UNITED STATES

ENVIRONMENTAL PROTECTION AGENCY

PESTICIDE PROGRAM DIALOGUE

COMMITTEE MEETING

May 21-22, 2008

Conference Center - Lobby Level

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P R O C E E D I N G S

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Debbie, thank you.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

And Session Number Three is related to that and

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

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

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

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

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

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

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

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

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

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

So, let's start.

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

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

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

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

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

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

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

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

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

businesses like Susan's.

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

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

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

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

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

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

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

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

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

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

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

And also, from a children's health standpoint,

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

strategies that education can provide to minimize pesticide exposure.

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

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

Thank you.

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

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

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

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

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

MR. BARON: Good morning. My name is Jerry

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

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

Thank you.

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

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

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

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

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

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

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

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

handlers and all the other issues.

Thank you.

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

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

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

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

the work protection stand.

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

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

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

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

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

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

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

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

apartments explode every year from the use of pesticides.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

I guess, sort of like Dan Botts, I just bring a lot of institutional knowledge. I've been working with the Agency on a number of initiatives over the years, I guess starting with insect repellant issues back in 1990 and working on a PR notice on insect repellants. I've worked with them on the consumer label initiative and termiticide issues.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

rules; it's another thing to implement them.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(Whereupon, there was no verbal response.)

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

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

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

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

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

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

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

better run FACAs that we know of.

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

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

(Whereupon, a brief recess was taken.)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

This is just what I'm going to go through

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

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

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

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

context may actually not be very enforceable.

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

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

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

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

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

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

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

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

that.

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

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

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

distribution of pesticide labeling.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Spray drift, obviously we're very much at work

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

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

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

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

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

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

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

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

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

But this would be more broad than just the

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

synergies between these initiatives.

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

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

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

Timelines, finally. On electronic submission

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

that, it seems a lot more feasible.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

know what to prove.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

getting increasingly nearsighted to put names with faces.

That was Dan Botts for the insurance groups benefit.

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

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

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

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

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

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

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

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

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

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

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

MR. JORDAN: Label builder does not now exist.

DR. FERENC: Okay.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

But I think just like the topics around

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

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

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

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

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

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

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

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

trade as well.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

pesticides.

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

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

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

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

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

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

UNIDENTIFIED MALE: Jenn Sass has a question.

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

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

DR. SASS: On the web?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

time because of legal words?

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

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

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

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

to these labels.

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

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

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

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

could have been.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(A brief recess was taken.)

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

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

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

Well, our next presentation will be a 10-minute

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

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

MS. EDWARDS: Jack Oudenger (phonetic).

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

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

a little bit about that today.

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

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

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

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

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

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

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

Finally, what are the methods that are actually

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

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

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

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

volatilization off of soils and plant surfaces.

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

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

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

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

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

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

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

go to the link here that we've provided.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We're trying to determine the best way to

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

So, over the many years, because it was a

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

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

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

validation now.

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

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

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

It was their recommendation that the Agency

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

the associated benefits.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Then, the last one, chlorantranillprole, which

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

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

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

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

prepare for these projects.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

initiative quite a bit. There are initiatives already planned.

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

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

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

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

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

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

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

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

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

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

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

UNIDENTIFIED FEMALE: First I want to say thank

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Questions? Comments?

MR. TAMAYO: Dave Tamayo, CASQA (phonetic). You mentioned that the benefits were for, I guess, the registrants and the users and EPA. I'm a bit concerned that, you know, where's the environment and public health in this registration process?

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

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

first and the second version of it.

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

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

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

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

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

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

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

aren't turning them in.

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

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

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

MS. ANDERSEN: Okay, thank you.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

MS. EDWARDS: Okay, thank you, Steve.

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

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

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

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

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

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

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

scenarios.

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

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

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

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

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

MR. BRADBURY: Yes.

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

MR. BRADBURY: Improving.

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

MR. BRADBURY: Months and it's --

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

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

With registration review, what we're doing,

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

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

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

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

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

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

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

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

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

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

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

about this. I'd be pleased to answer any questions, if that's appropriate.

UNIDENTIFIED FEMALE: As far as you know, have the pollinators or beekeepers not been invited to PPDC, because I believe that they have?

MR. VAN ARSDAL: I don't know. I'm not assigning any blame. I just know that they have not been an effective voice. It's in part because they're not that well organized.

UNIDENTIFIED FEMALE: Well, I don't know. I think you guys are pretty well organized. I think you have been invited. But, for sure, it's great to have you here. I think you could be more involved and I think that would be a really important voice.

MR. VAN ARSDAL: Well, the Pollinator Partnership -- I'm not an expert in the pesticide registration process or the pollinators themselves. I'm involved in the policy area.

UNIDENTIFIED FEMALE: Nobody is before they sit at this table.

MR. VAN ARSDAL: Right, but we have people out there that we can bring into the process -- that's part

of the role of partnership -- and be a resource to this committee to help focus on that insight. I'm a problem solver. What happened in the past, I don't know. But I know that they recognize themselves they've not been an effective voice. Right now they're playing amateur hour saying what's happening to my bees, talking about beekeepers.

The colony class disorder is just as serious this year as it was last year. There's some that talk to the press rather than those who are trying to -- in a position to solve problems. They make allegations, including about pesticides and classes of pesticides. We'd like to get to see them come into this process where we've got an opportunity to get real solutions.

Thus far, my understanding from USDA is that they're not finding any sources of pesticides in terms of the condition called colony collapse disorder. They're not finding that evidence yet. I think this committee and EPA need to be aware of what's happening over there as well as look within your existing protocols and say, are we doing the right thing based on what we know. What else do we need to find out to make certain that we've

got that base covered.

MS. EDWARDS: Thank you. I appreciate that. If you look at our web site, you'll see that we have -- I forget the name of the web site -- Emerging Issues. There are two issues there. One is the volatilization issue and one is the colony collapse issue. So, we're watching that research very closely and we will consider this be one of the topics that we will discuss here, certainly.

MR. VAN ARSDAL: Thank you.

MS. EDWARDS: Jen?

DR. SASS: Jen Sass with NRDC. I mean, I think it has been done before, to be honest, but I would like to recommend, if not, that pollinators be represented. I mean, with 45 people already, I'm sure we can work it out.

Just to sort of strengthen the timeliness of these kinds of issues with pesticides and pollinators, I've seen us submit some pollinators contributing tens of billions of dollars to the economy in this country because of the need to pollinate for agriculture. Today there was a press release by buyer released that they've

now withdrawn several of their miticloprin (phonetic) products in Germany because of concern but they were related to colony collapse.

So, I'm actually confused about why you're giving a past to pesticides on colony collapse. But, in any case, I think there's a timeliness to bringing these issues together and discussing it in a cogent way. I would like to recommend that they be represented.

UNIDENTIFIED MALE: Just point of clarification, I'm not giving a pass to anybody. I'm just saying let's just make certain that we base decisions on sound science and engage the right people who are in a position to do something about it.

I'm only trying to characterize what I've heard from researchers. I've heard other researchers saying well, it's nice to study adult bees but we're finding out that there's a lot of impact on broods and EPA's protocol doesn't consider broods if there's no adult bee problem.

Well, is that something that we ought to be changing? I don't know. But I think this is a good group to sort of air those issues, bring in resource people whether on the committee or off, so that we can

give the best advice possible to the EPA.

Of course, we're working on the farm bill. The farm bill is about to become law. Has conservation and research provisions on pollinators that we worked hard to get, including the report of a very broad range of groups to help make that possible. We're going to work to make those more that just lines on the page but good conservation and research provisions in the USDA.

MR. VROOM: Jay Vroom with CropLife America. I have not seen the press release that Jennifer is referring to and didn't come prepared today to have an in-depth discussion, Tom, about pollinators and pesticides. But as, I believe, you have alluded here, this is a huge issue.

No one has brought forward in the United States to this agency which regulates pesticides any scientific evidence to, you know, affect any new massive review of pesticide products. We've supported the work that your coalition has done around the farm bill and other research support. But I honestly believe that the way Jen just described one of our member company press releases out of Europe, it may be out of context here,

number one.

Number two, I would also like to remind folks -- and I think, Tom, you can go into some of the details of that -- there are a lot of pesticides that are used to the benefit of pollinators, like miticides. So, you know, there are risks and benefits here.

Again, I'm happy to support you being brought back here at a future meeting to have a more prepared and in-depth discussion about this, but again, I think there's been some things just thrown out here this afternoon that are unfortunate and not very balanced.

UNIDENTIFIED MALE: All I wanted to do is open the dialogue and give people the opportunity to excite their evening a little bit.

MS. EDWARDS: Thanks very much. You've achieved that.

UNIDENTIFIED FEMALE: Just one more quick comment on this. This has also been an issue that's come up at the ABCO meetings where there's been research presented. I know it was at the spring ABCO meeting there was a session on it. So, it might be a good topic to at least maybe have a panel or something on. Maybe we

can talk about it at sort of -- you know, as a future meeting item.

MS. EDWARDS: Sure. Yeah. We're going to have a session on that tomorrow in any event. But we appreciate you bringing it forward.

One of the things -- I'm about to adjourn. I just wanted to mention one thing about PRIA. It concerned me earlier that it was characterized that the advantage of PRIA is for registrants, users and the EPA. Therefore, it's all about registering pesticides. I disagree with that.

To say that it's in the advantage of EPA is to say that it's the advantage of public health and the environment because that's what's was focused on here. This is a licensing program. As we do our work, our objective is to license pesticides in such a way that their safety is for public health and the environment. That's our first and foremost goal.

What PRIA did was give us many resources to be able to do that job better. In addition, a fairly significant amount of money for set-asides for voluntary programs for integrated pest management, worker safety,

and so on and so forth. So, I just wanted to make that comment.

Thank you very much and I'll see you at 9:00 in the morning.

(Whereupon, the meeting was adjourned, to be reconvened at 9:00 a.m. on March 22, 2008.)

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I, Marilynn H. McNulty, do hereby certify that the foregoing transcription was reduced to typewriting via audiotapes provided to me; that I am neither counsel for, related to, nor employed by any of the parties to the action in which these proceedings were transcribed; that I am not a relative or employee of any attorney or counsel employed by the parties hereto, nor financially or otherwise interested in the outcome of the action.

MARILYNN H. McNULTY
Transcriptionist

P R O C E E D I N G S

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MS. EDWARDS: Welcome, and good morning. With a good agenda again this morning, we're going to start with a session on how we use our OPP resources. And to give that presentation here in Session Number 7 will be Marty Monell, our Deputy Director for Management.

MS. MONELL: Good morning, everyone. I apologize for not being here yesterday morning and missing all of the introductions. I am Debbie's deputy in charge of management matters, which includes quite a portfolio, one of which is managing information. Yesterday there was an all-day agency meeting on managing information. I thought that it was very important that our voice be heard, our needs be heard at that meeting. So, here I am today to talk about our budget.

The first slide -- you, hopefully, all have paper copies of these slides. So, I'm not going to go into excruciating detail, but the first slide basically gives you a snapshot of the decline of our overall resources. We, like other Federal agencies of domestic programs, are cut and have been cut and our future looks

like it will include further cuts.

The free slide show, the free bar show, all of our appropriations, we have regular environmental program management accounts, we have a science and technology account which basically funds research in our labs, and then we have the stag account which funds our state grants that are awarded generally through our regions, some from headquarters.

The next slide depicts our FTE, and FTE stands for full-time equivalents, which is the government's way of addressing employees and how we account for them. So, the numbers don't necessarily mean people. They translate more to hours spent working for us at any given period of time. So, again you'll see a decline in that area. That is a result of various mandates from OMB and the Agency to help address the overall budget shortfalls.

The next slide actually shows the breakout of the FTE by appropriation. So, you'll see that the bulk of our FTE, our employees are paid for out of the environmental program management account. We have a very small number out of the science and technology account, and that's because they are only utilized in our lab.

Then, the maintenance fee support, a larger number. And the PRIA fees support a fair number.

The next slide shows how the balance of our utilization of our funds is utilized. You'll see that the bulk of our money is spent on salaries. The pesticide program decided a long time ago that this program is best managed by federal employees. That while contract support is essential, that the kinds of decisions that we are called upon to make are best made by federal -- highly educated, highly trained federal employees.

We also did an analysis of the cost of having federal employees do this work versus contractors. Even if we hadn't made the philosophical decision to stick with feds making the decision, it's also the most cost effective way of doing our work.

So, while the salaries -- in previous slides, I indicated that our numbers of employees has declined. Salaries have increased. That's because of the COLAs that Congress appropriates every year and yet does not budget for us. So, our salaries are going up; the budget is going down. As a result, the amount we have to spend on contracts and other expenses is reduced.

To give you an idea -- next slide -- of the kinds of things that we spend our resources on -- and I'm addressing now the contract resources -- we spend a significant amount on IT contracts. This is because, as you know, this program is incredibly data rich and it's really important that we get that data in a useable format and manage it well.

So, we're doing a lot of investment in the areas of e-submission, electronic submission, electronic reviews where appropriate, documentum, which is a process for storing our information and making it accessible not only to us but ultimately to the public at large, and then we had to do a little bit of investment for implementation of portions of PRIA.

I understand yesterday you all heard about PRIA, so I won't go into that. But it's a program, a registration program which is funded by registrants, designed to help us do our job better. Part of that is managing information.

The next slide shows that in addition to the IT investments, we use money for providing a public service on pesticide information. We spend about $2 million a

year on NPIC, which is the National Pesticide Information Center, run out of Oregon State. It provides an incredibly valuable tool to the public as a resource that you can call.

The public can call if they suspect they may have been harmed by a pesticide or been exposed to a pesticide and get information 24/7 and then we -- this year we have expanded that to include multi-lingual access. So, a Hispanic worker that gets exposed can call and speak to someone who is fluent in Spanish and also other languages. I believe it's up to 20-odd languages now that are available through this NPIC.

