical companies where
2 they've told us that they have to repeat experiments for
3 registration in Japan because Japan has specific
4 endpoints and they actually don't accept one or two of
5 the OECD endpoints.

6 Also, in China we've heard from companies that
7 China requires some, especially ecological, testing in
8 their own labs. So, I'm just sort of curious about how
9 the harmonization process is working and how these joint
10 reviews will hopefully mitigate that process.

11 MS. ROSSI: I mean, with both of those
12 countries, we're -- Japan we're a little farther along
13 with getting them, at least, to participate in one of the
14 joint reviews that's coming up. I think -- I mean,
15 basically what we do with these joint reviews is the
16 docier has to have chemical -- country specific studies
17 in it. We have -- Europe has studies that we don't
18 require, but yet, if we're doing a global review with
19 Europe, those studies are in there.

20 So, OECD has done initiatives on harmonizing
21 the guidelines, but countries still have their own
22 country-specific guidelines, as we do and other countries

1 do. So, I mean, that initiative isn't resolved yet by
2 any means. I think by having them involved in a global
3 joint review, you at least start the dialogue.

4 With China, I think the impression that I got
5 after being in Beijing for a couple a days is that
6 they're sort of at a point of reinventing their program.
7 I think they want to learn as much about data
8 requirements and risk assessments and regulatory programs
9 as much as they possibly can.

10 I know they've had dialogue with other
11 countries, EU, Australia, and they will have with us.
12 So, that initiative I think probably has a lot of
13 potential for influencing data requirements.

14 DR. COPE: This is Stan Cope from the Pest
15 Management Board. I applaud the idea of a public health
16 summit. Kevin and I have had some discussions about it.
17 Since I'll be the boss of the Pest Management Board
18 starting August 1st, I'd like to offer our full
19 cooperation and assistance with planning, identifying
20 speakers, topics. Whatever you need, we'll be happy to
21 help you with that.

22 MS. ROSSI: That's great. Actually, we're

1 lucky enough to already have a venue. The Chartered
2 Institute for Environmental Health has come forward and
3 offered their facility and manage all the registration
4 things. That's the biggest headache right there. So,
5 thank you, though. That's great.

6 MS. EDWARDS: Okay. Well, thank you, Lois.
7 We're pretty excited about this work for a number of
8 reasons. I think in a global trade environment and a lot
9 of movement of food in and out of countries, it's
10 critical that we are on the same page with respect to
11 food safety and that we work to get the safest products
12 in use so that our growers can in fact use the safer
13 newer products as opposed to older products.

14 Plus, as Lois said, I think the expansion of
15 expertise globally in these issues can never hurt. It's
16 the same thing as bringing these people together, all
17 these together today. So, anytime you expand your
18 knowledge base, you're going to have a better product.

19 I think it looks like we do have time, in fact,
20 to do our registration updates because we don't have any
21 people signed up for public comment. If you did want to
22 do a public comment, maybe you could sign up and do that

1 tomorrow or let us know pretty immediately that you had
2 that desire.

3 But I think what we'll do now is move to Janet
4 Andersen who is going to do our registration update. And
5 then, after that, we'll do Steve Bradbury with our re-
6 evaluation update, and close until 9:00 tomorrow morning.

7 MS. ANDERSEN: Thank you. I promise to be
8 pretty brief because you do have the materials in front
9 of you. We have several new members so rather than go
10 through exactly -- I have a few things I'd like to have
11 clear to everyone who is here.

12 One, the Office of Pesticides Program puts
13 together its plan every year. We make a commitment to do
14 a certain number of new active ingredients. We will make
15 decisions on them. Those decisions are not always yes or
16 approval. They may be no. And that's still a decision.
17 So, we count the nos. And we count also the withdrawals
18 when we have done considerable amount of work on an
19 action before it's actually withdrawn.

20 We also set goals for new uses, especially
21 Registration Division. Actually, in the Biopesticides
22 Division, this doesn't make a lot of sense since we have

1 tolerance exemptions. If you do the first food use for
2 an existing active ingredient, you can end up with 274
3 just by making a tolerance exemption. It's not exactly
4 what we had in mind when we were thinking about counting
5 new uses. We count them when they are appropriate but
6 not terribly often.

7 We've also in the past done how many fast
8 tracks, how many non-fast tracks for new products and
9 amendments and set a whole series of goals. But our
10 world changed when we had the Pesticide Registration
11 Improvement Act come in in March of 2004. Now, our real
12 goal is that we make our PRIA date. It doesn't mean that
13 sometimes we haven't had to renegotiate because we're
14 missing some data, but we are not doing renegotiations
15 for extra time just because we're slow and behind our cue
16 and we need to have an extra six months to do it. We're
17 just not doing that.

18 I think we probably surprised everyone in how
19 well we made our numbers. I think our numbers are in the
20 order of 99 percent. Some years they're right at 100.
21 So, when the law was about to go out, which would have
22 been this year, about this time we should have been

1 worrying about whether or not we were going to have a new
2 one in.

3 Last year, industry put this new PRIA-2, the
4 Pesticide Registration Improvement Act, Version 2 -- they
5 actually called it slightly different wording -- but we
6 call it PRIA-2. They put it in place in October, so we
7 had a lot of confidence.

8 You're now seeing the Office of Pesticide
9 Programs out hiring people where we had had some
10 vacancies and hadn't been able to hire because we didn't
11 want to let people go. We actually have some of the feed
12 monies pay for some of our staff. So, it's quite a good
13 situation for us all. I think it's benefitted industry,
14 it's benefitted users for getting new and safer products
15 on the market, and it's benefitted the USCPA. I think
16 it's a far better place where we are today.

17 So, the only other thing that I want to do is
18 I'm not sure I can do it in such a (inaudible) place, but
19 I'm really practicing for anthromiliprole so I could be
20 close at least to the name of it. It is a challenge but
21 I want to credit Lois Rossi and the other divisions for
22 the work they did to a global joint review. This is

1 really a very remarkable achievement and one that she
2 really needs the leadership recognition for for what
3 she's done. So, I want to give her that plug and that
4 plug to her staff because they're very proud of what they
5 did and it should be that way.

6 Rather than going through the details of the
7 numbers, I would like to have an opportunity, if somebody
8 wants to ask any questions about these numbers or what
9 we've got planned. I can tell you that we've -- if you
10 add them up, we've made on the order of 12 decisions so
11 far this year.

12 So, I'll go through them. There's the six
13 conventionals and there's the four biopesticides to date,
14 and there's the two antimicrobials. So, we have done 12.
15 The goal is 22. We're well on our way to make that. I
16 think we will be able to easily do that. We've done 200
17 new uses in Registration Division, NFU, and
18 antimicrobials and biopesticides.

19 We're doing well on our Section 18 for the 36-
20 day turnaround. The goal is 50, great big numbers for
21 fast track amendments. But the numbers are good for
22 these. This again shows the -- there's the inerts

1 listing you've already had the update on. These are the
2 basic PRIA numbers showing the total number of
3 submissions, the number we've completed, and that we're
4 at 99 percent of making those deadlines.

