PESTICIDES: SCIENCE AND POLICY

U.S. ENVIRONMENTAL PROTECTION AGENCY

PESTICIDE PROGRAM DIALOGUE COMMITTEE MEETING

OCTOBER 17, 2007 (DAY ONE)

ARLINGTON, VIRGINIA

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A T T E N D E E S

Rebekah Freeman Adcock	American Farm Bureau Fed.
Lori A. Berger	California Minor Crops Council
Daniel Botts	Florida Fruit & Vegetable Assoc.
Joseph Conlon	American Mosquito Control Assoc.
Cannon Michael	California Cotton Growers Assoc.
Robert Rosenberg	National Pest Management Assoc.
Steve Balling	Ag Services, Del Monte Foods
Carolyn Brickey	Center for American Progress
Caroline Cox	Center for Environmental Health
Michael Fry	American Bird Conservancy
Caroline Kennedy	Defenders of Wildlife
Jennifer Sass	National Resources Defense Council
Susan Kegley	Pesticide Action Network
Shelley Davis	Farmworker Justice Fund
Amy Liebman	Migrant Clinician Network
Erik Nicholson	United Farmworkers of America
Kristie Stoick	Physicians Responsible Medicine
Cindy Baker	Exigent Company
N. Beth Carroll	Syngenta Crop Protection

Allen James	Responsible Industry/Environment
Phil Klein	Consumer Specialty Products Assoc.
Hasmukh Shah	American Chemistry Council
Julie Spagnoli	FMC Corporation
Susan Ferenc	Chemical Producers & Distributors

A T T E N D E E S (Continued)

Jay Vroom	CropLife America
Ray McAllister	CropLife America
James H. Wallace, Jr.	North Amer. Registration Section
Gary Libman	GNL Consultation Services
Matthew Keifer	Public Health & Community Medicine
James R. Roberts	Medical University of So. Carolina
Dennis Howard	Florida Agriculture/Consumer Svcs.
Mr Ellen Setting	Maryland Department of Agriculture
Rodney Marco Guske	Yakama Nation Environment Program
Jose Amador	Texas A&M
Amy Brown	University of Maryland
Larry Elworth	Center/Agricultural Partnerships
Robert Holm	IR-4 Project
Carol Ramsay	Washington State University
Patrick Quinn	The Accord Group
John D. Schell	BBL Sciences
Richard Colbert	EPA

Allen Jennings	USDA
Melody Kawamoto	Center for Disease Control
Nancy Golden	U.S. Fish & Wildlife Service
Nega Beru	FDA
Mike Bussell	EPA

I N D E X

OPENING REMARKS

MR. GULLIFORD: Good morning. I know that the discussions that occur amongst members of PPDC and those that attend are very important, but we're going to get started. So, I'll give you all 10 more seconds to grab coffee, grab chairs.

Let me start by introducing myself. My name is Jim Gulliford, I'm the Assistant Administrator for the Office of Prevention of Pesticides and Toxic Substances. Welcome to the PPDC meeting. It=s a pleasure to see you all, to see everyone represented. We certainly do thank you for the interest that you have in the activities of OPP. The information and the perspectives that you bring to the discussion, all that is very welcomed.

As you know, this is our -- PPDC is our FACA, our FACA Committee, which is designed under the FACA law to assure that the Agency gets a breadth of perspective and information on important issues to the Agency, to OPP. That, obviously, then, we incorporate into the decision-making process that we have.

As you also know, it=s important that we receive a breadth of perspectives. We understand that there are differences of opinion amongst participants, amongst people in the room, including not only members, but those of the public that are observing and want an opportunity to comment at a certain point in time, that=s good.

We appreciate the fact that those different perspectives are offered in a respectful way and that we also have an opportunity to be informed, not only as an Agency but you folks as members, as well.

A number of things that we=re working on, as well, at the work group process level, we also appreciate those of you that invest, again, beyond just the FACA participation in some of our work groups. We found it helpful to, again, some of the issues require more in-depth, more time, more complete discussion, if you will, on your part, and those of you who have an interest in that

and have participated in those, particularly issues like Spray Drift. Some of our worker risk, worker protection issues, as we=ve been working to develop the registration review process, again, we=re grateful for that assistance, as well.

The Agency clearly is committed to the FACA process. I want to mention that in about 50 minutes the Agency will be announcing the Agency=s first ever national -- well, excuse me, a new Agency-wide FACA on ag issues. Last year, as you may be aware, that the Administrator announced the Agency=s first ever national strategy for agriculture. And, as part of that, one of the goals -- one of the objectives -- that was key to that was to develop a strong interface with the interests of agriculture to assure again that the Agency would be well informed on those ag issues.

So, later this morning the Agency will be announcing what we=re going to call the Farm, Ranch and Rural Communities Advisory Committee, which will also be a backup. And that this Committee, again, will seek to advise the Agency on issues as they=re brought to the FACA from an agricultural interest perspective and from agricultural points of view, and that there will soon be an

announcement asking for interest in about 25 Committee members representing, again, that full breadth and diversity of American agricultural issues.

Three very important issues that they believe that this FACA will address initially are climate change and renewable energy, from the agricultural perspective; environmental strategy for livestock operations; and, then, the development of a constructive approach to advancing sustainable agriculture and protection of the environment.

One of our objectives, we believe, again, that PPDC has been a very productive and very effective FACA and source or information for OPP. Our intention is to continue this FACA and to maintain these functional areas -- the areas that you folks have been working on within this FACA.

So, we hope that -- and we expect, I should say -- that these two FACAs will complement each other and that they will not result in any type of overlap in our process.

And we=ll do that, again, by ensuring that each FACA understands the charges and the interests and questions and the issues that the Agency wants them to address.

For my purposes today, again, I want to thank you

all for coming, whether you just crossed the river, crossed the street, or whether you come from across the country, again, we welcome you today; we appreciate your participation.

I=m going to stay through the first session on Spray Drift. I=ll be available during the break, if there are things that we need to talk about individually, and, then, I=m going to move on to other issues that I have to take care of today.

But, again, know that, as I said, we appreciate your interest, we appreciate your participation and your respectful delivery of comments that are very important for you to make and for us to hear.

So, with that I=m going to turn it over to Debbie for a little bit of the introductory activities, and then we=ll get underway.

So, Debbie?

MS. EDWARDS: Okay, thank you, Jim. Good morning, again, I=m Debbie Edwards, and I=m the Director of the Pesticide Program. I want to welcome you all and to reiterate Jim=s welcome.

I also would like to draw your attention to what you have in front of you. This is your Pesticide Program=s

Strategic Plan Place Mat.

(Group laughter).

MS. EDWARDS: So, this is something we=re providing to all of our employees and providing some training along with it. Much of the information here was worked through with this FACA work group in developing our strategic plan and our measures and goals. So, I hope you=ll take it with you and let us know if you want more copies. We=d be happy to provide them.

As many of you know, our charter and memberships for this Committee will expire in November, and we=re in the process of renewing that charter for another two-year term and are working through the new membership development for the FACA.

Before I get into discussing the agenda, which I intend to go over in a minute, I wanted to take just a few moments to publicly express this Agency=s sadness over the loss of one of our PPDC members, that is Warren Stickle, who died just a few weeks ago. Warren has been a member of the PPDC for several years, and he made many important contributions to this Committee. He worked tirelessly to represent his constituencies and we will miss him very much.

I think we have a solid and meaningful agenda for the next couple of days. We have included more than the usual number of updates because we wanted to cover many of the topics that you requested we cover.

After I review the agenda, briefly, I=m going to provide an opportunity to go around the room so everyone can introduce themselves, as usual.

So, I=m going to ask you now to actually pull out the agenda, which I intend to go through.

(Participants comply).

MS. EDWARDS: Okay, Session I, this morning, will be a joint presentation between the Office of Pesticide Programs and the Office of Water regarding the EPA=s plan for addressing the recommendations of the Spray Drift work group.

This work group put an enormous amount of effort into deliberating on the issues, and we=re pleased to have very good stakeholder involvement; recognizing that we did not have consensus on all of the issues.

I=d like to welcome our colleagues from the Office of Water to the meeting. As you may recall, the Office of Pesticide Programs and the Office of Water have been working very closely together on a number of areas,

including Spray Drift.

And moving on to Session Number II, where Marty Monell will provide you with the background on the new PRIA II legislation and an update regarding our budget.

Session number III, still this morning, covers several topics for which we=ll want to provide brief updates. Those are volatilization, endocrine disruptors, cause marketing and incident data sources.

We=ve allocated only a half an hour for all of these updates, but if we find you want additional discussion about any of them, we=ll try to find time at the end of the day.

Then we'll have lunch -- hopefully we'll be timely in returning from lunch -- you have an hour and 15 minutes, if we=re lucky for that.

And, then, beginning promptly at 1:15, our Fourth Session will be on web-based labeling. This is a new topic for this work group, or for this FACA. Our panel, representing several PPDC members, will make presentations, followed by a full discussion with the entire Committee.

I=m looking forward to this session, as I believe this concept could provide many stakeholder benefits,

including a reduction in the time to achieve risk mitigation in the field, cost savings and so forth.

We very much appreciate the work that=s been done on this topic by our state partners and other stakeholders in researching options for electronic submission and distribution of labeling.

Session number V will be a brief summary on Diagnostic Biomarkers, following the recent public meeting held on this topic in the past few weeks.

Sessions number VI and VII will be updates from two of the PPDC work groups -- Worker Safety and, then, the Transition Workgroup, co-chaired by our colleague Al Jennings from USDA, along with Rick Keigwin, who directs the Biological and Economic Analysis Division.

Mr. Patrick Quinn will then provide us with a brief update regarding an alternative to the Draize Eye Test, in Session VIII.

Our last session of the day is intended to cover some high-profile issues. The status of Soil Fumigant Reregistration; the Interagency Import Safety Workgroup; and an update on our overall International Activities.

So, that=s the end of today.

On Thursday, we=ll start again at 9:00, with

presentations from two of our PPDC Workgroups, the Registration Review Implementation in Session X, and the PRIA Process Improvements Workgroup in Session XI.

Then Session XII will cover a presentation on Endangered Species Status, and Session XIII will be our usual update on Registration and Reregistration, Registration Review Activities. We intend to keep these very brief and allow some time for questions.

And, finally, in Session XIV, we=ll provide you with a status of our current efforts to renew the PPDC charter, which expires next month, and our efforts to invite new membership.

Our last Session will be to plan for our Spring 2008 meeting.

At the end of each day, we=ve allocated time for public comments, so if anyone in the audience wants to make comments, please sign up at the registration table outside the room.

Now, I=d like to move to the introductions. If you=d please introduce yourself and state your affiliation. And, also, if you=re representing a PPDC member who is absent, please state your name, your affiliation and who

you=re representing. That will be helpful to us.

And, then, I believe we also have at least one person on the phone, so we=ll be sure and take care of that, as well.

We=ll start to my left.

MS. LINDSAY: I=m Anne Lindsay and I=m the Deputy Office Director for Programs in the Pesticide Program at EPA.

MR. SMITH: Burleson Smith with USDA.

MS. WIEDEMAN: Allison Wiedeman with EPA=s Office of Water.

MR. COLBERT: Rick Colbert, Office of Enforcement and Compliance Assurance in EPA.

MS. GOLDEN: Nancy Golden, U.S. Fish and Wildlife Service.

MR. MCALLISTER: Ray McAllister, with CropLife America. I=m sitting in today for AJay Vroom@.

MR. BOTTS: Dan Botts, Florida Fruit & Vegetable Association.

MR. QUINN: I=m Pat Quinn with The Accord Group.

MS. BAKER: Cindy Baker with the AGowan@ Group of Companies.

MR. HOWARD: Dennis Howard with the Florida

Department of Agriculture and representing state lead agencies.

MS. BERGER: Lori Berger, California Specialty Crop Council.

MR. FRY: I=m Michael Fry with the American Bird Conservancy.

MS. ADCOCK: Rebeckah Adcock, American Farm Bureau.

MR. LIBMAN: I=m Gary Libman, GNL Consultation Services, representing biopesticides.

MS. FERENC: Sue Ferenc with the Chemical Producers and Distributors Association.

MR. MICHAEL: Cannon Michael, National Cotton Council of the California Cotton Growers.

MS. DERR: Becky Derr, Regional X, representing Mike Bussell -- that=s EPA.

MS. RAMSAY: Carol Ramsay, Washington State University, Pesticide Education and Department of Entomology, and also the President of the Pesticide Stewardship Alliance.

DR. SHAH: Hasmukh Shah, American Chemistry Council Biocides Panel.

DR. CARROLL: Beth Carroll, Syngenta Crop

Protection.

MR. GUSKE: Marco Guske, Yakama Nation, and I represent Tribal Pesticide Program Council.

MR. CONLON: Joe Conlon of the American Mosquito Control Association.

MS. KEGLEY: Susan Kegley, Pesticide Action Network.

MR. KLEIN: Phil Klein, Consumer Specialty Products Association.

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

MS. BROWN: Amy Brown, University of Maryland, Pesticide Education and Assessment Programs, and also representing the American Association of Pesticide Safety Educators.

MR. WALLACE: And I=m Jim Wallace of S.C. Johnson.

MS. STOICK: Kristie Stoick, Physicians Committee for Responsible Medicine.

DR. ROBERTS: James Roberts, Medical University of South Carolina, Pediatrics.

MS. SPAGNOLI: Julie Spagnoli, FMC Corporation.

MR. ELWORTH: Larry Elworth, Center for Agricultural Partnerships and also my responsibility has

been delegated by Dr. Steve Balling, and unbeknownst to him, I also secured power of attorney last night.

MS. BRICKEY: Carolyn Brickey, Center for American Progress.

DR. BERU: Nega Beru, Center for Food Safety and Applied Nutrition, Food and Drug Administration.

MR. JENNINGS: Al Jennings, USDA.

MS. MONELL: Marty Monell, Deputy for Management in OPP.

MS. EDWARDS: And I believe we have someone on the phone?

MS. WHITE: Yes, this is Dawn White with Monsanto.

MS. EDWARDS: Anyone else?

MS. SCHAEFER: Pam Schaefer with Monsanto.

MS. EDWARDS: I believe Matt Keifer will be joining in later.

All right. We will start now with our first session. Anne Lindsay, our Deputy Director for Programs, and Judy Davis, Deputy Director for the Office of Wastewater Management, on Spray Drift.

SESSION I, SPRAY DRIFT/NPDES - PATH FORWARD

MS. LINDSAY: Okay. Can everybody hear me? I=m not sure how close or far I need to be from the microphone. If you can=t hear me -- up? Better? Okay. Can you hear me? Okay, we=ll try this.

Actually before -- I=m going to walk through our plan, but before I do that, I=m going to let Judy say a few introductory words from the Office of Water, and maybe we=ll figure out how to deal with the feedback while Judy

is doing a few opening remarks.

MS. DAVIS: All right, good morning. It=s very much my pleasure to be here this morning. There is one familiar face to me in the room and that=s -- you may know her as Marty Monell, but to me she will always be AMaarty@ from ABos=ton.@ So, I=m pleased to be here working with Marty again and with all the new faces.

My boss, Jim Hanlon, expresses regrets. He is in San Diego right now. It=s tough duty, but somebody=s got to do it. So, he expresses his regrets at not being here.

I=m looking forward to the interactions this morning, and I=d like to reinforce my understanding of the relationship between OPPTS and the Office of Water, and the fact that we have a very strong commitment to continue working together where the Clean Water Act and FIFRA interact. And our work plan that we=re going through today is a very fine example of that coordination, so I=m pleased to be here for that.

Jim and I appreciate all the effort that you folks have put into this FACA and into the Pesticide Spray Drift work group's final report, and we want to assure you that we will be using it. So, thank you very much for sharing your opinions and your recommendations, and I=d also like

to thank the Office of Pesticide Programs for your very dedicated effort and increasing our coordination. Thank you.

MS. LINDSAY: So, all of you on the Advisory Group have a chance this morning need to show Judy just how productive and helpful you=ve been all along on Spray Drift, because really I think this is her first public introduction to it. I=m looking forward to your engagement on the Plan.

So, with that, let=s get started. The presentation this morning is actually going to be very simple. I=m going to give a very brief background. Almost all of you, actually, do know the background about the Spray Drift Workgroup and the general issues associated with Spray Drift, but on the off chance that there=s somebody who either doesn=t feel like they=re up to speed or is actually new, like Judy, to this particular group in the discussion, I=m going to give a little bit of background. And, then, I=m simply going to walk through the recommendations that the Spray Drift Workgroup made, and as I look at each of those recommendations, briefly describe the set of actions that EPA either has already got underway or plans to get underway once this meeting is

finished and we=ve heard sort of the initial reaction of the Committee.

You=ll just see, those are the lists, under the second bullet there, those are the list of the topic areas that the Spray Drift Workgroup focused on, and I=ll be just sort of systematically marching through each of them.

You also should have in your packet, you have a copy of this presentation, but you also have a matrix, which lays out the recommendation and is almost a verbatim recommendation from the report, as well as the action, and you can follow along, either with the PowerPoint presentation or the actual matrix, whichever format works better for you. But they=re pretty much identical in terms of the information in them.

So, background. The Office of Pesticide Programs and the Office of Water established the Spray Drift Workgroup -- I think it was now about a year-and-a-half ago -- under the auspices of the Pesticide Program Dialogue Committee, in order to get input on how to mitigate risk to water from pesticide spray drift.

But, not surprisingly, is the work of the group progressed. A lot of the ideas and ultimate recommendations from the group have application not only to

water risk but more broadly to spray drift and other kinds of risk that can be associated with spray drift.

The work group, actually, from my perspective was really a very hard working group. It met multiple times in more than one-day sessions, in most cases. Also, towards the end it did a great deal of work through some intensive conference calls, including some self-facilitation of the group, and produced it -- both an on-time report and, I think, a very robust report, with a series of good recommendations for EPA. So, I need just once again to congratulate the group for the good work that they did.

So, these are the areas in which we received recommendation and, as I said, we=ve put together a plan that addresses each of the recommendations for each of the topics.

What we hope to do is to get some feedback from you during the course of this session, in the morning, and the meeting of the Committee, as a whole. And, then, after we take in that information and decide how we may want to adjust the plan, we=ll actually be refining and enriching the plan by setting priorities -- which ones come first, the pace at which we think we can conduct the different

activities. Some of them, I think, we can probably move faster than others, putting together milestone schedules and what I would call points of contact, or leads, for the individual activity. None of those are in the plan currently, by design, because what we wanted to focus on here was sort of the concept behind the planned action rather than all of the details. But those will be coming.

And, then, the other commitment that I can make for all of them is that as we progress, according to this plan, there=s going to be plenty of opportunities for outreach, for involvement by the public, probably for involvement by this group.

What those different opportunities are probably going to vary in terms of what the specific activity it. Some of them have sort of standard processes, which you=re familiar with, others we=ll have be devising them, as appropriate. But they=ll all have plenty of opportunity for discussion and involvement.

Okay, the first area that the work group focused on was to further refine the scope of their work. And the group decided to focus on labeling that could be used to mitigate spray drift; education, training and stewardship; and then practices and equipment to mitigate drift.

There were two topics that we decided were not within the purview of this group. One of them was NPDES rulemaking that the Office of Water had underway at that point. That rulemaking, as you know, is now final, and we=d like that out of this group simply because we had a notice and comment and rulemaking process underway and that was the appropriate process to be using.

And, then, the other topic was volatilization, which came up at the first meeting. I think, pretty much everybody on the group agreed that volatilization was an important issue, but the Agency decided, ultimately, that the volatilization and exposures that occur as a result of volatilization were not actually the topic of the Spray Drift Workgroup, and it was really based on the different – what I'll call physical - principles by which spray drift occurs versus volatilization. So, the volatilization was actually set aside.

There was no other recommendation from the Spray Drift Workgroup with regard to follow-up action, so we=re not proposing anything specifically here in the context of the Spray Drift Work Plan. But, as you will see from a presentation a little bit later this morning that Jack Housenger is going to make, the Agency is, actually,

undertaking work in the area of volatilization. And we wanted to bring you an update as to what we=re doing, where we are, what our plans are, so that the larger group could engage in that, and if other people want to get engaged with us, we=ll be able to do it. We=re not going to talk more about volatilization during this presentation, but we will, before the lunch break, actually be having a separate presentation on that issue.

Labeling. The first recommendation was that we did need to come back to the topic of labeling statements for spray drift mitigation. And, in particular, that we needed to try, once again, to actually develop standardized labeling statements that could be used as the basis for individual product labels.

So, what we=re proposing to do are actually several things, the first of which is we do intend to put together a draft pesticide registration notice that will be specific to spray drift labeling statements. We will be using what I think of as our standard process for developing PR notices. Once we=ve got it drafted and it has gone through the Agency internal process, we=ll be putting it out for public comment. And, then, once we get that public comment, moving to a final version, and we=ll

also include an approach to implementation.

So, I can say even though there are not time frames associated at this point with doing this PR notice, but this will be, I think, one of the higher priority activities in the whole plan, and something that we would propose to get working on very quickly.

In doing that, I think we=re obviously going to be drawing on the discussions that the Workgroup itself had, a lot of which is actually reported in the text of the report. I think we would be looking to the work that our state partners have done. AAPCO has actually given us some specific guidance as to what they think might be appropriate.

I think we would actually look at our past efforts in this area -- where we were at that time, what we learned through the comment process, as well as what we=re learning as we look at individual pesticides where drift may be an issue.

That=s the first proposed action.

The second, which is sort of an internal companion piece, is to actually put together a standard operating procedure for when we would explicitly consider spray drift in doing a risk assessment associated with specific

pesticides. This would cover both human health, as well as environmental and ecological concerns, and would probably be done in tandem with the development of the PR notice.

We think in this way we will achieve a greater consistency in our approach to risk assessment, as it concerns spray drift.

Finally -- well, not finally, but the third element is that OW and OPP will also be developing another internal process that will allow us to coordinate, on the review for spray drift labeling-- as I=m envisioning this right now -- it=s not going to be each and every individual label, because, frankly, I don=t think it would be an efficient use of everybody=s resources -- but a version of how, when we=re looking at changes with spray drift --

(Brief pause in proceedings to adjust microphone system.)

MS. LINDSAY: So, we=ll be developing an internal coordination process between the Office of Water and Pesticides to make sure that when we=re looking at unique and important spray drift labeling statements, whether it=s for a particular pesticide or it=s generic, we=re actually coordinating up front as opposed to trying to fix the problem at the back-end, after we=ve got labeling in place

that=s guiding how people use the products.

And, then, finally, we also think that it may be valuable to develop guidance for state lead agencies and tribes that would be appropriate as a companion piece to implementing new spray drift labeling.

This is very much one of these things that=s a new concept. There would be, I think, a lot of details as to what this guidance might cover that would need to be worked out. I think OPP believes that this is definitely something that we would need to be doing in partnership with our state lead agencies and our tribal colleagues, because they=re the folks out in the fields who would actually have to deal with new spray drift labeling, as well as for some period of time existing spray drift labeling, but it might cover such things as how do you actually conduct an investigation? How do you build a case, if you actually think that there is a case to be built, because you think there may have been a violation of the spray drift labeling that was on a particular product?

It could encompass a lot of other things, but I think it=s one way in which we can try to achieve what I would call -- not an identicality from state-to-state,

because there=s a lot of variation and variety that needs to be taken into account, but a way to bring some consistency to our in-field approaches to making sure that the spray drift labeling is actually working.

The Spray Drift Workgroup also had a much farther reaching recommendation to step back and take a close look at labeling, not just spray drift labeling but the entire pesticide label. To look at format, to look at structure, to look at text, placement, and the Agency has decided that that=s a good recommendation and that, in fact, we do want to develop a more systematic approach to improve the quality of pesticide labeling.

And, this afternoon, you=re actually -- Debbie has already talked about it -- there=s going to be a presentation by the Agency and a small panel of this Committee on ideas for pursuing a web-based approach to pesticide labeling for the future, and we actually think that this web-based approach may offer some real opportunities for addressing some of the, what I=ll call, quality issues that the Spray Drift Workgroup identified in the course of doing their business. So, that=s our initial or our first recommendation or action in response to that recommendation.

And, then, the second proposed action is that we heard from the group that we ought to find a way to bring other kinds of technical expertise into our decisions about label statements prior to actually putting label statements on products. An example would be for aerial applicators who have a great deal of technical expertise, obviously, about aerial application of pesticides and how to write labeling so it actually achieved the intended affect of the labeling, as opposed to inadvertently putting limitations on our aerial applicators that might, in fact, lead to greater drift occurring rather than mitigating it as much as possible.

So, we=re going to be investigating options for a generic process that would allow stakeholder review of key label statements. This is similar to what I just talked about with regard to the Office of Water, but it=s for external stakeholders. While I mentioned aerial applicators as a concrete example of this, the process would not be limited to aerial applicators.

Carolyn?

MS. BRICKEY: Yeah, a minute ago you mentioned quality --

MS. LINDSAY: Um-hmm.

MS. BRICKEY: -- statement? I think you used the word quality statement in a label. Is that what I heard?

MS. LINDSAY: If I did, then, I was confused. I=m trying to say that we=re looking at a number of different things to improve the quality of labeling.

MS. BRICKEY: Oh, okay.

MS. LINDSAY: Okay?

MS. BRICKEY: Because I was going to ask whether you meant qualitative, because that=s some of the problems that we=ve found in the labels.

MS. LINDSAY: Well, that -- qualitative would be included, but I was trying to talk about improving label quality --

MS. BRICKEY: Okay.

MS. LINDSAY: -- and I probably misspoke. Okay?

Then there was a recommendation that Federal funding of programs for education, training and stewardship should be continued or, ideally, expanded. And, actually, thanks to PRIA II, I think we have some good news here, and Marty is going to be talking about this right after the spray drift discussion, I believe. So, I=m not going to go further into PRIA II.

But what we=re proposing here is essentially --

it=s a yes. We intend to continue our efforts towards education, training and stewardship. We=ll be using the funding that we=ve got to do that.

We are specifically going to go back and look at existing spray drift mitigation training, and think about mechanisms that we could use to evaluate the effectiveness of training. We actually think that there=s a fair amount of training out there, some of which has actually been funded by EPA over the years, others have been put together by other organizations and groups, but we are going to see if we=ve got a mechanism for judging its effectiveness, and, either, where we find that it needs to be improved, then how we would go about upgrading it or plugging gaps, if there are gaps in the training that could usefully be plugged.

We think that we=ll continue to be providing updates on our efforts to enhance training. We can do it through this advisory group, as appropriate, but we also have a lot of other mechanisms; for example, earlier this month we had a workshop and a lot of that workshop was devoted to a variety of training and stewardship efforts associated with worker safety.

So, we=ll be using just a bunch of different

mechanisms to provide what we think are appropriate updates. And we=re open to suggestions about other ways of doing that.

We also want to explore how we might promote the voluntary use of site-specific drift management plans. During the course of the Workgroup, we had a presentation from the State of Michigan about a drift management plan that they were putting into place -- a voluntary program in Michigan. I know that a number of people on the group itself talked about sort of what I would call voluntary plans that they used as they conduct their business, as an applicator, and we actually think there may be some value in encouraging the use of these sort of site-specific drift management plans. But we want to explore that and sort of see how that might unfold.

And, then, finally, we think that it would be useful, also, to develop something that=s intended for the general public, a Citizen=s Guide for Spray Drift. It would have, I think, an educational function, which is just to provide some basic facts about spray drift, but it would also, I think, go ahead and tell somebody if you felt that you had been exposed to a pesticide through spray drift, what you can do to assure yourself either that you=re

actually not harmed by that spray drift or that you have appropriate recourse if you may, in fact, have experienced harm due to the spray drift. So, it=s intended to be for the general public.

The next recommendation was that we continue the support of our Drift Reduction Technology project, and we are, in fact, doing it in the packet that you=ve got on the table. You=ll find a one-pager that is just a short summary of where we are with that project. We=ve actually made quite a lot of progress, and because of the accomplishments and the progress we=ve made in this Fiscal Year, I think next year we=re really going to be ready to start testing the initial technologies, that volunteered themselves for testing. And, then, hopefully later in the course of that year, begin testing -- more broad testing of technologies as the industries who develop the technologies decide that they want to do that, and maybe even to explore -- I=m looking at Jay to see if he=s making faces at me -- maybe even towards the end of ‘08, to begin looking at labeling for products that would be appropriate to change to reflect what we now know about individual technologies and their reliability in terms of reducing the amount of spray drift.

We also will, in this arena, work with other both domestic agencies, foreign agencies and organizations on kind of a standard-setting approach for technologies. We=ve been working for some time with PMRA and we=ve got some ideas about how we might enhance our efforts to work with Canada. We will be exploring with California how we might join forces with their work in this arena to promote better drift reduction technologies.

And, then, internationally the Organization for Economic Cooperation and Development is actually starting an activity in this arena, and we intend to be active players there.

Okay. This was one of those areas where the group had a lot of debate, back and forth, and had no recommendation. What we believe is that as we work on this draft Spray Drift Pesticide Registration Notice, the Agency is going to have to give some thought about design standards versus performance standards and what might be an appropriate balance. And we=ll be taking a cut on that in the proposed or the draft PR notice that we=ll put out for comment, and then we=ll see what kind of comments we get and be informed by those as to where we pursue it for a final PR notice.

Here we had kind of a broad recommendation. I think people on the group felt that it was appropriate to tailor regulatory restrictions to meet local conditions, and so the recommendation was that we work with states and applicators to explore mechanisms that tailor regulatory requirements to local conditions.

We=re proposing in this arena, we=ve already got work underway with the Office of Water to coordinate our FIFRA efforts, particularly in our Registration Review Program, where we will be looking at chemicals that are on the market, to coordinate that with our TMDL Programs and, more specifically, to try to pull into our registration reviews of individual chemicals monitoring data that may be available as a result of the TMDL Programs, and to use that in our re-evaluation action.

So, we=ve gotten existing standard operating procedures in place and functioning, and we intend to continue using that. And I expect over time that that will actually lead to changes and improvements in the coordination effort, but that=s something that will be a learning experience that comes out of our registration review process.

We also think that it is relevant for us to go

back and look at what we=ve really learned from the regulatory action that we took involving atrazine, which was, in effect, an effort to tailor restrictions to local conditions. It was a fairly novel approach for us, using our FIFRA authorities to do this, and we want to be able to go back and look at how that=s operating, both because we need to do that for atrazine, but also because we think there may well be learning lessons from that that can be adapted to other situations. And, so, that will be one of the internal assessments that we=ll be doing over time.

We also would like to have some exploratory discussions with state lead agencies and tribes about their thoughts as to how can we better address local conditions at the Federal level without becoming overly prescriptive and causing problems from doing that, and what mechanisms might be appropriate for doing that.

And, then, finally, in one of the sessions of the Spray Drift Workgroup, people talked quite a bit about Best Management Practices, and we would like to explore with folks the idea of Best Management Practices and possibly come up with a pilot program, which could be done either, I think, on a regional basis or a crop basis, to see if there=s value in Best Management Practices, would we want

to expand it? So that would be an exploratory activity.

Okay. This recommendation was also a very broad recommendation, it asked us to strengthen the collection, use and public availability of information regarding real-world effects of our regulatory approaches and, in particular, of labeling.

You=re going to have a presentation later this morning, I think right before lunch, that Lindsay Moose is going to do. We=ve been doing some initial inventorying and assessment of the existing incident data systems that we have, and we view that as a starting place and would expect that probably in future PPDC meetings and other venues, we=ll be coming back with proposals for improving the role of incident information in our regulatory system. But we=re going to be actually starting on this morning, with Lindsay=s presentation.

And, then, the other one that we think is responsive to this recommendation is the one that I=ve already mentioned, but our web-based approach to pursuing systematic labeling improvements. And we think that this will actually enable us to get feedback on user response to labeling.

This was a recommendation, which I=ve actually

heard from other quarters as well, particularly AAPCO and SFIREG, but basically to develop water criteria, or more water quality criteria, for current use pesticides that could then actually be used by the states as water quality standards. And, then, also to continue or expand resources for monitoring of current pesticides in water bodies.

We=ve been working for some time, through AAPCO and SFIREG with the state pesticide programs and with all of the offices in the Office of Water to identify high priority pesticides for consideration by OW as candidates for the next round of water quality criteria development, and that=s something that we will be continuing to do -- coordinating with OW and figuring out how we can support the development of water quality benchmarks. So, it=s an ongoing activity that we think is important.

Likewise, where there are risk management actions and decisions around particular pesticides that can really affect water quality, we=ll be continuing to work together. I think we already feel like we have a very robust working relationship as a result of some real dedicated effort over the last couple of years between our two programs. I like to think of it as a model of Agency collaboration, and we expect that that will continue.

And, then, finally, we will continue to make our own OPP aquatic risk assessment and benchmarks values of pesticides available for potential use by State water regulators and other State officials to help in their monitoring activities. That=s a process we started in the last year and will just be ongoing.

And that=s it. I think now -- I may actually stay up here, I guess, since this doesn=t do the feedback. I think we=re open for discussion from the group. And if you=ll just use your cards to indicate that you want to talk.

Okay, Julie?

MS. SPAGNOLI: Has there been any thought to how the labeling changes would be implemented? I mean, you=re going to issue a PR notice and then is it going to be, you know, by each, like, certain use patterns, or how are they -- is it going to be by amendment, is it going to be by notification? I guess, it=s just that when you look at these broad-scale label changes, you know, how do you do it fairly and equitably and, I guess, efficiently?

MS. LINDSAY: Actually, you=ve just articulated a lot of the things that we=ll have to think about so that the short answer is no, we=ve not developed the

implementation approach, which means that it is good, first off, to remind us that we need to think about that carefully, but if people have particular ideas about ways that would be better, would be more effective in actually getting it accomplished, with the least amount of resources involved on everybody=s part, that would actually be very helpful to us.

But when the draft PR notice is available for public comment, it will at least sketch out what we have in mind and, hopefully, will provide us with some good feedback about the best way to really accomplish it.

So, I think, if you don=t mind, I might just go around the table, because I=ve already lost track of which one of you put your card up. So, if I don=t see any objection, I=ll go down from Julie, so I guess that gets me to Carolyn?

MS. BRICKEY: I wanted to make a comment about the development of water quality criteria. I would love, in the actions that you=re going to take relative to that recommendation, that there would be like a timeline with a commitment to how many water quality criteria are going to get developed by what date. You know, at this point, if you look at the number of water quality criteria versus the

number of currently used pesticides that are often found in water, there=s -- there really is a problem there, and I would love to see that on a schedule to be addressed, with, you know, kind of a firm commitment about how much can be accomplished in what time period.

UNIDENTIFIED FEMALE: Thank you, I appreciate that. Certainly there are hundreds of ones we need to look at and we need to prioritize them and think about how to schedule them and how much we can do then. Thank you.

UNIDENTIFIED FEMALE: You might have said this and I missed it, but what=s your time frame for doing the draft PR notice? When do you expect to release that?

MS. LINDSAY: (No audible response.)

MS. DAVIS: I=ve got three issues I want to raise really quickly. The first one leads to the -- is kind of an implementation follow-up, but it=s on the enforcement side -- I know you mentioned that you=re going to work with your state stakeholders, but I want to have a sense of how specific, how nitty-gritty are you going to get, because in our review of violations in California, for example, where, you know, there really are investigations, there=s a pretty wide variability by how much drift constituted a violation and when it didn=t. And I know from talking with various

other State agencies that there=s a lot of variation around the board about this.

You had talked about design -- I=m not really sure what that means -- and performance standards, but I think that you need to develop guidelines for the state which gives them a very clear idea of how much drift constitutes a violation -- however you=re going to measure it.

So, my first question -- should I just give the three or one at a time?

(No audible response.)

MS. DAVIS: Very good. The second thing is I want to know how the fumigant IRED, re-registration or registration, I=m not sure, as to the process they=re going through. But if you=re going through a review of fumigants right now and obviously part of the issue with fumigants is drift. I don=t know how much of that falls into volatilzation, but we=re very concerned about the amount of the fumigant material that enters into the community. In other words, that goes offsite, and I=d like to know how that=s going to fit into this process.

And, thirdly, as you think about improving labeling in general, which I=m very in favor of and would like to have some input into, I really urge you -- and I

know I've said this a thousand times -- but please put on a date on these labels very near to the top, not the top, because one of the things that we have seen when we talk to growers is they=ll say, I've applied chlorypyrifos for years – you mean the label has changed?

So, folks do not know the label has changed unless the date of the label is so clear that it hits them in the face. So, please, make that something you do.

MS. LINDSAY: Okay. I=m back on. Let me take the last question first. I think when we get into the presentation on web-based labeling, one of the things that we think it is possible -- one of the real benefits -- is actually to deal with the issue of what I would call the currency of the label to both bring changes into place more quickly, but also to try to make sure that the user is actually using the most current label, and, if they=re not, to actually enable that to be an enforcement tool for our states. That if you wanted to see a current example of that, it would be similar, I think, to the way that we envision the endangered species bulletins working. So they would have a currency for six months, and after that a user would be expected to go back and make sure that they either had the current information for the label or not. So, I=m

expecting we=ll probably get some comment on that both this afternoon and as we develop the web-based labeling.

Shelly, if you don=t mind, we=ve actually got a discussion at the end of the day, a whole session on fumigants, and I think that that would be a good place to generally talk about fumigants.

And, then, on stakeholder involvement on this guidance for states, I think you=re actually -- Rick Colbert wants to answer it before I do, so I=m going to turn it over to Rick.

MR. COLBERT: (No audible reply.)

MS. LINDSAY: Well, I think you=re raising good questions. We=ve not actually sat down and talked with either AAPCO or with the Tribes about what might be in the guidance -- what might be the process that we would use to develop it, but I personally see a lot of value in getting some stakeholder input in appropriate ways. So, Rick.

MR. COLBERT: Yeah, I=m glad you asked the question, because one of the things that I wanted to get out of this discussion is what expectations, besides the one you just mentioned, do you all have that would be pinned to this guidance to States and Tribes in terms of implementation, and you raised one point.

I would say that we=ll need to look at that issue. It=ll depend a lot upon what is the violative act and what the labeling actually says, that will help go a long way in answering that question. But I think you want -- I think you=re trying to go a little further into that, which is basically the Agency=s expectations in terms of what it takes to be drift. And, again, I think that will be one that will come out in the PR Notice and what the proposed labeling change is.

MS. DAVIS: Just a quick follow-up which is that -- when the PR notice comes out I'll obviously comment -- but if you are going to invite some kind of stakeholder committee, could you include farm workers and other public interest folks?

MS. LINDSAY: I think if we have any kind of a process like that, we=ll be looking at appropriate representation from pretty much anyone who is interested and has something to offer. So, yes.