We fund the pesticide environmental stewardship program. We provide a little less than $3 million on worker protection and certification in training programs, then a little over $1 million in sort of our fields, outreach, international, cooperation, and then our tribal work.

For our travel money, we have an overall pot of about $920,000 and we -- some examples of what we spend that money on are invitational travel for PPDC. That's just to give you an idea of the kinds of things and the

proportion of the overall travel budget. This is not huge.

We support foreign travel that supports treaty implementation, pops, picks, methyl bromide. That's about $94,000. We also do a fair amount of international travel that supports work sharing and harmonization. That would include our work with OECD and NAFTA, which is also a treaty implementation effort.

Then, there is our domestic travel which includes participation in stakeholder meetings. Some of you may recall that over the past year groups of staff that were working on particular chemical issues went out to the field and actually had meetings with people that were interested in our decisions on the chemicals. That is another area that we feel is very important to fund with our travel resources.

And then, of course, training. Training for our staff sometimes includes travel expenditures, particularly those for executive training that the Officer of Personnel Management provides.

With the PRIA fees, you'll see that we made a conscious decision to try to keep a better balance in

terms of funding salaries versus funding contract services. PRIA does not pay for the cost of our registration program. It essentially covers about 20 percent of the cost of running our registration program. So, we decided it would be ill-advised to go whole hog and spend all of the money on salaries but rather spend some on the contract side as well. For the first couple of years, that was primarily in the area of IT where we had to adapt our systems to accommodate the requirements of PRIA.

For FIFRA, that's the maintenance fees, you'll see that that decision was made differently. Back when the maintenance fees first were provided us, we thought that we really needed to ramp up our employee base because we had a 10-year deadline to do all of the (inaudible) assessments and re-registration activity mandated by FQPA. So, we ramped up heavily on the employee side. As a result, those salaries still account for a lion's share of our maintenance fees.

Fortunately, PRIA provided for a level over the next five years that we can count on for maintenance fees, so we don't have to worry as much about taking

people off and on this particular account. We're in a steady state. We know what we can count on for finishing up our re-registration work of the non-food uses and then segueing into our registration review program full implementation.

This is just information for those that are detail oriented on pieces of PRIA. PRIA provides that because the coalition was so concerned that Congress not utilize this vehicle as a way of eliminating our appropriation, the PRIA coalition thought that there ought to be a baseline guaranteed appropriation before the fees could kick in. This was obviously supported by the registrant community.

But more importantly, I think, it was supported by the public interest groups because they didn't want the appearance of the registrants having too much influence over our decisionmaking process because they were paying such a large proportion of the fees to run the program.

As I said, it's about 20 percent, so it's not an overwhelming amount. But, nevertheless, it certainly is substantial enough to be very helpful to the program.

So, this indicates that our appropriation is well above the minimum threshold and we will be able to continue to collect the fees.

There are two fees that we're authorized to collect. One is the registration service fees. Those are otherwise known as the PRIA fees. You can see that these fees include tolerance petitions. In the past, we collected tolerance fees in addition -- preclusion of those.

The amount we collect depends upon the number of actions that are submitted. Then, there is a set-aside totaling $2.25 million for worker protection, for the pesticide safety education program, and for the partnership grants, which is essentially our pesticide environmental stewardship grant.

Then, the maintenance fees, which we've had for a period of time, a number of years now, but now we're guaranteed to collect $22 million every year for five years and we can use them for registration review program, which is obviously very important to us.

Many of you have heard about the -- actually, it's been '06, '07, '08 and now '09 president's budget

providing for different fee proposals. What it contemplates is that we would collect -- we'd have to adjust the fee schedule that's currently in PRIA to collect another $13 million -- $12 million.

Thirteen million dollars we'd have to figure out a way of collecting in tolerance fees, another $23 million additional in maintenance fees, and then it would eliminate the requirement for the minimum appropriation. This proposal has not gone anywhere in Congress for the past three or four years. We'll see.

This slide depicts the amount of fees that we've collected. It's a little bit less, I think, than what the coalition initially contemplated. I guess this reflects the economy of the time as much as we're all enjoying. You'll see that collections are a little bit down thus far in fiscal year '08. We've got our anticipated collections for '09 depicted as though it were a reality. We figure it will be somewhere between $10 and $12 million.

Performance measures, so what do we do with our money. What did we do last year? I just tried to sort of capture the registration program performance

highlights. You've heard some of this yesterday. Again, 27 new AIs, 11 of which were biopesticides and 6 antimicrobials, 10 conventionals.

Thirteen reduced risk active ingredients were registered, 11 of which were the biopesticides. We registered 233 new food uses, including -- and you see the breakdown. Then, included in the new uses, we registered four reduced risk new uses and one OP alternative.

These are the maintenance fees. This shows what was authorized under PRIA, both PRIA-1, the original PRIA, and PRIA-2. We have a very smart individual who can figure out how much to charge per product in order to get to our total amount that we're authorized to collect.

I don't know what we'll do when he leaves, but, in any event, we're going to keep him here for as long as we can, because you can see we collect pretty much right on the money what we're authorized to collect. We anticipate continuing that for the next five years.

What did we do with those maintenance fees? You'll see that we completed the 27 REDS. We have -- well, you can pretty much read this yourself. This is

just an idea of what it is that we do with the money that we collect through the maintenance fees. These are some our 2007 performance statistics -- highlights. There's a lot of other things that go on, obviously, in these areas, but these are the ones that are easiest to reduce to bullets.

That's the show. I know I went through that really fast. It's just basically to give you an idea -- especially those of you who are new to the PPDC -- of the resource picture for the pesticide program. I guess I could entertain a couple questions if anyone has any.

UNIDENTIFIED MALE: Just a question. Marty, when you put up the slide that said performance measures and it kind of looked like the old-fashioned one that I guess you started calling outputs and not what I thought were the new fangled outcomes performance measures --

MS. MONELL: Well, we in the pesticide program have a reality that we have to deal with. That is, we are a licensing program and we produce actions. So, the numbers, while they lead to an outcome, the numbers are important. So, we track both.

Anyone else?

UNIDENTIFIED FEMALE: You were probably hoping I'd shut up. I sort of -- I've been focused in for several years on what you're doing on registering active ingredients, but I hadn't focused very much on what you're doing on products. I don't know if that was the last slide you showed about products that you've registered. I noticed your goal -- yep, that's it -- I noticed your goal for this coming year is to complete 1,000 product registration actions.

MS. MONELL: Re-registration.

UNIDENTIFIED FEMALE: I mean re-registration, pardon me. My question is, given that the products have formulas that have a lot of other ingredients in them, how have you dealt with that issue? I mean, I know you've thoroughly looked at the actives. But, you know, there is an awful lot of data and information about additional ingredients in a formula. So, how do you deal with that when you're doing product re-registrations?

MS. MONELL: Well, for the product re-registration, the company has had to -- we issued data call-ins for product-specific data that included both the toxicity, product specific toxicity, and the product

specific chemistry. So, it's kind of a mixture analysis actually at that point.

Then, in addition to that, through FQPA, we re-evaluated all of the food use (inaudible). So, those are the two things that we have done and are doing to ensure that the products, including ingredients within them, are safe and the appropriate precautionary labeling is provided.

UNIDENTIFIED FEMALE: Okay. Well, it just seems like quite a jump from -- it was -- I'm just trying to read this. You've completed 21,000 product re-registrations; is that right?

MS. MONELL: We had 21,000.

UNIDENTIFIED FEMALE: To look at.

MS. MONELL: To look at.

UNIDENTIFIED FEMALE: Okay. And you did 500 last year? Am I getting this right? I'm just trying to get a picture of the workload is why I'm asking about these numbers.

MS. MONELL: What we are doing is we have ramped up our product re-registration activities. For many years, we had to focus, as you know, on getting the

REDS done and the outgrowth of REDS is the product re-registration activities. So, now that we're closing down on re-registration decisions, we're ramping up, as we mentioned yesterday, on the implementation of those decisions to try to get them all effective so that the public enjoys the benefits of the mitigation that we put into place in our decision.

So, what you're seeing is an increase every year in product re-registrations. But that's -- we moved some of the resources that we're working on -- the REDS into that area to get those decisions in place.

UNIDENTIFIED FEMALE: And are you able to accelerate dramatically this year because you will have reviewed a number of materials that are in these formulas already and you don't have to take, you know, time and activity to look at them again? You understand what I'm asking? It just seems like a big jump this year. I'm just trying to understand how that works.

MS. MONELL: I don't have the exact figures.

UNIDENTIFIED FEMALE: You don't have to have the exact figures. I'm just trying to get a picture of it.

MS. MONELL: Yeah. What you're seeing too in some circumstances is certain active ingredients have a lot of products and those come through in groups. For example, some of the -- like 24D would be an example of -- you're going to see -- you might have 700-some -- that's off the top of my head. I don't know if that's a right number. Whereas, for another product that takes just as much work to get it to the stage, you know, to do that, it might even be more work. You might have 20 products. See what I mean?

UNIDENTIFIED FEMALE: Yes.

MS. MONELL: So, in certain cases you're going to see -- and some of these active ingredients that had an enormous number of products came through late in the game, like pyrethrens and those sorts of things.

UNIDENTIFIED FEMALE: Okay. That makes sense. Thank you.

MS. MONELL: I don't know who is who but I guess we'll go around.

DR. WHALON: For the record, Mark Whalon, Michigan State University. I'm wondering when the last time was that you updated on some of your projects like

pests and some of the other more targeted field projects that you support through PRIA resources?

MS. MONELL: We just completed the process, actually, of figuring out the best way to utilize the PRIA set-aside for the environmental stewardship program, the partnership grant program. And I believe that paperwork is now in the process of going out for --

DR. WHALON: What I'm interested in is kind of a report back, you know. I mean, when was the last time to this group did you report back on the kind of progress that you've made or the impact that you've had or the type of projects you've funded in general sweeps, not necessarily in specifics. But generally, update up on what you're doing so that maybe we can have impact or some comment back.

MS. MONELL: I think that's a good idea and I think probably for the next meeting we could plan to do that.

MR. VROOM: This is Jay Vroom from CropLife America. Marty, thanks for a great presentation, as well data rich. I had a couple questions on slide 6, the last bullet. You referred to enterprise architecture workbook

process called OPP implementing studies at the desktop. I'm not sure that that -- maybe that's something we know about but under some other description through the PRIA process improvement stuff or is this something brand new?

MS. MONELL: No. It's been in the works for quite a while. Actually, it's a component of e-submission which you have heard about and some of the companies have been a part of which enables a company to completely electronically submit an application which includes the studies. What we're working to do is to make those studies available in an electronic format, obviously, for the reviewers at their desktop. So, e-studies of a desktop, basically, the colloquial term for it.

MR. VROOM: So, in the life cycle of that effort, where's that at? Is it midway, is it done?

MS. MONELL: That particular component is in development right now. But the front end piece is in, as you know, is in place. So, you can submit electronically.

MR. VROOM: Okay. On the next slide, 7, maybe you said this and I was just not keeping up with you,

what is NPIC and NPMMP?

MS. MONELL: I'm sorry. It's the bureaucratise. It's National Pesticide Information Center and the National Pesticide Medical Monitoring Program.

MR. VROOM: Okay. So, is the $1.8 million equally split between those two?

MS. MONELL: The lion's share is NPIC. I believe that medical monitoring is now up to around $300 with inflation and everything else. That's a service that provides health care clinicians. Doctors can call this medical monitoring phone and get sort of a doctor to doctor discussion of a possible pesticide incident.

MR. VROOM: Actually, I'd sort of be curious to know if you could give us more detail on really everything that's on this page, not just with regard to -- I guess this is fiscal year '08, right -- all these numbers?

MS. MONELL: Yes.

MR. VROOM: Is it possible -- reasonably easy for you to provide the PPDC membership the more detail around everything that's on this page just so we could

have a little more granular understanding of everything, not just sort of this year but sort of how all those numbers and programs and individual grants are sort of flowing over maybe a two or three year period so we could have a little better understanding of all that?

MS. MONELL: That's entirely possible.

MR. VROOM: How many grants are there under, for instance, this year, the $345,000? Ten? Thirty?

UNIDENTIFIED FEMALE: (Inaudible).

MS. ANDERSEN: It's Janet Andersen. I probably want to go back and do the details, but the predominance of the $345 goes to a contractor who supports the pesticide environmental stewardship program in a variety of ways, helping produce communications materials. There will be some grants in that or working directly with partners in that.

But the predominance of grant funds comes from what we call stag money that goes to states and tribes. Those funds are just about -- the amounts of grants have been decided and the regents themselves put out the announcements on those. Then the large -- $750,000 plus the $250 we did put in from our own program of money

where the RFP is now in the street. That will be the grants that will be issued this year. There's also, though it's not TFP money, it's called the strategic AG initiative. That program also does have grants.

They're in the process of issuing them for this year, but maybe, responding to what Mark Whalon said, the next time we talk about some of those field programs in more detail, we can give you more of an idea of where we've been spending those grant monies.

MR. VROOM: Great. Yes, I guess I would maybe just echo what Janet was saying. It might be appropriate for us to have a session in the October meeting dedicated to a lot more detail around all this and performance measures and the rest.

I think all of this gets a lot of leverage but again, as advisors to the program, the PPDC members may be able to contribute additional ideas for, you know, greater efficacy and leverage and synergies and the like around -- you know, again, these are small amounts of money in the overall scheme of things, but they result in synergies and leverages that are great.