5 Usually when we miss, we miss by a day or two.
6 One of my favorites is the one where we thought --
7 someone thought they'd get an extra day because it was
8 Memorial Day since we were approaching Memorial Day.
9 They don't. They actually needed to do it the day before
10 or so or the Friday before. So, we counted it as missing
11 the date. But the law actually says if we miss it by a
12 year, then they can go to court. So, we've never had
13 those kinds of -- we've done very well with it.

14 Yes, there is some renegotiation and there are
15 some Canite (phonetic) grants when we have not been able
16 to reach decisions with the data that we've had and work
17 it out. Those are rare. Those are the renegotiations
18 for BPPD. They are the highest you will see, but that --
19 percentage-wise, but that is going down because one of
20 our categories --

21 We all agreed when we did PRIA-2 that it was
22 way to short. We extended something for four months, new

1 products from four months to six months. Our
2 renegotiation numbers are dropping quite rapidly in DPPD.

3 That's back to the beginning, so we're done.

4 Questions? Comments?

5 MR. TAMAYO: Dave Tamayo, CASQA (phonetic).

6 You mentioned that the benefits were for, I guess, the
7 registrants and the users and EPA. I'm a bit concerned
8 that, you know, where's the environment and public health
9 in this registration process?

10 You know, it seems that there's so much of an
11 emphasis on let's crank these things through and meet
12 these dates. I understand the need to respect the
13 commercial interest and people that have put a lot of
14 money into this, but it seems like EPA's role really
15 needs to focus on getting the job done right. I'm not
16 really that familiar with what the constraints of this
17 legislation is but --

18 MS. ANDERSEN: Well, you've asked an excellent
19 question because there is more to it. In the first
20 round, there was a special area just for worker
21 protection, so a set-aside. So, the MTOs (phonetic) were
22 very much a part of the negotiations to develop this

1 first and the second version of it.

2 But I'm quite excited that in the second round
3 there was also what might be like an earmark but there's
4 money set aside for partnership grants. So, the other
5 half of my pollution prevention -- Biopesticides and
6 Pollution Prevention Division, the pollution prevention
7 one, we are actually put out on the web in the last day
8 or two. The announcement that we are putting forward
9 \$750,000 from PRIA money and \$250,000 from my budget from
10 my division for a million dollars partnership grant that
11 we have now announced the competition for.

12 So, we're very excited for what we can do in
13 the environment, because those are aimed at projects that
14 go beyond the regulation to make further reductions in
15 the risk and use of pesticides.

16 MR. TAMAYO: Okay, but I still think that the
17 basic protection should be the registration process and
18 then like there -- you know, really, I'm concerned that
19 when you list what the benefits are, those things weren't
20 kind of at the top of your mind when you mentioned that.

21 The other thing -- and it's really kind of the
22 basis for my being here -- what provisions are being made

1 to do a more thorough job of reconciling say like the
2 Clean Water Act water quality criteria with the
3 registration process? You know, if we're talking about
4 registration issues, that's our basic thing is that those
5 two things aren't -- they don't seem to be reconciled
6 with each other. It actually puts the receiving waters
7 at a big disadvantage.

8 MS. ANDERSEN: You're correct that those are
9 not harmonized right now, but we've begun pretty serious
10 conversations between the Office of Water and the Office
11 of Pesticide Programs. I think what we're going to be
12 doing is adding a long term project, hopefully not too
13 long term, but a short term and long term, to actually
14 have a harmonized risk assessment process for water
15 quality criteria and for the benchmarks we use in the
16 pesticide program.

17 One of the challenges right now for the Office
18 of Water, they like to see eight different species for
19 setting those up and we only require through our
20 regulations three species. So, what ends up happening is
21 they are not actually setting those criteria in the
22 absence of having the eight species because the states

1 aren't turning them in.

2 So, what we're going to do is get together and
3 figure out what do you really -- you know, what is the
4 appropriate risk assessment process when you have three
5 species, when you have five, when you have eight, and try
6 to get ourselves on the same page with how that would
7 actually be done.

8 We'll probably run that through some -- well,
9 we'll definitely run that through some public peer review
10 and so forth. But we have very recently made a
11 commitment to reach some harmonization there with the
12 goals having that issue resolved.

13 MR. TAMAYO: Okay. Well, I haven't volunteered
14 for any work groups yet, but if you establish one for
15 that, I would be very interested.

16 MS. ANDERSEN: Okay, thank you.

17 MS. EDWARDS: We'll move on to re-registration
18 and then we actually do have one public commentor.

19 MR. BRADBURY: Hello again. Well, I'm not
20 going to go through the entire handout because, as Debbie
21 said, we wanted to get you some background information.
22 What I'll do is spend a few minutes touching on some

1 highlights and maybe spending a little more time on
2 registration review. But I'll go quickly and make sure
3 there's time for questions too.

4 So, in terms of re-registration, that part of
5 our re-evaluation program which was working on all the
6 pesticides that are registered before 1984 is getting
7 near the end of that journey. Back in 2006, we finished
8 the re-registration decisions for all the food-use
9 pesticides. As we hit October of this year, we'll finish
10 all the non-food uses that are in that pool of pesticides
11 that were registered before '84.

12 In that context, as we went through that, we
13 completed tolerance reassessments for a little over
14 almost 10,000 tolerances that were part of that process.
15 So, that part of our re-evaluation program is getting
16 near the end in terms of getting those re-registration
17 decisions done.

18 Of course, there's a lot of other aspects to
19 that re-registration process. That includes product re-
20 registration. That's the process whereby all the changes
21 that were laid out in the re-registration decisions start
22 to turn into new labels that are on the product. There's

1 data call-ins, things that have to get done and
2 finalized.

3 We're making good progress in getting those
4 product re-registrations done. That's when the products
5 actually have label changes recommended in the REDs on
6 the street. We're done with most of the organophosphates
7 and making good progress on carbamates and other groups
8 of compounds.

9 There's also some significant post-RED
10 activities that are ongoing right now. During the course
11 of this summer, we hope to be making more incremental
12 progress. Those include the continuing process with
13 carbofuran and the post-registries and, with that,
14 finalizing our decisions on rodenticides, the organic
15 arsenicals, and PCNB examples of some challenging issues
16 that we're working through as part of the product re-
17 registration and post-RED activities.

18 Also, a number of petitions that we've received
19 over the last several months in terms of revoking
20 tolerances or cancelling uses associated with some of the
21 chemicals in this pool. We're working through that
22 process as well.

1 During the course of re-registration, we also
2 work through some of the first cumulative risk
3 assessments. That was part of FQPA that AFTAS has
4 charged us to take a look at chemicals that have a common
5 mechanism of action and figure out how to do a risk
6 assessment with management decision for all the chemicals
7 in a common group.

8 That included organophosphates, the N-methyl
9 carbamates, the triazines, herbicides, and the
10 chloroacetanilides. The OP cumulative is final. We're
11 working on response to comments on the triazines and the
12 N-methyl carbamates. That's another example of post-RED
13 activities that are ongoing.

14 A special review is a very intensive process,
15 more of a historical process, as we moved into
16 re-registration becoming a way to try to deal with
17 looking back at old chemicals. But since the 70s,
18 probably hundreds of special review cases were
19 undertaken. At this point, we're down to four, if I have
20 my notes right, with all the CARB and ethylene oxide as
21 ones that we're preparing to finalize with the post-RED
22 decisions.