UNIDENTIFIED FEMALE: I just wanted a couple of clarifications on the SOP that you mentioned. I don=t believe that we have heard that there is going to be one of those yet. This is the first time I=ve heard about it. I knew about the PR Notice, but the SOP is a little

different. And since it says it specifically addresses risk assessments, I=m wondering how much do you see it differing from how risk assessments are done for spray drift currently?

MS. LINDSAY: Okay. Can you hear me now? Okay. What we want to do, Beth, is actually take a look at what I would call our current set of internal practices. I think we=ve already got bits and pieces of this in place. We may have bigger bits and pieces than the term Abits and pieces@ implies, and what we want to do is to put it all together. If we see gaps, if we see that because we have not actually had internal written SOPs in this area, that we=ve not been as consistent as we think we should be, then we=ll be filling those gaps.

I guess at this point in time I=m not expecting this to be a major change or shift, but until you actually go in and take a look at how you=re currently conducting your business, you=re probably never 100 percent sure of what you=re going to find and what it is that you need to do.

UNIDENTIFIED FEMALE: Thanks, Anne. And, then, just a follow-up question on your incident data and that kind of thing. I=d like to see some terminology in there

about transparency, because when we look at what comes back on our risk assessments and we try to evaluate, you know, what actually was turned in, it=s very, very difficult to determine how EPA evaluated what they term an incident and whether it was moderate, medium -- I forget all the terminology that you use -- but we can=t tell that, you know, now. And, so, if you=re going to use incident data to evaluate whether drift mitigation is actually working or not, this has got to be looked at very, very transparently and probably differently than it=s been looked at in the past few years.

And I would just also point out that in your document, your matrix document, you still have in that section the word 'harm,' and I think we needed to go back to recognize that FIFRA states de minimis risk.

MS. LINDSAY: Okay. I, actually, on the incident data and transparency, in looking through the materials for this meeting, I was looking at the materials on registration review, and I think we actually got a very similar comment about needing to be more transparent with the incident data that we were using, not just for spray drift but more broadly. So, I think that=s a good bit of advice, which we=re already trying to incorporate that in

the way we=re doing registration review.

Dennis Howard, I think you=re next.

MR. HOWARD: Thank you. Well, I=d just like to start by thanking the Agency for taking the PPDC=s recommendations to heart and working in so many different directions to try to meet some of the recommendations that we arrived at. It reflects a lot of work on the Agency=s part, and at least from a state lead agency perspective, I appreciate it.

I have a couple of questions on both the local conditions having some forms of restrictions, regulatory approaches and local conditions. And, then, also, on the pursuit of drift management plans in site-specific areas.

And I wondered if you could elaborate on both of those a little bit, on what the Agency has in mind on the two of those. Presumably the local regulatory side of things -- are you looking primarily at restrictions that would apply to water quality or would you be thinking about other types of parameters?

MS. LINDSAY: The focus of the Workgroup in these recommendations was with regard to water quality, but I think as we sort of explore, is there something better we can do at the Federal label that allows the use of the

pesticide to be tailored to meet local conditions?

If we find that those are fruitful discussions and that there are things that we can be doing there, I don=t think they necessarily have to be limited to water quality.

MR. HOWARD: You said that they don=t necessarily need to be limited to water quality?

MS. LINDSAY: No.

MR. HOWARD: That could be a starting point?

MS. LINDSAY: That could be a starting point, just because you can=t do everything all at once.

And, then, drift management plans? In my mind, the first thing that I actually want to do is gather a little more systematic information about who currently has drift management plans. Are there other states who are doing something similar to what we heard from the State of Michigan?

NAAA, for example, the Aerial Applicators Association, do they have essentially what I would call a model management plan for their applicators or do individual applicators have essentially their plan, so that when they know they=re getting ready to actually get up and apply a pesticide, they=ve gone through all of the standard things that they should be doing?

We=d like to find out more about what is actually out there. And, then, based on that, decide is there something that EPA could do to promote the use of that kind of thing. I=m looking at it as almost kind of like a self-administered tool where you ask yourself, have I done all the right things before I actually apply?

You could also think about it in terms of enforcement officials. Am I, in my investigation, doing all the things that I ought to be doing in the right way to consistently collect information. And there could even be some correspondence between the sort of standard approach that an applicator might use to ensure that they=re doing things correctly versus what a State Inspector might use when they=re looking at the situation post-application or during application.

So, that=s the concept. But I think this is one of those places where we said explore or discuss. And what that really is code for is we don=t know yet real specifically what we might do, but we would like to start having some systematic discussions.

MR. HOWARD: I just had, quickly, a comment. I=m sure that AAPCO and SFIREG would be very anxious to talk with the Agency as you go through the development of these

processes. And one area, in particular, you mentioned the Office of Water and OPP working together on key label statements. I think that might be an area where participation early on by state lead agencies might be able to head off some problems that we would see in the field, otherwise.

Thank you.

MS. LINDSAY: Okay, thanks. Ray?

MR. MCALLISTER: The very narrow list of issues that the Workgroup was able to achieve consensus on, there=s ample evidence that many, if not most, of the issues are still quite controversial. And I think I would encourage the Agency to proceed as quickly as possible in development of the PR Notice and to get some policy guidance out there for all of the stakeholders involved.

I think you=re going to find, to no one=s surprise, that some issues can be resolved, others are going to take quite a bit of effort, and I hope that you don=t allow difficulty with some of these paralyze progress on other issues. You may find it necessary to acknowledge that some issues will take more time to address while going ahead and issuing policy on a more limited set of issues.

MS. LINDSAY: Okay, I think that=s practical

advice, and I think that=s our typical strategy with most of the issues that we deal with is to try to make progress, and if something is too hard, to figure out how to -- not to drop it but to keep on moving while we work the harder issues.

So, thanks.

Larry?

MR. ELWORTH: On the issue of the systematic comprehensive approach to pesticide labeling, we actually had some very lengthy but productive discussions about that. So, as you begin to implement this approach, it would be really useful to at least cycle back through either the Workgroup or some other consummate work group to get their view of what you=re doing as far as you start to move on labeling improvements. Because we had some really good ideas.

The other thing is, I think that I, and many of the rest of us, realize that there are a lot of other people who are going to be using these labels, and in addition, there=s going to be people who see ways of getting some reality testing. Did what we came up with in the room actually mean that somebody is using the pesticides how we thought, the way we initially suggested

it?

And I had one other thing I wanted to mention to Office of Water, and that is, as you=re doing various things in coordination with the Agency, with OPP, my observation is that OPP has, in this forum and in a lot of other forums, an awful lot of ways of getting to people that are affected by these regulations. And, so, to the extent that you need to use OPP=s mechanisms to go back out to stakeholders or in cooperation with OPP go out and contact the stakeholders on your own, that would be a very productive way of doing anything like the water quality criteria and things like that.

MS. LINDSAY: Debbie has reminded me that we have about two more minutes in this session, so good thoughts, Larry, and I=m sure as we work on all of these labeling issues that the Spray Drift Workgroup is officially finished, and you=ve all been returned to your normal pursuits, but we will be looking for ways to run things back through, definitely.

MR. GUSKE: Thank you. In my little niche out on the Yakama Reservation, I see things maybe from a closer-to-the-ground level, and one of the things I see out there is when growers read a label they look to see how much to

put on. Sometimes they look at what PPE needs to go on, sometimes they don=t.

And it=s really concerning for me when I see people loading out there without gloves, without goggles, without a respirator, without anything, like it=s nothing. And, you know, a lot of these people, when they go to get their continuing education hours, go to the local chemical company and they=re going to be introduced to all the new chemistries, and a lot of the times they don=t get this information. What is the new technology? What is going on on the Endangered Species Act?

On the other hand, if they go to other trainings, like Washington State puts on, it=s great information. A lot of times the growers will make this stuff and there needs, you know, in my opinion -- and I don=t know a whole lot about C&T, there needs to be some way to get these growers into this other level of classes where they can be introduced to this information.

MS. LINDSAY: Okay. And I think, actually, we will be looking at those kinds of issues.

Carol?

MS. RAMSEY: First, I want to thank Marco. He=s usually at one of my training programs.

Just to follow up with Larry=s comment on kind of a group to deal with these issues, I=d like to mention that the Pesticide Stewardship Alliance does have a conference in February on the 24th through the 27th that does have two days of drift management discussion as part of that conference. And, so, I would like to think that the Pesticide Stewardship Alliance can kind of serve the -- potentially serve the role of the old National Coalition on Drift Minimization, where you have a contingent of a wide group of stakeholders to be able to discuss these issues to further some of the Spray Drift Workgroup=s efforts.

MS. LINDSAY: Yeah, I=m glad you mentioned that, because that is one of the venues that OPP is looking at for moving some of this work forward.

I think with that, with everybody who wanted to comment had a chance, and I=ll turn the floor back over to Debbie.

MS. EDWARDS: Okay, thank you, Anne, and that was a very good session. And, now, what we will do is have a 15-minute break, so by my watch you should be back at around 10:33. Hopefully we=ll have these microphones figured out by then, thank you.

(Whereupon, there was a 15-minute break in the

proceedings.)

MS. EDWARDS: Well, we hope we have this under control now and that our microphones will work well. We=re going to move now to Session II, which is the PRIA II and Budget Outlook, presented by Marty Monell, our Deputy Director for Management.

SESSION II, PRIA II AND BUDGET OUTLOOK

MS. MONELL: Thank you very much. I have a good news story this morning, so those of you that are concerned

about EPA resources, OPP resources, this is a very good news story.

I=m going to start by just briefly talking about our >08 appropriation -- we don=t have one yet. We are among those many Federal Agencies that are operating under a Continuing Resolution that will be in existence until the middle of November. Our >07 budget, we got a percentage of our >07 allocation for the Office of Pesticide Programs. It was a little under $135 million. The >08 President=s budget, in both versions, in the House and Senate, pretty much allowed for that amount again, as an appropriation. So, with that appropriated and the fees that have recently been enacted and signed into law by the President, I think we=re going to be in decent shape to not only run our programs sufficiently but to provide for the varying kinds of interests that we want to fund.

PRIA II was the product of an incredible coalition, co-chaired by Phil Klein, who is with us today, and Steve Goldberg from BASF. But you=ll see here a list of all of the stakeholders that actively participated in the coalition and the work towards the enactment of PRIA II.

The highlights of PRIA II actually is going to be

the subject of my presentation. Some of the things that have not changed, I=ll just run through really quickly and try to just focus on the things that are new.

The President signed the bill on October 9th, it had a retroactive application, I think, everyone expected it to be passed well in advance of October 1st, but it wasn=t, so when it was signed into law by the President on the 9th, it became effective October 1st.

The two types of fees, again, there=s enhanced registration service fees and the maintenance fees.

The maintenance fees have historically --

UNIDENTIFIED MALE: (Inaudible question.)

MS. MONELL: Oh, if you don=t know it, there are copies of my slides -- of my presentation -- on the left side of your folder.

Maintenance fees have historically provided funding for our re-registration, our old chemical program, to a limited degree, and now they will continue to support re-registration, that would be the completion of our non-food use pesticide as well as product re-registration, the ultimate goal of registration eligibility decision.

And, then, under PRIA II, we=re very fortunate that we are able to use these maintenance fees for our

registration review program, which is going to be our ultimate re-evaluation, our old chemical program.

PRIA II also, in consideration for allowing the maintenance fees to be utilized for registration review, we also have a change from the goal of FTPA to have existing pesticides reviewed every 15 years, it is now a statutory mandate that we provide this review every 15 years. It puts a little bit more teeth and a little more pressure on us, but we have some funding -- a steady, reliable funding source with which to accomplish that.

Slide 5: The amount of the maintenance fees will be $22 million each year for five years. It=s very helpful for us to know that we=ve got this amount of money and we can do some effective planning, hopefully, with that amount of money.

The original, PRIA, if you recall, provided for some front-loading of maintenance fees so that we would be able to meet the FTPA tolerance assessment deadlines. And, then, there was a gradual phasing out of those fees. But now we have another five years of guaranteed funding in this area, and that should help us enormously.

The original PRIA registration service fees, which were imposed as a way to enhance service, not to be a fully

funded fee-for-service program, but to enhance the risk, provide time lines for registrants so that they would be able to know when to expect action on an application, and to provide a percentage of funding for the registration activities in the pesticide program.

PRIA II implementation will occur as of October 1st, and we have put up in the web, I=m happy to report, as of this morning, an updated website -- a webpage -- that actually includes a decision tree. So, if an applicant goes onto the website, they can go through a process of questions and answers that will help them determine which of the 140 categories is applicable for their application. And, then, determine the appropriate amount of the fee accordingly. There=s a lot of information that we=ve had to put together on an incredibly short time frame, but hopefully it=s very useful. We did run a little pilot of it through some folks a couple of weeks ago, and they thought it was helpful. Hopefully we=ve ironed out some of the bugs. There are definitions of the various categories up there, as well.

The legislation, PRIA II also continues the prohibition on the Agency collecting any other form of registration fee, as well as prohibition against imposing

and collecting tolerance fees -- separate tolerance fees -- through 2012.

As I mentioned, the time frames and the categories have gone from 90 categories to 140 categories. And this was the result of three full years of experience under the original PRIA and the realization that we hadn=t captured everything; fine tuning some of the existing categories; and, then, including some other categories where the Agency had expended a lot of time and resources to do the work, but we had not been able to collect any fees for the work because they just weren=t one of the original categories.

So, some of those categories of protocols that generally involve the more complex studies; study waivers, applicant-initiated refined eco/endangered species assessments, uncleared inerts. Again, this would be registrant-initiated actions.

Time frames further reduced for the reduced risk applications, initially under PRIA, for instance, a food use reduced risk application would get a four-month reduced time frame, now it=s reduced even further to six months, if it=s reduced risk. So, further encouragement to register reduced-risk products.

Fee payments: Essentially under the initial PRIA

we were able to collect fees up front, but we decided not to. We thought it would just be too confusing for everyone to try to figure out how much they owed, so we initiated an invoice system so that registrants would submit an application, we=d figure out what it was, what category it was, and then send an invoice for the fee amount.

This time, we=re not going to do that; we=re going to expect the fee to be paid with the submission of the application. And that=s why this decision tree is particularly important because it helps you not only determine what your category is, it also advises what the fee amount is.

So, we understand that this is going to be a learning process for everyone, and we are implementing it -- right now, we=re still invoicing people, because we just got the website up, the decision tree up there, but our plan is by the end of the month that everyone will be providing evidence of the fee having been paid at the time that they submit their application.

More to come. If there is a request for a small business, the waiver request must include 25 percent of the fee -- this is new. Historically small business waivers have been up to 100 percent. The Coalition decided that

perhaps we would get better applications if everyone had to pay a little something. So, the 25 percent minimum applies to almost everything, and we=ll get to the exceptions in a minute.

The additional fees may be billed. If, for instance, the applicant submits a registration with the incomplete amount or wrong amount or the wrong category, if the waiver request is denied, then we=ll invoice the applicant for the fee, and if it turns out that there=s just a total fee category and inappropriate fee submitted, then we=ll invoice for the proper amount in the proper category.

We will refund money if too much is paid, but 25 percent of every fee is nonrefundable, with the exception of two exemptions.

If an applicant is rejected by the Agency, we will keep 25 percent of the fee.

There=s a new provision that enables us to collect fees if they=re not paid within 30 days. This is like any other debt owed the Government, the IRS, for instance. It=s a debit to the Government if you don=t pay your taxes on time, and this provision of the law allows you to collect. Well, we now have that authority, as well.

I think I=ve talked about the interim invoicing.

The small businesses, this waiver is a little bit different. If the registrant or the applicant provides documentation that demonstrates it qualifies as a small business; in other words, the annual global gross pesticide revenues is less than $10 million, they get a 75 percent waiver. Again, everybody has to pay the first 25 percent except the exemptions.

And, then, for those with less than $60 million in annual global gross pesticide revenues, it can be a 50 percent waiver.

So, that=s a little bit different. It used to be 100 percent and 50 percent; now it=s 75 percent and 50 percent.

Other waivers: Historically IR-4 applications that have come in in conjunction with an IR-4 petition have been waived, the full fee has been waived. There was a minor, technical era and we=re working that. It will be resolved; the IR-4 applications in conjunction with IR-4 petitions will be exempt.

Minor uses: Same situation applies as is currently under PRIA.

And, then, the other entities that are totally

exempt are Agencies of the Federal and State Government.

If an application is withdrawn within 60 days of the submission, 75 percent of the fee is refunded; if it=s withdrawn after the 60-day time period, we make a determination as to how much work has been completed already on that application. There is a formula and sort of our process by which we make those decisions across all of the registering divisions, on the website, and there is a link to that site in the materials.

And, then, the determination of the amount of the refund must be made within 90 days of the withdrawal of the application.

The baseline protection is now in -- oh, I turned it off myself (microphone off) -- the full period of the effectiveness of PRIA II, meaning that we cannot assess fees if the amount of our appropriation falls more than 3 percent less than the 2002 appropriation for OPP. What that means is our appropriation cannot fall below $122 million in order for us to continue to collect fees. We watch that very closely.

The decision time review period begins 21 days after we=ve received the fee payment and the application. Again, we will not be invoicing; we expect and hope that we

will receive the fee or the 25 percent of the fee, in the case of a waiver request, at the time of the submission.

We will be performing a more rigorous screening initially at the front end to make sure that it contains all of the appropriate forms, data, draft labeling -- in accordance with out guidance, the A-65, among others. If it does not pass the initial screening within that 21-day period, we will be rejecting it and we will have 10 days to notify you.

The intent is of both the legislation and the program is that we will work very hard with you to try to get that fixed, corrected, whatever needs to be corrected, within those first 21 days, but if it isn=t -- if it does not happen -- then we will be rejecting and we keep 25 percent of the fee.

And, then, the time frames can be -- this is consistent with the original PRIA -- can be extended by both parties agreeing to a negotiated due date.

For the judicial review provisions, they appear to be exactly the same as the initial PRIA; in other words, if for new Als and new uses, if the time frames are exceeded by more than two years, then the judicial review possibility kicks in. You have to be more than two years

late. I can=t imagine such a thing, but that=s what the provision allows. The registrant must have requested a meeting with the administrator -- with the Agency -- four months prior to petitioning for judicial review. And the other provisions in that regard remain the same.

Worker Protection: And the various set-asides I will say, obviously, are the result of some significant negotiating and compromising with the Coalition members. We had worker protection set-aside in the original PRIA, that has increased substantially. It talks now about approximately 1/17th of the fees collected to be dedicated to worker protection activities. It now has a floor of $1 million. So, in no event can the amount set aside for worker protection activities fall below $1 million, and those specific uses for that $1 million are to enhance scientific and regulatory activities.

The other initiatives listed here are worker protection, but really they=re not totally worker protection oriented. They are partnership grants -- this is new. This is a new set-aside, if you will. For the first two years, it=s $750,000; for the remaining three years, it=s $500,000.

EPA/OPP has had a partnership program, if you

will, and we expect to be able to enhance that program significantly with this steady funding stream. That will be primarily organized out of the BBPD, the division that now handles the partnership plans.

There is also additional funding for the Pesticide Safety Education Program, and this is what Anne alluded to earlier this morning, where we have a set amount of $500,000 a year set aside to enhance those activities. That pot of money, if you will, will be handled by Bill Diamond=s shop, that=s the Fee, Field and External Affairs Division.

And, then, PRIA II also provides for continued process improvements. We=re going to be hearing from that group, the PRIA Process Improvement Workgroup, under the auspices of PPDC. I think tomorrow morning there=s going to be a report out on that, so I won=t go into that. But we still are required to do that.

No good deed goes unpunished. We have an enormous number of reporting requirements under PRIA II. I guess beware what you ask for. We have our usual accounting responsibilities to the EPA Office of Inspector General, that continues on. And, believe me, they do a very detailed review of every action and every penny that comes

in and leaves, the PRIA Fee Account.

The annual reports -- and I think it=s worthwhile our running through these -- because you=ll see that we really are to be held accountable for the funding that we receive, which is -- this has not changed significantly -- but the number of applications reviewed and the decision time frame; the name of label amendments reviewed using electronic means. Now, you=re going to hear later today about our use of label reviews by electronic means, and I think the program as a whole has really advanced significantly in this area.

The amount of monies from the registration and the expedited processing fund. This is the maintenance fees. We call it the FIFRA fund -- this is the official statutory name for that fund -- and the amount of money that we use to carry out inerts and similar application reviews.

There=s a little over $3 million dedicated to the review of inerts and we choose out of the maintenance fee part of money.

And, then, the number of applications completed for identical or substantially similar applications, and the number of those that are completed within 90 days.

We must report on the number of actions pending in

each covered category, including new inert petitions. You can see the legacy of Warren Stickle is a little flag throughout these reports.

Progress made in meeting time line requirements; description of the staffing and resource applications to support our decision-making for covered actions -- that=s in the registration side.

And, then, we=re to include, as appropriate, recommendations for the expansion of self-certification; accreditation of outside reviewers; broadening the scope of the notifications process; electronic submission and review of labels; and use of acute toxicity study summaries.

And there is clarifying language on the floor of the House, I believe, that made it very clear that this is not to Aencourage@ the use of acute tox summaries, but, rather, for the Agency to report if we have any recommendations; if we have any feelings one way or another about this issue. Right now, we do not rely solely on acute tox. They may be sent in, but we get the full data and review the full data sets.

We are to report on the use of performance-based contracts. We=re to report on the progress of registration review. This is consistent with our being able to utilize

maintenance fees for registration review, and that we must meet the 15-year deadline.

They want to know the number of pesticide and pesticide cases reviewed annually; the staffing and cost related to re-registration and registration review. As I mentioned earlier, this maintenance fee fund is to be utilized for our completion of the nonfood-use REDs, product re-registration, relabeling -- all of the post-RED work that needs to be done -- we=re to be reporting on that activity and the amount of resources that we utilize out of the maintenance fees towards that.

And, then, we=re to provide recommendations for process improvements in handling registration review, much the same as we report on process improvements for the handling of getting things on the market. We will be reporting recommendations for process improvements in registration review activities; our recommendations for accreditation of outside reviewers -- again, similar to registration; and streamlining the whole registration review process.

We also have to report on the time lines for antimicrobials under 3(h). We must report on the review of inert ingredients, with several different criteria; and all

of these reports are due March 1st of each year. And what we have elected to do is put them on the web. It=s probably the most efficient way of getting them to the broadest spectrum of interested stakeholder.

So, if you=ve ever looked at our annual report, it is quite lengthy; it=s full of great information, and when I read it I=m always amazed at what we are able to accomplish in a year, and we=ll be reporting even more now.

The phase out is similar to the original PRIA except the dates have changed, and the sun sets in 2012, at the end of the fiscal year. And, then, for the first year of the phase out, the fees are reduced by 40 percent, and the last year of the statute, it phases out by 70 percent -- this is to enable us to glide down resources.

And, you=re going to hear more about what we=ve done in terms of implementation, but we have already -- we took a chance and invested -- about two months ago -- on some IT systems so that should this be passed -- we said when this is passed -- we would be able to accommodate the new categories -- the additional 50 categories -- and the additional numbering of categories and the fees associated with those categories, we would be able to handle those

internally without having to resource to paper. We=ve done that.

And, then, the website, the information has been updated. I encourage you to take a look at it and provide a feedback on it. That would be very helpful -- is it confusing? Is it easy to navigate? Particularly the decision tree piece. We=re working with the Coalition to have a workshop in November to get down into the weeds of implementation activities. And then, as always, we=re willing and anxious to work with trade associations and other groups that are interested in any part of implementation of PRIA II.

I went really fast, if you have any questions, go ahead. I=m from Boston, we talk fast.

Okay, Larry.

MR. ELWORTH: I have a question and I=ll ask it real slowly. Where does all of this work get done within the Agency? Because there=s a lot of transaction work. Does it happen in each of the individual divisions or does it happen in registration?

MS. MONELL: Could you give me an example of what you=re talking about?

MR. ELWORTH: Well, okay, you=re talking about

doing all of the reporting, you=re talking about getting back to people in 21 days, where does that -- who does that? I mean, you don=t just have people sitting around with nothing to do and say, oh, can you help me with PRIA for awhile?

MS. MONELL: No, no. Actually, with the original PRIA, we identified each of the registering divisions --

MR. ELWORTH: Okay.

MS. MONELL: -- has an expert -- expert in the fee categories and it could be the kinds of things that the division needs in order to process an application. That expert group still will meet and they will be the ones responsible for identifying completeness of packages --

MR. ELWORTH: All the administrative pieces?

MS. MONELL: The initial administrative stuff, exactly.

MR. ELWORTH: Okay. And do they track that all the way through the -- do those experts continue with the tracking?

MS. MONELL: No. They, then -- it=s tracking through OPEN, which is to become PRISM, okay?

MR. ELWORTH: Okay.

MS. MONELL: Then it gets passed off to the PM, as

appropriate, and the PM, then, is responsible for following it through.

MR. ELWORTH: What percentage of the cost and time involved in implementing PRIA or PRIA II is transaction costs versus the scientific reviews?

MS. MONELL: About 25 percent.

MR. ELWORTH: Really? Okay.

MS. MONELL: It was very high -- actually, it=s even higher than that in many instances, because we had a -- part of the thing we do is we have monthly meetings with the Coalition, and we provide as much data as possible on what we=re experiencing. And, so, for instance, we had a lot of negotiated due dates. What that means is that for whatever reason that we don=t have sufficient data, we don=t have the proper formatting, we have a number of issues with the particular package: registrant may have tried to provide us with he information, maybe it didn=t come in in time to meet the initial PRIA deadline. We compile all the data around that activity and found that product chemistry issues, for instance, is the number one cause for negotiating due dates. There=s a number of other issues that we identified.

So, when you calculate how much is involved in the

negotiating all of the Astuff,@ beyond just the in-processing and the review by the experts, it comes out to about 25 percent, if not a little higher.

MR. ELWORTH: And that comes out of the fees, as well?

MS. MONELL: It will now, yes.

MR. ELWORTH: Thank you.

MS. MONELL: Yes, Amy.

MS. BROWN: First, I=d like to thank the Coalition and EPA for ensuring that some of the direction that members of the PPDC have given and that EPA has said before that pesticide safety education programs are very important to help achieve some of the goals that this committee finds important. So, I=d like to thank them for ensuring that that will happen.

And I have a couple of questions: On the bill for worker protection, is the worker protection going to be considered in the strict sense as far as the worker protection standard or is that sort of all pesticide workers? Has that been identified yet?

MS. MONELL: I=m going to defer to Phil Klein from the Coalition on that question, but my understanding is the initial set-aside for worker protection was specifically to

enhance ongoing worker protection activities. I believe that is the same -- with more money -- but with the same sort of idea for its use.

MR. KLEIN: That is correct.

MS. BROWN: So, it will be limited to Greenhouse, Forest Farm -- the existing --

MR. KLEIN: The existing programs.

MS. BROWN: -- definitions of who is a worker?

MR. KLEIN: That is correct.

MS. BROWN: Okay.

MR. KLEIN: The floor just simply has moved up from $750,000 to $1 million.

MS. BROWN: Okay. All right. And for the PCEPT support, do you know yet what form that will take? Whether that will be competitive grants or pass-through or --

MS. MONELL: We don=t know. Remember this was just assigned to us on October 9th. It=s very early, and, you know, I would refer to the feed folks on that, but I suspect -- it=s only been a week, so that will be discussed amongst them.

MS. BROWN: Well, either way, I think you=ll get some good products out of it.

MS. MONELL: Um-hmm.

MS. BROWN: Thank you.

MS. MONELL: Okay. Phil?

MR. KLEIN: I guess I just want to make a couple of comments. One, PRIA II could not have passed without NRDC and Heather Taylor=s efforts and John Brickey=s efforts. The industry group -- I=ve worked with both the environmental committee and the farm worker group -- and I think it=s been a great team effort.

But I want to also make another comment. When we first brought PRIA up on Capitol Hill, there were a lot of people saying to the different industry lobbyists that, you=re out of your mind putting the kind of fees you=re talking about -- over $200 million, around $200 million -- but we wanted a predictable system. And I must say that I think Marty, your implementation of PRIA, with Elizabeth and Rick and all the people within OPP, I think the fact that you=ve implemented it so well, that the way we had developed PRIA was based on the fees. Actually, in the year >08, maintenance fees were supposed to go down to $15 million.

But I think all the industry groups, from Sue to Ray to Jay to Allen to Bio, you know, we saw that the implementation of PRIA was done so well, and I think the

environmental community felt it was done very, very well, that we were able to get together and meet before it phased down and then put the stable funding into EPA.

So, I think there was a lot of great work by the EPA staff of making sure that the implementation was done well. Often, on legislative issues, it=s easier to pass but it=s harder to implement it. It=s never easy to pass something, but with environmentalists and farm workers and the industry working together, we were able to pass it. The tough part was really the implementation, and I think you guys should really commend yourselves internally for the excellent job that you=ve done.

MS. MONELL: Thank you. Susan?

MS. KEGLEY: Let=s see -- I=m not infinitely familiar with PRIA, so some of this might be a dumb question, but streamlining to keep things less burdensome for everyone often makes more sense, and I guess what I=m worried about is that I don=t see places for peer review and public review in the new registration processes that we had with FTPA, and while those might have taken more time, it=s certainly your better science and better public understanding of what EPA is doing and what the new products were.

So, I guess I=m wondering how that is being dealt with now under PRIA.

MS. MONELL: I would defer to the Coalition Chair for that.

(Group laughter.)

MS. MONELL: Well, I think it=s a subject that obviously that was discussed or not discussed during your deliberations on the enactment of PRIA.

UNIDENTIFIED MALE: I think one of the things with the development of PRIA, at least from where the environmental community was, was we don=t want anything with regard to A through Z of what industry is required to do to be circumvented to make the streamlined process.

So, basically, nothing was changed with EPA=s processing other than some possible improvements. But before PRIA I was passed, if industry or an applicant was supposed to do A through Z, nothing changed on that.

What, really, PRIA is is a funding package to provide and make sure there are enough FTEs and there=s enough stable funding at EPA to do the job. And, then, to have deadlines and decision time lines. Unfortunately, because of the President=s budget, EPA=s hands were somewhat tied, but they were able to provide technical

support to us to make sure that these decision time lines weren=t so fast that things would get short-circuited.

So, we were able to get in there and get technical guidance and, then, as you saw in Marty=s presentation, there are 140 different categories and EPA would provide a lot of technical support to make sure that those time lines weren=t so fast that EPA couldn=t do the job.

MS. MONELL: I think another Coalition representative wants to weigh in on that. Carolyn Brickey.

MS. BRICKEY: I just wanted to say that there are periodic meetings with EPA that they tell us about way in advance, and the people that participated, including me and NRDC and some other folks, are invited to all those meetings, and we can participate either in person or by phone.

So, we=re pretty much kept up to speed on how implementation is being done and whether it, you know, there=s any issues with regard to implementation itself.

MS. MONELL: Okay.

UNIDENTIFIED MALE: With respect to the peer review, under FQPA the peer review, in tolerance reassessment, was developed, and it=s a mature process now. And in registration review, which is the ongoing effort

for all of the chemicals that are registered, I believe it=s significantly enhanced the opportunity for outside review and input into the registration review program.

There dockets are established for every chemical; there=s the opportunity for multiple stages of input from stakeholders.

MS. BEGLEY: But not for new chemicals?

UNIDENTIFIED MALE: There never has been that opportunity ahead on registration on a new chemical.

MS. BEGLEY: That=s the point.

UNIDENTIFIED MALE: Well, there=s a notice of filing, yeah, yeah, there are Federal Register notices involved there.

MS. MONELL: Phil, did you want to --

MR. KLEIN: You might want to mention the docketing and the provision with regard to docketing that was put in on the 45 days with regard to registration review. I don=t think that solves your question but, you know, again, I think it=s a very transparent process.

MS. MONELL: Do you want to turn your mic on?

UNIDENTIFIED FEMALE: I mean, there is a process for when new tolerances are established, it=s in the Federal Register, there=s a notification of that, there=s

opportunities for comment. I mean, it=s not just existing actions that have opportunities for people to comment. It also occurs for new registrations and new uses and stuff.

MS. MONELL: Yes, I=m sorry, go ahead.

MS. DAVIS: It is our understanding that when new chemicals are put forward -- new active ingredients put forward for registration -- that the public comments, you know, the five-day process they=re all familiar with for new registration, does not kick in, or any kind of equivalent process.

I think it was one of the great contributions, really, of our advisory committee. And I=m not sure if it was TRAC or PPDC or what incarnation of it developed the five-part process, but I think it introduced a very valuable opportunity systematically for the public to weigh in.

Obviously it is more difficult with new active ingredients because, you know, less is known, you=re in a more rapid time frame under PRIA, et cetera, but it absolutely seems to me that we must have public input at a time that it=s meaningful. And I think it=s great that Carolyn and NRDC get notices and participate, but this must go to the broader public interest community. And I think

you have an example right now with methiazide. The chemical that, you know, we thought was at registration. Of course it=s not a brand new chemical that=s never been used before. There actually is data available, the public interest community could weigh in. There needs to be a time frame in which that process could happen, in which their comments could be meaningful in terms of the registration.

I, you know, with all due respect, have seen many instances in which the EPA accepts comments and says, okay, well, in 15 years when we reregister we=ll get to you.

Well, that really is not good enough. This must be done in real time when it has real impact, and perhaps this could be a topic of our next PPDC through the Workgroup or whatever to develop such a meaningful process, but I don=t think we can let this one fall through the cracks or, with all due respect, say, just trust us, we=re doing a good job.

MS. MONELL: Thank you, Shelley. I would just note that PRIA would have to be reopened, and we would have to discuss the time frames should we entertain a public process, such as you=re describing, and that definitely would need to have another discussion.

MS. DAVIS: I absolutely disagree. We do not have a new statutory provision added to FQPA when we added the public process. This is an administrative aspect of implementation, you do not need additional authority. This is to provide you with advice on the registration.

MS. MONELL: I=m confused. Are we still talking about PRIA or are we talking more generally about ag chemicals?

MS. DAVIS: We=re talking about when you add chemicals that go through PRIA. I mean, if they go through PRIA then they=re allegedly reduced years or allegedly substitute for some more dangerous chemicals, they=re going to get through a fast-track process, it=s completely without the public. We can=t have that. We just have this currently happening right in front of us with methiazide and it shows what a bad thing comes out when you don=t have a meaningful public process.

UNIDENTIFIED FEMALE: Well, I actually think that you=re right, that we should have a conversation about public process for registration activities. But what Marty meant by the time line, it wasn=t that we didn=t have the authority to do, but rather than the time lines have been designed bearing in mind the time that we needed with our

current process to complete the action.

So, what she meant was that in order for us to incorporate any public process into that, which frequently would take a year, probably, or a bare minimum of six months additional time, we would have to go back in and look at those time frames, because otherwise our scientists wouldn=t have sufficient time to do a thorough review of the application. That=s all she meant.

So, you know, we appreciate your comments and we do need to consider them carefully, but we just have to bear that in mind as we go into that conversation.

MS. MONELL: Gary?

MR. LIBMAN: A couple of things. One, a basic one, is on the fee payment, I=m real confused on one thing. A lot of the reduced-risk companies, the smaller companies, you say that they now have to pay this 25 percent fee. And, then, they say if the application is rejected, the Agency will retain 25 percent of the fee. Is that 25 percent of the 25 percent --

MS. MONELL: No, no, no. We will only collect 25 percent one time for whatever reason.

MR. LIBMAN: But if it=s rejected, do they get back 75 percent of the 25 percent or is that it?

MS. MONELL: That=s it.

MR. LIBMAN: Okay, that=s everything, okay. My other question is probably more significantly is on, probably my favorite topic in PPC, is on renegotiations, and I know there=s a difference in different registration divisions -- AD and BBPD and RD on those. On your annual reports, are you going to have a section for these renegotiations?

I know in almost all cases they=re all legitimate and unaffected -- they=re always legitimate -- but it=s a question of some frustration that registrants sometimes have that they=re going along and then all of a sudden there=s a renegotiation or a negotiation right at the end and starts the process over again.

MS. MONELL: Well, I think you raised a good point and there=s sort of two separate issues. Yes, we do have data which we provide at regular meetings and would be happy to provide to you on renegotiations, the numbers broken out by divisions, broken out by reasons.

So, that data is available for anyone, anytime. If you or any member of your association feels aggrieved or wants to talk about a particular matter, we=re always open to that. We=re always open to discussing, because we want

to improve our performance.

So, if you feel that a negotiation has been improperly handled, then, by all means, talk to the appropriate person in the division or even me.

MR. LIBMAN: Okay. But is it part of your annual report, that particular category?

MS. MONELL: It=s not specifically, but we certainly can --

MR. LIBMAN: Okay.

MS. MONELL: -- make it part of the report.

MR. LIBMAN: I think it=s a helpful number to have.

MS. MONELL: Um-hmm. We report on it quarterly to the Deputy Administrator as part of our quarterly management report. So, as I said, the data is readily available in various different formats. And, so, we could easily put that into the annual report.

MR. LIBMAN: Thank you.

MS. MONELL: Good suggestion. Dan?

MR. BOTTS: First of all, let me thank everybody involved and who worked on this very difficult task, not only the PRIA II but PRIA I, and from somebody who was sitting on the outside, though represented on some of the

internal discussions that went on on this, I have been pleasantly surprised with the outcome of the process and how it has been developed and worked on with the Agency. And from that standpoint, would like to congratulate the Agency for having implemented what was there.

Still, some issues, just for clarification purposes, only at this point, and it might need to be done offline rather than in this meeting, but one of the issues that=s there, and being a registrant for uses that would only be available, we=ve had waivers from registration maintenance fees or re-registration fees, and I=m assuming that as this is written here and that provision is still in there for the maintenance fee portion of this, is the policy within the Agency going to change on how those decisions are made on who qualifies and who doesn=t qualify for payment of the maintenance fee portion?

MS. MONELL: The policy will not change -- has not changed.

MR. BOTTS: Okay. The other question and on the registration fee side of it, the minor-use waiver that=s there -- and I don=t know whether your accounting does this or not, and this is something that might be in the process -- how big is that number that=s out there? How any people

have applied for specific minor-use waivers under the registration fee part of PRIA -- whether it=s PRIA I or PRIA II?

MS. MONELL: Very few.

MR. BOTTS: Well, I just need an idea of magnitude.

MS. MONELL: Yeah, very few.

MR. BOTTS: I=d like to get offline and talk to you about that.

MS. MONELL: Sure, we can provide you with the data on it.

Ray?

MR. MCALLISTER: I wanted to ask for clarification on the Slide 11, where you mentioned that if the application is rejected, Agency will retain 25 percent of the fee. That=s a rejection in the in-processing, isn=t it?

