Transcript of Meeting of

Pesticide Program Dialogue Committee

Conference Center - Lobby Level

2777 Crystal Drive (One Potomac Yard South)

Arlington, Virginia

May 9 & 10, 2007

COMMITTEE MEMBER ATTENDANCE LIST

James Gulliford	Assistant Administrator, OPPTS
Debbie Edwards	Director, Office of Pesticide Programs
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Anne Lindsay	Deputy Director for Programs
Ronald Smithson	USDA
Richard Colbert	Director, Agriculture Division, Office of Enforcement and Compliance Assistance, EPA
Nancy Golden	U.S. Special Wildlife Service
Vladimir Murashov	National Institute for Occupational Safety and Health
Seth Goldberg	Steptoe & Johnson
Carolyn Brickey	Center for American Progress
Dr. Robert Holm	Executive Director, IR-4 Project
Gary Libman	Principle of GNL Consultation Services, LLC
Jennifer Sass	Senior Scientist, Natural Resources Defense Council
Rodney (Marco) Guske	Travel Pesticide Program Council
Lori Berger	California Specialty Crops Council

ATTENDANCE LIST (cont'd)

Dr. Steve Balling	Del Monte Foods
Caroline A. Kennedy	Defenders of Wildlife
Frank Gasparini	RISE, Responsible Industry for a Sound Environment
Dr. Jose Amador	Director, Agricultural Research & Extension Center, Texas A&M
Shelley Davis	Deputy and Co-Executive Director, Farmworker Justice Fund, Inc.
Dr. Warren Stickle	Chemical Producers & Distributors Association
Dennis Howard	Chief, Bureau of Pesticides, Florida Dept. of Agriculture & Consumer Services
Carol Ramsay	Extension Pesticide Education Specialist, Washington State University
Jay Vroom	CropLife America
Amy Liebman	Environmental Health Consultant, Migrant Clinician Network
Dr. Hasmukh Shah	American Chemistry Council

ATTENDANCE LIST (cont'd)

N. Beth Carroll, Ph.D.	Senior Stewardship Manager, Syngenta Crop Protection
Daniel Botts	Director, Environmental & Pest Management Division, Florida Fruit & Vegetable Association
Cannon Michael	National Cotton Council, California Cotton Growers & Ginners
Julie Spagnoli	FMC Corporation
Robert Rosenberg	Director, Government Affairs, National Pest Management Association, Inc.
Amy Brown	Coordinator, Pesticide Safety Education Program, University of Maryland
Patrick Quinn	Principle, The Accord Group
Diane Allemang	ChemNova
Susan Kegley	Pesticide Action Network
David Lewis	& Harrison
Caroline Cox	Center for Environmental Health

ATTENDANCE LIST (cont'd)

Joseph Conlon	Technical Advisor, American Mosquito Control Association
Dr. Michael Fry	Director of Pesticides and Birds Program, American Bird Conservancy
Maria Martinez	EPA, Region Six
Allison Weederman	EPA, Office of Water
Jim Hanlon	EPA, Office of Water
Allen Jennings	Director, Office of Pest Management, USDA
Marty Monell	Deputy Director for Management, OPP
Matthew Keifer	Associate Professor, School of Public Health and Community Medicine
Frank Sanders	Director, Antimicrobials Division
Pete Caulkins	Acting Director, Special Review & Reregistration Division
Don Stubbs	Associate Director, Registration Division

ATTENDANCE LIST (cont'd)

Jack Housenger	Associate Director, Health Effects Division
Kevin Keaney	Chief, Certification & Worker Protection Branch, FEAD
Steve Bradbury	Director, Environmental Fate & Effects Division
Arty Williams	Associate Director, Environmental Fate & Effects Division
Pauline Wagner	Chief, Inerts Assessment Branch, Registration Division
Michelle Thawley	GIS Coordinator, Environmental Fate & Effects Division
Oscar Morales	Director, Information Technology and Resources Management Division
Larry Elworth	Executive Director, Center for Agricultural Partnerships
Dale Dubberly	Chief, Bureau of Compliance Monitoring, Florida Department of Agriculture and Consumer Affairs

ATTENDANCE LIST (cont'd)

Chuck Andrews

Scott Schertz

Jerry Johnston

P R O C E E D I N G S

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DAY ONE - May 9, 2007

MR. GULLIFORD: Good morning.

(All says good morning.)

This is sounding like a staff meeting. What's happening here? No.

Well, good morning. My name is Jim Gulliford. I'm the assistant administrator for OPPTS. I'm delighted to welcome you all to the PPDC meeting this morning. I know that many of you probably travelled late last night to get here, and I appreciate the reasonably early start-up time that we asked you to join us for.

I have two important functions today. The second is to, obviously, add to my welcome and thank you for your work. But, initially, I'd like to start off by introducing to you someone that all of you know but perhaps just recently in her new capacity, Debbie Edwards is now my office director for the Office of Pesticide Program, and I'm just delighted to have Debbie. You all know the work that she's

done, her roles as director for the reregistration and special review, and prior to that, the registration office as well.

But she brings a load, which is a technical term from the Midwest. She brings a load of experience and talent to this job that I think will continue to find work that OPP has done over many years. And she also brings the background and experience that I think add to her understanding of the issues that all of you bring to the PPDC, and they are very important to the work at OPP.

Now, having introducing Debbie, before I let her talk and let her take over this meeting, I also think it's very important that I want to thank and recognize the work that Jim Jones has done as well. Jim, as you know, has not left OPPTS, but, in fact, I selected Jim to be my principle career deputy for OPPTS. And so he's moved over to the other side of the river, the downtown side. And, again, for many of the same exact reasons I'm just delighted to have Jim's experience, his leadership, his reasoning abilities to be applied to the challenges that we

face from both in administrative, but also in leadership standpoint on the higher OPPTS mission.

So I'm very grateful for all of the work that Jim did as OPP director, office director, but also am delighted that he agreed to come over to the OPPTS portion of our leadership team. And I believe that with my selection of both Jim and Debbie in their new roles that we've continued the traditionally strong leadership program for all of our pesticides toxic work in OPPTS. So I'm delighted with my staff and to have them in place and to be able to do the work that is given to us.

The second part of my interest today is obviously to thank you all for coming and for continuing to engage, providing input to this FACA Committee, to look at the issues that we're facing on the OPP side again of OPPTS. We know that you do this because of your interest in these issues both professionally and personally, but also from our perspective, you bring a wealth of knowledge and a link to just a live source of information that is very important to the work that we do at OPPTS. We

know that you bring a diverse set of interests and perspectives which are critical to the information that we need to make informed decisions.

We very much appreciate the fact that for the lively discussion that occurs, it's respectful discussion, and that we all understand the different perspectives and different knowledge sources and interests that you bring. So I'm very grateful for that, and I want to thank you again for that, and I'm delighted to be able to spend a little bit of time with you this morning. I'm going to listen to the discussion, this Frazier report that is coming out and perhaps provide an opportunity tomorrow to spend a little bit of time again later with you.

But, again, thank you all for your interest, your commitment, your willingness to bring perspective and background and information to the -- to OPP. And with that, I'm going to turn it over to Debbie to conduct the meeting. But please join me in welcoming Debbie to this new position and thanking her for agreeing to serve on this most important role.

(Applause.)

MS. EDWARDS: Thank you, Jim. I appreciate that. I actually don't know probably all of you much as I would have liked to, but I think I do know many of you, and I hope to get to know all of you in this new role as director of pesticide program. I'm very happy to have been given this opportunity. It's, as many of you know, I've been in this program for more than 20 years. And to me this is kind of the pinnacle of my career. I'm really excited about it and I'm looking forward to all the challenges before me and before the Office.

I'm also very excited to be the Chair of this FACA subcommittee. It's been a very successful -- excuse me -- this FACA committee over the years has been very successful giving us enormous amount of excellent advice and -- which we have used much of. And so I think today we have a lot of very important issues on the agenda. It's -- I think it's going to be an exciting agenda, an important agenda for all of us. I'm going to go through it in a minute and also give you an opportunity to introduce

yourselves.

I just wanted to say a few things about kind of the way I view public participation. I think the public participation process that we used for (inaudible) assessment and reregistration was actually developed by a FACA subcommittee, not this one, but it was the carrot track subcommittee. It was very successful, very valuable to us in our decision-making process as we moved to meeting that ten-year deadline.

I think now it's considered by many to be a model in the federal government for how to conduct business. As a result of that, we actually with this committee formed, a subcommittee for registration review, if you recall, to develop the regulations and so forth to run that program. And we modeled the public participation process for that new Old Chemical Program on that original public participation process which is actually now somewhat expanded with the opening of dockets very early on in the process to get good input from people. And we're going to have a little session on that, too, I think

tomorrow morning.

I think it's important, as Jim mentioned to, have broad stakeholder views heard and carefully considered in pesticide regulation. This is because my belief is that pesticides have high benefits in many situations for society. They're bodily used. They affect the lives of nearly every person in the country. They also have the potential to impact human health and the environment. So we have to be very careful and deliberate to our regulation of them. And that's why, my opinion, it's important to consider all stakeholder opinions and all stakeholder views and all the information and data available to us so we can make the best decisions possible.

So I just wanted you to know before I start through the agenda that I am happy to have this job. I consider it to be a great responsibility and one I don't take lightly. And our doors are open to listen to you whenever you would like to meet with us.

Turning to the agenda now, maybe I'll pull it out. I want to go through it, and then we'll do our introductions. The first session is the work

group on spray drift. We're actually going to have reports out during this meeting from five work groups. Spray drift is the first one. It's actually co-chaired by OPP, Anne Lindsay and our colleague at the Office of Water, Jim Hanlon. It's a work group that's been going on for some time. There's been an enormous amount of work that's gone into the deliberations of this work group.

And the outcome of it is that we have consensus in some key areas, and I think we're very happy to have that. We also recognize that there are some disparate views still in many areas, the spray drift work group. I don't consider that to be a failure. Like I said before, we can't expect, I don't think, with this broad of a stakeholder community to have consensus on all issues, but it is extraordinarily important for the Agency to hear all of the stakeholder views. And I think we've provided a really good opportunity to do that through this spray drift work group.

Moving then to Session Two, we're going to provide the usual program updates for registration

and reregistration, and then we'll give you an update on our NAFTA label situation which we've had some successes with this year. We want to share that with you and some path forward. And then right before lunch, Marty Monell will provide you with our usual budget update.

Then we'll have lunch, which will be about an hour and 15 minutes, if we're lucky. And then in the afternoon at 1:15, we're scheduled to have a session on the work group on PRIA process improvements. Once again, Marty Monell will deliver that. And then there's going to be a short session to tell you some of our initial thinking on how we might open up and address the issue that have to do with possible need for diagnostic biomarkers. This has come up repeatedly in some stakeholder venues, and we want to take it head on and figure out a way to fully address that issue.

Then in Session Six there will be a report out from the work group on worker safety by Kevin Keaney. And then after a break, we will move to the transition work group which is actually co-chaired

again by EPA and the USDA. And Al Jennings, our colleague from USDA, is here for that today as well as Rick Keigwin from the Biological and Economic Analysis Division.

And, finally, the last government session will be the endangered species update, which will be presented by Steve Bradbury and Arty Williams.

Finally, we'll end the day with an opportunity for public comment. And if you do want to make a public comment as a member of the public, you should sign up at the sign-up sheet outside at the registration table during one of the breaks.

Tomorrow morning we'll convene again at 8:30 and start that out with the registration review work group report. And then that will be followed by the work group on performance measures report out, and then following a break, we'll move to a panel session, actually, on cause marketing.

I think after spray drift, this is probably one of the more -- is going to be one of the more challenging issues for us and one of the more challenging panels as we know that there are

disparate points of views in this area. We're going to actually have a panel with the representatives from the Red Cross, the Clorox Company, the public interest community and the states as well as an EPA presentation there.

Following that, we'll have the PPDC session describing the PPDC charter renewal and membership. We're coming up to need to do that piece again to keep the FACA going and then a little bit about planning for the fall PPDC meeting.

Finally, another opportunity for public comment, and we'll adjourn. So that's what's planned for the next day and a half. Pretty heavy duty agenda, but I think we'll get through it and we'll learn a lot.

I'd like to move now to the introductions. I'd like you all to introduce yourselves and state your affiliation. Also, if you're representing an absent member, if you could state who you are and your affiliation, but also who you're representing. That would be helpful. And also just as a reminder, you need to turn the microphones on, and when you're

done, please turn it off. It helps with our feedback problems we sometimes have with the AV equipment here.

So I will move to my right.

MS. LINDSAY: I'm Anne Lindsay, Deputy Director for Programs.

MR. SMITH: Ronaldson Smith with USDA.

MR. COLBERT: Rick Colbert with EPA's Office of Compliance.

MS. GOLDEN: Nancy Golden, U.S. Special Wildlife Service.

MR. MURASHOV: Vladimir Murashov, National Institute for Occupational Safety and Health. I'm an alternate for Melody Kawamoto.

MR. GOLDBERG: Seth Goldberg. I'm with Steptoe & Johnson. I'm here for Phil Klein of the Consumer Specialty Products Association.

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

MR. HOLM: Bob Holm, IR-4 executive director, retired.

MR. LIBMAN: I'm Gary Libman. I'm

principle of GNL Consultation Services representing the Biopesticide Industry.

MS. SASS: Jennifer Sass with the Natural Resources Defense Council.

MR. GUSKE: Marco Guske with the Travel Pesticide Program Council.

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

MR. BALLING: Steve Balling, Del Monte Foods.

MS. KENNEDY: Caroline Kennedy, Defenders of Wildlife.

MR. GASPARINI: Frank Gasparini with RISE, Responsible Industry for a Sound Environment, and I'm here subbing for my boss, Allen James.

DR. AMADOR: Jose Amador, Texas A&M in Weslaco, Texas.

MS. DAVIS: Shelley Davis, Farmwork for Justice.

MR. STICKLE: Warren Stickle with the Chemical Producers and Distributors Association.

MR. HOWARD: I'm Dennis Howard with the

Florida Department of Agriculture representing AAPCO and also Mary Ellen Setting, another member from AAPCO, who could not be here today.

MS. RAMSAY: I'm Carol Ramsay with Washington State University Extension.

MR. VROOM: I'm Jay Vroom with CropLife America.

MS. LIEBMAN: Hi. I'm Amy Liebman with the Migrant Clinician's Network.

DR. SHAH: Hasmukh Shah, American Chemistry Council.

MS. CARROLL: Beth Carroll, Syngenta Crop Protection.

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

MR. MICHAEL : Cannon Michael, National Cotton Council, California Cotton Growers and Ginners.

MS. SPAGNOLI: Julie Spagnoli, FMC Corporation.

MR. ROSENBERG: I'm Bob Rosenberg, National Pest Management Association.

MS. BROWN: I'm Amy Brown, University of Maryland, Cooperative Extension Pesticide Safety, and also representing American Association of Pesticide Safety Educators.

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

MS. ALLEMANG: Diane Allemang with Cheminova, sitting in for Cindy Baker-O'Gowin.

MS. KEGLEY: Susan Kegley, Pesticide Action Network.

MR. LEWIS: David Lewis with Lewis & Harrison, sitting in for James Wallace of S.C. Johnson.

MS. COX: Caroline Cox, Center for Environmental Health.

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

DR. FRY: Michael Fry from American Bird Conservancy.

MS. MARTINEZ: Maria Martinez, EPA Region Six, alternate for OPPTS Region, Region X.

MS. WEEDERMAN: Allison Weederman, the

EPA's Office of Water.

MR. HANLON: Jim Hanlon, Office of Water.

MR. JENNINGS: Al Jennings, USDA.

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

MS. EDWARDS: Okay. I believe we have someone on the phone, Mat Keifer.

MR. KEIFER: Yes, Mat Keifer, University of Washington.

MS. EDWARDS: Okay. Did everyone hear that? He's from the School of Public Health, University of Washington.

Okay. Thank you, Mat.

Well, I think we should -- we're a little bit behind now. We should probably move into our first session right away, which is the PPDC work group on spray drift, and I'll turn to our colleague Jim Hanlon in the Office of Water. Kick that off.

MR. HANLON: Debbie, thanks for the opportunity to be here and, Jim, also, to, first of all, congratulate the members of the work group. It was just over a year ago where the charge was

provided to the work group members in terms of dealing with an issue that, at least from the Office of Water's perspective, we are probably a little bit naive in terms of the complexities of the issue that OPPTS had dealt with over the years. And as we got into it, they described several conversations, I guess, they'd had over the years on the subject of drift. And it was sort of with that and in the context of a rule-making that the Office of Water was working on at the time dealing with the intersection between the Clean Water Act and the MPDS Permitting Program and (inaudible) for Licensing Program for Pesticide products -- that and that rule, in fact, was finalized in November of last year that clarified the products that are used in accordance with the label and are applied in over or near waters of the U.S. do not need MPDS permits.

And so the drift issue was sort of an issue that was discussed in the context of rule making. We made it clear on the proposed rule and then the final rule that the rule did not deal with drift, but we would have a separate process on that and the fact

that was the work that was charged to the work group.

There was a flow point charge provided to the work group, first, dealing with improving understanding both the members of the work group from the Clean Water side of the issue, both states and environmental organizations together with sort of those people coming from the pesticide industry and sort of state regulators from that side also to understand better how the Clean Water Act works. I'll speak personally and say I've learned a whole lot during that process in terms of the Pesticide Program and sort of the inner workings of it.

The second point of the charge was to find common ground for further work dealing with both occurrence and potential adverse effects of drift.

The third point was dealing with some options for undertaking work where common ground exist, and the fourth, exploring the extent of drift that occurs even with proper usage and the range effectiveness or potential responses.

The work group took extremely seriously the charge. There was a series of face-to-face meetings,

the energy and the focus that the work group brought both in the general sessions and the work in the break-out sessions and the then conference calls that were held were particularly impressive, and they have done their job. They completed a report that you will hear about in a couple of minutes, and I would encourage the full committee to listen to that report. I know a number of the work group members are on this committee and look forward to the committee's deliberations on that report and moving forward.

So, again, thanks for the opportunity, Jim, to work with OPPS and your staff. I think this has been a real step forward. I think the work group's report is of the highest quality, and we look forward to further actions on the drift issue. Thank you.

MS. LINDSAY: I just want to add a few comments to Jim's introduction, the first of which is I need to thank not only all of the members of the work group, but I would actually like to thank the EPA staff and the Office of Water and the Office of Pesticide Programs, Allison Weederman, Jeremy Arling,

and Jenny Garelic (phonetic), Bill Jordan, and Pat Janino (phonetic) because this was a very hard working group. And behind their hard working was a lot of hard work by those people I just named, and I wanted to recognize their contribution to the success of the group as well as actually a number of other EPA people who provided information at various different points.

One of the things that has really struck me about the group is their ability to listen. I know for myself it's very easy to talk. In fact, it's really easy to talk when you think you have clear views and maybe you think your views are actually the most informed and appropriate for everyone else to listen to, much harder to listen. I'm still struggling after many decades to learn how to listen.

This group only has not had decades to work, thank goodness, but over the course of a year, one of the things that I think really happened was that not only were all the members of the group willing to share their views, all of which were very clear, very important, very perceptive, but the group

actually learned, I think, to listen to each other's views, to ask questions in a way that they got more information about views that they may or may not have shared. And I think you will see the richness of that in this report.

So that's the basis for my thanks to the group. You worked hard. You produced a great report. And I'm actually -- as the Agency figures out after this meeting how to actually use the report most effectively, I'm actually counting on and expecting on the kind of participation the work group provided over the last year to continue into the future on this issue so that we will have a corps of people in the work group and then in this full committee who will be ready to be engaged on issues associated with spray drift.

And with that, just for practical matters, the game plan for this particular session, two of the work group members, Susan Kegley and Scott Schertz, and I can't see where Scott is at the moment. He's in the back row. We probably need to get you to the table, Scott, are going to kick off the session by

giving an overview of the report itself. So while I hope all of you have had a chance to look at the report, since we got it out to you last week, they're going to give you an introduction to the report, and then what we will do is open it up to discussion around the table in sort of just classic PPDC fashion. And so, Susan and Scott, I don't know which one of you I should -- you? Both? Okay.

MS. KEGLEY: As you might imagine, there were diverse points of view on this particular work group. Thank you. Great. And I think Jim gave a nice introduction to the way the work group got started and the mission statement. So we had a number of face-to-face meetings and some might think endless conference calls to work on this. And there were some -- well, as Jim said, you know, it's a combination of thinking about how the Clean Water Act and FIFRA come together. And we got information on the history of spray drift science and policy, some of the Office of Water, Water Quality Protection Program, ecological risk assessment methods, someone from California talking about the state water

permitting process, pesticide labeling. And we looked at a variety of specific labels on different pesticides to see what we are dealing with.

State perspectives and approaches, Dave Scott from Indiana was from AAPCO representing AAPCO was a very -- is a reality check for many of us, all of us, I think, and a little bit about education training and stewardship program how they're working the value of them. And then Jay Ellenberg talked about the Drift Reduction Technology Project, and we also heard a lot from each other.

The work group ended up focussing on labeling to mitigate spray drift, the role of education and training and stewardship and practices and equipment to mitigate drift and adverse effects from drifts. Early-on, EPA delineated the scope for the group. We decided that some things were outside of the scope of the spray drift work group, the NPDES rule, which is now in court, I believe, from multiple challenges and post application volatile application drift. It seems that there might be a different process for handling that, possibly through the risk

assessment process. And then post-application run-off pesticide movement didn't fall under the spray drift (inaudible).

What the group found -- is this you?

MR. SCHERTZ: Okay. I'm Scott Schertz, and where I'm taking over here for a bit has to do with the labeling issues. And, basically, we did look at the existing labels, and we did find there's a lot of inconsistency, particularly even in products of the same class, multiple 2,4-D labels, and we do see that as a problem. There is a real question on what is enforceable versus an advisory on labels. And then also when we get into many of these labels are a process that is went over for many years have become too wordy, and we will be talking about where the labels actually increase the drift potential.

There are many design standards that will be talked about later that actually have taken literally currently would increase the drift potential. And then, obviously, there's organization and other confusing and contradictory parts of the label. And basically we do recommend that the EPA

should work to clean up these things, and there's a detailed statement there on that.

Also, looking more in depth on this as far as identifying what is enforceable, what is advisory, get them on separate parts of the label and then also having the directions for methods separated. Currently, there are quite a few labels that actually have these mixed up, and we do believe that that would be helpful to straighten that up.

Okay. Then, also, continued on the recommendations to have a stakeholder group to review the generic label language process. We don't see that it is something that every single label would need this, but as far as having a bit of a format or template would definitely be worthwhile and then also utilizing the designing performance standards, which we'll go on into.

This was a big topic of discussion as far as what role they should play. And, basically, the design standards were specifying how something should be done and what type of equipment and then also as opposed to the performance standard, which is more

outcome based, and leaving more discretion up to the applicator.

Basically, there are -- there was agreement that there are factors to consider as far as enforceability, how effective it is both on an application side and also at reducing drifts, the regulatory requirements and then, as I mentioned earlier, labeling. Some of these design standards actually may increase in drift potential and they do need to be current as far as best practices. So we do recognize that these are appropriate standards, however, there was not agreement on the relative waiting. Obviously, from the applicator perspective, the performance standards were okay. What's that?

PARTICIPANT: Can you pull the mic up to you?

MR. SCHERTZ: It's all the way up. (Inaudible). Okay. And then -- okay. Okay. And, then, also, we did find that the education, safety, and training is a very important factor, and we do encourage that that is something to be continued and to be expanded on a federal basis.

Okay. So, also, we do recommend that the EPA explore with the experts to make these things worthwhile on establishing the performance and design standards and also encourage the use of this equivalent including the DRT. And we did have some comments, suggesting that the EPA determine how to best support the adoption of the DRT technology and how to best facilitate that adoption and also continue support for the basic DRT project. But we do have real concerns on whether or not this will actually be a hindrance to some effective technology if the DRT process is too complex and costly. Okay.

MS. KEGLEY: So we actually needed a good definition of spray drift, to start with, and I don't know whether -- I didn't say this at the beginning, but most of this presentation is issues that the group could come to consensus on. You'll hear the differing points of view towards the end of the presentation. So these are generally things that people agreed on. So we define spray drift to mean pesticide droplet and particle movement that occurs during the initial application that results in

deposition onto non-target sites. And excluded from that definition is that spray drift does not include particle movement onto non-target sites caused by erosion, migration, volatilization, or wind blown soil particles that occurs after the application. So we wanted to sort that out early-on.

There was a discussion about local conditions, and it turns out that there are many particular areas, maybe endangered species or particular weather patterns that are specific to a certain area that may need additional attention from the applicator to ensure that spray drift doesn't cause adverse effects.

And the recommendation to the group were that the EPA should work with the states and the applicators to tailor mechanisms that -- regulatory mechanisms that apply to the local conditions. And almost in most cases, this will probably be, if not all, impose additional controls on pesticide applications. So then the issue of communicating where those particular local conditions prevail need to be communicated -- those issues need to be

communicated to the applicators. And so EPA should look at different ways of effectively communicating this information. Possible models include the TMDL Watershed management approach, and California has county bulletins under the Endangered Species Protection Program where you can see clearly where the endangered species habitats are. GIS mapping often helps get that information across very quickly.

Okay. Determining real-world impacts. So the question is, once you modify the labels and work to get them the best they can be, how do you evaluate how effective they are in actually preventing spray drift. And so in order to determine that, EPA needs to strengthen the collection of information regarding the real-world effects of the way pesticides are applied under the new conditions, water quality monitoring data. Information on enforcement actions by state right now is kind of informal survey, maybe making that more rigorous and getting more input from the states.

Incident -- using incident databases and a lot of the incident data bases lately have only

included use or -- I don't whether -- there's been some question about what the databases actually include. And so we want to be sure that all the incidents are gathered there, and that includes wildlife as well as human. And then also looking at users understanding of label statements possibly by using focus groups to really understand what the applicators are getting from the label instructions.

Okay. If the real-world outcomes show that there are impacts that are not being mitigated by the label regulation -- or label conditions, we suggest that EPA consider whether these outcomes raise questions about the validity of the models that are being used or possibly indicate that the requirements aren't stringent enough to prevent harm and adverse effects may be -- it might be shown that they are limited to certain geographic or weather conditions, and also should be on the lookout to see whether users are complying with the regulatory requirements.

So, if after doing these evaluations of what the label effects are, if the existing regulatory requirements that are on the label have

failed to produce the expected level of protection, EPA needs to figure out why that's so and fix it.

Okay. So the -- there's real differences between the Clean Water Act and FIFRA. And so it's interesting to see the conjunction of the two laws in the Office of Water and Office of Pesticide Programs working together on this. The recommendations that the group came up with is that EPA should develop water quality criteria for current use pesticides. There really are about -- there's fewer than two dozen current water quality criteria federally posted for current use pesticides. A lot of them are for older no longer use pesticides. So having more water quality criteria would be great, and there was also interest in EPA providing resources for monitoring current-use pesticides in water bodies.

Okay. This part of the -- we worked really hard on this and to see if we could come to some consensus around drift and harm and adverse effects and what all that meant to different stakeholders. We did say that -- we did, you know, agree that all pesticides must meet the FIFRA standard for

registration and use, and we explored different ideas at what constitutes harm from spray drift and couldn't really agree on what we meant by harm. And I'm sorry for the small print here.

So this is -- you'll see in the report that different stakeholders sign on to different comments. And so one point of view that was represented by the public interest group workers, some of the state agencies is that EPA's real goals for regulating spray drift should include regulations and guidance that support the prevention of drift. And this takes a wide range of approaches and using non -- encouraging use of nonchemical pest control. There's no spray drift with those. Restricting the use of spray technologies and requiring substantial buffer zones where no spray -- no -- on-the-target site where there's no spray allowed so we have the target property absorbing the spray drift.

The other issue that EPA should focus on here is to resolve the ambiguities that applicators and enforcement staff now face in interpreting labels. And what happens is the no unreasonable

adverse effects is a very difficult statement for both applicators and enforcement staff to interpret and know what that means. And so it's hard to enforce. It's hard to know whether you're doing the right thing with that as a backdrop.

And so that's why we think that inserting FIFRA's no unreasonable adverse effect standard into the definition of harm actually undercuts the primacy of the states in doing enforcement. We also note that the FIFRA standard applies to registration primarily of the pesticides. So it's not clear whether it applies there.

Potential harm. We had differing views on this as well. And our concerns were that adverse effects may not be immediately obvious. You may -- there may be spray that just went to a school yard when the children are not there because the application might be done on a weekend, but the drift itself remains, but is invisible to the kids, and there's still the potential for adverse effects. And so we wanted to be sure -- we would like to encourage EPA to consider those cases and take into account

that many sites that are being drifted on are drifted on repeatedly in low level long term exposures to multiple different chemicals over -- you know, if you if you live right next to a field, over the lifetime of living in that house may cause harm down the road. So the other thing is that many states currently do consider potential harm from drift, and the worker protection statements that are now on the labels do consider potential harm for workers who may enter a field. Sorry. Wrong button.

Finally, in light of the real challenges in the field to do enforcement, the difficulties of, quote, proving drift, which many enforcement agencies require pretty strong proof before they'll take any enforcement action, the fact that pesticides act by a variety of different modes of action and there are a lot of different pesticides applied often simultaneously and there's a lot of scientific unknowns around long-term harm. We really don't believe that EPA should be in the business of endorsing any level of off-target pesticide particle movement as acceptable.

MR. SCHERTZ: Now we get the other view point on this last part. From the regulated community, I'll try to keep it simple and to the point as far as bringing the gist of our concerns on this.

First, we do strongly support, recognize that FIFRA is the relevant channel for pesticide regulation and use. We do a very disturbed at any notion of disrupting that, and we do believe that impedes the unreasonable adverse effect threshold.

Also, geodrift is unachievable, unrealistic. As an applicator for over 20 years, I've been able to run my business with very few concerns as far as complaints, but the reality is you can't get it to zero. And it really undercuts the validity of a label in the regulatory scheme if it doesn't have some basis in the real world. We want to be considerate, but it really does need to account for conscientious use and high achievable standard.

Another issue on this, though, is that there is a certain amount of drift taken into account on risk assessment for different products, and as a

somewhat knowledgeable applicator, there really does appear to be a double standard if you don't have access to what is actually used to reregister the product.

Also, another major issue, though, as technology advances, extremely small amounts of pesticide products can be found, and this allows questions on where parts patrolling actually came from. But then at some point, very small levels of pesticide products do not cause a harm or unreasonable adverse effect. This is shown by established tolerances and even finished commodity products, etc. So at some point there is a no effect level.

So, obviously, we did not have a full consensus on this, but we definitely spent a lot of time on addressing it and trying to understand the different view points around the table. Thank you.

MS. LINDSAY: Okay. Thank you, Susan and Scott. I think you've actually done a good job of going through the highlights of the report. And so this would be the part, as the last slide says, for

discussion by the full PPDC. As you think about how you want to engage, I think just a couple of thoughts: First of all, those of you who were not on the group itself may have questions of what I would call clarification, what did the group really mean by a particular recommendation or thought. And I think we probably got enough members of the group itself on the full committee or with Scott here as well that members of the group will be able to provide that clarification, if not, EPA will attempt to do so. And our goal is facilitator of the group.

Secondly, you may want to focus on the recommendations. They're quite a few recommendations within the report, and you may find some of the recommendations are, in your judgment, particularly valuable and you want to underscore their importance in your perspective. It is also quite possible that you see something that if you had been on the group, you would have raised as an issue or have proposed as a recommendation for the Agency. So you may actually want to add new material into the discussion. It won't be necessary to actually revise this report.

But if you have got additional thoughts that you just don't see captured here, this would definitely be the time to get them into the record so that the Agency will have sort of the most robust set of thoughts and considerations from the parent group as we can.

We'll do the classic, as some of you've already figured out, card routine. And I'll try to keep track of the rough order, although I'll confess I already don't know which one of you were first. So I'm just going to start, but all of you should be assured that I will try to get around to everybody. And with your help, if I'm missing somebody, I'm sure you'll point that out. And for Mat on the phone, if you have -- obviously, we won't be able to see you raise your card, but if you will just speak up when you feel that you want to contribute to the discussion, I think all the rest of us will try to remember that you are on the phone. And it's a little more difficult for you to actually intervene in the discussion when you have contributions to make.

So I'm actually, just because I don't know

who got up first, I'm going to start -- oh, over there. Bob Holm.

MR. HOLM: I want to comment from a perspective of supporting education as a part of the process. As a retired person, I have a lot more time to spend at home, and I've always done my yard work and I still do and I apply fertilizer and chemicals. But one thing I've noted, I live in a township. And in the last 20 years, it's gone from an agricultural area with 6,000 people and a lot of farms to 22,000 people and maybe a half dozen active farms. And the farming is done now by lawns and gardens and acre and two-acre lots and very few people -- I think I live in the subdivision of 50 people, and I think maybe three or four of us apply our own chemicals. The rest are done in yard services.

And it was kind of strange to me to see that a lot of the yard services now are using granular materials, which are fine. But instead of using a drop spreader near the curb -- between the sidewalk and curb, they're just using a spreader that spreads fertilizer and herbicides and insecticides

that tend to give a nice five-foot edging out into the street. Of course, you get a rain. It goes down the storm sewer. I live near Millstone River in the Delaware Raritan Canal that serves as a water source for a lot of people in central New Jersey. And it seems to me that these are custom applicators that should know better and an educational process through the state system on certification that would teach people to do -- these are professional people that are putting out a lot of materials to apply them more properly would certainly save a lot of runoff situations. So just a recommendation.

MS. LINDSAY: Thank you. Gary Libman.

MR. LIBMAN: Thank you. I've been a registrant for a lot of years, but mainly on the biological side, so most of our products have tolerance exemption, so this is kind of new to me from one aspect. So this is mainly for Suzanne and Scott. You talk about the consensus here of spray drift not including volatilization or wind blown soil particles. Is that really the consensus that that is not part of the spray drift?

MS. KEGLEY: That wasn't a consensus. EPA decided that. That was actually on the slide. EPA decided that we were not going to be dealing with that.

MR. LIBMAN: But is that typical -- typically not discussed in --

MS. KEGLEY: There was not consensus on that.

MR. LIBMAN: There was not a consensus. Okay.

MS. LINDSAY: Gary, if I could just add, I am in particular the EPA official who decided that some of those other issues were not part of the focus of this group. And the basis for that has to do just with the physics of spray drift and how it operates. The other issues that were not included are obviously actually very important with regard to environmental and human exposures that can occur as a result of pesticide application. But we were trying to look at -- I can't repeat the definition that the group came up with, but we were trying to look at the physical activity that occurs to the particles in the

initial application. And so the description that's in the group's report is actually a pretty good description of that particular physical occurrence.

Michael Fry.

DR. FRY: In this exercise the subcommittee had a great deal of difficulty coming to agreement on definitions of what spray drift was, and I think Gary Libman just, you know, brought up a couple of the issues, but also we had a very difficult time. In fact, we never did come to an agreement on what constitutes harm. Will EPA define these things for us at some point? And, if so, which I would really like to have done, so those kind of contention gets codified somehow, what would be the process for EPA coming to a definition for spray drift and a definition for harm?

MS. LINDSAY: If you don't mind, what I think I'd like to do is collect comments, observations, recommendations from around the table and then at the end of the discussion, EPA will spend a little bit of time about what we see as our next step. So I can hold that.

I'll go on down the line now. Julie Spagnoli.

MS. SPAGNOLI: I was not part of this work group and, you know, just looking over the report, but I guess I don't know if that was a last meeting that we had but we had a work group on consumer products and labeling for consumer products specifically and came up with recommendations for environmental hazard statements for consumer products. And I guess since the committee agreed to adopt those statements and that EPA has indicated that they're going to adopt those recommendations for those consumer labeling statements. Was that -- was consumer products looked at as a separate, I guess, topic in this discussion on spray drift because I wouldn't want to see us having inconsistencies that we've already adopted in a set of labeling statements and that it contradicts what this group is doing.

MS. LINDSAY: Just to answer that specific question. This group focused more on what I will call either agricultural application adult (inaudible) mosquito control. We were looking at two

particular chemicals as case studies permethrin and 2, 4-D. So, as I recollect, EPA didn't put in front of the group and there was not much discussion from the group as well around consumer labeling, per se, although I would say a lot of the labeling recommendations are very -- from this group are very broad and could easily apply in the consumer labeling arena as well.

Just on another note, I will tell you that EPA itself, because we knew about the previous groups efforts on consumer labeling and our working on a pesticide registration notice to implement some of those recommendations, we have actually taken the time to take a look at what we're doing there in that PR notice, vis-a-via, the kind of recommendations that were coming out of the spray drift work groups. So we're trying to be consistent across all of our PPDC work groups. Beth Carroll.

MS. CARROLL: (Inaudible.)

MS. LINDSAY: I'm just going to go around the table, so.

MS. CARROLL: I'm a little confused. At

one portion in the report on page 28 it says consensus at the bottom of the page, and then when you get over to recommendations, there's some -- there are a couple of things in there that I just have questions about if there was really consensus. Incident databases, including proper use and misuse incidents, as EPA should strengthen this collection and use. And while I don't have any problem with that, my experience with incident databases that have been used in risk assessments are often state-reported pieces of paper that you can't really tell whether it was an incident or not. And so if this was consensus, I would like to underline the next paragraph where you say "EPA should particularly emphasize the collection of data that are valid, robust, and publicly available." I mean, valid and robust in a lot of these cases is not true in the risk assessments that I've looked at.

And then down further in that third paragraph, the second -- first of all, model is another whole issue. But the second note says "indicates that the Agency's regulatory requirements

are insufficient to lead to changes in pesticide use that would result in preventing harm." Well, I thought we didn't have consensus on harm, so that's why I'm a little confused at why this says consensus.

PARTICIPANT: (Inaudible.)

MS. CARROLL: Page 29, third paragraph, Number 2.

MS. LINDSAY: Beth, just to remind you about the process, this particular language was developed by the group as a whole at one of its face-to-face meetings. I think it was actually the last face-to-face meeting the group. Everybody looked at it and had the ability to what I would call, live with the statements that you see reflected here. You are correct that the group ultimately, as Susan and Scott reported, didn't agree about the meaning of harm, but the group did actually agree to the wording that's in here. A number of your comments about robustness of data were actually discussed by the group, and I think you're actually capturing some of the discussion that was there.

I'm going to move on to the other people

around the table, and we can come back if other people want to pick up points. Carol Ramsay.

MS. RAMSAY: Carol Ramsay, Washington State University. Point of clarification for the individual that's doing granular application to some of these lawns, there's a possibility, depending on which state you're in, that that individual does not require certification because it may not be a restricted use -- my guess is that it would not be a restricted-use pesticide. So that might lead to some discussion this afternoon. But that may be the case.

Regarding -- education was brought up several times which is, of course, near and dear to my heart, and so I guess I would challenge the work group in their work when they leave here that they look at what sort of investment they'd like to make in coming up with educational materials, educational outreach programs that deal with probably more of the design standards because I think discussing design standards so people can figure out how those design standards fit best within their operation is an educational component. I think the report is very

good in showing that when you start dictating on a label design standards all of a sudden you have planes that now fly faster and because they fly faster than the planes did, you know, 20 years ago or some of the CESNAs, it doesn't work anymore. Pressure's changed, flight speed's changed, and so having designed standards on labels can become restrictive. So I think the report captures that. So I think design standards and educational components, performance standards is something you might want to look at for label.

MS. LINDSAY: Okay. I should clarify that this particular work group, the spray drift work group, has completed their mission. So they're not as a group going to be continuing work after the session. But the comments you just made will go into the record that comes out of the work as a work group.

MS. RAMSAY: Okay. Then I challenge EPA and industry to look at those investments.

MS. LINDSAY: Okay. Dennis Howard.

MR. HOWARD: Dennis Howard, State of

Florida. I just wanted to start by reflecting the state's appreciation for the work group's efforts, just kind of a dialogue, especially featuring two offices of EPA. It's very much appreciated. And while the groups didn't come to consensus, they did, in our view, meet and make a lot of observations that needed to be made and brought to the Agency's attention.

One of the questions in the report that I have -- maybe it's in there and I missed it -- it's a consideration of what happens in the absence of decision-making on labels. And I'm speaking from the perspective of somebody whose staff looks at pesticide labels on a relatively frequent basis. And in a number of products, the labels come in without drift mitigation statements on them because they're awaiting a process that may be a registration review now or reregistration then. And then in the absence of decision making, there's -- there are -- there are -- there's an absence of mitigation statements on labels sometimes. So there's a cost to send the states and being able to appreciate where the Agency

might be heading.

So we definitely encourage the Agency to move forward with the information that comes from the report and use it in the process that will help to provide some standardization in the labels in the future. And we really appreciate the understanding of the work group that enforceability is really an important part of the process. It's -- without enforceable language, we can't really do a good job of protecting the environment or human health. So the emphasis that the work group put on the need for enforceable language and clear and concise language is much appreciated.

MS. LINDSAY: Thank you. Shelley Davis.

MS. DAVIS: It's timely that I come right next because I want to pick up the point on enforceability, also. To my mind, enforceable standard is absolutely essential because drift incident have caused a significant number of agriculture worker reported incidents. And so we know that these incidents are causing harm.

I want to pick up what I see as a

misunderstanding of at least of what was reported this morning, and I'm sorry I haven't read the report, so I don't know if this is exactly accurately reflected in the report, but I think it's a really critical point about what the FIFRA standard means, and that is the FIFRA standard is not unreasonable adverse effect. It is not an actual harm standard. The FIFRA language is unreasonable risk of adverse effect. It is about the potential for harm. And so, for example, Susan's mentioning of the example of a school yard, drift onto a school yard, depending on the toxicity and the amount could certainly pose a risk of unreasonable adverse effects whether the kids were actually there at that moment or not. And so from my perspective, it's very important that EPA develops consistent label language which focuses on the risk of unreasonable adverse effects and that they issue guidance to the state so there is consistency about enforcement and that, you know, without -- from my perspective, without enforceable label language, we're really missing the boat here on a very important topic. Okay.