1 The triazines are one group -- atrazine and
2 trinazine, I think I got that right, are still hanging
3 out there because we want to get a final SAP on the
4 potential for cancer associated with most compounds
5 before they reach the end of that process.

6 The new old chemical program was a new aspect
7 of re-evaluation of the registration review program. I
8 thought I might just spend a little more time on that,
9 but not a lot. Let me just go through a few slides that
10 you have.

11 So, registration review was part of a new
12 process or part of this 15-year cycle to take a look at
13 all the existing pesticides and go through and update
14 their risk assessments if needed and ensure that the
15 current signs and risk management philosophy is
16 consistent going back through time.

17 Again, sticking with the same principles of
18 re-registration was ensuring that the transparent process
19 was an open process that includes public participation
20 and ensures continuity of protecting human health and the
21 environment.

22 I'm going to kind of be jumping around, so if

1 you're using your handout, I may skip a few things.

2 The registration review program was implemented
3 through a rule. That rule became effective in October of
4 2006 and we began implementing the program in 2007. Our
5 goal, or basically our statutory requirement, is to get
6 through that first cycle, going through the 15-year
7 process, and get that completed by October 1st of 2022.
8 It's a pretty significant effort. It encompasses almost
9 1200 active ingredients.

10 As part of this process, there's at least two
11 new components that exist or issues or programmatic goals
12 that we know we have to deal with right now and that's
13 including endangered species assessments and the goal of
14 becoming compliant with the Endangered Species Act as we
15 go through these re-registration decisions.

16 Touching on that brief highlight I did a little
17 while ago, as the endocrine disruptor program gets
18 through that first set of testing, we get feedback from
19 the SAP and others to begin implementing that on a
20 routine basis as we go through registration review.
21 There could be other issues in science and regulatory
22 policy that could play out during this 15-year cycle and

1 we'll have to adapt as we go on that.

2 Just real quick, a comparison of re-
3 registration versus registration review, we talked about
4 re-registration and all that stuff, all the AIs that were
5 registered before '84, refocused subset of the universal
6 AIs. Now we're dealing with all the pesticides, the 15-
7 year cycle, the throughput jumps from about 20 pesticides
8 per year and re-registration there's 45 to 70 of the ramp
9 up to meet that goal of 2022.

10 The idea here is we're updating reviews as
11 needed as we go forward. We're sort of a balancing act
12 with the throughput. We're not going back to ground zero
13 and starting all over again. We're building from where
14 we've been. So, we anticipate fewer data needs and more
15 focused updates and refinement. Having said that,
16 obviously endangered species work is not a trivial
17 activity to undertake as we go through this.

18 The review process, again, as I've mentioned
19 before, is one in which we're assembling background
20 information and then going through some various stages
21 where there's public participation starting with
22 preliminary work plans, like the problem formulation

1 stage, so we can get input from folks as we hit major
2 milestones through this process in ensuring that there's
3 public participation and input.

4 We're working into this and working with Rick
5 and colleagues and NOAA ensuring that this process we're
6 going to do can (inaudible) with working with the
7 services (inaudible) consult on a case-by-case basis. We
8 can work that into the schedule as best we can.

9 I think why don't I stop there -- I think I've
10 covered the high points -- and field a few questions if
11 we've got time.

12 UNIDENTIFIED MALE: Well, in addition to our
13 concerns about doing this in the context of potential
14 water quality problems, it's the same comments I made on
15 registration. We're also very concerned that as things
16 are being reviewed, that they not be done in sort of a
17 vacuum of well, if there's certain mitigation measures or
18 restrictions put on one type of active ingredient, that
19 the next one that's going to replace it in that
20 particular use pattern is going to be our next water
21 quality problem.

22 It's not just within, you know, one class of

1 pesticides, you know, we're concerned about high
2 (inaudible) rates, for instance, but what we're also
3 seeing problems with other things that peers are
4 beginning to come more (inaudible) such as gipronil
5 (phonetic).

6 So, as those things are done, we'd like there
7 to be some sort of alternative analysis done of what's
8 likely going to happen and then how do we, I guess, share
9 the pain amongst the other potential replacement
10 products.

11 Then, really, also, are there viable
12 alternatives that are either less problematic chemicals
13 or reasonable and effective non-chemical means? I think
14 that really needs to be put into the risk benefit
15 analysis that you guys are responsible for.

16 MR. BRADBURY: Thanks. To get back to one of
17 your -- your first comment, one really significant aspect
18 of the preliminary work plan and opening a docket or
19 setting up that problem formulation is a process that we
20 work through with the Office of Water and the regions and
21 piloted the idea with several states including California
22 was to ensure that when we opened the dockets, we were

1 accessing all the monitoring data that may be out there
2 and have an SOP as part of opening a docket so that we
3 can try to access -- it can be just a web site that a
4 state may have -- so that we're aware of all the
5 information that's out there in terms of monitoring data,
6 because I think that's really important to help us zoom
7 in on that risk assessment that we need to do.

8 We certainly want to know about all the
9 monitoring data that may be associated with potential
10 TMDL decisions that are being done or TMDL decisions that
11 have already been made to really understand what the
12 monitoring data was that we're behind that to the extent
13 th states -- agencies within the states or the Department
14 of Environmental Quality analogue to get that information
15 so that we can get a jump on understanding what's going
16 on with the particular compound.

17 We think that would be really helpful to look
18 at it both at a national -- or better understand how
19 there could be certain use patterns that are leading to
20 higher concentrations in the water than we anticipated.

21 UNIDENTIFIED MALE: Process-wise, how far in
22 advance have you -- I guess finishing in preliminary risk

1 assessment, would you be opening that docket and starting
2 to gather that information? Then, also, will your staff
3 be actively looking themselves doing some sort of a
4 literature review as well and not just depending on
5 agencies like mine to do what we actually think is your
6 job?

7 MR. BRADBURY: Well, I'll push back on the last
8 one, but before I do that, one of the last pages of the
9 handout gives you the web page where you can access our
10 schedule for opening a docket so you can see -- I think
11 it's through -- four or five years out we've got the
12 schedule by quarter.

13 So, you can see when these dockets are going to
14 open. So, if folks have information that they think will
15 be useful to us, you can certainly anticipate when that's
16 going to happen. We're definitely not asking for the
17 states to send in information, but if a state has a
18 public web site that we can go to just verifying this is
19 the web site you can go, EPA, to pull up our data.

20 What we found at the end of re-registration and
21 started getting into some of these topics, is it isn't
22 always intuitively obvious where in a state's web site

1 this data resides. In fact, we found out in some cases
2 that data doesn't exist on web sites. It's an internal
3 database that we would have no way of knowing unless we
4 can interact with the state.

5 So, we're definitely screening sort of the
6 obvious USGS data, EPA data that's coming in. This was
7 an attempt to make sure there wasn't a treasure chest of
8 information out there that's just aren't readily
9 available as you scan through Google or whatever that --
10 that kind of context.