MS. MONELL: Correct, that=s within the 21 days.

MR. MCALLISTER: That=s not if I submit an application and it=s ultimately not -- it doesn=t merit registration, and you reject it or deny the registration.

MS. MONELL: It doesn=t apply in that instance, no.

MR. MCALLISTER: And with respect to the annual reporting requirements, when you=re listing that on five or six separate slides, it sounds like quite a list, and I=m wondering if you could consider adding one more voluntary item to that list, and that is accounting for how the set-aside funds are spent. What projects they go to, whether it=s the PSEP, et cetera?

MS. MONELL: Sure. The information is always available, we=re very transparent about that, and, matter of fact, we=re rather proud of how we=ve spent the worker protection money. The only thing that we weren=t tracking as rigorously, because we didn=t have to, is segregating out the amount of money in the maintenance fees that was to be used for inerts and fast tracks -- fast-track amendments. We identified the pot of money and the amount of activity, but we didn=t necessarily break it out. Now we will be breaking it up.

Okay, time for one more question. Susan?

MS. KEGLEY: This is in regard to the phase out. I guess I=m curious what will happen after these funds are phased out to EPA. Will the work be done? Will there be no more new pesticides or is there any process or what are you thinking there?

MS. MONELL: No, it just would mean that we would not have the enhanced service fees. We would not have fees. We would have to rely solely on appropriated dollars, and the registrant community would no longer have time lines. So, we would revert back to backlogs and so forth.

So, the answer to your question is, we will still run a pesticide program, because statutes mandate that we do, but we would have to rely solely on appropriated dollars.

Thank you very much.

MS. EDWARDS: Okay, it=s time to move now into Session III, which is brief, and I underline the word Abrief,@ program updates and provide you with information on some initiatives we have going.

SESSION III -- BRIEF PROGRAM UPDATES

MS. EDWARDS: We will start on volatilization with our chair, Jack Housenger, who is Associate Director of the Health Effects Division.

MR. HOUSENGER: I brought friends in case there are questions I don=t want to answer or can=t answer. I=m

going to talk about volatilization. I think that=s a great subject for a PPDC meeting.

So, let me first define what it is I=m talking about. What is volatilization? It=s not on the board --

UNIDENTIFIED MALE: Are you asking us?

(Group laughter.)

MR. HOUSENGER: It=s basically vapors -- or how we see it, is vapors of a pesticide leaving a treated area.

An example would be soil fumigants, structural and commodity fumigation, or emissions from other pesticides, which is largely going to be what I=m talking about today.

What it isn=t, spray drift overspray, wind-blown soil. Although, you know, it was pointed out to me that you could think of when you fumigate a field, the gas comes up and it kind of drifts, but the difference between spray drift and vapors are spray drift is usually what we think of as aerosols and volatilization is a vapor.

So, why should we be concerned? Well, because we want to make sure that we=re accounting for exposures through the inhalation route in or near a field that=s been treated with a pesticide.

So, as we=re thinking through kind of this topic, we have three questions that we keep in mind: What do we

know about the potential for volatilization? What are the criteria that we use to determine when to conduct quantitative assessment? And what are the methods available to us to evaluate this?

In the past, two instances where we=ve considered volatilization; one being through the fumigants, either soil, structural, commodity fumigation -- and you can see some of the examples up there -- methylbromide, chloropicrin -- a lot of those are going through re-registration now.

And indoors, crack and crevice with propoxur volatilizes; DDVP pest strips volatilize, and some of the uses of pesticides in greenhouses we considered.

For the most part, we=re looking at these risks through the REDs; mitigation measures, including buffer zones, have been proposed for things like the fumigants. For new fumigants, like iodomethane, we impose measures at the time of registration.

We have information, which we=re going to talk a little bit about a little later, that we have considered informally -- they haven=t been part of our quantitative risk assessments -- for pesticides used outside that we know we get some vapors in the air, but typically these

exposes have been negligible and don=t impact overall risk that greatly.

We=ve got a couple of places where we have data on volatile pesticides: Pesticide action network through a drift catcher program has generated data on four pesticides. We=ve looked at their methodologies, we=ve looked at their data. We think it=s good methodology and good data that have been collected.

Air samples are typically collected over a 24-hour period at various places -- field edges, homes, schools.

What=s not known all the time, I think in all but one study, is when the specific pesticide applications occur. So, it=s hard to get a handle on when you might find peak concentrations or how long after an application concentrations might peak.

The California Air Resource Board, or CARB data, also gives us data on volatile pesticides. Again, most of this is ambient air, it=s not known when the application of the pesticide was made, and air samples, again, collected over a 24-hour period. Over 40 chemicals have been sampled over the past 20 years.

So, when do we, typically, evaluate volatile pesticides? Historically, we=ve looked at the vapor

pressure, and if it=s greater than 10 to -6 millimeters of mercury, that might lead us to do an evaluation.

Again, fumigants and certain indoor pesticides are the only scenarios that we=ve looked at over time, but given the recent PANNA data and some of the CARB results, we think it=s probably time to look at other factors and think about when we should start considering exposures from volatilization.

So, here are some of the triggers that we=re currently investigating. Obviously, if the temperature is high, there=s greater likelihood that the pesticide might volatilize from the field; it might be related to the solvents, the formulation type; size of the area treated could give you higher concentrations. If you=re treating hundreds of acres around residences, you might get higher concentrations than if you=re only treating a couple of acres. And, then, again, what role does application method play? Do you get higher volatilization with airblast versus boundboom? So on and so forth.

And I=m sure that there are some other ones that we=re looking into besides these, but these are the main ones.

So, in evaluating the risk from these pesticides,

obviously we need both exposure and hazard information. Historically, for the exposure end of it for the fumigants, we have monitoring data that we can use directly or we can use monitoring data along with modeling to determine what concentrations offsite we would see.

It=s possible to do this for other pesticides if we go that route.

On the hazard end, since these are vapors, it=s preferable to have inhalation tox studies to evaluate the risk.

If we don=t have those studies, we do use oral studies. But if we do have them, we typically use our reference concentration methodology, which is used to look at and assess noncancer risk from inhalation. This is a peer-review methodology that the Agency has used since 1992. It treats vapors a little differently than aerosols, and it=s used to extrapolate from animals to humans, based on the physiological and anatomical differences between animals and humans.

And I=ve given you the website in case anyone is interested in visiting it and reading about it.

So, since we do have data from both PANNA and CARB, what does the data tell us? And it tells us a number

of things: one, that it appears that volatilization is happening, we do find detectable exposures. However, these exposures are low and significantly less than estimated exposures from food, water, or residential exposures -- residential nonoccupational exposures.

And in using the RfC methodology, risks have generally been below our level of concern or negligible.

We=ve worked with both Canada and the States of Florida, California -- I know Washington has done some work in this area, as well, in evaluating these data, and this is kind of the consensus of everyone who has looked at what risk these exposures from these data tell us.

We do think it=s a next logical step to rethink probably our triggers; reconsider when we would look at volatilized pesticide exposure, especially given the data from CARB and PANNA that tells us that this is going on.

We need to determine the best way to evaluate these, or whether they should be put into our risk assessment. What=s the magnitude? What=s the duration? What=s the timing? And, again, what hazard data do we have available to us to evaluate this? A lot of chemicals right now don=t have inhalation tox studies, and we rely on oral studies.

And, finally, we put out an encouragement to other stakeholder, CARB and PANNA data are nice, but it would be nice to have other data available so we can look at the exposures that are occurring.

UNIDENTIFIED MALE: (Microphone not on -- question inaudible.)

MR. HOUSENGER: Anything that=s not highly volatile.

(Group laughter.)

MR. HOUSENGER: The fumigants are what we call highly volatile, DDDP and propoxur are probably highly volatile. Something like trifloralin, that PANNA looked at, you wouldn=t think that it would volatilize, but it does, it obviously does.

UNIDENTIFIED MALE: (Microphone not on -- comment inaudible.)

MR. HOUSENGER: Yeah. I mean, that=s one of the things -- I mean, all of the chemicals that our panel looked at would hit our cut-off, but typically we had thought that, you know, outdoors you=ve got a lot of mixing, the exposures wouldn=t really be significant, but they=re finding detectable residues, so maybe we need to rethink that cut-off.

MS. EDWARDS: Okay. We=re going to have to -- we wanted to get through all four of these topics by noon. If we begin to take comment on an initiative like this, I think we will be -- here we are taking comments on the first topic. So, I think what we might want to do is just move ahead and then get comments from you later on which topics you=d like to hear more about at the next session, if that is okay. I really don=t think we=ll get through them otherwise, and these are topics we specifically requested updates from you on. So, does anyone have a serious concern? Certainly, I know the public interest groups tomorrow we have a two-hour meeting, we could incorporate some of this in there.

UNIDENTIFIED FEMALE: Just a public correction. Exposures are low and significantly less than the estimated exposures from food, water and other residential exposures. The big tall bar there, Jack, is exposure for people who live right next to the field compared to all of the other teeny, tiny, little exposures through food and drinking water, and these kind of minimum, medium-sized bars show that we=re about four times the acceptable daily dose for people who are just in the areas for the ambient air monitoring.

And, so, I just wanted to correct that.

MR. HOUSENGER: Well, again, I think it depends on what methodology is used and what tox study is used and what the duration of the exposure is and what duration your tox study is. So, all those contribute, but I think the general consensus with Canada, California, Florida, us, is that when you use the RfC methodology and the available data, these are small exposures.

UNIDENTIFIED FEMALE: This wasn=t based on any toxicology, it was just dose -- calculating dose.

MS. EDWARDS: Well, I think what we wanted you to see today is that we=re taking the issue of volatilization seriously, we=re taking the data that have been recently generated seriously, and we=re beginning the process internally to determine what we might want to take, for example, to a scientific advisory panel meeting to discuss when and how to incorporate these kinds of assessments into our routine risk assessment. So, that was kind of the purpose, and there will be plenty of opportunity for public participation in that.

DR. KEIFER: This is Matt Keifer on the phone, can you hear me?

MS. EDWARDS: Yes, Matt.

DR. KEIFER: One quick comment. And that is, sometimes -- and I didn=t hear this mentioned in the presentation -- sometimes the metabolite or the converted ingredient, such as metam sodium and methylisothiosionate, are not the same, and I just was wondering if we=re taking that into account and measuring the volatilization of what is potentially a very irritant chemical but not the pesticide itself.

MR. HOUSENGER: Yeah, I think that=s a good point, where you get the MITC generators that you put one form of it into the soil and you get exposed offsite to a different form, and those are some of the types of issues that we=re looking now is to, if I=m asking for monitoring data, that we may identify things other than the parent that people are being exposed to.

MS. EDWARDS: Okay, thank you, Jack. Noticing that, obviously, the agenda today is jam-packed with issues and topics that are of great interest to many of you, and we may have been a little bit too ambitious, but we wanted to comply with your requests for covering these topics, and if anyone thought that after all this through 2006 the pesticide world would be boring, they were very wrong about that, I=m finding.

Anyway, our next speaker is Linda Phillips, who is from the Office of Science Coordination & Policy here in OPPTS, she=s the Director of Exposure Assessment, Coordination and Policy Division, and she=ll talk about Endocrine Disruptors.

MS. PHILLIPS: Good morning. I wanted to give you a brief update on the endocrine disruptor screening program. As Debbie said, I guess in the interest of time I can answer questions and come back either later today or tomorrow on questions. So, I=ll just run through this very quickly.

Okay. First I=ll run through our legislative mandate for the EDSP. Some of you already know this information, but I=ll try to do this quickly.

Under the Food Quality Protection Act, EPA was required to develop a screening program using validated assays to identify pesticides that may have an estrogenic effect in humans.

The Act also authorized EPA to look at other endocrine effects, as designed by the EPA Administrator, and those can include androgen and thyroid, and also to look at endocrine effects in species other than humans.

Under the Safe Drinking Water Act, we also have

the allowance to look at chemicals that are found in drinking water to which a substantial population is exposed.

So, in response to this, EPA established, in 1999, the Endocrine Disruptor Screening Program. The program was established with recommendations from a Federal advisory committee called EDSTAC, the Endocrine Disruptor Screening and Testing Advisory Committee, public comment, and, of course, the Science Advisory Board and the FIFRA Scientific Advisory Panel.

On the next slide here we have just a little of information about EDSTAC, because they were so key to the development of the program. And, as you can see, EDSTAC recommended that we include estrogen, androgen and thyroid, that we look at human and ecological effects, that we do priority setting for a broad universe of chemicals. And one of the suggestions that they made was that we sort of tape a small bit of the apple and look at 50 to 100 chemicals first, which I=ll talk about a little bit later, and that we have a two-tiered approach to testing.

With the first tier having in vitro and in vivo screens, the purpose of this would be to try and detect the potential of chemicals to interact with the endocrine

system.

And, then, Tier 2 having multi-generational studies covering a broader range of taxa that would provide the information necessary to conduct risk assessments.

So, the EDSP is being conducted with three major activities: Assay validation; priority setting to select the chemicals that would be the first into the system; and, then, developing the procedures that would be needed to require testing.

The first of these activities -- and, by the way, all of these activities are occurring simultaneously -- but the first of these is the validation process. And we have been conducting this over the years in steps, the first being developing the methodology and preparing a background paper on the protocols, for example, that were available at the time; doing prevalidation studies to optimize the protocols and determination about whether or not that protocol is ready to go into interlab validation.

And, then, conducting interlab validation studies. These are studies that are conducted in multiple labs with multiple chemicals to look at the reliability and reproducibility of the assaying.

And, then, independent scientific peer review and,

finally, regulatory acceptance.

In terms of the validation process for the assays that we=re looking at, we have a couple of them that have gone through peer reviews, through the OECD process; several that are in peer review right now, and others that are sort of making their way into the que.

And, then, in terms of the Tier 2 assays, they=re a little bit further out. We anticipate those will be done in 2009 or 2010, but for the Tier 1's we=re well on our way to getting those validated.

The second activity is priority setting, and what we=ve done on that is that we -- back in June of >07 -- we put out a Federal Register notice with the proposed list of 73 chemicals for initial screening.

And that list was based on a methodology that was developed and published in the Federal Register notice in September of 2005. The methodology was based on looking at potential human exposure as the criteria for selecting a chemical for the list. All of the chemicals on that list of 73 are pesticide-active ingredients or HP inert ingredients. In fact, there are 64 active and nine HPV. And it should be noted, also, that this list of 73 chemicals is not a list of known or likely endocrine

disruptors, it was entirely on exposure. So, it=s just a list of chemicals that are going to go through the screening and testing process.

We=re currently in the comment period for that. Initially we put it out with a 90-day comment period, but we had a request that that be extended for another 60 days. We did honor that request. And, so, the comment period will end on the 16th of November of this year.

The intent is that we will review the comments that we get on that list and, then, we will issue a final list early in 2008.

And, then, the third activity -- third major activity, I should say -- is the procedures. And we have been working very hard to develop the processes and procedures that EPA will use to require testing under the EDSP.

This includes a policy document that we will be putting out in the Federal Register. And, also, an ICR needs to be in place to require testing.

We anticipate that these documents should be out rather soon, and we will be holding a public meeting to discuss the policies and procedures, also, and that should be -- you should be hearing about that soon, as well.

And, then, the final slide here is our time line. As you can see, the validation has taken the longest, but we=re hoping that very soon all of these activities for Tier 1 will converge, and we should be able to start, you know, initiating testing.

And that=s it from my brief overview. I=m sorry if I took too long.

MS. EDWARDS: That=s fine, thank you. I think now we will be to Anne Lindsay, who will give you an update on where we are with Cause Marketing, a big topic in past PPDC meetings.

UNIDENTIFIED MALE: Just before we do that, can I ask what ICR is in that last information.

MS. PHILLIPS: Information Collection Request.

MS. LINDSAY: Okay. Up until about 8:30 this morning, I thought my report was simply going to be Awe=re working on it.@

But, miracles do happen, occasionally, even for bureaucrats, and what we=re passing out right now -- and you are the very first people in the whole world to get this -- is the Federal Register notice announcing the availability of a draft PR notice on the Cause Marketing sets of issues that we discussed at the last PPDC meeting.

Since it just got signed, it=s not published yet. I don=t even have a publication date for you. I=m pretty sure I can guarantee you it won=t be published this week; possibly next week or certainly, I think, the week thereafter, and that will open the official comment period. But the notice is signed and you=ve got a paper copy of the draft PR notice to take a look at.

Just really briefly, the draft PR notice contains the description of our legal and policy framework for evaluating proposed statements and graphic material that would be intended to appear on pesticide labeling regarding what we=re calling third party endorsements or a relationship between a pesticide registrant and a charity.

Our short term for that has been Cause Marketing Claims. This draft notice also identifies factors that we might consider when we=re reviewing such applications that propose to contain this material.

And, then, it also discusses the type of information that applicants may want to think about providing the EPA for our review of these statements. And these would include a mock-up of the actual label, as it would look, documentation of the third-party endorsement or information to establish the truthfulness of the claim, and

a discussion of potential consumer impacts, which might also include consumer marketing research.

So, I=m going to stop there, in the interest of time, but you are the first people in the world to have it. And I think you=ll see that it actually reflects a lot of the comments and the concerns that you articulated in the public discussion we had in May. And, as a point of interest for Susan Kegley, who asked about the draft PR notice in spray drift, if you count -- it=s been about four-and-a-half months since the last meeting, and literally it took us four-and-a-half months to the day to be able to deliver it to you. So, that gives you a feel for at least one PR notice, what it may take us to actually deliver.

That=s it.

MS. EDWARDS: Thanks, Anne. We have one more update before the lunch break, and that is a topic many of you, again, have asked for more information on, more discussion here, and to start that process off today, we have Lindsay Moose from the Field & External Affairs Division.

MR. MOOSE: Thank you, Debbie. This shouldn=t -- I should be able to get you out for lunch on time. Because

this is fairly introductory -- it=s really starting the whole process of getting into some discussion on this in the future.

The report that you have in your package, and it was on the table available out front, is an initial report. We promised you that we would do a series of reports on incident data, how we use incident date, where we get it from. What this report does is really sort of try to set the landscape a little bit.

Primarily it goes through what sources of data we have, gives a little bit of a primer in terms of our statutory authority, our assessment risk management processes and how incident data play into that and how they help inform that.

It=s not exhaustive in terms of the sources of data it talks about, but it=s pretty inclusive. The only things that aren=t included are some of the things which we do, which is literature searches, things of that nature, that help inform what we do.

But the design of this is really to give you a sense of where we get the incident data from, a little bit of flavor for how we use that data. There is a section within this that is entitled, AWhat does the incident data

tell us?@

There are no specific numbers associated with that. Basically the point we=re making is that the incident data does help inform our decisions. There are areas in the future that we might investigate to improve how that=s used, but what=s really important right now is for trending information and, also, using it to see where there=s a magnitude, where there are incidents occurring so that we know where we need to concentrate.

In terms of next steps, what we=re going to do now is start an intense internal process to look at ways that we can improve what=s already there before we even move to maybe add on to what=s there, but improve what=s already there in terms of how we use the data, how we interpret it, where it feeds into our process, and that will lead -- that internal discussion will take a number of months as we look at current resources, maybe ways to organizationally structure ourselves to take better advantage of our process and information that we have, and then that will eventually lead to us coming out with our second report to you and start moving into what we=re going to do in the future in terms of strengthening the way we look at intimate data and how we can use it.

So, this report is just to sort of tee up that discussion, sort of a landscape, so that you can get a feel for what types of data we get in, where we get it from and how we use it.

MS. EDWARDS: Thank you. Well, I hope you=ll be able to read this report and provide us with some feedback over the coming months as we continue to work in this area.

It is now high noon, and, so, the plan is that you will have one hour and 15 minutes for lunch, and we would be back here to begin the conversation -- hopefully it will be more interactive -- about web-based labeling, a new initiative we=re looking into.

Thank you.

(Whereupon, a lunch break was taken.)

AFTERNOON SESSION

MS. EDWARDS: Okay. We=re about seven minutes late here, but that=s not too bad, considering there=s not a whole lot of places around here to get any food.

This afternoon we=re going to start our session, Session Number IV, with Web-Based Labeling, our concept we want to explore with you, and that we have some ideas on how it might benefit all sectors of the stakeholder community.

So, to lead that discussion and actually leading this initiative within the pesticide program is Bill

Jordan.

SESSION IV -- WEB-BASED LABELING

MR. JORDAN: Thank you. This is something I=m really excited about, and it=s just getting off the ground. So, I hope that you=ll take this presentation as sort of an introduction to the concepts and ideas, although in some cases I=ll get fairly specific. None of the things that we=re talking about here has been firmly nailed down. And through further conversations with all of you and the folks that you represent, we hope to refine the ideas. So, with that in mind, let me move on to sort of an overview of what this presentation is going to cover, a little bit of background on how we came to this idea, explaining what web-based distribution of labeling is not and what it is. It=s probably more important to understand what it isn=t so that we=re focusing on what it actually is intended to accomplish.

The mechanics explains how the system would work, or at least how, at this stage, we=re thinking about it working. It will involve some changes to the container labeling, it will involve a process for people to get labeling, using the web, and there will be two different options. In addition to web-based distribution, there will

be a paper distribution system, and then a few words about enforcement.

We think that this idea, sort of 21st century labeling, is going to have benefits for all of our stakeholders. And I attempt to summarize what we see as major payoffs for all of us in moving to this program.

The last piece, and probably the one that deserves the most thought and attention, is where do we go from the concept stage to actually having something that will work?

So, with that, let me move on to background. The real credit for most of the ideas in this presentation goes to folks outside of EPA, particularly the states. And I wanted to really commend them for the efforts that they have put in over the years.

We began to pay attention to these issues when our office director, Debbie Edwards, a newly minted office director, attended the AAPCO conference this past summer. Debbie came back to Washington and told us to get to work and see what we could come up with, so here we are.

AAPCO and SFIREG have been working on this topic for a number of years. A prior issue paper done several years ago tackled the question of whether E-labeling could be useful in dealing with supplemental labeling --

primarily focused on new uses -- but, then, the Pesticide Operations and Management Committee expanded that concept to look more broadly at the way E-labeling could be used in a number of other areas, and the issues raised in that SFIREG issue paper have played a big role in informing how we=ve been thinking about this here.

Also, I want to note that that SFIREG subcommittee includes participants from four or five different pesticides companies, as well a representative from Kelly Systems, which is a private company that is already doing, in the private sector, web-based accessed labeling.

Now, while the states and pesticides companies deserve a lot of credit for it, I don=t want to overlook the contributions that folks in EPA have made on E-labeling, although our focus has really been in a different area. We=ve been working on E-labeling with an emphasis on electronic submission and electronic review of labeling, but that=s really a sort of companion piece to this web-based distribution. And I=ll talk a little bit more about how those connect in just a moment.

So, moving on to the next slide. Web-based labeling, what it is ANOT.@ It is not referring to electronic submission or review of labels by the Agency.

That=s an effort that we will continue to invest in and it, in many ways, will complement the web-based distribution of labeling, but it=s a separate enterprise conceptually from a management point of view.

Web-based labeling is not a system that will require standardized labeling. The Kelly system programs make the current labels available to users on the web, and we would be, at least initially, doing the same thing. But it probably will, again, be something that we=ll want to pursue -- standardized labeling -- and having web-based distribution will actually, I think, make that more possible.

There will be -- and, again, I=ll discuss this a little bit later -- there will be some elements that will have to be standardized; mainly, people will have to be able to find on the product label where to go on the web to get a copy of the full labeling.

Web-based labeling would not change the legal procedures contained in FIFRA that EPA must use to change labeling, and it would not change the process that registrants would use to amend product labeling. So, we will still be involved with a system that involves submission of applications to amend labels to add new uses.

EPA, if we decided to impose additional restrictions, would either have to get the registrant agreement to that, or we would have to go through cancellation/suspension proceedings to compel that kind of change.

And, finally, this web-based labeling would not change a user=s responsibility to follow labeling requirements. As everybody knows, under FIFRA, the labeling is the law, and that will continue to be the case.

So, since it isn=t any of those things, well, what is it? It is the distribution of labeling, in electronic form, that makes the most current version of the pesticides labeling available to purchasers and users by checking into a EPA-maintained website.

In broad breast strokes, it will simplify the label on the container a lot, and it will allow for much more rapid updating of the labeling.

Let me explain a little bit about what it would mean in terms of the container label. The pesticide bottle/bag/can -- the container that actually has the chemical mixture in it, would bear a label. The label would specify a URL website address that would direct the users to the website to get a full copy of all of the information that EPA had approved in conjunction with that

registration of that product.

At least, as we=re thinking about it now, it would replace the directions for use on the physical container so that those would not appear on the container label, but would be accessible through the web-based labeling.

The container label would still, obviously, have to have all of the information, all of the elements mandated by FIFRA -- product name, registration number, net contents, ingredient statement -- there is actually a longer list that I derived from the definition of misbranding in 2-Q of FIFRA. I won=t go through all of those, but all of those things would still have to be on the label of the container.

And, finally, the container label would have other key information that we would work out through conversations with stakeholders to figure out exactly what=s the key information that still needs to be on the label of the container -- use classification, storage and disposal instructions, hot-line help numbers, for example -- those are just some of the things that we=re thinking about; no firm decision has been made on that.

Okay. So, that=s the content of it, as we=re thinking about it at this point. Here=s the process piece.

Distributors, purchasers or users could go to the EPA pesticide labeling website, enter the product registration number, and the labeling would appear in printable format.

We would allow, under this system, dealers to distribute printed labeling. I recognize that there is an issue with the definition of Aproduced@ in 40 CFR 167, as to whether or not that would make dealers into producers. We=d have to work through that issue. We=ve already started talking about that. If necessary, it might involve a rule change.

But, anyway, the idea would be that either by from the dealer at the point of purchase or through subsequent action on the part of the purchaser/user, the user would obtain a copy of the labeling from the website.

Now, we know that not everybody who=s using pesticides actually has access to a computer that would allow them to go to visit a website and download labeling. And, so, we would create an alternative approach that would include, probably, a toll-free telephone number that the user or dealer could call and ask for us or somebody else -- whoever answers the call -- to mail out labeling appropriate for that product. We=re still open-minded as

to how to administer such a toll-free hot-line number.

The next two slides, using graphics showing how the system would work. You look at the container label, you see the web address, you go to your computer, you download the labeling on the printer, make sure it is in the hands of the user and the user then closely reads the label, as I=m sure every user now does -- or, at least, certainly ought to -- and, then, the part that=s cut off shows proper use of the pesticide.

The next slide shows the same system but instead of the computer connection it=s a telephone call, and that leads either to EPA mailing or somebody mailing out or faxing out the appropriate labeling and then you see people read the label and follow the label instructions.

So, how would enforcement work? Users under this system would need to have a copy of the labeling from the website at the time of use. Obviously, given the current system, that always happens because the labeling is attached to or connected to the product. And, so, they have that labeling and it stays with the product, according to the FIFRA rules. This would involve adding a statement saying, you=ve got to have it with you when you use it.

Here=s an idea that is sort of new, I think, for

folks. The labeling would be good for a specified period of time from the date that it=s printed or downloaded.

So, if it were printed on January 1st, it might be good until September 1st or it might be good until July 1st. It would have a specified period in which it was valid. After that time, you=d have to download a new label for that product. We haven=t figured out what the length of time would be, but what that means is that in terms of the user=s behavior, the user could download the label in advance of his or her use of the product, follow the instructions on that label, or, if he wanted, wait a week and download a label later and follow the instructions on that label. But it would expire a certain number of days, weeks, months, after the download, and they would be bound by whatever labeling they downloaded for the period that it was enforced.

An archival system that EPA would maintain would allow verification so that we could tell what labeling was actually in force and valid for a particular date, and that would assist the state enforcement or tribal enforcement staff as they were doing checks.

What this system allows is that it reflects the dynamic character of pesticide regulation. So, it would

allow the updating of uses. And, so, if a person bought a product on January 1, and EPA approved the new use on February 1, they could either apply the pesticide according to the January 1 label or they could download a new version on February 1 and have the label that would authorize the new use.

The same way would work with restrictions. If they bought the product on January 1, downloaded the labeling on January 1, they could use that product for, say, six months. If anytime after that they wanted to use, they=d have to get a new labeling from the web, and if that contained new restrictions, they would be bound to follow the new restrictions.

Okay. We think this is going to pay off in lots of different ways to pretty much everybody involved in the system. Broadly speaking, we think it will provide enhanced protection with human health and the environment by providing pesticide users with the most current and most accurate information available. And we=ve listed here all the different stakeholder groups.

Let me move to the benefits for users. Labeling information available on the website will always be current. Once EPA takes a regulatory action, we change the

website and that way the most current information is available on the website.

We hope that the PDF system that we=re going to be using will be electronically searchable so you=ll be able to find information quickly.

You=ll be able to print the labeling in larger font, if you need that, as some of us aging baby boomers now increasingly discover we need.

We think it will simplify the container label. You=ll be able to see very quickly and readily the health and safety information on the container label, it should increase comprehension and allow the most critical, fundamental information to be conveyed through that means.

And, finally, it will level the playing field. Users won=t have to worry about dealing with existing stock issues and different mitigation measures. The use direction and the labeling will be legitimate and valid for a particular period of time, and after that you=ll have to get a new labeling, and everybody will be in that situation.

Okay. So, moving on now to industry. We think it=s going to make it easier to modify the labeling. In a very simple way, you won=t have to reprint every time you

change the content of the labeling. Newly registered uses could be added and available to people in the marketplace simply because they can go to the website and get that.

They would be able to make other labeling amendments that might not involve new uses, but still might necessitate a new printing run. They=ll enter the marketplace better useful for clarifying directions and so forth.

All that we hope and expect will lead to lower printing costs. If there is ever a recall or some sort of requirements to add new restrictions by EPA that has to be implemented sooner than the next label run, there wouldn=t be a recall or a re-stickering as long as the change appeared in the web-based labeling.

And it promotes a more level playing field. One of the problems that we see generally is that it=s harder for people to make labeling changes across multiple products -- harder for us, harder for the industry, and this ought to allow products to make a regulatory change at the same time.

For example, everybody could change to new standardized spray drift labeling, once we had agreement on what that was, and then it could be done electronically in

all the products to which that new language would apply.

From the standpoint of organizations that are environmental advocacy, farm worker safety, public health advocate groups, we think that the payoffs are a significant reduction of the time to implement risk mitigation on labeling in the field.

If EPA decides on January 2 the new label is necessary to protect public health or in the environment, that labeling would become applicable when the labels that were downloaded on January 1 expire. So, if it=s a useful life for six months, that would mean the new restrictions would go into effect on July 2nd, as opposed to allowing everything to go through the channels of trade, and we would have less problem with existing stocks, with old labeling in the marketplace.

We also think it=s going to allow for searchable data bases that will make even more transparent the pesticide registration and uses available in the United States and the terms and conditions on which they are approved, and it will provide increased transparency about EPA=s risk mitigation. You=ll be able to see whether or not a particular risk mitigation measure has been implemented for a particular product.

For states, we think there are payoffs, as well. There will be a single, readily available, authoritative source of labeling for products. As I indicated just a moment ago, it should simply be the enforcement of existing stocks, it should ensure that enforceable labeling is always available for an application date, because it would be possible to say, well, what was that application date? And we can see what labeling was available on EPA=s website and then govern that application.

We think it will have benefits internationally. It will make it transparent for people using pesticides in other countries to help our lab to be used in the United States. Use of pesticide and importance with EPA-approved registrations leads to residues that would be acceptable under U.S. tolerances, and so folks know that they can use it the way that it=s described on the U.S. labeling. It should produce a residue level that will be acceptable on products exported to the U.S.

Foreign governments without a lot of resources, that don=t have the number of staff or technical capabilities that EPA does, can use our labels as a source of information that might make it more feasible for them to discharge their regulatory responsibilities, and we think

it could help the across-the-border purchasing issues around NAFTA labeling that have bedeviled us in the U.S. and Canada border.

It=s going to help us -- let=s be clear -- we=re doing this partly for ourselves. We think it will make it possible for us to communicate labeling changes, faster market entry of reduced-risk pesticides, earlier implementation of risk mitigation measures, greater ability to use the feedback that we get from people that are applying pesticides to modify labeling, and it should improve the accuracy of final printed labeling and make that more readily obvious to everybody involved.

So, it=s obvious we want to do it -- or maybe it=s not, but I hope it=s obvious -- that this sounds like a good idea and that we ought to be moving ahead to explore it, but there are, nonetheless, issues left to think through about how we do it.

One of the first issues to discuss is whether this ought to be voluntary or mandatory. Should a pesticide registrant be able to opt out of such a program?

Another one is whether this web-based distribution of labeling is appropriate for all products. Frankly, within EPA the conversations I=ve had suggest the answer is

no. But it would be interesting to get feedback from this group on whether you think it should cover all types of products or be available for all types of products or not.

Enforcement is going to be an important, if not critical, aspect of how this culture change goes on. This whole idea works ONLY -- ONLY -- if users actually get the labeling. If they don=t get the labeling and just do it by memory, then we may actually have made the situation worse. So, we need to have a culture change that gets people to go to the dealers or the websites and get the labeling and have the labeling and read the labeling and follow the labeling and recognize the fact that doing it by memory is not the way to do it.

So, a significant emphasis on compliance assurance is a necessary complement to switching over to this web-based distribution.

How long is the printed labeling going to be valid is another question. I think that has a lot to do with user=s expectations and behaviors about when they buy products and how long they have it in inventory before they actually use it. During the implementation issues relating to timing, one of the questions is whether we ought to have some sort of pilot project to get some limited experience

to see where the bugs are and debug it, and clearly there will be training efforts necessary for the compliance assurance, but also for dealers and users, as well.

So, there are plenty of issues on that page, but I have another page of issues. What content will go on the label? I=ve already alluded to the definition of production in our regs. There will certainly need to be some changes to our labeling regulations.

Technology issues -- what=s the technical format, the submission method, how do we handle labeling archives, how do we make sure that nobody hacks our website and we have adequate security for that?

All of this is premised on the notice that we=re just distributing the labels that we currently have, for the large part. But there are certain enhancements to the system that this web-based distribution of labeling makes possible that strike us at EPA as being really exciting and have huge payoffs.

One of the most obvious is that the labeling on the website can also include the endangered species bulletins, it could include a link to State requirements, it could give us greater capacity to make regulatory decisions that reflect local conditions, as Anne was

talking about in the follow-up on the Spray Drift Workgroup. It could have links to advisory information, rate calculators, demonstration videos, material safety data sheets, hotline numbers. We can use NAFTA labeling here, as well.

Another advantage or payoff is that it could be a direct way for users to provide feedback on labeling issues. They download a label, they read it and they said, wow, this doesn=t make any sense to me. I=m confused, I don=t know what to do. We could have a link that says, tell us what you think, and we would get immediate feedback from the field about what=s confusing or contradictory or whatever, and we could use that system to identify and correct problems.

More enhancements: Eventually, we=re hoping that we can do customized printed labeling, such that might be specific to a particular crop or site. You go to the label for product 001-005 and you notice that this product is registered on everything from alfalfa to zucchini, but you=re only interested in brussel sprouts. You could click a drop-down menu and get the labeling customized just for brussel sprouts. That would certainly reduce the time necessary to understand use directions, where there is

potential for error or confusion, make the material a lot more manageable.

Eventually, we could have labeling in different languages, making sure that people where English is not their first language can get it in a language that they understand more readily.

This is where the searchable database kicks in. You could search on the website for products used on cotton or products used on adamoria or whatever else you=re interested in and get a quick feedback for that.

All of this is going to require, I think, a new kind of approach. These enhancements on this slide will require our capacity to identify specific regions of the labeling that relate, for example, to a particular crop or packaging or storage or disposal, and so that=s a little farther down the road and links up well, I believe, with the electronic submission for electronic review of labeling.

So, last slide. What are the next steps? We want to get feedback from you all about the concepts, and where there are issues or concerns and what you think we ought to be doing.

This is just the first of the feedback. What I

anticipate is that I and several other folks from EPA will want to come around and visit with a lot of you and with other people from the organizations that you represent to have in-depth discussion of these questions, and get your feedback so that we can frame up a set of proposals that include elements of scope, rulemaking, implementation issues and so forth.

And, then, with that, we would put out a written proposal that gets into all of the details for broad-based public comment before we actually do anything.

This afternoon we have -- I=m done, at this point -- but we have comments from six folks and they are listed in the agenda and we=ll go in the order that they=re listed.

Lori Berger from the California Minor Crop Alliance; Cindy Baker from Exigent; Susan Kegley from PANNA; Jim Wallace from S.C. Johnson; and Ray McAllister from Crop Life; and, then, Dennis Howard from the Department of Agriculture.

Each of them has had a preview of these slides and a chance to mull it over and come up with their ideas of what we ought to be paying attention to.

So, Lori, you=re first, take it away.

MS. BERGER: Okay. Thanks. Again, my name is Lori Berger, and I=m with the California Specialty Crop Council, and I=m going to be giving thoughts on the E-label concepts from a couple of perspectives.

One from just the general ag and, then, also I=m a licensed pest control advisor in California, and because those folks would be the people reading labels and making a lot of decisions and giving direction, I thought that it might be helpful to include some thoughts from that perspective, as well.

So, from the crop perspective -- and, again, I work with specialty crops, so we have a lot more diversity, but this pretty much goes across ag. In general the concept and thought of going through E-label situation has many, many positives. It=s a great concept; the devil is going to be in the details.

Positives from the ag side: ease of use on labels. You can get very commodity and location-specific. This would work very well with pre-existing computerized-recommendation systems that growers have to keep log books with what they use on their products, as we live more into traceability and so forth.

And good agricultural practices. Documentation is

very important and this would feed well into their recordkeeping, probably.

This is definitely the way of the future.

Some of the concerns are that notification may or may not be timely enough. There might be label changes that can have extremely serious repercussions on where a product is used or where it=s ultimately sold, this type of thing. We just need to make sure that=s streamlined in the process.

Also, liability issues, and I=m probably referring more to the registrant community to talk about that, but there=s a lot of liability. Who has the label in hand? And who sold this product? Just where does the liability in this whole chain of kind of possession lie?

Another thing that would be of concern -- and Bill alluded to this -- is this system appropriate for all states, because for many states -- such as the state I reside in -- we have another registration layer that goes on and how could that be done? Is it just a link or is this a total other label? Can this system accommodate the specific states= needs?

And, also, thinking of state needs and so forth, who would be bearing the cost of that? And I know we

always talk about the philosophical sense, but it=s just something that needs to be thought about before we would be designing a system that there=s another layer, who would be responsible at that State level for paying for that?