Two other quick points just that I don't know, and this is not my (inaudible) workers, but if there are incident databases that collect incident data on, for example, contamination of water or effects on fish and terrestrial animals as well as threaten endangered species and their habitat, all of these kinds of data are really critical in terms of drift. So if this is not being collected, this would be a very nice opportunity to start collecting it or encourage states to start collecting it because I think that as the committee said, you know, the proof is in the pudding. You know, are we having drift and are we having, you know, risk of adverse effects and what's going on out there in the world. So collecting this data is very essential.

And then as a member of the PPDC, I really urge EPA to report back to us, what is it finding. We both in the -- you know, in different ways, they're collecting information in terms of, you know, what are the applicator's understanding about what they are up to, do they know enough about how to prevent drift, and what are the incidents showing

about how much drift is actually occurring. Thanks.

MS. LINDSAY: Okay. Thank you, Shelley. Steve Balling.

MS. BALLING: Thanks, Anne. Well, Del Monte Foods is on the wrong end of drift any number of times. It's unfortunate we had problems with herbicides that drifted into crops and we lose the crop. We've had problems with inadvertent residues -- speaking of drift, here's somebody drifting in right now.

PARTICIPANT: There's nothing inadvertent, about it, though.

MS. BALLING: Planned. Drift can create significant issues for us with residues that we don't even know are on the crop and might appear later when someone else is testing. This is a significant concern. At the same time, we rely completely on aerial application. We run about a hundred thousand acres of vegetables in the Midwest, Washington, and Texas, and virtually all applications are made with aerial application because we are running an IPM Program. And if you have -- if you're covering a

couple thousand acres at any one time monitoring that -- those, looking for pest problems, when you see them, you have to respond immediately. There is no time to take four or five days to get out and put down ground applications.

And so if you've got the list of pros and cons going, I hope you'll include on the pros list that aerial application and, unfortunately, attended drift is pretty critical to Integrated Pest Management Programs. We really don't want to have to go back to scheduled sprays with ground application because that's what would have to happen. Thanks.

MS. LINDSAY: Okay. Thank you, Steve. Jen Sass. I think you're next.

MS. SASS: Well, I was on this work group, and so I was actually really looking forward to what the PPDC would say about this report, and I'm, you know, excited and interested to hear what the group has to say.

I wanted to support what Beth Carroll said about the need for having robust data and doing some as much as possible. And I understand and Beth

understands, I'm sure, the limitations to the data, but I do have confidence that EPA's going through that process, but I do also want to support you in saying how important that is to make sure that we use the best available data, as much data as we have, and also that it's publicly available.

And I also want to support absolutely everything that Shelley said. And I would also encourage other people around the table who do support that to point that out, too, so that it doesn't come in as one person's comment because I think that Shelley really grabbed the essence of what we were trying to accomplish with this report, which is whatever we, you know, disagree on the definitions, I think we all agree that we want to prevent harm. And I think we agree that that harm is economic harm. It's human harm. It's ecological harm. So I want to, you know, support Shelley's stressing the EPA, with our help and even with our ambiguities, need to come up with something that's clear and that's enforceable and that prevents harm.

MS. LINDSAY: Thank you, Jennifer. Carolyn

Brickey.

MS. BRICKEY: Well, I learned a bit -- an awful lot in putting this report together, and I do want to commend reading it carefully to those of you who haven't already who didn't serve on the work group. There's a lot of useful information in here, so I want to commend that to you.

There were a number of difficult issues associated with the compiling of the report, no less than that a discussion about volatilization and what happens as a result of an application of pesticide and whether we can call that drift or not if it happens the next day or the next week or whatever. I'm not entirely satisfied with where we came out on that, but I do recognize that the issues that we did tackle were incredibly complex and difficult. So I'm not advocating that we should have added, you know, 50 percent more difficulty on to what we did.

I also would say that the issue -- there were two issues that really stood out for me in terms of what this report meant and what the problems are. And the first one would be that there's a tremendous

level of discretion in this whole process. And it occurs with the applicator who is putting pesticide on the crop and it occurs for the enforcement agent who's trying to figure out whether or not a violation has occurred and what the effects might be of that violation, if it did occur. This is a non-point source problem, as most of you recognize. It's not very well suited to the notion of we're going to monitor people when they're out there in the fields because we're not. We're not there. We don't know what happens. And although I think Scott has -- Scott Schertz, who was a featured member of our work group is a stellar aerial applicator. I'm sure there's some people out there who are not, and we don't know who they are or what they're doing.

So the second conclusion I came to was maybe one of -- maybe the most important thing we can do is make sure that the very best equipment is out there is being used by the applicators. I don't think the report stresses enough how important that is. I don't think we should leave it to the market place. And because it's a non-point problem that we

don't witness, I don't think it's such a good idea to limit it to performance. I think maybe we should say certain equipment needs to be out there and being used if we think it would help to detour any risk that might occur from drift. And I really want to emphasize that point because I think it's really important. And I hope EPA will continue to focus on that issue.

MS. LINDSAY: Okay. Caroline Cox.

MS. COX: I wanted to strongly urge EPA to use this report as a basis for taking strong action about this issue. I think it's a really important issue. And, obviously, this work group has put a lot of time and effort into discussing, you know, some of the complexities of this issue so EPA has a perfect opportunity now to actually take some action. I don't want you guys to miss that opportunity.

I think at almost every PPDC meeting that I've been at, in one context or another, the issue of label, ambiguity, and inconsistency and unenforceability has come up. And, you know, we've been writing pesticide labels for a long time. And

it seems like, you know, we ought to be able to do it right. And if we haven't done it right yet, then EPA really needs to take this opportunity to get it right and get a label that, you know, is clear and enforceable so that pesticide applicators and pesticide enforcement agencies can do their jobs.

I'm also concerned about the recommendation about education because I've heard multiple times at PPDC meetings that it's fine to talk about education, but there's no resources put to it. So the education doesn't happen. So let's learn from that, and this time, let's actually put our money where our mouth is or whatever and, you know, get some good educational materials and get the resources to get that information out to the people who need it.

I wanted to just tell a little personal story, about thirty years ago, when I was a first-time home buyer, I planted my first garden, and I was very proud of this garden. And shortly after I planted my peas, a spray truck drove down the alley spraying black berries. It was a city truck. I assume it was a licensed applicator, although I don't

know. And several days later, like all of the new leaves on my pea plants twisted and distorted. And, you know, it's a small thing. I didn't get sick. Nobody died or anything. But it's -- I was really upset. This was my first garden, remember in my first home. And I called the Department of Agriculture and made them come down and look at my peas, and they kind of walked up and down and looked and didn't do anything, and I became a pesticide activist.

(Laughter.)

MS. COX: So I just wanted to tell that story just to illustrate that. This is a really important issue, and it impacts people in many different arenas on many different levels, you know, all the way from my pea plants up to, you know, frogs that are dying and people who are getting sick and so on. And EPA really needs to put the resources and time into -- but let's get this problem solved this time. Let's not just keep talking about it.

MS. LINDSAY: Susan. Susan Kegley for you, ma'am.

MS. KEGLEY: Okay. Thanks. Just to follow up on a couple of things on what Caroline said. I think one of the main things that maybe didn't come out exactly but consistency of label, and this was mentioned, I think, by someone down at the end of the table. But, basically, having the label say the same thing for each, you know, product would be a very good thing to shoot for.

And then another point that I'd like to bring up just in the context of a non-consensus part of the report is that there was a lot of discussion about moving and some of us suggested that having more toxicity information on the label would help applicators make more informed decisions about what they're applying and the globally harmonized system of classification and labeling that's being used internationally would be a good start in that direction. And you'll find that in the other comments as a recommendation to EPA to include some of the other toxicity so an applicator can decide, you know, do you want to apply this biopesticide that has none of the bad symbols on it or do you want to

apply really the highly toxic organophosphate pesticide. And then we think that we'd have different outcomes if the applicators had some choice there or information.

And then just to address the issue of the word "harm" that ended up in the report, just -- we do have a kind of a common understanding of the word, and Webster's dictionary does have a definition of harm. I think what we're looking for is a legal definition of harm. And I guess I would hope that at the end of this process that EPA will have something like that.

MS. LINDSAY: Okay. Let's see. Lori Berger.

MS. BERGER: Well, I was a part of the work group, and it was a very interesting process, and a lot of people put in a lot of time. I think we met over six times. We had many conference calls, and there were a lot of excellent points raised, and there were a lot of disagreements raised as well. And I would encourage the Agency, as Susan said, to evaluate harm in context to FIFRA and other resources

that from the ag side, we really believe that this adequately addresses harm.

Kind of bleeding over into another work group I sat in on yesterday, and we've been working on that one as well, is the worker protection standard. And then there's a lot of overlap as far as need for training and communication. And you can have the best labels in the world, and we need improved labels for sure. But we do need training and there is also personal responsibility in communication, that if you don't have that communication at some level, there will be harm and there will be problems in the field.

So the concept of education and stewardship really goes across a lot of these topics, and we really support those activities and we really do need to seek funding in appropriate places to support those needs.

As far as labels are concerned, as a person that's worked in the field, clear labels are really important. This is one area I think that there was pretty good agreement on work group is that this --

we could really make some great improvements just on labeling, and that help on the enforcement side and it would also help on the user side as far as clarity. And we are at a time where we have the availability of improved technologies that we could certainly take these things to the next level and improve these or expand the training communication and so forth that's needed to ensure harm in a field.

So those were my points, and it was a very good experience to be part of the work group.

MS. LINDSAY: Thank you. Lori -- Larry Elworth. We think you're Larry, not Lori.

MR. ELWORTH: Thank you. I apologize for being late. I would refer all comments to the good folks at U.S. Airways.

I agree with Caroline about the range of discussion that took place, and there were a lot of important and difficult issues that were raised. I think the work we did on labeling was some of the most useful -- having dealt with pesticide labels for 20 something years, a lot of the issues that we raised were things that I never encountered both in

training employees and also as a grower and also looking at labels when I was at USDA. So I think that there was some real progress made in that.

On the issue some of the particular things that we didn't come to consensus on, I was actually quite comfortable not coming to consensus on it, I remember about a dozen years ago when Dan Barello (phonetic) first came to me and talked to me and a bunch of other people I'm sure about establishing this committee, Dan's real interest in establishing this committee was being able to have this wide arrange of candid opinions brought to the table to discuss important issues that the Agency had to deliberate on. And I think in that context, with that idea in mind, I think we did a really good job. I would observe that when we push to consensus, we come more rapidly with people's stunt speeches than we do otherwise. And so I think if we want to -- if the Agency or if the group early on decides here's some issues we want to try to get consensus on, I think that's worth doing. But I think weighing out the issues around some of these more complicated

topics is certainly a valuable exercise for this committee to do irrespective of (inaudible) consensus.

I'd also like to caution all of us in the PPDC that it's one thing -- we represent lots of people here, lots of points of view. But in order for the Agency to make regulatory decisions, there are a whole lot of people out there that aren't involved in this committee that will still have to be involved in discussion. So to the extent that we can (inaudible) the discussion and encourage further comment, I think we're doing our job.

MS. LINDSAY: Thank you. Frank Gasparini.

MR. GASPARINI: Thank you. I was part of the work group as well, and it was a good process. It was long, but it was a good process. And I will kind of shorten my initial comment on the fact that as an industry person, we do believe that pesticides can be and are used regularly safely. I'll go to my (inaudible) speeches, as Larry kind of commented. I also -- we believe that both EPA and the states would differ and the appropriate state statutes have very

good tools and are doing a very good job. I know some states have some budget challenges and are trying to refine their regulations -- their laws and regulations, and we worked with some of you on that. We have confidence in the EPA and the FIFRA process.

I do want to comment briefly on the idea of prescriptive measures, having worked on a number of other work groups with EPA and the state. And I always want to caution against real strict prescriptive measures to get to a point. The reason being, that when you use real strict prescriptive measures, you end up stifling innovation. We don't want better 1960s or '70s technology continuing improving '70s or '80s technology. We want grand new ideas as well. And if we're too strict with prescriptive measures, we can -- we can cut off the ability to do those. And we've had some of those discussions (inaudible) EPA in the past. That's all.

MS. LINDSAY: Thank you. Jay Vroom.

MR. VROOM: Two points. One is that spray drift management is a journey, not a destination and the work of this work group obviously has been very

thoughtful and exhaustive and without conclusion in some areas, which I think we all recognize as fine, but it's only part of this journey. The journey has been going on for decades. The decade of the '90s, I think, we haven't perhaps spent a lot of time reviewing and being reminded of in this discussion particularly this morning, but tremendous progress was made both from technology innovation along the lines that Frank just described and applicators like Scott commercially with aerial equipment, ground applicators, farmers, and everyone else who use pesticides have largely adopted the innovations driven by the investment of more than $30 million by registrants and the Spray Drift Task Force, advancing innovation, working with EPA and USDA and others in the public sector. So we've made so much progress that the glass is way more than half full. And I think that's an important reference point to ground all of these conversations. And the registrants that we represent, CropLife, certainly believe that a lot has been advanced still with the work of this particular work group.

The second point I'd like to make is that we believe, and I personally was involved in the negotiation of the exact language with regard to the risk standard and FQPA, which is reasonable certainty of no harm. I believe in my heart -- and based on the advice of counsel, both our own in the industry, as well as that from Capitol Hill, that was involved in negotiating that standard and those in administration, including Mr. Elworth, who sat at more tables than I did in those negotiations that that is a risk standard just as reasonable certainty of no harm is a statutory risk standard in FIFRA. And plenty people have the opportunity to have reasonable disagreement about that. If you want to argue about that, this is not the place. Capitol Hill is the place, and laws have to be changed in order to change that sort of a statutory risk standard.

MS. LINDSAY: Thank you. I'm going to pick up all the people who have not made initial comments, and then, Carol, I'll come back to you. So Amy Liebman.

MS. LIEBMAN: Thanks. I just want to state that the farm worker advocates have been really focussing on the worker protection standard, and that's where we put a lot of our effort in. So, unfortunately, we will not be able to be on the drift committee. And so thank you for the hard work of the committee. But I did want to just reiterate what Farm Worker Justice said and what Jennifer Sass said that, you know, this is an issue still for farm workers and folks working in the field. And we really support the need for the clarify in the labeling and the retraining and education part, because this is still a huge issue in where a lot of the incidents with farm workers are happening.

MS. LINDSAY: Thank you. Cannon Michael.

MR. MICHAEL : Thanks. I just wanted to just quickly from a grower's perspective and somebody who pays to use our job to apply chemicals and pays applicators. There's an inherent level of care that we use, and there's also from -- in the agricultural business where the profit margins aren't always very large and where we have to be very careful constantly

to refine and improve our methods of doing business in order to stay alive, we have a lot of incentive to apply less chemicals and also apply them directly where they need to go. And I just wanted to say we're constantly working to do that, and I think that there's this inherent level of care that applicators that we have and agriculturalist that we are, we're trying consistently to always do a better job, just as you wouldn't pay a guy who you paid to paint your house if he goes and paints somebody else's house, he's not going to be in business for very long. And it's the same type of thing. We're not going to pay some guy who drifts all the time. And, you know, that's just -- I just wanted to just bring that up.

I know that a lot of the stakeholders here don't necessarily have that grower's perspective all the time. And from our -- from our perspective, I don't know anybody in farming who does not feel the same way that I do, and I'm on a lot of boards in California, and I know a lot of the people who are involved with the industry. And I know that accidents do happen, but, I mean, there's no way that

we don't want to protect our workers, we don't want to protect the environment or in, protect the people around us who work for us. I mean, these are all valuable resources. So I applaud the work group for going and tackling this issue. But I just -- from our -- from my perspective as a grower, I'm letting you know that there are some definite standards that we hold ourselves to and the people that work for us.

MS. LINDSAY: Thank you. Nancy Golden.

MS. GOLDEN: I just wanted to comment that when you're talking about harm to wildlife, that just remind everyone that most of our wildlife statutes actually have a different standard than (inaudible) wildlife. Not only talking about the Endangered Species Act, but often the Migratory Bird Treaty Act and the Bald and Golden Eagle Protection Act.

There's no cost benefit analysis on any of those Acts. And we talked more about adverse effects as opposed to unreasonable adverse effects. So any time there's (inaudible) under any of those statutes, it's going to spark investigation and possibly enforcement regardless of the outcome of what we

decide upon for drift. So I just encourage the Agency in coming up with a definition of harm to just keep in mind those statutes and try to make sure the definition is consistent with those laws as well.

MS. LINDSAY: Carol Ramsay.

MS. RAMSAY: Be a short little advertisement here. I want to really commend the work group on the package that they put together because one of the ways that I envision that I'll be using it is that I serve as the president of the Pesticide Stewardship Alliance, and we will be holding a session a day to two days on drift mitigation at our Asheville, North Carolina meeting. And so we can take many of the items that you have here and set them as actually goals for that conference, maybe building the checklist or trying to develop some of those things. And so this is going to be a very valuable resource for that particular enterprise.

MS. LINDSAY: Okay. Thank you very much, and I'm glad to see that you are already starting to use it, which is, I think, what all of us actually

want.

At this point, it looks to me that the PPDC has sort of had their say on the report. And I'd like to do just a --

PARTICIPANT: Did you want to invite -- I don't know if Matt's on the phone.

MS. LINDSAY: Oh, sorry. Matt, are you there?

MR. KEIFER: Yes, I am. I guess I'd add from a public health perspective the importance of drift as a cause of illness and how important it is for us to focus on preventing these kinds of incidents. I'm sitting -- I have the advantage of sitting in front of the Web at this point, and I'm just reading a report, Morbidity and Mortality Weekly Report about (inaudible) drift in California and --

MS. LINDSAY: Matt, could you speak up just a little bit?

MR. KEIFER: Is that better? You there? Hello?

MS. LINDSAY: We're here. Go ahead.

MR. KEIFER: Can you hear me?

MS. LINDSAY: Yes, we can hear you now.

MR. KEIFER: Okay. I was just -- I just want to point out that about probably 30 to 40 percent of the cases that I see in clinic and of the cases that I read and study about are drift-related in one way or another. So I think this is really a very, very important issue. We clearly don't have a handle on it. I appreciate the work that the work group did. It's a tough topic, but a very important one. And that's all I'll say.

MS. LINDSAY: Okay. Thank you. And it looks like Carolyn is your card up again? And I'm going to say that, at this point, we probably after Carolyn makes her last set of remarks close off the discussion of the group and finish off this session.

MS. BRICKEY: I just realize that no one had addressed the recommendation about setting water quality criteria and putting resources into monitoring water bodies for current-use pesticides. And I just wanted to voice my strong support for that recommendation and how important those steps are and just make sure that they didn't get forgotten in this

discussion.

MS. WEEDERMAN: And this is Allison. Since we have like two minutes before the session ends, could I make a brief statement of appreciation?

MS. LINDSAY: Yes, I have a few things I want to say to close off, but if you want to go ahead.

MS. WEEDERMAN: Okay. Thank you. In addition to the hard work that the spray drift work group conducted, I also want to echo Anne's comments on thanking the folks that worked behind the scene in Office of Water and Office of Pesticide to make this -- make the work group happen, to perform the logistics behind the scene. In particular, I'd like to thank Pat Janino because she was the one that conducted a lot of the logistics to make the meeting happen smoothly, to plan the social events that were key to relationship building, which I think is essential in an effort like this, and also to work with Jenny in bringing snacks to the group which wasn't paid for by EPA.

So we'd like to present her with something,

and I'll get it in just a moment. It's a bottle that spray --

(Laughter.)

MS. WEEDERMAN: -- and --

MS. LINDSAY: It causes drift.

MS. WEEDERMAN: Right. It's to represent the idea of drift, but it also has a decal of a dead bug which, of course, only happens with the proper application of pesticide. And we're also giving one to Jenny Garelic and Jeremy Arling. And what this means to us is that it is a rather whimsical memorial of the work that the group did, but it's also a physical commitment or physical reminder as it will be on their desk, hopefully, of our commitment to continue to work together between the two offices in addressing the recommendations of the work group. So thank you.

(Applause.)

MS. LINDSAY: Okay. To close off this session, first of all, I'd like to thank the full committee. I think that you've actually given us a good set of additional comments. In many ways,

they're very similar to what we heard from the spray drift work group over the last year. But I will also say that I think each and every one of your individual comments added something new to that discussion that will be valuable to the Agency.

In terms of at least what I heard, my initial reactions are this: First, I actually hear pretty much everybody saying that they are expecting EPA to act on this report, that this is not a report that should go into one of our many shelves. We don't let you look see those shelves where all the ancient reports lie. And I think I can give you a commitment that the Agency will actually act on the report. As an example, the work group actually spent some time looking at permethrin labeling because permethrin was the case study, and it was also a chemical that we were in progress of changing labeling. And so we have taken the recommendations from that work group and tried to use that, to incorporate in the permethrin RED and the labeling activity that will be ensuing. And so those of you who are actually on the work group, you'll be able to

see very shortly within the next couple of days where that labeling is.

But we've tried to take in mind the need, for instance, to be clear as to whether it's advisory or enforceable. We tried to be shorter and more focussed, more clear. I'm sure that, you know, there will always be opportunity for improvement. One of my take-away messages from this activity is that addressing spray drift is not a once-and-done activity. It is actually, I think, a continuous effort. There are specific things that we will need to be doing both in the shorter and the longer term, but we're going to have to also be able to go back and monitor the impact of that activity and adjust where it's appropriate where we discover that, in fact, we're not achieving quite what we expect to achieve.

I heard everybody this morning talking about labeling consistency, clarity, enforceability, and it sounded almost like consensus from the full parent group on that point, the value of that, the need for that, the importance of appropriate

education and training. And we've gotten -- a number of you mentioned a number of activities underway outside of this spray drift work group to try to deal with education and training. And I think we at the Agency will work hard to actually make sure that the information, the advice, and recommendations in the spray drift work group are actually piled back into those education and training activities. But I'm also heartened to hear Carol Ramsay's commitment to start using the report as well in venues where she can be effective. And I'd actually like to invite each of you as you go about your sort of daily business in the pesticide world, if you see opportunities to use the report, to advance some of the recommendations that are in that report, I would encourage you to be doing that as well because it's going to take more than simply EPA's efforts to work improvements in this arena.

Application technology. As I think you all know, we have started down that road with the Drift Protection Technology Project, but I think this work group report gives us a platform to consider our

activities there and how we want to conduct them for the future. The arena that is actually a bit new for EPA and the pesticide program, but I would agree with everyone that it offers a great deal of promise.

And then I've heard everybody say that it would be important for EPA to try to be more clear with regard to what are our goals in terms of preventing harm related to spray drift and how can we provide appropriate guidance, whether you're the actual user of the pesticides or the state official or you're someone who might, in fact, be exposed, however, inadvertently to spray drift as a result of an application.

We at EPA are going to take this report and the comments that you made today and over, I would say, the next period of time between this meeting and the next PPDC meeting focus on the report. You've got -- there's a lot of material in the report, a lot of areas of opportunity and decide, I hope, what are the most -- what we consider to be the most promising areas and to come back with you with our plans for actual implementation of some of the items that are

in the report.

I hope that we will -- the report actually has so much material that I think if we were to try to do everything in there all at once, what we would probably be telling ourselves is that we're not going to get anything done. So I think one of the challenges for us is to identify where we can most rapidly put into effect some of the advice that is actually in the report and start making a difference in the real world rather than trying to do everything all at once and perhaps by doing that taking a very, very long time to do that.

So my first commitment is actually to come back to you at what I think will be the fall meeting of the PPDC with a more specific work plan as to how we'll implement it. And I need to pause here and see if either Jim Hanlon or Jim Gulliford or Debbie wants to add to that?

MR. GULLIFORD: The only word that I would have added also been productive outcomes as well as moving forward. And I absolutely agree, that was a -- as we talked in staff, as we looked at this

draft -- this report -- excuse me -- not draft report, but this report, in anticipation of today was to make, again, that commitment, to get back to you at your next meeting with -- with a path forward.

MS. EDWARDS: Let me just add that it's been clear throughout the entire discussion this morning that I think everyone actually has the same goal here and that is to continue to develop technology and so forth to make drift as close to zero as possible, if not zero, and, you know, to prevent harm, whatever form that takes. And so I think we can reach some really good solutions. And one of the -- I was actually talking to someone the other day about some of my priorities in the early part of this job, and naturally I mentioned the ones you all are aware of -- endangered species, Endocrine Disruption, so on and so forth. But actually spray drift was up there in the top five. I really think this has been going on for a very long time. And sometimes trying to achieve the perfect committee, enemy of the good, if you will, I think we need to get some, you know, guidance out in the next year or

so, at minimum for our own staff to try to achieve consistency in how we're handling these labels, both in the reevaluation program and the registration program and try to meet as many of the concerns that are voiced here as we possibly can in doing so. So you could expect that I hope. Thank you very much.

The -- it's time for the break. Actually, though, before we do the break, we should get -- I think we're going to aim for 10 minutes. I hate to do that, but we're behind. So that will be about five after eleven, you think. And then maybe we'll get sat down closely after that. But before we do that, I actually think this work group worked very hard. Everything I understand about it, it was people spent a lot of time, a lot of frustration, and -- but I think the outcome is excellent, a very good report. And so I think we ought to give the work group a hand in -- for achieving this. Thank you.

(Whereupon, a break was taken.)

MS. EDWARDS: All right. I think we should

probably get started. It's about ten after 11:00 with the next session, which is our program update session. And as usual, like I said before, we'll take you through what we been doing with registration and our plans there as well as reregistration and Old Chemicals, in general, and move on to the NAFTA labels. So we'll start with Mr. Frank Sanders, Director of Antimicrobials Division.

MR. SANDERS: Good morning. Pleased to be here. I'm going to give you an overview of what's going on in the registering divisions, which are Registration Division, BPPD, and AD. First, in FY-07, we have thus far registered five new active ingredients. These are five conventional new active ingredients that were done by RD. BBD registered seven biopesticides. And my favorite division, which is Antimicrobial Division registered three new active ingredients.

With respect to new uses, we approved 75 new uses. It's associated with 243 crops of 27 previously registered conventional active ingredients. We completed one reduced risk new use

and one OP alternative new use. We approved six new uses of previously registered antimicrobial active ingredients.

With respect to Section 18, there were 202 requests received; approved 130, and withdrawn 10. These were requests withdrawals. Requests that were denied were only two, and crises declared were nine. The average turnaround time for these actions were 28 days.

With respect to fast track/non-fast track decisions (PRIA and non-PRIA actions) with respect to fast track amendments (non-PRIA), there were 678. You see down right below that in parenthesis the number that were done by each registering division RD, 546; AD, 386, and BPPD, 46.

Non-fast Track Amendments is a total of 234. Again, it was broken out by divisions: RD, 141; AD, 81; and BPPD, 12. And fast track new products, we had a total of 245 so far. And again, it was broken out by divisions: RD, 186; AD, 54; and BPPD, 5. And Non-fast Track new products there were 318. RD did 235, AD, 61, and BPPD 22.

Moving on to the next slide with respect to Inert Ingredients Status Update, Status of Exemption Petitions, five were completed in FY-07, and all of these are FY-07, so I won't say that. Nine petitions received, 10 petitions pending at EPA. Six petitions were withdrawn, and five petitions in OGC review.

Okay. PRIA Program Performance. Since the start of PRIA, which was May 2nd, '07 of this year is what we are talking, 5081 total PRIA submissions, 3811 were completed. That's basically 99 percent have been completed by PRIA goal as our targets, and 29 "not grant" decisions were done. 518 actions were negotiated due dates -- 518 actions with negotiated due dates. That's 10 percent of total submissions were negotiated.

The following slide deal with the PRIA Program Performance continuance, "not grant" decisions, AD was, although it says one, we did two. BPPD 16 out of a total of 448. RD completed 12 "not grant" decisions out of a total of 3757.

With respect to actions with negotiated due dates, AD, 181 out of a total 876 actions; and BPPD,

136 out of 448; and RD is 201 out of a total of 3757.

Pending PRIA Actions. New active ingredients that are actually pending with the Agency, 22 conventional new active ingredients, 20 a.i.'s requesting domestic registration, and one a.i. requesting import tolerance only. Nineteen biopesticide new active ingredients are pending and eight antimicrobial new active ingredients are pending. PRIA goal expected to be met in all cases. Most new active ingredients scheduled for completion prior to PRIA goal. And that is the update as it relates to our registering division program update.

MS. EDWARDS: We probably have time for two or three questions, if there are any. Gary?

MR. LIBMAN: Thank you, Frank. This is the same question I had last time, too, and I guess I wasn't totally satisfied with the answer last year on this. But on the renegotiated, this 10 percent, I don't know if you have that broken down by the individual divisions, but I would be kind of curious to know what those would be and also what do they tend to be, Frank? Do you know, what the --

MR. SANDERS: Primarily, the negotiation fall within a category of product chemistry and acute toxicity. Those are the areas where they are most troublesome. And I don't have it broken down by division, I don't think I do. It's broken down by division? We can always find it and get that figure for you.

PARTICIPANT: We do have that data and we'd be happy to forward it to you, Gary. And we have it broken down normally by division, but also by the reason behind the negotiation.

MR. LIBMAN: The reason I think would be the most helpful, but also by the division is kind of interesting because, you know, the divisions have these broad segments of activities you can almost categorize things by that as well.

PARTICIPANT: We've done some pretty deep analysis of the causes and organizational units where they negotiated due dates are most likely to occur and I believe we've provided it to the PRIA Coalition, and we will be happy to provide it to you. The materials already there.

MR. LIBMAN: Great. Thank you.

MS. EDWARDS: Michael.

DR. FRY: Thanks very much, Frank, for your update on this. But I have a more general kind of question for registration. With reregistration or registration review, the docket is very complete. All of the E-fed environmental statement affects information is in the docket, comments from the public, comments from registrants are there.

When a product is registered, is there a docket opened at all and would it be possible to have the comments of E-fed put into a docket and the rational for the decision by registration division written down and included in a docket so that when advice is not taken from E-fed on a product, for instance, that that, you know, that there is rational given rather than just a registration or a denial?

MS. EDWARDS: I know that Lois has been having some conversations about this, and Don is here today, so he probably knows the status of that. But I think the answer is that we are considering doing some of that.

MR. STUBBS: Yes. As you know right now, currently at the (inaudible) uses the tolerance of dockets, the docket will have the reviews in it from HED and, of course, the (inaudible) number from EPA would also be in the data. The non-food use there is not a docket. The best we do right now is a notice of receiving an inactive ingredient. But we have been working towards putting all reviews in the docket and just haven't -- we're not there yet, but we'll get there.

MS. EDWARDS: Okay. Let's move to the reregistration program update with Pete Caulkins from Special Review and Registration Division, currently the acting director.

MR. CAULKINS: Thanks, Debbie. Good morning. I would like to provide a few comments on the update of our reregistration and tolerance reassessment program involving Special Review and Reregistration Division and Antimicrobial Division and Biopesticide Division. We have been working on these programs more than the last decade to ensure that the older chemicals that the databases

supporting them are -- meet current standards, that the risk assessments are state of the art and that any mitigation that's required to ensure that the pesticides used meet today's safety standards and at the same time trying to preserve the important beneficial uses of these pesticides.

FQPA required not only a new safety standard, "reasonable certainty of no harm," but gave us a ten-year deadline to complete all the tolerance reassessments. That deadline ended on August 3rd, 2006, at which time we have completed not over 99 percent of the tolerance reassessments. We still have 84 tolerance reassessments to complete associated with the N-methyl carbamates.

And moving on, FIFRA and reregistration has required that we ensure that no unreasonable adverse effects result from the use of pesticides as currently labeled, and we are on track right now to meet the PRIA deadline to complete the non-food uses by October of 2008, more of that in a few minutes.

The current status right now is we have completed 92 percent of the reregistration cases; 55

of those were completed by completion of the REDs; 37 percent were completed through voluntary cancellations. We have 49 REDs to complete, seven food uses and 42 non-food use REDs.

What our work plan requires us to complete this physical year, we had to complete the remaining -- the tolerance assessments for the remaining 84 tolerances and to complete those seven food use REDs. When the N-methyl carbamate cumulative is completed, they will be changed from I IREDs to REDs. We have to complete half of the remaining non-food use REDs, including the soil fumigants. We have to continue implementing the decision to mitigation requiring the REDs. We are taking steps now to close out some of the special reviews, and we are not only wrapping up -- going full speed on registration review program. More on that in just a few minutes.

The 84 tolerances are associated with five pesticides. There are 23 tolerances that have to be reassessed for Aldicarb, 11 for Carbaryl, 39 for Carbofuran, four for Formetanate, and seven for

Oxamyl. Aldicarb is the only one of those five in which we have not issued an IRED, and we intend to complete that by the end of this physical year, as well as the cumulative for the N-methyl carbamates.

We also have -- outside of these five, we also have Ethylene oxide, for which we have to complete the worker exposure assessment. We did the TRED last year, and the Methyl bromide soil fumigant uses that we intend to complete the end of this physical year.

The next page basically shows you the 23 non-food use REDs that we will complete by the end of this physical year. Five have been completed. That's the happy faces in red, and we will -- we are on schedule to complete the others.

In 2008, we have 24 non-food use REDs scheduled for completion, 11 of which are antimicrobials, 13 are conventionals; and we're working on those as well. The soil fumigants, we're reviewing those as a group to ensure consistency. We want to ensure that the mitigation that is imposed is consistent across the fumigants and that what

typically happens if you don't do things in a cluster, the most difficult one ends up being the last and you may end up inadvertently shifting use in a direction that you would not want it to go.

One, 3-D registration has completed reregistration. It's included there for both illustrative purposes and to -- as a benchmark for our consistency.

We opened our public commentary on page five, and we saw fumigants on May 2nd. We put out a revised risk assessment. We put out our benefits assessment, and we put out a paper on the option, the mitigation options that we are considering off of public comment.

During this comment period, we will be holding -- participating in three stakeholder meetings, one on May 22nd in Washington state; one on June 6th, in Florida; and we'll be participating in California stakeholder meeting on May 30th. Again, our intention is to complete these REDs and put them up for comment at the end of this physical year.

In terms of post-RED decision

implementation work, once the RED is signed, we have to prepare a DCI package obtaining its approval, issue the DCI, await for the registrants to submit the data, review that, review the revised labels, and get the revised labels stamped and approved. We have to issue six (f) notices and cancellation orders for any uses that were voluntarily cancelled.

All the recommendations in the REDs for tolerances, whether they were being raised or lowered or revoked or established, has to be done through rule making. We're on schedule right now to complete around 1200 final tolerance rules this year. DCI is a data call-in, and we continue to work on the product reregistration of label amendments.

We are initiating the process for closing out special reviews for these chemicals. We're going to be moving on a case-by-case basis, depending on the circumstances. For instance, Atrazine, Simazine are having SAP meeting on it this fall, so we'll await the outcome of that. But, basically, the process is to propose and then go final on the closure of those.

Registration review. We are moving ahead very quickly on this. I call this the ramp-up stage. We've already opened our first docket. We have 11 dockets now open for public comment. Some of them the public commentary will be closing shortly. We plan to open 25 dockets this physical year, 15 of them will be conventional chemicals, four antimicrobials, and six biopesticides. And we will be issuing final work plans for at least 10 of these.

As RED production ramps down, registration review activity, opening of new dockets, is going to ramp up. The RED implementation work is going to remain steady for a substantial period of time before we've completed all of the post-RED implementation work.

And, finally, a lot of this information is going to be found at our website, so we provide that for your convenience. Thank you.

MS. EDWARDS: Thank you, Pete. Okay. Lori.

MS. BERGER: Pete, my name is Lori Berger, California. Could you please explain the rational

behind not having a technical briefing in California on the soil fumigants, please?

MR. CAULKINS: I'll take a stab at it. It's my understanding there -- that the state was already having a stakeholder meeting in which we are allowed to maybe piggybacking on that, so we felt we could take advantage of that and not conflict with what the state's efforts were, wanted to compliment their efforts.

MS. BERGER: But, as I understand, I believe that's just one soil fumigant? I believe it's Metam sodium, and I don't know if there's any possibility of scheduling something else or an alternative means besides written comments, but those are very important products, and we have some real concern. And we just appreciate it if there's a possibility to have that type of forum in California like they're having in Washington and Florida, so.

MR. CAULKINS: Thank you.

MS. EDWARDS: Larry.

MR. ELWORTH: Just a good question. I know this isn't exactly your responsibility, Pete, but

what's the intersection between the status of registration of new fumigants and the cluster review? Are you still going ahead with registering new fumigants, and how are you factoring that into the -- actually, my concern is the -- how does the cluster review effect the registration of new fumigants?

MR. CAULKINS: Currently, I think we only have two new ones. One of them was -- had been in and was bundled in with the fumigants, and it's being looked at with the fumigants. The other one is brand new (inaudible) afterwards. So you got one brand new one that's bundled in with the registered ones, and we'll deal with it as we deal with the registered ones. The other one is a good year or two away, so it will follow afterwards.

MS. EDWARDS: Bob?

MR. HOLM: I'm sorry. Is it okay to like sort of not ask you a question but make a comment?

MR. CAULKINS: No.

MS. EDWARDS: Absolutely, yes.

MR. HOLM: Since we're talking about reregistration and maybe it won't be another

opportunity to do, you know, there's so much more transparency around the tolerance reassessment and reregistration process today than it was, say, 10 years ago. In fact, it's so overwhelming that it's like -- some of it I don't think you can understand most of it. But there's one piece of it that's not always been as clear to me as some of the other parts, and that's the question of when and how the Agency takes into account benefits when it makes a reregistration decision where benefits are relevant. And I don't think I'm looking for an answer here today, but it does strike me that it's a topic about which it would be useful to have some -- some more public dialogue at some point. Maybe it's an item that we could talk about at a future PPDC meeting.

MS. EDWARDS: Okay. That's very well taken. All right. Then I think we should move on to the NAFTA label presentation by Don Stubbs, Associate Director Registration Division.

MR. STUBBS: Okay. Now, exciting topic finally, the NAFTA label work group update.

(Laughter.)

What I want to talk about is a little bit of background and where we are in the short-term and long-term strategies and finally the future direction.

Back group. The NAFTA label work group charge was to find the solution to the longstanding issues that deal with the movement of pesticides across the Canadian/U.S. border. Short-term strategy was to find a way for U.S. growers to obtain certain pesticide products, both in Canada and the U.S. The long-term strategy was only to come up with the NAFTA label (inaudible) project, which would allow for transportation of pesticides across borders.

In the short-term, we had an agreement that would allow certain chemicals to be used bought in Canada and brought back to the U.S. It kind of follows our (inaudible) of regulations, one is that there's got to be an agreement with a retailer in Canada. That retailer then has to become a registered establishment. And once that happens, the products, of course, have to be similar (inaudible) somewhat. The registrant could send either sticker

labels or labels to the Canadian retailer who then re-label the product with the U.S. label. The U.S. grower could go over sign for it, file customs forms and bring it back into the United States. It's not a real simple solution to the problem, but, hopefully, one we can use for short term. The long-term strategy, once again, was to develop a NAFTA label that would allow us to get away from that.

We tested that program December 2, '06. It went fairly well. We still have some custom problems we're working on with that. The growers have given us a prioritized list of chemicals that they would like to have access to in Canada. We worked on two of those chemicals. One is Quadris Apron, kind of the pilot program to try and do this year. So we'll see how it goes.

Also, the final solution is the NAFTA label solution, and we're working on that, and there are key pieces we need to deal with. We have to have a regulatory harmonization between Canada and the U.S. We have to have a market. If there's no market, then we're really kind of wasting our time, but I think

it's a market. I'm not sure how big it is or how big it will get. There's got to be equal access to the pesticides, both from Canada and the U.S. and, of course, it's got to be free trade; i.e., treated commodities have got to be able to go across the border once it's been traded.

Format. The option we chose for the NAFTA format is, I think, a pretty good one. What we are going to do is take the basic required language to both Canada and the U.S., log on the label I'm talking about hazard statements, disposal statements, etc. That will go on the label. And then what you will have is you would have the directions for use, two sets, one Canadian on your left on a pocket or some kind of container. This could go back and forth on either side of the border. The farmer will pick up the can and use it in accordance with the directions for the country he's in.

So that's what we're trying to do. This should minimize what must be harmonized, i.e., we need to harmonize that which has to be on the container. Hopefully, it will be less confusing to

users because when we go to use the product, it will be what they normally do in Canada or what they normally do in the U.S., depending on which label they use. And it will help pave the way for electronic labeling, which is a topic of another discussion that we're trying to improve on.

We currently have one label out there that's been approved, as I just discussed, and it's Fargo or Avadex, the common active ingredient named triallate. We have seven labels drafted in-house, and we expect to approve two more this month. We recently have another label that someone's volunteered to work on and submit to us, and we have three labels volunteered for new active ingredients which are in the registration process.

That brings us to the process. Obviously, the registration process would be (inaudible) process to do this. Joint reviews, when you use the joint review, you come up with a joint label. And when you get to the side reviews and decide what you're going to register, you register the NAFTA label, and life would be nice.

So that's where we want to be, so we need to deal with the initial submissions, what they're going to look like, we need to deal with the equivalent. The two products have to be equivalent in NAFTA harmonization -- they should be. We have to come up with an incentive, I think, for NAFTA labeling, promote -- you know, we could do that through joint reviews and other mechanisms. And then other issues, regulatory changes could be easy compared to the marketing side of this. I mean, industry has a large stake in this and a lot of it is going to be industry issues, too. Also, we need to worry about how distributors affect distributors, existing markets, stewardship programs, and things like that.

So we still have quite a few things to work on and solve, but I think we're well underway.

Our future direction is to develop a routine, sustainable process, continue to address incentives for NAFTA labeling. We have developed an Internet site and should be putting those NAFTA labels that are approved on that site this month.

And our goals which are to remove the needs for import programs and NAFTA labels become a routine thing. Thank you.

MS. EDWARDS: Okay. Bob?