But, as we look at them in a more detailed

discussion, maybe in October we might come up with ideas for greater leverages and synergies, in particular around the money that flows principally to USDA, including one of my favorite uses of acronyms, PSEP as opposed to PESP. I think that would be useful for us to look at. In addition to that, the IPM pipe program and the NAS surveys line item issue that was referred to yesterday, both of those would be -- I think fit nicely into this for a general more granular discussion that we might have in October.

MS. MONELL: Thank you. In the interest of time, I'm going to take the cards that are up and I'll start with Dr. Sass.

DR. SASS: Thanks for the presentation. I think maybe my comment isn't directly at you but maybe to EPA in general. It sort of follows along with what Bob Rosenberg had said, but it struck me as well. The PPDC has had a conversation with EPA about the performance measures.

They know in the recent past we've mentioned at several different meetings that we want to hear more than just sort of the numbers of registration, even though,

you're absolutely right, that is important. To be honest, I want to hear that too. So, I'm not asking to take out any information. But we do want to hear what the effect has been on EPA's mission, which is to protect human health and the environment.

So, we've had a number of different workgroups and papers and things that have come forward. One, I remember having a long discussion -- and I think it got sent back for rewriting it. I've never seen it come up again. But it's looking at the association between the FQPA, mitigation measures and cancellations and stuff and how that might be reflected in poisoning events, hopefully reduced. I think they are reduced. These should be wins for you and you should be highlighting them and also (inaudible) data showing -- the (inaudible) data showing that the levels of the worst pesticides in people's body foods is reducing.

So, I know we've had this conversation before and I also know that EPA has some of this information. So, here's some things that I would like to know in addition. I don't know if you've collected the information in this way, but here's some questions that I

have -- that I would like to see in performance measures reports in addition to what you're already doing, unfortunately. So, I'm not reducing your workload.

I know from presentations by EPA not to PPDC but in other ones that the organophosphate pesticides have been reduced from about 90 million pounds annually to under 60 million pounds annually, according to an EPA presentation. That's huge. But I want to know how that's calculated.

So, what I would like to know for our work is what pesticides and was it all residential or was there also agriculture usage as well? I have a feeling it's just a few and I have a feeling it's the residential cancellation. So, that would be really big because that leads to the most kids' poisoning. So, I would like to know that too. So, what's leading up to those numbers? How are you calculating those? What are the pesticides? And how much pounds and where are those uses?

The other thing is that there's been a reduction in the OPs, organophosphates, that were the top 10 ones on kids food from 28 million pounds of active ingredients to 12 million pounds. So, it's more than cut

in half of the OPs that are on kids foods. But again, I want to know what they are, which OPs, and which foods were the top 10.

I remember way back in these meetings we all knew they were like grapes and apples and a few things. But I'd really like to know. I mean, was it all dymethoid (phonetic) on grapes or was there was (inaudible) on apples or what was there?

There's been a cancellation or phase out of 57 OPs that were used on kids foods. I want to know what they are because I want to make sure those are followed through to label changes. We have a suspicion that some of those are phase outs, that are four, five, several years phase outs, and we want to make sure that those labels are being changed at the appropriate time point so that the mitigation is not just on paper but really an action.

So, again, what in the residential has been cancelled? What in agriculture? What on the major kids foods? These are mostly for the OPs, but if you have it also for the carbamates, obviously, we'd love to see it. Again, this is exciting. I'm trying to help EPA to

highlight how it's meeting its mission under FQPA and also the mission of EPA.

There's been an increase in the number of reduced risk pesticides for kids foods that have been registered. I don't follow those very well, unfortunately, so I'd really like to know what they are. According to the EPA numbers, the reduced risk pesticide use on kids food has increased 1,700 percent. So, my guess is it's not that many pesticides. So, I want to know what they are and what kids foods.

Again, there's a number also -- the OP alternative pesticide uses, alternate stokeys (phonetic) on kids foods has increased 2,900 percent. So, I want to know what those are, especially because poisoning have gone down. OP exposure poisonings have gone down 72 percent, but I also know from other data that less severe but other poisonings are increasing as the use of those less toxic but now more readily available pesticides are on the market.

So, I want to really understand those trends better. They're good trends. They're trends leading away from the most severe poisonings and exposures and

incidences. But I want to understand them better and I also want to have more confidence that the phase outs are phasing out.

MS. MONELL: Thank you. Carolyn.

CAROLYN: First I just wanted to say that I am really interested also in the answers to Jenn's questions, so I hope that we could have a little presentation about that at some future meeting.

In addition, there are a couple other performance measures that I remember as seeming to me as being really important and one had to do with the levels of pesticides found in surface waters by the USDS monitoring program. The other had to do with the number of farmworker pesticide incidents reported. So, you know, I would love if some information about those performance measures could be included when we talk about these other ones.

Then, finally, I have what I hope is a really simple question. You did say here that there are 21,350 products that are sort of in the universe for re-registration. I wanted to know what percentage of the total number of products that is. I mean, there are some

products that aren't subject to re-registration because they're newer. But I don't have an idea of what the magnitude of that number is.

MS. MONELL: We're going to have to get back to you on that.

UNIDENTIFIED MALE: I had a question about what are the implications of the suspension of the minimum appropriation? What does that mean to EPA? I wasn't completely clear.

MS. MONELL: If we do not get in our appropriation, $126 million, then we will not be able to collect fees. Our authority is suspended until such time as it gets up to the minimum appropriation level.

UNIDENTIFIED MALE: You will not be able to collect registration and maintenance fees?

MS. MONELL: Correct.

UNIDENTIFIED MALE: And so, what does that mean for the organization?

MS. MONELL: Well, should that happen, we would be in a severe budgetary difficulty.

UNIDENTIFIED MALE: It seems like it would -- you'd be sitting around with nothing to do, right?

MS. MONELL: Oh, no, we'd have more to do with a lot less.

UNIDENTIFIED MALE: With less money, okay.

MS. MONELL: Everybody would still be submitting actions to us to be completed, but we would have fewer people and fewer resources for contracts and grants to help us get the work done.

UNIDENTIFIED MALE: Can I just comment a second? I think it would help. You know, that was a protection put in so that Congress wouldn't cut base funding any more to the Agency so that they became a purely fee-based system, something like FDA.

UNIDENTIFIED MALE: And then another question. Is it more inexpensive -- is it cheaper to register a reduce risk pesticide than a conventional pesticide, one that's not classified as reduced risk?

MS. MONELL: The fee is the same. The time line is different. And for biopesticides, they're a little bit less.

MR. KASS: Hi, Dan Kass from New York City. Dr. Sass asked a lot of what I was sort of interested in and also I'm going to ask you to present us something in

the future. But the related budgetary question that I have is, are you able to describe what portion of your budget and how many FTEs are specifically dedicated to tracking and surveillance of use and sales? Is that a budget line for you?

MS. MONELL: For tracking sales --

MR. KASS: For tracking trends and sales and use of pesticides, right. I mean, I've seen some methodology reports that have been published out of agency staff, but I don't know of regular reporting of those things. So, is that a -- are there lines? Is there a component of your program that's dedicated to that?

MS. MONELL: No.

UNIDENTIFIED FEMALE: There is a couple of reports on EPA's web site on market use, data and trends, but it just stopped about five years ago.

MR. KASS: Right. Was that a budget --

MS. MONELL: I think I heard it's being updated.

UNIDENTIFIED FEMALE: When would it be put up again?

MS. MONELL: By 2009, it would be back up.

Well, thank you very much.

MS. EDWARDS: Thank you, Marty. The discussion will move on now to a short presentation by Elizabeth Leovey as an update on the PPDC workgroup on PRIA Process Improvements.

I'll just put this a little bit in context. When PRIA was passed, we came to the PPDC and said there is this provision for process improvement identification to improve our efficiency while at the same time not diminishing our thorough review of the science. The PPDC came back to the Agency and said we would like to have a workgroup formed and report back periodically to the larger PPDC. That is why you're hearing this update today.

MS. LEOVEY: Now that we have the slide presentation, I'm Elizabeth Leovey. I'm the senior advisor for PRIA implementation. I'm going to give you a very, very brief overview of the PRIA process improvement workgroup. Marty has already given you the history of the workgroup, the reason it was formed. What I'm going to do is give you a very quick rundown of its major

activities.

Janet Andersen mentioned yesterday that PRIA, the Pesticide Registration Improvement Act, was recently reauthorized and that was reauthorized with the Pesticide Registration Improvement Renewal Act that we call PRIA-2. As Marty mentioned, it covers really two types of fees, registration service fees and maintenance fees.

And under both PRIA-1 and PRIA-2, there is the provision on process improvement. Essentially, and in a nutshell, the administrator shall identify and evaluate reforms to the pesticide registration process under PRIA with the goal of reducing decision review periods. The decision review period is really the time frame in which the Agency is to make a decision on specific application or action. Now, these decision review time periods or the time frames can actually be extended. We do extend a number of them as indicated on one of the slides yesterday from the report on the registration program.

The members of the workgroup are from industry, trade associations, the Agency and public interest groups. Since the workgroup was formed, we've had 10 meetings. Recently, we had one at the end of April,

April 29th. Now, the minutes of each one of these meetings is -- they're posted and they're posted on the PPDC web site at the address shown on the slide.

In general, I think the workgroup found that the dialogue during the meetings have been very productive, very cooperative, and essentially the stakeholders in OPP each identified their priorities for improvements in the efficiency of the registration process.

Then, the Agency reports on the status of implementing PRIA, also its efforts to reduce time frames and also the status of a number of projects that are of interest to stakeholders. For instance, we've been following the program's activities in developing GIS technology. One of the advantages of the workgroup is that we can actually develop and follow long term projects. There are many activities that require a great deal of development and consequently our long term projects.

In general, labeling has always been a high priority for the committee. This led to the formation of OPP's labeling committee. They have a web site where the

public can ask any question about labeling and receive an answer. They're also updating the label review manual that Anne talked about yesterday.

One of the major focuses of the workgroup is quality submission. We found in looking at our processes that the better the submission, the more efficiently it can be processed. We're also finding that small businesses, the infrequent applicant, the first-time applicant does have problems. Well, they do have problems developing a complete application. We find simple mistakes such as the confidential statement of formula doesn't add up to 100. There are unapproved inerts as P.V. Shah discussed yesterday.

Consequently, the workgroup is looking into developing what -- well, what needs to be developed in the way of guidance information and also application tools that will lead to better applications.

The Office of Pesticide Programs spends a great deal of time and money on in-processing, tracking and moving paper. A lot of this could become more efficient with electronic tools, consequently, the emphasis on electronic submission and also developing technology to

facilitate the review process, for instance, electronic review labels.

Our long term goal in general, and this is both to facilitate the development of better applications and also to facilitate the registration process, is to develop an interactive application and analysis system that would allow an applicant to go on the web and develop an application and also receive instant feedback as to, for instance, your CSF does not add up to 100 percent or that your inert is not clear and you're going to have to seek approval.

Also, it would allow information to be moved very efficiently into GIS system models and also, for instance, staff programs, because currently the information in the paper submission has to be re-keyed, has to be keyed into the various different databases, models, stat programs, GIS technologies, and so forth.

That's only a snapshot of the workgroup's major efforts. There are a number of projects. We provided a summary during the last PPDC meeting and it's available on the web at the address shown on the slide.

Also, we have to report every year on process

improvement in the PRIA annual report. The FY 2007 annual report is posted on the web at the address shown on the slide.

One of the things that happened in PRIA-2 is that the number of things that we had to report in the PRIA annual report was expanded. We now have to report yearly on process improvement in handling a registration review and the program's recommendation for streamlining the registration review process.

As a result, the workgroup's activities have been expanded to include registration review. During the April 29th workgroup meeting, the special review on re-registration division presented the results of a March 2007 external review of the product re-registration program. We anticipate in the future meetings that as we did under PRIA-1, that the Agency and the stakeholders will identify their priorities for increasing the efficiency of the registration review program.

With the emphasis being on not only increasing the efficiency of the process but also maintaining transparency and public participation. In fact, these are supportive activities, as demonstrated by initial

activities, to streamline the registration review program in opening dockets early -- opening a docket with all the information that's known about a particular chemical case before -- early in the process and also the development of work plan.

The next meeting of the workgroup is expected to be in the fall of 2000 (sic) and we expect to be looking at or discussing the Agency's and the stakeholder's priorities for process improvements in the registration review program, also discussing information management, particularly the status of e-submission. The full-scale e-submission is expected to be rolled out sometime this summer. Continue to discuss the various different projects that the workgroup is monitoring.

The workgroup meetings are public. If you're interested in any of these activities, please participate in a workgroup meeting. Thank you.

MS. EDWARDS: We actually weren't planning to take comment on this. The reason for that is that we have a good session coming right after the break on endangered species and I want to make sure we have sufficient time for that and also sufficient time for

talking about the follow-up meeting. So, I want you to take a short break and be back no later than 10 after 10. Thank you.

(Whereupon, there was a brief recess.)

MS. EDWARDS: Okay, thank you. Our final session before we actually just have our planning session and determine if there are any public commentors is our session on endangered species. Our session chair for that is Don Brady who is our acting director of the Environmental Fate and Effects Division. Don.

MR. BRADY: Thank you, Debbie. We'd like to spend some time on endangered species with the PPDC today and hopefully we'll have time to engage in some conversation at the close of the presentation. One logistical note, we are making additional copies of the presentation if people didn't get one when they came in.

So, I just wanted to say that for us in EFED, our overall objective is to achieve full compliance with the Endangered Species Act, to use our resources efficiently and to provide effective high quality decisions in regard to endangered species.

Arty Williams, associate director of EFED, will

describe our current activities, some of our current activities in regards to endangered species and how we are going about achieving our objectives. Near the end of her presentation, she'll share some ideas that we've been talking about in EFED on how to continue to improve our efforts in this area.

So, I'll turn it over to Arty for her presentation.

MS. WILLIAMS: Thanks, Don. Good morning. It's nice to see some of you return and it's nice to see some new faces at the table as well.