11 In terms of literature, you're beyond just
12 water quality monitoring data and getting a little bit to
13 what Debbie and you all were talking about a little while
14 ago is part of opening the docket also involves or as
15 they move through the preliminary work plan or the final
16 work plan is a literature search of all the open
17 literature ecotoxicology information. We're essentially
18 using the same search engine that Office of Water uses
19 when they generate a water quality (inaudible).

20 So, some aspects of this harmonization are
21 already in place. So, for a chemical that's been in the
22 market for quite a while that may have data beyond what

1 the registrant has, we're already accessing the same
2 information base on the ecotoxicology side as one step
3 towards that harmonization.

4 So, when we go into a risk assessment,
5 ecological risk assessment (inaudible) certainly we're
6 using the registrant information because it's very useful
7 information -- GLPs and all that stuff behind that -- but
8 we're also amassing all the open literature as well to
9 take a look at all the best available information and the
10 analyses that are going on.

11 MS. EDWARDS: Okay, thank you, Steve.

12 Oh, I'm sorry, Mike, go ahead.

13 MR. FRY: Michael Fry, American Bird
14 Conservancy. With regard to the monitoring data, somehow
15 going to the open literature, going to the gray
16 literature, is really not sufficient in many cases when
17 you know that there are deficiencies in the data. And we
18 know there are with the incident reporting. We know
19 there are with --

20 We had a really great example with the
21 volatilization. The assumption that inhalation and oral
22 dosing, they have to assume that they're equivalent or

1 that there's some relationship there. Nobody has done
2 the studies, you know, to document this kind of stuff.

3 With regard to monitoring data, when there are
4 deficiencies, who do you expect will provide the data?
5 The states certainly don't have the money to do it. You
6 guys don't have the money to do it. The registrants are
7 often very reluctant to do it. The only way that you can
8 force the registrant to do it is with a data call-in and
9 that's after you've done the RED.

10 So, without any money and without any field
11 data, really how can you just go forward with the sort of
12 treadmill re-registration procedure and really do an
13 adequate job?

14 MR. BRADBURY: Well, I think it's important to
15 review sort of how the exposure part of the ecological
16 risk assessment plays out. Let's do the aquatic resource
17 as an example. We're going to use all the best available
18 information from monitoring that's available. But that's
19 just one line of evidence in terms of estimating exposure
20 concentrations. We're also using state and transport
21 models and water quality models to estimate what the
22 water concentrations could be under different use

1 scenarios.

2 Even if you had all the money in the world,
3 it's pretty unlikely you're going to be able to monitor
4 every place in the country to get all the information
5 about all the watersheds in all the places. You're
6 always going to be trying to blend both modeling and
7 monitoring.

8 The modeling approaches that we're using, which
9 have gone through numerous (inaudible) advisory panel
10 reviews are designed to be high end estimates of what the
11 water quality or what the water concentrations would be
12 for the pesticides. So, I think it's important to
13 realize we're using modeling data as well as monitoring
14 data.

15 Is there uncertainty? Yeah. And that's part
16 of the challenge in working through what those
17 uncertainties can mean. But I think there's in the re-
18 registration process numerous examples of registrants
19 doing follow-up monitoring to confirm that the modeling
20 (inaudible) follow up.

21 UNIDENTIFIED FEMALE: Really quickly. Is it
22 true that when you guys issue a data call in, it has to

1 go through the Office of Management and Budget and get
2 approval?

3 MR. BRADBURY: Yes.

4 UNIDENTIFIED FEMALE: And what's your like
5 success rate or time frame for getting the data call ins
6 through that OMB process?

7 MR. BRADBURY: Improving.

8 UNIDENTIFIED FEMALE: Like, is it within months
9 or years?

10 MR. BRADBURY: Months and it's --

11 UNIDENTIFIED FEMALE: So, you have 100 percent
12 success rate of getting them through in half a year,
13 let's say?

14 MR. BRADBURY: Yeah. I think we -- if you
15 asked me this a year ago, we're still sort of working
16 through a standardized process with OMB so we can work
17 through some of the questions that they have in terms of
18 have you documented well enough the rationale for why
19 they want the information. We've started to get that
20 process smoothed out, so I think it's moving in a much
21 more efficient manner.

22 With registration review, what we're doing,

1 which I think will further streamline the process, is
2 that when we open a preliminary work plan, the Agency is
3 laying out the rationale as to why it thinks it does or
4 doesn't need certain data. By getting public comment on
5 that, that's a huge step to streamline the process of
6 OMB. We can say that went through a public process.
7 Here's the comments we got. Here's how we reacted to
8 those comments. I think that will also help that
9 process.

10 MS. EDWARDS: Thank you. We actually have one
11 public comment here, Tom Van Arsdal (phonetic) from the
12 Pollinator Partnership. Can you come forward and come to
13 the microphone?

14 MR. VAN ARSDAL: Good evening. I know I'm the
15 only thing between you and adjournment, so I'll try to be
16 efficient with my time. I'm Tom Van Arsdal and I'm here
17 on behalf of a group call the Pollinator Partnership.
18 Many of you are aware of this group. It's a tri-national
19 collaboration that's trying to improve awareness about
20 the importance of pollinators, both managed and
21 (inaudible) in the food we eat as well as in healthy
22 ecosystem.

1 We've got some problems out there and there are
2 a lot of people looking for solutions. This is an
3 important agricultural input too so a lot of the
4 commodity groups, producers that are dependent upon
5 pollinators for those services are also concerned.

6 There are a lot of people that are -- in
7 looking for answers, they're pretty desperate.
8 Beekeepers are at risk themselves, not just the
9 pollinators. There are some that are making allegations
10 that we don't see the science behind and we've been
11 looking for answers. USDA has been looking for answers.

12 I just left a meeting a little bit ago with
13 John "Short timer" Shull (phonetic) and Alesia Kyser
14 (phonetic) about ways to engage that community with EPA
15 to sort out fact from fiction. There may be other areas
16 of EPA that interface on this issues, but the pesticide
17 program is certainly an area.

18 We partner with the Pesticide Environmental
19 Stewardship Program, as the Pollinator Partnership does,
20 had good relationships there. What we would suggest as a
21 structured problem-solving way to get at the facts so we
22 get good information and decide what, if anything, to do

1 with it is to ask the PPDC to be a vehicle, perhaps the
2 next agenda, to add the interface of pesticides and
3 pesticide application with the fate of pollinators to
4 look at the current protocols utilized by EPA in that
5 process, to find out what researchers who are out there
6 looking at these problems are finding now and just begin
7 a problem-solving dialogue building upon that.

8 We are an organization that believes in sound
9 science. We helped get a National Academy of Science's
10 study that many of the groups around this table supported
11 to get better science (inaudible). We know far more that
12 we don't know than we do know.

13 Given that there's some existing problems out
14 there, we believe it's timely to get constructively
15 engaged, bring the beekeepers into the process, the
16 scientists into the process, as well as maybe pollinator
17 interests that are trying to figure many of the unknowns
18 on that side. Be a resource to this committee.

19 Maybe have us see you at the table? I don't
20 know. I just wanted to raise this issue this evening
21 with this body and with the Agency. We stand ready to
22 work with the responsible parties to see what we might do

1 about this. I'd be pleased to answer any questions, if
2 that's appropriate.