MR. HOLM: Don, I wanted to commend the EPA for their efforts, and I know with IR-4 we've been working a number of years with the convening counterparts to register products on specialty crops. I wonder if you want to -- if you would like to comment on incentives that the U.S. and Canadian governments maybe giving to registrants in order to make this happen, a number of field trials, regulatory requirements, and, you know, the costs of the dual registrations are very high, and I know the EPA has been working on that. And are there any specifics that you can relay to the group?

PARTICIPANT: Actually, you probably do know we are working on a number of projects with our colleagues in TMRA, looking at what I would call the most efficient use of residue field trial information. One of our mutual goals that we've had from the beginning of the whole NAFTA TWG project is

to make sure that the harmonization work that we do, at the very least, maintains food safety and oftentimes I think would actually improve confidence in food safety. So what one of our technical projects is actually to look at our current national requirements for residue field trials and then to say if we were looking at this from a NAFTA basis as opposed to either a U.S. or a Canadian basis, what would be the proper distribution of field trials, what would be the number of field trials, and are there some opportunities to actually end up with what I would call a more robust database, but at the same time to reduce where it's appropriate data development burdens is one of the incentives. And so that is actually an activity underway. I might note actually the NAFTA TWG is meeting here in Washington next week, the executive board. And so any comments that people have around any of these NAFTA issues will be able to (inaudible) into that session.

MS. EDWARDS: Okay. Gary.

MR. LIBMAN: Don, I think this is terrific. Just a question, maybe I missed some of the nuisances

here, but I see this more as a CAUSTA, Canada and U.S. Trade Agreement, rather than a NAFTA. Mexico has not been mentioned in this. Are they involved in this at all, or are they getting to the point where you're going to get them more involved?

PARTICIPANT: Mexico, it is a three-way relationship. We have some terms of reference. And one of the terms of reference is anytime any two of us decides that there's something we want to pursue, but the third partner, whoever that might be, for whatever reason, feels that they're not able to go in that direction, that's fine, and it's still a NAFTA activity. So some of our activities are fully trilateral. This labeling one right now is a Canada/U.S. activity. Mexico is fully informed of what we're doing, but has decided that they have domestic priorities that at least at this point in time don't make it possible for them to actually join in sort of a three-way labeling effort.

MR. LIBMAN: Okay. Are they part of your working group that's going to be meeting next week?

MS. LINDSAY: Oh, yes, all the time.

MS. EDWARDS: Larry.

MR. ELWORTH: Well, I for one was riveted, Don. Can you -- and actually, I'm tempted to ask questions about the tougher problem which is California, but that's a separate issue. Can you tell me a little bit about what the uses are that are in some of these labels, what the crop uses are, assuming they're crop uses? Do you know the range of the crop uses involved?

MR. STUBBS: No, I don't. I would guess triallate just for my herbicide (inaudible) is a wheat.

MR. ELWORTH: Uh-huh.

MR. STUBBS: Wheat use that I'm not --

MR. ELWORTH: I'm guessing the (inaudible) is what we're working. Okay.

MR. STUBBS: But I could find out.

MS. EDWARDS: Okay. Dan.

MR. BOTTS: I know this has been an issue before the NAFTA technical working group for at least the last seven or eight years, and the Agency's to be applauded on working to resolve this. I would wonder

just because of some of the history behind this process is there any intention to determine if, in fact, what the utility of the NAFTA label is at the end of the day and how much the product moves across the border as a result of this NAFTA labeling process.

MS. LINDSAY: Dan, I think the focus has actually been can we actually make it happen. And at least on a pilot basis, we figured out we know how to do it. We think we see a way forward. I think your comment is actually a good one, and since the NAFTA TWG is going to be meeting next week, I think one of the things the government's involve might actually have some internal discussion about is how do we monitor the actual impact of the program. So timely comment.

MS. EDWARDS: Okay. I'm going to take the two cards up and then we'll move on. Bob.

MR. HOLM: Yeah, and this is a -- this is really a Canadian problem, not an EPA problem, but -- and I guess the problem question is, has there ever been any discussion about joint reviews or

harmonization about non-ag labels or non-ag (inaudible). The reason I mention that is the markets for those products in Canada are so small. In fact, there's like, I believe, like an acre in Toronto where there's termites and then, you know --

MS. EDWARDS: Frank can answer that. The answer is yes.

MR. SANDERS: The answer is yes. We have had joint reviews non-ag side. Just recently we did the Polymeric betaine (inaudible) preservative. So there is activity, and I suspect there will continue to be joint reviews of a non-ag side.

MS. EDWARDS: Okay. Michael.

DR. FRY: This is primarily about some relationship to the NAFTA label. When these labels are translated into French, how is EPA dealing with certification of translation, and it sort of -- that rolls over into the current problem with Home Depot, Walmart, and Lowe's requiring labels in two or three languages. And how is EPA dealing with certifications for those translations?

MS. EDWARDS: I think that the translation

into French would be handled by the Canadian government, PMRA, since that's the reason it's being done, and they would review those labels.

Well, let's move into the last session this morning which is how we spend our money and time, and Marty Monell, our deputy director, will give you that presentation.

MS. MONELL: Okay. Well, we haven't done this one actually in PPDC for a couple of years now, and I guess you could assume then that's because we sort of had flat money available to us and that wouldn't be a bad observation. However, this year we decided, although we don't have any increases, that we ought to do a budget presentation because things have changed. Things have changed structurally with the OPP's budget so that it now aligns with our new strategic plan.

A few years ago the pesticide program decided that we needed to really focus on our program performance and do we have measures that tells us and the public at large whether or not we're doing the right job and whether or not we're doing the right

job well. And with a little help from our friends at OMB, we embarked upon a measures development exercise that you're going to hear more about tomorrow under the auspices of the PPDC. But we also took a look more broadly at what we were doing and how we were characterizing it and what really we were focussing on, although no one would have known that by looking at your budget structure.

So we looked at our mission. We started at the very top and, obviously, to protect the public health and the environment by ensuring that pesticides and alternatives are safe and available for a healthy America. So right away that leads us into our three mission areas which you will see flow into the strategic plan, but it also formed the basis of the focus of our measures development work.

We decided that we needed to do a little reality check with our statute, make sure that the statute aligned with what we believed our mission to be, and you'll see that nicely enough it aligns very well, that FIFRA provides for direct and indirect references to our mandate to protect human health.

It also provides very nicely for the mandate to protect the environment in our registration and reregistration activities.

And then, finally, it provides the basis -- FIFRA provides the basis for the underlying assumption that there is a value in making pesticides available to the public. And so that became our third basis for our mission area.

We then looked at our strategic plan against our budget structure, and under the old budget structure it was registration, reregistration, and field programs. And the object provided by this budget structure was that somehow field program was this sort of voluntary set of activities that somehow was different than registration and reregistration activity. And it didn't really capture the fact that the field programs, in fact, were a vital part of the other two programs and, in particular, the reregistration program or the review of chemicals that are already on the market are very much, in fact, impacted and addressed by our field program.

So we decided that what we really should be

doing is structuring our budget to reflect our mission areas. And after much discussion with the -- or Office of the Chief Financial Officer and folks on the Hill, and our friends at OMB, they finally agreed that, yeah, it does make some sense to align your budget with the mission areas in your strategic plan and with the overall performance measures that you've developed within those mission areas.

So the current budget structure, which will exist through the end of this physical year, provides for registration, reregistration, field programs, as you're all familiar with, and we -- we convinced them that since reregistration, as we've all come to know and love it, is on a downhill slide in terms of going out of business and that registration review is coming back, is taking it's place as our new Old Chemicals Program. So we really needed to get out of the old nomenclature under the budget structure.

Right now we also have about 25 different budget activities under these three major -- they call them program projects. And quite, frankly, nobody could tell me what they meant. Negotiating

with partners, what does that mean? Well, it depends on who you ask, that's what it means. And yet we have a budget category and money appropriated to us in that category.

So starting in '08, we're going to have this new budget structure, again, following the new strategic plan structure, which we have discussed that at a PPDC meeting, I believe, a couple of meetings ago and at a time prior to its being out for public comments. Hopefully, those of you that had comments were able to avail yourself of that opportunity. Strategic plan is in place now. It is -- and this budget structure is intended to come into alignment with that structure in physical year '08. And you'll see that our three new sub-objectives under the new strategic plan aligns very nicely with our mission areas.

And then we wanted to give you a picture of what is in those three mission areas. We're not hiding any of the old activities. In fact, we're very much going to be tracking money spent on registration activities, reregistration activities,

RED implementation is obviously a big area that we'll be focusing on now that (inaudible) assessments in the food use REDs are done. We're already starting that work. Pete and his folks are very actively engaged in it. And then anything that comes about as a result of the non-food use REDs will also have to be tracked.

Registration review is provided for here. Rule making, that has always been a component of field programs, but actually, rule making is encompassed in all of the three mission areas.

Program management, we never had a separate line sort of tracking the management costs of the program. We now have that within the context of the three mission areas as well as risk reduction implementation. We had many discussions about what this nomenclature should be. This is the follow-up work to make sure that any of the mitigation activities that we put forth in our registration, reregistration decisions are, in fact, carried out in the field.

The -- and that's the next slide,

basically. I'm rushing here, but you'll get a chance to ask me questions. But I know I'm standing between you and lunch, so I just want to make my point and let you eat. Registration, reregistration is still re-trackable. It's now going to recognize our new registration review program. Our budget activities are going down from 25 to 7, so it's a manageable group that makes sense that, in fact, comport with what we do here, our business, and is easy to track.

Links planning to operations. That's a very important component of running any major business and $160,000,000, I would say that we're a pretty significantly endowed business and we should be matching our planning with our operations.

Provides for greater accountability. If you've got -- we know now exactly what activities are associated with the various budget categories so we will be able to track things and hold -- and hold ourselves more accountable for our spending in these areas. And then it's also going to provide more transparency because we do have a definitions document that defines what do we mean by risk

reduction implementation. What exactly does that mean? What exactly is encompassed in program management costs? We have our own internal definitions document that we will use here as well as with our regional counterparts to enable everyone to understand what each of these mean and then be able to track our expenditures more appropriately.

Implementation time line. As I said, we're going to be starting being budgeted in this framework for '08. If you happen to have looked at the 20,000 page President's budget for '08, you would have seen this in there, this structure in there for the pesticide program. Actually, in headquarters for 2007, physical year 2007, when we did our planning at each divisional level, we decided to have the divisions produce their work plans and operating plans in the new structure so that we can get a sense of the proportionate areas, proportionate resources and workload in each of the three mission areas, and they did that, and that is the way we structured our budget based on that exercise. We structured our budget request for 2008 proportionately to the way we

were doing business in 2007. There will be an opportunity, obviously, within a new kind of structure like this to adjust it if we find out that in reality that proportions are a little bit different.

Let's see, the implementation time line. We've done a lot of work with our regions as well as internally. As with this meeting, I think that the more you hear about these mission areas and the way we're approaching the planning and accountability component, the more you do it, the more it just becomes sort of a way of doing business. We've been doing that with our staff as well, internalizing it to the extent we can.

Now the reality. The 2007, this is a crosswalk of our current budget within the old categories. That's on the left, and you will see it totals 122,705. And then if you then translate those into what the new structure will look like -- would look like, if we were doing those in '07, you'll see what the break-out is, and the bottom line is the same amount of money. We're not hiding anything

anywhere. We're not getting any additional resources anywhere. By the way, this is only appropriated dollars. This does not include the maintenance fees nor the PRIA fees.

The maintenance fees this year we're authorized $21,000,000. And thus far, we've collected about 8,000,000 in PRIA.

PARTICIPANT: (Inaudible.)

MS. MONELL: Okay. 8.6 million thus far in PRIA. So that would be on top of this 22,7 that we have been appropriated.

And then for '08, the President's budget that was announced last February, currently contemplates our receiving a 122.2.59 million (sic). And what this crosswalk does is show what the new structure will actually look like and then what it would have looked like under the old budget structure.

Again, it's the same amount of money under the old structure as well as the new structure for -- I should note, though, for the fees piece, we're only authorized to collect 15 million under maintenance

fees next year and, of course, whatever the PRIA fees become as the applications come in. We have no ceiling or floor for those collections.

And then my last slide, probably one of the more controversial, and this is in the President's budget for '08. It is a series of new fees contemplated in the President's budget for '08. And they would be -- the theory behind this is that those that benefit from regulatory action, agency action should pay for it or at least in part. And using the FDA as an example in their prescription drug program where there are actually quite significant, much more significant fees than the pesticide fees are, that was used as a model, both by the PRIA Coalition and now OMB. And so they felt that they needed to increase the amount of fees being paid by industry.

So the -- I'll just go right to the '08 fees being proposed. They're proposing 9 million more in maintenance fees. As I noted earlier, we're authorized right now to collect 15 million. They're proposing to bump that up by 9 million to a total of $24 million. They're proposing an additional 12

million more in registration service fees. So, in other words, we would have to take the current PRIA fee schedule and somehow tweak it in such a way to collect 12 million more.

Right now we anticipate in the budget context that we'll collect $10 million in PRIA fees for '08. They're proposing that we add another 12 to that. So that's a significant bump up in this proposal. And then $32 million in fees. This is on -- in addition to the maintenance fees for the registration review program, and also a certain portion of that to be utilized for endangered species review, compliance with the Endangered Species Act, which we have implemented through the registration review program.

And then, finally, but -- last, but not least, is the $13 million in new fees for setting new tolerances. And for those of you with long memories, tolerance fees have been proposed by OMB for years, and the authority contemplated them being collected through rule making, and so there have been rules, draft rules, for how long, Anne?

MS. LINDSAY: (Inaudible.)

MS. MONELL: A long time. Anyway, what this statute contemplates is, like PRIA, that the fees would be authorized and collected by statutes. So there would be no rule making. We would just figure out a way of allocating them to the new tolerances as they came in.

So this would be a huge amount of resources injected into our program if it passes Congress. Any questions? Susan.

MS. KEGLEY: Back to the mission statement in the categories, I'm looking at Slide Six, the statutory authority. I guess I read through FIFRA 2(bb) slightly differently. It seems like that picture requires taking into account the economic, social, and environmental costs and benefits of the use of any pesticide. And it seems like you've ended up with only looking at the benefit side. And I'm wondering what EPA is doing to look at the cost of human health and the environment and economic terms of pesticide use?

MS. EDWARDS: Currently, what we do, I

think you know, in that we evaluate the risks and the most part compare that to the value of the pesticide, not necessarily always in a monetary sense. So we're not doing sophisticated costs benefit analysis routinely. You know, we look at the risks and attempt to mitigate them to the extent feasible. And if that's not enough in our point of view, it's a fairly subjective decision, then we might propose a cancellation or a involuntary cancellation or major change to the use. But -- and you have to meet, obviously, the FFDCA standard, period. That doesn't involve what we're talking here. So pretty much any time you have a food use, we're not looking at the benefits of a chemical except in, you know, figuring out how to move through transition and that sort of thing, helping us find other -- you know, other chemicals that could -- or other control means that could meet the need. I don't know if I'm helping you here.

MS. KEGLEY: I just -- you know, like looking at the fumigants docket, for example, there are a number of evaluations of the economic benefits

of fumigants to potatoes and carrots and tomatoes, whatever.

MS. EDWARDS: Uh-huh.

MS. KEGLEY: And yet you don't find any economic analyses of the additional cancers, the additional birth defects that you could estimate -- a health economist could take, you know, existing epidemiological data and make some estimates there, the same for, you know, damage to wildlife. Perimanon (phonetic) has estimated a number of -- the average number of birds killed per pesticide application in a corn field. What -- I mean, it seems very one-sided that if all you're looking at is the economic benefits, it brings $15 million in, but you're not looking at the economic costs to public health and the environment that it's very one-sided.

MS. EDWARDS: Right. We actually do have some initiatives on that side looking at the cost benefit in terms of the environment and -- but, you know, we're not there yet. If you have any ideas about how we can better do it, we would be happy to meet with you or look at your comments or anything

else. But I think on the human health side, typically, what our goal is, is that no one is hurt. So that's kind of where we're aiming for. And so that's why we don't have the sophisticated cost benefit. We don't have a common denominator most of the time.

MS. MONELL: Pat.

MR. QUINN: Could we go back to the 2007, 2008 budget break-down slide?

MS. MONELL: That's 14 and 15 -- 14.

MR. QUINN: I guess my question, Marty, is, you know, when I looked at these slides, what occurred to me is that they're remarkably similar, you know, that the new budget architecture didn't seem to drive any different sorts of budget choices. Maybe what I'm asking is did you -- what did you learn from going through a budget planning process with this new budget arch, as you call it, and, you know, did it change the way your people thought about making budget proposals, or is it too early? Do you expect that to happen in the future?

MS. MONELL: It is too early. We -- as I

said, during the '07 internal planning process, the development of work plans and the divisional budgets to support those work plans, we did the best we could to come up with the appropriate allocation of resources to the new budget areas, the new mission areas. I think that we're really going to need a year to three of experience with it to really be comfortable and adapt enough to do budget proposals that way. These are formula-driven based on our best guess of what the work entails. But that's where we hope to be, obviously, you know. Julie.

MS. SPAGNOLI: I guess I just was looking for an all clarification. You have these seven activity areas and then the three mission areas. And then is it -- is it in each mission area you're going to break down budgets for the seven activities?

MS. MONELL: We will track them internally.

MS. SPAGNOLI: Uh-huh.

MS. MONELL: The gross budget will just have the three.

MS. SPAGNOLI: And then -- but then you'll track these seven different activities in use for

those areas?

MS. MONELL: Correct. Correct.

MS. SPAGNOLI: Another question is what about things such as, you know, issuing guidelines and things like that? Would that fall under an activity of rule making? Does that expand to interpretations of rules or guidance for compliance with rules as well from an activity standpoint?

MS. MONELL: It would be -- well, it would be difficult if either rule making or program management. The definitional document provides some guidance for staff, but it's going to be a judgment call in many cases.

MS. SPAGNOLI: What area activity it falls under because it could be risk mitigation, but it could be rule making? I just kind of -- it seems like there could be overlap.

MS. MONELL: We will learn by experience with using it. What we do know is that the 25 areas that we're tracking right now are totally irrelevant. It's just a guess. You just throw the money where you think it works.

Who's down there? Oh, Beth.

MS. CARROLL: I'm just curious and maybe in the interest of lunch we can talk about it during PRIA. But you used the term "tweaking" PRIA, and I just kind of wonder what that means? And how is that embedded with the PRIA work group?

MS. MONELL: When did I say that? If I was talking about --

MS. CARROLL: Actually, I wrote it down. I'm not making this up.

MS. MONELL: Well, if it was talking about tweaking PRIA in the context of the OMBC's proposal --

PARTICIPANT: (Inaudible.) You were talking about the 12 million more --

MS. MONELL: Yeah. Okay. Well, all of these proposed fees would involve changes to existing statutes. So FIFRA would need to be further amended to enable us to collect tolerance fees. It would have to be further amended to increase the amount of maintenance fees. It would have to be amended to enable us to collect fees for registration review.

So that's what I meant when I said tweaking. Jay? No, no, no. I'm working my way around the table.

MR. VROOM: Well, I just wanted to thank you for the entertainment of the way you presented the President's budget proposal. And I want to ask you to explain how a president who signs PRIA into law can, year on year, continue this fantasy of budget proposals. But, just for the record, this wasn't the first time a president's budget has proposed these kinds of outlandish ideas that somehow might be grounded and FDA and pharmaceutical company revenues and fees and the likes. So some of us might expect this President's budget to end up in the same place that previous presidents' budgets have ended up. Thank you.

MS. MONELL: Thank you. Yes?

PARTICIPANT: You mentioned that in the activities, the one entitled risk reduction implementation it took a little bit of time to come up with that category. Could you just give an example of the types of -- of a type of activity that risk reduction implementation includes? I'm looking

at Slide 10.

MS. MONELL: This is the field program and we -- when I said we had difficulty with it, I -- what I meant was the term, the verbiage. We had a lot of discussion about which word or phrase best captured what the field programs really do. Anne, you want to add anything?

MS. LINDSAY: Yes. I think we ended up with risk reduction because, I mean, one of the things with this new budget architecture that we've been trying to emphasize are the linkages between things. And, unfortunately, the term field program really did suggest to people that separate from registration and reregistration, we just had a bunch of what I'll call (inaudible) operations out there in the field. So, you know, we'd hand out a grant to do this or that. And that actually was not what we needed to know, being one of those (inaudible) field programs as a state official. That's not at all what the bulk of field programs is really about. So the name that was finally selected was to emphasize risk reduction and that is the way both in registration

and reregistration we make regulatory decisions that are intended to achieve risk reduction, to prevent harm, to pick up from last session's discussion.

But you can't just make the decision. You have to implement it. So all of those activities that we fund in one way or another that work to implement the risk reduction decision fall into that budget category. And so a lot of the training funds that we have -- that we've talking about in this group in the past would actually show up in that category as an example.

PARTICIPANT: I think I would just like to sort of echo and give a little bit of feedback. I hope that the new structure -- I know that there is --

PARTICIPANT: You've got plenty of feedback.

PARTICIPANT: A little bit, I know. No kidding, lots of feedback. There's been a lot of discussions and pressure on the Agency from OMB and others to value the programs better. And having gone through process with you guys a little bit to try to

do that (inaudible) program, I'm curious to see and wish you well in this new structure and hopes that that works out and please keep us posted and know that you have some allies on your side who are willing to help you shape the value and let OMB know that, in fact, you know, we're spending money wisely in the program and it's of value to each of us.

Secondly, I am a little concerned with the PRIA tweak. We also would have some concerns about the President's budget request, both from the perspective of the understanding of how we hope PRIA to be working and improving the program. And, also, you know, sort of (inaudible) notion that if and when these fees were to be generated and we're not necessarily sure we're very comfortable with that, the fact that they go to the U.S. Treasury would be wholly and entirely unacceptable. You know, any fee collected under PRIA or any other program needs to come back to you guys if that's, in fact, what the point is. So, I mean, that's just sort of an on-the-record from where our organization is coming from. So that's a fundamental non-starter with us

and that's even reserving the other issues with what we hope the agreement under PRIA would be.

MS. MONELL: Thank you. Jennifer.

MS. SASS: (Inaudible.)

MS. MONELL: Thanks. Okay. Gary?

MR. LIBMAN: I have a question about maintenance fees. Before I do that, I want to ask which of these mission statements that the PPDC fall under? Do we protect human health? Do we protect the environment, or do we realize our value?

MS. MONELL: All of the above.

MR. LIBMAN: Thank you.

PARTICIPANT: Do we have a budget?

MR. LIBMAN: Do we have a budget? That's a good question. My question is on the maintenance fees. When PRIA was first talked about a few years ago and then we held these PRIA meetings, and the PRIA II and the PRIA III and so on, we always talked about the fact that eventually the maintenance fees would go away. Doesn't look like that's going to happen.

MS. MONELL: Well, my understanding is --

and perhaps Jay could jump in here -- my understanding is that anything -- anything being discussed in terms of PRIA II piece of legislation would contemplate extending maintenance fees, but it would be for the registration review program as well as the wrap-up of all the (inaudible) tree assessment and post-RED work and product reregistration. But, Jay, you want to jump in?

MR. VROOM: That's correct. That's where the PRIA industry Coalition is at as well as the larger PRIA Coalitions. We crossed that bridge, but I'm interested to know what you know about PRIA III? I just made it up, I thought.

MS. MONELL: Okay. No more questions.

MS. EDWARDS: All right. Thank you very much. I think we had a good session this morning, and I will call us to order no later that 1:30, so please be back by then. Thank you.

(Whereupon, lunch recess was taken.)

MS. EDWARDS: Okay. Welcome back. I hope you all found something nice and delicious to eat

around here. Not too many choices yet, but it might improve one of these days.

Starting with the afternoon session, Session IV, which is a report out on a PPDC work group on PRIA process improvements, again, from Marty Monell, our deputy director for management. Marty.

MS. MONELL: Thanks, Debbie. Wait for the AV -- there we go. Very good. Want to do the next slide, please.

Okay. As some of you know and many of you probably don't know, but should know, when PRIA was passed, it contemplated more than just our collecting fees and producing registrations in a certain amount of time. It contemplated that we -- the program -- actually, it mandates that the program implement process improvements in the way we go about looking at potential pesticide registrations and other related actions and improve those processes. And so what we did with the sanction of the PPDC was to form a subgroup, and that group has been meeting about three times a year to discuss various ways -- well, various issues that need to be addressed and

processes to be improved.

We have actually done a lot of work and have implemented a lot of improvements in the registration process. Today we're going to talk about just a few. We're going to start with sort of our E-gov efforts. And Oscar Morales, who is the new director of ITRMD, will be presenting the -- our current use of an online payment system for PRIA fees as well as our efforts towards electronic submissions. Then we'll have labeling issues where top on the list of all of the registrant community as well as the internal OPPers involved with registration actions. So you're going to hear from Don Stubbs again about the labeling committee and a new project, which is e-label review, which is going to be a real time saver, we hope. And then Pauline Wagner is going to talk about -- Pauline is not yet here. Well, Pauline Wagner, the branch chief of the Inerts Branch in the registration division is going to talk about the latest and greatest in review of inerts. I think she's got some very exciting process improvements to talk about and a pilot project

regarding fragrances that she's going to discuss. And then last, but not least, is a presentation that I really, really was very excited about when I saw it. It's GIS and environmental assessments, and it's a new project that Michelle Thawley and -- oh, there he goes -- Nelson Thurman have -- have developed and are implementing to really refine our eco assessment process. So very exciting stuff and why don't we start with Oscar.

MR. MORALES: Hi. Good afternoon. I'm Oscar Morales, and I'm the new IT division director in OPP, so I'm the new kid on the block. And as you can see, I don't even get a printed one out. Maybe next time, if you'll allow me to come back, they'll make one up. So be general, by the way, is what my staff told me to say.

I'm going to update you on two projects, one of them are new. Next. Last year, as some of you know, we rolled out a new and easier way for registrants to pay for PRIA fees, Pay.Gov. I believe you've seen a demonstration here at one of your previous meetings. I'm happy to report that a lot of

companies chose to -- have, in fact, chose to take advantage of this new service, 35 percent, to be exact chosen to pay online.

Next, just to remind you if you haven't been there, this is the Pay.Gov home page where you start off. Next, this is the basic Web form that has to be filled out with some preliminary information. And then, finally, next, the usual convenient and safe and easy way we all use for paying things on the Internet today. No different.

Okay. Next, I --

PARTICIPANT: (Inaudible.) I'm sorry. Do people usually pay $50,000 on their credit card to Pay.Gov?

MR. MORALES: Yeah.

PARTICIPANT: Not too many.

PARTICIPANT: Could I have their names, please.

PARTICIPANT: And their card number.

MR. MORALES: Okay. Now I want to talk about a new pilot that we started under our e-submission project. As you may or may not know, we

initiated the work towards complete e-submission as a means of improving our service and to reduce the burden on industry. In addition, we were -- we are also investigating the possibility of standardizing our templates through things like XML, zip files, enough to be able to allow companies that were so inclined to be able to submit their data and materials to multiple agencies.

Next. The first step in this process was a small pilot that we initiated about a year ago. Next. From a IT perspective, this pilot will allow us to validate, to test out some of our initial assumptions about the methods that we had chosen, about whether we actually were reducing the burden and again the possibility of harmonizing our efforts, and as any other IT projects along the way, identifying any technical problems that we encountered before launching the entire project and making it available for everyone.

Next. Simply put, this particular project -- I think some of you have seen this chart before -- allow the registering company to submit the

application data and documents electronically on a CD or a DVD.

Next. What this allows us to do inside is for a limited number of applications types, it allows us to process them electronically, including an error correction for the -- the error correction submission.

On the next page are some of our initial participants and the status. And then, finally, on the last page, this is really kind of our vision for the future, although we are minus a few things.

PARTICIPANT: (Inaudible.)

MR. MORALES: That doesn't simply matters any, but we expect to finish this pilot by the end of the summer, make it available to everyone by the end of the year, if everything goes as planned. By way of the future, we want to be able to allow companies to have -- to be able to choose or select one of three ways of submitting information: Paper, which is probably always going to be the alternative, CD, DVD, and in the much distant future, encrypted web transmission, including the ability of checking on

your status online, including free submission electronic error correction, pretty much like what you do on Turbo Tax for those of you that used it, except I used it the night before, and it stopped the thing, and it got stuck. And I had to submit it the next day and my wife stayed up all night worrying that we were going to get sent to jail.

The -- if you note the other side of the diagram, however, it opens up the possibility now because I know there are a lot of other stuff has to be done as to who the companies could choose to share these submissions with, so I'm going to close and simply state to you.

MS. MONELL: Pauline. Any questions for Oscar?

PARTICIPANT: Don's next.

MS. MONELL: Okay.

MR. STUBBS: All right. I'm back. We're going to talk a little bit about the labeling committee and e-labeling.

Next. First, the charge of the labeling committee is to serve as clearing house for broad

cross-cutting labeling issues, and we've been doing that very well. There is a website which we have -- I'm not sure we manage it as well as we could -- and revise and keep the current Label Review Manual.

Next. I threw this in just because you would have the paper forms, so you would have the sites. Next. Questions and answers. We have received as of March 30th, 89 questions, completed 83, working on six, and referred 29 elsewhere, posted 56. That's probably up by about 10. We do get a lot of questions. And I just like to point out probably the quickest we answer one takes about a month. We have a committee made up of three or four divisions in OPP, Office of General Council, and OECA, and every question goes through everyone in that group before it's approved and put somewhere. So, if you have good labeling questions in the cross-cutting, please use the system.

Next. We're working on updating the Label Review Manual. We've updated the first three chapters. We have a subcommittee working on this. Chapters 4, 5, and 6 are being updated, currently

sitting on the committee. Hopefully, sometime in June we'll update Chapters 4, 5, and 6.

Next. We took on a project dealing with which contains the same active ingredient, would we allow it, how would we allow it. We have developed a guidance paper on that. It is posted on our website, if you would like to go visit it. It essentially says that you can only do a statement saying that one active ingredient -- one product contains the same active ingredient as another, by amendment. You cannot do it by notification. There's other guidance on product referenced, the placement of it, the disclaimer statement, and font size and type, etc.

Next. Minimum Application Paper. We did paper based on input, I think, from industry and (inaudible). This is one of the things they wanted done. We posted it on the Internet for a comment and got a whole six comments. So it was a hot topic. But based on those comments and based on our regulations, we have come up with guidance.

Next. And essentially, there are two times we think we should use the minimum use rate on a

label in a mandatory fashion. One is when the risk -- where there is a risk that the reduced application of the product could result in pest resistance, and the second is when the product won't work below that level. Any other time it should be put on as an advisory statement versus a mandatory statement.

Next. Next, we took on environmental hazard general labeling statements on outdoor residential products. This was presented us to -- from subcommittee, the PPDC, who reviewed it, accepted it, and are currently doing PR notice for comment. Those PR notices are (inaudible) about six months, but it should be coming up pretty soon.

Next. E-label. E-label means lots of things to lots of people, and there are lots of people doing different things on it. For the purpose of this group, it means electronic review of labels in-house within OPP. And we are currently training our staff. We trained about of half of RD. By the first week of January, RD should be totally trained in how to compare electronic labels. We will send

those by the company versus the last one on file. We will compare them and use that to comment and correct labels. Once RD is completed, we will move on and train PPD and AD. So I would hope that we will train by the end of July, at the latest.

Tomorrow, at two o'clock, we will hold another session for the registrants on how they should submit e-labels. So, if you haven't done one of those, please tune in and go to this one, and that's it.

MS. MONELL: Any questions for Don? Yes, Jay.

MR. VROOM: Oscar, I was curious to know how the OACD work and electronic formatting has been adopted or not into the EPA system?

MS. LINDSAY: It's kind of a what I would call an interactive relationship between the OACD work and what we're doing here within OPP. I'm not technically qualified to discuss it in detail, but I think we're making very sure that as we develop our parts to electronic submission, that this actually fitting with and advancing the goals for electronic

submission and global work sharing that the OACD working group on pesticides has espoused and promoted. It's -- I think it's actually one of the -- the value of this for global harmonization and global work sharing is actually one of the drivers for pushing electronic submission forward. And I actually think that a number of the registrants have contributed pretty significantly to explaining the value as well as the kind of commitment that it will take to realize this. The other thing that I think it's allowing us to do is where we don't have to figure out how to do it ourselves, but we can beg, borrow, or steal it from either one of our global partners such as CMRA or from OACD. We can do it. And it actually is a way to leverage each global resources.

MS. MONELL: Dennis?

MR. HOWARD: I have a question for Don. With the changes that are occurring and the way the labels are being handled, could you describe briefly what kind of training process you're going through to get the product managers up to speed on these

changes, and if to an extent you do any accountability checking on whether they're doing okay with the training?

MR. STUBBS: Well, we haven't got to the accountability part yet because we haven't had training yet. But what we're doing is we're taking them down to our classes and have PCs, etc., and running them through the entire process of when a new label comes in, what do you do with it? How do you get it? How do you put it in the system? Once you get it, how do you do the first label, which is actually a paper review label, but then starts the first electronic label that will be used from then on. Then go through the process of getting the second one in and actually comparing two labels on a PC, ensuring two different ways that will show which changed on that label. You know, we're also showing once you find something, how you can comment electronically and write on that label and send it back to the registrant. And then once you are done, how do you put that label into the electronic label library to be retrieved by the next person who uses

it.

MR. HOWARD: And that's helpful. I guess what I was trying to understand is just in compliance with the Label Review Manual that you have and the changes that are going on it with the content of Label Review Manual, how do you keep track of how your managers are doing on actually following the guidance in the Label Review Manual?

MR. STUBBS: When we make a change. And notice what we been doing in the Label Review Manual is just updating it -- taking it out of Word Perfect, putting it into Word, etc. There should be no policy changes, per se, in there so far. But, normally, whenever any of these guidance documents we put out of policies are sent to all the product managers and everyone on their teams. And, hopefully, they're following them. There's not a lot a follow-up to make sure they are other than through the normal feedback group where industry calls up and says, "Mr. Stubbs, I did this. I thought you were supposed to do that."

MS. MONELL: Larry.

MR. ELWORTH: Two questions for Don. What's the genesis of this minimum application paper, and that's number one. And, number two, what kinds of questions are you all getting that you're responding to in these questions and answers?

MR. STUBBS: The genesis for minimum application paperwork, when we first started the label committee, we went to (inaudible) and CLA and everyone else (inaudible), and said (inaudible) and assuming priority and then we'll take a look at it and deal with them. Well, that actually was one of the priorities (inaudible) for (inaudible) that we took on. Okay. That's how we got it.

MR. HOWARD: Okay.

MR. STUBBS: As far as what we're getting, we're getting actually quite a few things, but I'll just briefly go over most of them for you.

MR. HOWARD: No, I was kind of curious.

MR. STUBBS: We got antimicrobial things, a lot of definition interpretation, pictures and logo, product names, questions on establishment numbers.

MR. HOWARD: These are from like the

general public or from registrants?

MR. STUBBS: You know, it's interesting. A lot of them are from states, a lot of them from companies. Those are probably the two basic groups, every once in a while from someone we're not sure who they are.

MR. HOWARD: Okay.

MR. STUBBS: So it's very, very a lot of questions.

MR. HOWARD: Okay. That's great. And, Oscar, if you can (inaudible).

MS. MONELL: Let's see. Oh, Julie.

MS. SPAGNOLI: I've got a couple of questions for Don, too. Just for clarification, that contains the inactive ingredient guidance paper, did you say that's posted on the Web now?

MR. STUBBS: That's correct. It's posted on the labeling committee website.

MS. SPAGNOLI: I thought that's what you said. I wanted to clarify that. The other question I guess, you know, as these questions are brought in where interpretations are made -- will those be

incorporated into the Label Review Manual then? I know you're getting it updated and converted. But, you know, I guess instead of having to go to these questions, could these policies and interpretations still be working for the Label Review Manual and whatever appropriate chapter because it seems like it would be easier to find that way?

MR. STUBBS: We do anticipate doing that, exactly.

MS. MONELL: Okay. Let's turn it over now to Pauline Wagner to talk about process improvements in our handling of inerts.

MS. WAGNER: Okay. Good afternoon. I'd like to talk to you briefly about three items that we are considering process improvements.

First slide. On a trial basis, the front-end screening processes for a new registration has been redesigned to include up-front screening of the inert ingredients in the formulations to ensure that they are all properly cleared and properly used. The process will allow RD to allocate resources more efficiently and will allow the registrant time to

address any inert issues that should arise. So as of the past Monday, the Inerts Branch has been screening both the PRIA and non-PRIA actions. For PRIA actions after the PRIA code is assigned, the package then is screened for the inerts.

If there is a non-cleared inert present or if the inert is cleared but not for the use it's intended in this registration package, the process will stop and the registrant will receive a 75-day deficiency notice. And for non-PRIA actions, the process is the same, except there's no time line and that the registrant will be notified.

Next screen. Okay. These are your options. When the non-cleared inert is present, you certainly can reformulate. If it's a food use registration, a petition for an exemption from the requirement of a tolerance for the uncleared inert should be submitted. Or lastly, you could withdraw the whole submission and start over. If you have an inert that's not cleared for food use, it would be helpful if you would submit the petition before you submit the registration package, and that would allow

the Inerts Branch to determine if the data that you submitted with the inert ingredient are sufficient to support an exemption.

Next slide. This is a form we are using to record the inerts and their status, and it will accompany any deficiency notification that we make. At the top there is a comments field that will have the bottom line on the inerts which are why we rejected it. And each of the fields following will contain specific inerts or inert mixtures and tell whether they are cleared for the use for which registration is intended or not. And these will be signed by the screener and also dated. And they will be included with your letter.

Okay. The next slide. The next process we would like to talk about is the Fragrance Notification Pilot. We've initiated this Fragrance Notification Program for registrants that are seeking to modify or add fragrances in currently registered pesticide products. We are initiating the pilot to improve the current process used to amend registrations when fragrance ingredients are added,

removed, or modified. The FMA, on their own initiative, developed sociable database that contains approximately 1500 currently used fragrance components.

We are in the process of evaluating the database, and we are also interested in any comments anybody would like to have on the database. It is on our website, the database. The all-fragrance components must be on this FMA database. The registrant must certify that the proposed fragrance change is the only change in the formulation.

The pilot started May 1st and will run for 120 days and is also announced on our website. At the end of the pilot, we will evaluate your results, and if the pilot is successful, the process will be made permanent. And, as I said, the fragrance ingredient list, which we call a FIL, F-I-L, is now available on our inerts website.

Okay. Next slide. The next (inaudible) improvement is we're calling the list. As a follow-p to reregistration, the list on the inert website is in the process of being revised. As you are probably

aware of, the list on the website are obsolete and, in some cases, misleading. We're receiving a lot of questions on these lists, the 1, 2, 3, 4a, and 4b lists. The list contains both food and non-food use inerts, but there is no key that would identify which chemicals belong to which category. The food use inerts, having exemptions from the requirement of tolerance, are all listed in the 480 CFR, 180, 910, 920, 930, 950, or 960, which appear to have their own sections that are listed in the 180, a thousand series.

All of the food use inerts that will been successfully reassessed are essentially List 4b. The designation 4a will be eliminated and the minimum risk inerts will qualify for the Section 180, 950, which is called the minimum risk inert section. And they will be placed in that section.

However, the list of these inerts have not yet been compiled. There will be some -- we will communicate to the regulated community when these are going to be moved, and I'll put something on our website or an announcement that comes out saying why

we're doing it and why 4a is being eliminated, and so that remaining food use inerts has been successfully reassessed will just be List 4.

So in the process of -- in the spirit of process improvement, we are beginning to update these lists, beginning with List 1. Now, List 1 contains eight chemicals, and only one, isoferon, (phonetic) have a tolerance exemption, which means it's food use. It's use was reassessed and was restricted to only six crops, and the exemption may be found. It has its own exception now, 1801270.

The remainder of the List 1 chemicals are non-food use only, and we are in the process of determining if any or all of them are still in use. You have to understand, though, determining the non-use -- non-food use inerts is not a small task. Since they don't have tolerance exemptions, the use of these chemicals must be searched in our data by product by product, which is quite time consuming.

We do believe, however, that a number of these chemicals on each of these lists are no longer in use and we will rescind the permission to use

these chemicals anymore if there has a warrant for that action. But as with the reassessment effort, we will certainly communicate with the regulated community to make sure that our records are complete and we won't take anything away that is being used.

Those are our three. Any questions. Pat?

MR. QUINN: Having worked with Pauline and her team on the Fragrance Ingredient Pilot, I just want to commend them for the work that they've done in this area. I think with regard to that, we're going to have a much more contemporary, much more transparent list of those ingredients which are used in fragrances, and I think a significantly more efficient process. So I just wanted to pass that on.

MS. WAGNER: Thank you. Beth.

MS. CARROLL: I just wondered if you have any notion as to when the list analyzation will be completed and it will be -- the improved list will be on the Web?

MS. WAGNER: We're sort of doing it as our other work allows, so List 1, of course, has only eight chemicals, and we've pretty well gone through

that and pretty well identified which chemicals we believe have no uses and are double-checking that. List 2 is not very long. List 3 and 4 are huge, though. They will take literally weeks to do, so I would say not before the fall probably. Jennifer.

MS. SASS: I'm not -- I haven't worked on inerts very much, so these might seem -- well, they probably are dumb questions. They might seem off target, so just tell me if they are. The first one is Slide 29, when you fill out the chart there, I guess the slide says Clearance Status Form --

MS. WAGNER: Uh-huh.

MS. SASS: -- so if I understand that correctly, is that basically all of the -- somebody, a registrant is telling you what inerts are going to be in a particular formulation?

MS. WAGNER: Yes. That's correct.

MS. SASS: And is that information that is publicly accessible, or is that information protected by confidential business information?

MS. WAGNER: That's CBI.

MS. SASS: So I couldn't, even if I filed

the Freedom Move of Information Act request and went through the proper procedures, I wouldn't be able to get a list of inerts that are in a formulation; is that right?