I'm not going to -- for the benefit of the new folks, unfortunately, we don't have four days so I can't go back and like start from square one and bring you up to date as how we got where we are today. But if after the presentation you have historic questions or if you want to grab me after the meeting and find out more of the history, I'll be happy to provide that to you and send you information.

As Don mentioned, our overall objectives are to get into full compliance with the ESA using our resources efficiently and have effective quality decisions. To do

this, we think, as well, we have to kind of look at the two goals of the program. The first is to protect listed species, obviously. That's the intent of the ESA. But while we're protecting listed species, we also have to make sure we're minimizing the burden on agricultural production and other pesticide users.

That was kind of a pseudo-mandate from Congress years ago when we tried to put our program in place very broadly, limiting the use of pesticides beyond what was actually necessary for protection of listed species. So, those are two goals for the program as well.

We have looked at a number of ways to try to get into compliance with the Endangered Species Act. Where we landed was that we were going to assess the potential risks to listed species from pesticides during the course of our overall ecological list assessments that we're going to be doing for the registration review program. I'll explain why that's the course we took in just a second.

The idea was that we would do those assessments, determine nationwide what species were impacted by a particular pesticide and then where we

determine that the pesticide was likely to adversely affect the species, we would enter into consultation with the Service.

The reason that we only focus on likely to adversely affect determination is because at the time, the Services had issued a regulation called a counterpart regulation that provided that if we did our assessments in a certain manner, we did not have to consult with them on decisions that a pesticide was not likely to adversely affect the species.

By focusing our efforts on the registration review process and incorporating endangered species protection and determinations into our overall risk assessment, we think we achieve a couple of things. These decisions would address the potential risk to all listed species from the pesticide nationwide, rather than piecemeal, one species at a time.

It would provide the pesticide users with some certainty in terms of the schedule for when we might be assessing and limiting the use, as appropriate, of a pesticide. It would also provide them some certainty once we were done reviewing the pesticides that the

determination that we made and the limitations that we put in place would likely be stable for some time. So, it provides some certainty to them as well.

It also takes advantage of existing public participation processes that are being built into the registration review program. As you all probably know, there's a docket open for each pesticide. There's going to be a couple, I think, opportunities for public input into the initial docket opening and then the risk assessments as well. So, it wouldn't have to build a second public participation process.

Then, finally, it provides the broadest protection. Again, I'll touch on that a little more in a second.

I mentioned a little bit ago that there were counterpart regulations put in place some time ago by the Service that would allow us to forego further consultation on not likely to adversely affect determination. Under the standard regulation that we have to comply with under the ESA, there's a couple of outcomes. If we assess a chemical and there's no affect, no consultation is required. If it's not likely to

adversely affect, informal consultation is required. If it's likely o adversely affect, formal consultation is required.

Under the standard service regulations, Section 18s, emergency exemptions, under our statute, FIFRA, are viewed like any other agency action. So, we would have to consult on those actions before we undertook them.

When the counterpart regs were issued, it did a couple of things. The first thing that it did was it changed that second criteria to say that if we again conducted our assessments in a certain manner and determined that a pesticide was not likely to adversely affect a species, we could forego further consultation.

It also put in place definitions that would allow us to view Section 18s under FIFRA as emergencies under the emergency consultation provisions of the Endangered Species Act. What that would allow us to do is actually issue the Section 18, emergency exemption, under FIFRA and start consultation after the fact to see what impact that might have on listed species. So, it wouldn't delay our issuance of Section 18.

This regulation was subjective to some

litigation. The court that ruled on this particular regulation ruled a couple of different things. They didn't totally throw the regulation out, but what they did do was they said the provision that allowed us to forego further consultation was not appropriate and not legal and they struck it down.

Also, in terms of Section 18, what they said was that not all Section 18s can just carte blanche be considered appropriate for emergency consultation under ESA. You have to actually look and see whether it was kind of an unforeseen emergency before you can use those provisions. So, basically, what the court did in terms of the counterpart regulations was put us right back where we started from, pretty much.

The chronology of what we plan to do -- this is just a graphic that shows a couple of our different programs. At the top is registration, and that's ongoing, thus the arrow to the right. Below that is registration review, which is intended to be a cyclic 15-year process. Then, under that, re-registration, which is pretty much over at the end of this year. Down at the bottom is an arrow that's titled Species Specific,

Unusual Circumstances Process. That's kind of a whole separate time line of things we're doing for endangered species, mainly driven by litigation.

As you can see up at the top -- well, if you can see up at the top, it's pretty small from where I'm sitting, the numbers at the top show every two years, kind of the estimate of the number of different kinds of actions we're going to be doing. You'll see in the middle kinds of years there, it's like 50 new active ingredients every two years and 90 registration review chemicals every two years.

This was a kind of schedule and demonstration graphic that we had put together actually before PRIA-2 was passed. When PRIA-2 was passed, it expanded what we have to do in registration review. It about doubled it because of the deadline that it set for not initiating registration review within 15 years, but actually completing it within 15 years. As a result of that, we're going to be addressing almost double the number of chemicals per year as we had anticipated.

In addition to that, while that unusual circumstance thing at the bottom looks pretty skinny, it

seems to be growing and growing. I refuse to call it unusual anymore. I call it other because it's not so unusual. That's growing as a result of continued litigation, new litigation against the Agency.

Just to touch on what the new litigation is, I'm not going to go into a lot of detail on these because they're pending, but we do have a couple of new suits that have been either filed or threatened to be filed. One that has been filed is the suit that focuses in the San Francisco Bay area. It looks at 43 pesticide active ingredients relative to their effects on between 1 and 11 listed species in the San Francisco Bay area. The species scan a broad range of taxa. Might be the only thing that's not included are plant species, I think, but there are fish, birds, insects, mammals, salamanders, all different kinds of species.

In addition to that, we've received a 60-day notice of intent to sue relative to four chemicals that are listed there. That suit is a little bit different from the ones that at least I'm used to being involved in and that is it has both FIFRA and ESA claims in the notice of intent to sue. Then, finally, we recently

received a 60-day notice of intent to sue relative to our failure to consult under the Endangered Species Act for the chemical endosulfan.

In spite of the graphic that I showed where registration review is kind of more intense than we had anticipated and litigation seems to be if not increasing, at least steady -- it's certainly not decreasing -- in spite of all of those things, we still think registration review is the way we ought to be looking at these. I mentioned earlier I would explain why. Hopefully, this graphic will help me do that.

The top left graph or chart shows the various different kinds of actions that the Agency is engaged in. The purple or blue on the right hand side represents Section 18. The red section at the top left represents registration review actions. Then, going around the pie, you can see on your paper handout what the littler, smaller, slices represent.

The graphic down on the right represents for each of those kinds of actions -- if you can think of it as kind of the scope of coverage for endangered species, because, for example, the red, which is registration

review, about 70 actions a year. If you look down at the right, that actually represents about 378,000 decisions, a decision being does a particular crop in a particular location affect a particular species. Because these are national assessments, you basically get more bang for your buck.

If you look at a whole chemical nationwide at a rate of 70 per year, then you do looking at 250 Section 18s per year, which are very localized, it may impact one species in a very small geographic area. So, we think the way to get into compliance most effectively, efficiently, provide the most protections for listed species as soon as we can is still through the registration review program.

The way that the endangered species process kind of winds up with registration review is shown here. On the bottom in the blue is kind of the major steps of registration review. You initiate it by opening a docket. You do the assessments and integrate the assessments. You identify any mitigation that's necessary and then you implement that through labeling.

The boxes up on the top represent kind of the

three phases of endangered species and where they fit into that registration review process. The two green boxes represent the two major components of assessment which are the basic chemical assessment and then the assessment taking into consideration species specific information. The -- I don't know what color that is. It's supposed to be an orange box in the middle and represents consultation process. Then the two purple boxes on the right represent implementation.

There are two boxes there because there are really two kinds of implementations. The first is where we're working with the chemical company and the constituents to define the mitigation in a way that can be implemented out in the field. Then, the second part of implementation is actually implementing it out in the field. So, this graphic kind of demonstrates where those fall within the standard registration review process.

To make this all work, we think that we need to introduce even more efficiency into the process. We need to continue to look at building useful tools and we need to be effective and have effective systems for information gathering and information management. We

also believe that these three factors play into each of the three components of endangered species assessment or the endangered species program, that being assessment, consultation and implementation.

In the area of assessment, some of the efficiencies that we've been looking at developing and developing are noted here. One of the bigger ones, I think, that we've done to date is we've actually developed a template for our assessment documents, not just endangered species but our ecological risk assessments, that we think will not only provide some efficiency to the process, but will add some consistency and make sure that the various reviewers who are looking at these pesticides are approaching them in a similar manner and are touching on the same kinds of information for each one.

A couple of things here I want to point out specifically is the third bullet, which is considering the intensity of the overview document, the overview document was developed several years ago with the Services. We've been using it for litigation assessments that we've been doing. We're now working on our first

two registration review assessments, which, again, will be national in scope and look at all listed species that potentially will be affected.

It's becoming clear to us that the intensity of the assessments that we've done for the litigation chemicals which focus on a limited number of species in a limited geographic area just is not going to work, we don't think, for national assessments. We've got to find a way to get to the bottom line, the right bottom line, scientifically sound bottom line, in a lot less intense process. So, we've just started the process of looking at that to see where there might be some efficiencies that we can build into the process articulated in the overview document.

Then, the last bullet on that page, just to make a note of it, we are in discussions with some of the major registrants of these first two chemicals that are going through registration review to see if there's information they have that's not like required data, but just information they may have that can be brought to the table that can inform our risk assessment in a manner that would make it more efficient for us to complete that

risk assessment.

Some of the tools we've been developing are listed here. We've been looking at tools that will semi-automate some of our processes such as identifying the action area for an action which is the geographic scope of where we have to look at potential effects. We've developed a use site tool that links ag census data to lands cover data so we can better define where certain pesticides might be used on the ground.

An aquatic action area tool and one that we're working on that's not quite developed yet is the spatial framework for PRZM/EXAMS, which we think is going to be really good for our decisionmaking. PRZM/EXAMS is the model we use to look at off site movement of pesticides. What we're doing is building a spatial framework for that that would allow you to use foils data across the country, weather data across the country, rather than scenarios for specific locations and then extrapolating that to other locations. It would give you a much more geographic specific look at what the potential movement of the pesticide might be.

In the area of assessment, we're doing a

variety of things. We're looking at how we might gather and store and manage information a little bit better. We've paid for, with OEI's help and collaboration, and developed a hub that holds national level geospatial information for us. We're developing a tracking system for ES actions. We're also building right now a knowledge repository into which, as we gather information, we will store species specific information, things like not the range necessarily but their biological needs, what they eat, what the breeding cycle is, whether they migrate with the migratory passives, all the kinds of information that we consider about a species when we're trying to figure out whether it truly is going to be exposed to a particular pesticide use.

We're also exploring how best to populate the system. We've been in some discussions with the Fish and Wildlife Service and National Marine Fishery Service who would be the keepers of such information and they don't, at this point in time, have a national system where this is all conglomerated together. So, we're trying to figure out what the best way is to actually populate such a system on a national basis.

Two of the things that we have to do for our assessments are develop and provide with our analysis the environmental baseline for the species and develop a cumulative effects analysis. For those of you in the pesticide business and have been around it for a long time, I want to point out the cumulative effects under the ESA are very different from how we think about them in the pesticide arena.

There's a description on the slide in front of you of what cumulative effects means under the Endangered Species Act. These two pieces of what we have to provide with our assessments are pretty resource intensive for us. Right now, we're getting documents from the geographic area that we're interested in. We're pulling from old biological opinions to try and piece together the baseline and the cumulative effects analysis for each of our assessments. That's an area that we're hopeful that we can -- in fact, I think there's a meeting ongoing right now with staff from the Services and my staff to look at how we might better be able to do the baseline and cumulative effects analysis.

In the consultation process in terms of

efficiency, we're, I think, jointly struggling to find some with the Services. One of the first steps we've taken is that we did have a week long meeting with the Services with a variety of different levels of people involved in the process. We learned about the organizational structure of each other's agencies and the resources that we can bring to bear and how the limitations on that might influence work flow.

We identified several areas within our assessments that if we change, the Services believe would help them in their review of our assessments. Then, we're also observers at a week long session among the Services and EPA's Office of Water where they employ a process call kaizen. It's apparently a Japanese word that either means or implies ongoing progress and improvement. Our Office of Water met with the Services for a week long session to look at that. The preliminary reports back from that are that it was pretty successful. They identified quite a few areas of efficiency.

We've instituted routine interaction at various management levels with the Services in an effort to insure that assessments are moving along and that

consultations are moving through the process and to discuss any process issues that we might come across.

Then, in the area of information gathering, the Services, my understanding right now is that they don't have like a national data set for species information across the country for either the types of things I mentioned we were interested in or for geographic information. I know they've been working on that.

There's a web-based system that they're developing. My understanding is that eventually it will have in it critical habitat, locations, species by county location and then it will also have links to different documents that are relevant to those species. That's something I know they're working on as well.

In terms of implementation, we are using, as I mentioned, the registration review process to take advantage of a number of things, including public participation and risk assessment. We've developed an electronic system to relay use limitations to pesticide users. It's called Bulletins Live. It's up. It's online. It allows semi-automated creation of bulletins. The process of actually developing the bulletins is going

to be very efficient for us. It provides for an electronic QA before it's actually published to the web. So, we're really happy with that system.

So, the tools again are that system. We've got an 800 phone number established where people who don't have access to the web could call and get such information. States and EPA regions have been briefed and trained on field implementation and we've developed a training presentation to the states and the regions to use with growers. So, when we start putting limitations into this Bulletins Live system, they'll know what to do with those.