3 UNIDENTIFIED FEMALE: As far as you know, have
4 the pollinators or beekeepers not been invited to PPDC,
5 because I believe that they have?

6 MR. VAN ARSDAL: I don't know. I'm not
7 assigning any blame. I just know that they have not been
8 an effective voice. It's in part because they're not
9 that well organized.

10 UNIDENTIFIED FEMALE: Well, I don't know. I
11 think you guys are pretty well organized. I think you
12 have been invited. But, for sure, it's great to have you
13 here. I think you could be more involved and I think
14 that would be a really important voice.

15 MR. VAN ARSDAL: Well, the Pollinator
16 Partnership -- I'm not an expert in the pesticide
17 registration process or the pollinators themselves. I'm
18 involved in the policy area.

19 UNIDENTIFIED FEMALE: Nobody is before they sit
20 at this table.

21 MR. VAN ARSDAL: Right, but we have people out
22 there that we can bring into the process -- that's part

1 of the role of partnership -- and be a resource to this
2 committee to help focus on that insight. I'm a problem
3 solver. What happened in the past, I don't know. But I
4 know that they recognize themselves they've not been an
5 effective voice. Right now they're playing amateur hour
6 saying what's happening to my bees, talking about
7 beekeepers.

8 The colony class disorder is just as serious
9 this year as it was last year. There's some that talk to
10 the press rather than those who are trying to -- in a
11 position to solve problems. They make allegations,
12 including about pesticides and classes of pesticides.
13 We'd like to get to see them come into this process where
14 we've got an opportunity to get real solutions.

15 Thus far, my understanding from USDA is that
16 they're not finding any sources of pesticides in terms of
17 the condition called colony collapse disorder. They're
18 not finding that evidence yet. I think this committee
19 and EPA need to be aware of what's happening over there
20 as well as look within your existing protocols and say,
21 are we doing the right thing based on what we know. What
22 else do we need to find out to make certain that we've

1 got that base covered.

2 MS. EDWARDS: Thank you. I appreciate that.
3 If you look at our web site, you'll see that we have -- I
4 forget the name of the web site -- Emerging Issues.
5 There are two issues there. One is the volatilization
6 issue and one is the colony collapse issue. So, we're
7 watching that research very closely and we will consider
8 this be one of the topics that we will discuss here,
9 certainly.

10 MR. VAN ARSDAL: Thank you.

11 MS. EDWARDS: Jen?

12 DR. SASS: Jen Sass with NRDC. I mean, I think
13 it has been done before, to be honest, but I would like
14 to recommend, if not, that pollinators be represented. I
15 mean, with 45 people already, I'm sure we can work it
16 out.

17 Just to sort of strengthen the timeliness of
18 these kinds of issues with pesticides and pollinators,
19 I've seen us submit some pollinators contributing tens of
20 billions of dollars to the economy in this country
21 because of the need to pollinate for agriculture. Today
22 there was a press release by buyer released that they've

1 now withdrawn several of their miticloprin (phonetic)
2 products in Germany because of concern but they were
3 related to colony collapse.

4 So, I'm actually confused about why you're
5 giving a pass to pesticides on colony collapse. But, in
6 any case, I think there's a timeliness to bringing these
7 issues together and discussing it in a cogent way. I
8 would like to recommend that they be represented.

9 UNIDENTIFIED MALE: Just point of
10 clarification, I'm not giving a pass to anybody. I'm
11 just saying let's just make certain that we base
12 decisions on sound science and engage the right people
13 who are in a position to do something about it.

14 I'm only trying to characterize what I've heard
15 from researchers. I've heard other researchers saying
16 well, it's nice to study adult bees but we're finding out
17 that there's a lot of impact on broods and EPA's protocol
18 doesn't consider broods if there's no adult bee problem.

19 Well, is that something that we ought to be
20 changing? I don't know. But I think this is a good
21 group to sort of air those issues, bring in resource
22 people whether on the committee or off, so that we can

1 give the best advice possible to the EPA.

2 Of course, we're working on the farm bill. The
3 farm bill is about to become law. Has conservation and
4 research provisions on pollinators that we worked hard to
5 get, including the report of a very broad range of groups
6 to help make that possible. We're going to work to make
7 those more than just lines on the page but good
8 conservation and research provisions in the USDA.

9 MR. VROOM: Jay Vroom with CropLife America. I
10 have not seen the press release that Jennifer is
11 referring to and didn't come prepared today to have an
12 in-depth discussion, Tom, about pollinators and
13 pesticides. But as, I believe, you have alluded here,
14 this is a huge issue.

15 No one has brought forward in the United States
16 to this agency which regulates pesticides any scientific
17 evidence to, you know, affect any new massive review of
18 pesticide products. We've supported the work that your
19 coalition has done around the farm bill and other
20 research support. But I honestly believe that the way
21 Jen just described one of our member company press
22 releases out of Europe, it may be out of context here,

1 number one.

2 Number two, I would also like to remind folks
3 -- and I think, Tom, you can go into some of the details
4 of that -- there are a lot of pesticides that are used to
5 the benefit of pollinators, like miticides. So, you
6 know, there are risks and benefits here.

7 Again, I'm happy to support you being brought
8 back here at a future meeting to have a more prepared and
9 in-depth discussion about this, but again, I think
10 there's been some things just thrown out here this
11 afternoon that are unfortunate and not very balanced.

12 UNIDENTIFIED MALE: All I wanted to do is open
13 the dialogue and give people the opportunity to excite
14 their evening a little bit.

15 MS. EDWARDS: Thanks very much. You've
16 achieved that.

17 UNIDENTIFIED FEMALE: Just one more quick
18 comment on this. This has also been an issue that's come
19 up at the ABCO meetings where there's been research
20 presented. I know it was at the spring ABCO meeting
21 there was a session on it. So, it might be a good topic
22 to at least maybe have a panel or something on. Maybe we

1 can talk about it at sort of -- you know, as a future
2 meeting item.

3 MS. EDWARDS: Sure. Yeah. We're going to have
4 a session on that tomorrow in any event. But we
5 appreciate you bringing it forward.

6 One of the things -- I'm about to adjourn. I
7 just wanted to mention one thing about PRIA. It
8 concerned me earlier that it was characterized that the
9 advantage of PRIA is for registrants, users and the EPA.
10 Therefore, it's all about registering pesticides. I
11 disagree with that.

12 To say that it's in the advantage of EPA is to
13 say that it's the advantage of public health and the
14 environment because that's what's was focused on here.
15 This is a licensing program. As we do our work, our
16 objective is to license pesticides in such a way that
17 their safety is for public health and the environment.
18 That's our first and foremost goal.

19 What PRIA did was give us many resources to be
20 able to do that job better. In addition, a fairly
21 significant amount of money for set-asides for voluntary
22 programs for integrated pest management, worker safety,

1 and so on and so forth. So, I just wanted to make that
2 comment.

3 Thank you very much and I'll see you at 9:00 in
4 the morning.

5 **(Whereupon, the meeting was adjourned, to be**
6 **reconvened at 9:00 a.m. on March 22, 2008.)**

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P R O C E E D I N G S

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3 MS. EDWARDS: Welcome, and good morning. With
4 a good agenda again this morning, we're going to start
5 with a session on how we use our OPP resources. And to
6 give that presentation here in Session Number 7 will be
7 Marty Monell, our Deputy Director for Management.