MS. WAGNER: I believe that's correct, yes.

MS. SASS: Okay. My second question is -- and this might be off target for you, but I think it's on target for this topic, so I don't know where else to bring it up.

MS. WAGNER: Okay.

MS. SASS: Is there a way to understand where EPA is on looking at the nano silver issue? Is it (inaudible) to microbials? Is it in inerts? Is it being considered at all? Is it back to devices because it is being used in food packaging, and it is being used in food storage containers here in the U.S.

MS. WAGNER: Currently, it's not in the Inerts Branch, so I really don't know.

MS. SASS: Maybe I could get something back from EPA on that.

MS. WAGNER: Gary.

MR. LIBMAN: I have a question actually representing armory. I'm on the board of Organic Material Review Institute. They are in a quandary because of these lists changing. They need to know what's going to happen because they review against (inaudible).

MS. WAGNER: Uh-huh.

MR. LIBMAN: Is there anything that you could give them to help them out on this before this is even completed by the end of, you say, by the fall?

MS. WAGNER: We could discuss it with them. I mean, we have some ideas of what we make for a minimum risk, so maybe they could call me or we could arrange some sort of meeting.

MR. LIBMAN: Okay.

MS. WAGNER: We would be happy to --

MR. LIBMAN: I would be happy to arrange that. Okay. Sure. Thank you.

MS. WAGNER: Carolyn.

MS. BRICKEY: Yeah, I just wanted to ask you to remind me what the difference in 4a and 4b is,

right now?

MS. WAGNER: Okay. 4b are safe, but somewhat restricted. Say, they're only for certain crops or certain uses. 4a can be used anytime, anywhere, anyplace, no restrictions at all on them.

MS. BRICKEY: Okay. So your goal is to blend it the 4b inerts into 4a? Is that the deal?

MS. WAGNER: No. When we -- when we reassess under FQPA, we sort of dumped them all into 4b until we sort of sorted it out, and we're sorting it out. Now, there are a number of ones that have been reassessed that probably will qualify for 4a. We just need to go back and identify those with cast number and chemical name and we will then put them in a FR notice that takes them to 4a.

MS. BRICKEY: Is there a real possibility that some of them will go into List 1?

MS. WAGNER: No.

MS. BRICKEY: No.

MS. WAGNER: No.

MS. BRICKEY: How do we know it would be gone?

MS. WAGNER: Under FQPA, you can't have a List 1 for food use. That only applies to food use, though.

MS. BRICKEY: I wanted to clarify something about the question that Jen asked about whether the inert ingredient information is available under FYA, and the situation is that it is available under FYA under a case-by-case evaluation by the Agency. So for some products and some inert ingredients, the information would be available, and for some others, it wouldn't be. And the second thing I wanted to ask was with all these list changes for the inert ingredients, how is that going to impact the 25b products because right now there's a pretty small list of inert ingredients that can be used in the 25b products?

MS. WAGNER: I really don't know. I will look that out as we go along, if someone else can answer that. I don't know. Okay. Thank you. We want that.

PARTICIPANT: We want 25b for this so that everybody knows what we're talking about.

PARTICIPANT: 25b is the part of FIFRA that allows us to exempt products from registration, all or some portion of it, essentially because they don't merit regulation by EPA in the full-fledged registration manner. So we've got a set of products that we went through rule-making process for it to be exempt from the need for registration. And one of the conditions in that regulation is that the inert ingredients in those products have to be on list -- basically on the (inaudible) list. And so as we change 4a and 4b and modify that, we are going to have to think through how that fits with the existing condition in that particular regulation.

MS. MONELL: Okay. And let's move it on to our final presentation. Shelly Thawley.

MS. THAWLEY: Kind of a tough one for five minutes. But I will say that the -- as these updates progress, we will have fewer and fewer words on the slides until it's all pictures. So go ahead with the first slide.

This is a really broad-rushed one-minute super overview into the (inaudible). I apologize for

the simplification, but I wanted to make the concept pretty clear. What we're are in the process of doing and we've actually changed the terminology we used and accepted the idea that we're going to move away from our scenarios and what they are now for exposure assessments we use scenarios currently. Right now you see on a mass we have a point which roughly represents a scenario that we've developed in the past. And we have about 60 or 70 regular ones, and as we run into more and more special conditions, we've been increasing the number of scenarios. So over time you get more and more dots.

But these scenarios aren't really representing a specific location. They're, in effect, hypothetical situation. So we run an assessment through a hypothetical situation and to determine whether we're going to have risk or not. What we're trying to do is get away from this hypothetical -- next slide, please. Oh, gee, it doesn't look very good on the screen, but this is moving toward what we're calling the spatially explicit risk assessment. It's not very clear on

here. I apologize. But what I'm showing you on this slide is the -- an aerial photograph of an area in Pennsylvania which, in theory, covers a couple of our hypothetical scenarios in Pennsylvania. The blue you see is the stream network, and this is part of a hydrology network data set that's allowing us -- which was released this year that's allowing us to move toward the spatially explicit risk assessment, where instead of describing areas of risk, we can now show you areas of potential risk.

The green you see are watershed delineations. So we know -- you can see the fields. You know where the fields are draining because the watersheds are delineated and we know the flow of the network. So we have a very good spatial representation of the process, the exposure process.

Next slide, please. As it stands right now in this scenario concept, with the scenario concepts, on the left you see a map of corn grown in the U.S. The triangle represents a corn scenario. As we run our model and we do our test for exposure to determine whether we've exceeded the levels of

concern, either you pass or fail at this point. If you pass, up top you see a green map. That's where all the corn's grown, so in theory, you pass for corn. So your one point has passed this larger area. On the bottom, if you were to fail, you've failed the whole country. That's a bit of a stretch. So down below -- oh, good it showed up on here. On the handouts, you can't see this, but down below is a sort of pictorial representation of what we're trying to get to. You see the interaction of the stressor and the receptor. Instead of passing or failing the whole area where you have exceeding, we're going to point out where you see the circles overlapping, we can now hone in on a specific area and say, well, this is an area we need to go back and assess further to determine if we still have risk.

Next slide, please. Okay. Here is an example of an assessment that we done within our division that is spatially explicit, and this is the carbamates cumulative assessment, I believe. So on the right what you see is instead of all pastel and a description of the types of areas this represents,

you see a map where you have red, orange, yellow, high, medium, low leaching potential in this particular example. But this is a far more robust way of portraying your risks for your exposure or leaching potential or whatever it may be.

Next slide, please. Okay. This is a very simple demonstration of how we're going to go from this scenario modeling approach to spatially explicit modeling approach. In this case on the left you see the same polygons I showed you before the stream network, watershed. We have soils in there. We have land use, corn or whatever it may be. And what we're going to do is instead of running the model for a hypothetical scenario, we superimposed the grid here as you see here. And for each of those grid points, we will run the model and get a value. So then we can take that, intercalate it or tweak it or what have you to make a spatial representation of the exposure. You can make those points as far apart or as close together as you like. This is part of the process we're working on right now to determine what makes sense. But you can see now you have, you know,

for a given watershed, you have a variation in soils and variation in hydrography. So now we can be a lot more explicit.

Next slide, please. Okay. And this is just some words to tell you, since we've presented in November, just a few words to update on our progress, there are two pieces to this project. One is compiling the data set that we can use as the basis for this analysis, and the second is developing the software tool to run the models in new mode. We are currently developing a database, thanks to our Big Decisions Project from OAI, and that database will come online, I say, September '07 roughly, but certainly this year. The details of how it will come online and where and how access will be gained, we're working on that right now and we should know shortly the details of that.

The prototype for the model -- we're not actually touching the models. We're building wrap-arounds over the models so they can run continuously so that these two projects don't have to interact too closely. The spatial modeling tools are

currently in development as well through our Big Decisions Project. And, again, a prototype of those will be available at some point this year. Another whole in a lot of these assessments is we need to know where the use is, and from a GIS perspective we use land cover information as a surrogate for use. We've been pretty good at knowing more or less where agriculture use is -- where the agriculture is and what's being grown where. Some of these other uses have been a little more allusive, and we're trying to tackle some of those, especially urban uses, turf, and a lot of other non-ag uses. And we're working on land cover information for those as well.

And design validation, I think I cut that sentence off, but, you know, once we develop this -- the prototype environment, we'll certainly have to take it out and (inaudible) with our Science Advisory Panel and all the necessary steps before we can introduce this into the regular risk assessment process.

MS. MONELL: Questions? Cannon.

MR. MICHAEL : Yes. I just had a quick

point. We use GIS a lot, and I'm a big proponent of that technology. I would just like to point out that the mapping is only as good as the underlying data. And I hope that whatever decisions are being made from that are well understood by the people looking at the maps because the minor and alternate -- I'll say a minor tweak to something in a legend can lead to very different results and especially in statistical analysis, the way that you look at things and what type of normalization or what type of spin you put on whatever you're looking at can just incredibly change the way that a map comes out. So I just hope that the people who are analyzing the data and the people who in the end looking at those maps have a clear understanding of what they're being given.

MS. THAWLEY: I appreciate that point. And I will say as a GIS professional myself I spend most of my time repeating myself at work, making sure that our scientists do understand the nuisances of GIS data and how it's different in a lot of ways and the types of data that our scientists used to work in

this. So, yes, I appreciate your points. And I know I get old and tired to my coworkers when I go on and on about that. But, yes, we're working hard to make sure that's understood.

MS. MONELL: Larry.

MR. ELWORTH: I have a few questions. One is I noticed you mentioned design validation. What source of the data are you using for the watershed and sub-watershed? And also for the soil properties and in addition to validating the design, what are you doing to validate the completeness and appropriate use of the data sources for the kind of design and analysis you're doing? And then just one last question on that: What is kind of a projected time frame for actually using this in a regulatory framework moving away from -- I mean, generally when you think so that you're not relying on scenarios?

MS. THAWLEY: Right. As far as the source data is concerned -- that's why five minutes are tough -- when we came and presented in November, we demonstrated the modes, the NHD Plus, a hydrography data set, which is a new framework for spatial

modeling. It's a data set that was released by Office of Water this year that's been through a thorough EPA approved quality control process. The data sets that we use beyond NHD Plus at this point are all federal data sets that are in regular use in E-fed already, not necessarily in this particular way but certainly we use Statsco and Cergo (phonetic) and soil data, the mets station data which we use in our models now. In some ways the data sets that we're using in this framework other than NHD Plus are data sets that are all federally funded, all to have been thoroughly bedded and we use already on a case-by-case basis within our division certainly.

MR. ELWORTH: So do you use any less weight on soil properties database?

MS. THAWLEY: Yes. That's right.

MR. ELWORTH: Because NRCS has a --

MS. THAWLEY: We use -- the decisions (inaudible) database, I mentioned, is actually a collection of just about every single relevant or potentially relevant data set that has -- has to be federal test of meta data and quality control and all

those things.

MR. ELWORTH: Are you actually involving people from the USDA and some of this kind of goes back to Cannon's question?

MS. THAWLEY: Well, not only that we're obtaining data that's already out there for public downloads, so we're not going after any data sets that require telephone calls or arrangements at this point. If it's up on the website or if it's publicly available or if it's -- if we can order it through Cds, that's how we're -- that's the mode we're working in right now. This is the first step.

MR. ELWORTH: Well, there's always a theme so when I ask questions like this because I always try to figure out ways to get (inaudible) things to do. But it would be useful if you're making assumptions about -- because I'm familiar with some of the scenarios, and they're done that -- they're not even close to approximations of what happens on the ground, so looking at some ways of validating these actually represent not just -- this is what the land cover is with these risks, represent agriculture

situations will to be helpful.

MS. THAWLEY: Well, to be honest with you this is the early beginning.

MR. ELWORTH: Uh-huh. Uh-huh.

MS. THAWLEY: We will go through this process. I'm just a map maker.

MR. ELWORTH: That's okay.

MS. THAWLEY: We will go through this process, see how it works, how it -- you know, if it makes sense at all. And this is our first step. And it will certainly be many refinements over the years I would imagine on this process. So I'm not really sure where this will go, and hopefully that will be guided by our scientists and no shortage of data needs from the USDA, that's for certain.

Back to your time line for regulatory process, I really won't even try to take a guess at that time line. We're going to be delivering most of these tools this year. And then it will go into the process and it will be out of our hands and maybe you can get an answer. I'm not sure if there's anybody here from my division who could answer for me, but

hopefully soon we'll have a clear idea of what the time line will look like.

MS. MONELL: Jennifer and then Dennis.

MS. SASS: Now my question is also on the input data, I guess, because I guess I had the same reaction which is, wow, you know, your modeling is excellent and, of course, the input data is actually going to drive how valid it is. So I want to ask you about Slide 35, which is, is your concentric circle, and one of them is called stressor distribution and the other one is called receptor range and then the other overlap of the Venn is area exceeding level of concern. So I just want to make sure I understand it. Is your receptor range your target organism that you're concerned about --

MS. THAWLEY: Yes.

MS. SASS: -- like --

MS. THAWLEY: Yes.

MS. SASS: -- in an aquatic organ or plant or something?

MS. THAWLEY: Yes, that's right.

MS. SASS: And then your stressor is your

chemical --

MS. THAWLEY: That's right.

MS. SASS: -- that you're measuring. And then the overlap of the venn, the area of concern, is that coming from the bright line numbers of E-fed's assessment --

MS. THAWLEY: That's right.

MS. SASS: -- for that --

MS. THAWLEY: That's right.

MS. SASS: -- target receptor in this case?

MS. THAWLEY: Right.

MS. SASS: All right.

MS. THAWLEY: Sort of looking over there, I thought you were talking to her over there, but that's right.

MS. SASS: And then now when I look at Slide 35, you have like a big whack of red, if it fails and a big whack of green if it passes. But when I look at Slide 36, it gets a little more -- it gets a lot more precise. So I guess my question to you is how precise, based on these input data and based on these trigger levels of concern, which are

based on data that we've read and I'm not totally confident that those levels of concern are sturdy, and so when you start to use those bright line numbers to pair down, how precise are you -- are you going to say that there's a risk in this one stream?

MS. THAWLEY: No. No. Not at this point. That's actually part of our discussion right now is, you know, we can run this model a million times, but we will have to aggregate to some level a stream segments, (inaudible). There will be some aggregate answer, and that will be the unit, at least for now, that we will report on, and that is actively being discussed right now. This kind of also goes back to the issue of the data quality --

MS. SASS: Yes.

MS. THAWLEY: -- and the spatial scale and resolution --

MS. SASS: Yes.

MS. THAWLEY: -- and all of these issues. And we're fully aware of all these issues right now. But we think that given the data sets we have and being aware of these issues, I think we can still

move forward with what's out there right now. No problem.

MS. SASS: I tell you why I'm worried. Here's a parallel instance where this kind of technology hasn't been used, but this is why I'm worried. EPA is looking at atrazine in streams, right, atrazine. They're having the registrant measure atrazine in various scenarios. They identified 10,000 watersheds that EPA felt was at risk for atrazine, not measured, but potentially at risk. They paired those down to how many -- a couple of hundred that they were actually monitoring and measuring. And then of those, they identified a few that they felt now were at risk based on the monitoring, so now they're now only looking at those few. And it's never going back to those few as representations of that larger pool. So in the end, we might get mitigation on two places, let's say, for example, because that's pretty well how EPAs paired it down. And correct me if I'm wrong, but I have the data in my computer, and I don't think I'm wrong. So my concern is that this, you know, truly excellent

technique that you're developing in -- far in advance, I think, of the input data is going to be used to recommend mitigation for very small areas.

MS. THAWLEY: That's a bit of a leap, I think so. We will have to constrain the results based on the resolution of the input information. So I don't think we'd be able to draw conclusions, find detailed conclusions straight from that assessment. This will be a tiered approach by the way. So I gave you one outline of an approach. We have a few others, and we will tier this. So the outcome of an initial assessment will not be your -- this is where there is trouble and this is where there isn't. It just means this is where we have to look further. So we're not throwing out other parts of the assessment either. This is just one step along the way. The atrazine guys, they're here, if you want to say something about that, but this modeling -- the atrazine assessment was done sort of on a case-by-case basis. It wasn't part of our proposed methodology for the spatial risk assessment, and so I don't want to speak to that particular example

because I didn't work on that project.

MS. SASS: You see the kind of thing that I'm talking about?

MS. THAWLEY: Yes, I understand. I understand. And, you know, we're fully aware in the limitations of this step. And as a GIS person myself, I've seen this day in and day out, the level that the scientists work at now versus the level that I'm working at as a GIS person. I understand that huge leap and all of the implications and all the issues that we're going to have to deal with between those two. So I'm not saying we have the answers yet but we certainly aren't going to leap to the kinds of conclusions that you're concerned about straight away from this first effort.

MS. MONELL: Thank you very much. And Dennis, and then I think we're going to have to wrap this up.

MR. HOWARD: I just had a very quick question on the possible utility of a system like this would not only help EPA, but it could help us in state lead agencies as well as part of the plan to

make available to states the use of this type of tool on down the road?

MS. THAWLEY: I haven't -- we haven't had that discussion, but I would imagine that certainly these tools, the data sets, as I said before, are all publicly available information. I can't see any reason why these tools that we developed shouldn't be available as well. But honestly, we haven't had that specific conversation, but I can't imagine why we wouldn't make them available.

MR. HOWARD: It might be something that would be worth talking with the (inaudible) water quality and pesticide disclosal committee about.

MS. THAWLEY: Sure. And I guess the other thing I would say is that we're building this wrap around the model, around our existing model, but we're also keeping in mind to make it more flexible so that it could actually -- you could feed any points, model into this framework and be able to run it in the spatial mode.

MS. MONELL: Okay. Well, I was blind obviously when I said Dennis would be the last one.

We'll have Diane and then Michael and then we have to wrap this up.

MS. ALLEMANG: Thank you. I was just wondering if you've kept an eye on what, for example, universities are doing both to avoid duplication but then also to serve as a validation?

MS. THAWLEY: We haven't had that discussion. I'm actually from a university environment and from an environmentory adapt model (phonetic) in this way, so I'm familiar, more or less, from the environmental modeling perspective, not necessarily from exposure modeling. I don't know of any projects other than a project that's being developed through a consort -- an industry consortium, Geostack, which is a similar type of project, only taking a different approach. But that's an industry solution. Currently, I'm not aware of any university projects, but certainly for validation we would be looking out towards other places to see what we could bring in for validation. It's not something we've talked about.

MS. MONELL: Michael.

DR. FRY: Thank you. Couple of questions to follow up on Jen's question on the venn diagram. What universal receptors are you looking at and how finally are you going to do these with endangered species?

MS. THAWLEY: For now we're just taking one specific exposure model, quality exposure model to run through this process, so that's what we're limiting it to right now. But, as I said, we're developing this framework so that we can swap models. So, in theory, it doesn't have to just be aquatic exposure models that we put in there. Any of our models we could swap in there. So this prototype is just for aquatic exposure modeling.

DR. FRY: And the other is who is the work group that you are addressing in November?

MS. THAWLEY: This is the PPDC process -- process improvement work group, yeah.

PARTICIPANT: The subcommittee of this entity.

MS. THAWLEY: And there's a presentation, I believe, that these are being archived. There's a

more thorough presentation five minutes or top, but I think that one is a much longer and more complete with a lot of references. So and, you know, if you'd like, go back to that presentation, you could get a lot more information.

MS. MONELL: All right. So as you see, we've been doing a lot of work. I want to encourage you if you have any ideas for process improvement in the registration process, contact Elizabeth LaVaye. Raise your hand, Elizabeth. She is our senior advisor for PRIA implementation, and we're anxious to continue improving our processes. Thanks.

MS. EDWARDS: Okay. Thanks to everyone that participated in that session. Obviously, you share my excitement about this being an emerging scientific area with GIS layers of bringing science. And I think they're going to help us tremendously in the future as we try from a federal position to regulate very locally so that we can take care of the risks without huge impacts on agriculture. So there will be more to come on that.

Now we're going to move to a short session

on diagnostic biomarkers with Jack Housenger, the Associate Director of the Health Effects Division, giving you some of our preliminary thoughts about how we might most effectively tackle that issue.

MR. HOUSENGER: Too bad Oscar is not here. I have my own name tag. I'm kind of a sit-in for Tina who's recuperating very well at home after surgery. So I was told I was going to do diagnostic test, really didn't know too much about it, but here goes.

Next. So what do we mean by a diagnostic test? A simple to use, relatively inexpensive tool that -- with quick readout that physicians can basically determine what -- for people that are exhibiting symptoms that may have been exposed to a pesticide, whether or not they've been actually exposed.

Next. So how is this useful? Obviously, if you can tell what pesticide you've been exposed to, it can lead to improved treatment. It can also help us in interpreting incident data that is currently pretty difficult to interpret, knowing a

lot of the symptoms that we see are similar or similar pesticides and not knowing what the exposure has been, what people have been exposed to and even sometimes the level. And this can lead to better risk assessments, better risk management decisions.

Next. It's interesting because in food, we have methods that will determine not only the identity but the level of residues. We have a multi-residue method that's an easy, cost-efficient way to determine what pesticide is present and at what levels. The workers, there's really no comparable way to determine the identity or the level of a pesticide.

Next. So just kind of queue up this session to get the committee's input on what are some of the questions asked, what -- like what chemicals, class of chemicals are diagnostic tests important for? Should we also be able to identify the level of exposure to a pesticide? It's just showing that you're exposed to a pesticide doesn't mean that the pesticide actually caused symptoms if you weren't exposed at high enough level. And, finally, what's

the best way to start this discussion? Should we have a planning session in advance of a workshop? Should we go right into a workshop?

Next slide. And who would be involved in kind of these discussions? You can see a list of people there who obviously have a stake in this topic.

Next. In October, there's an Occupational Safety and Health Symposium at the Hilton, I think, up the street. We could do it in the morning before, the afternoon after. If people thought we could have it before, I would be interested in hearing it, and I guess I would like to open it up for comments, suggestions, something.

PARTICIPANT: So, Jack, I guess we're still trying to understand what the problem is that needs to be addressed from what we understand about the emergency room inquiries and the like and what we think we know about diagnostic methods and/or biomarkers. We don't see the point of connection there and, you know, perhaps that's the same question you're asking.

MR. HOUSENGER: Well, I think that's -- yeah, I think that's one of the questions. I can see a benefit in being able to say this person -- from the Agency standpoint, this person was exposed or a number of people were exposed to this pesticide and look at what our risk assessment say. And if we think people are trying to be, you know, adequately protected, but people are still getting sick, there's something wrong with how we're doing things. Maybe it's that they're not wearing proper protective clothing or whatever. But if you see that happening time and time again, I think it's kind of the feedback look to your risk assessment to say are we really doing things right or not and should we put other protection in place to guard these -- you know, guard for these people.

PARTICIPANT: But there's a notion that there are not adequate tools available to the medical profession and the Agency today that you think there are significant gaps that need similar technology or regulatory requirement, or is this much more ephemeral stage than that?

MR. HOUSENGER: I think the latter, and I think it's beginning a discussion are there the tools out there, so what are the tools and maybe we need to make them more widely known. My sense is that there are not good quick, cheap tools to identify pesticide exposure.

MR. KEIFER: This is Matt Keifer. Can you hear me?

MS. EDWARDS: You need to speak up a little, but we can hear you.

MR. KEIFER: Okay. I'd like to point out as a -- somebody who does research on health effects of pesticides and somebody who sees patients pretty regularly.

MS. EDWARDS: Could you speak up a little bit more?

MR. KEIFER: I'm one who sits on the Incident Tracking Panel in Washington state for the last eight or nine years. We are definitely in a need -- in a -- we have a very severe need for diagnostic tools to make diagnoses. There's way too many times that we see cases come in with a great

deal of uncertainty as to whether or not a person's been exposed to a pesticide or they're suffering from a viral illness. The only one we really have on hand at the present time is cholinesterase, and that's a pretty weak market because we always need a base liner in order to compare a person's exposure to it.

So I would emphasize from a clinical perspective this is an extremely important thing for us to enhance the surveillance capability of all surveillance mechanisms for pesticide surveillance to give certainty to the diagnoses this is critical. And I would also add that one of the things that we've talked about particularly in the worker protection standard discussion is that the rules we have today that protect workers are based on preventive activities, but we don't have a way of knowing most of the time whether overexposure is, in fact, occurring. So not just the diagnostic value of these tools but the biological monitoring value of these tools should also be emphasized. Both of these goals should be sought after at the same time.

On that, I'd add that I think if we limit

ourselves only to an understanding of biomonitoring or diagnostic methodology as just measuring a chemical in blood or urine we're missing several opportunities, such as syndrome or syndromic presentations that are characteristic of a particular kind of illness related to a chemical. If we -- there's been little -- so little work done on this in terms of characterizing it, particularly with some of the newer chemicals, that there may be some very characteristic what we call pathopneumonic presentations of chemical illness, chemical-induced illnesses that may serve as biomarkers. But I'd just like to keep the idea open so a work group could talk about this, I think, would be very appropriate with a pretty broad spectrum of participants because there's a lot of different things to talk about. That's all.

MR. HOUSENGER: John.

PARTICIPANT: It's sort of a follow-up to something that both the questions Jay and the other question. What exactly is the goal. Is the goal to provide with the name says biomonitoring, be able to monitor workers in the public for simple exposure, or

are you trying to develop diagnostic tools, tools of injury because they're often two different things?

MR. HOUSENGER: I'm sorry. Tools of --

PARTICIPANT: Of either trying to provide -- they were talking about basing -- starting the program with the general information that's been developed over the years from emergency room. Toxicologists have used them for years, but they're looking not only at a particular exposure, (inaudible), they're looking at an indication of an injury.

MR. HOUSENGER: Right.

PARTICIPANT: Other states, other -- the work force over in Europe, for example, they do just plain old biomonitoring where they're just interested in the exposure of workers. Is the goal of this program just to develop an estimate of overall exposure to pesticides, or are you trying to enhance the ability to do -- you have a slide up there that it would provide a definitive cause/effect linkage? That's an injury. That's not just biomonitoring. That's looking for injury.

MR. HOUSENGER: Yeah. Well, I think the people that I listed on possible participants, certainly -- public health workers, medical community, I think would weigh in here in terms of what's most useful to them. I guess from the Agency standpoint, it would be good to have that knowledge if the tool exists that you could basically say this person was exposed to this pesticide, exhibited these symptoms. We determined that, you know, through blood or urine that they were exposed at these levels. I mean, that would be a great thing. I'm not sure that we can ever get there, though. So I think that's kind of the purpose of this discussion or the planning work -- you know, planning for a workshop or a workshop. What are we actually talking about.

MS. EDWARDS: Yeah. I'm noticing that there's an enormous number of cards up, and I want to make sure that people understand that this session today is not where we intended to have the meeting that Jack is talking about. The reason we put it on the agenda, to be honest, is that we are hearing

from -- repeatedly, from the public interest groups, in particularly, the farm worker advocates and Dr. Keifer, not just here in this venue, but in other venues that this is an area that we need to look into and take seriously. This is a significant concern for them.

We admit that we don't fully understand exactly what we think is needed. We think it needs a lot of discussion. You know, is there -- for example, we start with is there a problem and then really define the problem. We're probably not going to seek diagnostic biomarkers for 800 and something pesticides. You know, you're going to start out with where you really need, if you need, you know, to go in and figure that out and what's the best venue to get the research done and what's the most practical to provide to doctors and so on and so forth.

And so, if what your card is up for is to weigh in on that opinion, our goal is to have a session where in you would be able to do all that and, hopefully, we could come to some consensus on what priorities might be, what some path forward be

and some articulation of what the problem is more clearly, so just to give you that. We're a little bit behind already, but I don't -- you know, I don't want to totally shut it down either, so.

MR. HOUSENGER: I didn't see any cards go down.

(Laughter.)

Well, why don't we start -- well, thank you, Susan. Let me just start around the table here and I guess Carolyn will begin.

MS. BRICKEY: I thought it was worth pointing out that the Agency for decades, I think, has made a step in addressing what I think the basic issue is by publishing that Recognition and Management of Pesticides Poisonings book, but I think the medical technology has, you know, outstripped what's in that book. We now have the potential to do a whole lot more precise biomonitoring diagnostic tests. And so I think what we're asking is for the Agency to kind of move into the 21st Century here in terms of what's available for medical technology.

PARTICIPANT: I just wanted to say this is

not a reason to go down this road. I just think it should be gone down with eyes open, which is I don't see how at some point you don't avoid human testing to make sure the thing really works, unless you're satisfied that it works on a rat and that's going to be okay. You're going to end up human testing that that's a nice big (inaudible) for you to step in, Jack.

MR. HOUSENGER: Yes.

PARTICIPANT: I can see several reasons why the Agency would want to do that and develop some biomarker data and I, as a toxicologist myself, who runs studies that go through my IRB, I understand all the problems. I see John's point about two diverse reasons here, and I think that's very important. I think you have a possibility for using it for surveillance, a possibility for using it for diagnosis and remedy, and those two are very different. And I think if you're going to look at these kinds of things, Matt Keifer said, you want to know about overexposure. If you're going to know about overexposure, you have to know about regular

exposure, base line exposure. And you have to know something about the levels at which you start seeing symptoms and adverse effects. So you really are going to have to do it at different levels. You don't want to just -- you're really going to need to be developing all kinds of data from this and all kinds of -- getting really good data that will be useful and not just markers of exposure unless all you want to do is classify who -- what's exposed, and we can sort of figure out who's exposed by knowing what they use.

So if you want to go further than that, you have to have much better data, and you have to spend a lot more time and money. It will require some use of humans, and whether you do that with people who are already in the work force and already exposed and set your tests that way, which is obviously the way you're going to have to try to do it, that's going to be a hard job.

PARTICIPANT: I'm just looking at who would be the potential participant and I guess it's kind of adding on to what Diane's saying. Obviously, it's

going to involve some type of human testing at some point. So do you bring in the HSRB early-on or after some, you know, initial discussions. But I think at some point you want to (inaudible) the issue through the HSRB.

PARTICIPANT: I think it would be the people in this room, wouldn't you? It's a joke, okay.

(Laughter.)

PARTICIPANT: I just wanted to say that from (inaudible) network point of view where our front line providers are seeing farm workers exposed that I really commend the EPA for wanting to take up this issue. It's incredibly important and, you know, I have a number of goals I would like to see addressed in a work group like this, but we'd be satisfied with diagnostic. We'd be satisfied with surveillance components. And I also am very impressed with this group that you are all so concerned about human testing. That's great. And -- but we really think that this is a great idea and really are happy that you're looking at it.

PARTICIPANT: Well, as I've listened to more words spoken about this, it seems to me like there's a lot of stuff being mixed up here, biomarkers, biomonitoring, medical concerns, it seems to me that the top two organizations you have listed in this chart is where this ought to go. CDC and for EPA, the Office of Research and Development. And the Office of Pesticide Programs maybe contributes to this. But if all these things are vitally needed in the emergency medical treatment community, why are we starting here and what expertise does OPP have other than to contribute to a larger initiative. But I just -- as one member of this advisory counsel oppose EPA spending more resources at this level. If there's a need, it ought to be heard at CDC and ORD, and OPP should respond.

MR. HOUSENGER: Shelly.

MS. THAWLEY: Thanks. There are three different purposes that I see this being used for. The first, as Matt said, is to help clinicians diagnose people, including farm workers who may have been exposed to particular pesticides. And I think

it should clearly be laid out. The only available -- widely available clinical tests we have right now is cholinesterase and that only covers a very limited set of pesticides, primarily organophosphates and only a little bit carbamates and the rest not. So that's kind of where we are in the clinical side.

Now things have gone forward at the CDC in terms of detection, ability to detect pesticides in the human body and this primarily through urinary metabolites, and that's just not available as a clinical test. So obviously the CDC folks would have to be involved. I think RD would have to be involved. But the one I think -- so anyway, one of the primary purposes is diagnosis. But I think another primary purpose that Matt also mentioned is prevention. I mean, one of the things that we have now you use cholinesterase for is a prevention model, you know, medical monitoring and, hopefully, for other classes of pesticides we could get to that point. And I think the third thing is what Jack said about a feedback loop to EPA's risk assessment.

So where is OPP in all this. Well, OPP is

a player because you are putting that risk assessment and you don't know how good they are. So you should be incredibly interested potential consumer of this information. So, yes, we're going to you because you're one of the players in this game. But no one has asked you to do this alone or go it alone. The CDC should be involved. The Office of Research and Development should be involved. But somewhere along the line this has got to get off the dime. I mean, we have limped along four decades with just one widely available test. And, you know, basically we're here to say that's not good enough.

Right now, I mean, part of the reason our incident data is so weak and everyone is always concerned that we really can't rely on it is because we don't have these widely available diagnostic tests which would not just say exposure, but exposure that potentially could cause adverse effects. So you definitely are wanting what we're calling diagnostic tools. That will be an immeasurable dual benefit to everyone sitting in this room. So we should all be, you know, behind it. And I'm shocked that anyone

would be opposed to it, to tell you the truth.

But in any case, starting with the workshop is a good thing. I think there are -- there are now a lot more players who have begun to identify biomarkers of exposure to pesticides which could potentially be used as tools in this process. So I think there are, you know, a number of obvious interested players, you know, the CDC, there's this whole research community focussing on exposure biomarkers, and we really welcome EPA beginning to articulate these problems and bring together folks who are interested who could think on it. I mean, nobody is thinking that, you know, in November we're going to have a test that's going to go public with 2.5 million farm workers. This is the beginning of the journey. But if we don't begin, we'll never get to the end.

MS. EDWARDS: Lori, is that your card? Larry, is that your card?

PARTICIPANT: (Inaudible), but it's mine.

MS. EDWARDS: I think this will be the last one, and then we'll actually do a break, but go

ahead.

PARTICIPANT: Well, thanks for concisely raising this issue for us, Jack. I -- my concern about this is not, I think, the merits of the issue of what's really considering (inaudible) obviously some needs medically. I really -- and Jay may want to revise his remarks if he finds that I'm saying something similar to what he said.

(Laughter.)

PARTICIPANT: But I do think it's important that the role of OPP in this be real clear. Obviously, there's a lot of people doing a lot of research on this. You folks ought to be involved and make sure that whatever research comes out, serves your purpose. But I would hate to see y'all get dragged into the research and it really pulled you away from the (inaudible). So thank you, Jack, once again.

MS. EDWARDS: All right. Well, we'll be back to you on this in terms of what kind of venue we'll use to have. It's almost like a problem formulation meeting, to tell you the truth. You

know, exactly what is the problem and what should we be doing and who should we be interacting with, so. It is -- it's seven minutes until three, and I'm going ask you to be back at five minutes after three, and we'll start on time. We're behind, but we'll see what we can do to catch up. Thank you.

(Whereupon, a break was taken.)

MS. EDWARDS: Okay. Thank you. I just want to do one more bit of clarification about that last slide. What we're talking about at the moment is one meeting, probably half-day meeting or full-day meeting, whatever's more appropriate, depending on the agenda, for problem formulation around this issue so that the Agency can better understand what a path forward might be. We're not talking about a subgroup of the PPDC right now. We think that's -- we're not ready for that yet. We need something to flesh out the issue a little bit more and determine what the problem really is. So I just wanted to clarify that because I heard some people were thinking we had declared we were having another subgroup or work

group, and we're not there yet.

Okay. Let's move into the -- speaking of work groups. The work group on worker safety, and we have Kevin Keaney here to lead that session.

MR. KEANEY: Let me take a few moments to reacquaint you with the process we're involved in and the nature and scope of the work of this particular work group. We had conducted a number of assessments of pesticide worker safety programs, the programs that are related to the ag worker protection regulation and the certification and training of applicators program and regulation. We did a fairly extensive set of meetings and workshops and projects coming out of those workshops ending up in a national assessment report that's on our website, arraying a variety of concerns with these two regulations and the programs that they drive and presented some of the results of that to the PPDC, which evidenced much more interest in specifics and involvement in the process. So the work group -- this particular work group was formed after our general presentation to the whole PPDC of what we had discovered in the

assessments and some of the intended focus areas for regulatory change.

So in February -- in February of '06, we met for the first time with the work group that was formed, gave the regulatory charge that we were pursuing and described the role of the PPDC subgroup in this activity and reviewed the current issues, reviewed essentially the focus areas coming out of your national assessment, discussed some of the issues there and framed out some activities for further discussion, some more specific focus areas.

And in the next work group meeting -- I'm sorry, could you move that back. And in the June meeting, we ranked the issues after the members had -- had seen them and worked through them. There was a general request for more detail. We framed out -- my staff, rather heroically, worked through the issue papers and expanded the issue papers with more detail, and we conducted conference calls, 20, I think, is an underestimate of the hours we spent on conference calls, with the group going through the particular issue papers. And the group then

submitted written comments to us.

Now in the course of setting up e-mail lists and conference call notices, the group expanded from a fairly manageable size to meet with physically to more than 70 folks on some of the conference calls that we had. The antimicrobials group, particularly, was concerned about the scope that we were envisioning in the regulatory change, and there were some very specific issues that were not common to the more conventional pesticide use groups. So we split the antimicrobial group off at that June meeting dealing with them in a separate track with added conference calls and issue paper expansions.

In November, the variety of comments that had come in from the work group to that point on the issue papers were -- and the issue papers themselves were placed in the docket -- in a docket, and that meeting was devoted to the discussion of revised issue papers. The issue papers were evolving and a little bit of expanding expedientially as a result of comments and involvement of the work group and others.

In the May meeting that we had, the schedule was revised to accommodate added stakeholder involvement. So our initial schedule was quite aggressive, but it's changed now so it's the proposal date of December 2008. The issue papers were continued to be revised and more options presented and more robust rationales presented as a result of the comments. The number of papers or issues were linked in such a way that they were combined. Those were overlapping were combined as a matrix, I think that you can see the variety of issues that we're dealing with.

The next steps that we have are two-tracked actually, our internal work and then work with the work group. We will continue to analyze state program information and do information gathering there. We're going to be also working with a contractor on the economic analysis. And when that is in a releasable form, the work group will have access to that. We'll begin developing the regulatory proposal in preamble language. We'll essentially be bringing the work internally and going

to the particular work that we have to bring something to a proposal stage within the Agency.

In the spring of 2008, the full PPDC will have an SRAI presentation of the state of play, the state of our regulatory development play at that point.

As far as the work group, they will continue to review the issue papers that they have and the ones that they still will get and give us comments on all of this by June 15th, and all of this will be factored into our regulatory development.

Now the work group itself will report back to the full PPDC the fall of 2007. So I'll be working with them in conference calls to help facilitate the development of a report back to you to the full PPDC. And, as I said, that will be in the fall of 2007.

Now, as we have been doing, we'll present back to this group the results of the preceding day's meeting, and that's what we'll do next. The various stakeholders will report back to you, and we broke the interest groups out in this way, non-ag use,

ag-use, the states, the extension service, and the worker advocates. So Bob Rosenberg would lead off from the non-ag use perspective and give a report back on yesterday's work group meeting -- well, a whole series if he needs -- if he cares to.

MR. ROSENBERG: Hundreds, in fact. And just so you know, we've been sacrificed at the alter of functuality (sic). We've been told that we can't put on the very elaborate multimedia power point presentations that we had prepared, so this is going to be extremely brief. Look, you know what, I think Marty said this earlier today, you know, the field programs have always been considered kind of a boutique, a bit of a back wanderer. We've spent lots and lots of time at these meetings and probably over the course of the last 30 years talking about product-related issues, risk mitigation measures, label improvement. And while those are all extremely important, there are a lot of us, you know, particularly those of us who represent applicators who think that there's probably not anything more important than a comprehensive high-quality

certification and training program that it's the -- that it's the, you know, cornerstone, the backbone of an effective regulatory program. There's not any amount of improvement for labels that you can make or mitigation measures that can be applied that if an applicator does not understand them and do it, that will improve or change anything. So we applaud the Agency, number one, for bringing this issue to the forefront in a serious fashion for the first time in probably 30 years.

I'm going to talk very briefly. There's all kinds of very distinguished, bright, much more qualified people than me that are going to be talking. Some of them are even doctors, like Amy. They're going to talk about the specifics. The one thing that I did want to talk about, just very briefly, was a one unique perspective that I think commercial applicators have on the issue of certification and training. We support the Agency's efforts to toughen the standards. We want to see the scope of certification and training programs expanded. We want better competency gauges, and, you

know, we're pretty much on the same page where the Agency's going. There's been a remarkable amount of, well, concordance agreement amongst folks on the work group. This has not been a terribly contentious work group, I'd say, which is kind of refreshing.

The one unique circumstance I want to talk about, though, is this, and this just maybe applies to lawn care companies, pest control companies and maybe a small other group of commercial applicators. Folks that I represent, pest control operators, typically don't do business in one place, unlike, say, a farm that's located in a single county or state or a business that's geographically located in a single place. Folks that I represent, commercial applicators, routinely do business in many jurisdictions. For instance, and an example I'll give and always do give is if there's a pest control business located here in Arlington, even this very small pest control business, a mom-and-pop business, in all likelihood, that person will do business in Virginia, in the District, in Maryland, maybe in West Virginia, maybe in Delaware.

In the structural pest control certification and training world, those persons have to be licensed, trained, and certified in a -- they have to take a core exam, and typically, have to also be credentialed in a variety of categories. So, for instance, in structural pest control in other areas that are the same way, they're typically in the state schemes are general household pets, termite control, food processing. Some states have school ITMs. Some have fumigation. There is as many as 10 different subcategories within structure pest control.

Here's my point. A single technician doing business here in northern Virginia, running a route that covers this multi-state area, could conceivably have to be tested in and tested differently in each of three, four, five jurisdictions in each of five, six, seven, or eight different categories. Where we very much support training, we tend to be very supportive of testing.