In terms of implementation, this bulletin program online actually tracks every iteration of a bulletin. So, as species are added or chemicals are added or subtracted from the bulletin, it retains each iteration.

There also is a password protected access that will be provided to state enforcement people and regional enforcement people that will allow them, for purposes of enforcement, to go back and retrieve the bulletin that was in effect on any day for any county. It also allows

users to directly write to EPA relative to issues that they come across with the bulletins or if they're having trouble with the system.

So, we've been trying to do a lot. The question now is, okay, we've done all of this. Where do we go? How do we move forward from here? In terms of process, one of the first things we wanted to do is start engaging groups such as the PPDC. We're also considering some other ways to get input from stakeholders and government and non-government entities involved in this. We've been kicking around some ideas like well, should we do a keystone kind of enterprise such as was done with FQPA and which resulted in similarly good recommendations for how to move FQPA forward.

We've thought about maybe going to like the National Academy of Sciences with some specific questions for them to help us with. I'm sure there are many other ways that we could go as well, and we'd like some input on that.

Then, in terms of the specific priorities that we think we need to focus on next in the areas of assessment, consultation and implementation, the three

majors parts of the program, those are articulated here. Under assessment process, we think we need to, again, identify methods to decrease the intensity of what we're doing under the overview document but still wind up with geographically focused and scientifically robust assessments of listed species. We want to continue to seek ways to obtain national scale information on species so that we don't each time we come across a species have to go out and gather information about it.

In terms of the consultation process, our next priority we think should be to assist the Services in identifying ways to help them be positioned to undertake consultation on the volume that we anticipate we're going to be consulting on based on the PRIA-2 changes and the increased litigation.

Then, in terms of implementation, basically, we're ready to go. What we need is to complete consultation, in order to identify through other means, limitations that we need to put in place and get some bulletins developed and online and get the labeling out there and get going. So, those are our next priorities.

What we would hope you all could help us with

today after we answer any questions you have is to help us look at what other areas relative to the three parts of the program -- assessment, consultation, and implementation -- should we be considering as priorities right now. Then, also, what your thoughts are on processes for engaging a broader audience to help us look at what the path forward is, you know, be on like a keystone or a NAS kind of approach. We'd like your input on that as well.

Thank you. I'm done talking. Do we want to take questions, first, Debbie? Are there any questions?

MS. EDWARDS: I'd just go around the table. They put the cards up. Shall we start with Bob?

BOB: Maybe this is a comment, maybe it's a question. If it gets to be too much of a comment, then stop me. I'll come back. I know this is going to sound like whiny and critical and I swear to God it's not. But let me try to explain. It's frustration.

As I understand the situation, and maybe I don't understand it correctly, that until this gets fully implemented after registration review is completed, it's pretty much true that anybody can go into a Federal court

and sue the Agency for noncompliance and will probably win.

The reason I mention that is when that occurs, the decisions, it seems to me, end up getting made in the least transparent process possible, which is to say that the litigants get together in a back room and cut a deal. That's a very frustrating thing for us.

A specific example I've got is a San Francisco case. There's a lot of rodenicide (phonetic) on that list. There's been a very thorough, you know, very public, very transparent process involved in the re-registration of rodenicides. Now you get a group going to court, file suit that they almost certainly will win and will have their legal expenses reimbursed and the final decision on rodenicide won't be made in that public transparent process but will instead be made in a very private process between the parties. We're not one of those parties. Yet, we're very much affected by it.

I guess what I'm asking is, is there -- one other element, as a small trade association representing a small industry, it's not possible for us to intervene or file amicus briefs or get actively involved every time

there's litigation.

Is there some way that the Agency could create some process that would bring effected parties into their negotiations with the litigants?

MS. WILLIAMS: Stop whining. I'm sorry. I had to, Bob. I apologize.

Those are good points. First off, I would like to say that what is decided by the courts or what is decided in negotiations to try and settle a court case out of court are scheduled. It's not the science. We're not doing the science in a back room with the litigants. I want to make that crystal clear. Once we've either been given or negotiated a schedule, we do the science ourselves just like we do for anything else.

I think you're right in that the time frame for those particular assessments don't allow for the kind of public participation in the science that we would like. The opportunity to provide comment is generally after the assessment is done. Then we would bring that into the process of consultation with the Service. I don't know how that can change. If we have a deadline, we have a deadline.

In terms of being involved actually in the discussions, the kind of closed discussions that result in a schedule or being involved in the court case, I understand that it takes resources to intervene in cases. I think the one opportunity there to have input is that we have insisted that all settlement agreements or like documents be published for a short time for public comment. We've committed that should public comment convince us that what we're agreeing to is not in the public interest, we would then not agree to it. So, there is a small opportunity for participation in that process even if you can't intervene into (inaudible).

DR. BERGER: This is Lori Berger, California Specialty Crops Council. I have a question regarding assessments and the tools that you referred to. One of the things that you're going to be using for this use site development tool is the NAS data. I was wondering in your discussion if you all considered the fact that that information may not be available any longer? What will be used in its place, because it seems like it would be a pretty important piece of this big puzzle?

MS. WILLIAMS: That's a good question. One of

the requirements, Lori, as I know you know, for what we do is that we use best available data. So, as long as that kind of data are available, we're going to be trying to take advantage of it. If the Ag census data goes away, I mean, we're basically left at the starting point of the land use data, which makes the assessments pretty broad. If you're looking at all road crops instead of where the soy beans versus where some other road crop, you get pretty broad geographically.

I don't know what's going to take its place. I know in California there's pesticide use data that could come into play that we've used in the past for various things. But not all states, as you know, have use reporting. I'm not sure. I'm not sure what we would use. It would either have to be very broad or states or organizations would have to come up with more specific information. We can't use what's not there.

MS. EDWARDS: I think Al Jennings wanted to speak to this issue.

MR. JENNINGS: It sounds like there are two different things going on here. This refers to the Ag census data which is a different animal from the thing we

were talking about before, the chemical use surveys. It's the chemical use surveys that are in trouble. The Ag census which occurs every five years, all plans are for that to go ahead. It's happening right now.

2007 is a census year, so it will be published sometime in 2008. That's not chemical use data. That really is how many acres of what is planted where. It's aggregated at the county level. The plans for Ag census are okay. It's chemical use that's not okay.

MS. WILLIAMS: I'm glad to hear that. Thanks.

DR. WHALON: Mark Whalon, Michigan State University. As you know, in Michigan, we're up to our ears in ESA questions and ag. A couple points I'd like to make is that we talk about best available data. In the three species that I'm dealing with right now in Indiana Bat, Pitcher Sissle (phonetic) and the Conner Blue Butterfly (phonetic) and the specialty crops in Michigan, the best available data is often natural features inventory data from 1942 or some such.

So, when we put all that best available data into a map, we see a lot of encouraging points and a lot of issues. EPA tends to make decisions on at least

county or even bigger aggregates. That affects a lot of growers that may not have any interaction with an endangered species.

So, the whole thing hinges, in my view, on the quality of the maps involved and the availability to populate those maps with actual endangered species habs, habitats. Then there's this issue of protectionism versus broader knowledge and that's really a key thing for us in these three species.

One of the things that I think is really understood -- it's not understood well and it's not being utilized but could change the whole scene in biodiversity and endangered species, and that is that agriculture and the most affected people on private land relative to endangered species are ag producers. They have the greatest incentive to help endangered species, thus avoiding problems for themselves.

So, what I see in this legislation and in the approach that EPA is taking and also the Services is that in a consultation process with a commodity, I believe, proper incentives in place, that growers would actually re-establish, improve, develop alternative habitats for

endangered species such that we could do extra patients and re-establish in very significant areas if the agencies and services involved would actually promote such a process.

We've seen that in Michigan with the cherry industry. They're very willing to do things, including move orchards. One of the key features of endangered species is yeah, you can have patch sizes but often it's the corridors between the patch sizes that are key for mating and movement and survival. Those are often in ag land.

So, if we're really serious about endangered species, why don't we have a facilitative rather than a top down approach in managing them? Growers could turn this thing around for many species in a fairly short order of time, I believe. If the proper incentives were there and if the resources on a national level were made available site by site to do that kind of thing, we would change it.

The Conner Blue Butterfly, we could re-establish very significant habs and extrapate (phonetic) and establish into those. We've got wildlife services,

and Michigan Natural Features inventory, NVA, DQ, all of those agencies interested in that. Our hands are tied to do the kinds of things that we would do to re-establish the biodiversity needed for endangered species.

We're not harnessing agriculture. We're shackling agriculture to deal with this issue. That's a real frustration for me because I work with growers and I'm really concerned about biodiversity. I think the key to the future -- maybe that's a whole new program in the process, but there needs to be a coming together of the environmental community and the production community to do this in a real way.

MS. WILLIAMS: Thank you.

UNIDENTIFIED FEMALE: I'm wondering as you get to the mitigation and implementation phase what kinds -- how are you going to track whether what you're doing is actually being effective in terms of preventing pesticides from getting into critical habitat, species abundance and those kinds of things.

Will there be any monitoring of what's in the environment or requirements of the registrant to monitor endangered species, habitats or areas where there have

been problems in the past?

MS. WILLIAMS: We don't have any plans right now to try and institute any kind of broad monitoring program. It's not perfect, but one of the things we use right now to look at issues like that are incident reports. We would continue to do that to see if chemicals were being found off site where they shouldn't be.

One of the things that provides me a little bit of comfort, in that we don't, as a nation, have a system that goes out and monitors all of the things that we do, is that the standards I think that we have to mitigate to are pretty strict standards. While we're being specific geographically, we're not going to be doing this at a county level, as was alluded to a minute ago. We're also not going to do it at such a specific geographic level that, you know, if we're off by 10 feet, we've killed the species. So, it gives me a little bit of comfort.

And I think, as well, we need to make sure we look at the standard we're being held to. The Endangered Species Act requires that we ensure that we're not jeopardizing the species. That doesn't mean, you know,

ensure that no chemical ever gets into the habitat. So, no, we don't have a national monitoring program for this or anything else that we're doing, I guess. I don't think we have any plans to try and do that. I don't think we as a nation could afford to do that.

UNIDENTIFIED FEMALE: Just one more thing. I mean, you say it's a strict standard but we have lots of problems with pesticides where the models are not predicting what is actually happening out in the environment.

The pyrethroids come to mind. The model for looking at how these things run off in urban environments, I mean, it's just not accurately accounted for. So, while the model might predict that you're being very, very conservative and very careful, the actual results are sometimes quite different.

MS. WILLIAMS: Right, right. You're absolutely right. I think one of the keys here is best available data. If we discover situations like that, you know, we need to look. We need to make sure that we're putting in safeguards beyond just the model number.

UNIDENTIFIED FEMALE: Can I quote you on that?

MS. WILLIAMS: I'm sorry?

UNIDENTIFIED FEMALE: Can I quote you on that?

MS. WILLIAMS: I said it. I guess you can quote it. If we've got a model and it clearly isn't working, we're going to be looking at, you know, environmental information that we have as well. We do that to try and talk about the uncertainty in the model. Most of the time it's a model -- the uncertainty around most of the models we use indicates that the models are overpredicting. But I know there are situations where they may underpredict and we've got to account for that as well as best we can.

CAROLINE: I think my question is really similar to Susan's. When you're asked about priorities for the different phases of the -- I was thinking about implementation. As far as I know, there hasn't been any attempt to measure use of the bulletins and whether growers are actually going to the web site and looking at the bulletins and then following the mitigation measures that are required in the bulletins.

It seems like that's a really key thing to try to figure out, especially as the number of bulletins

increases, just to make sure that they're actually being used and their requirements are actually being followed.

MS. WILLIAMS: Yeah, that's kind of a different kind of monitoring, not environmental monitoring, obviously, but that's something actually that I think we could look at down the road. Right now there aren't limitations in place through the bulletin system to be looking at whether they're being followed. But that is something that years ago when we tried to implement this program we wanted to see if we could do.

The web site, while it will not capture and keep specific information about the address, the web address of somebody who comes into the system, we're not keeping that data, but it is going to account for the different counties in the system. That's kind of a first step in that direction just to see if anybody is even visiting the site.

But after it's in place a while, I don't see why we couldn't look at something like that using our regions and our state enforcement people and the extension people perhaps in some kind of concerted effort to see if they're actually being used and followed out in

the field. It's a good idea.

UNIDENTIFIED MALE: Really quickly, could I understand the 18s exemption, the emergency permit? Could you just explain to me how that happens, how it comes about?

MS. WILLIAMS: How a Section 18 comes about?

UNIDENTIFIED MALE: Section 18 comes about.

MS. WILLIAMS: Is anybody from registration here that wants to address that or should I take a crack? Okay, I'll take a crack.

The statute -- Section 18 of our statute, Federal Insecticide, Bungicide and Rodenicide Act (phonetic) provides for emergencies where a state can declare that there's an emergency within the state for which they need to use a particular pesticide in a manner for which it is not currently registered. They have to document what the emergency is and then basically apply to the EPA for an emergency exemption from certain provisions of FIFRA.

Those emergency exemption requests are reviewed at the Agency. I think we have 52 days to review them and determine whether or not we'll allow that particular

pesticide to be used in that location in that manner to address the emergency.

UNIDENTIFIED MALE: And EPA stipulates the time and area?

MS. WILLIAMS: The state in their application talks about the time and the area and we review it to see whether we think that's appropriate.

UNIDENTIFIED MALE: And only a state can apply?

MS. WILLIAMS: States and I believe it's moving to some tribes right now.

UNIDENTIFIED MALE: And this can include, I assume, public health and agricultural needs?

MS. WILLIAMS: Yes, any emergency that the state believes it has relative to the needs of a pesticide.

UNIDENTIFIED MALE: Are these tracked on the web? Is there someplace the public can see that these are issued and where they are?