On the pest control advisor side or the practitioner side, a lot of positives are the same. And some of these thoughts came out from my interaction with the Spray Drift Workgroups, just talking about labels, and there=s a lot of room where labels can be improved, as far as where the advisory language or the compulsory language is located, there=s a lot of things that through a visual set-up of a label that really could be enhanced or improved upon existing format, and if we=re going to be making a lot of the changes, we might as well make them E-label, too. But I think that there=s a lot of things that could make stewardship activities just built-in. And, so, there=s a lot of opportunity there.

Also, on the commodity side, some states have a lot of specialty crops, and there=s new labels, there=s things you can=t explain next to, and a system like this could put in place a lot of safeguards or links to not making mistakes to just being a better steward of the product.

This would also, as I said earlier, work well with existing computerized systems for recommendations and reporting.

The enforcement would probably be somewhat difficult; again, where does the liability lie, the responsibility on having a label in possession? Also, you know, if you=re printing something out, okay, so that has a date on it, what prevents someone from just making a xeroxed copy of that and having that in hand? I mean, so would someone become a certified or having official user ID for this system?

And just kind of wrapping up here, how often could it be updated and how could we communicate to the end users that it is being updated either daily or every six months?

And, as Bill said, this would be a culture change, and even though most of the people -- most of us are extremely, if not entirely, dependent upon computers, a lot of the people operating at the field level are not as computer literate, and they=re not using this type of technology every day. And, so, there definitely would be a technology transfer element to switching over to E-labels, and an overall culture change.

So, again, it=s a great concept that holds a lot

of promise, but there=s some complications and details that will need to be worked out.

MR. JORDAN: Thanks. Cindy Baker is next.

MS. BAKER: Okay. I=d like to begin kind of a similar way that Lori did, which is to applaud the Agency and say I think this is a move in the right direction. I mean, I think we=re moving this way, and I applaud you for taking this on, because it=s tangled. And you=ll hear in my comments here, it=s complicated, but I see a real need for coordination, because we=re talking about it in SFIREG, we=re talking it in the NAFTA label process, we=re talking about it with the All Star project, which is the State registration and the State repository thing. We=re got Kelly Systems, we=ve got TDMS and, so, right now we=ve got a number of things out there, and I think it=s really important that we try to coordinate and bring things together.

That being said, I think there needs to be some flexibility, as you go forward, because, well, personally, as Gowan Company, I would be happy to move quickly on some of this stuff, but not every registrant is in the same place. I hear a company that has 3,000 labels or whatever, I mean, it=s a huge transition for you to think about that,

it=s huge within your organization, and all those things. So, I think the Agency needs to think about that as you go through. We=re not all exactly the same and in the same place.

While I=m willing to talk about -- and I think there=s merit in talking about EPA hosting this on their website -- I also think there=s merit to talking about the registrant being the one responsible for having the most current labels available for their products. That=s how it is right now. I mean, I=m the one who is responsible for making sure that what I put on that jug is the most currently approved label, not only by EPA but by the State of California and the State of New York, and all those other states. And there becomes a real complication if when EPA approves a label they put it up on the website as the most currently approved label because California might require something specific later, New York might require something specific later, I might, as a registrant, choose not to market a certain piece of that label exactly at the time that you approve it. And so, there are a number of different issues that take place once EPA approves the labels that are all legal, right and fair.

But I would put forth a position that you might

want to consider some flexibility being that the registrant might say, like the Gowan Company, we prefer to host what=s the most current label for our products, because the ultimate liability and responsibility is with me once somebody uses one of my products.

I would say you need to think about the transition to this. While it would be nice to believe that products move quickly through the channels of trade, the reality is that they don=t always. And sometimes growers or distributors stock up on materials, and they might have a year=s worth of a product that is labeled right now.

So, if you go to a web-based labeling and there happens to be some products out there that still have use directions on the jugs, what are we enforcing? What=s on the jug? What=s on the EPA label? What=s on the EPA label in three months? There=s some complications that just need to be, I think, thought through as you go through that.

I think this is right for a work group, not that I=m a huge advocate of work groups, but I do think that retailers and distributors need to be at the table. I mean, if you=re going to have point-of-distribution labels printed by West & Farm Services or UAP or something like that, those people, I think, need to be here and provide

some input about what does that really mean to their organization and how they do things. And, certainly some of those states, like California, where they allow you to have a master label, a product label, you know, that kind of input, I think, needs to be factored in so that we understand what=s there.

The Gowan group of companies does have a retail operation, the Dune Company. When I talk to those PPAs -- licensed PPAs -- there=s a lot of people who love the idea of being out in their truck with his laptop and walking to an alfalfa field and pulling up a label, okay? So does that constitute a copy of the label? You know, if they have it on their computer and they pulled it up?

So, again, some flexibility as you=re looking at what=s a copy of a label? Is it a CD-Rom that you printed off, you know, for the month, and it might have the 20 different products that you use on alfalfa and carrots, if you=re a PPA that=s covering an area that has that? So, I think this kind of going through some of those issues would be useful.

I made just a couple slide-specific comments, on slide 6, where the first bullet point talks about a URL that=s placed on the pesticide label. I think that URL is

going to have to be able to link to multiple labels. You might have a 24-C that goes to that container label; you might have a 2-EE; you might have a full section 3; you might have section 18. All of those would link to a base contained label for one EPA reg number. And, so, you=re going to have to think through that, as you look at that.

On slide 10, again, what constitutes a copy of the label? The time and trade issues. There are pluses and minuses to an expiration date, I think, on this. Clearly one of the pluses that we identified that I think is huge for users and for registrants is getting those new uses available right away, so that people can start using them.

One of the minuses is what do you do about stuff that was already in these? Your example, Bill, when you were talking, if I have a label that=s on January 1st and a new one comes out on February 1st and I=m the state enforcement guy in Arizona, which one am I enforcing? Is it either/and, so, are both labels on there, so that when the enforcement guy looks at that URL, he then looks at all of them that have been approved in the last whatever period of time we set? Because technically I don=t think any of them would be legal under that system.

Slide 19 is content of the container label.

Through the NAFTA label process, we actually did that with one of our products. This is the NAFTA-approved container labels, and it works nicely for this product, because there is not a lot of information that has to go on it, but there are some examples of some other registrants in the NAFTA process where this doesn=t work as nicely. If you=ve got a little tiny packet, for example, of a product that you use, a contained label containing a lot of information may not work nicely, whereas now they put a whole booklet on there that has everything in one. So, I think, again, flexibility as you go forward is going to be important as you look at it.

And when you=re discussing the concept with stakeholders, I would just reiterate my point that I think we need some of those people involved -- some people from those states that do have master labels and packaging labels, and they differentiate clearly between those.

And my last comment is I always love the idea of a pilot, and I think the master group has talked about a pilot like this. I think that people in that group are ready; the products are ready; and when we did the pilot on own-use, for example, we learned a ton. And, so, until you actually get one out there and doing it, you don=t tend to

find out where are all the problems.

So, I=d rather take -- I=ll be happy to be a pilot, since we already have the container label approved and you could try it. But I think until you get your hands around it, you don=t often find out where are all the issues.

MR. JORDAN: Thank you. Susan Kegley is next.

MS. KEGLEY: I, too, agree that this is a nice idea, in concept, and making it work has a few things that need some attention.

I guess what we=re faced with right now is if you want to find out what a pesticide label looks like, there=s the Greenbook site and there=s one more, PDMS. And they don=t have all the labels and all the MSDS systems. Then we have the EPA label database of TIFF files that pictures of either the bar code or the label or a letter that was written to or from the registrant by EPA.

And those -- you don=t know what you=re getting, first of all. You have eight things that might be related to the product and you download one, it takes a long time to download it, and it turns out it=s the bar code, and you=re like shoot, and off you go again and try to find the right one. So, this has got to be a real improvement on

that process. I think that=s a good thing about it.

I=m concerned about several things. Probably the biggest one is -- well, there are -- and I talked with Larry Elworth about this -- he couldn=t be here -- because he=s talked on several occasions in the spray drift workgroup about his farmers and whether his farmers had access to computers and ability to use them well enough to do something like this. And that=s not a given, and it=s certainly not a given for, I mean, say you have a pest control advisor who is supervising a worker, and the worker, you know, if they could read English, which is not always the case, but some of them might want to be reading the label themselves and not just trust that their supervisor is giving them the right scoop. You know, how in the world are they going to go -- they=re out in the field, they=re seeing this product for the first time, there=s no web access at the field, they don=t have a computer with them anyway -- maybe they don=t have one at all -- you=re missing that group of people altogether.

I=m really concerned -- the second thing I=m really concerned about is if the directions for use are not on the physical container. This might/maybe possibly be okay for people who use pesticides for a living, like the,

you know, the Western Farm Service and the farmer who does this, you know, has a business and is doing this. For consumer products, what a disaster that could be. And, you know, you=ve got someone who has an ant problem, they race out to the hardware store to buy something, they come back, they look on the label, it says, go to http.blah-blah-blah, and they want to get rid of the ant problem, they don=t want to spend time on the web looking this up.

So, that would be a real problem, and I would say if you=re going to select out products that this does not apply to, that consumer products might be high up on the list that you do not remove the directions for use off of the label.

The other thing that should be included on the label is all the safety information. I hope that is not dropping off. The hazard warnings -- is that the intention, Bill?

MR. JORDAN: The hazard warning is required to be on the label by the statute and it would remain there.

MS. KEGLEY: And the PPE. It seems like having the PPE on the labels, no matter what else goes on there, is really important.

Again, I=m worried about technical capacity for

someone to, you know, make a phone call and wade through multiple menu systems. They have to figure out -- probably they=re going to have to do it by registration number and they=re going to have to figure out what on the label that they do have. Is the registration number -- this looks like a formula for people going, phew, this is too much trouble, I=m not doing this.

So, enforcement issues like this has no way to really be enforced, and it seems like a -- who=s going to be checking that you have a copy of the label? If you called it up on your computer in the field and it=s now gone, does that count? How is anyone -- how is Dennis -- going to go and check and be sure that, you know, someone actually did read the label? Or you have a database where people have to log in and put their name and pesticide and licensing number in so that they can verify that they=ve read the label? That would do it, but that seems pretty command and control -- you guys don=t usually like that.

I think that all of the -- some of the benefits that you put out are quite good. The fact that they would be electronically searchable is great; the large font, I agree with you, Bill, is great; and, then, the additional -- the things that you might add, which would be links to

the other -- like the endangered species list -- I think you would need a list to the other states -- the New York, the California label, the, you know. But I think that would be kind of essential, that without that you lose a lot of the benefits of going through web-based labeling systems.

They were kind of the main points, but I think there was one other thing. I do worry, also, just like Cindy said, about changes. And we don=t want every product -- we do want a date on this thing to come out, but you don=t want to have to fiddle with what doesn=t change. You don=t want for your 3,000 products to have to go in and change the file and re-PDF it and then send it to EPA again. You want that date to be stamped on the download so, you know, that would need to be dealt with. But, then, you know, which one is viable for the date they=re using it.

I think those are my main points. Thank you. And it=s a nice effort. I=d love to see something like this.

MR. JORDAN: Great, thank you. Jim Wallace is next.

MR. WALLACE: Thanks, Bill, appreciate it. I=ll try to keep my comments brief.

First, we want to commend the Agency on its efforts to innovate such labeling. I think it=s necessary and it=s a worthy cause. I also would acknowledge that there is a need to have most current labeling available to users. And, boy, would I love to see certain label elements removed from the container. The consumer products, in particular, are somewhat crowded labels, difficult to read, and I would absolutely love to be able to delete the directions for use from those products.

But, there is a pretty significant flaw in this concept, in my mind, and specifically for consumer products. This plan assumes that consumers have access -- or most consumers -- have access to the required technology to implement this plan, and that they=re willing to use it. And that=s important -- that they=re willing to use it.

I did a little bit of research in preparation for this meeting, and it appears to me that there is still over 50 million households in the United States that do not have internet access. So, they have to use the alternative method, I assume. The consumers that would be using consumer pesticides would have to use the alternative method. In the Agency=s alternative, the proposal is a toll-free number.

I seriously doubt that the consumers are willing to call a toll-free number and wait for the label to arrive in the mail before they use their product to conduct whatever pest they are trying to control. So, as a practical matter, I just don=t think it=s feasible.

And, frankly, the Agency has got to address this prior to implementing it on consumer products or just carve out consumer products from this particular plan.

And I want to address benefits or perceived benefits. I=m not real clear on the thought that it=s easier to change a label under this system. I=m just not real clear on that. I mean, the process doesn=t change in terms of the interaction between the registrant and the Agency. And I=m not real sure, other than the printing element, you know, how this makes that interaction any easier.

And, with respect to printing costs, I can see that there could be some possible long-term savings, but short term, every label that a registrant has registered would have to be changed. So, the printing cost would actually increase short-term before any reduced cost would be realized long-term.

In terms of reduced stickering or recalls, I can

only see that they would work in the event that the container label -- that the portion that=s being changed is the portion of the container label that=s been removed.

If there=s an issue that would constitute a recall and it=s not relevant to a portion of the label that=s being accessed, you know, on the web, stickering or recalling would still be something that would have to be considered.

And in terms of the level playing field, I=m not real clear on how this would level the playing field, at least for industry. You know, compliance day is compliance day, regardless of whether it=s implemented over the web or whether there=s existing stock provisions.

So, I=ll conclude by just saying that as the Agency progresses on this, I would truly encourage broad stakeholder involvement. In the event that consumer products were left in, which, again, I=d reiterate that I can=t quite get my mind around how that would happen right now. But in the event that they did, we=ve got to find a way to reach out to consumers with limited access from a technological standpoint.

I would also encourage a pilot. And, finally, I would say that you can=t underestimate the need for

training and education on this, because, as Bill indicated, this is a culture change, and it=s going to require a lot of training, a lot of education to get people to actually utilize the system.

MR. JORDAN: Thank you. Ray McAllister, you=re next.

MR. MCALLISTER: I was telling Cindy before, during the lunchtime, that if I went last, I wouldn=t have to say anything, which is almost the case, because most of what I had written down has been expressed.

But, over the past year and a half, I=ve had the opportunity to express some of my ideas in a couple of different forms with AAPCO and SFIREG Committee, and so forth. My ideas of how electronic labels might work -- and I=m glad to see that the EPA folks and I are thinking along some of the same lines -- I think they are great concepts, we need to explore them seriously. I=m glad that EPA is taking this very seriously, and what I want to say here I don=t mean as any form of discouragement in pursuing that. It=s just some things that have come to mind that need to be addressed in the whole process.

You suggest that six months is an expiration date. That is just an initial figure to initiate discussion. I

think that=s probably not the right number. Expiration has its positives and negatives, and how we may need to go in that direction, but we need to find the right number, and it may not be the same thing for every product nor for every type of change on a product.

I think you mentioned somebody who wants to call this label up on a computer and use it right then and there, that needs to be resolved whether having it on a notebook computer in the cab of the truck or on a CDA is meet the letter of the law or regulation or what ends of governing web-based labeling.

And your presentation sort of gives the impression that after a product is registered there is a single document that represents the label of that product, which isn=t -- probably not true in more cases than it is true. There can be multiple market versions of the label, based on the registrant=s choice of marketing different uses in different areas; there can be slight variations in labels from state to state, depending on individual state requirements; or the registrant may choose to wait and satisfy all of those State requirements, print a single label before, you know, what=s going to happen sometime after the EPA approval process, before it=s actually

printed and marketed.

There=s distributor labeling, which may all be tied back to a single EPA registration number, along with sub-registrant. A registrant can legally market a single product with multiple different trade names.

So, there can be -- for a given product there can be quite a web of different documents that are all labels for that same product.

It=s important to consider a phase-in time for any additional product use, restriction or risk mitigation that would take effect through a web-based labeling system.

And, I think Cindy also mentioned this, that a user has to be able to plan ahead. They may need to purchase a product well in advance of its use, certainly more than six months, and must be able to plan on use directions and restrictions that are in place at the time of the purchase. If there are significant changes in that registration or additional restrictions or changes which might mean that under the new circumstances it would no longer fit that grower=s production practices, then he has the inventory, which he may not be able to use, and that=s a significant concern.

If they=re not imminent hazards or concerns, we

need to look at the interaction of a grower who plans ahead with a labeling system which could have a limited time of effect, it=s important to tie the web label to an unambiguous product code on the container label, and it=s going to be much more complex than an EPA registration number. And not only in multiple labels tied back to a given container label, but a product -- or a web-based label may tie to multiple versions of the container label, if there are changes on that container label between the time of purchase and the time of use.

Jim has been able to explain the concerns and problems with consumer products. That, along with Cindy=s idea of flexibility, point toward a voluntary system, which would be more appropriate than a mandatory system.

And given the numbers and the amount of product out in the marketplace already, using a web-based system for risk mitigation or putting in place new risk mitigation, could require quite a long-term transaction in order to account for real product labels that are already out in the marketplace.

And the forum for continuing these discussions, there are three or four forums already discussing it. They need to be incorporated. I don=t know the details to

delegate the discussion at that forum -- in one of those forums -- but, as others have mentioned, there are additional groups that need to be brought into the discussion, and I just want to encourage the continued discussion, and we=ll certainly help you with it in our organization from Bill and others to talk through the issues.

MR. JORDAN: Thank you. And Dennis Howard.

MR. HOWARD: Thank you, Bill. Going last, I have no more comments to give.

(Group laughter.)

MR. HOWARD: There aren=t a lot of things to say that haven=t been said, except that from the state lead agency perspective, we really applaud the Agency for taking this step out and trying to, I think, for the first time ever in the history of pesticide regulation, actually take a comprehensive look at labels and how they are used and how they could be better used to serve the entire community of pesticide users and regulators and manufacturers. And, so, from that standpoint, we thank you.

We do think that there are already electronic labels out there, and the Agency needs to take a step to address policy and how those can be used, the ones that are

already out there, and having an architecture to really think about the big picture -- how we can use these for the future would really be a benefit to all of us.

We=ve already heard a number of concerns about implementation and some of the state lead agencies, we have a lot of those concerns ourselves, but we don=t think that they=re collectively insurmountable, and we really strongly encourage the Agency moving ahead with some form of group discussion on this, gathering more information, and representing AAPCO and SFIREG, we really would applaud the Agency, again, for letting us serve in a co-regulatory capacity with you to be a part of the further discussions that go on.

We=ve heard a number of areas where there are concerns or things to think about. Most of those that I had already written down were covered, but there is a question about the use of the electronic portion of the labels versus what=s on the container label itself, and Jim may have alluded to this. But, for example, if the Agency realized that a change needed to be made on the physical part of the label, would you be able to use the electronic version to modify what was on the other side of the label, back and forth, and there could be a lot of confusion if

you tried to do that? On the other hand, if it was important to make a change quickly, that might be something you would be thinking about.

And I think the expiration dates, the shelf life for labels, is going to be a very important issue. Coming from Florida where the way we use pesticides is considerably different in the way that other parts of the country might use them, growers are operating in some places all year long versus somebody who is operating in the spring and summer and then shutting down for the rest of the period.

If there could be consideration of geographic flexibility in expiration dates, I think that they would be helpful to some of the growers.

And, also, if you purchase a label -- if you are a user and you purchased a label and the time that you have set on the label expires and you go in and print out another one, it would be really helpful if you could see what changes had occurred in that label since the last time you bought it. If there was some way of doing that, electrically, to say that, oh, by the way, you can=t use this on mangoes anymore. Just to highlight those changes and make it available.

We=re looking forward to further dialogue and appreciate the Agency=s efforts.

MR. JORDAN: Thanks, Dennis. Let me say thank you to the folks who prepared comments. All of those comments were very thoughtful and showed that you had spent a lot of time pondering how this all could work. I am heartened that so many of you said that you thought it was a better idea than not, and I will say that we=ve already identified many of the concerns that you raised, but the time constraints on my presentation didn=t allow us to float the specific solutions that we have in mind, but you raised some new points that we haven=t thought about, and that=s the reason why this kind of dialogue is very valuable.

Debbie, I note that it=s not 2:30 and that=s when this session is supposed to end, and I don=t know how you want to handle the comments and barter discussion beyond this.

MS. EDWARDS: Well, I think, as you mentioned at the beginning, this is the -- let me take a step back, actually. There obviously is, as many have mentioned, several ongoing efforts that have to do with electronic labeling. It=s something that wasn=t just once with the states but actually three times in a period of six months.

I was strongly encourage to let this out. I think what I=m hearing is that all sectors of the stakeholder community think it has some pros and it has some very difficult implementation aspects, in particular, for consumer products, just in general.

I would note that this is already the plan that we have in place for endangered species protection through the bulletins, which is a web-based system. So, we may be able to learn from what we=ve already looked at for that, as well.

But, I guess I feel like in situations where all sectors of the pesticide stakeholder community can see some good in something, we have a much better opportunity to succeed, and they actually, in this case, it appears to me, the various sectors share, to a great extent, what you view as the pros and the cons -- not entirely -- but, you know, a great deal of it.

So, I think that that means that it=s worth continuing to talk this through and try to actually make some progress on a Federal level.

So, I=m not going to open it up right now, because the whole point of having this kind of a broad panel was so that we would get all those points of view, and I think

there will probably be some additions, which I would welcome anyone calling to talk to Bill or write us a letter with your perspectives. As we=ve vetted this today, it=s the first time you=ve heard it from us, at least, and so you=re probably going to go back and think about it, and come up with some thoughts about how it might work, and some additional things that we should consider that might be issues that we need to address -- if that sounds okay.

What I think I=d like to do now, though, as to where we=re staying on time with our agenda, is move to the diagnostic biomarker piece, which is a topic that has come up, at least in a couple of previous PPDC meetings, and we took the advice and actually aired this topic in conjunction with a recent worker safety workshop. And Liz Mendez, who is a toxicologist from our Health Effects Division, chaired that workshop, I believe, and is here today to tell you how that went.

SESSION V -- DIAGNOSTIC BIOMARKERS

MS. MENDEZ: Good afternoon. Can everybody hear me? Okay. As Debbie mentioned, the outcome of the diagnostic group workshop was the comments that we seek from this group regarding some of the challenges and difficulties that clinicians face when presented with patients that may be suffering from pesticide-exposure-related illnesses.

So, we could be apprised that this could happen, and we put together a workshop, and the goal of that workshop was to gather information on the critical needs, the current state of the science and the research needs for, and the feasibility of, developing diagnostic tools to

identify exposure to specific chemicals or level of chemicals.

It is important to note this meeting was held on October 4th, so just 13 days ago. We=re still going through the comments that we received in the course of that. We are still listening to audio tapes of the meeting, which was recorded, and trying to get to that information. But we just wanted to give you a perspective of what happened 13 days ago.

We had two formal presentations; one from Dr. Matt Keifer of the University of Washington, and he provided us the clinician=s perspective. The title of his presentation was The Need for Diagnostic Tools for Pesticide Overexposure: A Clinician=s Two Cents.

Our second formal speaker was Dr. Dana Barr from the Center for Disease Control, and her presentation was entitled The Role of Diagnostic Tools in Informing Current and Future Exposure and Risk Assessments. Her perspective was that of what tools need to be developed and how we may go about doing that.

Following these two presentations, we had a roundtable discussion. At that point in time, it was important to keep in mind that we were not trying to get

consensus or group advice, but we were simply gathering information to understand the lay of the land and the issues and the problems.

The roundtable discussion we had participants from several sectors: the medical community, CDC/NIOSH, industry, farmworkers justice, FDA, and even within the Agency, the Office of Research and Development.

What I=m going to go through are some of the questions that were posed in groups. I want to emphasize that what you see here is the response that the Agency received from the participants at the meeting. It does not reflect the opinions of the Agency or any determinations that we would make. It is simply the feedback that we received from our participants.

So what are the challenges faced by clinicians? And we actually spent a great deal of time discussing this particular issue. And one of the things that kept emerging was that the symptoms are defused and nonspecific.

Just because a pesticide exposure occurred does not mean it is linked to the illness. And what several members of the medical community said, if a patient presents to me and he says, I have a rash, or I have a fever, or my stomach hurts, it could be a host of things

that is causing that. So, that=s one of the issues that they=re faced with. That=s one of the challenges. Does this have to do with pesticides? It could be any other host of things that could be happening.

We also heard that there is a disincentive to diagnose pesticide-related illnesses. And I thought that was a very interesting perspective to bring to the table. And the reason for that -- that our clinician participants said -- was every time we diagnose a pesticide-related illness, we have to go through the Worker=s Comp process. The tort rule applies, we have to do more than 50/50. There is a lot of litigation; there is a lot of time investment that goes into that. The documentation that we have to go through is exhaustive and excessive.

Some other concerns are that every time you report a pesticide-related illness, my rates go up and that=s from the people who employ the workers, who are willing to pay these things out of pocket rather than have it reported and going through the Worker=s Comp system.

The other issue that was identified for us is that there is not a widely known network of medical toxicologists that clinicians can contact.

If there is a physician in the emergency room, he

or she may not have the expertise to identify what this may have to do with this kind of chemical. And the resource isn=t there for them to know who to call, other than the poison control center. And, then, there is time before they can get to this medical toxicologist.

So, they need a simple, cost-effective diagnostic tool but it just is not available.

Other challenges is correlating exposures to specific biological effects. So, we got exposed to chemical Y and now I have a stomach ache. How did we get from that exposure to that symptom? We have a difficult time making those connections.

Obstacles for human testing, and this is something that we=ve raised both as clinicians and members of industry. They were concerned that ultimately they feel that there was a means to make those correlations -- the genetics, trying to understand and relate -- there is this amount of compounds metabolized in the urine, how did it get there? And in order to do that we have to monitor human subjects, and how would we go about that?

And the need for better dose-response, route of exposure and pharmacokinetic in humans.

There=s no good information on the relationship

between human exposure and animal exposure. By that we mean that we don=t have a common test matrix such as we=d measure compound or metabolizing blood of a human and we=d measure compound and metabolizing blood of the animal. So there is that disconnect there.

The next question the group needs is what test or diagnostic tools are used by clinicians. And the response was, we won=t use differential diagnosis. We start weeding out what it isn=t, and then what=s left is what it must be.

We can measure cholinesterace inhibition for organize phosphates and carbamates; we can measure urinary metabolites, if we have an idea what the compound exposure was; and we can do some skin patch testing, but that is not readily available or understood by most physicians.

That led us to the next question. How do clinicians choose treatment options, given the circumstances?

The response that we got time and time again is that treat the symptoms and remove from work. And the reason for that is that there are very few antidotes for pesticides, with a few exceptions.

If you have a cholinesterase inhibitor that you suspect is the culprit, then the treatment is atropine; if

there is overexposure to a rodenticide, then a Vitamin K treatment is prescribed; paraquat, then you treat it with bentonite; and the ultimate catchall is decontamination with either charcoal or Fuller=s earth.

Well, now that we=ve established the treatment options that are available, are they effective?

Decontamination and removal from exposure is usually effective; and for OPs, atropine and protopam are usually effective; as is Vitamin K for rodenticide overexposure. For paraquat overexposure, what we heard from these physicians was that it usually is not as effective as they would like it to be.

But the most effective treatment option is aggressive, supportive care. Basically going back to where we started at the previous slide.

Now, obviously, we=re talking about limited treatment objections; limited effectiveness. Would the treatment change if we had better diagnostic tools?

In the case of misdiagnosis, as a nonpesticide-related illness, new tools could correct the diagnosis and allow for more appropriate treatments. It could also allow the clinicians to say, you need to stay away from your work situation and the work environment for a little while.

Earlier screening with simple tools would lead to more timely treatment.

And in critical care conditions, the thing is we=re treating the symptoms, and better diagnostic tools would not be helpful.

One of the expressions that I heard from one of our participants, who is a clinician, I=m trying to keep my patients living, at that point.

However, what somebody else mentioned was that these patients may serve as sentinel population for alerting to possible overexposure to a broader population.

So if you can identify the person who shows up in the emergency room as if it were in Case X, you need to be aware that there may be some issues for the rest of the people in that arena.

How would new diagnostic tests inform the Agency=s risk assessment? Ultimately, that=s what we were trying to get at.

Increased accuracy of surveillance and/or incident data. We feel that there may be a number of incidents that may not be reported -- that=s their comment.

Greater awareness of pesticide-related illnesses would help refine default assumptions, may help inform the

Agency=s risk management and mitigation decisions, but it also -- and I did not put this here -- but it may also help clear a company or a chemical that has been accused of being the cause of an illness, which was misdiagnosed and it wasn=t. This could also go the other way.

So, the next question that we=ve heard was what organizations can contribute to the development of these tests?

And the responses were: The Center for Disease Control; industry and stakeholders; the national network of agricultural centers, academia and children=s centers; migrant and community clinics, and legal establishments, as well as the health care system.

I want to talk for just about two seconds about the legal establishment and the Worker=s Compensation. And that is because they felt that that was one of the biggest challenges we have to deal with, spending weeks, maybe three or four days, in a court of law is a business incentive for most physicians.

So, if we could -- their concern was, is that a process that could be streamlined? Could it be made more user friendly? That would help them a long way in how to more accurately and efficiently diagnose pesticide-related

illnesses.

And going to my very last slide -- possibilities. That was a time that we were circling around at the end of the meeting -- it was a half-day meeting.

Improving the health care system. One of the things that was a concern was that it may not be -- an adequate health care system may not be adequate.

Improve the Worker=s Compensation system; establish a better medical toxicology information network as a resource; clearly define the difference between diagnostic tools and biomonitoring; use emerging technologies, like the metabolites; and don=t limit this work to pesticides, other chemicals should also be considered.

These are the comments that we received from our participants. So, what are our next steps? Well, as I said, this only happened 13 days ago. We=re still listening to tapes. We need to process this information, talk about it amongst ourselves so we can understand what the problems are, digest that information, and what our next steps may be, if any; or if this is a role that EPA has a significant role in in doing this task or in being involved in this task, or is it maybe the purview of other

Federal agencies, and we have not yet determined that.

But we just wanted to come back to the group and let you know we did take your advice to heart, and we did try to explore this subject further.

And with that, I=ll be happy to take questions.

DR. KEIFER: This is Matt Keifer, may I ask a question or make a comment?

MS. MENDEZ: Yes, Dr. Keifer?

DR. KEIFER: Very nicely done. I thought they summarized the comments quite well. Although I would add one other thing that I think doesn=t quite fit into your talk exactly, and that may be why you didn=t mention it, but I think it=s something that should at least be on the table and understood by the PPDC.

And that is the comments that I made in my presentation about the economics of the decision-making that should possibly be -- or probably -- be considered in the cost/benefit analysis of something like this.

And that is that an insecure diagnosis, one that depends on differential diagnosis and the rule-out of many other conditions, because of the absence of a diagnostic market to give certainty to the diagnosis of overexposure, is among the most expensive approaches to diagnostic work.

You=ll remember that I quoted from an email that we had received just recently from a farm worker clinic that identified a worker, that they had been trying to figure out what was wrong about him, and they said that they had done several work-ups, and they finally concluded that maybe this is a pesticide.

Well, that, in fact, would have been circumvented had they had the diagnostic marker available, and the cost of doing several work-ups -- which can be very expensive -- would have been avoided.

So, I don=t know how EPA takes this into consideration when they do their cost/benefit analysis, but I believe this and other things, such as the uncertainty of diagnosis and the cost to workers when diagnoses are uncertain, needs, in some way, to be considered in the cost benefit process.

And that=s all I have to say. But very nicely done, I thought you did a very nice job summarizing.

MS. MENDEZ: Thank you, Dr. Keifer. Thanks for your comment.

Dr. Roberts?

DR. ROBERTS: Thanks. I=m really glad that you had this meeting. I wish I had been able to come to that.

I=m wondering, as I look through your presentation -- which I thought was excellent -- whether there were any pediatricians there or not. Because as I look through a lot of the comments, there is a lot of stuff about worker exposures and Workman=s Comp, but children=s exposures can be very different. And, of course, we don=t have to go through Workman=s Comp, but it can be extremely challenging trying to figure out some of the kids= difference in diagnoses; especially the comment about using difference in diagnosis.

But you would be amazed that when I talk to physician groups about pesticides, how many physicians truly don=t understand pesticide poisoning. It=s frightening, to tell you the truth.

If kids come in and there might be ingestion of an unknown substance, they might have a tox screen, which is primarily drugs of abuse, and maybe a few other specific things like Tylenol or aspirin. But they don=t do any specific testing for pesticides, and a lot of organic phosphates and other pesticides can present with mental status changes, common fevers.

And, so, it really is almost -- when you talk to ER physicians, especially, and most clinicians, it=s almost

a role of the dice if they can even figure out what that child ingested, because adults are going to often present with maybe a intentional ingestion, so it gives you the actual exposure, but you don=t with kids.

And, so, I guess all that said, my question is I hope that EPA does pursue this more, and I really would hope that you look more seriously about getting some specific testings.

MS. MENDEZ: Thank you for those comments, Dr. Roberts.

I=m sorry, I can=t see very well to the end of the table. Is it Ms. Davis?

MS. DAVIS: A couple of comments. I think there are two gigantic benefits here. One problem we face right now is the under-reporting of pesticide-related illness. And one reason for that, which I=m pretty sure came out at this workshop, is that if we physicians have too much uncertainty, they=re going to be disinclined to file a report on suspected pesticide illness. And that is, not withstanding the word Asuspected,@ in the reporting requirement.

And, so, they just simply don=t do it, and probably the reason that=s said is that there=s lots of

headaches afterwards if they do.

But, if they have a diagnostic tool that said, yes, this is quite likely pesticides, because it will rule out anything that doesn=t hit the test, and it would give them the assurance they need that this is worth doing.

And that would give EPA critical data that they could use to roll back into the risk assessment/risk mitigation process to have the kind of feedback group that would really be meaningful. All we need to do testing people; what are the situations where people are getting overexposed; what can be done; and can this be mitigated, et cetera? Okay.

Secondly, it would answer the Worker=s Comp program, because this relates to the same thing. The only ones who pursue the Worker=s Comp claim is that it=s Aiffy.@ However, the benefits, when a claim is valid, are quite substantial. And that=s because the workers would get the treatment they need; that there are replacement wages to stay off from work, because they really will stay off from work.

One of the problems with our current Atreatment@ of removal from work is that when you tell a guy who has mild or moderate symptoms, stay off work for two weeks,

he=s going to say, who is going to feed my family in those two weeks? I=m not getting any money.

But if you say to him, we=re going to give you replacement wages, then the whole thing looks a lot different.

And it looks different from the clinician=s point of view, too. Because the clinicians know that some of these guys who have mild to moderate symptoms, might develop more significant symptoms later, and that=s the kind of thing that if you just pay under the table, okay, I=ll three-fourths to stay at home and work, well, it doesn=t cover stuff that comes up later. And that=s the value of the Worker=s Comp system. It=s another value of it.

So, this has got to be looked at in a broader context. And I would say there=s two other things to keep in mind on the broader context.

The connection back between better diagnostic tools is that people need to know in real time what they are looking for, and this is an enforcement issue. Right now existing regulations say that if a clinician calls up and says, I=m treating somebody I think might have been poisoned with pesticides. What was he or she exposed to --

I=m talking about the work context now. Well, I have reams of cases where that is not so, and that is a gigantic problem. So that all the good diagnostic tools in the world aren=t really going to be nearly as effective if you don=t know what you=re searching for, because then you have to search for, you know, hundreds of things when it=s really you=re looking yes or no on one thing or two things.

So, you know, before we invest a ton of money on the diagnostic tool side, then we should at least link up to something in real time. So, anyway...

The other thing I just wanted to say is that when they metabolize this plan -- not a clinical diagnostic test -- that kind of data comes back in six months or more, so that=s not really relevant. And what I understood Dana Barr to have discussed is the idea of, you know, some type of dipstick-type test, and that=s the kind of thing you could do in real time that would be of value, and that=s the kind of research that I=d like to see some of these new PRIA dollars go into.

MS. MENDEZ: (Microphone not on properly.)

UNIDENTIFIED FEMALE: Just one clarification for my own information. The Worker Comp reporting, is that the only way that pesticide incident reports come in? I know

it=s one of the ways it can come in, but are there other mechanisms for reporting incidents of pesticide?

MS. MENDEZ: Yes, there could be pesticide reporting to a pesticide through a call to the Poison Control Center. And there may be some other ways of reporting it in some of the states. In California, there is a Commissioner.

UNIDENTIFIED FEMALE: Okay. But one hindrance is the Worker=s Comp issue. Did anyone have ideas -- I=m not an expert on Worker=s Comp -- I know that it is a very real and meaningful expense for employers. It=s a very important thing, but it also is a factor in their operational costs. Does anybody -- any of the clinicians who may be familiar with that system have ideas on how we can better leverage that system without -- I mean, there are incidences, both in agriculture and outside, where people have chosen to do something else or not run their operations because of exploding Worker=s Comp costs or having a particularly bad year where there were several accidents and they simply said, we can=t do this any more.

I don=t think that=s a good situation for an operation to be in and for the workers depending on the work of that operation to be in. So, were there any ideas

from them? I=m curious about, you know, what they saw as an improvement that would make it less of a hassle for them that wouldn=t put the operation in a financial fix and sort of take that business end of it away.

MS. MENDEZ: I=m trying to go through my recollection of the meeting. To the best of my recollection, that was not raised, but as I said, we=re still listening to our audio tape, so it may have been, but to the best of my recollection, I don=t think it was.

MS. EDWARDS: We=ll take the three cards that are up and then do a break. So we=ll start with Dr. Fry.

DR. FRY: Yeah, given the enormous variation in pesticide modes of action and new chemistries, finding biomarkers for individual chemicals is a really daunting proposition.

I=ve given thought to this over the years, and one alternative could be tracer chemicals in the pesticides that could be detected in blood or urine. This could be, you know, six different tracers for different chemistries, a combination of two of those -- there=s a variety of different things to make the detection more unique.

But, you know, a nontoxic chemical that would follow the reactive ingredients will be detectable in

urine, could be an enormous cost savings to a lot of this stuff. And you don=t, then, have to develop the biochemistry of the diagnostic markers themselves.

MS. MENDEZ: This is a very intriguing proposition. Thank you for sharing that with the team.

MR. MCALLISTER: I understand that the Agency recently awarded some $4 million in research grants for pesticide biomarkers. Can you explain the nature of those grants and how it may address this concern?

MS. EDWARDS: I think we=re going to have to get back to you on that.

MR. MCALLISTER: Okay. One other question. In developing a diagnostic test or a diagnostic biomarker, who has the authority and the technical expertise to verify and validate that it does, indeed, identify what you think you=re identifying?

You=ve got to be pretty certain that it was valid/positive, not false/positive, not false/negative. How does that happen? Is that within EPA=s purview or who does that type of work?