The one thing that we would love to see come out of this process -- we think this is probably -- well, I think it's reasonable to say it's

a once in a life time opportunity to bring up the bar on the federal certification and training requirements. We hate to see us miss the opportunity to try to encourage greater consistency between the jurisdictions. We'd love to see Maryland reciprocate with Virginia, reciprocate with D.C. -- well, we'd even like to see it go further than just simply reciprocating. We don't understand why it's really all that necessary in this era of very scarce resources for each of 50 state lead agencies to have to develop categories, have to develop examinations, many of which are some cases 20, 30 years old, and the instructional pest control examines talk about the use of cloridane and heptachlor haven't been updated since then.

Cu have to be evaluated in each and every one of those jurisdictions. We think there's a really good case to be made for some kind of uniformity. Let's have a single set of categories. Let's have a single set of content for those categories. Let's have one set of examinations. Let's have one set of CEU requirements. I know it's

difficult. I know there's a lot of folks that, you know, may see it differently. We just hope that in this process there's at least some dialog around that. Instead of having each one of those 50 states to, you know, use those very scarce resources, replicating what the other 49 states are doing, we'd love to see some way to see that some more consistent or more uniform system.

Anyway, that's the bottom line. We applaud the Agency. We think you've developed an extraordinarily transparent stakeholder driven process. We're grateful for the opportunity, and applaud everything you've done.

MS. RAMSAY: All right. I'm going to follow up that up. I'm Carol Ramsay with Washington State University. I mean, you give -- you talk about certification and training, and I don't have any power points, but two handouts came your way. One is strictly just the issue papers, and I wanted that just so you could see that there's a lot of issues that are the table. On many of those issue papers, there's many options and sub-options. So what I

tried to do is take five of -- or four of those issue papers for certification and training and boil them down into the single legal sized matrix. And so if you look at the table that you've got, I basically am just trying to get across to the full PPDC the complexity of the issues that's being taxed by EPA and the work group. And I've used different names for categories than EPA has on some of their issue papers just to be a little bit more descriptive, and so you can look at those through your leisure. And then I have a column that talks about the scope of the people that are affected in each of those potential categories as well as kind of who the regulated community would fall within that particular category. And then the functions of those particular certification levels or technician levels would allow that individual to do, what sort of access to products would they have. And then competency gauge we've been talking about training, testing, those issues. We've shown some of the options that might be considered depending on the different category and the different responsibilities.

Another issue that we're dealing with within certification and training is should there be a minimum age for application? Should there be minimum ages for certification? And so this -- we can't tell you everything that's going on, but I think this shows you that it's a pretty complex set of issues. And the two issues that came up this morning, the lawn care company and the government employee that was probably doing some blackberry control in the alley way, chances are, those individuals were not required to be certified because they were using general-use products. And if you see in this chart we subtilely added that this would include not just restricted use pesticides, but also in some circumstances general use pesticides as well. So it is -- it is a very broad expansion potentially of the scope that would be impacted by certification and training. Thank you.

MR. ANDREWS: Hi. My name is Chuck Andrews with the California Department of Pesticide Regulation, and I'm going to be talking about some of the impacts on the state lead agencies for

certification. And Dale Dubberly is going to be talking about impacts to worker protection. I also have a handout that was passed out earlier. It's a one-page back-to-back.

First of all, for CPA is looking at raising the bar to improve the CNT Program. Several states have expanded the program, and I think one of the things that we need to do is take a look at what the potential impacts are to states overall with what's being proposed. There are three areas -- three issue papers that we're looking at right now that we discussed at the worker meeting yesterday, and that's all I'm going to be talking about. One is expand the scope of applicator subject to regulation. The other is ensuring that occupational applicators of potentially harmful pesticides pass a reliable certification exam to determine their competency, and also to improve standards for the use of restricted use pesticides.

The first issue on expanding the scope, I think broadening the scope to include all employees that handle pesticide or the occupational users could

have a significant impact on the state regulatory programs, could reduce our ability to enforce laws and regulations without additional resources. Since the expansion could include actually -- we don't have a number, but, you know, I expect it could be up to millions of applicators involved. That's also including the bio side uses, which is actually being addressed in a separate issue paper.

The implementation of these extensive changes to the program, all at once, could be difficult to achieve. We're looking at possible changes to state laws and regulations, development of examination study materials. The outreach to the new regulated community if it's including, you know, all occupational users, is a broad spectrum of use settings, though a lot we have not regulated in the past other than use and compliance with the labeling requirements. And then also just development of a database and testing of employees.

One of the things that we think is important is that EPA has initiated this is for them to finish their evaluation of all the state

certification and training programs, the matrix of that, to really look at the overall impacts to state-lead agencies.

Some of the questions that I'd like to pose to you is whether or not data supports the scope of this proposal, and that's something I'm sure that we'll be addressing in our report to you in the future. The risk of -- associated with incidental use of bioside is a, one, regulatory oversight and, of course, EPA has not made a decision on that. So that may not be an issue. And then should we look at modifications to the proposal to address higher risk pesticide use settings, whether or not that's appropriate or not.

As far as Issue Number two, and that's really to look at a competency gauge for occupational applicators. We're concerned with the EPA only accepting an examination process as the only means to gauge competency. If the scope is expanded for all users -- as I mentioned, it has a significant impact on setting up on exam process for all those applicators -- we suggest as an alternative

considering training, possibly both classroom and on-the-job training and our regular compliance inspection activities to determine the competence of pesticide handler that's been trained.

Again, I think we're looking at asking the committee to consider whether an alternative competency gauge is appropriate for certain pesticide use settings. And we're actually not opposed to setting up exam process for, I think, the higher risk situation.

Issue Number Three, we feel that if the program is expanded to include competency gauge, then we think that this issue isn't as critical as it is at this stage. If we have, you know, an examination process or training of all occupational users, then we think that, you know, the supervision isn't as critical. Thank you.

MR. DUBBERLY: Good afternoon everybody. My name is Dale Dubberly, and -- oh, yeah, the power point.

PARTICIPANT: Lori.

MR. DUBBERLY: Oh, okay. Sorry.

MS. BERGER: Okay. My name is Lori Berger. I'm with the California Specialty Crops Council, and I sit on the work group. And we were in our meeting yesterday, and I'll be talking just some general comments from the ag sector, and that includes commodities, registrants, trade groups, farm bureau, etc., and (inaudible). Thank you, Steve. Thanks.

Next slide, please, Joanne. Okay. First of all, I just want to say that -- yeah, I do have slides. I gave up my (inaudible) to do five slides. Labor is very important to us. And no matter what level of worker we're talking about, as Bob said, certification and training is really important to protect all interest involved.

Right now in agriculture, we have a real shortage of labor, so it really behooves us to do everything we can to protect the laborers and just preserve that tremendous resource. This is true from specialty crops to major crops, and we have a great incentive on many levels to protect our workers. And stewardship is definitely our goal.

Next slide, please. Okay. We do support

certification and training. And all of the issues that Carol summarized and we've been discussing -- I mean, the information this work group has been going through is voluminous, and it's very, very complex, and it can't be covered right in a half-hour session. The training is critical to safety. We need to determine what training is most appropriate for the task. There have been comments on how often we have training, the different styles: Do we go to the Internet? Do we go -- do we send out DVDs? Do we develop info cards? We need to find out what works best and figure out the most cost- and time-efficient way to deliver that to different layers of the work structure in agriculture.

Next slide, please. One of the things that haven't been touched upon that is going parallel with all of these issue papers is that EPA has contracted out for an economic analysis. On the ag side, and I'm sure from all other sides, it's really important. If we're talking about the many levels -- many ways we could approach this issue area, we do need to assess the cost. And so they are working on this,

and we would really like to respectfully request that this is part of the PPDC presentation from this work group at some point in the future. We just really feel that that's a critical component of this. And we should evaluate the relative values of not just a new regulation, but the training certification and, very importantly, communication. I mean, we just -- even if we add regulations, does it merely make it safer in the field? We need to put all these things together. Many times it is simply a communications issue and being a good neighbor, you know, last minute decisions that are poorly made. We need to figure this out as far as overall safety of everyone in the field.

Next slide, please. So our concerns are the effectiveness of the proposed changes and way that we can deliver certification and training. Also, some of the methods -- some things being proposed sort of like info sheets or fact cards for different crops we just would like to see are these -- are we realistic. We live in a -- I live in a state where there's over 250 crops grown. Is this

realistic with the multiplicity of languages, crops, etc. Also, the availability of cooperative extension, state pesticide training. All of these programs, where are they? Where are they going? They've been our traditional needs to deliver most of this training. And then also just the cost of these programs, we're really concerned about that.

Next slide, please. I think I might have left something out that it's alluded to in Carol's comments and that has to do with there's an imbalance -- or we need a harmonization between state and federal language and vocabulary. There's things like competency versus certification, just a lot of terminology and lingo that it really makes it hard to put it all together. So it would really be good to have common language when we think.

And then, finally, I just want to share that we consider training as an incentive. To the businesses that are involved, this does help reduce insurance costs. And then also when someone is trained, it does help on an individual basis, to help them recognize their individual contribution to

safety in the workplace. So those are our comments and you're on.

MR. DUBBERLY: Thanks, Lori. If I can ask you to pull that power point up. What I want to talk to you today about is the complexity of the worker protection standard, and we've been working for a couple of years, as Kevin pointed out in his presentation, on trying to get our hands around the issues and narrow the issues down to what we think maybe workable. And I'm not going to try to cover all the issues, all the options because we don't have enough time here today, by no means at all. But what I do want to do is -- can you go to the next slide, please -- just to tell you that we're working on a pretty fast time line here. We have to have our comments back to the three issues that we discussed yesterday by June 15th. And the fourth issue, we haven't even had the opportunity to review that issue yet. So I think I'm speaking for the work group that we may need a little bit longer period of time here to actually do justice to reviewing these issues here. So we may have to talk about that time line

there a little bit providing the comments back on this.

Next slide, please. Just to give you how complex the issues are, when we just started out, we basically had 39 issues that were put on the table.

Next slide, please. The four that we're going to narrow down to -- but before I go there, let me back up -- we had 39 issues. Through those various conference calls, 20 plus conference calls, we narrowed those down to, I think, 15 issues through the conference call process, lots of hours, lots of work has gone into those. Now we're down to, I think, seven issues, and I think that's on this handout here that we basically had seven issues. But I'm going to run through basically three with you here today and fourth, as I mentioned, is one that we haven't had the opportunity to review or comment on yet.

PARTICIPANT: (Inaudible.)

MR. DUBBERLY: There's a single sheet says --

PARTICIPANT: (Inaudible.)

MR. DUBBERLY: There's a handout that says issue papers for May, 2007. That's how complex this is. We have lots of paper.

PARTICIPANT: (Inaudible.)

MR. DUBBERLY: Well, we'll get to that one, too. We'll get to that, right. It has combination CNTN WPS. Okay. So we started out with 39, reduced it to 15. Yesterday we talked about three, and we're going to have a conference call on the fourth one here. However, there's a couple that we took off the table, and those were WPS 5, 6, and 7. So we decided not to even go there yet with those WPS issues. The first one is probably the largest complex change we would be recommending in this program here. I made a mistake to show you how complex this issue is. Actually, it's one issue talking about establishing a hazard communication program. Actually, there's six issues under this issue of hazard communication program where 22 options for consideration within this particular issue. I'm not even going to attempt to go into those options here today, let alone the issues. I think the paper will be made available to

everybody. You will have the opportunity also to comment on that, also. We haven't agreed on any consensus within our WPS work group on any of these considerations or these options.

Next slide, please. We also have the second one is talking about training, administration issues, retraining intervals, grace period associated with training. There's five options in there, just that one particular area of re-training and grace period. Options for competent trainers, there's four options under that.

Next slide, please. And then also wrapping up that particular issue there, options for recordkeeping, there's five options there for consideration.

Next slide. The third issue is also talking about the expansion of safety training content. There's five options under consideration there.

And the last one, next slide. This is the one that we kind of grouped many issues in dealing with anything from enforcement of worker protection

standard to any other issues that may have come from those previous 39 that we started out with. We haven't reviewed the entire proposal. We're hoping to do this one by a conference call, then we'll have some options under consideration. The point today is that we're down to basically about four issues and about 40 something considerations to take into account. So we've been working real hard, and I really want to thank the subgroup for working diligently on this. We've kept it on the best time line I think we can, but -- next slide, please.

The report back from our subgroup to the full PPDC, I'm not sure we can meet this summer/fall deadline, so we're trying, but we may have to push back a little bit here from our perspective to do diligence to these considerations that are under these issues. They're very important. Do not get me wrong, but I think we need to take our time, proceed very cautiously and tread water very slowly on some of these issues here and make sure that we make the right decision here. And I thank you for your time today.

MS. BROWN: And I'm Amy Brown. I'm going to be presenting the cooperative extension viewpoint on the worker protection. Just to -- I had not planned to say this, but we never seem to get enough time to really point out the scope of this, and it's really hard. You can see how complex and what a huge scope this is. If you go back to this table that Dale was just talking about that has the CNT issues and the WPS issues, I imagine that many of you don't really understand fully the difference between CNT and WP.

The CNT generally have to do with those who actually apply pesticides and the worker protection. Some people who apply pesticides but more to people who are exposed to their residues by going back into the treated fields or treated areas. So -- and they have different histories of why they develop, but they both have to do with providing training and regulating those people to some extent. So I'm going to be talking about cooperative extension perspective on just the WP issues, just the worker protection issues today. Carol will address the CNT issues.

The first paper that we did look at, as Dale said, was the hazard communication which is basically to provide pesticide specific hazard information to workers and handlers. And, generally, you know, we agree right-to-know is a given, but there are different views on how best to do that, what pieces to use to inform the community and how to transmit the information to those people. When we talk about what, we're talking about some of options considered are MSDSs, which there's consensus within cooperative extension that MSDSs are not appropriate for this group. These are the workers who go back in. They're exposed primarily to pesticide residues. And finding out technical information that's contained on a material safety data sheet is not particularly helpful or appropriate to them. But then if we talk about fact sheets, as Lori mentioned, who's developing that? Is it the registrant? Is it EPA? And remember that all of these things -- the worker protection standard originally required that things provided as part of this has to be in a language that the worker can understand. So we

aren't talking just English and Spanish here. We have workers out in the fields who speak Russian, Punjabi, Creole, a myriad of languages, so that gets very complicated developing all of these fact sheets into all of these languages, and it gets very expensive.

We also have questions about how best to deliver it. Is it going to be written or oral delivery? There's some evidence that some people seem to prefer things delivered verbally. Written materials are good, but how are we going to do all this? Are we going to do it through a central location? Are we going to give a copy to -- a fact sheet to each handler or worker? If so, how do we do it, when do we do it, how do we make sure that it's kept updated? Who's going to be responsible for making sure that they have the current copies, and remember, that not everybody who has workers working for them has access to the Internet and can necessarily pull it down from there. So these are all issues we have to consider.

So some of cooperative extension's concerns

with this have to do with cost in terms of the dollars to support this, just this hazard -- just this (inaudible) piece now, the dollars to do this and the people that would be involved. And if we pulled in the people to do this, what is it going to take them away from if we don't have other resources to replace that with? What's the infrastructure going to look like to deliver that and to keep it current and to make sure that nobody's hanging out there from a liability standpoint because they have old fact sheets or whatever? The language issues, once again, translating it into all of these possible languages because it's an inequitable situation if you're only providing it in a few languages. You've got to provide it in all of these languages.

And then, again, a concern from a trainer standpoint, from cooperative extension standpoint, we've learned over the years that providing too much detail on very specific products, for instance, can create a false sense of security when you're using pesticides or products that your perception is that they have a lower risk than some other products. And

what we would prefer to do as educators is to create a culture whereby our workers and our applicators are using best practices to protect themselves regardless of what product they're using, and we want to make sure we aren't undermining that by providing them so much detail that they're focusing on that and forgetting the overall practices that keep them safe regardless of what they're using. Because data on what they're using, a new test can come out tomorrow and provide something -- some other avenue of concern that we would want them to take into consideration, but they aren't protecting themselves because they aren't perceiving it as a risk.

If we move to the second issue paper on training administration, this has to do with the grace period, retraining, trainer competency, and recordkeeping. Some of cooperative extension's concerns are we recognize the benefit of having skilled, competent trainers, but we also see the scope of the training to be done by somebody. This is not necessarily by cooperative extension, but by somebody. Currently, certified applicators can serve

as trainers of the workers out in the field, and at least they do know about the pesticides and they understand the background. They have some content training themselves that they've had to pass. If we had to run everybody through the train-the-trainer sessions that have been one of the options, how would this impact the availability of those trainers when they're needed? Nobody -- there's pretty much a consensus in the work group that we want to do away with the grace period so that everybody gets appropriate training before they're out in the field. But if you have to have your trainers go through a train-the-trainer program before they're available and if you no longer have just a certified applicator available to do the training, I can guarantee you you're not going to be getting all those trainers out there to train your workers without some kind of a grace period having to be necessary. And also what do you do in very rural areas with a very small number of workers who may need to be trained? Somebody's still got to go out there, spend four hours traveling out to that farm and get those people

trained. So those are the kinds of things we're thinking about on that one.

On the third issue paper, enhancing safety training to better protect workers and families. The items and concepts under consideration for being added to the existing body of information that's communicated in training. I want to make sure everybody knows there is already training that goes on for these people, but we're considering -- this subgroup is considering what we might want to add. And there seems to be a lot of consensus around these items as far as the concept.

There are a couple of proposals there about restriction of field access for children under 12 and setting REIs, or restricted entry intervals, for farm worker children as opposed to adults. There is far less to zero support among cooperative extension for these two options because of the feasibility involved here. We just don't see how that's going to be possible. And then there are miscellaneous WPS issues that we have not had a chance to review yet. So I'm not going to talk about those.

But there are just a couple of overarching issues that I want to leave you with from cooperative extension's perspective, again. I'll echo Dale Dubberly on the time frame to complete not only our discussion and input, but the PPDC's discussion and the whole time necessary to get this rule ready. To be a good rule, we're not all convinced that it can be done within the current time frame. And we would like to see you have a good rule at the time that it's proposed with proper thought and proper time to attend to this huge number of options that we're addressing and to get the input that you need to make it be feasible at the time it goes forth.

The economic impact study is a concern. This is going to be key. Cooperative extension supports in concept many of the options being proposed, but a key issue is whether they're going to be resources in term of dollars and people to do this. And this is not necessarily resources I'm talking about for cooperative extension, but primarily a lot of it goes to our state lead agency partners. We're concerned about them having enough

resources to do it and how much will what we're adding here take away from what they already have to do. So we really need to figure that out. We don't want to create more of a problem for them. And we certainly can't recover the full burden from our stakeholders here.

We also have some concern that pesticide applicators not be short-changed at the expense of some of the discussion considered under worker protection. When you think about it, both workers and pesticide applicators have personal exposure issues that we want them to be very careful with. We want them to be personally very safe, whether they are a worker exposed to farm residues -- to residues on the farm or whether they are a pesticide applicator exposed to actual residues -- actual products. But the applicators also have the potential through their actions to affect both public health and environmental safety, which is not something that the farm workers are involved in. So we have additional issues there to consider in training issues and regulatory issues for the

pesticide applicators that we don't want to see forgotten, and we think that's another resource issue.

And, then, my final comment is just that AAPSE, is going to be -- AAPSE is the American Association of Pesticide Safety Educators. We comprise both extension and state lead agency members, and we will be submitting formal comment on these issues that we've had a chance to discuss by June 15th.

MS. LIEBMAN: Last, but not least here, I'm Amy Liebman from Migrant Clinician's Network. That's not mine. And I'm going to be talking today about the view from the worker advocacy point of view as well as a public health point of view. There we go. And I think that my colleagues on this work group have done a really good job and, you know, in expressing the enormity of the issues that we're talking about and just the complex number of options we have. But at the same time, it's been a long time since we looked at worker protection and the time is right, and I don't really think that we need to wait

any longer.

Next slide. I just -- I wanted to just start out sort of taking a little bit more of a global view, because when we get down to all of these issues and there are numbers and CNT Number 1 and WPS Number 6, you're like, oh, my god. But I just wanted to take a step back for just one moment and look at this what we call the hierarchy of control, and this is like Occupational Health 101. And when you are looking at protecting workers, we start off on the top, and the best protection we can do for workers is to eliminate the hazard at its source. Next to that, underneath that we can substitute for something less hazardous. Then going down the hierarchy, we can isolate that hazard by total containment of the process. Underneath that we can look at some engineering controls. And then what I've highlighted in red, like Number 5 on the list here, is safe work procedures and administrative control. And then the last one is personal protective equipment.

And where we are at in the WPS process is that we are really looking at this in an upside down

way that we are at Number 5 and 6 on this hierarchy of worker protection. So as we sort of get, you know, involved in it and look at, you know, the grace period and the training and certification and all that, let us keep in mind that we are really not necessarily getting at the best protection, but we're working on the other end of it.

Let's go to the next slide, please. And I've tried to just sum up right here what I'll be talking about, and I think a lot of us have touched on it already. But as far as some of the worker protection thing and what's specific to farm workers, we're looking at expanded training. There already is training under WPS. We're looking at some expanded training. We talked a lot about hazard communication. I will retouch on that, training administration issues. And then there are a number of remaining issues that we were handed WPS 4 yesterday which has a plethora of issues that we do need to talk about by conference call, and I won't touch on those today, but those are issues that are going to be coming up as well.

Next slide. As far as the expanded safety training -- and we are very pleased, and I'm thrilled with the EPA that we are looking at expanding the safety training. And I think everyone on the committee is echoing the need for this expanded training. And some of the things that are on table that we're talking about to include in this training, we're looking at protecting workers' rights and training workers on their rights, protecting families and children. This is something that's very important. It is not necessarily included right now in the WPS training, and it really does need to be included. Workers need to know how to prevent the take-home effects and how to prevent exposing their kids and their families from pesticide exposures. We're also looking at training on helping them to report detected pesticide illnesses, where to go, how to do that.

And then, lastly, we talked about already without going into a little bit more detail is the hazard communication.

Next slide. And basically, just to give

you just a little bit of background on where this hazard communication is coming from is that we're not inventing anything new for WPS, and I think that's really important to remember that. What we would like is something similar to what OSHA has, but OSHA's hazard communication covers almost all workers exposed to hazardous chemicals except for farm workers, and that protection then comes under the EPA, and we would really like for something similar to what OSHA has. They require training before workers are exposed to a chemical. They require access to MSDS, and they also require very specific labeling. We had had on the table at one time, but it never became final was some kind of hazardous communication requirement for farm workers, but we haven't seen anything about that.

And, lastly, that -- I just wanted to point out that the GAL has found that the implementation of a hazard communication standard has led to the reduction in the use of hazardous chemicals and an increase in safety awareness.

Next slide. In looking at the unique needs

of farm workers and what we need to be doing for farm workers with hazardous communication and where it differs from OSHA, I think, you know, Amy Brown touched on some of this, but really we are dealing with folks that have a low, limited English proficiency, so -- and we also are dealing with people that don't necessarily have a lot of formal education. So we would like to convey hazardous information in a very easy way, using pictures, using as few words as possible on what would make the whole translation issue a lot easier.

We would also like to see our hazard communication cover short- and long-term health effects, better deeper explanation of the re-entry intervals and also specifically about when the pesticide is being used in the growing process. We think that the EPA can develop this pictorial format and information sheet, and we think that employers should be able to provide these to their workers.

Next slide. Also, we also looked at improved training administration and really, from the worker point of view, there's just no bones about it,

we really need annual training and no grace period. Just like with OSHA, workers shouldn't be allowed out in the field without training. We do have a number of issues to look at with the training of trainers, but we really want us to remember that the population that we are dealing with doesn't necessarily have a high level of education. It needs to be participatory. It needs to be effective. Putting a video in for a few minutes talking about the points of worker protection is not going to cut it with this population. So we really want to make sure that we recognize the population that we're dealing with here.

Also, we touched on the whole training verification. We would really like to see the continuation of the cards. We feel that the state lead agency, the grower, and the trainer could easily retrain any verification that is needed that a worker was trained.

Next slide. There are a number of issues that we still have on the table. We have that conference call coming up, and so I'm not going to

get into all the other issues out there. But one of the things that we're very concerned about what is missing from the conversation, and I can assure our work group that we will probably see another issue paper on it is the -- we need a national (inaudible) monitoring program. California has it. Washington has it. It's effective in these states, and there's no reason that we can't have it at the national level.

And, you know, why -- why is this important, like why do we care about (inaudible) monitoring, and I'm going to go to the next slide. And here we have a slide from the Washington State Department of Health that's looking at 600 handlers in the state of Washington last year. And basically, as we've mentioned in previous presentations is that in order for us to understand a depression in cholinesterase, we need to have a base line test and then we need to have a test again.

So the workers in this slide have all had a base line test and then they were tested again. And they basically were exposed to an OP for at least 30

hours over a 30-day period. And really what the gist of this chart is showing is that the majority of handlers have had an absorbable effect here, and that's very significant and important for us to remember. And if you can see that little line where it says no alert level, there's a big arrow pointing to it, right there is just showing, just to sort of exemplify the data that we're talking about here, that's just showing approximately 50 people of the 600 showed a cholinesterase depression between 15 and 20 percent. That's very significant. And, you know, really what we're seeing is, A, the majority of handlers had an absorbable effect, and that's pretty incredible to see. And, also, that some of the protections that we have in place shows that it's not adequate. So we really need to remember as we're looking at WPS -- moving on to the next slide -- that there are a number of issues that I would like to see us take up in that hierarchy. But for the most part, we are at that safe work procedures in administrative controls. And there are some things on the table that would bring us up in that hierarchy, and so I

would like to make sure that as we go through this process that we remember where we are and when there are certain procedures where we can better protect the worker that we keep that on the plate.

MR. KEANEY: I'd like to thank all the presenters. I'd certainly like to thank the group as a whole for the fairly intense work that we've been doing over the last number of months and as well as thanking my staff for providing the work group with more than enough to consider on some very complex and important issues. So this was to give you a taste of what's been going on in this work group, the complexity and variety of issues and the heroic effort we're making together to work through those issues and reach a coherent set of regulation change proposals.

MS. EDWARDS: Thanks, Kevin. I agree this is clearly a work group that's working very hard under tight time constraints and an enormous amount of interest. From what I can tell, most people in the room are on the work group, so that's great. I'm actually not planning to take comment right now

because I think we could lose the ability to get to the other topics. What I'm going to suggest to you for now, at least, is that each of you I think has someone on this work group that represents their interest. I know it's a very large work group in the middle of a deliberative process. And so what I'm going to suggest is that you -- if you're not on the work group yourself, that you talk to a colleague that represents your interest and bring that back to the next work group meeting, maybe is a way it would be a little bit more efficient here today. Yes?

PARTICIPANT: What is the intersection between the rule making and this PPDC work group? Is this work group putting together comments considering --

PARTICIPANT: The work group all along has been providing comments on the issues as we've evolved the issue presentations with the work group. So they've been feeding in comments through the various work sessions we've had. That's their participation in presenting their perspectives and in the complexity and variety of things that are there.

You see the -- now you see the active representation of any number of comments coming from the members and their stakeholders -- their stakeholder networks, not the members alone necessarily.

PARTICIPANT: And how is that incorporated into the proposal making?

PARTICIPANT: It becomes the -- it will become the substance of what we use to derive the text preamble and text for the rule.

PARTICIPANT: But you don't have a rule drafted?

PARTICIPANT: No. We're moving into that process now. As I said, we'll be going into the internal process of developing a language which essentially will be the taking of the evolved issues and framing them out in regulatory language.

PARTICIPANT: And can you at some point, maybe not right this second, but if you have it, give us what the charge is for the committee?

PARTICIPANT: To the -- to the work group?

PARTICIPANT: To the work group, yeah?

MS. EDWARDS: We can actually mail that out

to you, can't we, Margie?

PARTICIPANT: But do you just have a copy of it?

MS. EDWARDS: It's on the website, apparently.

PARTICIPANT: It's on the website, the charge is.

PARTICIPANT: And is informing the rule making process part of that?

PARTICIPANT: It's interacting with us -- I think it was phrases in there -- interacting with critical junctures and providing insights and information.

PARTICIPANT: In the process of developing rule? Is that part of --

PARTICIPANT: Leading to the development of the rule, yes.

PARTICIPANT: Okay.

MS. EDWARDS: Okay. I'm wondering if Arty Williams is here.

MS. WILLIAMS: Yes.

MS. EDWARDS: Arty, we're going to switch

around our agenda just slightly today and do endangered species first and then come back to transition hopefully, if we have time. And Steve Bradbury.

PARTICIPANT: Here he comes.

MS. EDWARDS: And Jerry Johnston. Thank you.

MR. BRADBURY: Good to see you all again and provide another update on the evolution of our Endangered Species Program and give you an update on the activities that we've been undertaking. Arty Williams is going to lead the presentation. And, also, joining us is Jerry Johnston, sitting next to Arty. Jerry joined the division a year and a half ago. He's a branch chief in Environmental Fate & Effects Division and leads the group that's developing the information technology and the geospatial tools that Shelly Thawley had mentioned briefly earlier today. And so with that, I'll turn it over to Arty and take us through the discussion.

MS. WILLIAMS: Thank you, Steve. Good afternoon everyone. Everybody still awake? Wake up.

I hate when people start a presentation and apologize, but I really apologize because this is not showing up these colors very well. I think the room is a little too light. I don't know if we can dim the lights or not. But you do have a paper copy of this in your folder that you can look at if the overhead projection isn't working for you.

I'm Arty Williams. I'm one of the associate directors in the Environmental Fate & Effects Division, and we did want to provide you an update today on what's going on with the Endangered Species Program. There's been a lot going on, some of which you may have already heard about, but other things that are going on that we've not released yet and want to kind of give you a little bit of insight into that. I'd like to cover -- I can't even see the overhead -- a couple of topics today. We're going to be looking at litigation driven assessments and where we are with those. I want to touch on the work that we're doing to support Registration Review Program. I'm going to have Jerry talk to you a little bit about some of the tools we've been developing that

are going to help us scale this mountain we're trying to scale, and then also some of the work that we're doing in terms of information management internally that we think is going to help us make our process a little more efficient and effective in the long term.

So litigation driven assessments, I just wanted to mention a little bit about some of the assessments that we've already done that are completed. Each of these are on our website, so you can go there and read to your heart's content. But over the last nine months we've actually completed five sets of -- I'm sorry -- three sets of litigation driven chemicals, the first three are there on that list, and we're about ready to complete the second few on that list. I just want to touch a little bit on each one of those top three and articulate for you where we came out and what the status of those are at this point.

On the first one that was on that list, this is an assessment that looked at the potential effects of Atrazine to seven aquatic species in the Chesapeake Bay area, and we did complete that

assessment on schedule in August of '06. And the determination for those species -- actually, for all of them was that Atrazine was not likely to adversely affect those species from its use in the Chesapeake Bay area and the Chesapeake Bay Watershed. I specify that because some of these species actually have ranges that go much further south than the Chesapeake Bay area, but the litigation was focussed on the Bay. And so we looked at the implications of use in the Chesapeake Bay Watershed.

Did you have a question? Oh. Sorry. Forgive me if I do that. I'm having trouble seeing short and long term here. Currently, that assessment is with both the National Marine Fisheries Service and the Fish and Wildlife Service for review to see whether they concur with our assessment. It's with both of those organizations because some of the species are actually under the purview of the National Marine Fisheries Service. There's some sea turtles involved in this and two other species. I think it's one mussel species in the Bay and then also the Alabama Sturgeon in the Alabama River are

species that are monitored by the Fish and Wildlife Service.

The second assessment that we've completed in the last several months is one that also relates to Atrazine. You're going to see a lot of Atrazine here because one of the lawsuits focussed specifically on Atrazine. But it is the effects of Atrazine to one particular species in Texas, and it's the Barton Springs Salamander, which lives in a spring system in Austin, Texas. This assessment was also completed in August, and the result of that was that Atrazine was not likely to adversely effect this species. The area that we're looking at doesn't have a whole lot of use of Atrazine, and the way that contaminants can get into the spring system is very limited. And our assessment determined that while it wasn't impossible, it was not likely to adversely effect the species.

We've submitted this assessment to the Fish and Wildlife Service for informal consultation, which is the process we use when we determine something is not likely to adversely effect a species, and we're

currently in consultation with them on that effects determination. And then the most resent assessment focussed on eight mussel species in kind of the mid-continent and southeast, and again, this is related to Atrazine. And that effects determination was completed last February and submitted to the Fish and Wildlife Service.

We determined for this particular action, the use of Atrazine as it's used in that part of the country, related to these species, that there could be adverse modification to critical habitat principle constituent elements. These are specific biological requirements or environmental parameters that the Service has determined are necessary for the well-being and recovery of the species. We did determine that there could be some adverse modification to one or more of those constituent elements.

We also determined that, based on best available data at the time we did the assessment, that Atrazine was likely to adversely effect these species based on indirect effects to the aquatic

plant community in waters where these mussels live. We are currently engaged with Fish and Wildlife Service in the process called formal consultation, which is a more in-depth process than that for not likely to adversely effect determinations. And we have kind of a path forward where their technical people are looking at our assessment currently and then we'll be getting together to discuss how we might be able to refine this assessment based on more specific information about species location, based on more specific information about the watersheds themselves that the species are in and then to determine whether or not we can move forward and get a biological opinion from Service on this.

Now I did mention two others on that first slide, and one of them is the pesticide metolachlor relative to the Barton Springs Salamander. Again, that's the species in Austin, Texas. And the court order on that is a settlement agreement shows that it's due to be completed on May 14th. Likewise, with the second Barton Springs Salamander assessment which is focussing on diazinon, same date, May 14th. We

are going to be meeting those dates. I just got the packages on my desk today. So for all of your benefits, shortly after the 14th, you'll be able to see those assessments online with all the other effects determination, and particularly for Nancy's benefit, you can expect that beginning very shortly from us.

I also wanted to touch a little bit on upcoming litigation assessments. Kind of the next ones out of the gate here are going to be relative to the California red-legged frog, which is the jumping frog of Calaveras County, from stories you might have read when you were younger. We have 10 active ingredients that we have to make effects determinations for and determine whether or not they're going to have an impact on the species in California by July of this year. Those are underway right now. We then have an additional 10 active ingredients that we have to make similar determinations on by October of this year. Those are the next two sets in that particular lawsuit. That lawsuit encompasses over 60 pesticides, and the

schedule then requires us to do between eight and 10 different active ingredients every three months until they're done.

In addition to those, there are six aquatic species, fish, and mussels, which we have to look at in relation to the use of Atrazine, and that assessment is due to be completed in August of this year. And then, finally, for the rest of this year, we have three more pesticides that we have to look at in relation to the Barton Springs Salamander. Those are Prometon, simazine, and carbaryl, which will be done in September of this coming rear.

I wanted to touch a little bit on some of the other aspects of the stipulated injunction in the case that relates to the California red-legged frog. One of the things that that stipulated injunction required us to do is develop a bilingual brochure that provides certain information, not only about the litigation and the stipulated injunction, but about pesticides and frogs in general. That stipulated injunction also -- all of these were enjoins, vacates, and sets aside are authorization of the uses

of 66 pesticides in certain parts of 33 counties in California. Those parts of California that this applies to are areas where there is critical habitat, designated critical habitat for the California red-legged frog. But in addition to that, it applies in upward of 500 sections of land in California outside that critical habitat where the Nature Conservancy of California -- I'm not sure if that's the exact term for them, but the Nature Conservancy Group, has located or had sightings of California red-legged frogs. So it applies in areas beyond the critical habitat itself.

This is -- you should have a copy of this in your folder. This is the brochure that we developed, and most of the panels on there contain information that you were required to put into the brochure under the stipulated injunction.

In addition to simply developing it, the stipulated injunction required that we provide this brochure to all of the county extension offices in the 33 counties where the injunction applies. We had to provide 250 copies of the brochure to each of the

agricultural commissioners in the 33 counties where the injunction applies. And, in addition to that, we obtained and were required to mail individually this brochure to almost 60,000 certified and -- certified, commercial, and private applicators in California. We completed that task within the past couple of weeks. Unfortunately, we've got some returns. The California certified applicator list needs to be updated, but not many, considering the number that we mailed out. So we completed our obligations in that regard.

This brochure on one side is in English. On the back side it's in Spanish, and this as well is posted on our website for people to look at if they don't want a hard copy of it or can't get a hard copy of it.

In addition to posting that brochure on our website, we also put up information for pesticide users. The provisions of the stipulated injunction are pretty complicated and we wanted to try and see if we could provide information that would help pesticide users figure out whether their use was

caught up in this or not. The information on the website kind of walks people through four steps to try and help them figure out whether their potential use of a pesticide is subject to the injunction, provides a list of the active ingredients and instructs people to first look there. It provides general geographic areas that are subject to the injunction, and by that, I mean a list of the counties. It provides information on some of the exceptions that were included in the injunctions. And then it provides a method, kind of a screening method, to determine not necessarily whether you're in but definitively whether you're outside the scope of the injunction. In order to determine whether your particular use side is really in, you really have to have some knowledge of the particular area you're looking at, and we obviously can't do that from here.

To help the user figure this out, we've provided the definitions that came from the injunction of the specific kinds of area around which the injunction applies, and these are all terms that

are in the critical habitat designation. They're different kinds of critical habitat: Aquatic breeding, non-breeding aquatic, and upland critical habitat.

In those sections of land outside the critical habitat, there are also similar definitions for aquatic features in upland habitat around which this injunction applies.

If you go to the list of counties that we provided in Step Two that I just mentioned, and you click on those, you'll actually get a map of the county, and it'll designate on there the areas and geographically in which the injunction applies. In this particular example, for San Bernardino County, the only area subject to the injunction are sections of land outside the critical habitat, and those are noted in red on here. We've provided a section, township (inaudible) overlay for each of these maps so people could hopefully locate themselves on them.

In this second example in San Mateo County, California, the injunction applies in areas that are both outside the critical habitat and there also is a

critical habitat area here that the injunction applies in and then as opposed to the red sections of land. That area is noted in green, and it's a polygon. It's not a square.

So we've provided those for each of the 33 counties in hopes that this information will help pesticide users figure out what they ought to be doing with the pesticide, or more importantly, I guess, what they ought not be doing with pesticides.

I want to move on to registration review. I think you had an update this morning on what's going on with that program, is that correct, had a registration review discussion, a short one? Oh, status report. But everybody is familiar with that program, yes? Good. We have -- the program has opened -- last I counted anyway, it was 12 dockets that are the first ones to start through the registration review process and address work plans for each of those. If you look at some of those, you'll note that there's a discussion of not only ecological effects and potential data requirements that we need to complete by today's standards, good

ecological effects assessments, but it also will articulate in there what we think the status of endangered species assessment is for each of those chemicals.

We went back and looked at assessments that had been done in the past. We looked at the data that we have in-house. Where we could, we looked at public literature before we did this. That would be a routine part of future docket openings. But some of these, we were able to get that information. I think for a couple of them we were not, and we'll have to address that in the next round of work on these. But what we did was we tried to consider what the potential effects from these chemicals might be to different (inaudible), whether there were particular (inaudible) that we were concerned about and articulate what we thought the path to completion would be for each of these.

I think for most of these you will see in there that we will be needing to do some additional endangered species work because it does appear as though each of these chemicals may hit one or another

initial trigger. And when we do that more work, we may discover that there is not a problem with all of these. I want to make that clear. But the initial trigger that says you have to look further to determine that appears to have been hit for one or more (inaudible) for each of these.

So the process will be after we take comments on these to develop a final work plan which will more specifically articulate what we're going to be doing in terms of not only eco risk assessment in general but endangered risk assessment. If you all recall I remember about -- gosh, it must have been a year and a half ago or a year ago, we noted that our main way of getting into compliance with the Endangered Species Act in a routine manner was going to be through the registration review process. And I think opening these dockets and looking at what pieces we have to look at in order to do that is a good step forward in that. And we're looking forward to getting into the guts of it and starting to do some of these assessments nationally and (inaudible).

With that, I'm going to turn over to Jerry,

who's going to talk to you a little bit about tools that we've been developing to help us be able to do all these great things that I told you we're going to be able to do.

MR. JOHNSTON: Thanks, Arty. As Arty mentioned, we have started down the path of doing some of these assessments for endangered species. And as Shelly Thawley mentioned in an earlier discussion, we've started to do a lot of the processing in a spatially explicit framework. And as we started down this path of implementing a complete geospatial assessment framework for endangered species specifically, we've identified a number of different areas for process improvement in efficiencies. For example, there's a lot that commercial GIS software can do, but in many cases we need to be able to pitch together pieces of the functionality that's already there, and in some other cases, we're actually writing completely new functionality to integrate into an in-depth environment that our scientists are using to complete these assessments. I just wanted to talk briefly

about some of the things that we're working on right now and some things that we have that are already available to our staff and being used.

The first of these is a terrestrial action area tool. It indicates where we're piecing together existing functionality that's common in most (inaudible) GIS applications. And what this tool allows our staff to do is to use a number of geospatial layers. You might have data on watersheds or data on habitat patches, data on management status of land, and to grab shapes from each of those different -- those different geospatial layers and piece them together into one cohesive area that describes what can be a terrestrial action area, the tool also works to let you create a series of watersheds, for example, and then remove certain pieces based on criteria that you've identified during the assessment. And that's available now what's being used by some of our staff on concurrent assessments.

We're also working on a use site development tool that we expect will be available in

late summer. This tool is linked to the National Agricultural Statistics and the National Land Cover Database to help us quickly identify areas of potential agricultural chemical use. So the way that this tool will work is it simplifies the process of determining which counties in the country report having certain crops in the last ag census and then quickly pulling out the agricultural lands from the land cover database that corresponds to those counties so we can get a proxy measure of where we think the chemicals could be based on the cropping patterns in the country that's reported in the census of agriculture.

Another tool that we're currently working on that we expect might be a little bit later than the use site development tool probably early fall is an aquatic action area development tool. And the idea here is that while we're not doing, flowing water modeling of pesticide dissipation and transport, we want to be able to identify downstream reaches from terrestrial use areas that may be impacted to the aquatic transport of pesticides. So

this tool is relatively simple, but just works on the premise of looking at the percentage of cropped areas upstream to determine when you've moved far enough downstream based on our risk quotions and levels of concern to dilute essentially what we expect to be the pesticide concentrations in the streams. It's a very conservative tool. It just gives you an idea of what part of the stream network that's outside of the actual area where the chemicals are applied that we might need to consider.