MS. WILLIAMS: That I don't know.

MS. EDWARDS: Yes.

MS. WILLIAMS: Yes.

MS. EDWARDS: Also, other federal agencies can

request these as well.

UNIDENTIFIED MALE: I'm sorry, I didn't hear you.

MS. EDWARDS: Other federal agencies can also request these. For example, AFUS (phonetic) sometimes makes these requests.

UNIDENTIFIED MALE: Okay, thank you.

JULIE: I was thinking about other stakeholders that would probably want to be involved in the process and probably can help provide information on use patterns and usage information. Besides growers on the non-ag side, I think you probably want to look at things like vegetation management uses, golf course uses, and engage those user communities as well because I think they'd be able to provide valuable information on usage -- how they use products, manners in which they use them. It's just a suggestion.

MS. WILLIAMS: Thank you.

DENNIS: Arty, thank you for a very educational presentation. When you showed the pie charts, and if I understood what you were trying to articulate there, it was that as the Agency has a variety of different types

of registration actions that you process, some of those are more rich in actions and product, basically. That may be a greater benefit in a sense that there's more areas or more species or more crops that are considered; for example, registration review.

But the Agency still needs to look at all the pieces of the pie, right? Even though registration review is the most efficient from a standpoint of actions per decision -- decisions per action, I guess -- you still have to look at Section 18, 24cs and new active ingredients and that sort of thing, right?

MS. WILLIAMS: Technically, yes. I think what we've tried to articulate over the last couple of years is when you look at the whole pie, we haven't gotten enough people to eat the pie. So, we're going to try and take a big slice of the pie and do that. Technically, each of these kinds of actions is subject to review under the Endangered Species Act.

DENNIS: Okay. And that was going to lead me to the pie eating question. Just looking at the timeline chart and the increase in the number of actions that you have to take into account under PRIA-2 now on an annual -

- bi-annual basis and what was already a daunting schedule, how is the Agency -- yesterday we had -- or actually, it was earlier this morning when you had graphs that showed that the number of staff in the Agency are dropping.

So, your requirements are increasing, your resources are decreasing. How does the Agency shift those resources to make these goals achievable? Not only your agency, but how does Fish and Wildlife and the other service fit in? It just seems to me like you've got a really tough road to hoe here.

MS. WILLIAMS: I would agree with that. It is a tough road to hoe. I was not here during this morning's discussion, but I can tell you that even though resources are declining within the office, we've been shifting some resources to try and be able to focus more on this.

We've actually in our division, the division that's responsible for doing the assessments, been granted an increase in our ceiling. It's a significant increase in our ceiling. It's not near significant enough to do necessarily all of this work in the time

frame that's required. So, we still need to look for other opportunities to be more efficient.

But I know that within the office and within the administratorship we are doing things like shipping resources, personnel, and dollars where we need to to try and address this program. I'm not sure we have enough leeway to do enough, but we're certainly doing what we can.

If Debbie wants to speak to that, or Anne further, or Marty -- and I'm certainly not going to try to speak for the Services regarding what they're trying to do to address the increase workload. I have no idea what they're trying to do. Maybe Rick would like to speak to that.

MS. EDWARDS: Let me add a little bit and then if Rick would like to weigh in, that would be good. As you know, when we were doing -- we had the tolerance re-assessment goal, 10 years. We were very focused at that time on coming into compliance. That was almost entirely human health risk issue. Although we were doing re-registration, looking at ecological effects for many chemicals at the same time, we had to look at every food

use chemical for the human health aspects.

So, now we believe that in registration review, although we're going to be looking at human health concerns as we move through that process, we think we're probably in pretty good shape with respect to food, drinking water, and residential uses. We had to look at all of them.

We think we may need to do some additional work there on the worker assessments, for example, because those weren't looked at for the chemicals from '84 forward. That wasn't part of that assessment. But principally, in registration review, we think it's going to be -- the biggest piece of it is going to be the ecological effects assessment in general and also as they feed into endangered species assessment.

I'll let Rick speak for the Services.

RICK: Thanks, Debbie. The short answer to the question of are we getting increased resources to help with this is no. We're not in Fish and Wildlife Services. I believe that my colleagues at National Marine and Fishery Service are looking to add a couple of people to their Washington office staff to help deal with

the consultation work for pesticides as well as other EPA-related work, mostly in the Office of Water.

But our attempts to secure additional resources to help with this have not been successful at this point. So, we basically have in our Washington office two people who can work on EPA consultations. That includes Office of Water and any others that we might get from EPA. Right now it's really been just Office of Water and Office of Pesticide Programs. So, we have a pretty limited capability to help out with this. That's the fact.

UNIDENTIFIED MALE: You did say two people?

RICK: That's correct.

UNIDENTIFIED FEMALE: Does that include you?

RICK: No, that does not include me. I don't do real work anymore. That's why I'm in a meeting like this, unfortunately.

MS. EDWARDS: Thank you. I wanted to go back to what I was saying a minute ago. The reason I made those statements about moving towards more the ecological is that we're able to move some of those resources into that area. That was the point of what I was trying to

say.

CAROLYN: This is a big topic. We might want to spend another hour on this in a future meeting because we could probably do that easily. I guess I have three things I want to comment on. I'll try to be as brief as possible.

First would be with regard to the consultative process with the Services. I know that there's been efforts at EPA for a long time to engage folks from the Services and these issues. I also know that what Rick says is totally true; they just have not had the resources to step up like they would have needed to. But for a quirk in the law, which could have been drafted differently, the legal responsibility for this and all this litigation could have fallen on the Services instead of you. But the way the law works, of course, it's your legal responsibility to come up with a solution.

So, I do think the notion of making this a higher profile issue and engaging more people outside our circle in the fact of how we need to solve the problem and the resource issue would be very valuable. So, I would highly recommend that.

Secondly, a lot of what you said about access to data kind of flew over my head. I'd have to think about it a little bit. One question I had was, what kind of data are you able to access from the jeopardy opinion and how -- you know, what more do you need and how could we do some interacting on that issue to help the process?

MS. WILLIAMS: Thanks, Carolyn. The kinds of information that we routinely are going to need to conduct our assessments, they span. There's a set of information relative to species, again, such as what their breeding cycle is, whether birds eat grains or insects, whether plants are pollinated by wind or insects, or something else. All of those kinds of biological statistics and data influence whether a particular species is going to be affected by a pesticide.

For example, if the pesticide we're reviewing kills insects and the species that we're concerned about in that geographic area is an endangered plant, but we know that it's wind pollinated, it doesn't rely on insects at all, then we know that if this pesticide were to kill insects in that area, this endangered plant would

not be affected. So, very specific information like that.

CAROLYN: I was going to say, that sounds like an incredibly qualitative analysis of the jeopardy opinions, to ferret that information out.

MS. WILLIAMS: Well, that's sort of our analysis. We need that kind of information. Then, there's another kind of information we need to do the baseline assessment, baseline status assessment and the cumulative effective assessment that we can glean from past opinions.

The issue that we have with that is A, we wind up developing what's the baseline status for this species. I'm not sure that we're qualified to do that, frankly. But the second issue is, the documents that we're researching to try to pull that information together are generally very, very geographically specific.

Again, you know, we get an opinion that the Services have done about species A in northern Arlington County, Virginia, when they put the Wilson Bridge in place. So, it's very specific. It might not even cover

the whole species. It's just the species in that area that the bridge affected.

We've got another one for that species in southern Virginia where its range extends to -- that was issued by the Services when somebody was building a government center in Richmond.

CAROLYN: So, going forward prospectively, if you could, you know, in your mind, design what a jeopardy opinion would look like or the basis for the opinion, I guess is the more correct term, are there things that you would do to change it? I don't mean for you to go into specifics, but are there ways that we could communicate that to the Services in a way that would make the data more helpful to you and more accessible?

MS. WILLIAMS: Well, I think all of that first kind of information that I was talking about, I'm told, is available in different field offices, in cabinets, in people's heads, and on their computers. If there was some national access to that, that would be a tremendous benefit.

CAROLYN: Okay.

MS. WILLIAMS: And then, for the second kind of

information, the baseline status, the environmental status, that we have to pull together, to be real honest with you, I mean, the Services could do what we're doing just as easily as we're doing it on a national basis.

CAROLYN: Okay.

MS. WILLIAMS: That's not to say it's easy.

CAROLYN: I understand.

MS. WILLIAMS: It's not easy, but I'm not sure where the right people to be doing it.

CAROLYN: Well, in the context of just putting this effort together to do something more frontal about, you know, responsibilities, that that would be a key issue that we should deal with.

And I guess my third point is I thought the comments that Mark made, Mark Whalon, about the, you know, involvement of the growers and helping to mitigate, was incredibly valuable. And I recall that back in the late 90s, we were doing in this program what we call habitat conservation plans.

Is that still an ongoing thing, Rick? So, how could that feed into what Mark's talking about? That's another question I would have. Do you have some thoughts

on that?

UNIDENTIFIED MALE: I do. That was actually why my flag was up. Habitat conservation plans are still out there and available. They're not easy to undertake and to complete. They tend to take years in development and they're very expensive, I guess is the main thing. You know, you have to think carefully about is that the tool you really want to use. In some situations, it has been. We actually did a statewide habitat conservation plan in Wisconsin. It covers only one species, Conner Blue Butterfly, one that Dr. Whalon mentioned.

There are a couple of other tools, I think, that are potentially just as helpful. We also use something similar to ACPs that we call Safe Harbor Agreements. Those are a little easier to put in place on a smaller scale than HTPs tend to be, but they can also be developed in a way that essentially establishes a baseline condition for the species on a particular property or group of properties and then establishes some management practices that we think everyone thinks would be beneficial to the species.

It provides at the end of the day, at the end

of the agreement period, the possibility to return conditions to where they were at the start of the agreement. That can be described in terms of habitat conditions, raw numbers, you know, individuals that were thought to be present at the time that the agreement was started. So, there's a lot of latitude there.

We did have a program called the Private Stewardship Program that provided direct funding. It's one of the very few times that Fish and Wildlife was engaged in direct grant making to private citizens land owners for the -- to help conserve threatened and endangered species. That program has dried up and gone away.

In its place we've shuffled some of that funding over to the program that we call Partners for Fish and Wildlife, shuffled it to a different program called Partners for Fish and Wildlife. That's not a grant program. Partners for Fish and Wildlife is a cost-sharing program.

We don't enter into grant agreements with the recipients; we just enter into cooperative agreements. That one has -- it's a lot easier to put those into

effect locally, but I will be candid and say that some of our offices have been shy about doing them when there are endangered species involved.

We're trying to kind of do some education right within our own agency and make them realize that we actually think getting Partners for Fish and Wildlife projects out there that will help threaten an endangered species would be a good use of their program funds. So, we've got a little internal work that we have to do there just to make that happen a little bit better.

That's generally run out of our ecological services field office. There are a couple places where there's a specific office called the Private Lands Office. It's going to depend what part of the country you're in as to exactly who you need to go talk to about that. You could start, if you want to know more about it, start with your local Fish and Wildlife Ecological Services office and they'll know who to send you to if it isn't them.

MS. WILLIAMS: Could I respond to one thing? We've been working with one of the Fish and Wildlife field offices recently to try and address that pesticide

issue related to a species that isn't under a habitat conservation plan. Not that these aren't great programs, but I don't think it's crystal clear yet among the Service and EPA how those plans and those programs then play into EPA's responsibility to ensure that a pesticide doesn't jeopardize the species.

So, what I don't want is people walking away thinking oh, it's just one of these plans, everything is golden, because I don't think we've really figured that out yet.

CAROLYN: The question would be whether there's some way to have amendments to the plan. That would also be less expensive and hopefully less, you know, difficult.

MS. WILLIAMS: Yeah. I mean, I'm sure there's lots of opportunity there. Again, I just don't want people walking away thinking oh, we've got a plan so EPA is going to leave us alone, because I'm not sure that we know that we can do that yet.

UNIDENTIFIED MALE: And I'd like to clarify. There are relatively few existing HTPs that have specifically included pesticide use as one of the covered

activities. We do have a few. The Conner Blue one in Wisconsin is one that I know of. I think some of the Red Cockhater Woodpecker (phonetic) projects have also included pesticide use -- some pesticide uses, at least, if not all. But your idea of can we amend existing plans, the answer to that is yes, we can.

One of the things that I would advise anyone who is looking to do that is, you know, have the local office that you're going to have to work with check in with folks up here in Washington.

One of the concerns that came up when we first started doing HTPs, particularly folks in California, where we have done both numerically the most ACPs and the largest ACPs, a lot of those folks were interested in having pesticide activities covered. And at the time we were doing those, the Services' position was we're not going to cover that kind of activity until we've gotten consultations completed with EPA.

I think we've had a little bit of a shift in mindset since that time, but I'm not going to -- I want folks to realize they may hear something like that if they try to engage and we'll probably have to talk our

way through it.

MS. EDWARDS: Okay. I'd like to have three more of the people that have their cards up, which is Cindy, Dan and Mark again. Then we'll close this particular conversation for today.

UNIDENTIFIED MALE: -- because they brought up what I suggested and talked about.

MS. EDWARDS: Yeah, you go first.

UNIDENTIFIED MALE: I'd just like to say that in Michigan, I think we've done something that's pretty unique. It's not unlike some of the initial parts of the Wisconsin Conner Blue effort, but we've put together a committee that involves the Services, that involves the Natural Futures Inventory Group, it involves all the Department of Environmental Quality, the Michigan Department of Agriculture, the effected industry.

We've met as a committee about eight times. We basically have a plan that if the incentives were there, the effected commodity grower group would invest its own resources to help some of the affected growers who may be having an impact, may not, because the maps are so poor and the monitoring system is not in place.