MS. MENDEZ: We had some discussions about that during the meeting. I think that our participants felt that this would be a collaborative type of effort with the

Federal government, you have State governments, academia and industry.

So, there was no clear direction from the participants as to who might have the purview or the ultimate rule.

MR. MCALLISTER: If a physician now orders a diagnostic test, blood test or whatever, to be done by a lab, doesn=t somebody have to validate that that lab test is, indeed, showing the right results, and isn=t that something FDA does?

MS. MENDEZ: My understanding is that for what is available now, FDA does do the diagnostic certification, as it were.

MR. MCALLISTER: It looks like FDA should have the lead role here, then, in developing any diagnostic test that is going to be used in the clinical study.

MS. EDWARDS: That could be an outcome. I mean, obviously, we invited FDA to the workshop, and we=re just digesting the report. But depending on what people view as appropriate options for the path forward, we would be back in touch with FDA.

Carolyn?

MS. BRICKEY: This is really a comment, not a

question. But this subject of diagnostic biomarkers, you know, it really changes the way I think. Like, instead of thinking objectively, I start to think emotionally. It=s like I think as a parent rather than a scientist. And I think, you know, if when a registrant registers a pesticide, they have to provide analytical methods for, you know, soil and water and plants and stuff like that, but they don=t have to provide a method for a doctor to be able to tell if my child has been made sick by a pesticide?

It=s just a really, you know, it=s almost a philosophical issue that I feel like EPA should really put some serious resources into this so that, you know, the Agency can answer that question in a good way when parents, or whoever, ask.

MS. EDWARDS: Okay, thank you all for your comments, and we will return at 3:20.

(Whereupon, there was a break in the proceedings.)

MS. EDWARDS: Session Number VI is a worker safety update, and our session chair for that is Kevin Keaney, who is the Chief of our Certification and Worker Protection Branch in the Field and External Affairs Division.

SESSION VI -- WORKER SAFETY UPDATE

MR. KEANEY: Before I give you the update on the regulatory development process we=re involved in, I=d like to highlight a conference we did last week, and for those of you who didn=t attend it, I=ll let copies of the agenda outside on the table.

A conference on Pesticide Worker Safety and Health, which we used to highlight a variety of things that we=re doing with grant money and also bring together a variety of topic areas, or folks dealing with topic areas, having relevance to pesticide worker safety and health.

I thought it was a -- I and a number of others mentioned it specifically to me as a good forum to discuss issues and to make sure that resources weren=t duplicative in activities so that folks could share information and focus their studies and their activities in productive ways to help us and inform us, particularly in regulatory development or in future activities that we might be taking through grants and uses of PRIA money. So, it was valuable

for us; it was valuable, I think, for a lot of the attendees and presenters to engage each other in break-out sessions and see the reaction of an audience representing disparate interests to their research and their directions of study.

And we are committed to do this regularly. We ask that people at the conference take advantage of the evaluation forms that we gave them to give us guidance as to how we could do this differently, better, more frequently, however the people felt.

The general consensus, after a quick look, is that we will be doing it regularly, perhaps on an every-other-year basis, and we=d like you, as a group, to help give us guidance into how we can structure the next exercise of this sort in 2009.

The presentations, the notes from the general sense of the break-out sessions, and something that is, in effect, our to-do list that comes from the session, will be published in a proceeding package in a month or so. So, we=ll provide that to you when we get that.

But it=s, as I said, I think it=s a valuable exercise. Take a look at the agenda, if you weren=t at the conference. A number of you were at the conference, a

number of you presented at the conference, but take a look at it, because we will be contacting you as we approach the planning of the next exercise. We=ll get to you, after you=ve seen the proceedings, as well, and ask your guidance as to where we might go in the future with this type of activity.

Regulatory development. We=re continuing to develop the regulatory proposals, but many of you were engaged with us in issue-paper discussions and conference calls. We have all your comments that we asked you to send in on the various issues and papers, and we=re incorporating those comments into working papers for our internal work group to deal with. So, we are in the process now of dealing with the internal EPA work group. We=re engaging contractors and discussions with contractors in developing the regulatory impact analysis, the economic impact analysis of a range of options that we would be considering.

It is customary to have a work group report back to the whole, so there was a work group we were dealing with and it expanded dramatically, but the members of the initial PPDC workgroup will be contacted. I=ll be contacting you to discuss the nature of the report back to

the whole PPDC, how we can go about helping you facilitate that development of that report, and we=ll be in contact with you fairly soon about that and how we can proceed with that.

And in that discussion we=ll determine what the deadline would be; presumably, not the next PPDC, but perhaps the one after if we can get the report back from the pesticide worker safety program workgroup.

We are considering all of the options -- all of the options are still on the table that we had presented to the workgroup. We met recently with the Farmworker Justice Fund, and that was an issue that Shelly raised, the assumption that some of the issues are off the table already -- they aren=t. We are arraying them all for discussion internally, discussion with the workgroup, presentation up the line through the management chain, and when we go through that process, we=ll probably see some of the options will fall away. Some of the options may fall away simply because of statutory constraints, not having adequate oversight through statute, so there are a number of reasons why some of the things that were presented to us will not be in the mix of options as the mix of options shrinks. But at the moment we aren=t ignoring any of the

options, they=re all still in play.

With that, I have something of a counterpoint that came out of a meeting that Rebeckah called, again, with the assistant administrator -- Rebeckah from Farm Bureau -- saying that some word from the State Farm Bureaus were that there was some word of concern for the opposite extreme that every recommendation that had been presented to us was going to be in the mix -- in the final mix -- which is, obviously, not the case.

So, both of the positions are extremes, and don=t acknowledge the process that we tried to describe to you quite a while ago and certainly in great detail with the workgroup, that there is a process where we=re engaging a number of stakeholders in getting a variety of suggestions and recommendations from the stakeholders that we will consider -- the internal workgroup -- will consider, but the whole universe that we=re dealing with now is certainly not going to be the universe that=s going to wind up in regulatory language and proposal language.

And at, I think, the last meeting, we did say that when we reach that stage, the workgroup, itself, will get an FYI look at the final package before going to proposal. And, of course, as with any part of the proposing

regulation and through the administrative process, there will be the formal comment period where everyone can come in, again, with their comments and assessment of where they think we should be going, even with what we have to deal with as statutory reality, fiscal reality, and economic reality as to the proposals we will be making.

So, are there any comments on any of that?

MS. DAVIS: Thank you for this update. A couple of quick comments. One is, as a member of the workgroup, which I really appreciated being, it struck me at our last meeting that there isn=t really a lot of consensus, and one possibility, in terms of writing a report, might be just to have, you know, four reports, or however many sectors we were, you know -- farm worker/public interest is one set; the growers; chemical companies -- something like that -- but have each of the sectors write their own report. We all listened to everything, and these people could put forth what they thought were the most important suggestions, and we wouldn=t just have an endless rehash of the debate that has gone on to date. So, that=s one thought.

The other thing I just wanted to ask was when, in terms of a time frame, would you have the packet of

proposals that you think you=re going to go forward with to proposed rule?

MR. KEANEY: I=ll have to get that to you after we talk further with the internal workgroup. I mean, we have our schedule, obviously, and we=re going to have a reality check in keeping pace with the schedule, but I can send that to the workgroup after we have the internal discussion.

And, as to your earlier discussion, I think that=s a good approach. However, we can provide the framework for the process, obviously. We can help with that. But, of course, it=s up to the workgroup how you want to approach this, but that probably is a good way to capture the, you know, the disparate interests that were in the workgroup, you know, and I certainly would second your proposal that we don=t get into endless discussions again. I would like to not do that.

I think that=s a management approach to it, though, to designate sectors and have some parts of the workgroup deal with that, and we=ll provide the overarching discussion of the process that we went through.

Ray?

MR. MCALLISTER: Over the summer you accepted

comments on kind of an informal basis on some of the proposals you=re addressing for the worker protection standard. Are those comments going to be made available in a public docket?

MR. KEANEY: They should be in the docket, yeah.

MR. MCALLISTER: They=re in the docket now?

MR. KEANEY: Yeah.

MR. MCALLISTER: Okay.

MR. KEANEY: Okay? All right, thank you.

MS. EDWARDS: Okay. The next session, which is Session VII, is the Transition WorkGroup/AZM Case Study. Our chairs are Rick Keigwin, Director of the Biological and Economic Analysis Division, and Al Jennings is the Director of the Pest Management Program at USDA.

SESSION VII -- TRANSITION WORK GROUP/AZM CASE STUDY

MR. KEIGWIN: Thanks, Debbie, we have a little bit -- this is actually going to be more of a work group members= presentation, as opposed to Al or I talking for too long -- Al and I both like that idea.

Adam Sharp from the Ohio Farm Bureau Federation is joining to present one of the case studies. And, then, on the phone should be Jay Brunner and Mike Willett. Jay is with Washington State University, and Mike Willett with the Northwest Horticultural Council.

Are Jay and Mike here?

MR. WILLETT: This is Mike Willett.

MR. BRUNNER: This is Jay Brunner.

MR. KEIGWIN: Okay, great. So, as I mentioned, we=re here today to really more give you an update on our work group process and progress. Over the past seven months, we=ve really focused our efforts on developing tools to track the progress through the transition.

These types of tools include tracking tables on the registration status of new alternatives in the progress toward establishment of maximum residue limits or MRLs in key export markets.

We=ve also begun discussing the development of some performance measures to track progress through the transition. One of the ideas that we recently discussed was looking at the use of percent crop treated data on a regional basis to help us evaluate that as a performance measure.

We=re also scoping out what a website might look like to serve as a resource on avian transition issues for folks.

But what we really wanted to do today is to focus on the two case studies that we have underway. I=m going to ask Adam to go first and talk about some progress that the Ohio Parsley Growers have made on transition area in Ohio parsley.

MR. SHARP: All right, thanks, Rick. I have to go first because I=m going to be very brief.

We=ve had a little bit of a struggle starting this. As you can imagine, this is, you know, getting into the transition strategy, getting the growers, getting their researchers and folks together, just even within our state, it=s a very small community, as you can imagine, on parsley growing. We=ve got about six major growers in the state and trying to get them organized was a bit difficult this year, and I do send my apologies along to Jeff Dellards (phonetic), who many of you do know.

Jeff was going to be able to give the briefing, but he was one of the victims, if you will, of the weather this year. We=ve had -- between heat, drought, freezes, flood, hail -- it=s been a bit biblical in Ohio. We ended

up with -- Jeff at his farm -- ended up with over five inches of rain in about an hour about a month or so ago. They lost 155 acres out of 500 acres of vegetables.

Now, if any of you know the value of an acre of vegetables, times that by 155. So, we=ve had a bit of a time getting our parsley guys to focus on this this year, given the struggles that they=ve been dealing with, which has outlined some actually interesting issues that we=re going to be talking about at the meeting, I=m going to mention to you right now.

And one of those issues is, you know, we had a prolonged set of drought situations around Ohio for most of the summer, until late August, and then all the rain came within about a week=s period. Some pest issues, interesting enough, had been relatively moderate for most of the season, and some of the applications had already been made of the products.

And, of course, a lot of growers had already completed most of the applications that they thought they were going to need for the summer and, then, lo and behold along comes all of this rain and all those dormant pests and pesticide insect eggs that were in those plants, et cetera, exploded, and within a week or two afterwards, they

ended up having all kinds of pest issues at a lot later date than they typically would have.

So, it just brought a whole different element to transition strategy and planning here that, frankly, we hadn=t thought of until this one happened. So, that=s going to be part of our discussion, as well, at our meeting.

We have scheduled -- and the apple folks are going to get into the detail of where they are here in a minute -- but on parsley in Ohio, we scheduled for November 15th, at a PMFP meeting, in Worcester, Ohio, it=s OSU -- Ohio State University -- and the Ohio State University Extension folks, along with -- and I wanted to say thanks to Al Jennings at USDA and the North Center IPM Center -- those folks have been very helpful in getting this meeting together.

We=re going to get a group together on November 15th to do the PMFP plan for parsley. We=re starting kind of a little bit more from square one on parsley than apples and some of the others who have already had some of these base-work plans in place, so we=re working just to get our PMFP plan first put together here. That=s going to happen on November 15th.

We have about six or seven folks from OSU Extension participating. As I mentioned, EPA, USDA, several of the grower groups in Ohio, and others will be at that meeting.

If folks are interested, let me know. We do have the arrangements all set up, so we=re looking forward to that meeting.

We do have a few folks -- there haven=t been a whole lot of folks, as you can imagine, who have done research in the field on parsley and parsley alternatives. But we do have a couple -- Casey White from Ohio State University, is going to be there. He=s going to be presenting a lot of the information. He=s done work on a number of alternatives. And we have identified and drafted a draft transition strategy plan. We hope to turn it more -- right now, it=s pretty much in outline form -- we hope to turn it much more into a more in-depth document following this meeting, on the 15th.

I=m going to stop with that and ask if folks have any questions, comments, or if you have an interest, there=s a couple of folks here in the room who are coming out to the meeting, but if anybody else, if you have any questions or comments, I=ll take some now or following. If

you want some more specific information about the meeting, I can give you a copy of the letter. Okay?

Larry?

MR. ELWORTH: Adam, when you get a chance to develop this plan and stuff like that, are you going to come back to the work group or to the PPDC, and then what=s your plan after all that?

MR. SHARP: Well, we=ll follow the guidance in the interest, I guess, of the group and the Agency on that. As you know PMFP plans, when we are just developing those, we need to first get that put together. Now, that, as you know, is going to be a full day session, and maybe even more -- five or six -- and then we=ll put together the draft afterwards and share it and make sure we=ve captured all alternatives.

Right now, we have a very bare bones outline that has about five alternatives identified, and we=re going to start with those five and work through some other ones. But, yes, it would be our interest after that to share it as the groups get set, really.

MR. ELWORTH: All those all registered alternatives?

MR. SHARP: Well, they are registered for some

crops, not necessarily are all registered to parsley.

MR. ELWORTH: Okay. Are you all going to have report data?

MR. SHARP: Yeah. Any other questions?

MS. EDWARDS: Ray, do you have a question or is your tent card up from a -- okay.

MR. SHARP: Okay. If you have questions at the end, we may have time.

MS. EDWARDS: Now we=re going to turn this over to Jay Brunner and Mike Willett and talk about the transition plan in Washington apples. Jay?

MR. BRUNNER: Okay. We have our PowerPoint up.

MS. EDWARDS: Yeah, the PowerPoint is up and the presentation should have been distributed over the break.

MR. BRUNNER: Okay. Well, thanks for the opportunity to talk via phone instead of in person. Just based on schedules and commitments, it was very difficult to get out there this week.

I=m probably going to take the lead on this, and Mike will jump in when he feels the need to correct me, maybe.

Let=s go to the second slide. And this slide shows the mass data -- the pesticide-use survey -- and I=ll

just make a comment that that survey has been very helpful over the years in being able to track changes in pesticide use in different crops, and I hope that continues.

As you can see, over the last decade, roughly the use of organophosphates has declined, that=s due to use of pheromones and regulatory pressure or removal of certain -- some OPs. And yet azinphosmethyl remains in the Washington apple production area, the highest used organophosphate that we have, approximately over using, and that=s targeted only for codling moth control.

And approximately 75 percent of the apple acres in Washington are treated with theromo, which is part of a pest management program.

The next slide, the third slide. This summarizes the EPA decision on the phase-out of apples for Washington, and I think this is pretty much standard throughout the country. Essentially the pounds of active ingredients translates to the number of applications that could be used per season. So, it declines from three to two to essentially one in the final two years, and that=s the impact on restricting the use of the product over time.

This next slide shows the -- defined as organophosphate product for control of the pest, codling

moth, and the alternatives available. These are the trade name alternatives or generic descriptions in terms of oil and virus and pheromones that are available for managing the codling moth.

And we, as a land grant university, have tested these various products in our program, at least for two years before we make any recommendations to the industry as to how their applicacy and how they fit into an IPM program.

Delegate and altacor are shown in the next slide. These are two new insecticides that will be registered for use against codling moth.

Altacor is a new class of insecticides developed by DuPont. It is reduced risk. There was a noncrop destruct experimental use permit provided in 2007, and that allowed us to work with growers on a limited basis to examine the fit of this product in pest management programs and full registration is expected early in 2008.

Delegate is a product developed by Dow, and it comes out of the spinosin family or class. It, again, is reduced risk, and it, I think, just received full registration or registration in October, so it will be available next year for use.

This, again, looks at the alternatives and talks about some of the known issue with alternatives. We don=t approach this transition, period, thinking that we can just substitute without any impact on our system, these alternatives, and we know from our research that alternatives, especially assail and calypso, have been involved or implicated in disruption of spider mite biological control, which is an important component for our pest management programs in the west. It also has negative effects on other natural enemies.

Rimon, which is a insect-growth regulator. We=re having increasing concerns about its negative effects on the biological control agents, which would be nontarget effects.

Pyrethroids are broad-spectrum insecticides. We generally, as a rule, do not recommend these products for codling moth or any other pest control in Washington, because they=re disruptive of biological controls that we=re trying to conserve and encourage.

Intrepid is a product that we have used, but we know that there=s resistance in the population -- in codling moth -- and this is actually a cross resistance with organophosphates.

And we know oil and virus can be important components of a multi-tactic pest management program, but they suffer from having short residual activity and viruses in a highly selective product.

Can I just repeat that we don=t expect to use just these alternatives of substitutions for defining, but they need to be incorporated into a program.

MR. WILLETT: Jay, before you leave that slide, maybe one of the reasons why there even was that slide there was because these impacts are impacts that aren=t evaluated completely prior to registration and use of a product in the field. And, so, this information is information that is often collected after a product is registered. And, unlike a lot of other impacts in the system in terms of registration of a pesticide, this is not included.

And, so, that=s why this information is really important to growers, and that=s why Jay summarized it here as one of the things that people that either have to write recommendations for these alternatives in this transition or are using these products, they need to know this kind of information, and it=s not available and it has never really been done, as opposed to other types of impacts of these

particular pesticides.

MR. BRUNNER: All right, thanks, Mike. So, now we=ll go to slide 7. And I just mention that before the ACM working group was formed, the Washington fruit industry was embarking on a kind of a proactive strategy to help growers transition to new pest control technologies.

Key industry leadership groups joined with WSU to develop a plan, and these leadership groups -- especially the Hort Association -- took the concept of the State legislature and received funding.

Since then, we=ve floated the concept and the idea of the pest management transition project to other funding agencies, and we=ve received some additional funding. So, this project had legs before AZM -- the AZM working group and some of the AZM decisions were made. And, so, we=re going forward, and it looks like, you know, we=ve made a lot of progress maybe in a few months, but it=s been a longer process than that.

MR. WILLETT: Yeah. And, also, Jay, if I could, I think that it=s really important to understand that as we go through this project, you=ll see that it has significant scope and significant involvement. And the reason for that is that the Washington and the northwest apple industry is

a huge industry -- 3,000 or 4,000 growers, a lot of allied industry people that are involved in the process of this transition. And, based on experience that Jay=s had and I=ve had when I used to work for Washington State University, it takes a project like this in order to reach the maximum numbers of people.

But this is not what we=re proposing as a one-size-fits-all approach to other commodities or even apples growing in other parts of the country. Those regions are going to address the transition in their own way, based on the realities of the industries in those areas and the challenges that the transition faces in those districts.

MR. BRUNNER: Yeah, thanks, Mike, that=s a good point. We know that pest management programs are site-specific and regional differences are certainly in the eastern and western apple production areas, and even within the west there are differences.

The next slide, eight, shows the elements of the transition plan and has an administrative component and executive committee that will, then, hire the project manager and an assessment documentation specialist.

The focus areas are going to be education and communication for new knowledge on what the tools are and

how to use them.

Implementation will definite strategies and work with small groups of growers to address their specific needs in these alternatives, and we won=t be just focusing on codling moth, but the entire system.

And, then, assessment and documentation is very important for us to identify the successes and failures of the alternative programs and to document the social and economic benefits of the program.

This next slide is just kind of a reiteration, in a different sense, of the objectives of the plan. So, our first objective is to enhance understanding of these new IPM technologies through education and communications. And this information is centered around a research-based knowledge that we have from working with these products.

We want to obviously increase adoption of IPM technologies, and the model we=ll be using here is one we used in the codling moth area-wide management project, where we=ll be getting growers and technicians to share their experiences instead of spending a lot of time on lectures from university or academics, because it=s a better way to transfer knowledge.

And, finally, we=re going to document changes in

practices, attitudes and perceptions, not only of growers but of farm workers and other stakeholders that I=ll identify.

And the next slide shows an organizational chart. Again, we have an executive committee made up of myself, the executive director of the Hort Association -- the major grower association in the State. The manager of the Treefort Research Commission, which is a grower-funded research commission. A WSU extension person, who works with the industry, especially the Hispanic community. And, then, the director for the Center for Sustaining Ag and Natural Resources, which interfaces with a lot of the bio-ag sustainable groups in the State.

We=ve put together an advisory committee, and I=ll mention that briefly. We are in the process of hiring an assessment specialist and a project manager. And, then, you can kind of see how the organizational chart flows, at least at this point. It=s a work in progress.

We=re also working with Equip to identify and help growers identify resources they can access through implementing IPM programs, as part of this project.

For the next slide, it shows the advisory committee. These are all people in different categories, a

broad cross section of industry and other stakeholder groups that have committed to serve on the advisory committee. The advisory committee was formed by the executive committee, looking at the people we were aware of who could provide input into the direction and assessing the progress of this project. And we plan to have our first meeting sometime in mid-November.

The next slide, slide 12, shows the time line for the transition plan. We=ve actually achieved the first two objectives, and we=ll be working through the rest of these in the next two years. We anticipate a full project will probably take three-and-a-half to four years. So, we=ll have to access some extra funds toward the end of the first two years of this project.

And, then, finally one of the big barriers to any transition program is exports. And I=ll just turn this last slide over to Mike Willett.

MR. WILLETT: What we have here, on the left axis of this table, are the top 10 markets for northwest apples. It lists them in order of volume. And, then, we=ve listed the alternatives, as identified by the Agency to AZM, in the phase out.

And approximately 30 percent of all the apples

grown in northwest orchards are exported. So that export is a big factor in most growers and packers= minds in terms of being able to grow fruit that meets the requirements of those markets.

But growers don=t specifically grow for a market. They grow the best quality fruit and then hope that it can be sold into a market that is going to return them the highest dollar value at any given moment in time, and that changes depending on the season and even within the season.

So, they need to have fruit that=s available to go most flexibly to whatever market meets that requirement of greatest return.

And, so, you can see on this list here, for example, let=s use Acetamiprid. Acetamiprid is probably the most widely used alternative to AZM right now, because of the relative efficacy. Obviously, efficacy is really an important issue in this, as well, because codling moth and a number of other pests in the complex that are impacted by this transition, are also quarantined pests in export markets. So that being able to get adequate control by moving to these alternatives that have lower toxicity is a real -- both of those issues are really important in this transition.

Unfortunately, Acetamiprid, as you can see, doesn=t have MRLs in a lot of these countries. And it=s used now because it can be used relatively early in the growing season when the likelihood of having residues at harvest is very low, but, then, if control is needed later on, it can be supplemented with AZM, which, as you can see, has -- over on the far right-hand side -- has MRLs in most of the markets that we are going into, and particularly in those markets are scrutinizing the product very closely as it arrives.

And Jay even talked today about two additional alternatives that we think will be very valuable. Well, it=s going to take some time to get MRLs in those markets so that people have the most flexibility in using products with the assurance that they won=t have issues upon arrival in a foreign market.

We know we need to have those MRLs -- industry is fully aware that we need to have those MRLs -- and the Northwest Hort Council started a project in working directly with the registrants to encourage them, as they submit for registration, to start the process of registering these things in these key markets. And this information about what the key markets are is on the

Northwest Horticultural Council=s website.

But this decision is not in our hands in terms of even to go forward with pursuing a registration in a foreign country. For example, to the best of our knowledge, based on communication with the Acetamiprid registrant just a month or so ago, they haven=t even tried to pursue a Codex tolerance for Acetamiprid yet on any commodity.

So, that this is a real balancing act, and it=s really an important issue that the AZM work group is following, and the slide I=m showing you here mirrors the tracking approach that the work group is using, and we may need to expand it as we look at these other alternatives where we=re concerned about residue issues.

MR. BRUNNER: That=s it, Rick.

MR. KEIGWIN: Okay, thanks. I want to leave a little bit of time for questions, just a couple of last points I wanted to make.

One is, we=re going to continue to work on developing these case studies further, as well as some of the work group members have also expressed a desire to move beyond the tools that we=ve been developing to begin to identify industry needs to specific research and what can

be done in those regards. So, we=ll begin to have those discussions.

There are some commodity groups that have earlier phase-out dates, and we=re starting to hear about potential emerging issues, especially with the phase out. And, so, we need to get a better understanding of what issues are facing those crops as they try to transition.

And, then, additionally, some other groups have talked about developing regional-specific transition plans along the lines of what the Washington apple folks have already done, and the Ohio parsley folks are beginning to do, and we=ve been encouraging them to do that.

And, finally, Canada is now going through a similar phase out, as are we, or as we have been. And, so, they have decided to form sort of a Canadian analog to this PPDC work group. And, so, they=ll be having their first meeting of their industry stakeholder working group on AZM transition in November. And, so, we=re looking at opportunities to work together, you know, bi-laterally and across North America to try to monitor the phase-out units together. And, so, with that, we can take some questions.

Cindy?

MS. BAKER: Thanks, Rick, and thanks Jay and Mike.

This has been big with Gowan. I want to just do one quick clarifying point for Phosmet, because I just wouldn=t be doing my job for if I didn=t.

There is a tolerance in the United Kingdom. There=s some confusion in talking to PSD about that because of the process that=s undergoing in the EU about harmonizing MRLs, but there is also a proposed tolerance for an EU-MRL. So, rather than fight the issue, by December we=ll probably have it resolved.

But that=s the point I really wanted to make. What I really wanted to make is that I think this is a huge undertaking, on a huge scale from a number of different standpoints, and I really think it=s important that we get this feedback as to what you have learned as you go through something like this, because this is, I mean, a product like azinphos has, that had such a key role in the apple industry and the effects of that, I think is very valuable to understand, you know, what process you went through and how that has played out real time, real world and what the implications are.

I=m curious to know, while this talks a lot about codling moth, a product like azinphos or AZM, for that matter, is very broad-spectrum, and one of the things that

we were talking about for years, as we looked at FPMA and transitioned away from some of these broad spectrum materials, is what=s happening to some of those secondary pests. So I=m curious if there=s any data being collected through this transition process to talk about, you know, some of those other pests.

(End of CD 4/beginning of CD 5)

MR. WILLETT: Cindy, this is Mike. Thanks for pointing that out. We may have looked at the EU when we constructed this table. We=ll go back and look at that again on Phosmet in the UK, and maybe Jay could address the question about nontarget and other pests that might be affected by the phase out, as well.

MR. BRUNNER: Yeah, this is an implementation education program, not a research program, but there are ancillary activities going on with secondary pests, and what we=ve already -- you know, I=ve mentioned some of the negative effects we=ve already seen from the class. When we went to mating disruption and reduced organophosphates in orchards, we had more problems with leaf rollers.

So we know that these transition effects will occur. And we=ll do the best we can to document not just successes and failures with codling moth, but what happens

in terms of positive and negative effects with secondary pests.

One example is a leafroller larva, which seems to be increasing as a problem. And while we don=t know exactly why, we suspect it=s possibly disruptions of biological control or removal of organophosphate pressure from codling moth, allowing the pest to increase.

So, those are things we=ll be looking at and documenting them, as best we can.

MS. BAKER: And just one other clarifying point. I think on Acetamiprid part of the problem you=re going to have, Mike, is different registrants. In the U.S., you know, it=s agreed, but globally, outside of the U.S., it=s netho-America. And, so, talking to the U.S. registrants, they=re not -- there=s no incentive for them to -- I mean, other than your apple industry -- for sure there is -- but I think that=s another good lesson as you look at some of these things, that not every active ingredient has the same registrant globally. And, so, sometimes if you look at the priorities for what you can do and where you can go with them, that factors in.

MR. WILLETT: Okay, good point, Cindy, it reinforces the fact that this is a challenge and not in

either the EPA=s hands or the industry=s hands in some cases in determining what are going to be the appropriate alternatives down the road.

MR. BRUNNER: Okay, I think we=ll keep going around the table. I think, Shelly, you had your tent card up?

MS. DAVIS: Just a couple of quick points. One is that I think this is a very good, you know, case study to show, you know, what=s going on. I applaud them for moving along as they have.

But there=s also, you know, an overlay of activities that the EPA is up to, the work group we=ve talked about, and one of things is to have an in-depth matrix on the MRL question in terms of where there are proposed MRLs, where there are, you know, finals, et cetera.

And, also, information about apples and what percentage of the crop goes to the new countries, so what really are the key export countries.

But something that we have debated and left out of the apple case study that we just saw, and I think what really needs to get back into the mix is that there=s no real point in going through an extensive transition process

to adopt widespread usage of a pesticide that also causes adverse health effects.

So, we have urged, as part of the transition, a package of information to include information that is available on the adverse health effects of the particulate pesticide alternative or the alternative, so that people can factor that into their decisions about what they=re going to choose. And I think that it=s really just a corollary of things, X-products as, you know, resistant or causes X problem with, you know, a beneficial or whatever.

You=re not going to choose that. Well, surely, you=re not going to choose something that=s also going to cause these health problems.

So, as we go forward, I think it=s really important that that information gets back into the mix.

MR. KEIGWIN: (Inaudible.)

UNIDENTIFIED MALE: Jay and Mike, thanks for doing this. I had a couple of questions and wanted to make a couple of quick points.

The thing that I look for here is some sense of what the relative applicacy of these alternatives are, and I know you guys have that information. It might not be generally interesting, but I=d like to see some relative

applicacy and the range of pests that it works on.

And, also, you know, coming from the grower=s side, I=d be kind of interested in the relative cost of these materials, so they can be compared to each other.

And, so, if you all just have nothing to do and want to pass that information along, that would be great.

Second, Mike, you talked about exports. Do you want to -- I=m not sure everybody understands how many bushels you all export every year.

MR. WILLETT: You want me to tell you that now?

UNIDENTIFIED MALE: Yeah, yeah, yeah.

MR. WILLETT: Okay. The average crop in Washington State is running about one hundred million and forty two-pound cartons of apples a year. And I said about 30 percent of that, so roughly 30 million cartons of apples are exported a year, about half of that is going to Mexico and Canada. And, then, the other half is going to any number -- 30 or 40 countries around the world. And we do have the information about the volume that=s going to different countries on the Northwest Hort Council=s website, should there be some interest. But it=s a large volume, and it obviously becomes a significant part of the decision-making process.

UNIDENTIFIED MALE: Yeah, I just wanted to point that out, because it=s a huge amount of apples.

The other thing is, sort of along the lines of Shelley=s comment, I think it would be interesting when marketers currently know MRL, to yield at least whether there is a proposed MRL and what the schedule is -- only for assessment purposes. I mean, I=m not going to do anything about it. But it would be interesting to have that information.

But the other thing I want to mention is I think it should really get exercised, and I want to follow up with something that Mike and Jay both said, is that to the extent you see this array for western apples, the situation as you get east of the Mississippi is as complicated, if not more complicated, both in terms of -- which is not anything to brag about, by the way -- but more complicated in terms of the number of pests and the number of secondary pests or other pests that might come up, so I just want to kind of point that out. It would be just a worthwhile exercise, but I think we=d see even a vast number of more variables to look into here.

MR. BRUNNER: I will make a comment. We have relative efficacy guidelines for these products in our

literature, and that=s based on not just a per-application basis, but on a programmatic season-long comparisons. And the cost of new technology is more expensive than older technology -- 30 to 100 percent more -- if you use rate of Azinphos as a standard.

MR. KEIGWIN: Okay, I think in the interest of time, we=ve got two more cards up and then we=ll have to move on to the next topic.

Carolyn?

MS. BRICKEY: My name is Carolyn Brickey. I have a couple of different kinds of questions. With regard to this chart, which is slide 13, I think I heard you say that registrants are pursuing what I would call a unilateral strategy in terms of getting MRLs. And, if so, what does that say about the Codex process, and why are some of the -- it looks like three -- of the countries have Codex in paren, so I don=t understand what that means. I mean, Codex is supposed to -- although it does operate slowly -- it is supposed to provide information that will make MRLs appear more quickly.

Do you have any comment on that? I don=t understand your chart in that regard.

MR. WILLETT: Sure, no problem, I am glad to

explain that. First on your questions about the unilateral issue. Most registrants are pursuing Codex tolerances, but one of the challenges we have is that not all countries will accept Codex tolerances. Some do, some set their own, and then if they don=t have one, they=ll accept the Codex tolerance or maybe even the exporting country=s tolerance or MRL.

Some countries defer completely to Codex, in the case of Hong Kong, the United Arab Emirates, and India. And in the United Arab Emirates, we=re looking at countries that are -- particularly in Hong Kong -- generally defer to Codex, and India is a little different story that=s sort of influx right now, how they=re handling it.

But generally speaking the problem we have with Codex is that while it is a multi-lateral strategy, which is really good and we think it ought to be embraced a little more widely, you know, even in the United States, the wholesale acceptance of Codex is not automatic, and a lot of other countries feel the same way.

So, there always needs to be a two-track approach. We think Codex is really important, but we also think that in those countries that don=t immediately defer to Codex, that the registrants are going to have to pursue tolerances

or MRLs in those countries on a compound-by-compound, commodity-by-commodity basis.

MS. BRICKEY: You indicated earlier that this is not a research project, but it seems that there=s a lot to learn from the experiences that everybody goes through as part of this process.

What about the two new chemicals, we didn=t really hear very much about them, and how are they being incorporated into these plans? Because the way you use these different chemicals and with the way you adopt spray plans and so on will be research, in a sense.

MR. BRUNNER: Yeah, I think I can address that. Well, there is going to be some research, not on the chemicals, necessarily. We think we have a pretty good understanding of how they work and how they fit into our pest management program. These two products we=ve worked with in an experimental sense for four or five years already.

And we have strategies, you can go to our website, WSU, Treefort Research Extension Center website, and we have some PDF documents you can look at on transition strategies for these products. So, we have some ideas on how they would be incorporated into programs.

The research that=s going to probably go on is more in the area of how people make decisions, how they accept and receive information, who they receive it from, who they trust, and how that changes practices or perceptions of either IPM strategies or the alternatives that are being used in orchards.

MS. BRICKEY: Do you have funding to do that kind of research?

MR. BRUNNER: Yeah, the ancillary funding we got from a project called Ag Pilots Project, it=s a Washington State-based kind of a policy group that has State funding, and we competed for funding from them, and that=s dedicated to hiring a post in our Department of Community and Rural Sociology. And actually we=ll be probably interviewing someone in a couple of weeks for that position. And the focus there is going to be on process change -- change process, and not just counting how many pesticides are used, but how people make decisions and change programs.

MS. BRICKEY: Well, you know, an awful lot of research has already been done in that area, so I hope you=re taking advantage of that.

MR. BRUNNER: That=s not my areas of expertise, but I=m sure the people we=re working with in rural

sociology are aware of it, yeah.

MS. BRICKEY: Okay, thank you.

MS. EDWARDS: We now have Pat Quinn, who will talk to us about the Non-Animal Testing Alternative to the Draize Test.

SESSION VIII -- NON-ANIMAL TESTING

(ALTERNATIVE TO DRAIZE TEST)

MR. QUINN: I=m bringing back to all of you a topic that I know you waited for all day with bated breath. About four years ago, there was a discussion -- I think at the fall meeting, actually, in 2003 -- for those of you who were a part of the group at that point, about future topics, and one of them was progress on non-animal alternative testing. And there was fairly diverse interest within this committee about pursuing something.

And, so, after four years of efforts, I thought it was appropriate to bring back to you a quick summary of the completion of the science on an approach to replace the Draize test, the rapid eye test, that is presently required for acute toxicity. So, I=m going to summarize that for you here today.

We call ourselves the Alternative Testing Working Group. We=re not an official work group of this committee, but that is how we=ve been known to people who have worked with us over the last several years. So, that, when you look at the project history, Jim Jones wrote to Bill Stokes, who=s head of something ICCVAM, Interagency Committee that approves alternative methods, back in 2004 and said, look, I=d like to conduct an industry workshop and we=d like to make some real progress on this. And Jim went so far as to indicate a goal of implementing a new science policy on eye by the fall of 2005. It=s taken us a bit longer than that.

At the time Bill Stokes, who heads up ICCVAM, wrote back to Jim and said, look, this is really what we do. You know, we approve alternative methods, that=s our charter, we=d like this to be a background review document, that=s what BRD stands for. It=s reviewed by ICCVAM formally and so, we, as the companies participating, agreed to that and EPA did as well.

So, then in 2005, we had to conduct a lot of non-animal testing in order to match up with what was some older animal data. There was no new animal testing conducted. And we briefed several people here who have

been enormously helpful, among them Debbie, Jack Housenger, Tina Levine, John Redden, a senior group of toxicologists throughout the process here.

We also traveled down to North Carolina to make sure we had some alignment with what NICETM and Mr. Stokes were expecting.

We actually briefed something -- this is actually a wonderful acronym -- the ODTWG, that=s the Ocular and Dermal Technical Working Group of ICCVAM. And, so, for those of you not at that meeting, we briefed them on the progress of our work in October of 2006. We now have what we are calling a final draft of our background review document. It is with the companies who participated in this effort for final comment, and our intention is to submit it to ICCVAM on Halloween. I don=t know whether that=s a good thing or not, but that is the goal.

So -- and I want to emphasis to all of you, because I know Beth and others, over time, have said that, you know, there=s interest on the part of companies who are not in the consumer product industry and making progress in this area. There was no intent to be exclusive. We simply felt, given the history of ICCVAM=s inability to rapidly complete broad validation exercises, that we would do

something that was very narrow; that we would do a small module where we are talking about a limited group of products for a limited regulatory purpose for one agency.

And, so, the companies that ended up participating here, all of whom have contributed data, are up there on the screen, and they are, you know, in many ways, a who=s who of the consumer product FIFRA world.

The technical work has been done by the Institute of In Vitro Sciences out in Gaithersburg. Roger Curran is the head of that Institute, and Roger has done the bulk of the technical work.

This is simply the, you know, the overview of the project. These are the kinds of products we=re talking about -- Mr. Clean and Fabreze, Scrubbing Bubbles. What we=re trying to do is do a non-animal evaluation for purposes of EPA being able to make toxicity category decisions and, then, decide on appropriate labeling. That=s all it is.