And the last tool is, as Shelly mentioned in the earlier discussion, the spatial framework for our exposure models. The delivery date for that is to be determined, but as she mentioned, we anticipate that will be available in the fall as well.

So on the same token, I think one of the big challenges we have is not just tool development and software. It's really getting all of this information into one place or a group of discreet places. We have a tremendous amount of geospatial and nonspatial data that's going into every single one of these assessments. And one of the big

problems that we've had in getting to where we are right now is the fact that that data is spread all over the place, all over EPA, throughout your organizations, throughout our other partners in the federal and private sectors. And we've got a couple of parallel initiatives to try and help consolidate our data resources into a place where we know that our staff can always go to and access everything that they need.

The first of these were mentioned again during Shelly's discussion is the -- our collaboration with the Office of Environmental Information in creating one centralized geospatial data repository that we think will contain all of, at least for now, the geospatial layers that we will need to carry out these endangered species risk assessments. We expect that when that's done, it's going to be roughly a terra byte in size. So for those that are technology inclined, it's a massive repository of geospatial data that actually other organizations inside and outside EPA have expressed an interest in partnering with because we're not the

only people that are faced with some of these problems. We hope are system can be a prototype for something that goes well beyond endangered species risk assessments for pesticides.

The next two bullets are really components of the same project, which is a proposed module for the pesticide registration information system, or PRZM, that some of you may have heard the folks from RIT staff talk about in previous meetings.

The first component of this is the tracking system that would really just be designed to help us keep track of the information regarding where we're at with various assessments, mitigation options, the production of endangered species bulletins, and issuance of those bulletins just so we have all in one place a time line and a work flow so that it's going to keep track of where we're and, as Arty pointed out, a very busy schedule for completing many of these assessments.

The second component of that system is actually a knowledge repository. And the idea here is that we want to make sure that once one of our

staff has identified any piece of information -- it could be a document. It could be just a fact about a species, crop, chemical -- once that piece of information is captured, that it's accessible the next time somebody needs a similar piece of information, so we don't have staff going out and collecting the same information over and over again. So we're trying to build a combined document and data repository that would help us to maintain a permanent archive of all the information that goes into our assessments, and we're hopeful that this will be available in the next year or so.

MS. WILLIAMS: In addition to those things that we're building and Jerry's staff is helping build to facilitate the endangered species assessments and beyond internally, we also are working very diligently to put more user-friendly information upon our website. We have redesigned the endangered species website. It's going to prove we're transferring it over to a live site now. What you're seeing here is a draft prototype of the front page. We tried to simplify it and make it a lot

more -- a lot easier to access and find particular pieces of information. As part of that, we will have an entrance door to the Bulletins Live System, which is the system I think I've talked to y'all before about where pesticide users will go to find enforceable use limitations that might apply to their use of a pesticide once we find the need to put those in place for a particular pesticide and its use.

When this launches live, you will be able to access the Bulletins Live System. There will be a bulletin for every county in the country, but there will not currently be enforceable use limitations in those bulletins. Nonetheless, once it's live, we would encourage people to go explore it a little bit. We will also have on it a tutorial that will show when there are use limitations, what all of those screens will look like. And we're hoping that between now and the first time we actually have to use it for an enforceable use limitation, people can become a little bit familiar with it so it's easier for them to use and therefore our program will be more effective.

With all of this, I don't know if our office director agrees with me, but from my perspective our big challenge is the following. We are currently looking at opening dockets for a number of different pesticides in about a year and a half. I think the number is going to be about 45 each year. Opening the dockets itself is a big piece of work, but then you have to actually like respond to comments and do something with those. And then you have to do the assessments. So in a couple of years, we're going to find ourselves in a position of trying to crank out 45 or more assessments each year. There will be lead time on all of that, but eventually, it's going to be production of about 45 a year. On top of that, we've got, as I tried to express early in this, a pretty intense litigation schedule. And while we're trying to do these dockets and these litigation chemicals, as Jerry mentioned, we're developing tools that we need to be able to do it more effectively and efficiently, and at the same time struggling to manage huge amounts of information that we need to keep track of and need to be able to

access again.

So any one piece of this program is a challenge, but I think our real challenge is kind of doing all the pieces at one time. And I think we're making a lot of progress on each of the fronts, and I hope I was able and Jerry was able to articulate some of that progress for you today. And I thank you for your attention. And if there's time, we would be happy to try and answer questions.

MS. EDWARDS: Yeah. I just have a question for -- I don't know if we can get a show of hands or something. We do have another session today on the transition work group, and we have one public commenter. I don't know if, for example, the people that are making the transition work group presentation could stay until 5:30, much less the rest of you. But could I get a show of hands who could stay until 5:30? Rick and Al, you'll be here tomorrow?

(Inaudible.)

MS. EDWARDS: You have a -- they have a two-hour presentation so. Is there anyone that was

really earnestly in need of hearing the transition presentation that wasn't -- that isn't going to be here tomorrow? Okay. We'll do it tomorrow. All right. So let's spend about -- what time is it -- fifteen minutes on some comments on this, and then we'll hear from the public commenter and be done at five o'clock. How's that? Okay. Thank you.

MR. BRADBURY: Why don't we -- it looks like the name tags all kind of went up at the same time. How about if we just start at this side of the table and just work our way around, if that's agreeable to folks.

PARTICIPANT: Arty, with respect to the red-legged frog stipulated injunction, how would the schedule for effects determinations made, what went into that?

MS. WILLIAMS: What went into that. I believe that the judge in that case indicated to us and to plaintiffs that a schedule that was similar to that which was issued in a prior case in Washington seemed like a good schedule. So that was kind of the starting point. We looked at a lot of different

things and tried to figure out what a reasonable schedule might be that we could actually accomplish. It's a lot of work. So, you know, through negotiations, that's how you get to a stipulated injunction. All the parties wind up agreeing with one another that we can live with this. The schedule you saw which gave us about a nine-month window up-front to kind of start the pipeline and then a production schedule of approximately ten every three months was the result of this negotiation.

PARTICIPANT: Can we go back to the slide of the map? I just have some --

MS. WILLIAMS: I don't know. We can.

PARTICIPANT: Yes, she can. Good. The one with the red and green --

MS. WILLIAMS: -- uh-huh.

PARTICIPANT: -- squares. Okay. I guess I have a suggestion for -- I didn't understand your legend. So is the red a place that you can't spray? It says noncritical habitats, so it seems like, well, if it's not critical, maybe you could spray there. But it's red, so --

MS. WILLIAMS: Yeah, actually, you have to read all the text that goes before the maps to understand.

PARTICIPANT: Is there a way to make that more clear because a lot of people aren't going to read that text? I know --

MS. WILLIAMS: I don't think at this point there is a way to make it clear.

PARTICIPANT: And what about the yellow?

MS. WILLIAMS: What about it? It's the map. It's the county.

PARTICIPANT: In other words, you can apply anywhere where it's yellow?

MS. WILLIAMS: There are no limitations based on this injunction except in the red and the green.

PARTICIPANT: It would be nice to make that really clear in the -- so noncritical habitat section in which applications are restricted. Just changing the legend -- the wording in the legend would make it very clear. The yellow meaning, you know, okay to apply. And then I just -- what happens -- what's

the -- if people don't comply with these, what's the penalty for the applicator?

MS. WILLIAMS: There's no penalty under FIFRA because it's a court-order limitation. It's not a use limitation under FIFRA, so I would -- I actually don't know how court orders are enforced by the Court. I just don't know the answer to that. And we're trying to provide people information so they can comply. So I really don't know how a court order is enforced by the Court.

PARTICIPANT: Does somebody from EPA know that?

MS. WILLIAMS: I'm sure there's somebody who does. I don't think they're at this table.

MR. BRADBURY: You can try to -- you can try to follow up on (inaudible) talk to counsel.

PARTICIPANT: A follow-up question to the first one. What criteria and factors are EPA considering in selecting the compound in the 10 at a time for that schedule prioritizing those compounds?

MS. WILLIAMS: We're considering a variety of different things. We're considering probably

quite heavily how we can do it most efficiently. So one of the things we're looking at is where these chemicals fall out in terms of registration review schedule so we're not like conducting an assessment for this one species and then, you know, six months later we have to look at the chemical all over again for registration review. We're looking at very practical things such as the workload balancing among the five branches in our division that are doing this work so that we're ensuring that we don't have 10 coming out of two people in one branch at a time.

We also had gotten a little bit of input from the public in terms of, gee, would you do this one first because it's an important chemical to us in terms of being able to use it, and we've gotten some input from people saying would you do this one first because we think it's a problem. And in the framework of looking at how we can manage this workload, we're also considering that kind of input that we have gotten. But did that answer your question? Okay. Just as a side note, we do have up on our website now kind of a candidate list for the

second 10, and I think it's like -- there are 18 or 20 of them there. But from that list of 18 or 20, the second 10 will be taken.

PARTICIPANT: This is just a very small point, but it applies not only to this slide, but probably to anything that goes up on the web or in presentations or out in publications. Red/green color blindness is a very, very common color blindness, particularly in men. They can't see the difference between red and green. They can see both colors, but it looks the same to them, so they're not going to be able to see the difference on your map. So anytime you're trying to show differences like that, I would encourage people, in presentations, as well as particularly things like this where you're going to be relying on them to get the message, to use some other color scheme, either red or green with some other color.

MS. WILLIAMS: I appreciate that, and we'll make sure we don't do that again in the future. For purposes of this, we distinguish it only because the injunction distinguishes it in terms of different

areas that have to -- that are subject to the injunction. The specific limitations on use within those areas are not different, so I think practically it's not going to result in people being confused about, oh, I can do one thing in the green areas and a different thing in the red areas. But I do appreciate what you're saying.

PARTICIPANT: I don't mean to overburden with this, but it is a point that I see being --

MS. WILLIAMS: And I acknowledge that, and I appreciate it. We will not do it in the future. Thanks.

PARTICIPANT: You know, I told the cops the same thing about their red/green. He didn't buy it either. Well, you know, it's kind of hard to hear you talk, Arty, without feeling some regret over the fact that there's so much time and resources being allocated to litigation. I know there was a significant effort in the counterpart regulations to try to address this in a systematic way and I guess those have been held up. It looks like to me, and I don't understand how this all works, but it kind of

looks like you can almost go into court and win just for the asking. And I guess the question is, is there some kind of strategy to avoid 15 more years of this through the registration review process?

MS. WILLIAMS: Our strategy, you know, behind closed doors and public have consistently been, you know, we can only do what we can do and the way that we think we can get ourselves in compliance and provide the best protection for species, given our starting point, is to do this systematically through registration review. That's the only strategy we have at this point.

PARTICIPANT: I just wanted to make it clear because I'm not sure it was clear to me in the discussion about the eight mussel species that you just made the assessment for Atrazine.

MS. WILLIAMS: Uh-huh.

PARTICIPANT: You did say it was based on the best available data at the time. I just want to be clear with everybody that additional data has gone into the Agency and it was taken to Fish and Wildlife, and Fish and Wildlife has the nature sort

of data that should also be put into this assessment when it's refined.

MS. WILLIAMS: The comments that we received also are up on our website right along with the assessment, and I think I did mention, that the Service, and we have a path forward where we can bring to the table, you know, refinement to that location information and the watershed information. But I thank you for articulating it again.

PARTICIPANT: Arty, just a -- I may have missed it, but did you say when the Bulletins Live is going to become activated?

MS. WILLIAMS: No.

PARTICIPANT: Would you say when it's going to be activated?

MS. WILLIAMS: No.

PARTICIPANT: Okay.

MS. WILLIAMS: The person who -- it's all been approved. We have to go through like a product approval process whenever we do something major on the web. And it's all been approved and it's being transferred to a live site now. My guess is it's

probably going to be about a week to get that accomplished.

PARTICIPANT: Okay. And could you briefly mention the status of the counterpart regulations and --

MS. WILLIAMS: Status of the counterpart regulation is that the judge in that case made a ruling related to the victims filed against the Services, and throughout parts of it, upheld parts of it. The federal government was considering whether or not to appeal that decision, and the Department of Justice recently sent to the court a document, a letter, whatever they send, saying that the federal government was withdrawing its request for appeal. So the case is concluded, I believe.

DR. AMADOR: Arty, I appreciate the work that you all are doing, all the documentation that you need to consider in order to, you know, make an assessment with what's going on. So my question is regardless of the legalities of it, have there been any direct effect between, for example, Atrazine in the red-legged frog and the diazinon salamander? Has

it been proven that either one of those two products impacted the species directly and show that there's an actual effect, the amount of potential, anything like that? I mean, I still (inaudible) -- I mean, I know that we need to protect the species, if they have been declared to be endangered. So has there been any correlation to prove to (inaudible) between the user of the chemical and the reduction of the number of either one of the two species -- by either one of the two chemicals?

MS. WILLIAMS: Yes. And it's a good question. I don't know of any specific data that, you know, shows diazinon or metolachlor, I think is the one you mentioned --

DR. AMADOR: Diazinon on the frog and the -- on the salamander?

MS. WILLIAMS: Yeah. I don't have any direct data that shows that, but I need to make two comments about that. The first one is that we have an obligation, all federal agencies do, to determine that our actions will not have an effect, not to --

DR. AMADOR: Yeah.

MS. WILLIAMS: -- assume that they won't because we haven't seen evidence. But the other thing I want to mention, though, is that, you know, by their very nature, endangered species are not broadly distributed. You know, you don't see them every day walking around. And even with species that are broadly distributed like that, it's really hard to find -- I don't mean to be crass about this, but basically, you know, dead carcasses that you can analyze and see what the cause of death was. You know, a lot of times things die for whatever cause. And before anybody ever sees them or maybe nobody ever would see them, the carcass is hauled off by another critter that relies on that as a food source or it decays. So looking at, you know -- where's Michael Fry sitting? Where are you? Forgive my saying it this way, but, you know, looking for dead birds in the field isn't really the way that you can determine whether or not something is going on in our view. You just can't rely on it. It's -- you know, I can walk through my twelve acres of woods, and I probably pass over little dead bodies all over the

place, and I don't know it because I haven't been out there for a week. Things die of natural causes. They die of all different causes, but we don't often see them. So while we've not seen particular effects, can't really rely on that to say there wouldn't necessarily be any or couldn't be any.

DR. AMADOR: But is that being pointed out? You know, the fact that we know finally means good. I mean, I don't want to --

MS. WILLIAMS: Well, if they're not there and that's why we're not finding them, yes, that's good.

DR. AMADOR: You know, should it be brought up to the (inaudible). So far we are not finding correlation?

MS. WILLIAMS: And one of things that we look at in our assessment is whether there have been reports of incidents for the endangered species but also for the (inaudible) of species we're concerned about. And we use that information kind of qualitatively, but you certainly can't say because there are incidents, it's going to kill everything or

because there aren't, it's fine. But we do try to look at that and consider it.

PARTICIPANT: Just a real quick question on that tool development. I didn't get a sense from Shelly's talk earlier. When you are developing one sort of independent of other offices, is there going to be a grand GIS tool that's coming out of super fund and Office of Water?

PARTICIPANT: No. That's a good question and the answer is it's a little bit of both. There are things that we're developing that are specific to our process and our risk assessments, but the data repository and some of those tools, we all -- this is a multi-program effort. Right now the main entities are Office of Water and ORG, and we've started talking to (inaudible) as well. So there's recognition at the agency level that what all of us are doing needs to be better coordinated than it has been in the past.

PARTICIPANT: Yeah, I'm just going to say when you start going from program to program, the basic information is all going to be the same?

PARTICIPANT: Yeah, that data repository -- we're -- you know, we, since the project was funded by LEI on our behalf, we have a lot of control over what we want in it. But we've gone out to the other programs and asked them what do they want. So what we're kind of seeing is, you know, where we're at right now is a pilot for an agency level that will soon be available inside to that regulatory program.

PARTICIPANT: I completely understand what you said about you wanting to do a systematic assessment of endangered species potential impact through the registration review process. And what troubles me is that in the two chemicals that were kind of introduced to the registration review work group, for a lot of data call-ins to get the kind of information that you should be using to do those assessments, that were just waived. And I'm concerned that you're not going to have the information that you need to do what needs to be done in order to protect endangered species.

MS. WILLIAMS: I appreciate that. Let me tell you where we're coming from and then offer a

piece of advice, if I might. What we tried to do with those is look at where they were -- I'm going to call them knowledge gaps -- where there were gaps in our knowledge about how a pesticide behaved or what it might affect or how it might affect it. And then to look at not only do we have laboratory data submitted for the registration to fill that knowledge gap, but are there other means to fill that knowledge gap. What we're -- one of the things we're trying to frankly get beyond in this is, you know, another 10 years of data call-ins before anything is done about a potential species problem. So we're looking at, you know, literature. We're looking at are there data we bridge to this to figure out what the chemical's going to do and so we can get the job done and move on.

So you're right, we did say that there was a potential that we would not need certain data. We hope that we articulated why we felt that way, but maybe we need to do a better job of that. My advice would be that during the comment period on these that that comment be made formally if we see data that

we've waived that you think are essential because this is a draft work plan. And the whole idea of putting it out for public comment is to get that kind of input and then we'll -- you know, if you make a compelling argument to us, we obviously will change the way that we're approaching that. So we'd appreciate your comments on that.

MS. EDWARDS: Well, thanks to all of you. Good comments for us to take back and consider. I'd like to ask now Hope Driscoll if you're here, the public commenter, to come forward. Okay. She must have left. All right. Well, in that case, thank you for a good day. I think we got what we wanted. It was a solid agenda, good input, and I appreciate all your energy, your participation, the fact that you came from far away to attend the meeting, and I hope you'll be here bright and early at 8:30 because that's when we're starting. So thank you very much.

(Whereupon, the meeting was adjourned.)

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LINDA J. CARROLL, Transcriber

COMMITTEE MEMBER ATTENDANCE LIST

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Margie Fehrenbach	Designated Federal Officer, OPP
Rebeckah Freeman Adcock	Director, Congressional Relations, American Farm Bureau Federation
Lori A. Berger	Ph.D., Director of Technical Affairs, California Minor Crops Council
Daniel Botts	Director, Environmental & Pest Management Division, Florida Fruit & Vegetable Association
Joseph Conlon	Technical Advisor, American Mosquito Control Association
Cannon Michael	Board of Directors, California Cottons Growers Association
Robert Rosenberg	Director, Government Affairs, National Pest Management Association, Inc.

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Dr. Steve Balling	Director, Agricultural Services, Del Monte Foods
Carolyn Brickey	Executive Director, Protected Harvest
Caroline Cox	Staff Scientist, Northwest Coalition for Alternatives to Pesticides
Dr. Michael Fry	Director of Pesticides and Birds Program, American Bird Conservancy
Caroline A. Kennedy (May 9th only)	Director of Special Projects, Species Conservation, Defenders of Wildlife
Jennifer Sass	Senior Scientist, Natural Resources Defense Council
Susan Kegley, Ph.D.	Senior Scientist, Pesticide Action Network
Shelley Davis	Deputy and Co-Executive Director, Farmworker Justice Fund, Inc.

ATTENDANCE LIST (cont'd)

Amy Liebman	Environmental Health Consultant, Migrant Clinician Network
Erik Nicholson (not attending)	Pacific Northwest Regional Director, United Farmworkers of America
Kristie Stoick	Research Analyst, Physicians Committee for Responsible Medicine
Cindy Baker	President, Exigent Company
N. Beth Carroll, Ph.D.	Senior Stewardship Manager, Syngenta Crop Protection
Frank Gasperini (for Allen James)	Responsible Industry for a Sound Environment
Seth Goldberg (for Phil Klein)	Legislative and Public Affairs, Consumer Specialty Products Association
Dr. Hasmukh Shah	Managing Director, American Chemistry Council
Julie Spagnoli	Executive Director, Regulatory Affairs, Clorox Services Company

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Dr. Warren Stickle	President, Chemical Producers & Distributors Association
Jay Vroom	President & CEO, Croplife America
David Lewis (for James Wallace)	North American Registration Section, S.C. Johnson & Son, Inc.
Gary Libman	Vice President, Regulatory Affairs and Quality Assurance, Emerald BioAgriculture Corporation
Matthew Keifer	Associate Professor, School of Public Health and Community Medicine
Dr. James Roberts (not attending)	Associated Director of Pediatrics, Medical University of South Carolina
Dennis Howard	Chief, Bureau of Pesticides, Florida Dept. of Agriculture & Consumer Services

ATTENDANCE LIST (cont'd)

Mary Ellen Setting	Assistant Secretary, Office of Plant Industries & Pest Management, Maryland Department of Agriculture
Rodney Guske	Salt River Pima-Maricopa Indian Community
Dr. Jose Amador	Director, Agricultural Research & Extension Center, Texas A&M
Amy Brown	Coordinator, Pesticide Safety Education Program, Univ. of MD.
Larry Elworth	Executive Director, Center for Agricultural Partnerships
Dr. Robert Holm	Executive Director, IR-4 Project
Carol Ramsay	Extension Pesticide Education Specialist, Washington State University
Patrick Quinn	Principal, The Accord Group
John Schell, Ph.D.	Vice President, Toxicologist BBL Sciences

ATTENDANCE LIST (cont'd)

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Allen Jennings	Director, Office of Pest Management, USDA
Dr. Vladimir Murashov (for Melody Kawamoto)	National Institute for Occupational Safety and Health, Centers for Disease Control & Prevention
Dr. Nancy Golden	Branch of Environmental Contaminants, U.S. Fish & Wildlife Service
Michael Kashtock (for Dr. Nega Beru)	Office of Plant and Dairy Foods, CFSAN, FDA
Maria Martinez (for Mike Bussell)	Office of Compliance & Enforcement, EPA

P R O C E E D I N G S

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DAY TWO - MAY 10, 2007

MS. EDWARDS: Good morning. Thanks to those of you who showed up on time. As advertised, we're starting at 8:30, right on time. You can expect that in the future.

(Laughter).

MS. EDWARDS: Yes, and finishing on time, that's the goal. So, we're going to change the agenda just a little bit this morning because we did move the Transition Work Group presentation to this morning's session. But we are going to start with the Registration Review Work Group session and then move to the Transition Work Group. Depending on how long that goes, we'll move on to the work group on performance measures and then have a break. If it goes a little extra, we'll have the break before that and then move into the Cause Marketing, Charter Renewal and Planning for the PPDC -- the next PPDC this fall in the afternoon and provide some time again for public comment.

If you would like to make a public comment, you

need to sign up at the registration desk outside the room.

So, with that, I will turn the floor over to Kennan Garvey who's a Senior Advisor in the Special Review and Reregistration Division and chairs the Registration Review Work Group.

Kennan?

MR. GARVEY: Thank you. I'll just give a little brief background and then turn it over to Bernalynn McCahey (phonetic) and Michael (inaudible) here to step forward and to help present this.

Basically, I think you're all familiar with registration review. We have the mandate from FQPA and it covers all pesticides periodic review which is all the 15 years. We did open the first docket in February and March for conventional. We've opened 11 so far. Actually, two of those were not opened because there were not federal registrations left by the time we got to them, but we're following up on tolerances and 24(c)s for those. But basically 11. And the first biopesticide dockets were opened in April and we expect to open the first antimicrobials very soon.

We had a good work group meeting March 8th. In November, Jim Jones asked the PPDC to establish a work group on registration review implementation, and a number of you stepped forward and others, and we had a good work group meeting on March 8th. The purpose is to provide input on several of the initial registration review dockets, look at our docketed presentation, see how we explain what we know and how we presented the preliminary work plan for chemicals, and see if we've emphasized the right topics in the summary documents that capsulize everything in the docket.

And, today, we're to the point of having the work group advise you on the initial docket recommendations that you may want to consider endorsing in some way or changing and giving back to the agency. This will help us improve the initial stages of registration review.

I'm going to turn it over to Bernalynn for the next slide.

BERNALYNN: Thank you and thank you for this opportunity to participate in the new process of registration review. I, first of all, would like to say

that the work group had a productive session. Our charge from Debbie was to consider the process, not the details, and I think the group did a good job of that. We certainly heard a lot of expressions of appreciation for this forum and ability to speak to the dockets in an emerging process, and we look forward to a continuing opportunity to input into this process since it is a new and development program.

Moving on then to the recommendations of the group, the first for guidance on how to navigate and use the docketing system, it is a little bit unclear. That's something we have to work with, though, because we realize that it's a general forum. But we do ask that there be some guidance there and I think EPA is already accommodating that request.

Additionally, posting the documents themselves, some of them are searchable as PDF files, some of them are images, and it's much easier to work with a PDF file. So, some consistencies in that initial docketing process was requested by the group.

A second point that was made was the organization of the docket and how they can be better

identified so that a person perhaps new to the process can move from one part of the docket to another. If you go through the compounds that are currently docketed, you'll find that each is slightly different in its content and titling, and that makes it difficult to compare them from one to another or perhaps to find a certain item that you may be searching for in the docket.

For example, it's hard to tell if three of the dockets are missing screening usage analysis or it's simply given under another title or buried within a document on the docket.

Additionally, label data review is clear on three dockets, but not clear on nine of the dockets. So, it's a matter of titling and identifying those documents.

Another request from the work group was to provide more detail on incidents. Again, if you look at the dockets, eight dockets have instant summary, four have summary documents that do not address the subject and two have acknowledgment that there are no incidents. So, a more -- maybe perhaps a more consistent way to define and detail those records would be helpful.

Including all available background documents

would be helpful. There are some references in the summary document that do not appear to be supported by the underlying documents on the docket. For example, it appears that these data were only addressed in two dockets and it's unclear in the other dockets how that data -- if that data was handled and provided.

Listing PRIA scheduling was requested to assist in overall understanding of registration actions and the context of registration review.

Next slide. The implementation work group also recommended that there be more summary and highlighting of the conclusions drawn and provided in the summary document. For example, in the discussion of endangered species, two documents clearly explain the need for proximity data, eight express a desire for use data and two are silent on the subject. So, perhaps a more consistent approach would help.

There was a request for less jargon, more writing in clear language since this is a very public process now. One example of that is varying references to eco tox searches and what will be done with eco tox searches and how EPA intends to utilize those type of

resources.

More consistency in the format of the summary documents and the flow of the summary document. An example there is that in addressing acreage, five of the summary documents have no specific information, two use 1997 USGS data, one uses 1997 USDA statistics data and two use 2004-2005 data. One has a table that doesn't give a source. So, just, as the process evolves, becoming consistent in how these information sources are used and portrayed.

There was a request to give more usage information, including 24© registration. These are covered to varying degrees in the summary documents as well as in the underlying documents on the docket. Seven dockets appear to have a review of registration, but it's unclear to what depth the additional dockets do.

A request was made to highlight data requested or not requested with the rationale. While it's clear what the data requirements are, the rationale underlying the final decision is not always clearly expressed to someone that may not be familiar with the evaluation process.

There was a suggestion to add trade names to the summary document, but it was also recognized that that would be a very lengthy, complex and dynamic list and, perhaps, difficult to maintain.

There was a request from the states to provide resources, references to analytical methods so that the states may have ready access to those when it comes to their role as the enforcement agencies. And a request, finally, not to go overboard on information delivery, to recognize that this docketing process is establishing a baseline. It's not establishing a conclusion. It's a place to start, not an end. And, therefore, a nice clear baseline would be a good place to start.

And, lastly -- next slide...

MR. GARVEY: Thank you. I should have mentioned since Bernalynn's not on the full PPDC, Bernalynn McCahey of the FIFRA Endangered Species Task Force and Combined Services (inaudible). Thank you very much.

Michael?

MICHAEL: Yes. The suggestions for status are really -- for the status page are really just a continuation of the recommendation. But there was a

request to put links for pertinent information for active ingredients on the list. We all search EcoToxNet and Pesticide Action Network information, places like that. But to have specific links would be a help for some of these compounds, especially our -- not obscure, but difficult to find information on.

Similarly, some of these compounds don't have water quality benchmarks and there was a request to have those -- do you have that -- go to the next slide. Yeah. To develop or publish those water quality benchmarks for those that do not have them.

There's always been an interest in diagnostic biomarkers for pesticide exposure. We all know cholinesterase, but, you know, pesticide biomarkers for the nicotinoids or herbicides, a lot of these really there are not specific biomarkers that haven't been developed, and it would be good if people know about them to include them in the docket.

Similarly, we wanted EPA to clarify how stakeholders could provide information, say on endangered species assessment, what -- where these organisms are located, what crops they might be in, that kind of thing,

and exactly what's the process for letting the EPA know putting this information in the docket.

Next slide. Water quality data submission, now, the standard operating procedure for putting in the water quality data was listed on the web prior to the opening of these dockets as a general thing and comments came back that people were very happy with that process put on the docket.

Similarly, positive feedback came from the clomazone and hexythiazox PowerPoint presentations that were given and everybody got brought up to speed very quickly with that and the suggestion was it would be nice to have this for other dockets to bring people up to speed and even the playing field, as it were.

I think everybody was really happy to get an early picture of EPA's thinking and plans. I think EPA has come an enormously long way in this kind of transparency and public presentation of all of the information and really should be congratulated for really trying to get as much of this information as possible into the docket.

It was apparent that EPA put a lot of thought

into how to organize the dockets and has continued to improve those.

Next slide. There have been several improvements that have been made just in the past few months. Dated signature page is included on the front page of the registration review summary so, you know, we know when things were done. The list of all the product registration numbers were put into the summary document so that label searches could be done more easily. And so far, the incident reports that were available have been included. Some of us would like to see the incident reporting changed so that we could have actually more incident reports, but that's a separate issue.

And, then, the docket in regulations.gov has been difficult to negotiate sometimes, and, so, EPA has been working to fix the search functions in that docket so it's easy to open the dockets by pesticide name and generally making the docket more friendly. I think that's going to be a continuing thing as time goes on.

Back to Kennan.

MR. GARVEY: Thank you very much, Michael. Yeah, a couple of other things on initial improvements,

even though the recommendation doesn't have your endorsement yet and we were far along on the March 28th docket when we had the March 8th meeting, but we did, as Michael mentioned, managed to make some improvements. We've also included in the March 28th docket a reader's guide. It's the third document in each docket and it just explains what each document is, a little background on each document. So, it's helping provide a little structure.

One other thing we just discovered this week that they have made a change to FDMS that you can now link into docket from outside, which is a nice feature because you -- if you go to a docket now, in the upper right, you'll see a link and you can just drag that to your desktop and go back there any time you want. You don't have to plug in a 12-digit number to find the docket. Even the basic search, you just go to FDMS and you can plug in clomazone and you don't have to plug in a 10 or 12-digit docket number. So, we're managing to get a few improvements.

But, basically, the next steps at this point are your consideration today as the initial recommendations

and see what you think of them and then we will consider those. We also anticipate meeting again sometime this summer to consider the initial biopesticide and antimicrobial dockets and there may be a need for other meetings after that.

And, then, at some point, we'll need to consider the need for PPDC input on subsequent stages of registration review beyond the initial docket, and that's it.

Yeah, comments, discussion?

(Break in recording.)

UNIDENTIFIED FEMALE: I would just like to caution the agency on the suggestion to put links to other organizations and their information because, quite often, it's not updated. A cancer classification can change, a reference dose can change and those sites are not updated, and that would be in probably direct conflict with the Information Quality Act from the standpoint of dissemination. So, I'd just like to caution the agency on that.

And from the standpoint of incident data, once again, it needs to be validated data that's not just --

well, you know, we think this caused this, but we're not sure. I would just like to caution the agency about putting that kind of information up on the docket.

UNIDENTIFIED MALE: We all go to various sources and we do realize that they are not updated, all of them, and it would be really helpful to have the registrant provide links that they know of to this kind of information, if it's available or, you know, have it all included in the docket. I agree that, you know, we need caution on outside data.

UNIDENTIFIED FEMALE: Well, the data -- I mean, if a cancer classification changes, the agency knows about it because they're the ones that change it. You know, I don't think the companies can be responsible for updating PANIS (phonetic) data, for example.

UNIDENTIFIED MALE: I wasn't --

UNIDENTIFIED MALE: (Inaudible).

UNIDENTIFIED MALE: -- suggesting that -- updating PANIS data, but that if there are appropriate links that the registrant knows about, to have them included in the docket.

MR. GARVEY: Let me explain the link, I probably

wasn't clear on that, but you can now link from -- into FDMS from outside -- if you want to put a link on your desktop, you can go directly to a docket. You can't link from inside the docket to outside organizations or anything. So, we have to put into the docket everything that we think is essential to present the case.

But we can now, for example, in our registration review status phase, which is a useful reference for all open dockets on the OPP page, we now have stand-alone summary documents. We double-post the summary documents from the docket. We no longer have to do that. We can simply put a link there and go directly to the summary documents in the docket.

I see a couple of others. Amy?

AMY: I'd like to thank EPA for taking steps already to, I think, make this docket practice a lot easier to get into. From somebody from the outside who acts as a liaison with my state on people who might want to have comment on open dockets, it has gotten a little bit easier and I really appreciate that. But I still think that it would be very helpful in the little pieces that go out asking for comments, such as the OPP update,

if we could know of what the crops are that are involved and what the risk mitigation pieces are if you're at that stage because that's the kind of thing that the cooperative extension and crop consultants and other people that you might be able to get some very good comment back from are looking for.

If they have to actually go into the docket and read the whole summary docket for each pesticide that I notify them of that's coming open for comment, they're probably not going to take the time. But if they can look very quickly at the information there that says, these are the crops that we have concerns in or these are the types of risks that we're looking for mitigation practices, feasible ways to mitigate, I think they would really go and look at the docket and give you some feedback about usage practices, about possible ways to mitigate and a whole lot of probably valuable information.

MR. GARVEY: Thank you. Susan?

SUSAN: A couple of things, and I'm sorry I was late this morning, but as far as docket improvement, it would be really great if there would be a zip file of

everything that's posted by EPA so that you could quickly download all of the documents instead of having to do them one at a time. Because, right now, there's a program called Page Sucker that will, you know, pull down everything that's linked on a page, but it doesn't even work on those pages.

So, you spend like half an hour downloading documents. It would be really great to have one zip file that has everything that you guys are posting.

Secondly, with regard to a pesticide info database, we -- the cancer list, by the way, needs to be updated by EPA. The latest one I could get was dated April 26th, 2006, and a lot of decisions have been made since then. But since that's the official list, without having to go through every single docket, that's what we put up there. So, right now, metam (phonetic) is up there, MITC is up there as a possible carcinogen because it used to be rated that way, but it sure isn't different on the list, and so, I need -- you know, we need to have that information updated by EPA.

And the cancer list, too, suffers from a lot of typos in the cast numbers. And I send them back

corrected every time and they don't get changed. So, I would request that someone pay attention to that.

MR. GARVEY: Thank you. Carolyn?

MS. BRICKEY: One of my concerns about the registration review process is with the endocrine disruption screening program, which FQPA mandated 10 years ago and is still not really going. And now, from what I can tell, the agency is moving forward with registration review still without that screening information. And, so, for the chemicals that are going through review now, I don't -- I think it will be and other 15 years before that information will be incorporated into the assessment and that just seems like -- I mean, I'm not a lawyer and I can't tell you if it's meeting the letter of the law, but it's certainly not meeting the spirit of the law, and I think that needs to be addressed.

MR. GARVEY: Thank you. Susan, are you up again or -- anyone else? It looks like not. Okay. I take it from the comments that there's general endorsement of the recommendations, so we'll certainly be considering them and looking for further improvements, plus the additional

comments made today.

MS. EDWARDS: Thank you very much. As you obviously have understood, we're very excited about our new Old Chemical Program, you know, the future of our Old Chemical Program and we're very happy to have your insights early on so that we can make it as effective as possible. As Kennan said, this is an ongoing work group. So, there will be probably another meeting this summer to roll out some of the biological pesticides and antimicrobial dockets to see how those look as well and get your feedback on that.

Our next session will be pulling forward from yesterday or pulling backwards from yesterday, however you might want to view it, the transition work group, a presentation, and then we'll move on into the performances measures after that. This is, as I said earlier, is a co-chaired work group between the Environmental Protection Agency and the Department of Agriculture and the co-chairs are Rick Keigwin, our Director of the Biological and Economic Analysis Division, and Al Jennings, who's Director of the Pest Management Program at USDA.

MR. KEIGWIN: Thanks, Debbie. What we're going to do this morning is more or less provide you an updated on where we are. I think this is the first time that this group is coming forward to the full PPDC, and sort of educate you a little bit on how this group came to be and what we've been doing these past few months, and then, obviously, answer any questions or address any comments you may have.

So, basically what we're going to do is do a quick overview of the AZM decision; again, how we came to be as a work group, what our mission is, what we've been doing, and then a number of next steps and documents that we have under development.

So, as you all know back in November, we announced our decision to phase out azinphos-methyl, and on that same day, the agency announced the formation of this work group whose mission is really to help both EPA and USDA focus on key activities that are needed to help carry out the phase-out. These activities would include helping to understand the effectiveness of alternatives and then providing a forum for sharing information about any successes or failures that are going on as we

progress through the transition.

So, again, there are basically three phase-out schedules. There are a couple of crops that begin their phase-out by the end of this fiscal year, in September, and then subsequently, two years later, the nut crops are phased out, and then the remaining uses, apples, blueberries, cherries, parsley and pears, will phase out by September 30th, 2012.

And then as we progress through the phase-out, there are a number of mitigation measures that we begin implementing, including lowering application rate, increasing buffer zones around water bodies and occupied structures, gradual elimination of what remains of aerial uses -- aerial applications, excuse me, and then the implementation of a worker stewardship program.

Okay, so, the work group is composed -- we probably have about 30 people on the work group, a very good cross-section of folks. A number of you, as full PPDC members, are on the work group, including Rebeckah Freeman Adcock from Farm Bureau Federation, Lori Berger from California Specialty Crops Council, Steve Balling from Del Monte, Michael Fry from ABC, Shelley Davis from

Farmworker Justice and Larry Elworth.

And here's basically our mission statement: To provide advice to EPA and USDA on how the transition is going, identifying a framework for that transition with the goal being towards lower risk strategy, taking into account grower concerns and economic trade and regulatory barriers to adoption of alternatives, identifying ways to improve understanding of critical grower need, identifying alternative control practices.

This keeps skipping ahead a couple, I'm sorry. Let me see if I can go back. It's not working.

(Brief pause.)

MR. KEIGWIN: Okay, moving to lower risk pest management strategies, if they're available, and this is looking at both chemical practices and non-chemical practices. And then -- can you move ahead one slide, please?

(Brief pause.)

MR. KEIGWIN: You have it in your packets, so we won't go by the overhead, I'm sorry. But increasing transparency and providing process recommendations to the agency.

What's important is what -- what is equally important perhaps is not what we're charged with, but what we've elected not to charge ourselves with, if you will, some ground rules for how we're going to progress through our work group deliberations. We're not going to revisit the AZM decision through this work group. We're not discussing the rationale for the decision and we're not going to discuss any pending litigation. The idea is the decision's been made, how are we going to progress through this effort.

So, we held our first work group meeting in early March and it was largely a day of brainstorming that resulted in the basic outline of four areas that we should be considering as we develop transition strategy. Looking at trade issues and the establishment of MRLs in exporting countries, regulatory issues including what new registrations may need to occur, both at the federal level and at the state level, researching implementation issues and trialing of alternatives, and then looking at impacts, including the economics, resistance management and sustainability issues.

As part -- we wanted to test this outline, and,

so, two groups actually stepped forward to develop case studies around that basic outline that I just discussed, and Al's going to give you all a progress report on these two in a few minutes. One is Ohio Parsley Growers, which is very narrowly focused, only a couple of growers that are affected there, and then Washington Apples, a much more difficult situation.

We've had two work group teleconferences and a lot of email exchanges. And then we've also got a couple of tools under development, basically matrices. One is on crop alternative pest control practices, and one of the ideas here is to have a repository for things that have been tried, how successful they've been or not been, and have this available to be a look-back for all of us as we progress through the transition.

The second is a regulatory matrix that will look at the status of -- largely on the chemical side, but some of the biochemicals as well, track where they are in the registration process, whether they've been registered, and then on the MRL front, how things are progressing either through Codex (phonetic) or in the individual export market countries.

Where we are is that these matrices are in work group review at this point. We're still having some discussions about what elements we should be capturing as part of those matrices, and then we've got two active case studies in review. Like I said, Al's going to talk about those shortly. Then we've also had two other groups who have volunteered to develop transition strategies on their own, Michigan Blueberries is one and Michigan Cherries is another.

Al and I have been approached by some other groups about maybe starting their own. So, there's been some discussion about the value of these. But the case studies that we're focused on are just these two.

MR. JENNINGS: Okay. As Rick mentioned, out of the work group came a couple of volunteers, and I think it is -- may be significant that none of the volunteers for those two groups actually made it to this meeting, but they all had their reasons. So, therefore, I get to talk to you about these draft plans. I emphasize draft. This is a little bit like looking at a building foundation and trying to describe what the building is going to look like.

But those of you who are familiar with pest management strategic plans, which is an exercise that we've been going through in USDA with our land grant partners and grower organizations for the last seven or eight years, the idea of looking ahead at your production system, particularly at the IPM system and identifying vulnerabilities and needed research.

That exercise is a basis and what you're going to see in these plans will be a lot like that, except obviously more focused on the specific issue of replacing AZM in those IPM systems, and, of course, much more specific and detailed tasks and timelines for how, within this phase-out period that Rick described, are you going to do everything that needs to be done to essentially rebuild your IPM system.

Let's see, and we're already on the right slide. This may be entirely too much detail given where we are. I don't want to mislead you into thinking that these plans are anyplace close to primetime because they're not, but as I said, look at a pest management strategic plan on our website if you want to get the general content -- but Ohio Parsley, what we've got are some -- a

number of bits of information at this point on the general agronomic information on the crop as identified here.