But my crew -- I have nine people in my lab -- we do Conner Blue Butterfly survey ourselves and will participate in the (inaudible) National Forest survey. I have an educated crew. We understand the habitat and we know the plants involved. We know the kind of habitat there is.

The reason I raise all of that is that expertise is not just in the Services, although the Services have a big influence on it. The Services participate in our committee. But the point isn't that if the incentives were there or if a grower was certain that if he grew 1,000 Conner Blue Butterflies and actually got drift from an orchard and killed 10, that he wouldn't be fined, we would do it today. They would do it today. Move orchards. Re-establish habitat.

We already have permission from the Services to extirpate out of high population areas and put into these others the idea that -- the concept is there but there is -- the ESA is such that if you get accused of a take, you're going to pay a fine. I mean, if it's a documented deal, you're going to pay a fine.

So, the facilitative process and the incentive

need to be from the government agencies to the affected community. We could change this in western Michigan probably in three or four years. Even though we'd have to continue to do burns and other kinds of things that enhance Conner Blue Butterfly, we would probably get that species de-listed pretty quick in Michigan.

UNIDENTIFIED MALE: Debbie, I guess I feel the need to respond to one aspect of that.

UNIDENTIFIED MALE: Respond to the incentive, not the negative part.

UNIDENTIFIED MALE: Well, I want to respond to two then. I mean, we collect in the thousands of dollars of fines annually. I mean, the amount of fine money we collect is not a problem for anybody in this country unless you're the one individual who gets hit with one fine. But I guess what I'm not quite sure I understand is the incentive -- and we can dialogue after. I'd be happy to do that.

I mean, the incentives that I thought I heard you describing are exactly the incentives that come with a completed habitat conservation plan. You get assurance that the government will not require any additional

conservation activities on your part and that the government will stand with you as a defendant if somebody tries to bring a third party case against you. We'll hold up the permit and say, Your Honor, that was exactly the kind of take we were anticipating when we issued the permit.

So, Mark, I'd be happy to talk a little more and try to get a better understanding of what additional incentives you're talking about.

DR. WHALON: Basically, what it is is that on reading the process -- and you can't have every grower involved in those eight meetings that have gone on and the kind of trust that we've built around a habitat restoration plan. But getting specific growers involved who are affected or could be affected or just in habitat that could be converted, to move forward, they are so afraid when they read the Endangered Species Act, that there's nothing about incentives anywhere in that Federal piece of legislation.

So, what you may say from here in Washington versus a guy on the ground in Mason County, Michigan, is a lot of worlds apart. So, somehow, if we really care

about biodiversity and about saving species in affected areas where agriculture and private lands are involved, we've got to incent growers to do it.

MS. EDWARDS: Cindy.

MS. BAKER: Cindy Baker with Galon (phonetic). I'll try to go quickly. I'm sorry I didn't think in order of cards. I'll try to do better at that next time.

It just seems to me in listening to the comments from all different stakeholders here that there's a very common theme in that we don't know what you don't know, what you need, and we don't -- and at least I don't understand completely the process. I don't know what's in like your template development for ecological risk assessments. I don't know what all the inputs are to PRZM/EXAMS.

I don't know where the many opportunities might be for users and people out in the university system that might understand very well what's going on with some of these species and habitats and can provide information. I don't know how to -- what kind of a process to put in place so that these people can bring this information into the Agency.

I mean, I think we saw it in dietary risk assessments early on and FQPA getting that information in and how much it helped. Worker risk assessments understanding what are the actual activities that people are doing, what are some of the mitigation things that you can do.

It just seems to me that this is another area that's right to have some kind of a forum where you sit down and say, here's the information that we don't have that we're trying to put into our risk assessments. Here's what we do with the information that we have when we have a risk assessments, the assumptions that we make, and what we do. And here's the areas that, you know, we need.

I mean, it seems like in all risk assessments, something drives them. What's driving these? It might be different in different cases. But if people had a better understanding, I think, of how you're doing it and where the opportunities were to provide more refined information or look at more refined risk assessment methodology or whatever it might be, that we might be able to bring some of that information and it isn't all

falling on two people at Fish and Wildlife and limited resources here, because I suspect it's there.

MS. EDWARDS: Thank you. Dan?

MR. BOTTS: Dan Botts, Florida Fruit and Vegetable Association. The conversation around the table has been absolutely amazing. I have to go back to historical perspective because some of us predate most of the people sitting around this table that have been involved in this back to the '87 cluster analysis.

In Florida, we sat down and did exactly what Mark is talking about. This is not a condemnation of national offices or anything else, but we were more effective in the dialoguing and negotiation about determining exactly what needed to be done to protect the listed species that were identified in that process in Florida working with the regional office of U.S. Fish and Wildlife than we were with any other group in this process.

We engaged the environmental community, the natural areas inventory, state regulatory agencies, our Department of Agriculture, and we worked through a process over about 18 months, from biological basis --

came up with a program that we felt was protected. At the end of that program, probably the most positive outcome was the fact that the people that we had never worked with in the past before, which was U.S. Fish and Wildlife, were on our side.

They wanted agriculture to stay in Florida because it was more protected than even what the state land management people could do through private landowner agreements and other things to protect the species to work at conservation easement and similar types of programs and plans that you have.

Quite frankly, we're still scared to death of this bulletin process because of the broad brush aspect that's created there and especially some of the potential enforcement problems and issues that we see in a requirement where -- and this is unfair to the registrants but they put one statement on their label, this product may impact endangered species, check your endangered species bulletin at county's (inaudible).

I'm a grower in Florida who purchases products for a tomato operation that moves from one end of the -- the south end of the state of Florida all the way to the

Chesapeake Bay in Virginia. I purchased that product one time in the fall of the year for a whole season's work. Am I bound by the bulletins that were in place at the time I bought that product or am I bound by the bulletin that I need to look at every morning before I go out and spray it to determine if, in fact, in all the geographical locations that I'm farming the restrictions might have changed?

From an enforcement standpoint, how do I know when I've been protected and what do I have to do as a grower to document the fact that I've done what the Agency thinks they're doing to be protective in this process.

So, it's not a real simple click one button and you're covered kind of issue. Those are the kinds of details that I think need to be further discussed in a dialogue group or something as this process moves forward to determine how you can actually get to some of the issues of once you institute these mitigation steps, are they effective and are they working? Thank you.

MS. WILLIAMS: Thanks, Dan. I respect the concerns you have. I think we've actually in other forum

maybe you were unable to participate in, addressed some of them, certainly not all of them, but issues relative to, you know, planning for pesticide applications so that growers aren't in positions where they've purchased a product and then the rules changed on them.

We've addressed issues with the system itself that were raised some time ago and we're in the process of addressing our situations where somebody isn't applying just because they own property in a county, but they're applying across counties, even across states. I think this actually was raised in the context of like chermiticide (phonetic) companies but would apply to the situation you're talking about as well.

We're putting a feature into the system that allows a person to go in and look at for a pesticide what are all the counties in which there are limitations, rather than going into their 3,000 county bulletins to find out if there are limitations.

So, I think some of the kind of process issues that you're raising, and implementation issues that you're raising, we have thought about, we have or are addressing. Again, that doesn't certainly mean that

we've addressed all of them. Clearly, we recognize we still have issues to address or we wouldn't be asking everybody's input at this point.

So, I'm looking forward to further dialogue and, hopefully, in the not too distant future, some other kind of forum, whether it be a facilitated forum or something more focused on the science where we ask specific questions of certain entities to help us move this along further. Thanks.

MS. EDWARDS: Thanks, Arty, and Don, and thanks to all of you. That was an excellent exchange, a lot of ideas thrown around. I think it's obvious that this may be our most challenging area right now in the pesticide program.

The concept of regulating to an extraordinarily local level from a Federal seat and when it involves two agencies, three agencies, it just couldn't get more complicated. In addition, there's large challenges around information, both the collection of it and the management of it. Obviously, you heard some of the resource challenges that we have.

So, we will be looking for additional ways to

dialogue on this, obviously. Our mission, our vision and our goal is to come into compliance with the Endangered Species Act. It's not that we don't want to. We'd like to do so very much. It's that we don't like to run this program and we haven't ever had to through lawsuits. We don't want this to devolve into that sort of a management process here.

It does, as someone mentioned, take away from our ability to have a robust public participation process when our work is managed that way. So, in between, in addition to any dialogue that we might convene in the future to address this, which obviously will involve the public, I would challenge all of you as you think about this, as you know people that have good ideas, to write them down and send them to us. We would be happy to read any and all ideas on how we might be able to improve this process. So, we're looking to you. You're the experts in the field, at least in your sector. So, we'd love to hear from you on this.

I wanted to move now to just spend a little bit of time on what we'll be doing for the next meeting. First of all, I'd like to announce the dates, October 8th

and 9th. It will be here in Potomac Yards, same place.

At that meeting, I think what we will want to do is have some workgroup reports out just on where we are, in particular, what we've been able to start up with the workgroup on 21st century toxicology and web labeling. We want to get those workgroups started soon. At that point, that will only be six months from now, I think it would be useful to have them come back. You'll be able to know who is on the workgroup and exactly what sort of a work plan has been developed around both of those.

Then, in terms of topics, there has been a number of things discussed in the last two days. I think -- let me just let you know what some of my notes are. I think obviously late yesterday afternoon at minimum some of you might like to hear what the government is doing and how EPA is participating in that with respect to the pesticides and pollinators.

So, we'll at least have a presentation on that and where we're going on that. We will look into whether we should have representation there. Make sure we get the right people invited, in any event.

We've heard today that you'd like to have some more breakdown reporting on how we're spending some of our money in PESP, PSEP, IPM Pipe, in the government, in general, know about the NAS surveys, just in general more on PRIA funding and use for contracts and grants. And then, you'd like a pretty robust breakdown of our outcome measures.

There was a lot of discussion on that today for OP's, carbamates, human health, water quality, farm worker incidents, and so on and so forth. I'm guessing from the conversation today there might be some interested in a future dialogue here on ESA. I found it to be very productive today with some interesting ideas. So, that's obviously an option.

And then, I would like to broach a topic that actually wasn't discussed here but I'd like for you to think about it as a possibility as we begin to develop our agenda. I think all of us know there's a lot going on out in the retail sector and even with the industry about wanting to be able to make distinctions between pesticide products with respect to their safety.

There's been a lot of talk about -- you've

heard of design for the environment. Some companies have approached us about possibly having -- to be able to classify their products based on the ingredients within them. For example, it's designed for the environment so that people can make some choices in the consumer market.

There are also various independent green labeling initiatives going on. There are large retail box stores, Wal Mart, here today looking for ways to provide or to make choices about what products they offer in their stores. That's based again on ingredients. There's a lot of this going on. There's a lot of interest in it out in the public.

What we're wondering is, what should the government role be in this? Should we make any distinctions of that sort between the products? Should we help facilitate this? Even if we don't, should we allow those plethora of logos and so forth that might exist to be on the products? Should we allow advertising around that that have those -- they've met some sort of criteria? For example, should products that can be sold at Wal Mart be able to say, and we can be sold at Wal Mart, we meet their criteria? There's a lot going on

about this. So, I am wondering whether or not it might be useful at the next meeting to have some presentations around what's going on with that and then possibly some workgroup formation.

So, with those ideas on the table, I wanted to open it up maybe for the next -- up until noon just to get some of your ideas.

MR. TAMAYO: Dave Tamayo, CASPA (phonetic). I think that the last idea that you brought up would be of great interest to us. So, I think that's something I'd like to participate in.

You might guess that I'd be very interested in some sort of discussion and also presentation by staff about what the Agency is doing to reconcile the problems that we're being subjected to because of inconsistencies between Office of Water and the Clean Water Act and your office, you know, in particular the issues about water quality criteria and how those are adopted, or not adopted, and the compliance monitoring that we're subjected to, and how you can make your registration review processes more protective of, you know, the receiving waters that we're held responsible for, and

looking into some of the tools that you might be able to do that with, modeling the types of species that are used to determine the environmental facts.

Really, I'd also really like to find out what the -- more detail on the regulatory basis for how those decisions are made, whether it's in regulation, whether there's things that are just done on a policy basis, whether there's some statutory things that just get in the way of being able to reconcile those two things.

Also, I'd really like to have some sort of a discussion about how the risk benefit is done on products that are approved for use in not necessarily just urban areas but -- I think it's a different animal in urban areas because you don't -- it's harder to establish what the economic benefits are for certain types of uses.

You know, we'd like to see how mitigation measures can be brought in to the registration decisions and consideration of what the alternatives are, whether it's another chemical or whether there are cultural or biological practices or structural practices that can make it so that even if you change what use patterns are available for particular chemicals, there's still a way

to deal with the pest management means.

MS. EDWARDS: Go back to Cindy now and then go down the table.

MS. BAKER: Just a couple of ideas. I can't remember right now off the top of my head one of the topics we did this for but I know we've done it before in the past. On the subject of endangered species, just because I think it's such a big topic and there would be such an opportunity, I think, for dialogue and more presentations about what you're doing and where the holes are, you might set it up that we have a workshop the day before.

I know we've done that for those big topics before, so maybe on the 7th those who are interested and want to hear that come in and there's some sort of a workshop that you hold to walk through some of those things for us.

Then, the other topic that we had some conversation about that I think would also be valuable to get an update on is the performance measures. Wasn't it Sherry who was doing that? I think in addition to the stuff that Jennifer and some of the other folks raised,

there was also, you know what's the impact been out there in the world for users as well. So, Mark or someone else might bring some input into that as well.

UNIDENTIFIED MALE: Just to add to what you said, Debbie, about this whole issue about environmentally friendly and green (inaudible), I mean, it's just such a hot issue for the guys that I represent. Just two thoughts.

One, I'd just like to ask that you kind of expand the category to include the kinds of things that service providers, applicators, can say and do, to the extent that you can.