8 MS. MONELL: Good morning, everyone. I
9 apologize for not being here yesterday morning and
10 missing all of the introductions. I am Debbie's deputy
11 in charge of management matters, which includes quite a
12 portfolio, one of which is managing information.
13 Yesterday there was an all-day agency meeting on managing
14 information. I thought that it was very important that
15 our voice be heard, our needs be heard at that meeting.
16 So, here I am today to talk about our budget.

17 The first slide -- you, hopefully, all have
18 paper copies of these slides. So, I'm not going to go
19 into excruciating detail, but the first slide basically
20 gives you a snapshot of the decline of our overall
21 resources. We, like other Federal agencies of domestic
22 programs, are cut and have been cut and our future looks

1 like it will include further cuts.

2 The free slide show, the free bar show, all of
3 our appropriations, we have regular environmental program
4 management accounts, we have a science and technology
5 account which basically funds research in our labs, and
6 then we have the stag account which funds our state
7 grants that are awarded generally through our regions,
8 some from headquarters.

9 The next slide depicts our FTE, and FTE stands
10 for full-time equivalents, which is the government's way
11 of addressing employees and how we account for them. So,
12 the numbers don't necessarily mean people. They
13 translate more to hours spent working for us at any given
14 period of time. So, again you'll see a decline in that
15 area. That is a result of various mandates from OMB and
16 the Agency to help address the overall budget shortfalls.

17 The next slide actually shows the breakout of
18 the FTE by appropriation. So, you'll see that the bulk
19 of our FTE, our employees are paid for out of the
20 environmental program management account. We have a very
21 small number out of the science and technology account,
22 and that's because they are only utilized in our lab.

1 Then, the maintenance fee support, a larger number. And
2 the PRIA fees support a fair number.

3 The next slide shows how the balance of our
4 utilization of our funds is utilized. You'll see that
5 the bulk of our money is spent on salaries. The pesticide
6 program decided a long time ago that this program is best
7 managed by federal employees. That while contract
8 support is essential, that the kinds of decisions that we
9 are called upon to make are best made by federal --
10 highly educated, highly trained federal employees.

11 We also did an analysis of the cost of having
12 federal employees do this work versus contractors. Even
13 if we hadn't made the philosophical decision to stick
14 with feds making the decision, it's also the most cost
15 effective way of doing our work.

16 So, while the salaries -- in previous slides, I
17 indicated that our numbers of employees has declined.
18 Salaries have increased. That's because of the COLAs
19 that Congress appropriates every year and yet does not
20 budget for us. So, our salaries are going up; the budget
21 is going down. As a result, the amount we have to spend
22 on contracts and other expenses is reduced.

1 To give you an idea -- next slide -- of the
2 kinds of things that we spend our resources on -- and I'm
3 addressing now the contract resources -- we spend a
4 significant amount on IT contracts. This is because, as
5 you know, this program is incredibly data rich and it's
6 really important that we get that data in a useable
7 format and manage it well.

8 So, we're doing a lot of investment in the
9 areas of e-submission, electronic submission, electronic
10 reviews where appropriate, documentum, which is a process
11 for storing our information and making it accessible not
12 only to us but ultimately to the public at large, and
13 then we had to do a little bit of investment for
14 implementation of portions of PRIA.

15 I understand yesterday you all heard about
16 PRIA, so I won't go into that. But it's a program, a
17 registration program which is funded by registrants,
18 designed to help us do our job better. Part of that is
19 managing information.

20 The next slide shows that in addition to the IT
21 investments, we use money for providing a public service
22 on pesticide information. We spend about \$2 million a

1 year on NPIC, which is the National Pesticide Information
2 Center, run out of Oregon State. It provides an
3 incredibly valuable tool to the public as a resource that
4 you can call.

5 The public can call if they suspect they may
6 have been harmed by a pesticide or been exposed to a
7 pesticide and get information 24/7 and then we -- this
8 year we have expanded that to include multi-lingual
9 access. So, a Hispanic worker that gets exposed can call
10 and speak to someone who is fluent in Spanish and also
11 other languages. I believe it's up to 20-odd languages
12 now that are available through this NPIC.

13 We fund the pesticide environmental stewardship
14 program. We provide a little less than \$3 million on
15 worker protection and certification in training programs,
16 then a little over \$1 million in sort of our fields,
17 outreach, international, cooperation, and then our tribal
18 work.

19 For our travel money, we have an overall pot of
20 about \$920,000 and we -- some examples of what we spend
21 that money on are invitational travel for PPDC. That's
22 just to give you an idea of the kinds of things and the

1 proportion of the overall travel budget. This is not
2 huge.

3 We support foreign travel that supports treaty
4 implementation, pops, picks, methyl bromide. That's
5 about \$94,000. We also do a fair amount of international
6 travel that supports work sharing and harmonization. That
7 would include our work with OECD and NAFTA, which is also
8 a treaty implementation effort.

9 Then, there is our domestic travel which
10 includes participation in stakeholder meetings. Some of
11 you may recall that over the past year groups of staff
12 that were working on particular chemical issues went out
13 to the field and actually had meetings with people that
14 were interested in our decisions on the chemicals. That
15 is another area that we feel is very important to fund
16 with our travel resources.

17 And then, of course, training. Training for
18 our staff sometimes includes travel expenditures,
19 particularly those for executive training that the
20 Officer of Personnel Management provides.

21 With the PRIA fees, you'll see that we made a
22 conscious decision to try to keep a better balance in

1 terms of funding salaries versus funding contract
2 services. PRIA does not pay for the cost of our
3 registration program. It essentially covers about 20
4 percent of the cost of running our registration program.
5 So, we decided it would be ill-advised to go whole hog
6 and spend all of the money on salaries but rather spend
7 some on the contract side as well. For the first couple
8 of years, that was primarily in the area of IT where we
9 had to adapt our systems to accommodate the requirements
10 of PRIA.

11 For FIFRA, that's the maintenance fees, you'll
12 see that that decision was made differently. Back when
13 the maintenance fees first were provided us, we thought
14 that we really needed to ramp up our employee base
15 because we had a 10-year deadline to do all of the
16 (inaudible) assessments and re-registration activity
17 mandated by FQPA. So, we ramped up heavily on the
18 employee side. As a result, those salaries still account
19 for a lion's share of our maintenance fees.

20 Fortunately, PRIA provided for a level over the
21 next five years that we can count on for maintenance
22 fees, so we don't have to worry as much about taking

1 people off and on this particular account. We're in a
2 steady state. We know what we can count on for finishing
3 up our re-registration work of the non-food uses and then
4 segueing into our registration review program full
5 implementation.

6 This is just information for those that are
7 detail oriented on pieces of PRIA. PRIA provides that
8 because the coalition was so concerned that Congress not
9 utilize this vehicle as a way of eliminating our
10 appropriation, the PRIA coalition thought that there
11 ought to be a baseline guaranteed appropriation before
12 the fees could kick in. This was obviously supported by
13 the registrant community.