We have ended up with an approach that involves three non-animal assays. They are called the Cytosensor, the EpiOcular, and the Bovine Cornea Opacity and Permeability Assay.

These are used in harmony with each other,

depending upon the severity of the material. I mean, on how corrosive, what the ph is of the material. One or the other will be most appropriate for purposes of testing.

So, this is a chart that sort of illustrates that point. What we do is, because these chemistries are so well known and so well understood, it is relatively easy for the registrant to decide what is likely to be the appropriate assay, and for the most severe materials, that will be the Bovine Cornea study. These are discarded eyeballs from dead cows.

And there was a wonderful moment early on in the process where my client, Len Sours, who is a bit of a character, was briefing Marsha Mulky, and Len said, Marsha, you know, I can get you one of these eyeballs. I mean, we could put in epoxy, it could be a paperweight. You know, you could just keep it in front of you each day. But we didn=t do that.

(Group laughter.)

MR. QUINN: The other two assays measure moderate to mild materials. So, therefore, Category III or Category IV materials.

So, what have we learned? We=ve learned it=s a lot more difficult to put this kind of an approach together

than we thought it would be. It=s very difficult to put together parallel in vitro and in vivo data sets. The animal data is older, and it=s not easy to get these paired sets of data neat.

Though never validated, like many of the tests that are used for acute, the Draize has been considered, continues to be considered, by those people in the toxicological community as the gold standard.

Animal tests are generally very conservative. And, as I said, the data are older. In vitro assays tend to have been developed to be more predictive of the actual endpoint.

This is just one example that, I think, you know, helps illustrate at least how consumer product companies are currently assessing these kinds of hazards. You know, when you look at a company like Proctor, you know, they=re an $80 billion company selling products all over the world. They have four billion consumers using those products -- about a 50 percent market share in terms of soap and related products in the United States.

Ninety-five percent of those are non-FIFRA. So, these are cleaning products that are not pesticidal products. In many cases, their formulations are exactly

the same, but they simply don=t make any sort of a claim.

All of that safety assessment is done without animal testing -- all of that is done through in vitro and ex vivo methods.

And, of course, we have a lot of human experience data with these products, because they are so widely and regularly used. And, so, we do have the company with 800 numbers as well as a lot of poisons that are control data.

So, everybody told us that we were nuts to bring this to ICCVAM. That=s not meant to be flippant, but ICCVAM has not been able to put a lot of victories on the board rapidly over the years. And, perhaps more importantly, we were advised by people in the animal welfare community and elsewhere that this wasn=t that needed to go to ICCVAM, because the statute that created ICCVAM talks about assays that would be used by many different agencies and broad validations across many different chemical classes.

Nevertheless, we decided that we would go to ICCVAM. Why did we do that? We decided to do that because we think it has the potential to establish a precedent of what we want to call a modular approach. So, a narrow approach plucking some of the low-hanging fruit, where

there are robust data sets and where there are particular endpoints where we=re ready to make some progress and go forward. And we hope that that=s going to be successful.

This is really the question that we believe ICCVAM needs to answer, and it is a nontraditional inquiry for that panel. As I said, they deal mostly with very broad validation exercises.

Does this group of assays assure EPA, with a reasonable degree of certainty, that there will be little to no underlabeling of antimicrobial cleaning products. In other words, can the Agency be certain that these assays will allow them to determine that there is reasonable certainty of no harm for those people who are going to, then, use the products?

So, this is where we are. As I said, Halloween submission. We have talked with Debbie and Tina, very recently, about how we think they can assist the submission in terms of clarifying, for ICCVAM, the intended scope and nature of the review, as well as the fact that this is a very narrow regulatory need. And we think that the science is sound enough so that there is a solid basis for OPP to begin use of this approach, as an alternative to the Draize, at some point next year.

We think after reviewing it with whatever resources are at the office=s disposal -- whether that=s an SAP, whether that=s thero-scientists, that that=s the conclusion they should and will reach.

So, with that, I=ll ask if there are any questions.

Julie?

MS. SPAGNOLI: This is a quick question. Since the non-FIFRA products are, I guess, under the jurisdiction of the Consumer Products Safety Commission, has CPSA -- have they -- do they have any particular position on that?

MR. QUINN: Marilyn Wynn, from CPSA, sits on the ICCVAM. She=s part of that panel that will review the approach. They have not, really, had any specific comment throughout the process.

MS. SPAGNOLI: Okay, because I know they don=t actually review the studies, themselves, or the data themselves, but they have not made any position to say this is -- we deem this appropriate?

MR. QUINN: They really haven=t. As a matter of fact, you know, they have used alternative assays themselves, including the low-volume eye test over the years, as acceptable alternatives, but they really haven=t

specifically engaged.

Kristie?

MS. STOICK: Thanks. I just wanted to thank you, actually. I came in kind of in the middle of all this. Thank you and the companies involved for putting this forward, because ICCVAM is sort of a wait-and-see-what-comes-to-us type of committee, so without all that effort, these types of things would not be going forward.

The second thing that I wanted to encourage was for EPA to try to get an interim science policy going, whether it=s through TBEC, whether it=s through some sort of public process -- a Federal Register notice, something like that -- just because I=ve been dealing with ICCVAM now for about five years, and I know it takes a long time for them to do things. And this is really something that could happen fairly quickly because it=s so specific to the EPA.

MR. QUINN: Thank you. Beth?

MS. CARROLL: I was, just quickly, curious as to have these three tests that you=re talking about been validated?

MR. QUINN: They have not been validated by ICCVAM. They are in various stages of review. The BCOP, Bovine, assay being probably the furthest along, but all of

them have either undergone -- all of them have undergone partial review by either ICCVAM or ECVAM.

But, again, you know, the consideration of the BCOP, for instance, was across a very broad range of chemicals and was considerably more complicated than what we=re asking them to look at here.

Thanks.

MS. EDWARDS: Okay. Thank you, Pat. How many people can stay until 5:30? Maybe I should do this the other way, then. How many people cannot stay until 5:30? One, two, three. Okay. Well, we=ll try to do the best we can here, but these updates are going to have to be quick -- expedited updates.

Let=s do the fumigant update.

SESSION IX -- PROGRAM UPDATES

MR. KEIGWIN: Okay, we=ll make this very quick. There should be a slide packet on the right side of your packets for Session IV.

So, in the interest of time, we=ll just speed through this. I know Mary and Jay have their presentations to do.

At the last PPDC meeting, Pete Hawkins gave you an update on where we were at that point with a fumigant update. Just by way of reminder, in the fumigant analysis, we=re primarily focusing on methyl bromides, chloropicrin, metam sodium, metam potassium, and dazomet, although we are also looking at 1,3-dichloropropene, although that completed registration back in the late 90s. Now with the recent registration of iodomethane, we will still be looking at that chemical, particularly as it relates to additional mitigation measures that we currently put out for public comment. And, to the extent to which we see those mitigations being appropriate for human fumigants as

a class, those measures would also be adopted for iodomethane.

Again, by way of reminder, three major goals for this analysis. We realize the importance that fumigants play in agriculture, but we=re also mindful that they have the potential to propose concerns for handlers, applicators and bystanders.

So, as we progress through this analysis, we are trying to make sure that the soil fumigants are safe and available, that we maintain a level playing field by looking at all of the chemicals in the group in the same general time frame.

And that=s one of the reasons while we=re also still looking at 1,3-D and iodomethane, just to make sure that we, thirdly, make good management decisions for all of these chemicals, considering both their risks and their benefits.

So, then, we=re using the six-phase process, which you all are very familiar with and we have discussed a few times today.

So, we=ll just go to the next slide. We=re largely through the process; we=ve put out initial risk assessments for public comment; we=ve held technical

briefings on those assessments; and we have completed reviewed risk assessments, as well developed benefit assessments and risk management options.

So, that=s where we are now. We=re in the midst of a public commentary that will close on November 3rd. One of the primary pieces that is new is an options paper on various risk mitigation measures, with comment on the cost visibility and effectiveness of those additional measures.

For each of the mitigation measures, we have provided a series of questions for the public to consider in preparing their comments.

Just for you all to understand the scope of what we are facing ourselves, we=ve already received upwards of 500 comments on that revision paper.

The option paper is largely on two general areas of mitigation; one is direct measures, things such as mandating the use of tarp, including buffers, respiratory protection for applicators, certain types of techniques or limitations on application blocks or other application restrictions.

And we=re looking at indirect measures, things like training, recordkeeping, stewardship, fumigant

management plans that will help to facilitate and ensure compliance, enforcement and planning.

To help us get some additional feedback beyond, sort of through the docketing process, we=ve been holding stakeholder meetings across the country. To date we=ve held three in the Pacific northwest, Florida and California, in conjunction with efforts that the states have ongoing with some of the fumigants.

A number of tour sponsors, who provide educational opportunities for EPA staff, have also included fumigant discussions on many of those tour spots.

So, once the public commentary closes, we will take into account all of those comments, revise the risk assessments, revise the benefits assessments and develop the risk management package. Our plan is to issue those re-registration decisions during fiscal year 2008.

I just wanted to mention, as part of our ongoing efforts to continue to learn about different ways that we can reduce emissions, working with Dan Botts and others, who are organizers of the Methyl Bromide Alternative Outreach Conference, EPA is having two sessions that directly relate to our work on fumigants at the San Diego meeting at the end of the month.

One will focus specifically on soil fumigant emission reduction factors, trying to gather some information on certain factors; such as, what types of films help us reduce emissions and to what degree -- what influence, for example, does soil moisture have on reducing emissions and what the influence of organic matter is on emissions.

Then a second session will focus on field-scale soil fumigant emissions profile, looking at many of these same types of things, but from a slightly different perspective. The second session will begin to summarize the available data on field-scale emissions and use that data to identify critical factors that could be considered related to how emissions vary from region to region.

We=re also working closely with the State of California as they put in place their program to reduce VOC emissions.

And, then, finally, we=re also working with other parts of USDA, including the ag research service, as they are developing new research through their methyl bromide program.

MS. EDWARDS: Thank you. We=ll move on now to the Import Safety Work Group. Our next two presentations have

an international bent to them. So, Mary Hanley is from the AA=s office.

MS. HANLEY: Good afternoon. I have worked with Jim Gulliford and Jim Jones, and I=m here to talk about an import safety effort that=s underway, and I=m very fortunate to have Jay sitting next to me. Jay Ellenberger is our expert in an internal work group we have on important safety for pesticides.

When I talk about import safety, I am talking about human health and the environment. It=s a pretty expansive term, as the working group is using it. It clearly covers EPA programs, standards, requirements, and the like.

As you=ve all probably seen in the headlines over the past couple of months, there=s been a heightened interest in safety of products imported into the United States. In July, the President issued an Executive Order that established an inter-agency working group. The purpose of the group was to do a comprehensive review of current important practices and determine where improvements could be made.

The interagency working group is headed by Health and Human Services Secretary, Mike Levitt, and made up of

senior administration officials. Our AA, Jim Gulliford, represents EPA as a member of that working group. Other participants include Agriculture, Commerce, USTR, CPSC, states and the like. There=s a rather large group.

One of the three areas that the group actually is interested in looking at was gathering information on exporting countries, non-U.S. importing companies and experiences, as well as Federal, State and local governments.

The group was given the task of reporting back to the President in 60 days. They were rather busy up until September taking comments. We at EPA were very busy and continue to be with an internal work group that=s supporting Jim Gulliford in his role, as well.

The Administrator, Secretary Levitt, and other Cabinet officials, has been traveling quite extensively since July to hear directly from those on the ground, in ports, agricultural centers, or retail establishments -- this is across all sectors -- to hear first-hand what the experiences are.

Taking that input, as well as the inter-agency discussions, and a lot of information and data provided by all of the agencies throughout the process, including EPA,

the work group issued its initial report within the 60-day time period on September 10th.

It is the strategic framework for approving safety of imports. The idea is a strategy and the working group is continuing to work to put together an action plan that would be issued later next month that would identify short and long-term actions for implementing the strategies.

In the interim, at the same time the strategy was issued, an immediate actions document was also released, and that contained four areas where Federal agencies were asked to initiate work in the interim before the action plan is issued.

I=d like to just briefly touch upon a couple of the two principles of the strategy, talk just for a few minutes about the actions document, and a couple of meetings we=ve held.

The strategy is a framework for continual improvement in import safety. The working group found that challenges and deficiencies in the current import system required somewhat of what we call a paradigm shift. The strategy shifts us from relying on intervention, border-focus strategy primarily to, instead, more of a life-cycle approach that is rooted in prevention at the source, with

verification throughout the supply line. And that=s sort of the underlying principle, I would say, of the strategy.

Two other principles, prevention, intervention and response. In terms of intervention and response, the underlying idea, I think, of the framework is that you=re reducing and focusing your intervention and your response by improving, through the supply chain and at the source, the prevention of the issues in the first place.

The other area of focus for intervention is improving our technologies and abilities at the border to be able to identify imports that present problems.

In addition to the strategy, the immediate actions document identifies four areas for action: global collaboration, working and coordinating among the Federal agencies, themselves, with our various work we have going on with various foreign governments, sort of establishing regular meetings and coordination in that respect.

Also, increasing our collaboration with the private sector, sharing more information.

And one thing I wanted to spend just a moment on is inter-operability acceleration. Why they call it that, I don=t know. Basically the idea here is for the Federal government to focus on making its data systems inter-

operable to assist all the agencies that are involved in import safety to understand, you know, what type of information other agencies have and make it easily accessible. The other aspect of this is to look at making the non-CDI type information also available to the public.

So, as part of this immediate actions document, agencies were instructed to complete a plan for how they were going to become inter-operable with a customs database, which is referred to as the ACEITDS Database. It=s the Automated Commercial Environment International Trade Data System.

We also, in the interim, the working group, in preparation for putting the action plan out, held a public meeting on October 1st. The panel heard comments, testimony from over 40 presenters, who were probably centered in the 25 or more registrants.

Their comments were from a broad spectrum of stakeholders. Of course, this is stakeholders across all of the agencies, but including comments with our safety and safety of pesticides regarding imports.

Some of the commentors included the Grocery Manufacturers Association, the United Fresh Produce

Association, the Association of Food Industries, academic consumer groups, and many others.

Currently, again, the work group is working pretty steadfastly to have an action plan issued in late November. A good place to go to keep up with these activities and get copies of the framework and the action plan, when that=s issued, is www.importsafety.gov, which is the HHS inter-agency site for the effort.

MS. EDWARDS: Okay, thank you very much, Mary. And Jay will be the last session of the day, and then we have one public commentor. Jay Ellenberger is our Associate Director in our Field and External Affairs Division.

MR. ELLENBERGER: I=ll try to make this quick, give you a broad-brush overview of activities on the international front.

OPP has been involved in the last year or two in things that are coming up in the near future. I really cut this down because I know a lot of you want to get home or want to go back to your hotels for happy hour.

So let me start off by saying that OPP=s work -- really OPPGF=s work in international activities is central to our specific mission in viewing our core projects or

program objectives, I should say.

The kind of international activity work that we do is very amenable to international cooperation. If you really think about it, you=ve got global markets on pesticides and other chemicals; you=ve got global markets on food and feed commodities.

All the developed countries have their own inventory pesticide program and doing the same kind of registration work that we=re doing, and it=s just a terrific opportunity for scientists and regulatory and policy folks to get together to collaborate on how to do things better, faster, cheaper, and so on and so forth. You know, in focusing in the science areas, as well as registration and now registration review, tolerance levels or maximum residue limits, so on and so forth. So, we can=t help but not do it.

I have a very full range of activities, and with the five minutes or so that I have, I=m only going to cover some of the real key areas, but leave with knowing there are a lot more specific areas that we=re involved, both in technical and regulatory areas.

On the science front, some of the things that we=ve been doing in 2007 are just continuing to advance.

The development of harmonization on data requirements and guidelines for conducting the studies, the various studies that industry studies and submits to regulatory agencies across the world, and even things like harmonizing the formats of review of these studies to help our scientists go through and review much quicker.

By the end of this calendar year, there will be three test guidelines that are harmonized and completed, as well as a guidance document on analytical chemistry methods.

Also, we will be initiating work on other test guidelines for crop field trials.

We=ve been working with OECD, you=ve heard about them earlier today. Our work with them on how do you interpret repeat dose and chronic tox and other studies.

We=ve also been working with other countries through OECD on developing templates, 87 templates for the most widely conducted and committed to regulatory agencies simply for how industry should put together and formulate, if you will, in context, the summaries of the studies and, then, how the regulatory agencies would present their reviews, so that sharing that kind of information is much more efficient and effective. The scientist knows what he

or she is going to get on a carcinogenic study or a field participation study.

And, also, our last activity in the science area that I wanted to just draw your attention to is PMRA in Canada and OPP have put out for public comment what we call the MRL, maximum residue limits calculate. It=s a really effective tool, a statistical tool for calculating perhaps what an MRL should be. We put that out for public comment.

In the area of a registration, a part that all these science and technical activities for harmonization are all going to lead up to being able to do more work sharing on registration activities. In 2007, this year, we made great strides in furthering our program for joint reviews on work sharing with other countries on the registration of new active ingredients. Almost half of OPP=s new active ingredient registrations, five of 12, turned out to be collaborative efforts with other countries. There were joint reviews and were some kind of work sharing.

In fact, this year, one of those is the first time that we=ve accomplished that trilaterally for new act ingredients, with Canada and Australia. So, again, continuing to make advances on how we collaborate across

the world with other countries.

In progress, we=ve got six other active ingredients, new active ingredients, that we are doing joint reviews and some kind of work sharing with other countries.

And, then, also, in discussions with registrants in other countries, trying to figure out the process for conducting additional work sharing and joint reviews for 11 other potentially new active ingredients, ranging from conventional agricultural chemicals to biopesticides and including one antimicrobial. So, really expanding out that kind of work activity.

Many of you also know that this year is the first year that we=ve accomplished the registration of a natural agent between the U.S. and Canada. So that was a big first for us. There=s consideration of more labor like that underway.

Also, with OPP=s new registration review program, we are in discussions with Europeans and Canadians on how we might work share with that kind of program, because in Europe and Canada they also have programs for reassessing older pesticides. So, hopefully that will be very fruitful for us and the other countries in the next few years and

beyond.

In the area of maximum residue limit harmonization, many of you know -- you=ve heard about Codex. There was a little bit of discussion about that on our earlier talk about AZM transition. You know, Codex is really the pre-eminent international forum for harmonizing MRLs, it is internationally recognized, and it=s included in the International Trade Agreement.

Some of you also know about Codex where in prior years it has been relatively slow making progress, harmonizing, coming up with MRLs for Codex. OPP=s work group, along with representatives from other countries that are involved in Codex, have really revamped the process so it=s much more expedited; in fact, the last about year and a half, I=m happy to say that through Codex they=ve harmonized about 400 tolerances for 31 active ingredient pesticides. So, a lot of good work has gone in there and it=s certainly going to continue.

Also, OPP is very active with USDA in working with other countries on a bilateral basis; for example, with Japan in helping Japan transition from their older MRL basis to a newer one that=s more like the U.S. So, we=ve been providing them technical assistance.

Also, as many of you know, Europe is also transiting from a system of individual country MRLs to one unified MRL system in Europe. And, so, they have published some proposed MRLs. USDA and OPP and other stakeholders are looking at those proposals right now to come up with comments that we hope can minimize future trade barriers with the European countries on agricultural commodities.

And, then, the last two areas I wanted to briefly cover is the area of minor uses, the work that=s going on there. That=s harmonizing MRLs for minor uses. It=s acutely important. Most crops are minor uses, and we=re particularly interested in MRL harmonization or the safer pesticides that are reduced-risk pesticides that we=ve registered over the last number of years so the growers in the United States can use those and feel that they can export the treated commodities overseas without fearing trade barriers.

So, there=s been a lot of work in that area within OPP, working with the minor-use community -- IR4, USDA and others. We=re looking at areas within the data requirements and maybe how we can reduce data requirements for some of the minor-use commodities without jeopardizing safety. Looking at things like how to expand crop

groupings, not only within the United States, but taking that idea or that principle globally for crop grouping. The idea of regional studies, how to take a region -- not only in North America but other continents that have very similar environmental areas -- and be able to basically share the kind of field trials from those different areas around the world among countries for setting MRLs.

And the last area I wanted to just quickly mention is OPP is really -- just this past year -- is really trying to open up a dialogue with our colleagues in China. You all know that China is becoming much more productive in the area of pesticide production and other chemical production, exporting pesticides, exporting agricultural commodities. They are becoming much more interested in playing in the international pesticide area. In fact, this year they have stepped up to the plate and are now sharing with the Codex Committee pesticide residues. So, they are really coming forward, if you will, internationally in the whole pesticide arena.

So, we have started collaboration with them on trying to find ideas of mutual interest that would, obviously, assist them and vice versa, hoping that later this year that there will be a letter of intent of how we

would collaborate in 2008 and beyond, working with the Minister of Agriculture.

So, just to wrap all this up, this highlight, a lot of these activities wouldn=t take place without international meetings, so there=s a number of those coming up within the next couple of months.

Next month there=s two meetings with NAFTA, one with the technical work group of the government and another one with stakeholders, open to the public.

Right after that, there=s an OEPD meeting with the registration hearing group and, also, the risk reductions work group.

Also, in December, there will be an international meeting for minor uses that I know we will be attending and I=m sure some of you might, as well.

Also, next year, there will be another OECD meeting on some other areas, and so on and so forth.

And, then, additionally there are, you know, international travel. Our system administrator, Jim Gulliford, and Debbie, traveled to Europe to meet with senior officials in the European community not too long ago, and so on and so forth.

So, a lot of these activities clearly fit within

OPP=s mission of core programs and our goals for increasing protections to the public and the environment, reducing trade barriers, increasing efficiencies, and so on and so forth.

So, with that, I=m turning it back to Debbie.

MS. EDWARDS: Thanks Jay, that was a great summary.

I believe we have one public commentor who signed up, and the person=s name is Mark Whelan.

MR. WHELAN: I=ll make my comments very brief and I=d sure as heck hate to be in the way of you guys getting a beer pretty quick.

So, I just want to say that I think that the matrix and the approach that the Agency has taken and the joint process with USDA and EPA is key. And it=s going to grow, I think, in importance, when you look at the AZM process.

I want to talk about the upper midwest and the situation there. I represent maybe about 1,100 growers, about 95 percent of them in Michigan, the rest of them scattered around the upper midwest, in three cropping areas that are affected right now -- apples, cherries and blueberries.

And in those settings, the comment that Larry Elworth made earlier about complexity changing as you go from west to east, once you cross the Rocky Mountains and you=re into the Plain States and headed east, the pest complexity goes up -- three, four, five and in some times six times.

So, in the upper midwest, we have humid climate, with lots of pests, and AZM has been a key in that process. I just want to point out several things about what we=re facing in this transition.

Not only do we see a much more complex system, but when we look at available alternatives, we don=t have the kind of spectrum of control that we see.

So, when we look at the cost of transition, we=re looking at a 40 to 120 percent increase, depending on the crop and the area that you=re in.

In terms of available alternatives, so-called reduced-risk alternatives, are from a human perspective but not from an ecosystem perspective. We have very good data, very high quality, scientific data, showing that what we=re being forced to move to in many ways is very disruptive and has significant ecological impact on systems that we=re working in. And we=ve been able to put some dollars to

that. Generally a grower might expect $35 to $85 an acre from biological control and from native pollinators in the upper midwest, and we=re seeing in some cases that reduced by 50 to 70 percent, and that is pretty significant and not figured in any of the economics that I know of that EPA has done historically on this.

In terms of the complexity, if easy on pest management is one AX,@ when we move to generalized oxidizing and IGRs, we=re looking at a three to four AX@ complexity for the producer to integrate. And there=s a whole bunch of reasons for that, and I don=t have time to go into it, except that I=d just like to point out this: that neonichachinalites are both repellant and anti-feedant as they weather. So, they may not kill something, but they may still affect some level of control. But if you=re going to follow a neonichachinalite with another compound, like an oxidiodine, that has to be ingested to be effective, then you=ve defeated that oxidiodine. You better get that straight with growers and the complexity of that, you can see, perhaps.

Now, in cherries, it is a unique case, in a way. But with AZM, cherries had, essentially, below limit-of-detection residue, and in a mechanically harvested crop, so

very little worker exposure, anyway, but below-limit-of-detection residues harvest.

With the new systems that we=re moving to, we=re detecting a parts per million for all of those compounds in cherries at harvest. So, we=ve taken a commodity that had no residues and forced them into a situation with residues.

And in terms of just a report on farm research representing 18 different orchards, in a transition effort over the last four years, in the first year we had no bail-out growers. They were all able to do it with the alternatives that we had.

In year two, we had one bail out. In year three, we had three, and this past year we had five bail outs. Now that=s 18 total orchards but only nine of those were alternative orchards and nine of them were AZM for direct one-on-one comparisons.

So, we had over 50 percent of the growers in four years bail in our alternative system because of the complexity and because of the challenges of the weather that we had this year.

So, that kind of lays out in brief why this matrix is so important and why we=ve got to continue to work on this, because it=s economically vital to the upper midwest

today.

Thanks.

UNIDENTIFIED MALE: Let me see if I start doing the public announcements here. Public comments?

UNIDENTIFIED FEMALE: (Microphone not working at all.)

(Whereupon, Disk Five ended at this point.)

(Whereupon, the meeting was adjourned.)

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U.S. ENVIRONMENTAL PROTECTION AGENCY

PESTICIDE PROGRAM DIALOGUE COMMITTEE MEETING

OCTOBER 18, 2007 (DAY TWO)

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A T T E N D E E S

Rebekah Freeman Adcock	American Farm Bureau Fed.
Lori A. Berger	California Minor Crops Council
Daniel Botts	Florida Fruit & Vegetable Assoc.
Joseph Conlon	American Mosquito Control Assoc.
Cannon Michael	California Cotton Growers Assoc.
Robert Rosenberg	National Pest Management Assoc.
Steve Balling	Ag Services, Del Monte Foods
Carolyn Brickey	Center for American Progress
Caroline Cox	Center for Environmental Health
Michael Fry	American Bird Conservancy
Caroline Kennedy	Defenders of Wildlife
Jennifer Sass	National Resources Defense Council
Susan Kegley	Pesticide Action Network
Shelley Davis	Farmworker Justice Fund
Amy Liebman	Migrant Clinician Network
Erik Nicholson	United Farmworkers of America
Kristie Stoick	Physicians Responsible Medicine
Cindy Baker	Exigent Company
N. Beth Carroll	Syngenta Crop Protection

Allen James	Responsible Industry/Environment
Phil Klein	Consumer Specialty Products Assoc.
Hasmukh Shah	American Chemistry Council
Julie Spagnoli	FMC Corporation
Susan Ferenc	Chemical Producers & Distributors

A T T E N D E E S (Continued)

Jay Vroom	CropLife America
Ray McAllister	CropLife America
James H. Wallace, Jr.	North Amer. Registration Section
Gary Libman	GNL Consultation Services
Matthew Keifer	Public Health & Community Medicine
James R. Roberts	Medical University of So. Carolina
Dennis Howard	Florida Agriculture/Consumer Svcs.
Mr Ellen Setting	Maryland Department of Agriculture
Rodney Marco Guske	Yakama Nation Environment Program
Jose Amador	Texas A&M
Amy Brown	University of Maryland
Larry Elworth	Center/Agricultural Partnerships
Robert Holm	IR-4 Project
Carol Ramsay	Washington State University
Patrick Quinn	The Accord Group
John D. Schell	BBL Sciences
Richard Colbert	EPA

Allen Jennings	USDA
Melody Kawamoto	Center for Disease Control
Nancy Golden	U.S. Fish & Wildlife Service
Nega Beru	FDA
Mike Bussell	EPA

I N D E X

P R O C E E D I N G S

MS. EDWARDS: Welcome back to the PPDC. We appreciate those of you who were able to make it on time -- very much.

I think we had a good session yesterday. I hope this morning will be equally productive. And, so, we=re just going to jump right into the agenda.

Our first presentation is going to be made by Kennan Garvey from the Special Review and Re-registration Division, and it is on how we=re doing on registration review implementation.

So, Kennan?

SESSION X, REGISTRATION REVIEW

MR. GARVEY: Thank you. And I=m going to be

helped significantly by Sue (inaudible) and Carolyn Todd on this, members of the work group.

You may recall that we reported to you at the May meeting on the outcome of the first work group meeting that was held in March. We, then, based on your endorsement of those recommendations, we prepared responses and presented those to the work group at the July meeting, and those are in your package.

We also, at the July meeting, presented the first antimicrobials and biopesticide dockets to them. They=ve looked at the conventional docket and at them marginally.

So, today I=m just going to briefly cover an update of the registration review program and then turn it over to them to talk about the recommendations coming out of the July meeting.

Those of you who are new to the PPDC, you have probably gotten some background on this already but, as you know, in 1996 SPJ provided for the periodic review of pesticides and developed rules to put that program in place. We=ve put the proposed rule out and, then, final in 2006, and we actually implemented the program in this fiscal year -- this just ended fiscal year, 2007.

We said we would open 25 registration reviews to

begin to get our feet wet and get the program off the group, and we did that. Several of them, I think two of them, we determined that they didn=t need to have dockets opened because there were no Federal registrations left, so we just needed to determine what to do with the tolerances and any 24-Cs that remained.

We did have, on 12 of the ones that were open, a public comment period, as provided for in the rule. And registration is, as most of you know, provides for extensive opportunities for public comment at the opening of the docket and in all cases when the preliminary risk assessments come out, when the proposed decision comes out, and at other times, as appropriate.

Of the 25 that were opened, 13, following public comment, 13 had final work plans completed and the reviews on those are commencing. And normally the only reason final work plans weren=t done for the others yet is that they were opened later in the fiscal year, so by the time you get through the public comment period, we normally allow two months after the public comment period to develop and post the final work plans. So, the others will be open soon. And those are posted.

We have a nice registration review website that

has a section for status of all the cases that have been opened, so you can just glance on there. We do put out updated when those are coming on.

We said we would do 45 dockets in 2008, we=ve already got the first and second quarter ones for those that are already in our pipeline and moving through so that we can open them, as planned, and we=re starting to work on the third and fourth quarter soon.

And we do plan -- well, we will be issuing our annual update shortly to the registration review schedule. The rule provides that we have to have a three-year schedule posted for registration reviews. And, actually, we posted a four-year schedule when we first put it up last October, but we do plan to update that annually, and at this point plan to keep putting up four-year schedules. So, 2008 through 2011 will be posted in the next couple of weeks.

And we plan to increase 2009 from the 45 or so that were in the current posted schedule up to 70. That reflects the PRIA II passage, which calls for completing registration reviews in 15 years. Before it was a goal. So, our goal is to basically open essentially all dockets and by 2017, to give us five years to complete the process.

PRIA II, as Marty described yesterday, continues product maintenance fees through 2012 and allows their use for registration reviews. And, as I said, the annual schedule will be posted shortly.

We really appreciate the work group -- the PPDC forming the work group. The members that have spent so much time on it. I think it was last fall that Jim Jones asked you to put it together, and we did that, with the help of many of you, and others -- and met in March and July, as I mentioned -- and giving us input on the first phase, the docket-opening stage.

And, at this point, I will turn it over to Sue. You=re on to Slide 4 for the IT recommendations.

SUE: We=re using the regulations.gov for access to the docket, and one of the suggestions was that there should be another server or more than one server added to the thorough docket system to increase its speed, and I know that the speed has increased over the past six months. So, I certainly don=t know if that=s because of the addition of a server.

And there has also been recommendations to make the process for submitting documents through the docketing system more straightforward. And, as a semi-computer

idiot, I have to say that I have tried to submit -- unsuccessfully tried to submit and had to get somebody else in my office to do it. So, at least the directions, I think, could be improved, if not the actual process. And, also, provide rapid confirmation that comments were received.

It was also a suggestion that there be zip versions of all the docket documents for easier downloading, and I must say that, given the fact that many of us prefer not to work in the docket system, but actually to download documents, and given the fact that there are numerous pieces to the EPA background documents, that could assist us a great deal. It=s a very time consuming process. But, again, I guess it would be time consuming for you all to create the zip files, so you=ll have to choose.

Also, there was a recommendation to make sure that scanned documents are legible. And I think this arose primarily because there were some historic documents that had been essentially, you know, entered into the system, and they were poor quality, they were old, they probably were xeroxes of xeroxes, you know, of photocopies, over and over again. And I think what=s not stated here is that

would imply that I think a lot of these documents would actually have to be re-input, and maybe with some blanks where they truly were illegible. So, I don=t know what the Agency will do with that recommendation, but it is an issue with some of the historic documents.

And the final IT recommendation was not to archive earlier dockets, docket materials or website materials that could be useful during the registration review process. And I think that is an important issue because the registration review documents, summary documents, are based on information that=s been provided to the Agency over time. And even outside of that 60-day public comment period, I foresee people wanting to work with those background materials beyond that 60-day comment period, reviewing the, you know, the older various risk assessments in toto, or ERs or whatever may be available.

I recognize that=s a resource issue, but I think it=s really an important recommendation. I think the historic materials are really important to have access to through this whole process.

MR. GARVEY: So, in this you are actually recommending to archive the earlier document materials?

SUE: Not to archive, to make them available.

MR. GARVEY: Oh, okay.

SUE: Yeah, that would --

MR. GARVEY: To keep them in the docket?

SUE: Right -- or at least accessible somewhere online with links to them or whatever. I think the issue was that many of the materials have been archived and, therefore, you don=t have access to them. And I think the desire is to have access to the original risk assessments, to the ERs, that kind of material.

UNIDENTIFIED MALE: (Inaudible question).

SUE: Yeah, yeah -- actively available is the recommendation.

MR. GARVEY: Thank you. And we=ll get back to some of this later. Sue, are you ready to move on? Or now Carolyn picks up? Okay, they=re sharing the next slide, okay.

MS. TODD: So, there was some discussion at the meeting about ecological incidents that are being used as part of registration review, and this recommendation is to do more documentation about those incidents. And it was all the underwriting of ecological incidents, it seems that as much documentation as possible of the ones that are reported is really crucial.

The second recommendation is explain why similar studies involving two species are needed. I think I=m going to take advantage of having the microphone just to make a comment here.

You know, in terms of the ecological pest testing that=s required to register a pesticide, there are so many groups of species that aren=t represented at all. There=s no amphibians; there=s no reptiles. In terms of plants, virtually everything that=s tested is a crop plant. The only insect that=s tested is the honeybee, so there are huge groups of insects that aren=t represented, and on and on and on.

So, my personal feeling is that we need as much of this kind of testing as we can get. And so, that, if there=s a requirement for two species to be tested, it=s really important that that happens.

I think Sue is going to do the next one.

SUE: The antimicrobial case that was selected for review by the task force raised some interesting issues in terms of regulation of food contact uses. And to those of you not familiar, there=s a very complex and arcane regulatory jurisdictional divide overlap between FDA and EPA when it comes to regulating certain food contact or

even nonfood contact; in some cases, it appears, uses of antimicrobials. And this raised a lot of confusion, because I think probably 10 people know what the system is.

So, it would be very helpful in those instances -- can you hear me? (Microphone problem).

Anyway, to make a long story really short, it would be very helpful in the future if there was an explanation of the particular uses and where they fell within this jurisdictional quagmire. And I think that is important for the benefit of the reading public.

MS. TODD: The last recommendation on this slide has to do with the information that=s provided about the actual chemical that=s being reviewed. And, I think, all of us who were part of the work group realize that, you know, with 45 or 70, or whatever it is, chemicals coming up each year, that everyone is going to have to be really efficient so that getting some of the important up at the beginning of the document so that we can make a decision about whether we need to read the whole docket or not is really important.

The next recommendation had to do with data submission and data compensation, and this is not an area that I know very much about, so I=d defer to the people who

do, but this is the recommendation. Just to make sure that it=s really clear when data can be submitted and how to do it and what the compensation policy is.

The next recommendation has to do with acronyms and jargon in the registration review document. Just that if the intent of the docket is really to make this a public process, that ordinary people, if there are any of those, who read the docket can participate in, then we need to be really careful to stay away from jargon and acronyms that will just make it impossible for ordinary people to understand what=s being talked about.

Clarify when and how any of these products will be addressed. I guess that was pretty clear in the re-registration process about the difference between an active ingredient and an end use product, and it=s not quite as clear in the registration review document so far. So, that=s just something that EPA can work on.

And the last recommendation is actually just a restatement of one that Sue talked about and it is making sure that all the relevant documents are in the docket, even if they=re old. And when you think about it, as this process matures, most of the registration review will be going on with chemicals that were last looked at 15 years

ago, and probably most of us don=t keep our files that long. So we=re depending on EPA to dig up all those old documents and make them available to us so that we can get a sense of the whole process and find the old information that=s necessary.

MR. GARVEY: Okay, thank you. Just positive feedback in terms of what we heard, I think, and Carolyn, you can jump in here if you want. But we did present, as I mentioned, the Agency=s response to the recommendations from the March meeting to the July work group meeting, and that was favorably received, I guess. One of the major concerns about that, that=s in your package.

The general feeling, I think, from the work group is the presentations that AD and BCPD gave them on their dockets were very thorough, very good.

We did hear at the July meeting that there had been enhanced search capabilities and regular book marking and linking functions put into regulations.gov. You can now actually create a link on your desktop to any document in regulations.gov or any docket. So that was good to hear.

And, also, after the July meeting, based on some back and forth communications with SCMS docket staff, we

found that they were responding to user concerns and had put additional servers in place, and we=re finding -- Michele Schultz is testing as far as finding much faster response time. So that was good to hear.

Before I get into the next steps -- and we will be preparing a response to the July recommendations, but just one thing on the archiving. We=re learning this new system ourselves -- I think all Federal agencies are -- but we=ve been assured that as long as there=s activity in a document every couple of years that it won=t be archived, and they can last up to 20 years. So, we=re hoping that that=s the case and we=ll see, but that=s the assurance.

In terms of next steps, we=re preparing a response and we=ll also be thinking -- I think this is the last -- we have the last meeting needed in July for this work group for the docketing phase of legislation review, so we=re laying it down for the time being, but it may be resurrected at some point for another phase of registration review.

And, thanks a lot. I just wanted to recognize, also, Maurice Johnson, in the back there, order facilitator, and -- can you stand up there, a little wave? And thanks to everybody on the work group who helped to

get to this point. Thank you.

Questions?