Secondly, related to that, I don't know if you had this in mind, but it's such a hot topic and so timely that from my point of view it would be useful, even though it hasn't been fully keyed up as an issue here, it would be useful to actually put together a workgroup in advance of the next meeting and actually start the process now and not wait until October.

MS. EDWARDS: Okay. As we go around, I'd like to hear from other people on that as well.

JIM: Thanks, Debbie. Well, obviously, I would

strongly endorse the PPDC for forming a workgroup and looking at environmental labeling such as DSE. I think it's critically important to be able to provide consumers with some sort of meaningful distinction, at least types of products at shelf.

I think government can play a role in ensuring that those distinctions are, in fact, meaningful to consumers. Obviously, you know, to meet this, the labeling scheme has to be regulated to some extent. If it's left unregulated, I believe strongly that the types of claims you'd see on shelf would be essentially meaningless. So, I think that you do have a very important role to play in that respect.

As for forming a workgroup prior to the next meeting, I, along with Bob, would say this is an extremely hot topic and I would endorse that approach as well.

Two other things for the next meeting that I would propose. I'd like to hear what the Agency is doing with respect to the GHS program. I think it would be timely to have an update on GHS. I'm concerned about it, so I'd at least like to have a progress report on that.

The other thing that I'm a little concerned about and perhaps we could do a little bit deeper dive in the next meeting is this 13,000 products, end use products, that are left to be re-registered through the re-registration program.

From my perspective as a formulator, the heavy lifting and the re-registration program is just beginning. I cannot see -- and perhaps I don't have -- I'm not thinking about this correctly, but I don't see how the Agency is going to have the resources to process 13,000 applications for re-registration in the next upcoming two to three years. I just don't see how it's going to happen. But I know there's a lot of them coming and I'd like to understand a little bit better about how -- you know, what the Agency's plan is for tackling that endeavor.

UNIDENTIFIED MALE: I'm taking a second shot here. I wanted to support what Bob Rosenberg said about including a discussion about what the pest control industry can say and do. We did run into that issue. It was very important to us in California. I think that we at least made a regulatory change that hopefully

addressed it. It remains to be seen what sort of complications. But that is a very important thing.

I also wanted to add on the types of things that I wanted to be discussed about the water quality, I'm very interested in how that might potentially -- our interests, how those might potentially impact other people here who either like with Bob's industry or the vector control and how folks who are involved in IPN can help inform and participate in development of alternatives.

So, I'm really glad -- just from the discussions that we've had here, I think that this is a great forum to talk about that sort of thing. So, thank you.

DR. ROBERTS: Jimmy Roberts, Medical University of South Carolina. As folks have said at the table, I also strongly agree that we should talk about the idea of distributing the different products and labeling or classifying products for the environment. I'd like to extend that to also some claims that some products are safer for kids.

I get questions on a weekly basis from people

saying well, this product is labeled as a green or an organic pesticide or an organic cleaner or other kinds of products and is that safer for families. So, I'd like to definitely have that on the table. As far as a workgroup for that, I'm certainly in favor of that as well.

UNIDENTIFIED FEMALE: I'd like to thank you for a very good meeting. I think it's been very efficiently run and I didn't realize how much I had missed hearing Carolyn Brickey sneeze. So, I thank Carolyn.

A few things. As far as the secondary certification, there's a lot going on with the retailers and so forth. Another thing along those lines is this national standard for sustainability. I think it would be very interesting to hear what the Agency's thoughts are on that and maybe some external stakeholders, just the pros and cons. Where did the existing risk assessments fit in with something like that? There's a whole array of controversy out there about these programs, and confusion. So, that is a suggestion.

Also, just as a vehicle for information back to EPA, at our last meeting we had, you guys assigned some little subgroups to present on e-labels and different

perspectives. I thought that that was a very good way to bring information back in a concise and efficient format for the discussion group and also for you guys. So, I would recommend that as much as you can do that, I think that people appreciated that format.

Then, the third thing, I do believe that a workshop or some sort of supplemental technical briefing on ESA would be very helpful. If we could incorporate some real world examples from stakeholders, not hour long presentations but some overviews of real world situations and how they're being resolved or addressed, that would be very helpful.

UNIDENTIFIED FEMALE: Let's see, a couple of ideas. On the topic of the kind of green certification and labeling, it might be worth -- there are some cities who are already doing this for their own city program. San Francisco is, Palo Alto is, and Seattle is. It might be worth you guys talking to them to see, you know -- they might be able to share some of their ideas and it might be -- I mean, they've actually got a working system now.

Then, there's also in the Bay area, there's the

eco-wise certification for services. So, these kinds of things are being implemented in various places kind of independently. So, you might get some ideas by talking to them. I can hook you up with the right people if you want.

The other idea that I'm interested in and I think a lot of us in the area -- working in the area of protecting public health and the environment is how we can beef up EPA's role in enforcement, because we have such diverse state systems. I think it would be interesting to see this discussed in the context of the (inaudible) labels that are going to be extremely complex.

The enforcement to make that happen is actually key to success of mitigating risks. There doesn't seem to be a good system in place in many states to do that. So, I think a discussion about how EPA could help beef up enforcement, help the states, would be a really useful discussion to have.

MS. EDWARDS: Thanks. Gary.

GARY: Yes. I, too, support the concepts of discussing the labeling. You're hearing from many people

here that it's much broader than just what you brought up there. So, let's keep it broad.

But one question I want to bring up, or a consideration probably more than anything else, is how much is this regulatory and how much is legislative? If it is legislative, probably any -- you should have a representative from OGC involved in this one from the get go so we don't spend a lot of time and effort and find out that FIFRA says no and it will take an act of Congress to change it. Thank you.

MS. EDWARDS: We don't do anything without talking to our lawyers.

Caroline.

CAROLINE: I had a couple thoughts of things that I would like to see added to the discussion about green labeling. One is -- correct me if I'm wrong, but there is a very small green labeling program right now which is that little logo that can go on the organically -- products approved for organic production.

I thought it would be useful if you could just report on how that's going and what you learned from doing that. I mean, it's not retail; it's agriculture.

But it seems like there might be a lot of kind of lessons learned there that would be helpful.

The second thing is in terms of household pesticide use and green labeling, it seems like with a lot of reduced risk products, if that's what you want to call it, a really important component is the non-pesticide modifications that go along with it.

So, if you've got a cockroach problem, you know, in addition to just trapping for cockroaches or baiting for cockroaches, there is, you know, the structural modifications of leaky pipes and ways that the cockroaches are getting in and out, and that kind of thing. I thought it would be useful if we could talk about how some of that maybe could be incorporated onto a label, especially if a label had some kind of a green icon or whatever on it.

Then, on a completely different subject, I really appreciated the update on the inerts rulemaking petition at this meeting. I wonder if we could do that again next time.

MS. EDWARDS: Okay, thank you.

MR. KEIFER: Matt Keifer, University of

Washington. Thanks for reappointing me to the PPDC. I appreciate participating in this.

One of the things that I'm interested in is the human incident data, a report that had been, I think, promised under PRIA-1. We'd like to know -- I'd like to know where we are in terms of getting that together. I know that Jerry Blundell (phonetic) is now gone. Who is doing that? How are you doing it? What data are you using to create that? It would just be nice to know the process and where you are with that to get some information on the human incidents data.

MS. EDWARDS: Okay, we will.

MS. DAVIS: Shelley Davis, Farmworker Justice Fund. Another aspect of information that we're requesting under PRIA-1 was about enforcement of -- I think that this is -- the enforcement issue is coming up currently, at least in two different contexts. One, for example -- as you are reviewing the fumigant labels, for example, the label for iotamethane (phonetic), there are a lot of complex compliance requirements which, unless they're actually enforced, are not necessarily very meaningful or protective. So, the questions of

compliance and enforcement are very much front and center.

There's also another way in which this is coming up and that is that farmworkers or agriculture is now expanding in states that hadn't previously had a lot of hand labor; for example, the southeast states like Arkansas or Louisiana. I know that EPA gives some money to these states to do worker protection standard enforcement. Yet, we're having a lot of problems getting these states to be responsive.

So, if you could focus on a session on enforcement of worker protections at large, not just the LEPS (phonetic) itself, but, you know, protections that are also embodied in the labels, that would really be helpful.

MS. EDWARDS: Okay, thank you. Next.

DR. GREEN: Tom Green from the IPM Institute. I want to second Bob's suggestion for a working group on the green certification agenda item for the next meeting, and also suggest one on the performance measure side. On that side, I think it would be great to involve theional IPM impacts task force that EPA is represented on along

with USDA and others, looking specifically at that issue, how to report on a national level, the impacts that we're having with our IPM program in agriculture.

MS. EDWARDS: Thank you.

MR. KASNIER: Dan Kasnier (phonetic), State Department of Health. I'd like to echo many of the comments earlier about environmental labeling and also about the human impacts reported. I think that would be great.

I'd like to broaden it, to some extent, to go back to the issue of whether we can discuss either at the meeting or prior to that in a briefly constituted workgroup, to look really at this question of ongoing surveillance of use and sales both in the agriculture and in the structural and urban markets for commercial and off-the-shelf products.

I think I want to make a plug for potential involvement with the Centers for Disease Control. They're environmental health tracking program is embarking on an effort to attempt to regularly track in a nationally consistent way the human health impacts that are known or trackable from pesticides which largely are

focused on the cutasecs (phonetic) and not chronic. Nonetheless, they want to do that as well as incorporate hazard related data that would draw on sales and use as well as exposure data from poison intracenters (phonetic).

So, if there is an opportunity to constitute a workgroup to talk about this or to sort of look at what's been done in the past that I may not be aware of, I'd really appreciate that.

MR. KLEIN: Phil Klein from CSPA. With regard to the Center for Disease Control, one thing that I would really like to see as a topic is insect-borne disease and what is happening in the United States. What is happening with lyme disease? What's now a virus? What are the trends? What is the (inaudible) possibly some State Departments of Health in Colorado, from Arizona where they've had some significant disease in those states?

I really believe, as an overall perspective, we need to look at what is happening in the United States and really all over the world with regard to insect-borne disease.

MS. JOHNSON: (Inaudible). I'd like to third, fourth, or fifth, or more, the proposal to put together a workshop on what I guess I'd prefer to think of as third party endorsements because it's really -- you know, it's broader than environmental or, you know, other safety kinds of claims as well. It is another party providing some kind of endorsement or some kind of qualitative assessment of a product.

I'd also like to second Jim Wallace's recommendation that we look at how the Agency in a pretty compressed period of time is going to re-register those 13,000 end use products.

UNIDENTIFIED FEMALE: I'd also like to endorse the idea of forming a workgroup on the, I guess, environmental preferable or whatever you want to call it. With that, probably -- this is also a very hot topic for the Federal Trade Commission. I was at a workshop just a few weeks ago, an all day workshop, just to talk about nothing else.

So, if we do form a workgroup, maybe even some solicit some input from the Federal Trade Commission, where they're going in this area and, you know, how

they're trying to wrap their, you know, head around -- what kinds of claims can be made? What do they mean? What is sustainable?

They're also looking at it from the standpoint of kind of separating products from packaging. So, we might want to look at that as well. What types of things you can do or say about the product versus what kinds of things can you do or say about packaging? And then, also, what kinds of things can you do or say about services? So, I think, you know, there's different aspects of this to look at.

I support Bob's idea. I think it's probably good to put a workgroup together to kind of frame this out and look at the issues before the next meeting.

UNIDENTIFIED MALE: Thank you for a very interesting and well-run meeting. On the green certification or whatever you want to call that, I think states would have harmonic cords struck with having a discussion about that. There's probably a number of states that are looking at label statements on 25b type of registrations at the state level now. That would help to focus their discussion in that area. I appreciate

that.

One other thing, too, I don't know if the PPDC has done this in their recent past, but there's been some discussion about pesticide usage information. It might be helpful to have a framed discussion about how the Agency uses pesticide usage information, where it's valuable to the Agency, where it's valuable to stakeholders and whether there's an opportunity to think about maybe a different way of obtaining that kind of information rather than the sort of piecemeal ways that we do it now.

MR. MICHAEL: Yeah, Cannon Michael. I was just thinking that it would be interesting to -- I know after the end of the meeting yesterday we were talking possibly about having it on the agenda. But something I wanted to reiterate about having the pollinator issue maybe followed a little bit more. So, I just think that's an important issue to look at going forward.

MS. EDWARDS: All right, thank you very much. We will take all these suggestions back and probably have some dialogue with you subsequent to the meeting about them. It's probably not an option to discuss all of them

in the next meeting, unless we're going to be here a couple weeks. But we want to address the ones that are of uppermost importance.

For some of them, we'll be able to provide just materials for you. In certain cases where you've just asked for additional information, we may not have to have an actual session about it. But we want to get sessions in here where we can actually have dialogue and get feedback in a meaningful way. It's sometimes a little difficult to strike a balance there. We tried to do it this time. We'd also be interested in hearing your feedback on that. You can just send your ideas to Margie.

So, again I'd like to thank all of you very much for your participation in the last few days. I think I've really learned a lot and enjoyed the meeting. I'd like to thank the workgroups that are continuing to work. There are going to be three new ones formed, so that will be exciting. Probably we'll have a -- you know, definitely have reports out from those three newly formed workgroups at the next session.

I'd like to thank the public for participating.

I'd like to definitely thank our EPA presenters. People work very hard to get these meetings together. So, I want to thank them. In particular, I'd like to thank Margie Fehrenbach and also Michele Devoe (phonetic) who is on detail in our immediate office now who did an enormous amount of work on travel logistics and so on and so forth.

(Applause)

MS. EDWARDS: I hope you have a very nice lunch and a good trip home. Thank you.

(Whereupon, the meeting was concluded.)

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