14 But more importantly, I think, it was supported
15 by the public interest groups because they didn't want
16 the appearance of the registrants having too much
17 influence over our decisionmaking process because they
18 were paying such a large proportion of the fees to run
19 the program.

20 As I said, it's about 20 percent, so it's not
21 an overwhelming amount. But, nevertheless, it certainly
22 is substantial enough to be very helpful to the program.

1 So, this indicates that our appropriation is well above
2 the minimum threshold and we will be able to continue to
3 collect the fees.

4 There are two fees that we're authorized to
5 collect. One is the registration service fees. Those
6 are otherwise known as the PRIA fees. You can see that
7 these fees include tolerance petitions. In the past, we
8 collected tolerance fees in addition -- preclusion of
9 those.

10 The amount we collect depends upon the number
11 of actions that are submitted. Then, there is a set-
12 aside totaling \$2.25 million for worker protection, for
13 the pesticide safety education program, and for the
14 partnership grants, which is essentially our pesticide
15 environmental stewardship grant.

16 Then, the maintenance fees, which we've had for
17 a period of time, a number of years now, but now we're
18 guaranteed to collect \$22 million every year for five
19 years and we can use them for registration review
20 program, which is obviously very important to us.

21 Many of you have heard about the -- actually,
22 it's been '06, '07, '08 and now '09 president's budget

1 providing for different fee proposals. What it
2 contemplates is that we would collect -- we'd have to
3 adjust the fee schedule that's currently in PRIA to
4 collect another \$13 million -- \$12 million.

5 Thirteen million dollars we'd have to figure
6 out a way of collecting in tolerance fees, another \$23
7 million additional in maintenance fees, and then it would
8 eliminate the requirement for the minimum appropriation.
9 This proposal has not gone anywhere in Congress for the
10 past three or four years. We'll see.

11 This slide depicts the amount of fees that
12 we've collected. It's a little bit less, I think, than
13 what the coalition initially contemplated. I guess this
14 reflects the economy of the time as much as we're all
15 enjoying. You'll see that collections are a little bit
16 down thus far in fiscal year '08. We've got our
17 anticipated collections for '09 depicted as though it
18 were a reality. We figure it will be somewhere between
19 \$10 and \$12 million.

20 Performance measures, so what do we do with our
21 money. What did we do last year? I just tried to sort
22 of capture the registration program performance

1 highlights. You've heard some of this yesterday. Again,
2 27 new AIs, 11 of which were biopesticides and 6
3 antimicrobials, 10 conventionals.

4 Thirteen reduced risk active ingredients were
5 registered, 11 of which were the biopesticides. We
6 registered 233 new food uses, including -- and you see
7 the breakdown. Then, included in the new uses, we
8 registered four reduced risk new uses and one OP
9 alternative.

10 These are the maintenance fees. This shows what
11 was authorized under PRIA, both PRIA-1, the original
12 PRIA, and PRIA-2. We have a very smart individual who
13 can figure out how much to charge per product in order to
14 get to our total amount that we're authorized to collect.

15 I don't know what we'll do when he leaves, but,
16 in any event, we're going to keep him here for as long as
17 we can, because you can see we collect pretty much right
18 on the money what we're authorized to collect. We
19 anticipate continuing that for the next five years.

20 What did we do with those maintenance fees?
21 You'll see that we completed the 27 REDS. We have --
22 well, you can pretty much read this yourself. This is

1 just an idea of what it is that we do with the money that
2 we collect through the maintenance fees. These are some
3 our 2007 performance statistics -- highlights. There's a
4 lot of other things that go on, obviously, in these
5 areas, but these are the ones that are easiest to reduce
6 to bullets.

7 That's the show. I know I went through that
8 really fast. It's just basically to give you an idea --
9 especially those of you who are new to the PPDC -- of the
10 resource picture for the pesticide program. I guess I
11 could entertain a couple questions if anyone has any.

12 UNIDENTIFIED MALE: Just a question. Marty,
13 when you put up the slide that said performance measures
14 and it kind of looked like the old-fashioned one that I
15 guess you started calling outputs and not what I thought
16 were the new fangled outcomes performance measures --

17 MS. MONELL: Well, we in the pesticide program
18 have a reality that we have to deal with. That is, we
19 are a licensing program and we produce actions. So, the
20 numbers, while they lead to an outcome, the numbers are
21 important. So, we track both.

22 Anyone else?

1 UNIDENTIFIED FEMALE: You were probably hoping
2 I'd shut up. I sort of -- I've been focused in for
3 several years on what you're doing on registering active
4 ingredients, but I hadn't focused very much on what
5 you're doing on products. I don't know if that was the
6 last slide you showed about products that you've
7 registered. I noticed your goal -- yep, that's it -- I
8 noticed your goal for this coming year is to complete
9 1,000 product registration actions.

10 MS. MONELL: Re-registration.

11 UNIDENTIFIED FEMALE: I mean re-registration,
12 pardon me. My question is, given that the products have
13 formulas that have a lot of other ingredients in them,
14 how have you dealt with that issue? I mean, I know
15 you've thoroughly looked at the actives. But, you know,
16 there is an awful lot of data and information about
17 additional ingredients in a formula. So, how do you deal
18 with that when you're doing product re-registrations?

19 MS. MONELL: Well, for the product re-
20 registration, the company has had to -- we issued data
21 call-ins for product-specific data that included both the
22 toxicity, product specific toxicity, and the product

1 specific chemistry. So, it's kind of a mixture analysis
2 actually at that point.

3 Then, in addition to that, through FQPA, we re-
4 evaluated all of the food use (inaudible). So, those are
5 the two things that we have done and are doing to ensure
6 that the products, including ingredients within them, are
7 safe and the appropriate precautionary labeling is
8 provided.

9 UNIDENTIFIED FEMALE: Okay. Well, it just
10 seems like quite a jump from -- it was -- I'm just trying
11 to read this. You've completed 21,000 product re-
12 registrations; is that right?

13 MS. MONELL: We had 21,000.

14 UNIDENTIFIED FEMALE: To look at.

15 MS. MONELL: To look at.

16 UNIDENTIFIED FEMALE: Okay. And you did 500
17 last year? Am I getting this right? I'm just trying to
18 get a picture of the workload is why I'm asking about
19 these numbers.

20 MS. MONELL: What we are doing is we have
21 ramped up our product re-registration activities. For
22 many years, we had to focus, as you know, on getting the

1 REDS done and the outgrowth of REDS is the product re-
2 registration activities. So, now that we're closing down
3 on re-registration decisions, we're ramping up, as we
4 mentioned yesterday, on the implementation of those
5 decisions to try to get them all effective so that the
6 public enjoys the benefits of the mitigation that we put
7 into place in our decision.

8 So, what you're seeing is an increase every
9 year in product re-registrations. But that's -- we moved
10 some of the resources that we're working on -- the REDS
11 into that area to get those decisions in place.

12 UNIDENTIFIED FEMALE: And are you able to
13 accelerate dramatically this year because you will have
14 reviewed a number of materials that are in these formulas
15 already and you don't have to take, you know, time and
16 activity to look at them again? You understand what I'm
17 asking? It just seems like a big jump this year. I'm
18 just trying to understand how that works.