UNIDENTIFIED MALE: I wasn=t able to be at the last work group meeting. You may have covered this, but I didn=t see it in the recommendations, and we talked about this a little bit at the first meeting, and that is that there are a lot of people who submit information out of state and registration review decisions -- and, actually, I have information in hand, both grower groups and land grant universities, both to the IPM centers but also through individual universities where people actively are at least aware of regulatory issues -- and I wondered if there was any further discussion about active outreach to these people, letting them know, here=s what the system is, here=s how it=s going to operate, here=s why you have some stake in this -- people that aren=t either here or part of the work group. And also some mechanism to inform them, here=s what the information is generically that we=re going to need, and if there=s a way -- specifically for grower groups that don=t have big data operations -- for the individual chemicals -- identify the information gaps that are there, kind of up front, for the purposes of getting data from those people, separate from, you know, the

registrants or people like that.

Have you all talked any more about that?

MR. GARVEY: Yeah, we=ve talked about that when we have met. And I think the IPM centers are -- when people come in, we talk to them and keep them aware of what the schedule is coming up and stuff. So, we=re trying to do that. There may be better ways or other ways we need to think about doing it. And, of course, you know, we always advertise the specific chemical document in the dockets that are open.

MR. ELWORTH: Do you advertise them through notification or you actually go back out? You know what I=m asking? I=m not trying to give you a hard time about this.

SUE: I actually think it would be helpful to get suggestions from people who are -- how do I say -- very intimately connected into those systems to get an effective way to do that outreach.

MR. ELWORTH: Okay.

SUE: You know, we will typically do the things that we think make sense to us and that we=re familiar, and I think you=ve seen that there=s a real dedication here to outreach and public involvement.

You may actually see, because of the nature of your business -- and I=m talking to all of you now -- that there=s really a much more efficient way to kind of channel that information than what we=re using, and it wouldn=t cost us a lot to do it to actually deliver it.

MR. ELWORTH: Right. I don=t want you to do like a lot of personal -- well, if you feel like doing personal phone calls, that=s fine -- but there may be ways of more actively doing it and establishing the communication and telling people the flag, here=s what to look for, and then you could just basically send out notifications and they=ll know how to do this stuff. And I would -- how you could, at least through our shop and through the IPM centers, if that=s the most effective way to the USDA system, or something like that. And, then, maybe, through FCMA or some of the other grower organizations. So, you have to kind of focus people=s attention on it, but just getting a notification on it does not always focus their attention on it long enough for them to -- and you know what=s going to happen -- somebody=s going to say, I didn=t know about this.

MR. GARVEY: And, Al, of course, meets with us regularly, staying on top of this.

MR. JENNINGS: Yeah, we do try to keep them informed about what=s going on, but I think there=s two levels of information that we=re looking for. The first level is where we=ve already been through tolerance reassessment. The second level is the endangered species level, which is a huge return because it=s so highly, geographically isolated, I think, in most cases. And there we=ve tried to tell the land grants, gee, we=re going to need this level of data at the county or even sub-county level, field by field, heaven forbid.

But until we get a better idea of where, everyone=s waiting.

MR. ELWORTH: Right.

MR. JENNINGS: We can=t go out and look at a couple thousand counties --

MR. ELWORTH: Sure.

MR. JENNINGS: -- in terms of use data. So, as soon as we get some better resolution of where are those specific endangered species concern, then we=ve got to figure out how to drill down to that level of expertise and try to get the information together.

MR. ELWORTH: Right. Well, I know for a fact -- I=m on the advisory committee for our regional IPM center,

and except for the time that I raised it at a meeting, this registration review hasn=t come out. But I think the important issues have been addressed, so we may want to talk about some more active way to kind of focus.

MR. GARVEY: Thank you. I think we=ll just -- I saw Amy and Susan and Dan and Beth.

MS. CARROLL: I was going to comment on Larry=s question. The American Pathological Society has a public policy board that=s been trying to become more active in working with EPA on getting the kind of information that you need for registration review, and it may be appropriate to think about going to APS, ESA, and just being in touch with those people that put things on the website. We have an APS net that comes out, probably weekly, and what I try to do is go through the Federal Register for them, but that=s kind of a time consuming thing.

The other thing I have suggested is -- and I=m not sure they=re doing it yet -- is that the Societies get on your notification website, which pops up, you know, and should be able to tell them what to do.

So those are some things you might want to encourage at the Society levels. There are a lot these applied agriculturists that exist.

MR. GARVEY: Okay, thank you. And, Amy?

MS. LIEBMAN: To follow up on this same topic of getting input from those who are out at the user level, consultant level, extension level, I know first-hand that the frustration with getting back to USDA and EPA from my extension people in my state and my consultants in my state, let alone the growers, is that nobody has time to go to the docket and follow through and read through everything to get to the nitty-gritty.

And, as Carolyn said before, if you can summarize -- not just the chemistry information for the active ingredient -- but what it is that you=re doing or what are the important points for the particular document that you=re being asked to give comment on.

So, maybe at the beginning of the registration review process, where you=re just sort of saying you=re collecting data, that=s not so important for my folks. But, as you get into the process -- particularly when you get to the potential risk mitigation, and also even when you get to the point of trying to figure out how much use it has on various crops in various states -- how much of a percent of the time has it really used, and do we have other alternatives and what are the resistance problems

with it, and what are the impacts on IPM and biological predators and parasites.

I know we have people who could provide that information, if you could summarize for them, in the beginning of any information that you send out, where you are in that process and what you=re looking for. But if they have to read through the entire docket -- I try to do that for them, but I don=t have time, either, and they definitely don=t have time. So...

MR. GARVEY: Okay, thank you. Susan?

MS. KEGLEY: There=s a nice example of just what you said in the (inaudible) docket -- I don=t know who put it together, but it=s really good -- where they=ve gone through and said, these are the things we=re considering, we want your specific comments on this. So that was very helpful.

My comment is, I just ran into one more thing that made the document quicker to use, and I=ve been running into this with several of the fumigant documents that EPA has put up there -- they=re stand-in -- they must be coming from word files -- but they=re stand-in instead, which means they=re not searchable.

So, if there=s any way to make it so that things

are PDF, directly from the file, that would really facilitate finding the appropriate things because you can then do a word search on, you know, some issue important to you.

MR. GARVEY: Okay. Three more. And real quickly, on bulk downloading, we have made that a priority. In OPP we=re working with the Agency and we understand they=re really starting to look into it. So, we hope that that proceeds.

Dan?

MR. BOTTS: Just a couple of quick points, and one of them goes to Larry=s comment relative to outreach and the process. Minor Crop Farmer Alliance represents the whole universe, especially for our growers. We meet quarterly, essentially, and every quarter we go through what=s been docketed. We don=t respond specifically on individual compounds, but our job is to get out to the commodity groups that are there so that their compounds that are in that list that are important to them, they know that they=re up on the docket.

I guess one of the questions that I would have back to the Agency -- because we push really hard to get the ability to have this docketing process in place -- are

you all getting the types of responses back to the docket on the compounds that are helping to guide your decision process as you go into the work plans and the action plans? I would have anticipated there would have been a spurt right at the first initial document that came up, and there=s been more and more put up on the docket that the responses have probably slowed down. I know we haven=t, as Florida Fruit and Vegetable Association, been able to have the time -- even though I=ve got another person who=s searching at the same time I=m doing it, to be able to go in there and provide the responses to everything that we probably should be responding to, just because of the rate that they=re going up there. And that=s going to increase, not slow down.

So, are you all seeing people taking advantage of it, is the first question?

And, then, the other part of it, on the old dockets and some other things, it=s not, I guess -- and I don=t know, it might be there -- is there a cross reference to docket ID numbers for all other dockets associated with the active ingredient, whether it=s SAPs or other regulatory actions? Is that anywhere in some of the overview that you put up as kind of the Reader=s Digest

version of this is what it is and this is where it goes?

Because that would be, having tried to work with the docket system, unless you know exactly what that docket number is, if you try to do an ID search or word search, it becomes next to impossible to get to the document unless you go back and, I mean, physically -- I go back to the original Federal Register notice that has a document number in it to be able to get to what I want to in that process.

So, is that something that=s currently being done or is it possible to add that going forward?

MR. GARVEY: We do have now on the registration review status page entries for every docket that we=ve opened for registration review, and that now, because of the linking feature, goes directly into the right docket for registration reviews.

MR. BOTTS: But that=s just the registration review documents.

MR. GARVEY: Right. But you=re asking about more broadly --

MR. BOTTS: Yes.

MR. GARVEY: -- and we are not doing that right now. We can certainly consider how to do it, but there is the expanded, faster search capability, but you indicate

that gives you a bit of a mess sometimes in the returns that you get.

MR. BOTTS: I=m just suggesting in your original document, if you can just list other dockets that have dealt with that. I mean, Atrazine, if you look for dockets for Atrazine, there=s probably 30 different SAPs that have dealt with it and all kind of other things that there=s multiple dockets that probably should be referenceable as you=re looking through this process. I=m not asking to be linked in that, it=s just if we could get a list of those, it would be extremely helpful and make the search process move a lot faster.

MR. GARVEY: That=s a good idea, thanks.

MR. BOTTS: Just a little bit on the other deal, too, and I appreciate the zip file deal, but going back to my MIS department and my people, if I get anything that=s zipped, it automatically goes to the SPAM file and my computer won=t let me open it. It strips out everything, so there are issues associated with zip files.

Are there other options if you wanted to get everything in a docket through a DVD system or a CD process that can be accessed at the docket system? Or, if you can=t get zip files without moving the earth and the moon

and the sun from your MIS department?

MR. GARVEY: You can, of course, continue to do them individually. But in terms of ordering a DVD, the government doesn=t offer that feature yet, to my knowledge, but we can explore that. It=s an interesting concept. Thank you.

UNIDENTIFIED FEMALE: I=ll try to be quick with my comments, because they=re similar to what other people said, and I would say to Amy and Larry -- and you know Larry from being in the work group with us -- we had a lot of discussion about how do we get the input, and the balancing act with them -- you know, how much work does the Agency do up front to identify where the problem is -- because you could take an active ingredient and say, okay, if used on 20 crops and so what=s the use data and what=s the critical needs, but if they=re not going to have a problem with 19 of them, then we=ve wasted people=s times getting it.

And, so, I think that the balancing act that we=ve been trying to play with is when do you go and get that input? Can you get it early so that it helps the Agency if you don=t come up with a problem or do you wait until you have a problem and go get it from the user groups?

And, so, I would say that while I=m comfortable having the work group rest for a little bit, I think as you get along on, you know, hexiphiophos (phonetic) or therneramol (phonetic), which are the two that I have in this group, where you have identified that you might have a concern, that might be the time to bring the work group back together and say, okay, now what=s the best way to go out and get this information, because now we know what we=re dealing with. Is it an endangered species issue? Is it an actual tox issue? Is it -- whatever?

And, so, I think that=s the balancing act problem that we had as we discussed it in the work group. For sure, everybody was on the same page with the comments that you guys made about how do we get that done.

MR. GARVEY: Okay, thank you. Michael?

MR. FRY: Yes, three quick points. One to follow up on Carolyn and Amy. If, in fact, the summary paragraph that people are asking for were in the Federal Register notice, you know, you could find out an enormous amount of information before going to open the docket at all.

And, so, many of the Federal Register notices have a lot more information than others. Some of them just basically have the boilerplate, but others have

information. And if that summary paragraph were in there, then that would save a lot of time.

The second thing is, many of the dockets now contain almost a reader=s guide to where the material is in the docket, as one of the docket entries, and that=s a good place to put the stuff that Dan Botts was asking for -- reader=s guide not only to the docket but to other links.

The third point that I want to make is that zip files are great, but to make that information really accessible and downloadable, if there were an FTP site and the docket were a separate folder, you could just download and entire docket off the FTP site in a one-step way, and it would really save time.

Thank you.

MR. GARVEY: Very good. I haven=t heard much about FTP sites for a long time, but I=m sure they=re still out there. Okay. Thank.

MS. EDWARDS: Okay, thank you for that. I want to make a couple of comments about registration review, and that is that, as Kennan mentioned, with the new PRIA legislation, we would be, within a very few years, need to be making 70 decisions a year. We=re probably not going to make any decisions the week of Christmas and New Year=s or

Thanksgiving, I=m guessing, so you=re ending up with on, just routinely, over one decision a week. That requires that we have the resources and the wherewithal to do that. We have actually expanded the public participation process, which is a great process. It=s also a very expensive process.

And we=ve said, and made commitments, that it is through registration review that we will come into compliance with the Endangered Species Act and implement the Endocrine Disruptors Screening Program.

So, it is critical that this process be done smartly and efficiently, and that we focus in the areas that are the most important, that really do need to be pulled up, dusted off, reassessed and possibly risk management taken care of. It cannot be done through a checklist approach, where everything is treated the same.

So, I agree with everyone that this work group will very likely need to come back together as we start to develop decisions to determine how to do what we need to do, what=s mandated by the law, and what=s the appropriate thing to do to make sure these pesticides can be used safely, but that we can get through these with the resources and the time and attention that all of you have

available, as well. I=m hearing repeatedly that, you know, you don=t have the time. Well, if we=re talking about 70 decisions a year, you=re really going to be strapped. So, how can we help you and ourselves be most efficient in getting this done? And we=re going to need a lot of good ideas to do that as we move forward.

So, thanks very much for your attention to this, and we=re not done yet with it.

UNIDENTIFIED MALE: On that, in terms of the work group, Kennan, I wonder if it=s not useful, separate from having meetings, but have kind of a feedback group back to the work group, periodically, and your number will help if it happens, in terms of progress on the recommendations. And this isn=t like a test or like a progress report, but to flag issues for it and then when we get to the point where we=ve got enough issues flags, or we come up with, as Cindy said, kind of a decision point, then get us back together.

But I really liked Anne=s idea of a feedback group where we expected all this information -- oh, gosh, we didn=t get any of it, so now what do we do? So, I mean, I just think it=s efficient for you folks, as well.

MS. EDWARDS: Great idea. Sort of a focus group.

Okay, let=s move to the next session, Session XI, which is an update on the PPDC Work Group on PRIS Process Improvements, and chairing that today will be Elizabeth Leovey of OPP, and Greg Watson, of Syngenta.

SESSION XI, PPDC WORK GROUP/PRIA

MS. LEOVEY: Good afternoon. I=m going to be starting off.

As Marty mentioned yesterday, under PRIA and also PRIA II, there=s a provision on process improvements, and essentially the administrator shall identify and evaluate

reforms to the pesticide registration process under this Act with the goal of reducing decision review periods.

A decision review period is really the amount or the time frame that the Agency has to make a decision on an application.

Now, in implementing this provision, it was felt that we really needed suggestions from applicants, and others, in order to identify improvements.

And it was felt that a FACA group would be an appropriate vehicle to do that. And, so, the PPDC PRIA Process Improvement Work Group was formed.

Its members are from industry, trade associations, the Agency and public interests groups, and a number of its members are also on the PPDC team.

Since March 23rd, 2004, when we started to implement PRIA, the work group has had nine meetings. The latest one was two weeks ago on September 27th.

Now, what Greg and I are going to do this morning is, basically, go through some of the history of what the work group has accomplished and, in general, what has been accomplished in implementing PRIA. Really, the Agency would have not been able to implement PRIA without a lot of help from the stakeholders.

So, I=m going to do part of this presentation and Greg is going to do the other part of it.

When PRIA was passed, of course, the Agency was all of a sudden faced with collecting fees, registration applications, trying to review waivers, fee waivers, and a monitoring due date. So, we had to modify all of our systems.

Now, since we had to collect payments, initially applicants had to submit checks. Well, during the Process Improvement Work Group meetings, there was a request that, well, let=s join the electronic age and the Agency should be able to take credit cards and wire transfers. And, in fact, as of November of 2006, applicants can pay their PRIA fees by credit card or wire transfer, and in some cases get all those frequent flyer miles.

The Department of Treasury has a mechanism called pay.gov, and that accepts credit card and wire transfers -- credit cards up to $99,999.99.

We also salvage a number of processes, for instance, reviewing fee waivers and, also, in the front end -- as Marty mentioned yesterday -- assigning fee categories or determining what fee to invoice an applicant.

Now, since we were dealing with a lot of money,

and also, initially, people paid by check, applicants wanted to know, well, did you actually receive the check. And, so, we started out, as a result of some requests, we started mailing out, by email, notifications that we had, in fact, received payment.

And, of course, there=s a lot of interest in, basically, how much the Agency has collected, how many applications, and so forth. So, there has been an effort to develop a fairly extensive reporting system to keep track of payments, due dates and all the various different activities that it takes to process an application.

Of course, in the past we=ve had work plans with some due dates, but under PRIA we had real due dates. So, the registering divisions had to look at their processes and found that in analyzing the various different steps that it takes to reach a decision on an application, they needed to focus in on some fairly specific ones, one of which was really to identify things that were missing, have early discussions with the registrant, for instance, if studies are missing, to get the study, things like that.

Also, we really tried to determine early in the process how much work would actually be required to process the application, and this resulted in, for instance, RD

having a scoping meeting where they went through and tried to identify fairly early in the process what the real risk issues were with a specific chemical.

Resources, there was an increase on joint reviews, the use of other data and bundling applications. In this case, we thought bundling applications means that if there are a number of applications in-house for a specific chemical, process them together and not at different times -- it=s more efficient for us to do that.

The science divisions, HED, streamlined their peer review process. Basically, they combined committees, developed fewer documents, ESED improved their models, and, as you heard during the last PPDC meeting, is developing geospacial tools to find their risk assessments.

We=ve also developed processes for approving timeline extensions. Marty mentioned negotiated due dates yesterday. And we also developed a process for what is called a PRIA determination/do not grant.

Now, we have a lot of data on the reasons why due dates are extended, and we=ve been doing a lot of analysis on that data. And one of the things that we=ve observed is product chemistry submission isn=t approved, and we=ve been having, quite honestly, a hard time trying to address this

issue and it=s an issue that really needs everyone=s attention.

We=ve also observed that less experienced applicants tend to have more problems and, consequently, there=s a need to develop more guidance. One of the things that we=re doing is revising the guidance on registering a pesticide product in the U.S. -- commonly called The Blue Book, because it had a blue cover. And, also, trade associations are also doing their part to inform their members about how to apply and how to improve their applications.

In general, we=ve been reducing some of our in-processing time frames, in spite of the fact that we=ve had additional work that needs to be done under PRIA.

And one of the comments that we heard during the work group meetings was that, well, it=s taking you too long to review fee waivers, and the average decision time for a fee waiver has been substantially reduced. On an average, it=s about 21 days.

At the same time, the number of decisions have increased. If you look at the slide, you=ll find that there=s been a steady increase in the number of decisions. A decision is, essentially, a product that=s been

registered.

And that in FY >06, we had 1,347 and in FY >07, we=re getting up close to 1,600. So, consistently there=s been, over the last couple of years, about a 20 percent increase.

Now, as Marty mentioned yesterday, under PRIA there=s been increased accounting, increased reporting. Our tracking system and data systems have been modified, and we=ve also developed reports to provide stakeholders with a lot of information. And we do that through stakeholder meetings, through the work group, and so forth.

And, also, having all of that increased reporting is of help because we are audited annually by the IT. And the information also goes into the annual report that we issue every year on March 1st.

Now, the PPDC Process Improvement Work Group went through and identified their priority for improvements. High on the list -- and I think it was, if I recall correctly, on top of their list -- was label consistency. There was a feeling that the manner in which the different divisions and branches throughout OPP, the way in which their policies varied or their practices varied.

So, to assure some consistency, the OPP labeling

committee -- the OPP, in response, formed the OPP Labeling Committee. It=s actually an OPP-wide group, and what they=re currently doing is updating what is called the Label Review Manual.

Now, the Label Review Manual is available on the web, and I think they=re updated. It=s done about 40 percent of the chapters for it.

Also, the Committee has a website, and the website has a question and answer site, and anyone can forward a question to the Labeling Committee, and if it=s a generic question, the answer will be posted on the site. And if it=s a very specific-type question, related to, let=s say, a product, the individual would get a response directly.

The Committee has also done staff training -- has also done some staff training of staff, and this is on warranty statements and, also, mandatory versus advisory labeling. And, then, we solved a number of label language issues, and what you=re going to find on their website is some guidance that has been developed for both the Agency and applicants.

I=m now going to turn this over to Greg, who=s going to start by talking about IT.

MR. WATSON: Thank you, Elizabeth. Part of the

Process Improvement Group has been to, again, work on both sides of the application process to improve the IT part, what would be coming from registrants or applicants into the Agency, as well as what would be happening internally.

So, actually, when the Agency moved to this building, there was an establishment of the standard IT platform on every desktop of an EPA employee, and that=s the first that actually had happened within OPP, so it allowed a lot of tools and website information and sharing of data files internally.

Part of that process led to the scanning of what used to be called the registration jacket, and that would be all the information that had been collected by a PM and a PM team over the period of a product=s approval.

There was also, when PRIA was created, there was a need to do all this tracking in terms of categories, so there was a new IT platform that moved away from -- I=m having trouble remembering what the new system replaced. I was trying to remember that this morning -- but -- PRAT -- thank you -- so what that allowed the Agency to do is, again, keep track of the work plan and the PRIA dates and other information. I think that was substantial, because for the first time it allowed the program to see the whole

breadth of what the work plan was down through new product approvals. So that was very important.

And there=s a goal now to actually improve that even further into updates, particularly the long-term goal of PRISM, the Pesticide Registration Information System, is to try to make the applications internal to EPA more web-based, and from the registrant community side, we have requested email notification of when an application reached a critical milestone. And the primary reason why is that a process improvement, because that=s what the Registration Division is spending their time doing, is answering questions from applicants about where their application is.

So, if we have that sort of automated, we=re hoping that there will be more time available internally to do other things.

Another part that=s been very important in this work group is to provide a forum for stakeholders to bring forward ideas that could be addressed in priority and look at the places, again, both in the registrant community as well as within EPA where efficiency gains could be achieved.

Again, critical to the development of PRIA II, honestly, was to take a look at, you know, where were there

categories, where were there things that needed to be improved, and some of the things that Elizabeth has already spoken about came about because we=re able to fit together, across the stakeholder community, again, NGO community, registrant, and EPA, to look at what projects that we should be working on, which ones should go to the top of the list in terms of where could be the best efficient gain.

So, I think from the SACOL (phonetic) community this has been a great pathway for introducing topics for discussion and for resolution and a way forward. And I think it also allows us to put things that are not only short-term gains but to have projects that can be followed. And one that I selected to talk about or mention here was, again, it speaks of the product chemistry improvement question, there still is an issue of knowing in the applicant community what in EPA the approved inert list is.

Now, we=ve had a lot of discussions how to do that. Our firm belief is that doesn=t need to be in the 40 CFR, but on a website so that all can have access to that. But, again, it=s just an example that it=s not something that=s -- it=s going to take awhile to get organized and published. So, again, this forum has allowed us to put not

only short-term but long-term goals and improvements on the table.

What I=ve tried to do over the next couple of slides is just sort of summarize the highlights from the stakeholder point of view within those that have been involved in this FACA. And the first point would be to remind ourselves that PRIA actually established timelines for completion of the food we spread. And those timelines, I think, Deb, gets credit for your previous role, those timelines were met, and the nonfood red timeline that is coming next August is on track for completion. So, those things were done and underway.

There are also additional funds made available for worker protection, and in those funds, again, we=re allowed important work in that area to go forward. And, again, as Marty spoke about yesterday, PRIA II actually expands on that work and that effort.

I also wanted to say it=s very important that OPP has met the PRIA decision timelines overwhelmingly for the majority of the decisions. There=s a later presentation -- I didn=t actually want to actually talk numbers, because there will be a presentation that shows the data, but it=s very clear this has been very successful in meeting the

decision timelines.

For those of us in the registrant community, as well as the grower community, having predictability of a decision timeline is so important. And I think it is particularly important for new uses. We looked at the backlog that existed for new uses at the time of PRIA, there were some fairly significant issues there because of PRIA that has become much more predictable, and I think that=s very important to the minor crop user community as well as to the grower community in general.

Since I work mainly in the RD world, I think this is one of the things that has been very significant. If you look at the average new active ingredient decision timeline since PRIA, it=s been right at 16 months. Now that=s -- that=s good. And I think, again, it just shows that there has been efficiency gains through that process and, again, that led us to be able to propose and have accepted a reduction, actually, in the PRIA timeline in PRIA II for reduced risk active ingredient, and that=s very positive.

The other thing I=ve alluded to, as well, is that we now have, both from the stakeholder community and within EPA, a multi-year ingredient work plan that allows the

Agency to do resource planning and there=s also visibility of new AI new uses that extends over several years, and I think that, again, is an important outcome.

One of the things that we still have to do for implementation but has been really critical, has been, again, in the area of electronic submission. And we=re very pleased with the pilot that Tom Harris, particularly, has spearheaded within the Registering Divisions, and that is to utilize electronic methods to review labels as they are internal to the EPA.

I=ve highlighted that because if you look at the amount of time that=s spent by a PM team in reviewing a label, it is very significant. So, I think that=s one of the reasons that we think this has the biggest gain in terms of efficiency, upon implementation. We=re very pleased that all the Registering Divisions have been trained on using the tool and there actually is, in PRIA II, reporting that would be done about how many electronic versions of labels are submitted. Again, that=s where the applicant community has to step up. We have to provide submissions under that SOP in order for the Agency to be able to do them. So that, again, requires work on both sides.

There has also been a very successful pilot and electronic submission of study reports and there=s a move toward moving that to applications. There has been work within the Agency with PMRA. PMRA actually does take -- you don=t send paper copies of study reports to PMRA any longer if you have an E-submission format. So, we=re still trying to work to move forward there.

And within the Antimicrobials Division there was cooperative effort between the folks, Ron Bibershire (phonetic) and others, within the FACA on electronic submission template within that Division.

I really believe, having worked in regulatory affairs from the industry side for some years now, there has been a cultural change within the Agency, and I think critical to that has been, again, you can see the universe, so you know what it is and that allows managers in appropriate sections in the Science Division and the Registering Division to be able to have predictability in the work flow.

And I think this has been led strongly by Marty, by Elizabeth and her predecessor, Rick Keigwin, by the leadership of the Registering Division, Gannett (phonetic) Anderson, Lois Rossi, Frank Sanders, as well as the

leadership of the Science Division with Tina Levine and Steve Bradbury.

And, across the board, this would not have happened without that kind of commitment from leadership and the Agency is to be commended in delivering on that.

I think, also, it=s been important to have a look at, as Elizabeth has mentioned earlier, to look at submission diagnostics and to be able to use that data to see where there needs to be continued prudence. Thank you.

PRIA II, we=re active now. We=re going to switch gears a little bit to talk about building, certainly in our view, has been a success and we=re going to shift gears and talk a little bit about what are the challenges, operationally and otherwise, about beginning PRIA II.

One, of course, is that it=s in place now and that we have a very short transition period both, again, within the registrant community, the applicant community, as well as the within EPA.

We had been working or the Agency had been working in the background to establish websites and decision trees that would help delivery on the IT changes. That website is up now so that people can take advantage of those new tools and utilize the new categories.

One significant change, again, as has been discussed, is that the payment from the registrant side is due at application, and that=s, again, why it was important to have the website layout, what the new categories were and the expectation there.

It=s also very important that OPP develop guidance within that 21-day clock that we have for looking at the completeness on applications to make sure that there is an agreement on the PRIA category. That=s extremely critical on implementation because if it doesn=t happen then the system will begin to collapse on itself. So, I know that=s being worked on, and we look forward to seeing the final version of that.

The contents screen, in terms of looking at the completeness in applications, needs some redesign to be able to do that, again, within the 20 days -- the 21-day process. And there=s going to be an increased need for communication among the registrants and the Agency because if there is some uncertainty or some disagreement on either the completeness of the application, as well as the key category, we=ve got to work that out and we=ve got to work it out quickly.

It also, again, continues to be important that we

get the Blue Book -- and every time I talk about the Blue Book, I always think about the copy in my office is gray because it=s been xeroxed or copied so many times -- I don=t know of anyone who has a blue one anymore -- but I think that=s very important because, again, it provides guidance for how and what an application should look like.

Product chemistry. Boy, that should be easy to do, you know, but it still is a struggle in terms of what -- and, again, that=s why the inert proof list is important and things like that -- so we still need to work on that.

And, I think, the additional kinds of applications that are going to come in in the PRIA II are going to create a need to look at, again, specifically in those new categories, because those applications will be new to the Agency and new for the registrant community, so we need to make sure we=re paying attention to those.

And, I think, again, the whole of taking true advantage of what the internet provides as we=ve worked towards, for example, a portal that would allow an electronic application, becomes even more important going forward.

So, we=re not done, I think, on the PRIA process and permit factor, but I=m very, very proud of the work

that the FACA has done and, again, commend OPP for its implementation of PRIA I.

Thank you.

MS. EDWARDS: Are there any questions? This is a long list of activities, and I think basically after we looked at it, we said, oh, we really did a lot. Thank you.

Ray?

MR. MCALLISTER: I just wanted to comment that this particular work group is probably one of the most positive areas that the Agency has done, one of the most positive results of the PPDC as a whole. It=s been an opportunity not only for the registrants to bring in concerns that can be addressed from a perspective of efficiency, but I hope the Agency and personnel as a whole understand it=s a two-way street, and it needs to come back to the registrants and tell us where we need to be more efficient to make your work easier.

You know, we in the trade associations representing the registrants, we use this as an opportunity to funnel the concerns that are brought to us by our member companies to the Agency for consideration in making these improvements and it=s very helpful.

I wanted to make a suggestion, and I haven=t put a

lot of thought into this or run it by anyone else, but this might be a home for a session of the website=s labeling, as opposed to creating a new discussion group.

MS. EDWARDS: Interesting. I will definitely look at that. Thank you.

All right. It is time for a break. You have until 10:30 and then we=ll talk about endangered species. Thank you.

(Whereupon, there was a break in the proceedings.)

MS. EDWARDS: All right. We=re ready to start again. Our next session is an update on where we are with our endangered species assessments. This is Session XII, and our session chair today is Arty Williams, who is currently the Acting Director of the Environmental Fate and Effects Division.

SESSION XII -- ENDANGERED SPECIES

MS. WILLIAMS: Thank you, Debbie. I want to thank all of you for the opportunity to speak with you once again about our endangered species program -- where we are and what we=re doing and where we=re going.

The last time that I had the privilege of addressing this group was last May, 2007, and on that occasion I provided the status of several aspects of our work on endangered species. That included where we were on assessments relative to litigation and what we were doing in the context of registration review.

I provided you some information about some tools we have been developing to help us do our job more effectively and efficiently. And, also -- this is a good statement -- information about information management.

I=d like, again, today, to touch on those four

areas -- not to repeat what I told you but to provide an update of what we=ve been doing since the last time that we met and discussed those.

First, in terms of litigation assessments, which is consuming a lot of our time, I mentioned in May 2007 that there were some assessments that were upcoming in the near future. Those included assessments of 10 active ingredient potential effects to the California red-legged frog, which is a species designated as threatened under the Endangered Species Act.

There were 10 due out in July of 2007. Those have been completed and they are on our website. Then we have initiated consultation with the U.S. Fish and Wildlife Service regarding those assessments.

There are 10 more that were due in October, and this would be October, and they=re actually due this Saturday, which my lawyer tells me they=re due on Monday. Those are completed and we=re just putting the final touches on those, and I=m writing my transmittal memos to the services, and those will be transmitted by Monday. And, then, it will probably take us a couple of days to get those up on the web, because to do 10 of those takes a little bit of time.

So, we=ve, to date, met our requirements under the settlement agreements for that case to assess these chemicals, make determinations and initiate consultation, as appropriate.

I think I also mentioned back in May that there were some assessments that were coming due relative to a case that involved the Barton Springs Salamander down in Austin, Texas, at Barton Springs. And in May we had completed assessment of several of those, and we had three more to go -- simazine, promoton (phonetic), and carbaryl. Those were due in September of this year and those have been completed and are posted on the web.

We have initiated consultation on those, where appropriate, and I stress on this group, where appropriate because one of them, simazine, was determined to have no effect on the Barton Springs salamander. So, for that particular assessment, we did not initiate consultation.

For promoton, we took a little bit different approach than what people maybe are typically used to seeing in actually making the determination, distinguishing where it had the potential to affect the species. Because of the youth patterns of promoton, it was really difficult to look at how much of that pesticide was anticipated to be

used in the water shed that could, then, impact the springs and, therefore, impact the Barton Springs salamander.

That particular assessment assumed different amounts of use in the water shed and below certain amounts it was determined that the pesticide would have no effect on the salamander. If use were between a low and medium number it would have potential effects, but it would not likely adversely affect, if use in that water shed area was above a certain amount of pounds. The call was likely to adversely affect.

This is actually one of the areas that I think is going to be a real challenge to us as we move forward, and that is for chemicals where you=re not applying it to cotton and corn and things that you can look at land cover data for and distinguish where those land covered occur, we have to make some pretty broad assumptions about use, for things like white=s the ways and one kera chemical.

So, I think it=s going to be an ongoing challenge for us to figure out how to manage those kinds of assessments.

And, then, for the third chemical in that group, carbaryl, that was determined to be likely to adversely affect based on the current labels of carbaryl, but it also

notes, if you want to go in and read the multi-hundred page document, that if the label had limitations on the number of uses that could occur in a season; and, again, if we had better information on the percent of lawns in a particular area that might be treated at the same time, that determination could look different.

Again, another problem with lawn care is you have to assume that those people who are going to be using it and are treating their lawns are all doing it on the same day, because we don=t know.

So, I think those two are going to be particularly challenging for us and the services as we work through the consultations on those, just because of these kind of unknown entities that we have to make some assumptions about.

With the completion of those three assessments relative to the Barton Springs salamander, we have completed our obligations for assessing chemicals under the litigation that was brought relative to the salamander.

We still have the obligation to, you know, work with the services through consultation on these, but we have completed all the assessments under that case.

In the near future, the assessments that are due

out are seven additional pesticides relative to the California red-legged frog, and those are due in February. It=s kind of the next big chunk of it due out the door.

On our website, there is a candidate list of pesticides. It contains about 20 pesticides and right now the 20 includes the 10 we=re getting ready to go out with this weekend.

Once those are out, that list will be updated and it will be a list of about 20, and from that list of about 20, those next seven will be taken. And, then, when those are out, we=ll again take those off the list and update the list again.

While it=s not definitive, I can=t tell you precisely which seven. I=m still looking, obviously, on more than seven at a time, but the seven that will come out will be from that list.

We=re also in the beginning stages of a new lawsuit. It=s a suit that was filed by the Center for Biological Diversity, and it focuses on the sum of 40 pesticide active ingredients, and 11 issues of varying taxa from mammals and birds to insects and reptiles in the San Francisco Bay area. It=s not just in the Bay, but in, I think it encompasses about seven counties in the San

Francisco Bay area.

That=s a recently filed suit and we=re just in the beginning stages of having discussions with the Center for Biological Diversity about that suit. There=s not much else I can tell you about that except that perhaps next time this group meets we will have some resolution of that.

Moving on to registration review, in the May meeting I described that that is the process through which we are going to be trying to accomplish endangered species assessments on a national scale for each pesticide that goes through the process. At that time we had provided preliminary -- assessment isn=t the right word -- scoping information to support opening 12 dockets. We continue to provide that support for opening additional dockets, and this year, Fiscal >08, we are beginning work on an assessment for one of those first 12 that was opened.

We have anticipated in, I think, >08 and >09 and years beyond, that there would be 45 dockets opened per year, and that would kind of be the rate at which, then, we would have to be completing assessments, as well. But it looks now like in >09 that rate is going to bump up to about 70, and it=s going to be about 70 per year for the remaining years, in order to meet the 15-year time frame

for concluding assessments on all of these chemicals. So, that=s going to bump up our workload pretty significantly.

In the area of information management, there are two things that I mentioned last time that I think are going to help us in a pretty significant way that we=re beginning to work on, and will be helping us simply internally. It=s not going to necessarily help us get work done, but it=s certainly going to help us track what we have done and kind of keep a measure of how far we have yet to go.

And that is a tracking system that will help us track assessments by chemical and species and what the determinations were, so that in 15 years, when somebody else is doing this and I=m happily retired and sitting on a beach, they will be able to very easily see what had been done, whether there are new species to consider within their new use patterns to consider.

The other information management tool that we had begun to think about developing was a -- I think Debbie had coins for this particular effort -- an encyclopedia, so I will call it that -- I have no better word.

But it=s going to be a system into which we can put and then easily retrieve information that we compile as

we=re going through these assessments regarding species, biology and habitat and whatever we find that is useful, for example, for the California red-legged frog, the life history, documents that were put together to support our assessments.

All of this information will be put into the system in such a way that it=s easily retrievable and useful again for future assessments where we have to do work on those particular species.

The contractor that we had been working with did a requirements document, which when we first started on that endeavor I thought, well, this should be easy, I know what we need, turned out to be a very, very specific, huge document that outlines every single aspect of what this system ought to do, what it ought to be able to contain, how we want to be able to retrieve it. So, that piece is done.

The piece we=re working on right now is called a systems requirement document. My understanding of that is that it will outline, for the person who is actually going to build the system for us, and his computer requirements -- how much storage we need, what kind of -- I=m probably using the wrong terms -- but what software we want it

written in, how we want to be able to update it. And all that will be spelled out for the contractor, who, then, in the third stage, will actually build this system for us so we can start using it.

That=s going to be the first of the two that we=re going to build, the information storage and retrieval system, as opposed to the second system.

We think that will help us approach our assessments more effectively and, therefore, be able to do them a little more rapidly, and then we=ll have more to track. So, we=re going to focus on the information storage and retrieval system first.

Finally, in the arena of tools and tool development, we=re continuing to build tools internally related to our assessments in terms of upgrading models. One of the similar recent things that we=ve accomplished was, actually, the result of having to work on the California red-legged frog assessments. We have a model that we call Keywreck, which helps us anticipate the exposure to different animals from eating food, be those vegetable or animal, that are contaminated with a pesticide. And we=ve upgraded and modified that to focus on the diet of amphibians, so it can better predict the

exposure of amphibians to pesticide based on dietary intake from food sources.

We continue to work on things like that to help us better do our jobs and to help us do it more effectively.

The one tool that we had been working on upgrading for the public was actually our website, and we have launched our new and improved website, which was supposed to make it easier for people to navigate the information and find what they were looking for.

I think we were very successful in that, except maybe in the most important regard. We=ve actually gotten some input from the public that whereas we used to be able to easily find the page that had a sex determination for endangered species, it=s now a little difficult to find that page.

So, we are going back and looking at that. And, if, in fact, they are correct, it=s takes like four, maybe five clicks even to get to that page, which is not acceptable. So, we=re redesigning that part of it so once again it will be easy to find. It was not our intention to bury them somewhere.

So, that=s kind of an update of what we=ve been doing and where we=re going, I think. And, with that, I=m

just going to stop talking and see if there are questions you have about any of that or if there are other aspects of our program that you would like me to try to address.