Probably the most valuable part, ultimately, will be the task and timelines, what has to happen by when in order to make it through this transition.

One of the pieces that's lacking right now in both the plans is the who. It's easy to write task and timelines if somebody else is going to do them, and right now, we haven't figured out who's going to tie the bell on the cat for all of these tasks that need to be done.

Let's see, again, not to belabor this, but, you know, within the draft plan there are a number of elements that Rick touched on. You know, what are the management tools, the analysis of the potential alternatives, and a lot of that needs to be expanded with much more discussion of the barriers to adoption, the technical barriers, the economic and regulatory barriers that do exist or will exist for many of the potential alternatives.

Education and outreach programs, again, the work group thought that that was going to be a major element

of a successful transition. In Lori's words, the infrastructure, how to build up the infrastructure to really deliver new IPM programs to the growers who are affected by the phase-out.

Okay. The Washington Apple study, again, a lot of the elements are the same and just different words describing them. I guess I should point out that in both these case studies, they may be a little bit simpler than some other cases we'll run into because both are driven by single pests, as least as far as we know right now, and I say that because past experience, not on these particular crops or this particular chemical, has been that when you change one of the main chemicals in your IPM system, things appear that you didn't realize were there. In other words, you were getting control of secondary pests and, so, therefore, they were never a problem. But change is a key ingredient and sometimes a secondary pest can become a major one.

But, for now, anyhow, both of these plans are focused on a single pest. For Ohio Parsley it's the carrot root weevil, I believe, and in Washington Apple, it's the codling moth. And, of course, there has been a

link in successful effort at using mating disruption pheromone technology for codling moth control and it works, to some extent, but one needs a chemical back-up. And for many years now, azinphos-methyl has been the key ingredient to get the population of codling moths down to a level where you can actually achieve some reasonable control using the pheromone technology. So, again, it's part of a system, an IPM system.

One of the good news items recently from Washington State has been Jay Bruner's proposal -- well, the start of this draft transition strategy was a Jay Bruner proposal to the Washington State legislative body to get money to fund transition and they recently did approximately just over half a million dollars for a transition effort. So, that's good news in that there does appear to be some funding at least for the northwest apple production plan.

Well, what else is in these plans? Again, the apple folks have identified a fairly thorough identification of the potential alternatives, at least those chemicals that look like they are good candidates and a thorough discussion of the research that's needed

to get there, as well as the task and timelines. But, again, the who is missing on -- who's doing all that. Presumably, since Jay got the money, we're going to rely on Jay Bruner to be the who in this apple strategy.

The apple case study does take kind of an interesting step forward in really looking at how one is going to know when you have a successful transition by identifying these areas on this slide as ways of evaluating the alternatives, if you will, to being successful.

So, where do we go from here? We obviously need more work group meetings. We need the authors, the volunteers who stepped forward, but couldn't be here, to do more work, really to flush out these drafty case studies and as well as further developing the matrices that Rick mentioned earlier.

So, there we are. It's early in the game -- and I think that's my last slide. Yes. It's early in the game and we will get back to you. One of the problems we have is the authors, though, have already said they are going to be really busy until sometime in the fall. So, I think part of the problem is in growing season it's

very difficult to get the extension expert's attention on these matters. But we'll work on that and, hopefully, have more to report at the next work group or PPDC meeting. Thanks. We're available for questions.

MR. KEIGWIN: Bob?

MR. JENNINGS: Bob?

BOB: Well, Allen and Rick, I commend you for what you're doing and I think the group should recognize that this is really a special case and extension of what the USDA has been doing all along, as Al mentioned, with the strategic -- pest management strategic plans, and I think the mechanisms that have been put into place to get growers and stakeholders together for those strategic plans have provided, I'm sure, very helpful organization for the meetings that you've held.

Since I've been away from IR-4 the last six months, I'm not sure -- I certainly hope the IR-4 has been part of the work group. I think it's a good thing they are. And, obviously, this has been a mission of IR-4 for the last 10 years since FQPA looked at working with the agency to work on transitions.

I'm reminded of a case about five years ago in

context of the importance of international trade and international registrations when the reduced risk product, spinosid, was registered on apples in Washington, but growers couldn't use it because the apples were exported to -- some of them were exported to Canada and there was no tolerance for spinosid in Canada. And I'm sure now with the NAFTA cooperation, a lot of those barriers will be broken down.

But I think that's a major issue that I think we all realize that food is now an international commodity and the EPA has been doing a remarkable job the last 10 years in getting a lot of new projects registered. Unfortunately, they're not cleared in a lot of countries, and I know this has presented a lot of artificial trade barriers, and I certainly hope that countries that we export food to will be cooperative in this case and help get registrations.

MR. JENNINGS: Bob, one of the items in the matrix that -- one of the matrix that Rick mentioned is exactly that, the MCL issue, where are the trade barriers and that's a path that needs to be worked on.

MR. KEIGWIN: We're going to use that as a tool,

Bob, as we go into different bilateral and multi-lateral efforts, be it through Codex, through OECD or others to try to accelerate, if you will, the establishment of MRLs for these (inaudible) strategies. So, that's one of the reasons why we're going together to help us in that prioritization process.

Jennifer?

JENNIFER: Yeah, I, for some reason, don't have the actual -- is there an actual report to go with this presentation? Was the report emailed and --

MR. KEIGWIN: No, but the report of the first meeting is on the PPDC website.

JENNIFER: I didn't know we had a website.

(Laughter).

JENNIFER: Okay. I, unfortunately, have not read the full report. But here's my concern actually. Well, first of all, thanks, and, also, Al, thanks for -- in the position of having to present without your people there, that's really crummy of them. So, I guess that's kind of my concern.

My concern is that we keep people -- and I'm actually, at the moment, thinking of Shelley Davis, who

was one of the key people on this, unfortunately isn't here, and I wonder if it isn't possible to put discussion of this later. But in the meantime, I have a letter that was sent to EPA from Carol Dansaro (phonetic) of the Farmworker Pesticide Project and I wonder -- it's very short. It's like three pages and it provides a couple of sort of key points that they think are sort of things to be working on on this, maybe things that are overlooked, things to pay attention to.

And I think without the full PDDC either having the key people on the work group who were representing worker issues or having some of those things in writing that EPA has but that we don't have, I feel uncomfortable having any kind of -- I don't think the PPDC can really evaluate it without having a full report, without having the key people here, without having that kind of stuff in writing.

If you'd like, I can spend three minutes going through these couple of points that Carol raised.

MR. JENNINGS: Well, I don't think we're here asking for any guidance or feedback because, as I said, this is very early --

JENNIFER: So, it's kind of a skeleton presentation to us?

MR. JENNINGS: It's a progress report saying we've had a work group and we do have some drafts, but we're not ready to share just because it is so early and part of what you're describing is that work group process where everyone's commenting, so --

JENNIFER: So, you're not looking for any PPDC --

MR. JENNINGS: No, just letting you know we've been busy.

UNIDENTIFIED MALE: Carol's letter was circulated to the work group. The whole work group --

JENNIFER: Oh, is that right? So, I got it on the full list then.

MR. KEIGWIN: It was circulated. She did circulate it to the work group and we've begun discussions on her -- the issues that both she and Charlie have raised as part of the work group.

JENNIFER: Okay, I guess I didn't realize I got it on the work group and not from here then. So, I guess what I -- then the one or two points that I would like to

raise then, I think, is just what Carol raised, the issues that, for me, really strike is the importance of considering that the potential risks of the alternatives that you're thinking and so that we're not just risk trading, and even risk trading down is, you know, better than nothing. But I think we can do better than that because we are at an early stage, so just to keep in mind.

They've also presented, I think, a pretty nice matrices to consider that weigh the potential risks and also the data gaps from some of the alternatives that you'll be looking at. So, I know it's a lot of work, but taking those into account early is better than having to be hit with them later, which I know that you know and I know that the work needs to be done.

MR. KEIGWIN: Susan?

SUSAN: I'm just curious. I'm not on the work group and I'm curious as to what the specific alternatives are that are being considered, chemical alternatives that is, and the non-chemical.

MR. KEIGWIN: It depends upon the crop in the past and apples there -- I think we've got a list of 15

or 20 alternatives that Jay and others are looking at. Many of them, they include pheromone technologies, they include a number of chemicals that have actually gone through the agency's reduced risk pesticide program. So, they've already been identified as lower risk alternatives at the time of registration. They're largely the newer classes of chemicals.

But we're also focused on what's being demonstrated in the field to be working.

SUSAN: And just kind of a follow-up on that, that's not necessarily directly related to this, but it's something I hope EPA is at least looking into. There's been speculation that the bee kill -- the bee die-off, the colony disorders might be caused by imidacloprid, which might be one of the substitute chemicals that are being brought in for azinphos-methyl. I guess I'm curious as to whether EPA is looking into those to see, you know, if there's a connection, if so, what the connection is, those kinds of things.

MR. JENNINGS: USDA has a major effort going on trying to sort through the colony collapse disorder issue, and I don't think anyone -- there have been a

number of theories. One of them, as you mentioned, is the imidacloprid thing, which came to us, I think, from Europe. But there are arguments on the other side as well.

So, we will certainly avoid killing bees, but I think it's premature to identify any particular chemical.

MS. EDWARDS: EPA is participating in an interagency effort to look into the colony collapse disorder.

MR. KEIGWIN: Carolyn?

MS. BRICKEY: I don't know if the work group has had a formal discussion about what the definition of alternatives to azinphos-methyl is, but I just want to make sure that you all are considering a really broad definition of that term and that it needs to include not just alternative chemicals, but things like resistant varieties and cultural practices and all those other things that can go into making a low input agricultural system successful.

I think if you just focus on replacing one chemical with another, you often miss the best alternative. So, I wanted to make sure you didn't --

that there was that vision of looking wider.

MR. KEIGWIN: Yeah. The vision isn't necessarily that one chemical on its own might substitute for another, but we're looking at different systems approaches that could include some non-chemical practices altogether.

JENNIFER: Can we comment on that? In Carol's letter, she raises the point -- again, I'm not on the work group. But she raises the point that you guys might not be consulting with organic growers in this process, so that really non-chemical alternatives aren't built into the considerations that you're going through. Is that accurate or is that something that can be altered at this point?

MR. JENNINGS: Well, there are no organic growers on the work group, as far as I know. But, again, we're not talking about an organic production system. We're talking about a conventional production system. I think they're two entirely different things. So, I'm not sure how much one can learn from the other. It's a different production system.

UNIDENTIFIED FEMALE: (Inaudible). In

considering the full ranges of alternative growing practices, moving -- transitioning away from azinphos-methyl, are you considering, in addition, non-chemical, as well as reduced risk and other practices?

MR. KEIGWIN: The answer's yes.

MR. JENNINGS: Sure, whatever works. I mean, we're very early --

JENNIFER: How can you do that fully if you don't have people included who can bring that kind of expertise to your table?

MR. KEIGWIN: It's an open process, Jennifer, and if you have suggestions -- we did put out a solicitation for membership and that included all of you here and suggested that if you all weren't the right people, you could nominate other people. There's an opportunity to add additional people to the group or existing members could bring that information forward. But we are looking for data to support the inclusion of these as alternatives.

MR. JENNINGS: Certainly. And the insecticides that the organic growers use are certainly candidates for alternatives to azinphos. They do use spinosid. I'm not

sure how well it works on codling moths, but...

MR. KEIGWIN: I think Amy's been trying to get in.

AMY: Yes. As somebody who's quite familiar with the transition strategies developed through USDA and the state lead agencies, while I haven't done one myself, I would like to say that conventional growers use alternate methods. They're just as interested in non-pesticidal alternatives as organic growers are, and, so, they are interested in the whole spectrum.

And the people who are putting together the transition strategies in the state, like Jay Bruner, are very familiar with all of the alternatives and they are specifically -- that's part of their mission when they're developing these transition strategies for USDA is to look at not just replacing one pesticide with another pesticide, but looking at the whole system, as Allen said, and looking at other possibilities, be they chemical or non-chemical practices that you can implement or whatever they are, and it would not be limited to just organic growers who would be interested in moving away from a pesticide alternative. And, in fact, conventional

growers do often utilize other non-chemical means in their regular conventional practices.

MR. KEIGWIN: Rebeckah.

MS. ADCOCK: To build on what Amy has said and to speak for very directly some of the growers that are actually in the transition, both apples and parsley, their interest is in what works. You know, EPA and the Federal Government isn't here necessarily to tell them how to run their operations or whether to adjust their yields or whether to change their business structure; EPA is to help them try to find a material process, a practice, and with USDA's help, that fixes their problem. And they don't have a preference whether it's a chemical, whether it's not a chemical.

I will tell you that many of them have found the most successful with pesticides and synthetic chemicals. If we're trying to compel people to become organic growers because it's a social choice, that's not the role of the Federal Government. If we're trying to help people find something that works, specifically in the case of apples for the codling moth and, to my knowledge, I don't know of a lot of non-chemical treatments that

satisfy the import and export challenges of shipping something out of the country with an absolute zero tolerance in some countries for any moth, any larvae, anything. The whole batch goes home if there's anything there.

If there are things out there that fix that problem that are non-chemical, I assure you they would be more than welcome, especially if they are in the realm of affordability.

So, the notion that we're sitting around the room only swapping out chemical for chemical and nobody's open to anything else, what's on the table is what will work and, you know, I represent organic growers and conventional growers, and they both feel very strongly about how they do business, and at the end of the day, they both want materials, processes and practices that work. They want to keep their operations going, they want to make their own choices about their business structure and how they run their farms, but they just want things that work.

So, if anybody here is suggesting that that's -- we're not open to that, you know, I would defer back to

what EPA said, you're welcome to come to the table and bring us your great ideas. But if your great ideas don't work and they're not great, then don't get your feelings hurt.

MR. KEIGWIN: Larry?

LARRY: Whether the apple industry is going to change from azinphos has already been decided. So, I think we lose an opportunity here if all we want to do is talk about what the parsley growers are going to do or the cherry growers are going to do or the apple growers are going to do. My guess is the agency is going to be faced with this set of situations again and needs some sort of framework for looking at it, both in the process of making a regulatory decision and also understanding what agriculture looks like in the wake of a regulatory decision.

So, I would -- I have certainly been interested in the work group deliberations in terms of coming up with a framework of how do you actually look at transition, both pre and post-regulatory decision making, because I think from the PPDC's point of view, it's our job to inform the agency on how to look at forming

policy, not simply on how to look at specific crop pesticide situations. I look at the case study as the means for thinking about the larger issues that I think the transition group has been convened to accomplish.

Having raised apples for more than a decade and been involved with the apple industry for more than 30 years in various ways, one thing I would say about the people involved in the apple industry who have been involved with this, that they're -- the scientists involved are probably the most progressive scientists in the country, if not in the world, and are probably, in terms of the work they're doing, several steps conceptually even beyond where people are in organic systems in terms of understanding the ecological impacts of the production of apples.

So, I think that you may have specific concerns that people want to raise. I think they'll be welcome to them.

MR. KEIGWIN: Lori?

MS. BERGER: Well, to address some of the concerns that were raised by Jennifer, a number of the people that are on the work group represent several

commodities and they are there on behalf of the commodities, which encompass both organic and non-organic growers. So, you are getting those perspectives.

And the work group, to the best of my knowledge, was open to all interested PPDC people to participate and those invited participants. So, those perspectives are incorporated as far as I know, and certainly the discussions and the conference calls that I've been on have encompassed the organic viewpoint. I'm not sure -- actually, a number of people touched upon this. We're looking for alternatives and this is not just an AZM or an apples issue, although we are looking at Pacific Northwest apples and Ohio parsley as case studies.

I'm interested in this as a person working from the ag side, what are the lessons learned, how can we project, what are the realities. And one of the realities is these are very, very complex issues and it's going to take time to unravel them and there's many implications of these types of decisions.

And, you know, concern has been raised to me, well, California apples are different than Pacific Northwest apples and they're different from Eastern grown

apples. These things are very, very local. I mean, Northern California pears are very different than pears produced in the more central part of California. So, these are complex issues across commodities and within commodities and all of these things have repercussions and I really do believe that the work group is trying to -- if they are successful, they will be able, at the end of the day, be able to summarize some of the many issues associated with moving away from AZM or other materials.

Growers are, frankly, very happy to embrace reduced-risk products, but it really takes a lot of research and outreach to deliver these systems in ways that people can economically grow crops and have those crops accepted in the domestic and export market. I really feel like the work group is open to perspectives and I think the record should show that and I think the case studies will be enlightening.

MR. KEIGWIN: Michael?

MICHAEL: Yes. I'm on the work group and I want to just reinforce what Lori and Larry have said. I think the draft report that has come out from Jay in Washington

really covers an enormous spectrum of different alternatives. I'm on the work group to see how the process works as other chemicals go through this kind of transition for the worker safety things but also environmental concerns. And I've been quite impressed with the range of alternatives and the thoroughness with which people have looked at the different alternatives as this is coming up.

So, I have a lot of your concerns, Jennifer, but this one, I think, right now it's moving forward in a very comprehensive kind of discussion.

MR. KEIGWIN: Carolyn, was your card still up or -- okay.

MS. BRICKEY: I'm really glad to hear that there's a really broad spectrum of alternatives being looked at, but it does seem that -- and I really agree with what Amy said when she said, you know, conventional growers are using techniques that are acceptable in organic production. It isn't like two distinct things. There's an overlap there.

But, on the other hand, if you want to look at who has the most experience dealing with growing whatever

crop it is, without azinphos-methyl, it's going to be organic growers. And, so, to not give the work group the benefit of that expertise seems really shortsighted. And if you don't have any organic growers on the work group, then I think you should either reach out to either get some or at least get them to review the report and make sure that there wasn't something inadvertently left out.

There's lots of pest management techniques that farmers use that farmers know about that have kind of not reached the level of being out in the wider -- you know, they're not published, they're not being studied, and it seems like it would be really shortsighted to miss out on that expertise.

MR. KEIGWIN: I think Lori wanted to respond.

MS. BERGER: Yeah. Well, I believe that through various commodity groups and extension and research personnel on the work group, those people are involved, what their perspectives are. Am I right or wrong on that?

MR. KEIGWIN: I think you're right. But as I said, we're open to having additional people on the work

group. So, if you are aware of somebody that could help us in this regard or if you have ideas of organizations that we might approach to help us in this regard, we will certainly do that.

MS. EDWARDS: Well, thank you very much. It was a good session, lots of good feedback. I think before the break, since we do have some time left, almost 25 minutes, we'll move on to the Work Group on Performance Measures presentation. Our session chair for this is Sherry Sterling of the Field and External Affairs Division.

MS. STERLING: Good morning. This morning I will give an overview of the revised performance measures report on behalf of the Performance Measures Work Group. It's a very hard-working group, by the way. They presented their report to you -- well, first, let's talk a little bit about the history.

Okay, the history, they've had a number of sessions to come up with their conclusions. At the last meeting of the PPDC, a report was presented and, as you may recall, a number of tents went up and Jim Jones thought it might be helpful if the group had some

opportunities to air those comments outside of the meeting, just because there were so many of them. So, we set up some comment sessions. Too big, too many comments for just one short session, so we ended up having two sessions that fit together as one in January and March of this year.

The report that was sent to you last week, and I believe is in your packet, is the result of the previous work by the Performance Measures Work Group and those comment sessions. So, what I'd like to do is just provide for you the highlights of the changes that the work group made.

This will go section by section from the report. In the introduction section, the major changes that were made were just to update the history and to include the fact that there were comment sessions.

The general observation sessions -- and you'll notice that the numbers after each of these comments relate to the observation numbers that you'll find in the report. Under general observations, there was a lot of discussion, we put in additional information, about providing relevant detail regarding each of the measures.

The group also decided to -- that we needed to add a little bit more information about linkages between actions and the measures, that those linkages should be clear. That was included in observation number eight.

Under the Protect Human Health Section, we made the change on observation number nine, putting in -- the group decided to put in some additional information about NHANES. The change to observation number ten deals with the reductions in the levels of pesticides. There were some differing opinions, and you'll notice that in observation number ten, it will present what different members' ideas are on this issue.

Observation 11 provided some range of opinions on PCC or Poison Control Centers.

Then in the final slide, the Protect the Environment Section, observation number 15, again, incident data. There were a range of opinions about incident data and that observation now includes that range of opinions.

The section called Realizing Other Benefits, and as you heard yesterday from Marty Monell's presentation, in the final strategic plan, we did revise that title to

realizing the value from pesticide availability. But it's still -- back when we were working through this, it was still Other Benefits. So, that's why it retains that title.

Observation number 16 included some discussion about the name change. They wanted to add additional information, the group did.

Finally, observation number 17, once again, kind of looks at linkages or makes -- includes the fact that linkages should be there between program actions and the measures. That point was made in several points in the document.

Those are the major changes from the November document, and I would say that's where we are.

MS. EDWARDS: Any additional comments in this area? Okay, Amy?

AMY: Sherry, I'd just like to thank you and the group for the work that you've been doing on this. I know it's been tough. I was involved originally and wasn't able to keep up with the group, but I've tried to follow what you're doing. I particularly appreciate the way that you've done your report out here, letting us

know very briefly what those changes are. That was very helpful. Thank you.

MS. EDWARDS: Diane?

DIANE: I have a question about the appendix and I don't know if that's appropriate to ask now.

MS. EDWARDS: Sure.

DIANE: Forgive me because here I come in and I have a question about what transpired and what's going ahead. But one thing about performance measures, whatever they are for whatever purpose, they need to be pretty specific so you can actually then measure whether you're achieving the goal. And I noticed a variation in specificity.

For example, I'm just looking at the very first page of Appendix A, the first one which on the left-hand column is HH1, you know, there's a year, there's a number, and then NHANE, which is where you're going to look for that number. And, yet, if you look down below on WS4 and WS6 -- well, there is a year and a number, a percentage reduction -- it doesn't identify the source of the incident information. Is it Poison Control Centers, is it State incident reporting, it is 682 information

into EPA?

So, I would think to determine whether you've made that goal, you need to define what sources of information you're looking at in order to measure the accomplishment.

MS. STERLING: Absolutely. And that information is provided in the back-up documentation. Because of the length of -- because this was meant to be kind of a snapshot, it certainly does not include that information that's absolutely critical. That's some of -- we went into great detail on those pieces with the work group, and so I -- it is there, to the extent that it exists. Your point is very well taken.

MS. EDWARDS: I don't know if Julie or Jennifer were next, but -- okay, Julie?

MS. SPAGNOLI: I'm going to comment on the -- you know, we're looking for linkages, and I guess after hearing the budget discussion yesterday and how the agency's activities are kind of being put into these strategic areas, it seems to me there's a very logical link now that we can link the agency's activities to measures that are in the strategic plan through the --

how those activities are being budgeted and how they're being categorized.

So, I think from the -- just from the measures that have already been identified and that have been put into the strategic plan, I think it might be helpful to get an update then of what activities are being done to help meet that strategic target.

MS. EDWARDS: Thank you. Jennifer?

JENNIFER: Yeah. I also really appreciate, Sherry, the way this is presented. I think this is one of the -- this is clearer than my work group presentation because we've been seeing this before, and I really appreciate you actually just helping us to identify the changes. And I also appreciate how patient you've been with me because I was one of those people that wasn't involved early and then kind of freaked out at the last meeting and then got involved. So, I appreciate that, too.

And, also, I appreciate the changes that were made. I think they're clearer and I think they're also -- I think the report is more -- I think it's got more -- I think it's a more valid report actually. I

think taking the extra time to be clear about the language and to be really clear and concise and use technical language properly makes it a much more structurally valid report. So, that's all good.

I also appreciate number nine because that's where I mostly was whiny on. The description of the NHANES data is really very good now. It's -- so, that's really good.

On number 11 -- ooh, and the other thing I appreciate actually, like in seeing now, working on my spray drift work group and also, again, you mentioned, I think, looking at how EPA is restructuring its budget, I can actually see now EPA already integrating this stuff in and I think that's really good. I'm impressed. It's difficult. I mean, I can tell you that my own organization is trying to line up budget with priorities and we're not here yet. So, this is something that's really good.

On number 11, that's the Poison Control Center data, this looks a little shaky and I want to say that we had a conversation in the -- was it the spray drift work group I'm on or was it a different -- actually, it was a

different meeting I had with EPA -- where the person at EPA, and I don't remember who was presenting to us, described all the different -- I think they had three or four different incident databases that EPA uses, including FIFRA 682 and Poison Control Centers and State reporting and NIOSH center, which has some State reporting in it, and we -- I, at the time, expressed the kind of uncomfortableness that's in point 11.

But I think EPA actually did an amazing job of assuring me that there is some across the board quality control and real consideration, and that doesn't mean the data gets better, it just means that EPA is really aware of the data weaknesses and the data strengths and the data limitations and is using it in as much of a composite as they can and as appropriately as they can. I felt better after hearing from EPA the thoughtfulness that's going into that process and I don't think that's captured in point 11.

Point 11 seems like it's, again, like the stakeholders are expressing that concern in the quality of data. So, I don't know how to capture that, but maybe whoever at EPA is really looking at that could help all

of us to be more confident in EPA's process because I certainly felt more confident after hearing from EPA. And maybe part of that would actually be listing some of the databases they're using and where that comes from, because they're not hokey-pokey databases, you know.

On number 15, I don't like the term "objective data." It's one sentence there on number 15. It's the only sentence in number 15. The PPDC encourages EPA to use FIFRA 682 incident reporting, I agree with that. I do encourage them to use it appropriately. And other objective data. Does that imply that the FIFRA 682 is objective data as well, and if it is, I think you should just not change the sentence, but take out the word "objective data" and just put other data sources, because it's not objective data. It's self-reporting, right? It's industry self-reporting data and that's not -- doesn't come under the definition.

So, I think the sentence is fine and I think using the data is -- I think it's important to use all the data you have, I would just drop the word "objective" there.

And then on 18, I just wanted some help. I

actually read -- 18 is like a little paragraph. I literally didn't understand -- there's obviously conversations underlying this that I'm not privy to that I want some help with.

So, like the second sentence says, the stewardship and virtually all of the other benefits measures are well behind in the process, and then the only example of other benefits I see is the integrated pest management in that paragraph, which is good. Is there a way of helping me to understand what you're considering other benefits? And it's not just your list in 19, I hope. Is there a -- maybe you could add a little paragraph for an appendix or something because it's just not...

MS. STERLING: I'm kind of torn about this because, in fact, if this were my report, I'd be happy to do that. But it is not the EPA's report. This is a report of the work group. We do have the information available. We presented it to the work group. So, the feeling of -- we can certainly go into what is included in realizing other benefits. I can go into that either here or separately. But the idea that it is well behind

in the process, those were thoughts of the members of the group.

JENNIFER: Okay. Maybe as a reader then, it would help to have some kind of an example of a list or even a laundry list -- not that everybody agrees with it, but just some idea of what you're capturing there, because there isn't really and, so, I didn't understand, which then unfortunately brought me to number 19.

If 19 is your list of other benefits -- because 19 said it's the observation of the PPDC that there are so many more possibilities. This is -- this -- all of these number 19s -- do you remember EPA's budget has the three wings that had human health, it had environmental and it had values. All of these number 19s speak to economic value. So, I'm not against these, that's okay, but that's a very limited list. It's your -- it all speaks to your value and not to your health -- human health and not to your environment.

So, if I read 18 and I go, what are they talking about because nothing pops into mind -- well, things pop into my mind, but I'm not sure they're popping into your mind, let me say -- and then I go to 19, I think it's too

limited. So, either help the reader to understand that you've got more broad -- there's something more broad going on or -- I don't know. But I don't think 19 -- 19, standing alone, I think, to me, gives a reader, I hope, an inaccurate impression that all you're paying attention to is the economic value stuff.

And then I think your appendix is really great. I think there's lots of really great ideas in here and that must be really tough because it's really tough to come up with measurable markers, and I think the longer list you have, the better, and I think this is really great.

MS. EDWARDS: Thank you. Bob?

BOB: Sherry, I'd like to commend the group. I know with the diversity of opinions, there's always compromise and that's what's important in this group.

I'd like to recognize on the last page of the appendix the new objective of 12 low risk pesticides approved with international partners. I'd like to comment the EPA on -- I know there's at least one test case with a global registration of a new active ingredient, an insecticide, and I think this goes back

maybe to some of the transition issues that Al and Rick were raising.

I think the more strategically the agency can work with global partners on getting active ingredients registrations initially rather than having to do it country by country and then address all the trade barriers is going to help everybody, including our American growers substantially because they're going to adapt these new technologies very quickly. So, I commend that goal.

There wasn't a time limit there, so I don't know whether that was during the strategic plan or in a longer period. But I think it's a laudable goal and I appreciate it being included.

MS. EDWARDS: Thank you. What we'll do is take all the cards up and then go for a break. I believe there's another at least four cards up, maybe five, actually. So, Seth?

DR. KEIFER: This is Matt Keifer, I don't have a card, but if I could be --

MS. EDWARDS: Okay, you'll have a card now. You'll go next after Seth. Thank you.

MR. GOLDBERG: I'd just like to comment on goal -- what is this -- HH4 in the appendix, which reads ensure efficacious public health antimicrobial products in the marketplace. That's a goal certainly I wouldn't disagree with, but I think it's sort of necessary but not sufficient. And the other piece to that really is ensuring that there are adequate public health antimicrobial products to meet in merging public health threats.

And so, that leg of kind of OPP's mission, how do we meet emerging threats, which is particularly sort of germane in the area of antimicrobials. It really does seem to have been overlooked in this report. Perhaps it's somewhere buried in the other measures, but I think certainly under that HH4 metric, it's something that ought to be included. So, I hope EPA will consider that.

MS. EDWARDS: Thank you. That's a measure under development, so that's good insight.

Dr. Keifer?

DR. KEIFER: Yes, I'd like to comment about paragraph 15. That is that one of the things that's been enacted recently is HIPAA and the 682 depends on the

reporting of people to -- in some way to various sources that will end up being captured by pesticide manufacturers, is my understanding how 682 works, and then obliges them to report.

HIPAA has significantly weakened the possibility that valid information is going to end up being reported back to EPA through the 682 requirement. HIPAA is the Health Insurance Portability Act, I think it's called. And puts very onerous punishment upon anyone who releases confidential health information that is not required by law. And given that throughout the United States, most states do not require pesticide poisoning reporting by law to any registrant or any surveillance system, the likelihood of a person in any way spontaneously reporting it to anywhere has just decreased because of HIPAA.

A release of any identifiable information by a health care provider is punishable by a $50,000 fine. If it's intentional, it's a $100,000 fine. If there's malfeasance, it's $250,000. So, these are the kinds of things that just send chills up and down the spines of clinicians. And just the general chilling effect that this is going to have on the willingness of people to

report in any way other than obliged reporting which is exempted. State requirements trump -- State requirements for reporting trump the HIPAA block. But most clinicians are not going to be dealing with these fine points of the law and are basically going to be as quiet as they can be with respect to releasing any information.

So, I just would recommend that EPA look very carefully at the implications for 682 that HIPAA brings with it. That's all.

MS. EDWARDS: Thank you, we'll do that. Caroline?

CAROLINE: I just wanted to ask a really basic question because I'm kind of ignorant about performance measures. So, in the appendix, can you explain -- there's like the light gray, the dark gray and the no shading at all. What's the practical significance of those differences? Like the ones that aren't included in the strategic plan, are they being measured some other way, and if they're not adopted by OMB, does that give them less status? How does this work?

MS. STERLING: Sure, good question. The acceptance by OMB means we've gone through and done a lot

of formal paperwork about it. Most of the things that are in -- that are not shaded at all are either under development or we're currently using them, collecting information on them to measure. Measures aren't just for OMB. We've taken the tact that measures are to help us manage our program. So, many of them are at a level that are not of national importance, so to speak, but they are very important about managing our day-to-day program in smaller chunks than on a national basis.

So, the significance is that they don't have -- generally don't have as much paperwork established that's out in the public domain. It also means that some of them are still under development and we're working on them and trying to make them stronger.

CAROLINE: So, is OMB going to do more or have they finished?

MS. STERLING: The strategic plan represents the biggest picture element and OMB reviews that. Every -- it's all pretty nested actually, all the reviews OMB does. But, basically, I'd say every five years OMB comes in and looks at all of the measures that you're using to support your program. So, they'll eventually look at

many of these because they are evidence that we're actually doing something in the world because of our programs. So, they'll eventually have a view of these things, but they're not -- they don't go through the same scrutiny that those have gone through in developing them at the strategic plan level. It's complicated. I'm sorry.

MS. EDWARDS; It is complicated. Susan?

SUSAN: This is one that's not been developed very much, but just a little clarification on OB2, what exactly does that mean? Decrease cost associated with pesticide exposure, benefits from me-too registration.

MS. STERLING: That's basically -- the concept there was that if -- there are less costs to us in processing me-toos. Me-toos are those products that mimic another product that's already on the shelves and has already gone through the data analyses that need to be done to get it to that stage. And, so, they really are less cost to EPA.

Also, I guess the thought is from an economic standpoint that there may be more competition if they're the same product out there and that prices can go down

for purchase of those products.

SUSAN: The word "exposure" then seems like --

MS. STERLING: Yeah.

SUSAN: Decreased associated with pesticide registration?

MS. STERLING: Yeah, I agree with you. That word is --

SUSAN: Is that what you're setting out there?

MS. STERLING: Yeah.

MS. EDWARDS: Jay.

JAY: So, two areas I'd like to focus on. One has to do with the use of the NHANES information which is under item number nine, plus HH1. It's still just not clear to us in any scientific context how both the agency, because it's on your appendix list, as well as the work group can envision connecting the dot of biomonitoring data from NHANES to an actionable performance measure by the agency and then, in particular, as evidenced by HH1, the notion that you could, by the year 2011, accomplish that 50 percent reduction goal.

The basis of biomonitoring data just can't

statistically or scientifically connect back to that unless there's some other hidden activity going on in the agency that we're not aware of.

MS. EDWARDS: I think that what we're looking at here, as I recall, is organophosphate insecticides principally and they've been taken almost entirely out of residential environments.

JAY: Right.

MS. EDWARDS: And, so, I think the baseline was far enough back where we had the original data that we actually do expect to see at least a 50 percent decline.

JAY: Right. So, then, this should be -- shorthand here and organophosphate insecticides --

MS. EDWARDS: Yeah, these are very -- all of these are shorthand. There's more specifics within the fuller text.

JAY: Right. So, in that kind of a total succession of registered uses that would result in that kind of exposure then we can see how that can make sense.

MS. EDWARDS: Right. Yeah, all of these have actually -- especially in the strategic plan, have actually specific chemicals listed and so forth.

JAY: Okay. And then on bullet 15, the reference between connecting FIFRA 682 incident reporting to water quality data, again, maybe there's just some compression and shorthanding of the language here that we've overlooked, but I can't begin to see how those two dots can come anywhere close to connecting into a performance measure.

MS. EDWARDS: Well, we have some performance measures around water quality, and, so, we're using some of the USGS data to help us determine whether we're meeting those goals. But I'm not sure --

JAY: But those 682 incident reports --

MS. EDWARDS: Right. I don't know, Sherry, if you have any insights on that. This was the report of the committee.

MS. STERLING: 682 does include information about wildlife and -- as well as humans. So, I think that was kind of the thought. I'd maybe like to turn to Michael Fry because I think maybe he was helpful -- he was one of the people instrumental in getting number 15 written into this. Sorry to put you on the spot there, Michael, but --

MR. FRY: No problem. Yeah, we're very interested in getting accurate, more comprehensive information reported from 682. That part of FIFRA has pretty much dwindled away with the rule change in 1998.

JAY: What? I'm sorry.

MR. FRY: The incident reporting in 682 is almost non-existent now. It is.

JAY: I'm sorry, would the agency agree with that? I'm sorry, but that's not our experience.

MR. FRY: Well, in terms of wildlife reporting, there are summaries that are given, but the actual meat of the reports is no longer there. An analysis we did of the current law versus previous law indicated that of the 2,600 cases we have, only 130 of them were reported on your regulations as actual incidents. We can discuss this later.

JAY: Right.

MR. FRY: But my point in this, you know, some members believe that revisions of the current FIFRA 682 could greatly improve incident reporting. I think there's no question that going back to the -- at least in the birds, mammals, fish incident reporting prior to 1998

would greatly change the incident reporting and would improve it. And that was one of the issues that we brought up here.

JAY: So, let me just see if I maybe can understand. Are we talking about not the reporting from registrants to comply with 682, but how that information is then, in turn, compiled, composited and accessible to the public from the agency?

MR. FRY: Well, that data is compiled in the EIIS database and where there is sufficient data to, you know, describe the incident in detail, that's done in the EIIS database and also in the Ames database that the American Bird Conservancy has for birds, in particular.

Most of the individual incidents now are reported as summaries and the species is not listed, the numbers of birds are not listed. You know, the reporting has decreased considerably with the change in the rule in 1998, and we would like to see, you know, accurate complete reporting of incidents that are observed.

Now, in many cases, the incidents probably don't have enough detail to be included in the database, but that's not a reason for eliminating pretty much all of

the reporting.

JAY: Okay, well, I guess we need to talk about this further in some other venue, but it just seems to me that this is important that we've brought this to light and I'd like to have further conversation, but probably not to interfere with moving ahead on the agenda here today.

MS. EDWARDS: Okay, thank you, we'll do that. Lori, you're the last commenter.

UNIDENTIFIED FEMALE: Larry.

MS. EDWARDS: Oh, it's Larry.

(Laughter).

LARRY: You can imagine how hard it was checking into my hotel last night.

(Laughter).

LARRY: We have your room, Mr. Berger. We have to talk about this, Debbie.

MS. EDWARDS: You two shouldn't sit next to each other next time.

LARRY: Some observations on this, a couple of things. Not to correct, but to add to what Sherry said about the history of this. One is, Sherry understated

the amount of work that she did on this. Long suffering would be a not adequate statement for Sherry's role in this, number one.

Number two, what this doesn't really explain is when we started this work group, there was an enormous amount of work, multiple day briefings by multiple people at the agency, literally a pile this tall of documents from the agency, and what was clear to us early on was that the agency was not just kind of wondering if maybe they ought to do performance measures. The agency was deeply in the middle of doing performance measures on an OMB level, on a budgeting level and on a management level. And all of those processes were moving. It was a little bit like having a work group meeting on a train platform as the train was moving by.

So, the reason I mention that is that we spent a whole lot of time, Bob, a number of other people, Michael, trying to move through this material as quickly as possible and very intensively over several or a couple of months and put together a report that then was out for review at the spring meeting and then came for approval at the fall meeting.

I think it is great that people have lots of comments on it. I want to encourage people to have comments on them. What I would like to suggest is procedurally when we're pretty far along, I think we should have up front said that we have to move fairly quickly to have meaningful comment to the agency, given how quickly the process is going.

Secondly, that this is a report that's a snapshot in time, not a report for the ages on performance measures. So that maybe what we could do, when we have substantive comments on a report that is the result of an awful lot of work, that's fairly mature, that we include those comments in the docket as part of the report, but that we not open up the entire report process, not to -- I don't want to eliminate comments, but would not revisit the entire report.

My concern in this is that we're -- that most of the information from which this report is based is stuff that we looked at 18 months ago. And unless I'm wrong, we all just haven't sat around waiting on this performance measures thing until we were done with this report, right? So, I would like us to work in as timely

a fashion as possible and incorporating people's comments.

I'd also really like, and, Sherry, you can -- you don't have to be involved in this (inaudible) Debbie and Marty. I would like to know where, at some point, and it may be the next PPDC meeting, especially in the context of Marty's budget discussion yesterday, see really where we are with performance measures, because I think you folks are quite a bit beyond where we were when we started this process, and I'm not -- I'm partly interested in seeing what value the PPDC provided to you, but I'm also really interested in where you are given that it will be almost two years from the initial establishment of the committee.

MS. EDWARDS: Thank you. Thank you, Sherry. Very good session. I think, obviously, this measures business is not going away. It's a very good thing. What it does is totally focus us on putting our resources where they need to be, defining our goals and constantly having those goals before us as we develop our resource planning, work plans and so on and so forth. So, we'll be doing this over and over again and looking at the

success of it and where it needs to be tweaked.

We're going to take a 15-minute break now and we'll start promptly again at 10:30 with the Cause Marketing Panel. We can take a shorter break if you'd like, 10 minutes, all right, 10:25.

(A brief recess was taken.)

MS. EDWARDS: Okay, folks, the break's over. Thank you. Our next session, Session 11, is on Cause Marketing. It's been somewhat of a controversial issue for us. The session chair for this is Anne Lindsay, our Deputy Director for Programs, and Dennis Edwards, who's the Chief of our Regulatory Management Branch in the Antimicrobials Division is here, too, to present from EPA, and Anne and Dennis have put together a panel for this session. So, Anne?

MS. LINDSAY: Okay. Just a couple of introductory things on this session. In this session, what EPA is hoping to get from the PPDC members is your initial thoughts, advice, guidance on two kinds of questions. One is you will see through the device of the panel presentation, I hope, the kinds of factors that we think about when we evaluate pesticide labels to

determine whether we think a statement might be false or misleading. In this case, this particular case study is labeling that we've called cause marketing type labeling.

We had a set of factors that we thought about as we made the decision. You'll see that illustrated, I think, in the panel presentations, and then when we open it up to the full group for discussion, we're actually going to have -- we have three questions we'd like you to focus on, and they go to were they appropriate factors, should we think about modifying those factors in some way, was there a missing factor that we should actually for the future incorporate into our decision making processes, what kinds of information might we request from a registrant who's proposing this type of labeling to help us ensure that we're making the best decision that we can?

And then, finally, what kinds of mechanisms for public participation should we use to solicit views on these criteria for the future? In other words, would you recommend that we do some more work and come back to this advisory committee, do you never want to hear about this again, but you'd like us to be doing something else? So,

that is going to be the area that we're most soliciting advice from you.