19 MS. MONELL: I don't have the exact figures.

20 UNIDENTIFIED FEMALE: You don't have to have
21 the exact figures. I'm just trying to get a picture of
22 it.

1 MS. MONELL: Yeah. What you're seeing too in
2 some circumstances is certain active ingredients have a
3 lot of products and those come through in groups. For
4 example, some of the -- like 24D would be an example of
5 -- you're going to see -- you might have 700-some --
6 that's off the top of my head. I don't know if that's a
7 right number. Whereas, for another product that takes
8 just as much work to get it to the stage, you know, to do
9 that, it might even be more work. You might have 20
10 products. See what I mean?

11 UNIDENTIFIED FEMALE: Yes.

12 MS. MONELL: So, in certain cases you're going
13 to see -- and some of these active ingredients that had
14 an enormous number of products came through late in the
15 game, like pyrethrens and those sorts of things.

16 UNIDENTIFIED FEMALE: Okay. That makes sense.
17 Thank you.

18 MS. MONELL: I don't know who is who but I
19 guess we'll go around.

20 DR. WHALON: For the record, Mark Whalon,
21 Michigan State University. I'm wondering when the last
22 time was that you updated on some of your projects like

1 pests and some of the other more targeted field projects
2 that you support through PRIA resources?

3 MS. MONELL: We just completed the process,
4 actually, of figuring out the best way to utilize the
5 PRIA set-aside for the environmental stewardship program,
6 the partnership grant program. And I believe that
7 paperwork is now in the process of going out for --

8 DR. WHALON: What I'm interested in is kind of
9 a report back, you know. I mean, when was the last time
10 to this group did you report back on the kind of progress
11 that you've made or the impact that you've had or the
12 type of projects you've funded in general sweeps, not
13 necessarily in specifics. But generally, update up on
14 what you're doing so that maybe we can have impact or
15 some comment back.

16 MS. MONELL: I think that's a good idea and I
17 think probably for the next meeting we could plan to do
18 that.

19 MR. VROOM: This is Jay Vroom from CropLife
20 America. Marty, thanks for a great presentation, as well
21 data rich. I had a couple questions on slide 6, the last
22 bullet. You referred to enterprise architecture workbook

1 process called OPP implementing studies at the desktop.
2 I'm not sure that that -- maybe that's something we know
3 about but under some other description through the PRIA
4 process improvement stuff or is this something brand new?

5 MS. MONELL: No. It's been in the works for
6 quite a while. Actually, it's a component of e-
7 submission which you have heard about and some of the
8 companies have been a part of which enables a company to
9 completely electronically submit an application which
10 includes the studies. What we're working to do is to
11 make those studies available in an electronic format,
12 obviously, for the reviewers at their desktop. So, e-
13 studies of a desktop, basically, the colloquial term for
14 it.

15 MR. VROOM: So, in the life cycle of that
16 effort, where's that at? Is it midway, is it done?

17 MS. MONELL: That particular component is in
18 development right now. But the front end piece is in, as
19 you know, is in place. So, you can submit
20 electronically.

21 MR. VROOM: Okay. On the next slide, 7, maybe
22 you said this and I was just not keeping up with you,

1 what is NPIC and NPMMP?

2 MS. MONELL: I'm sorry. It's the
3 bureaucratise. It's National Pesticide Information
4 Center and the National Pesticide Medical Monitoring
5 Program.

6 MR. VROOM: Okay. So, is the \$1.8 million
7 equally split between those two?

8 MS. MONELL: The lion's share is NPIC. I
9 believe that medical monitoring is now up to around \$300
10 with inflation and everything else. That's a service
11 that provides health care clinicians. Doctors can call
12 this medical monitoring phone and get sort of a doctor to
13 doctor discussion of a possible pesticide incident.

14 MR. VROOM: Actually, I'd sort of be curious to
15 know if you could give us more detail on really
16 everything that's on this page, not just with regard to
17 -- I guess this is fiscal year '08, right -- all these
18 numbers?

19 MS. MONELL: Yes.

20 MR. VROOM: Is it possible -- reasonably easy
21 for you to provide the PPDC membership the more detail
22 around everything that's on this page just so we could

1 have a little more granular understanding of everything,
2 not just sort of this year but sort of how all those
3 numbers and programs and individual grants are sort of
4 flowing over maybe a two or three year period so we could
5 have a little better understanding of all that?

6 MS. MONELL: That's entirely possible.

7 MR. VROOM: How many grants are there under,
8 for instance, this year, the \$345,000? Ten? Thirty?

9 UNIDENTIFIED FEMALE: (Inaudible).

10 MS. ANDERSEN: It's Janet Andersen. I probably
11 want to go back and do the details, but the predominance
12 of the \$345 goes to a contractor who supports the
13 pesticide environmental stewardship program in a variety
14 of ways, helping produce communications materials. There
15 will be some grants in that or working directly with
16 partners in that.

17 But the predominance of grant funds comes from
18 what we call stag money that goes to states and tribes.
19 Those funds are just about -- the amounts of grants have
20 been decided and the regents themselves put out the
21 announcements on those. Then the large -- \$750,000 plus
22 the \$250 we did put in from our own program of money

1 where the RFP is now in the street. That will be the
2 grants that will be issued this year. There's also,
3 though it's not TFP money, it's called the strategic AG
4 initiative. That program also does have grants.

5 They're in the process of issuing them for this
6 year, but maybe, responding to what Mark Whalon said,
7 the next time we talk about some of those field programs
8 in more detail, we can give you more of an idea of where
9 we've been spending those grant monies.

10 MR. VROOM: Great. Yes, I guess I would maybe
11 just echo what Janet was saying. It might be appropriate
12 for us to have a session in the October meeting dedicated
13 to a lot more detail around all this and performance
14 measures and the rest.

15 I think all of this gets a lot of leverage but
16 again, as advisors to the program, the PPDC members may
17 be able to contribute additional ideas for, you know,
18 greater efficacy and leverage and synergies and the like
19 around -- you know, again, these are small amounts of
20 money in the overall scheme of things, but they result in
21 synergies and leverages that are great.

22 But, as we look at them in a more detailed

1 discussion, maybe in October we might come up with ideas
2 for greater leverages and synergies, in particular around
3 the money that flows principally to USDA, including one
4 of my favorite uses of acronyms, PSEP as opposed to PESP.
5 I think that would be useful for us to look at. In
6 addition to that, the IPM pipe program and the NAS
7 surveys line item issue that was referred to yesterday,
8 both of those would be -- I think fit nicely into this
9 for a general more granular discussion that we might have
10 in October.

11 MS. MONELL: Thank you. In the interest of
12 time, I'm going to take the cards that are up and I'll
13 start with Dr. Sass.

14 DR. SASS: Thanks for the presentation. I
15 think maybe my comment isn't directly at you but maybe to
16 EPA in general. It sort of follows along with what Bob
17 Rosenberg had said, but it struck me as well. The PPDC
18 has had a conversation with EPA about the performance
19 measures.

20 They know in the recent past we've mentioned at
21 several different meetings that we want to hear more than
22 just sort of the numbers of registration, even though,