Dennis Howard is first, thank you.

MR. HOWARD: Thanks, Arty, thank you for the update. I=m just curious about the level of effort that it=s taking the Agency to respond to these lawsuits, and the comparative effort that you=re able to send on registration review. I don=t know if you could put a number on it, but I=d be interested in knowing how those efforts compare. And, also, just from the outside, it seems kind of like the Agency is on somewhat of a treadmill here with these lawsuits coming in. They must be taking a fair amount of your resources to address, at the expense of broader program needs. And do you see any future way of getting off of that treadmill? And, if so, where is the escape hatch?

MS. WILLIAMS: Personally, I think I mentioned I=m going to be retiring in the next couple of years.

(Group laughter).

MS. WILLIAMS: It=s an excellent question, Dennis, and I can=t put a number on it for you. I think at past PPDC meetings actually there is a graphic to kind of show

our timeline and track for completing endangered species work through registration review. I think that graphic had a second line on it that was, at that time, re-registration, which is almost completed now. And, then, at the bottom there was a little skinny line that said litigation. The fatter the skinny line gets, obviously, the skinnier the fat line has to get, if you have stagnant resources.

I can tell you that we=re expending quite a bit of our energy and manpower on meeting obligations that resulted from litigation. We have been able to dedicate the resources to opening the dockets that we need to open. But, again, if you=ve got a set amount of resources, as you have to apply them to one area, they=re obviously not going to be available for another area. So, it=s something that we need to keep real close tabs on.

And I don=t know how we get out of the cycle of litigation driven work, and into the cycle in earnest of doing this work in the context of registration, we=re expected to keep trying to do that.

MS. EDWARDS: I just wanted to add a little bit to that. I mean, it=s a very astute observation that there=s only so many fees and so much appropriated funds, and we

are now financing the responses to all of the lawsuits out of our old chemical program, because they have to do with existing registrations, so that=s what makes sense to us.

So, right now in registration review, we=re developing dockets. We=re not actually doing the full bore nationwide endangered species assessments that we intend to do through that process, but as more lawsuits come in there was no particular pot of funding that allocated to that. You=re right that in a couple of years that will be -- if it continues at the current level -- we would have to make decisions between complying with, you know, what=s required by the lawsuits or going out of compliance with the mandates under registration review. There=s just no two ways about it -- it=s not funded.

MS. WILLIAMS: Anne tells me that Cindy Baker was next.

MS. BAKER: Thanks, Arty. I just have a question. We=ve been to the website and looked at what are the next 20 candidates, but then it becomes kind of a guessing game as to which are the seven that you=re working on. How are you -- and I heard you say you=re having to make some assumptions about some of these chemicals because you don=t have information -- on home lawns, for example -- is there

a process in place where you can engage the registrant early, as you pick those seven, and talk about it, because that=s the kind of information that we have very easily available.

For example, I could give you where my sales are on home lawns, because it=s a completely different side of my business than it is the ag business. And so, if there=s a process where we could get engaged, kind of like we had been in the re-registration process, I think we could answer some of those questions for you and provide actual documentation of where is this product going. It might only be going to one area of the country, for example, where that is, and we could do that. But I=m not -- and it might be my own ignorance -- I=m just not clear how to engage in that process.

MS. WILLIAMS: No, I don=t think it=s showing any ignorance on your part at all. In the registration review program, when we start doing a substance there and looking at these chemicals across the country, it is our intent to get information from whomever might have it, including the registrants -- extension coordinators, grower organizations -- so we can better define the use of the pesticide.

Ultimately, the assessment has to be based on

what=s on the label, and then the risk is characterized based on information such as we=re talking about. And it is our intention to do that, much like was done in re-registration.

The problem that we=re facing with the assessments that are ongoing right now is that they are very compressed in terms of time schedule. We=re working on probably a dozen at any given time just to ensure that we=re going to have seven in February that can come to completion.

Because of those compressed time schedules, it=s really difficult to say, okay, it=s going to be these seven and let=s go meet with the registrants and meet with the grower groups and get the information we would like to have up front.

What we have been doing, however, is after these assessments are done -- and I know this is not ideal -- but if information comes in to us regarding a different way to characterize the use or even of a study that we were not privy to, for example, we=ve been sharing that information with the service that we=re in consultation with, and it=s our intention that that information will then be considered in the context of consultation.

So, if it=s not a firmly shut door, it=s just a

matter of when the door is open. And I know that=s not the ideal process, but it=s about the best we can do given the schedules we=re bound to on these.

MS. BAKER: And I=m not suggesting that you=re not doing the best thing here. I mean, just one real world implication of that is when those findings come out and you say, okay, you impact the red-legged frog when, in fact, we might not, then we=re in a loop that=s bigger than just the Agency loop of having to go back and try to explain, here=s the information up front.

And, so, I understand you=ve got a compressed scheduled and, directly to Dennis=s point, but if there=s any way to even just give us visibility to what are the seven you=re working on -- not set up meetings with the registrants maybe of those seven, but if we knew up front these are the seven that you=re working on, we can take the step to say, okay, here=s a summarization of the current use patterns. Because not always the most current label is there, especially if it just went through a RED or something like that and the label changed, you might not have exactly the most current labels if it=s something that was very recently reviewed.

And, so, I think if there=s a way to just unveil

what are the seven you=re working on, then the registrants will -- because it=s in their best interest -- will take the initiative to make sure that you have all the best information that you can have.

MS. WILLIAMS: Yes, just two real quick comments. We actually have a process that we=ve established with the Special Review and Re-registration Division and Registration Division to make sure that if, as we=re working on these, labels come in as a result of RED that have changes on it that impact the assessment, that we are aware of that. So, we=re trying very hard to make sure we have the most recent information.

In terms of the main issue that you raise, and I=m not sure that I can say more about it than this, and we=ll probably have to go on to Mike Fry, but all I can say is that I can=t identify for you the seven, because we=re working on probably almost all that are going to be on the list for the seven, and the best said is that those on that list will be done in the next set or the one after. And if a company wants to be proactive and just look and see what chemicals are on that list that are theirs -- we=re not trying to trick people, you know, we didn=t put like the last ones up there that we think we=re going to do. So,

the best we can do is that candidate list, I think, at this point.

But thank you for that input, I appreciate it.

MS. EDWARDS: Now, there=s obviously a lot of interest in this topic. I think what we=ll do is take all six cards that are up and then move on.

MS. WILLIAMS: Michael Fry.

MR. FRY: Kind of a two-part question. One, I don=t know if there the red-legged frog issue was part of the litigation over the counterpart regulations, and do you have any update on how that was going or settled over a consultation with your sister agencies?

And, then, following on from that, how able have the sister agencies been to keep up with your schedule for consultation, you know, we have NOA and Fish and Wildlife, both, that are required to consult on these things, and has that litigation really created a bottleneck or a problem in the pipeline there?

MS. WILLIAMS: Thanks, Michael. On the first part, the litigation that was brought against the services -- and I=ll let Nancy say more on this, should she choose to -- regarding the counterpart regs, we didn=t have any specific focus on any of the assessments that we=re doing,

but the big thing from EPA=s perspective that that litigation did was to state the judges=s result -- whatever you call the document he issues -- the decision, stated that the provisions in the counterpart reg that would allow us to forego further consultations were not likely to adversely affect decisions was not appropriate.

While I don=t believe the Department of Justice has said anything about whether that decision applies in the district of that judge or nationwide, we have been consulting on both likely and not likely to adversely affect determinations since that decision came out.

So, I think the implication for us is that it=s kind of increasing the joint workload, because we=re going to be having to consult on those, as well.

On the second part of your question, I don=t think I=m the right person to answer that, and maybe I could have Nancy to address that.

MS. GOLDEN: Twenty-nine assessments involving different combinations of pesticides, some of those have been grouped into single assessments. And we=re in the process of working on them. We=re working diligently on them. It=s a new thing for us. Pesticide consultations are a bit of a different beast than other consultations.

They are more complicated, they=re broader in scope, and having this in hand it=s our first opportunity to sit down and really look at them.

So, we=re still finalizing our initial responses to the first request that came in from EPA. We=re working diligently on the new ones, and we=re trying to take this as an opportunity to work out what is the most efficient consultation process to pursue. I think we kind of see the same workload that EPA sees down the line, you know, two, three, four years from now we=ll be getting requests on, you know, maybe 70 requests on more broad scale consultations that will involve larger geographic areas of the country.

So, we see this as a preview, and we=re really trying to work on what responses can utilize like the most efficient process for us for interagency consultations. We realize we=ve got to come up with something that will work for both agencies and that we can do within the time frame of both this litigation and the farther registration review that=s going on. So, we=re working on it.

MS. WILLIAMS: Thanks, Nancy. Dan Botts.

MR. BOTTS: The main points that I=d like to refer to probably already have been touched on, but I just --

recognizing -- and, Nancy, this probably goes to you rather than EPA, because looking at the litigation responses in the created consultation requirements, those are very tight, specific and geographically limited, they have been across a broad diversity of geographical areas in the country, because they focus on different areas. From that standpoint you=re getting a feel for what=s there, but after having gone through the cluster analysis process back in >87 and looking at some very broad ranging impacts across large geographical areas in a whole bunch of species, quite frankly, the thought of having 70 active ingredients going through this process in an individual year, dictating weekly decisions of where they stand in this process, if registration review 15 years from now is going to be absolutely completed, that=s going to be a resource intensive operation for not only the Agency but both of the sister agencies and the services.

Are you all looking at what resource base it is going to take to do this, looking at just what=s come forward as a result of litigation in anticipation of the workload? Because I think it=s going to be horrendous, and the Agency is under statutory mandate now to have to complete this, and may have to depend on you guys to

complete the consultations to be able to meet what Congress has told them they have to do. And short of being set up for a whole new round of litigation, I don=t know what we=ve accomplished unless we get a lot more efficient process than what we=ve got out there now, which a lot of us had hoped the counterpart regulations would deal with, which evidently they haven=t worked quite a well as everybody anticipated.

I=d like EPA to answer that, too.

MS. WILLIAMS: What was the question?

(Group laughter).

MS. WILLIAMS: I think it=s very resource intensive, yes.

Nancy, would you like to add anything to that?

MS. GOLDEN: I=ll just say that I completely appreciate your comments, because, you know, what we=re trying to discuss is we, like you said, we=ve got these small scale geographical consultations, but we=re looking at them with an eye for what=s coming down the road, and we=re having the same conversation that you=re bringing up here. How can we do this? What resources do we need? How can we engage people all over the country, within the Agency, that might be able to input to this? And it=s part

of this discussion that we=re working on, but you=re right to bring it up, and we have the same questions, and we=re working for the answers now. That=s all I can say.

MS. WILLIAMS: Thanks, Nancy. Carolyn Cox.

MS. COX: The first thing I wanted to do was answer that question that Dennis asked about how do you get off the litigation treadmill. And I don=t want to sound snide, but the way you get off the litigation treadmill is to follow the law. And, you know, I really appreciate that EPA now is having to bear the burden of 30 years of ignoring the law, but that really is how this treadmill ends, and I think there is a commitment at the Agency to do that, but let=s just keep that in mind that what we=re doing is catching up over decades of ignoring a really important law.

And, then, I actually have a question, as well. Arty, you talked about these, you know, information tools that you=re developing to help you with the assessments that you=re doing, and they sound great. And I=m curious if any of those tools that you=re working on incorporate inert ingredients in the products that you=re assessing?

MS. WILLIAMS: Not probably in the context that you mean. When we=re doing our assessments for endangered

species, we start with the active ingredients. We look at product specific label requirements to do the determination of whether actual use in the field of products with that active are going to result in exposures that are anticipated to have toxic effects on the various types of species that we=re interested in looking at.

One of the things that we are doing in these assessments, as well, is looking at, albeit in a limited way, product specific data to see whether, at least for mammals, which is what we have the data on, the formulation of any additional toxicity above and beyond the interest from the active ingredient.

In that context, we=re considering the inert ingredients. But, again, it=s a very limited context. We=re not specifically reviewing inert ingredients relative to a species effect.

Marco?

MR. GUSKE: A quick question. Where are we going to start seeing the labeling on pesticide fabricating, and to what extent is that going to -- when, you know?

MS. WILLIAMS: That=s a real good question. I don=t have as good an answer as it deserves. But, as soon as we get to a point with a chemical that we=ve assessed

and have identified some risk from, and work with the service and the grower community and the states and the registrants to determine what limitation needs to be put on a product to ensure the safety of the species, at that point the chemical or the product will have to be labeled with the statement indicating that there are changes to the use based on risk-of-species issues.

So, procedurally, I can tell you; calendar-wise I can=t tell you. It depends. When we get done with consultation, if that consultation results in a need to do something, that=s when we=ll do it. Or, you know, if we=re reviewing something and Cindy Baker calls up on the phone and says, hey, you know, I can fix this, I can do this to my label.

And, so, it really depends on when the need is identified. Once it=s identified, we can do it pretty quickly. But first we have to identify the need and define the risk and specifically what the limitation is.

That=s probably not a satisfactory answer, but that=s the best I can give you.

John Schell.

MR. SCHELL: Thanks, Arty. You mentioned some of these tools that you=re developing. Do you make them

available to the public so we can play with them? You know, sort of like the benchmark that=s been distributed and pro-use and things like that?

And, second part, you=re doing so much litigation work, are there -- you might not be able to answer this -- but are there tools that you develop as part of the litigation that you=re not allowed to release to the public?

MS. WILLIAMS: The answer to the second question is no. Just because we develop a tool as a result of litigation to help us meet our obligations under litigation doesn=t in any way limit our distribution of that tool.

The tools that we=ve been working on, like the Team (inaudible) Model that has allometric equations and brands it in, all of those kinds of tools we are preparing to put on the web. So, it is our intention to make those publicly available.

There are a couple that aren=t up yet, in fact, I just learned yesterday that T-Rex (phonetic) isn=t up on the web yet. So, we are working very diligently to get that resolved. Any kind of modeling scenario -- spreadsheets, an automatic calculation thing that we developed -- will be made publicly available once it=s been

QC=d.

Rebeckah Adcock.

MS. ADCOCK: A couple of questions. First question is my understanding is that EPA is still honoring the processes. My question is reconciling the processes of evaluation and review between the services and EPA. And my understanding -- and please correct me if I=m wrong -- is that EPA is still trying to honor the process. And for the science review that was established, or that was directed to be established in the cooperative agreement, that was not part of the counterpart regulation but that was related to the counterpart regulation, and that was not stripped down or affected by the court decision.

And this may be a question for the services, is it the service=s opinion that the processes in that agreement are still valid and moving forward and that that is the -- sort of the foundation of review -- both at EPA and at the services? If so, how is it working out, in the opinion of both Agencies? If not, please explain where the inadequacies are and what needs to be done to remedy them.

And the second part of the question is for both Federal Agencies, are there additional resources that those of us who advocate for additional resources for needs in

the government, might be able to identify to, you know, maybe can hopefully convince people to provide the resources needed to catch up, because from a user=s perspective, you know, if the system becomes bogged down for whatever reason -- in either Agency -- the people that pay the price -- the two systems that pay the price -- are the users that wanted a safe, effective product that they understand how to use properly, and secondly, you know, we need to know what the effects are, if they=re out there, so that way we can make the adjustment?

So, you know, first of all, what is the process? Is there agreement on the process? What is being done to expedite it if there is not? And, secondly, what are the resource needs that can be identified?

MS. WILLIAMS: Thanks. If you don=t mind, I=m going to answer the first question, from EPA=s perspective, and then go right into resources, and then let Nancy answer from her perspective, if you don=t mind, Nancy.

In terms of the scientific methodology and processes that we=re using to conduct our assessments, we are doing those consistent with the two features outlined in the document you referenced, which was shorthand called the Overview Document.

The services reviewed that document some time ago and their evaluation of it was also on our website. It was an evaluation that needs us to believe it=s probably the best process we have right now.

That evaluation also indicated some areas where there are gaps in knowledge that aren=t unique to EPA, but span the scientific community. And one of the things that we=re doing currently is beginning a process to talk about how you might go about focusing research efforts to fill some of those gaps.

But, beyond that, it=s our opinion that the services in that letter of evaluation agreed that this was a process that would result in adequate and even robust assessments, so that is the process we=re using.

In terms of resources, I mean, you=ve heard some of the things here today about what resource means. The services and us have been talking, as well, about just the need for information sources that are presented nationally. A lot of the information that the services have, because endangered species are so localized, are kept in a localized manner. And, as Nancy mentioned, pesticide assessments are a different beast, I think she called them.

And when we start looking at these pesticides

nationally, you know, we=re going to need data nationally on where species are, what they rely on, how they interact with different things.

So, in addition to just assessments, there is an array of resource needs, both at our Agency and the services, I believe, that would make us far more capable of doing this job in an effective and efficient manner.

In terms of funding for those, I=m certainly not at liberty to ask anyone to ask for anything on my behalf. But, I can certainly express to you the areas in which I think we=re lacking information or equipment or methodologies or whatever. And, again, we=ve articulated some of those here today, and I=m sure there are many more from both our perspectives and the services.

I=ll now turn it to Nancy.

MS. GOLDEN: I guess from the service=s end, what we=re seeing here, these litigation driven consultations are the very first products that have arisen from this process that we=ve worked out with EPA and NOA, and that=s one of the reasons that we=re taking such a careful look at them to assess, in a real-world situation, where we have a product, we have a consultation regarding the species in the field, we can look at the data regarding the species,

look at the data that=s in the literature, and that=s provided by EPA, and assess how well did the process work.

And we=re in the process of doing that. And that=s an important part, not looking at these individually, but looking at the entire process. And, I guess, I would defer any comments on how our final results of that until we actually finalize our responses and get back to EPA on that.

MS. ADCOCK: I guess I=m confused on where the services stand on the agreement and the terms, understanding that there were some gaps in information across the board that everybody acknowledges needs to be filled in. Is generally the overview document acceptable at the services or is it not acceptable? What is the opinion of that, for those of us who are depending on the products you=re going to process, we realize that=s the biggest concern is making sure the process is smooth and expedited.

So, what is the opinion?

MS. GOLDEN: And I think the reason why I can=t give you an absolute answer on that is, you know, in general, that=s something we did create with EPA, and, you know, we=d like to see if it works, and that=s what we=re

looking at now when we look at these assessments and see what came in and see what the final conclusions are for the individual species. We=re looking at both the process and the individual species.

MS. WILLIAMS: And I think we=re running out of time, so I=m going to give Michael Fry the last word.

MR. FRY: Just a comment, really. This backlog, the litigation and the problems of funding and Agency resources, are not unique just to this group of people. Neither is a result of pesticide residues in the environment as a result of legal uses. The Fish and Wildlife Service is certainly not responsible for those pesticide residents.

The drinking water agencies that have to get them out of the drinking water are not responsible for these pesticide residues.

Are the registrants responsible for the pesticide residents or is EPA, as a result of registering these pesticides, responsible?

Somebody has got to determine at some point who should bear the cost of this stuff, and I think it will have to come back to the registrants.

MS. WILLIAMS: Thank you, and thanks for the time

and the input. It=s a good discussion, I appreciate all the comments, and that=s it. Thank you, Debbie.

MS. EDWARDS: Okay, thank you very much. Obviously this probably is, from at least my perspective, the biggest challenge we face in the coming years. Tools aren=t all in place to do it and it=s probably the first time we have tried or actually must ultimately regulate on an extraordinary local level, from a Federal feat. And, so, I think, that is what makes it so incredibly challenging.

But the most important thing, I think, for us and for you to think about and be doing now independent of what resources we do or don=t need to get this done -- I=m not sure we even know fully at this point -- but is that you make it clear, all of you -- I think every stakeholder community has an interest in the pesticide world of seeing that the public is focused, the Congressional people are focused, you know, anybody who is a decision-maker in this area in pesticides, is focused on the fact that you want it resolved.

You know, you want -- you as registrants, you as growers, you as public interest groups, us as government agencies that have this work to do -- we all want this to

be able to become routine and to be able to be resolved in such a way that we=re in compliance with the Endangered Species Act.

And, so, continuously making that clear, that you=re onboard to get it done, I think right now is probably the most important thing you can do -- in addition to helping us with the data and any other and all ideas you have on how we might get it done. I don=t want to belittle that, either.

Let=s move on now to -- thank you, Arty. Let=s move on now to our updates. I=m going to keep these very brief. It=s intended to provide you -- and you do have materials in your packets on them -- just with accomplishments and fast forward on both registration and the reevaluation programs here. And, then, we=ll move into a discussion about next meetings and our charter renewal.

So, we=ll start with Lois Rossi, the Director of the Registration Division.

SESSION XIII -- REGISTRATION AND REREGISTRATION UPDATES

MS. ROSSI: Okay, I=m going to basically do a review of the last fiscal year, giving a lot of statistics on our work.

Okay, that slide basically presents to you a listing of the decisions that we made on conventional pesticides. And of interest among these are some reduced risk pesticides, as well as our first trilateral that we completed this year, which was a joint review with Canada, Australia and the United States. And it was our first attempt to do this and extend the honor across the borders, and it was very successful. And several other chemicals are the result of some collaborations that we=ve had with other countries.

Presented on this slide are the listings of the biopesticides that were registered this year, 12 biopesticides.

And those are the antimicrobials, we had six new active ingredient antimicrobials.

For new uses, we authorized 201 new uses that are associated with over 600 crops for previously registered conventional active ingredients. Four of these are officially classified as reduced risk, but actually the number is substantially higher than that, only because we haven=t officially made the reduced risk finding more classification for these uses that are associated with active ingredients that were classified as we go through, but we=re hoping to correct and get those statistics up.

And there was one organophosphate alternative.

And, then, the last bullet contains the new uses for the antimicrobials and the biopesticides.

With regard to the Section 18 activity, this activity, overall, is certainly decreasing. If you look at the figures from the late 90s on the number of Section 18s received, it was in the 500 and 600. That has gone way down. We only received 226 requests and this is obviously as a direct result of the registration activity on uses that are going through the full Section 3 review rather than the Section 18 review. So, we=re very pleased with this.

As a result of the new uses that we registered this year, over 120 Section 18s were avoided. And our

turnaround time is still roughly about 36 days.

And, then, these are some statistics on our -- some PRIA actions and some non-PRIA actions. Our fast track amendments represented there, non-fast track, and they=re given in the bullet, by divisions, for the registration of Antimicrobials and Biopesticides Division. You can see there=s been quite a lot of work and decisions there on ME-2s (phonetic) and fast track amendments.

This is a very brief summary of our inerts. We have a continued inerts program. Largely we finished the bulk of our work for reassessment last year by the 2/06 deadline, but the inerts branch is still active, and we=re getting a stronger inerts problem by the day.

We have completed four actions this year on new petitions. We received nine new ones. We currently have 26 that are pending. We had a substantial number of petitions withdrawn this year, pretty much because they were reviewed and not found to be complete.

This is a summary of our PRIA. It=s a huge number. It=s an aggregate through 2/06 from the beginning of PRIA, with total PRIA submissions well over -- almost 6,000, with approximately 4,600 completed. More than 99 percent have been completed by the PRIA goal.

There is the statistics for the not-grant, which is less than 1 percent of the total submissions. And the negotiated due dates -- the renegotiations that we have is about 11 percent of the total submissions.

On the next page, this gives you further details, by divisions, of where the not-grant decisions have occurred, as compared to the total.

And the next page also gives you the ones that had renegotiation due dates.

And, then, the last slide, I have presented the number of PRIA actions that are pending with regard to new active ingredients. We have total pending for conventional, 13. And many of these, I=m pleased to report, are joint reviews or beyond. Most of them are tri-laterals or we even have one that=s quatro-lateral.

We have 15 biopesticide new active ingredients pending, and four antimicrobials.

And that, very briefly, is a nutshell of what we accomplished in the last year.

Thanks.

MS. EDWARDS: I think we could take just a couple of comments or questions.

Okay, Ray and Dennis.

MR. MCALLISTER: On your PRIA performance slide, I don=t know the number, where you give a grand total of 5,800 submissions. The actions with negotiated due dates, are they part of the 4,616 completed? They=re all part of the 6,836?

MS. ROSSI: Right.

MR. MCALLISTER: Okay. That was the only question I had.

MR. HOWARD: Just a question on the Section 18s. It=s interesting to, as you pointed out, to see that the trend is declining for the number of submissions. I wondered if the Agency keeps a matrix on Section 18s requests that are avoided. In the states, we frequently -- when we=re approached by industry for the need for a Section 18, our first step, after getting some background information, is to talk to the Agency, to the folks in Emergency Response, and that=s a very constructive dialogue that we have with them. In many cases, we learn about problems that a Section 18 might have or we learn about areas that we need to be sure to address when we send it in.

And, to the extent that the Agency is providing a service to the states to help us avoid sending in and doing

a lot of work on Section 18s that ultimately may not be supported, it would be interesting if you have data on that or maybe start collecting it, to, as a matrix for performance on your part, to reflect the service that you=re providing for us.

MS. EDWARDS: Thank you, Dennis. We=ll definitely look into that.

Michael.

MR. FRY: I just wanted to make a comment, mostly. I find the registration review dockets to be extremely useful, and all the background information that is there. I would like to see the Agency entertain the notion of opening a docket for new chemicals for registration that would have in that docket the risk assessments done by E-Fed, and, especially, if a compound is registered and the risk assessment from E-Fed was adverse, I=d like to see a written explanation of why Registration Division has decided to register that compound.

MS. ROSSI: That=s a good comment. Actually, we do have the risk assessments on the website. And, of course, the health risk assessments are in a docket. We could easily add the E-Fed, but the E-Fed and the HEB, the health assessments, are on the web. You have to click on

the active ingredient and it will take you to the risk assessment.

MS. EDWARDS: Only after registration, right?

MS. ROSSI: Yes, that=s correct.

MS. EDWARDS: So, I think, before registration was your point, right, Michael?

MR. FRY: Yes.

MS. ROSSI: Yes, we could work on that.

MS. EDWARDS: Okay. We move not to re-registration registration update with our new Director of Special Review and Re-registration Division, Steven Bradbury.

MR. BRADBURY: Thanks, Debbie. I just wanted to spend a few minutes touching on some highlights out of the information that you received. I=m not going to go through all these slides, but just hit on some of the highlights over the last year and talk a little bit about going into 2008.

During 2007, we completed all those tolerance reassessments that we completed. So, over that time frame of going through this whole reregistration process, there are now 9,700 tolerances that have been reassessed with recommendations on several thousand where we=re ensuring

the safety and making changes in those tolerances. The 3,000 that were results from 5,400 where the tolerances were evaluated; 5,000 stayed the same; and there was a thousand here and there that went up and that we ensured safety.

As far as the re-registration accomplishments, as of the end of 2007, there were 95 percent of the re-registration cases are completed with the remaining 27, 25 of those being nonfood use compounds, that still need to be done, but the tolerances for those compounds have been completed.

And, as we=ve been going through this process and ensuring, again, the health safety, ecological risk assessment and ensuring that the benefits of the product are on the market, the enmethyl-carbanic was completed near the end of September, that=s out for public comments, and then if you all haven=t already been looking at it, you should be looking at that and providing us any input that you have.

As we move into 2008, and over the course of the last day and a half, we=ve been touching on some of the challenges ahead of us. We certainly have to finish the re-registration process on those 27 compounds that need to

have their REDs completed, their re-registrations completed. I think another important point is that there=s a lot of work to be done in terms of implementing the decisions that are in the RED, and I think that=s one of the most important aspects of the re-registration program is still in play. And one of the things we just talked about was looking at the label as we do the endangered species work, and there=s a number of decisions made in these REDs that are increasing buffer zones, changing use patterns, changing use rates -- many of which were designed to reduce the likelihood of adverse ecological effects. We need to get those into the system and being labeled now so that our endangered species assessments are focused on the most current uses and capture the good work that went on in those REDs.

Thinking about registration review, over the course of this last year we completed 25 dockets, which Kennan described this morning, and as we move into FY-08, we=ll be taking on 48 aces. And, as we talked about over the last couple of cases, there=s a number of challenges as we go into >08 -- endangered species, endocrine disruptors -- all starts with the older end of that, the registration

review process and move into the future. And, so, we=re starting to get ourselves ready to take on those challenges.

The last thing, there=s a lot of coordination with Canada starting to get into place so we can try to match up reevaluation and registration review to try to get some consistency.

And, finally, looking at performance and taking a look at our performance measures that we=ve talked about to see how those are playing out. One of the points Anne made yesterday was the atrazine monitoring work that is an important aspect of those performance measures in terms of the atrazine decision, as well as giving us tools to work with water quality issues. We=ll be having an SAT on that the first week in December. This will be an important milestone in both following up on our RED decisions and giving some insights on performance measures.

MS. EDWARDS: Any comments or questions for Steve? You have an update in your packet. We went through these pretty quickly.

All right. We might actually get done on time. Thank you.

I think Margie was going to make a few remarks on charter renewal and membership.

SESSION XIV -- PPDC CHARTER RENEWAL AND MEMBERSHIP

MS. FEHRENBACH: Actually, I think I=ve talked to everybody almost individually, so I=ll keep it pretty brief.

As you know, the current charter for the PPDC expires in early November, and also the membership, the current membership, also expires at the same time. And we=re in the process of getting both the charter renewed and getting a membership package through the system. So, we don=t have names of peoples to announce at this meeting. Some people thought we were going to do that, but that=s not true.

Membership will be for two years and the charter will also be for two years. That=s a fact or rule that they can only go for two years. It seems like it=s happening every year, but it is a two-year process.

I had made copies and given out at the last meeting the FACA essentials, and I won=t pass it out here, but if anybody wants it, there=s a copy of it out at the desk. But responsibilities for new advisory committee members, the ability to attend and participate in meetings is important; be willing to engage in an exchange of views

and perspectives and, if possible, search for consensus, although it=s not required; and, then, I=ll repeat my favorite, which is to cooperate with your committee=s designated Federal official, which is me.

(Group laughter).

MS. FEHRENBACH: Anyway, that being said, I also just want to publicly say thank you to Nicole Zinn, who has taken care of all of the AD process. There=s Nicole. Come over here, they can=t see you.

(Group applause).

MS. FEHRENBACH: And that=s it. So, if you have any questions, you know how to reach me. Let me know. Thanks.

MS. EDWARDS: Okay. Thank you, Margie.

SESSION XV -- PLANNING FOR SPRING 2008 PPDC MEETING

MS. EDWARDS: I wanted to just spend a few minutes getting any reactions you might have about what I spoke about toward the end of the day yesterday, which is that I actually feel like this is a very good meeting, so don=t get me wrong. I think we got a lot of good feedback, a lot of good interaction, and actually before Larry Elworth said, he said, some of the topics are so focused in on pesticides and very technical issues, but we get incredible participation here, so we really appreciate that.

Having said that, I am often wondering, we have so many topics on the agenda, that whether or not you=re feeling frustrated at times that there=s not enough time for discussion.

And there are a couple ways of handling that. One is to have a longer meeting and one is to discuss fewer topics and just have some of these things that you very specifically asked for as updates provided to you through

either a website or materials in your packet, or both.

But, then, to focus in on maybe two topics, like two topics in the morning, two topics in the afternoon, and so forth, and provide time for everyone to fully participate.

I guess I=m just feeling like right now that if we had allowed a lot of comment on each one of these individual topics, we would have gotten through about half the agenda. And, so, I=m not frustrated about that, but I want to make sure that you=re not and that, you know, this time that we all have is very resource intensive, many of you travel, many of you certainly take time out of your normal work to come here, and we appreciate it, but we want it to be productive for both sides.

Anyway, I=d appreciate some thoughts on that, if you have taken some time to do that.

Cindy.

PUBLIC COMMENT

MS. BAKER: I did my homework last night. I even made some notes about it. I actually think this meeting was one of the better run meetings that we=ve had in terms of keeping us on track, so congratulations to you on that. But I did have a sense that there were a number of topics that came up that people would have liked to discuss more.

And, so, I liked your suggestion. I don=t know if it is on EPA=s website where the PPDC meetings are or you could put some of the items that probably don=t need a lot of discussion. I mean, everybody wants an update on them, but put them there. I mean, I love to hear Lois and Steve talk, but theirs, for example, might be one that you could put on the website for updates and people would tell you ahead of time if there=s something in there that really needs some discussion. But it could be made available that way.

And I would pick, you know, maybe four topics at the most that you really want some discussion on. And I think the model that we used yesterday for the web-based

labeling discussion, where you send the information out to maybe four or five representative people on PPDC, ask them to come prepared with some comments, they give those and then everybody else gets an opportunity to do it, as well.

And I actually put two ideas down for that. One is web-based labeling, because I would think between now and the spring there=s a lot of activity that=s going to take place, either with a pilot or with a work group or whatever it is that you=re going to do along those lines.

And endangered species. Based on the discussion that we had this morning -- what are the data needs; what are the process needs; what are the resource needs; you know, what ideas do we have now that we=ve heard from you and Arty today about things that we might be able to do to help in that arena?

And, so, those are just some of my preliminary thoughts.

MS. EDWARDS: Thank you. Lori.

MS. BERGER: Along the same lines, I really thought that yesterday=s presentation was a very efficient way to look at a topic and get some preliminary takes from a variety of stakeholders, where people came to the meeting really prepared. And it also gave room for discussion.

So, I really liked that format, and you had expressed, Debbie, that a lot of times you guys aren=t getting as much feedback from this group as you would like. And, so, I think that that=s a really efficient vehicle to do that. And, also, I think it helps the general committee, as well. So, that was very good.

There were some questions about, should you continue to update? And, yes, that=s very helpful. I go back to my groups that I work with and have a -- there=s so much information -- it=s really hard to take notes and get it all back. So, it=s really helpful to have the handouts, the reports, so that we can filter those out to our subgroups and so forth.

Maybe on some of the things that are more statistical in nature, we don=t need a full report at the meeting. So, if you could maybe look at the slate of topics that EPA=s reporting on that are more statistical versus evolving process or something, that might be helpful.

And, then, as far as the length of the meeting, talking about should it increase to a full two days, for those of us that do travel in, we=re basically here for two days whether or not the meeting goes for the full length.

So, just maybe consider that as you=re planning. I mean, it doesn=t have to go the full two days, but for people that are coming in, that time is pretty much invested any way. So, if you can get more out of us as a result of that, I would suggest you may be try to do that.

Those are my thoughts.

MS. EDWARDS: Thanks very much. Dr. Schell.

MR. SCHELL: Well, I like what both Lori and Cindy said. Maybe a way to save some time is requiring us to do a little homework. The information is all sent out to us, especially on the program updates. Maybe if the folks don=t give the presentation but they=re here to answer questions. So, we would all go through the presentations, and you could say, does anybody have a question on registration? They=re here to answer them. And, then, we could get to discussion.

So, we could save the time that we=re currently giving the presentation for questions. And, so, those of us who really have questions about particular things would be able to do both of them.

MS. EDWARDS: Thank you. I think -- Shelley is that you with the card up?

MS. DAVIS: I guess I am concurring here that I

think there needs to be more time for discussion. I think that there were several topics yesterday where people felt cut off in the middle of the discussion. So, I definitely agree that, you know, putting updates in the packet -- not just on the web, because for some of us the web is tough -- but putting them in the packets and maybe allowing, you know, 15 minute questions on all the updates, that would be fine. And, then, focusing on some of the big-ticket items.

And I just want to throw out, too, big tickets that I=m interested in in upcoming meetings. One is, I think, your view of having a discussion about how can there be an effective public participation process as part of the PRIA process.

And the second thing is, as the discussion of web-based labeling moves forward, I=d like to hear how we could incorporate foreign language labels and low literacy labels as part of that effort.

MS. EDWARDS: Okay, thank you. Amy?

MS. LIEBMAN: I=d like to also second the idea of putting stuff either on the web or sending it out to us ahead of time, but we need it at least a week ahead in order to give people time to read it and digest it and make questions. If we get it the night before, some are

traveling and won=t get it. And even those of us who get it, aren=t really going to have time to digest it and give the input that we could.

And, also, I think Lori=s suggestion that everybody is here for two days if they fly in, well, even those of us who are local, my afternoon is pretty shot. I=ll go back to my office, but I won=t get a whole lot done. So I=d be willing to stay until, say, 3:00 -- to keep working until 3:00, and maybe that would be a way that other people are flying in could do it, too.

Along the lines of topics for next meeting, the issue of inert has come up pretty dramatically in California, over the light brown effal moth issue. And it seems to me like a more extensive discussion of what you guys are doing on the inerts programs. If you go to the inerts web page now, it=s cobwebbed and, you know, what=s going on with List 1, 2, 3 and 4, and how many List 1 ingredients are still in pesticide, you know. It would be really good to get kind of an overview of where you guys are on kind of phasing out the really toxic inerts and, you know, other issues related to that.

MS. EDWARDS: Thank you, very much. Anyone else for now?

Okay. What time is it? We=re going to end early -- by about eight minutes, I think.

Just let me start, then, by thanking Margie Fehrenbach. These meetings would not go well if Margie didn=t work so very hard and so very long hours to see that they do, and she does it with a great spirit.

(Group applause).

MS. EDWARDS: She does things I don=t even know she=s doing, but it makes it very nice for all of you; such as, the food out here and the refreshments and so forth.

I also want to reiterate the thanks for Nicole Zinn. She=s been very helpful in getting this meeting ready and, also, Pineapple always comes and helps out when getting these meetings ready -- volunteers to do that. Thank you, Pineapples.

(Group applause).

MS. EDWARDS: I=d like to thank, also, special thanks to our colleagues at other Federal agencies who come and participate in these meetings, as always. The USDA, Food and Drug Administration, Centers for Disease Control, and Department of the Interior Fish and Wildlife Service.

I=d like to thank the people that have participated in the work groups. I think this work group

approach has proven to be just an excellent way to do business in many cases for many of the more complex topics.

I=d like to thank the people that participated in the panels yesterday, in particular. The web-based labeling panel. We=ve gotten some kudos just in the last few minutes on that. I think that went very well, and we appreciate the input that you did ahead of the meeting. It was very thoughtful.

And, finally, I=d like to thank all of you for coming. We have good participation in these meetings, and we appreciate that, and also the public who came to participate. So, thank you very much and have a good day.

UNIDENTIFIED FEMALE: One more little comment about the problem with the microphones. We found out that one of the things that was causing the feedback was anybody who uses their computer and there=s a microphone in their computer, apparently that was contributing to today=s problems. So, we=re going to work on that, and actually I would like to say thank you to Pablo Vaca (phonetic), who has really tried very hard to help us get through this.

(Group applause).

UNIDENTIFIED FEMALE: But we=re going to make some changes and some improvements. Thanks -- thanks, Pablo.

(Whereupon, the meeting concluded).

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