We have put together a panel and it's going to go in a slightly different order than is in your agenda. We're actually going to start with American Red Cross, Kristine Templin, who's over here in the corner. We're then going to move to Clorox and it's going to be a brief tag team of Bill McCormick and Mary O'Connell, and then we're going to move to Dennis -- and Mary is sitting right here at the table, Bill behind her. Then Dennis Edwards, our Branch Chief from Antimicrobials Division. We're then going to move to Jay Feldman sitting here in the middle, Beyond Pesticides, which is one of the organizations that's actually provided comment on our decision in this case, and Dennis Howard who is not only being Dennis Howard this morning, but he's going to actually present the AAPCO perspective because they've also submitted comments to the agency.

And I will note that just very recently we got some additional comments from the Pesticide Stewardship Alliance and they're being circulated. Since the president of the Alliance is on our group, Carol Ramsey,

I'm anticipating when we open this up to general discussion of the advisory group, Carol will probably have some points that she wants to make along the lines of the points that are in her very recent letter to it.

So, while we do the panel presentations, we're just going to go one, two, three, four, five right through them, not open up for questions. Everybody on the panel is prepared to give you a succinct about five-minute presentation. Yes?

DIANE: Is this being presented in the terms of just consumer products or is it an issue you would be thinking about for any pesticide product?

MS. LINDSAY: I think any time an applicant came to us and said that they wanted to have this type of cause marketing labeling on their product, we would have to take a look at that and use the criteria and the factors we've got for evaluating the request. So, whether it would happen for, say, an agricultural product as opposed to a consumer product, I don't know. But you should think of this, I think, as broadly across all categories of pesticides.

So, with that, unless there are more clarifying

questions such as Diane had, I'd like to turn things over to Red Cross and Kristine.

MS. TEMPLIN: Good morning. My name is Kristine Templin. I'm the Director of Corporate Partnerships and Cause Marketing for the American Red Cross. I want to thank you for inviting us to participate in your discussion today and to share a little bit about cause marketing and the value that it brings to the American Red Cross.

The American Red Cross is a humanitarian organization led by volunteers. We provide relief to victims of disasters and help people prevent, prepare for and respond to emergencies. Although guided by a Congressional charter, the Red Cross is not a government agency. Our services are delivered for free and we rely on donations from the American public to fulfill our mission.

One way that the Red Cross raises funds and awareness of our programs and services is through cause marketing. Occasionally, cause marketing is called different names, such as philanthropic marketing and gift-based marketing. From the Red Cross' perspective,

cause marketing is when a company donates a percentage of sales of a product or service. It's a combination of a philanthropic benefit, support for a cause and tangible business benefit.

So, why do non-profits cause market? Cause marketing benefits go well beyond a traditional donation. For example, awareness. Cause marketing offers the potential to gain marketing exposure. At no direct cost to the Red Cross, we can reach the public where they are and with ways that can raise awareness of both our mission and a particular message.

Cause marketing offers visibility, public awareness of an issue in an innovative way to reach a broad base of consumers with important educational and action-oriented messages. For example, our cause marketing relationship with Clorox allows us to raise awareness of the vital steps that we recommend all families take to be prepared for all of life's emergencies.

Another added benefit is revenue. Cause marketing offers the Red Cross new sources of revenue beyond the traditional investment pool. Not only do

companies make contributions to support the Red Cross, but the cause marketing promotions frequently trigger additional donations and support from employees, customers and other company constituents. The revenue is applied to the overall work of our organization and helps pay for our critical operational costs.

Finally, consumer engagement. Encouraging consumer engagement can be a critical component in cause marketing programs and the Red Cross benefits enormously from this support. For example, our organization is one that is moving away from just educating to motivating. Our corporate partners can be critical sources of human muscle and brain power for our programs and services.

Just as the Red Cross has an incredible responsibility to help as many people as we can through our services, we also have an obligation to support those services by developing strategic relationships and programs. The Red Cross guidelines for development cause marketing relationships ensure that any partnership will have a clear commitment from corporate partners, mutual benefit and a transparent execution.

As an organization, we acknowledge that the Red

Cross logo is universally one of the most trusted and recognized symbols. We take great care in protecting the brand and consumers when participating in a cause marketing promotion. The Red Cross strictly follows Better Business Bureau cause marketing guidelines to clearly communicate how much of the purchase price supports the Red Cross, the minimum or maximum donation, and the duration of the promotion.

The Red Cross also requires any partner to include non-endorsement language that states, the American Red Cross name and emblem are used with its permission, which in no way constitutes an endorsement, express or implied, of any product or company.

Thank you.

MS. LINDSAY: Okay, I'd like to turn the floor over now to Clorox and I think Mary O'Connell is going to start.

MS. O'CONNELL: Thanks so much for the opportunity to talk to you today. Kristine just mentioned to you things that are really important in evaluating a cause marketing program from a partner perspective. The cause needs to be genuine, it needs to

be sincere, it needs to be transparent, and for us, on the company side, it also needs to make one other hurdle, to achieve one other hurdle, and that is that the cause makes sense to the consumers who buy our product. Does it make sense for the Red Cross and Clorox to partner?

We'll take a look at our history. I think most of you in this room know that this partnership didn't begin today, it didn't begin last year. We have a long history of partnering with the American Red Cross. I think -- the way I think about it is that we've come together during times of disaster.

Product donations through years and years, more than 35 years. For generations, we have donated products to the American Red Cross for disaster relief. The American Red Cross recommends the use of bleach to disinfect water during emergencies. We are used in the clean-up of hurricanes from floods, from tornadoes, from tsunamis. I think all of you are aware of that, and it's an important part of why we came together as partners. Bleach actually is one of the most common items distributed by the Red Cross during times of disaster.

I've talked about sort of broader domestic and

international donation and partnership over the years, but there's also local efforts. For us, helping out following Katrina was a local effort. More than 100,000 gallons of bleach distributed down to the Gulf States at that time.

We are also a partner with the Red Cross in our backyard. So, we're the largest corporate contributor to the Alameda/Contra Costa American Red Cross Blood Bank. That's one of the missions of the Red Cross. We all think of it in blood donation, but we also help other local chapters of the Red Cross on another important mission for the Red Cross and that's fund raising. So, a couple of summers ago when the New York Chapter of the American Red Cross was celebrating its Centennial, we held an event in New York City, White T-shirt Day, to raise $100,000 for that chapter for its Centennial. We made a pledge of $100,000, we raised it and we donated it to the organization.

From that point and really from those moments following Katrina, we had a strong desire between both organizations to broaden the partnership. It's not just what we wanted to do, and I must say it's what consumers,

the American public, is hoping that leading brands do, they expect leading brands to support non-profits, to support causes. If you haven't heard numbers before like this, they'll be amazing. I know they're very compelling for me in the job that I do for Clorox.

Eighty-nine percent of Americans say they expect leading brands and non-profits to work together to raise money and to raise awareness of causes, hugely important. There's another 86 percent of Americans that say they expect companies to tell them about the causes they support and nearly half of those people surveyed -- and this is by Cone (phonetic), I don't know if you're aware of Cone Research. It's a public relations firm up in Boston that tracks consumer perceptions of cause and the importance of cause and they do an annual survey. It's called the Cone-Roper Report, and that's where I'm pulling this data. This is 2006 data.

Nearly half the people expect companies that support a cause to tell them about it through packaging. It's a hugely important thing. It's actually a wonderful thing that the American public is saying, we expect companies, we expect businesses to support causes that

are important to us.

Next slide. As we got together and decided about our partnership, we thought it needed to be very transparent. We talked about that early. It needed to have a single point of focus and that would be education. We started out by putting together a mission statement and then the purpose of the partnership to be very clear to the people who are Clorox consumers, to be very clear to Red Cross and the Red Cross organization and the volunteers of the Red Cross system.

So, we would focus on fund raising and we would focus on educating families on the importance of being prepared for life's emergencies. As I mentioned before, we've come together, the Red Cross and Clorox, during times of great emergency, but emergencies are every day and they're something families need to be ready for and need to be motivated to get prepared and they need to do that every day.

And how would we do that? We would do it through consumer materials, through education materials, like you see on the left of the slide, A Family Preparedness Guide, the simple steps you need to do to be

ready every day. We would do it through website education, very important right now. And we would do it through customer outreach. For us, customers are retail stores and partners.

If we go to the next slide, that would take us to packaging. This is one of five labels that we presented to the EPA asking for their input on this cause marketing program and on the ability for Clorox and the Red Cross to talk about the cause on packaging. What you'll see on this packaging is a very clear message that this is a cause marketing program. It's very transparent. Help Clorox raise $1 million for the American Red Cross. Bill will talk you through the steps that led to the approval of this production label.

MR. McCORMICK: Thanks, Mary. Just one point that some folks in the room may not be aware of is in the wake of Katrina when we were trying to ship 100,000 gallons of bleach into the New Orleans area, part of what we wanted to do is make it easy for consumers to do emergency disinfection of drinking water and we worked with Frank Sanders. This was actually his suggestion on how to translate drops per gallon into something that

folks could easily do, and we did a conversion of capfuls per volume of water, and Frank was really instrumental in getting that information out and approving that kind of label amendment so that we could get easy water disinfection instructions to folks in an emergency situation in Katrina.

So, if we can go to the next slide. We knew this was a high bar because of the Red Cross emblem and we knew it was going to take some time to get label approval, and we really commend the agency for working with us and keeping an open mind on this. The program was conceived after Katrina in late fall and we put together the program with the Red Cross and then began our advocacy with the agency on this.

And this is basically the timeline. The agency, you know, to use a sort of crude term, did not simply roll over and stamp these labels because we asked them to. They really set a high hurdle for us to let's understand what bleach does. That was sort of the hallmark product in this presentation. We presented some safety data for them with Dr. Toby Litovitz, who was the American Association Poison Control Center lead for about

15 years and really knows bleach well.

And after that presentation, they also said, well, are consumers going to perceive a Red Cross in the way we're thinking about it and the way you saw it in the previous slide, are they going to perceive that as a safety message and they asked us to go out to consumers and we did a four cell, 200 person per cell study to take a look at the perceptions of safety with these products. And the answer came back that they were clear that the American Red Cross and the way it was positioned on the label was not an endorsement of safety of the product that it was on.

So, we came back with that information with the agency. In November of last year, they approved the label. And that's it. Thanks.

MS. LINDSAY: Okay, thank you. We'll now go to EPA and Dennis Edwards.

MR. EDWARDS: Next slide and scroll down. Next one, too. All right. I thought I'd start off by talking a little bit about the agency's authority in situations like this. Section 12E of FIFRA states that it's unlawful to sell or distribute any pesticide that is

misbranded. FIFRA 2Q defines what misbranded means. 2Q(1)(a) specifically talks about a product that's considered misbranded if its label bears any statement design or graphic representation which is false or misleading, and then our regulations in 156.10(a)(5) then provide examples of statements or representations in labeling which constitute misbranding and false and misleading statements.

The next two slides you've already seen but these are the actual language that we approved last fall for five Clorox products. You can see at the top of the first one the Red Cross symbol and the Red Cross name, the phrase, Dedicated to a Healthier World, and then the cause marketing, help Clorox raise $1 million for the American Red Cross. And then on the back panel, again you have the Red Cross name and symbol, the Clorox name, you have a paragraph providing detail of the fund raising. And then the last statement as part of that section is the disclaimer that says the American Red Cross name and emblem are used with its permission and it's in no way an endorsement of the product or the company.

In our initial discussions with Clorox, the agency expressed concern that the Red Cross symbol may represent a safety claim to many consumers, and as such, would be a false and misleading statement. We were very cognizant that our label review manual cites the Red Cross symbol as a symbol of safety or implied safety. I'd point out that our label review manual is guidance and that issues like this have to be considered on a case-by-case basis looking at the guidance that we have available.

We were also concerned with how the consumer would perceive cause marketing associated with the Red Cross and, finally, there were concerns that the public might believe that a particular product was being endorsed or promoted by the Red Cross through use of their symbols on the label.

As you've already heard, Clorox addressed these concerns. There was a presentation by the National Capital Area Poison Control Center on sodium hydrochloride or bleach incidents. There was a consumer market survey that Clorox conducted which the results indicated that consumers were not influenced by the Red

Cross symbol placed on Clorox products, and then to address our endorsement, our promotion concerns, there was a disclaimer statement that they came up with that was added to the label.

So, having had our -- most of our concerns addressed, realizing that there was still some, I guess, concern in the program about this approach, but having the false and misleading part addressed, we went ahead and approved the labels.

Once we approved these labels, we recognized that we would need to determine what factors that we would use to consider other logo charity language. Since we consider logos and charity on a case-by-case basis, we would need to put together the factors that we would use in determining whether or not that logo or charity text would be acceptable.

The very first and overriding one that we used is what's listed in our regs in terms of the examples, in 156.10(a)(5) of what's considered to be false and misleading label statements. Once we address that question in making a determination, if we think that the answer might be yes, you know, whether it's yes or could

be yes, then we would ask for a survey to be -- a consumer market survey to be conducted. In order to determine whether or not the text or the logo could be considered false and misleading by the consumer.

Some of the questions that the survey might need to address would be whether or not consumer use of the product might be altered by that text or logo that was being proposed, and if consumer use was altered, how serious might the consequences of that be. If the product were misused, for example, what might be the results of that misuse in terms of acute toxicity or otherwise.

If we decide that a survey is needed because there might be situations where the logo or the text were okay and we wouldn't carry this any further, then the survey would need to be submitted to a third party independent entity. They would look at the design and the questions of the proposed survey and see if they would address our concerns about the logo or text being false or misleading. And then, in some cases, we actually may need some type of post-market survey in order to then follow up and make sure that the logo or

text that we accepted did not end up being false or misleading to consumers.

Next slide, all right. Another factor that we would want to see addressed with any application of future submission of either logo or cause marketing text would be the possible impact that that would have on the consumer, different age groups, different cultural backgrounds and people of limited reading ability. So, we would expect that the submission that would be submitted would have to have -- would have to address that in some manner.

Finally, any future submission would also have to address the consequences that that logo or text might pose to consumers if, indeed, they were misled. We would expect there to be a very thorough discussion of the possible consequences, some examples provided, and then, along with that, we would expect there to be mitigation potential addressed in terms of if the consumer was led, what might the mitigation that could be undertaken.

And the next slide. Obviously, having gone through all this, you cannot submit the submission through our notification process. We would expect it to

be submitted as a label amendment. Now, I have not addressed all of the factors that we've looked at, but I think just the major ones that I -- that we believe would need to be put up front. There are other factors such as how you group the text and logo together, how you -- the font size, using the Better Business Bureau guidelines and some other -- and preparing the logos and text and other criteria.

And then the final slide are three questions that we put together that after the presentations are made we'd like to come back to and have some discussion and comments on these three questions.

MS. LINDSAY: Okay, thank you, Denise. Jay Feldman, Beyond Pesticides.

MR. FELDMAN: Thank you, Anne, and thank you for the invitation. I'm going to give everybody some PowerPoint relief here and I'm not going to have any slides put up.

First, I should say as background we certainly are not questioning the Red Cross and its motives and its efforts and its work, historically, and we're not questioning Clorox's program, its humanitarian concerns

and its commitment to support for the Red Cross. That's not what this discussion is about in any way, shape or form.

This is a rather simple conversation, I think, about whether -- what the agency should have done legally and what the agency should do in the best interest of protecting public health and the environment in the future. There may be a difference of interpretation over EPA's existing guidelines and the force of law that those guidelines have and whether, in fact, EPA has the authority under its existing guidelines to make a case-by-case decision, taking into account its own restrictions.

Those are all questions I will leave for the lawyers and, perhaps, the courts. The question here really for a panel such as this and the agency is how can it best ensure that there's compliance with its mitigation measures because, as we all know, the label is the law. The label is really the only mechanism by which EPA can bring to the consumer information on how a user can protect not only him or herself, but the environment and others around him or her. And, so, this is not a

small issue. This is, in fact, the only way EPA can really protect and ensure so-called proper use of a product.

Now, for us, if we want to go deeper into this, this, for us, hinges on EPA risk assessment decisions as well because, in fact -- in point of fact, EPA is making risk assessment decisions based on the presumption that there's label compliance, in fact, based on the assumption that there's 100 percent label compliance. So, anything the agency might do inadvertently to affect that percent of label compliance and, therefore, mislead the public is something of concern to the public and this panel and the agency, of course.

I think one of the questions on the table is the use of a logo that has implied safety associated with it. Does the use of that logo equate with a safety claim? And if it does equate with a safety claim, even if it's for a small percentage of the population, if it's for one, two, three, four, five percent of the population and it equates with the safety claim, then we have a problem here because EPA has regulations that say that no registrant shall put a safety claim on the label. We

believe this equates with a safety claim.

Now, certainly, you all know we're dealing with a hazardous material here. Clorox, on its own label, refers to, although not expected -- and I'm quoting here -- heart conditions or respiratory problems such as asthma, chronic bronchitis or obstructive lung disease, maybe aggravated by exposure to high concentrations of vapor and mist. Now, you say, well, it's not being used in that manner and I say to you, there's a dilution factor, there are instructions, there are requirements that this product be handled in a manner that ensures, at least under EPA's analysis, that we will minimize risks and that we will protect people from this very condition.

Isn't it ironic that we're trying to protect people with asthma and respiratory problems in cases where there's mold and we're doing remediation work, important work that the Red Cross does, and we may be inadvertently undermining the health of those very people who we're trying to protect because of a small percentage that may not comply with the label?

Now, I would suggest that the protocol that Clorox used and presented to the agency by way of

defining that this was, in fact, not a safety claim is inadequate. A study of 800 people in four cells is inadequate. And, in fact, I would suggest that the agency have a protocol, have developed a protocol to define what is an adequate assessment of whether a symbol equates with a safety claim. The Red Cross symbol equates with a safety claim.

And, so, lacking that protocol, lacking that protocol, the agency really needs to deny this label or future labels like this because it is not able to determine that the product is not misbranded. The agency doesn't have the data. The Clorox study is inadequate. The agency does not have a protocol for telling registrants the kinds of studies that must be conducted to make a determination as to whether the conclusion that the symbol does not equate with a safety claim is, in fact, true. Lacking that protocol, the agency must find that it does not know whether the label is misleading, at which point it must deny the label.

Now, understand, I come to this, as do others within the agency, from the perspective of having worked through the label improvement program for many, many

years, and I can tell you from that work that -- as many of you know, I'm not telling you anything new -- that it's really hard to determine what people see in symbols, very difficult. We had -- we, over the years, have considered all kinds of pictograms to warn people about the fact that they should just read the label, not follow the label, just read it. Get their attention, direct their attention toward the label. And we had a really hard time.

We didn't have -- the EPA didn't have the expertise, we tried to do various studies to make a determination as to whether, in fact, we could get people to read the label. And as you know, EPA does have a campaign, Read The Label, because again, it's very important that there be this compliance.

But this is what the agency did find, and I'm quoting from a '96 review. "Studies showed that consumer perception of product hazardousness" -- is that a word -- "is the most significant indicator of whether or not they will read the precautionary label followed in significance by the level of familiarity with the product." So, that's a piece of information that really

undermines the conclusions of Clorox and this is based on a literature review, not one study, mind you, but a literature review of what information is out there in terms of whether people follow the label and so forth.

So, I think we need to put this in a historical context. And, again, you know, we applaud the Red Cross and we applaud Clorox for supporting the Red Cross, we just don't believe that this is the mechanism. And I fear, actually, that we're shifting some of the burden here to the states to -- in terms of an enforcement nightmare, because clearly what EPA should be doing is facilitating enforcement. And we're also shifting some of the burden here possibly to the courts. Does the Red Cross want to be held liable for hazards associated with product use with a lawyer claiming that my client assumed this product was safe because it had the Red Cross symbol on it? Again, a safety claim violation of the law.

Now, last thought, despite whether we agree or disagree on whether this is a violation of law, the real question here is, how do we set up a process to make a real determination that protects the Red Cross? We want the Red Cross protected, we want that symbol protected.

It's a very valuable symbol. The process we have and that was just described by Dennis is an inadequate process. We need protocol, we need reviews, we need determinations. And if there's any question in the end that we just don't know, that we don't have good enough information, then these sorts of symbols must be denied. Thank you.

MS. LINDSAY: Thank you, Jay. And now we'll go to our last panelist, Dennis Howard.

MR. HOWARD: Thanks, Anne. Well, I represent the Association of American Pesticide Control Officials, at least today that's my capacity, and I'm actually representing Mary Ellen Setting, who's a member of the PPDC, but she was called away on business with gypsy moth control in Maryland. It happens to us all the time. So, I'll try to fill in for her as best I can.

A lot of what's been said by Mr. Feldman is actually similar to what I have to say for our organization and the concerns that we have about this step that EPA is taking in allowing for certain types of logos to be allowed on pesticide containers that they have refrained from doing so in the past. Just to give

you a sense of our concern -- we put those concerns together in a letter to Steven Johnson, the Administrator of EPA, and you all should have a copy of that in your packages.

But I represent the people who are back in their capital office buildings looking at pesticide labels that come across their desk every day, and what they're doing when they look at those labels and making a decision on whether to register that product for sale and distribution in their state is to make sure that the label follows the policy, the guidance, the laws that have been set up by EPA and, in some cases, by their own state regulations to make sure that they comply with those requirements.

We're very careful -- our reviewers are very careful to not accept pesticide registrations that vary from what the requirements are and, in many cases, we act as sort of a back-up for EPA because EPA has so many labels that go through and they don't have as many people in total as we do out in the states to take another look at these and find problems and bring them back to the attention of the agency. There's been a good mechanism

to do that.

In the particular case that we're looking at here, and I'd just like to make sure that everybody understands that AAPCO's concern is not about either the Clorox Company or the Red Cross Company. We certainly think that the efforts they're making to partner in raising funding for the Red Cross is a very valuable thing to do. Our concern is really the mechanism that's being used here and that's the pesticide label.

We have -- I think our mantra has probably been, recently, especially with the spray drift task force, that we need label statements that are concise and that are clear and that don't have mixed messages. And we see this type of an approach as being one that provides a possible mixed message for the users of the pesticides when they make a decision.

I understand that the Clorox Company did a -- in this particular case, did some consumer marketing or consumer awareness and focus groups to understand what the message that was going on the label would be and there are probably lots of ways that you can do that. Just from my perspective, and I mean, literally from my

perspective, when I sat back here and watched the slide that had those little copies of the labels, from here I would see Clorox and I could see a Red Cross. I couldn't see the little words that mention about the disclaimers and the many conditions that EPA was careful to ask that would go on their label.

So, reflecting back on the fact that people have a hard time reading labels to begin with when our concern is that it's really essential that they not be misled, we're very strongly objecting to this approach for these types of consumer marketing types of approaches with labels. I understand that consumer markets are different from agricultural markets, but when we look at labels, we really have to look at them from the standpoint of whether the information that's being portrayed there is in accordance with statutes and with regulatory requirements.

So, that's kind of a general point of view of where we are. I think that one way that -- I believe AAPCO's talked with EPA about perhaps a way around some of this is to look at something other than the label as the mechanism for using -- for getting this information

out. A label has to be permanently affixed to a container. There may be ways to get messages that aren't permanently affixed. But we will -- we'll pretty much stick to our guns at AAPCO that if there's a question about a product, statements being potentially misleading or false, that that doesn't -- that does not belong in the instructions for use of a pesticide.

That's my comments. Thank you.

MS. LINDSAY: Okay, thank you, Dennis. And we have left up the questions that we have at least in our mind. And I'm actually going to start with Bob because I think you had your flag up, and then I'm going to go up the table and I'll go back and pick up.

BOB: Well, that was a good choice. I appreciate that.

(Laughter).

BOB: And the reason I say that is not because I have a lot of insight into this, I just had a question that would help me understand the issue better and I guess I'm having some difficulty understanding all the hubbub around it. Is the issue whether or not cause marketing should be permitted on labels, more or less if

it had been literacy or anti-poverty or human rights cause -- type of cause, would it have been a problem? Or is the issue the narrow issue of because it's the Red Cross and it somehow implies safety? Which of the two is it, or is it all of the above?

MS. LINDSAY: Well, for EPA, no matter what the proposal was, we would always have to examine whether we thought there was some way in which that proposed statement or logo could be false and misleading. It's just -- as Dennis noted, it's always a factor we have to think about with such statements.

I think in this particular case, because it was the Red Cross symbol, and even in our own label review manual, we identify that Red Cross symbol as an example of something that can be, in context, false and misleading. This represents a particular additional feature of the case in question. What we're really asking the group to focus on though is not specifically this one case in question, but knowing that we've got to do this regardless of what the symbol might be or the statement might be, what would constitute a rigorous examination and what I would call an information and

database decision on whether something's false or misleading. Does that help?

Okay, Pat, I think you're next.

PAT: Thanks. I guess like Bob I'm somewhat surprised by the visceral reaction that this has drawn. I think I understand the concerns that have been expressed by Dennis and by Jay and want to respect them. However, you know, cause marketing is something that is a broad and, I think, as you listen to the Red Cross and Clorox, you know, quite valuable practice that we have ongoing with a very broad range of products.

And so, while the pesticide label is unique and while there needs to be avoidance of confusion, I think it's unfortunate to single this particular group of products out and take that opportunity to spread that message broadly.

Let me just offer you another example because I'm working with a client on a label that EPA has recently approved. The company is Proctor and Gamble. Proctor and Gamble has been involved in global efforts on safe drinking water and on children's health programs for many, many years. They've developed a product that has

gotten a fair amount of attention in the press. It's called Pure. It is a little sachet that basically replicates what goes on in a water treatment plan. The acute endpoint are all Tox 4 except for one at one Tox 3. It is used -- it's been used in Sub-Sahara in Africa, in Southwest Asia after the tsunami. CDC has done clinical studies showing reduction in diarrheal disease of 50 to 80 percent in several different African villages. This is a not-for-profit product and this is a product that has also been used in hurricane relief efforts.

It kills bacteria, viruses in the water, cleans the water and, you know, is clearly something that has great societal value. Proctor and Gamble has wanted to tell their consumers, has told their consumers about that in other ways, and wants to be able to go ahead and convey their support for an organization called Population Services International, who essentially is one of the NGOs that helps distribute these products in various portions of the world.

In this case, there is not a logo involved, but to be clear, the company would have preferred to use the Safe Drinking Water -- Children's Safe Drinking Water

logo that it's always used and may want to revisit that. But the message is quite similar to the Clorox message, that by purchasing this product, you are helping Proctor and Gamble contribute X amount of dollars to PSI's efforts at children's health and global safe drinking water.

So, I just wanted to make clear that Clorox is not alone in this, that there is a considerable amount of interest on the part of other companies to go ahead and, in a responsible way, engage in similar cause marketing.

MS. LINDSAY: Thank you, Pat. And, Amy, I need to apologize, somehow -- I can see your card clearly now, but I couldn't when I skipped over you.

AMY: That's okay. To me, as an educator, this issue -- and, again, this is not for me about Clorox or about the Red Cross, but a more global issue of what's going on here and what implications and precedents might be set for the future.

To me, this really does muddy the waters and take the attention off the focus of the label as a legal document and it shouldn't be just about whether something is false and misleading, but also whether it's

interfering with what -- behavior that we want to change, and the behavior that we want to impact here is to have people read and follow label directions.

To me, when you're putting something on -- this is not a pair of jeans or a cup of coffee where I can sort of follow my own social choice as to what I'm choosing. The choice of a pesticide product should be first based on whether I have a pest problem that needs to be controlled, whether a pesticide is an appropriate way to control that pest, whether the pesticide that I'm looking at is effective against that pest, and what are the safety parameters with regard to human health and the environment. And, to me, this begins to muddy that process of making those evaluations.

And I wonder if we're going to step into social issues why then we would not want to know a little bit more about the product's other impacts. Go for a net social impact then and take a look at, huh, well, it's really doing a wonderful thing here -- and I agree that it is, helping these organizations, doing some very good things -- but what are the costs that that product poses in terms of is it paying its workers fairly, is it using

a good workforce, is it creating other problems? I mean, we're stepping into a huge issue, to me, once we step into the issue of social good.

But my basic premise is that as an educator, I think that it really does pose a chance of taking away from that message of needing to read and follow the label.

MS. LINDSAY: Okay, thank you. Diane, I think you're next.

DIANE: First, a question for the agency. My assumption has been that within the confines of the advertising regulations and requirements, that a company could put on a website or an ad in a magazine that they're supporting, you know, breast cancer research, they'll match dollar for dollar or whatever it is, that the issue here really has to do with the label, putting the statement on the label.

MS. LINDSAY: Our focus is on the label. I mean, I'm not an expert in our advertising requirements. I know that we have a care and concern for advertising that may, in fact, really mislead somebody with regard to the registration status of a product, for example.

DIANE: Well, it would sound like that, unfortunately, the Red Cross has such a good reputation, that if you put a Red Cross symbol on your website, you may possibly have an implied safety claim. That's outside the context of the question.

MS. LINDSAY: I can't speculate about that.

DIANE: So, we're really focusing on the idea of putting it on the label. Then I would follow up Amy's comment by saying, I'm surprised that the first question isn't should you even approve -- should cause marketing statements be allowed, period. And then if the answer or the decision is that, yes, they can be on the label, then you have the tier of in what context and what. But I would think the first question is whether they should be permitted at all on a pesticide label.

MS. LINDSAY: Susan?

SUSAN: I have some new product ideas for you all to consider. Ortho-phenylphenol product to clean your air duct, dedicated to a healthier world. Roach kill propoxur, dedicated to a healthier world. Tide with triclosan, dedicated to a healthier world. As Patrick indicated, I'm sure there's lots of other companies who

want to jump in with this. For each of these products, ortho-phenylphenol is a carcinogen, pumping it into your air ducts once a month to prevent mold may not be the best approach for preventing mold. There are alternatives that do not bring with them some of the hazards that chemical pesticides bring, and this is not to denigrate the benefit of sodium hydrochloride to water cleanliness because certainly that's been a big lifesaver, there's a real benefit to that.

But it gets into gray areas when you're talking about situations where you do have other non-chemical means, non-toxic means of controlling pests, but this implication that it's -- you know, you're making the world healthier by using this product just isn't going to cut it.

I also, like Jay, question the surveys. It's well-known that how you ask a question of a focus group really affects what their answers are, and unless that focus group, the questions were reviewed by someone who doesn't have an interest in pushing this forward, it's hard to accept that as a valid study.

MS. LINDSAY: Thank you. David Lewis?

MR. LEWIS: Speaking on behalf of S.C. Johnson, I guess S.C. Johnson believes that there are a number of questions that the agency has to ask in terms of cause marketing. The types of organizations and symbols may or may not be appropriate. I think certainly everyone in this room would applaud what Clorox is doing in terms of support of the Red Cross and utilization of the Red Cross symbol. But on the other hand, there are other symbols and other causes for which the agency may not want to provide an endorsement.

There needs to be some sort of standards that are established for that, and I'm not really sure that the agency wants to be in a position of deciding, in terms of political correctness or anything else, that this symbol is appropriate or this cause is appropriate and this one isn't. But if you're going to allow it, there need to be some standards there for that.

I guess secondarily we talk about the tops of information that are required to support that and I applaud sort of the questions that the agency is looking at there in terms of surveys. Whether those surveys should be submitted to outside panels in terms of the

questions that are being asked is certainly something the agency needs to consider, but, again, those standards need to be made public so that everyone can avail themselves of the same opportunity.

And I guess sort of finally in a related manner is the issue that gets to the use of symbols in general on pesticide products. The agency, for years, has been working on design for the environment. You know, when Jay had spoken earlier, one of the things that he indicated is a need in terms of the labels to help guide consumers in terms of how to protect themselves and the environment. And I think that most companies certainly recognize that consumers are looking for products that are, on a scale, more beneficial to the environment or more safer to use than others, and that's long been a goal of the agency from the time of creation of the EPPB.

There has not, however, really been a mechanism for distinguishing between those kinds of products. We would certainly urge the agency to continue looking at means to utilize those with objective standards.

MS. LINDSAY: Thank you. Carolyn?

CAROLYN: I wanted to try to address that second

question up there, what factors should EPA consider in deciding whether or not to approve these kind of applications, and the factors that they should have considered when approving this first one. My first boss loved this saying, which is like consistency is the hobgoblin of small minds. But I actually think that consistency is a good thing for an agency. So, I think it's really important that EPA be consistent with the earlier work, that it's done on labels and what's important about labels and what people read about labels.

So, I think it's important to look at the information that came out of the CLI surveys that were done and it's almost 10 years ago since that happened, I think, but I think the information is still important and valid. And the things that came out of that survey that I think are relevant to the cause marketing issue are when they ask consumers like what part of a label do you look at, people said they look at the front of the label, they don't always read the back. They ask consumers what on the label do you read and consumers were much more likely to look at pictures rather than words.

And then the third thing, which I think Jay

mentioned, is that the more familiar they are with a product and the more that they feel like it's not a very risky product, the less likely they are to read the label.

So, if you put those three things together, EPA basically contradicted all of that information in its approval of this label. What they did was put the picture on the front and the small print disclaimer on the back so that most people are going to see the logo but not read the text that's supposed to accompany it, and they also used it on a product that's kind of a household cleaning kind of product, which people are -- feel pretty familiar with and feel like it's an everyday thing and are just not likely to read the label at all.

So, I would suggest that EPA take a second look at what the CLI said and try to incorporate that into these kind of decisions.

MS. LINDSAY: Thank you. Michael?

MICHAEL: Thanks. I really appreciate Clorox's support of Red Cross. I appreciate the efforts taken after Katrina. But -- and I think it would be wonderful to have the Red Cross logo on all of the consumer

products that are not pesticides that are marketed by Clorox or Proctor and Gamble or other companies.

I think cause marketing labels on a pesticide label, which is supposed to be a legal document, or at least a large portion of that label is supposed to be a legal document, are completely inappropriate. I think having a pesticide company contribute to Trouts Unlimited so that they can put a fish on their pesticide label would be inappropriate. I certainly don't want to see World Wildlife Fund's panda logo on rat poison.

And, you know, if you start someplace, I have no idea how you're going to regulate it going forward. So, I would deny the cause marketing labels as a uniform thing on all pesticide products.

MS. LINDSAY: Okay, thank you, Michael. Julie, and then I'm going to move over to this side of the table.

JULIE: It appears that the issue I think that we've been struggling with here is what is considered false and misleading, and it seems in this particular one it's whether it's false and misleading in that it's considered a safety claim. So, I guess just looking at

that separated from whether or not -- what factors should EPA consider in cause marketing, I'm just going to reflect on -- just on cause marketing and I'm not really going to debate whether we should have cause marketing or not have cause marketing. But I just think a way to minimize the probability of anything being false and misleading is to consider, as a factor I guess, the relevance of the cause to that product or to the user of that product.

What I would think of would be something like if you have a pet product that's raising money for the Humane Society or local pet shelters or something, there's a relevance to the user, or if you have an insect repellant and they're raising money for the Lyme Disease Foundation, again, there's a relevance to it. So, I think there's a lot less likelihood that it would be false and misleading or confusing to the consumer if there's a particular relevance to the consumer for that cause. Just as, I think, a factor that could limit the probability of being false and misleading.

MS. LINDSAY: Okay, thank you. We're going to do just a time check. I think we've got about five more

minutes for this discussion. So, I'm going to do the three cards that are up, and I'm assuming the cards that are still up over here are leftovers. Okay, good, get your card up. This is the signal for if you need to get your last two cents' worth in. You need to let me know now. So, Seth, we'll start with you.

SETH: Thank you. I'm here today for the Consumer Specialty Products Association, and I'd kind of like to do three things. First, tell you what CSPA thinks about the cause marketing situation generally; and then, two, give you some thoughts about the three questions the EPA has posed and sort of the way EPA is approaching this issue; and then, finally, perhaps a couple of additional short, I promise, comments on some of the other comments from members of the committee.

CSPA really strongly support EPA's position in the availability of cause marketing on labels for registered antimicrobial products. CSPA believes that this is an important tool that its members should have available, subject to appropriate controls.

What are those controls? I think EPA really has it about right. The controls are the misbranding

standard in FIFRA. So long as the cause marketing language is not such that it will cause consumers to be misled, that's really the only legal hook that the agency has to say we shouldn't be allowed to do this.

In fact, there's a reasonably strong argument that this isn't even a FIFRA element of the label at all. You know, to the extent that you have a combined product and you have cleaning directions, for example, those are not subject to EPA regulation. And while the CSPA certainly supports the approach the agency has taken, it's important to recognize that this may not even be within, you know, the scope of what a required label approval would be under FIFRA.

In terms of the level of review, I think it is important to recognize that cause marketing is very prevalent these days. You know, last evening I spent about five minutes looking at the web. I found cause marketing on clothes, coffees, cars, KitchenAid appliances, all kinds of different cosmetics and even over-the-counter drugs. What that goes to say is that people in the American public understand cause marketing, they understand what buy this product and you're donating

X to a good cause means. And that really goes, I think, to put into context the potential for having cause marketing on a pesticide label, again, particularly with respect to antimicrobial products, be misleading to consumers. Consumers are used to seeing these things and understand that that is sort of a separate piece of the label from kind of the required use directions and caution statements.

In terms of the data that should be required and the way that EPA looks at these labels, I also think, as I said, the agency got it about right. Their concern was, will this be perceived as a safety claim, will it be perceived as an endorsement, both of which, you know, are things that are legitimate concerns under FIFRA and the companies, certainly in the case of Clorox and I'm sure certainly in the case of Proctor, provided actual data that demonstrates that isn't the case.

Now, you could quibble about sort of, well, the data aren't good enough, you know, we'd like to see something better, but that's basically sort of, to me, haggling over price. The fact is that EPA really did do the kind of review and asked and answered the questions

that it needed to answer to be able to make a finding that, you know, yes, these products are eligible for registration. So, my sense is that, one, EPA got the standard right and that, in fact, EPA's level of inquiry here is about right.

Finally, I think it's important to recognize that, you know, the pesticide registration process is a process that is driven, in the first instance, by individual registrants. You know, they show up and say, we'd like to do this, in this case, cause marketing. EPA has to address those requests.

The agency did it in this case in a way that is sort of thorough, I think, and comprehensive in the questions that it asked and in the ways that it answered them. I feel like the description that's been provided today has been equally candid in the way EPA describes what it did. And, so, from CSPA's perspective, we believe the agency is on the right track. I would urge you to continue along the course that you've charted. We would also urge you to sort of make the guidance that you've discussed today and the questions that you asked public in a more general forum and in a more general way

so that, you know, everyone who is a stakeholder in the process can sort of have access to that information.

You know, as the Red Cross representative said earlier, cause marketing does have benefits. It has benefits for charities, it has benefits to companies that sponsor it, it has benefits to consumers who, you know, identify with the cause marketing programs, and there's no reason, per se, not to allow cause marketing on pesticide labels. And I'd go so far as to say that the statute really doesn't support that. Thank you.

MS. LINDSAY: Thank you. Jen, I think you're up next.

JENNIFER: I didn't even put up my card for a long time because I was sure this question would be asked. Jay, do you have the survey? Have you seen the survey questions and survey results and analysis of the survey, the perception survey, the public survey of the 800 people? Is that available on that PPDC website I just learned about? Can I see the survey? I mean, the entire question here seems to be hinging on whether or not there's going to be a perceptual issue, and EPA is making the claim that the survey says that people don't

think that the Red Cross symbol means the product is safe. I'd like to see the survey and the questions and the results and the analysis.

MS. LINDSAY: Let me get back to you because we don't have it handy at this point.

JENNIFER: But it is -- it's not CPI protected and it can be put on the website?

MS. LINDSAY: I actually don't personally know the answer to the question. That's part of what I need to check out. Has?

DR. SHAH: I represent the ACC (inaudible) panel. (Inaudible) menu of the points that I wanted to cover. I just want to reemphasize that cause marketing is an important activity. The society benefits from this and consumers will benefit, the charitable organizations benefit. And we do endorse the cause marketing program when they are conducted in compliance with the EPA criteria. Thank you.

MS. LINDSAY: Bob, is your card still --

BOB: It is, and I --

MS. LINDSAY: Well, just be brief because this is your second bite at the apple.

BOB: (Inaudible).

(Laughter).

BOB: Seth said what I was going to say much better than I could have.

(Laughter).

MS. LINDSAY: Thank you. Pat?

PAT: Three very quick points. First, I think I want to just get an atta' boy to the agency for what I think is actually a very thorough job of not only developing criteria, but then bringing it to (inaudible) to vet it, bringing it to this group to vet it, and I'm quite sure will end up being available for public comment.

Second, I think that everybody needs to take a deep breath. Cause marketing is, as Seth said, very widely practiced in this country and very well understood by consumers, as are the products we're talking about here. I think it doesn't make sense to me that people who are buying Yoplait Yogurt think it's somehow giving them some cancer resistance to breast cancer. I don't think that's going on.

Finally, I guess what I wanted to say, and this

is, you know, one of the lawyers and for Rick Colbert, you know, Jay said, and of course he's absolutely right, that the label is the law. And, so, what we may be talking about here is really a de facto prohibition of these products communicating this cause marketing in any shape or form because if the label is the law, then you probably can't do it on related materials, like stuff that's adjacent to it in the store, like advertising materials. So, you know, I think we -- that may be a subtlety, but it's important to remember that you may be totally shutting this down and there may not be a distinction.

MS. LINDSAY: Okay. Well, I think -- I promised Debbie we'd be done on time, so I need to bring this session to a close. I'd actually like to thank all of our panelists, and you need to know -- you need to give them a hand for not only being good in their presentations, but being on time. We got a bunch of different people all actually doing it just as was requested.

I need to thank all of you because you've actually given us some very good food for thought, some

very thoughtful comments, and we appreciate the input. Thanks.

MS. EDWARDS: Okay, we are going to get done on time or early today. I don't believe there are any public commenters. Is that correct, Margie? We had no public commenters signing up? Okay.

I'm going to ask Margie to come to the table now. For those of you that haven't noticed, and you should have noticed, Margie Fehrenbach is our designated federal official for this very successful FACA. She works long hours, she worked very late last night as a matter of fact. I was getting emails late last night. And I think she's one of the biggest reasons that this FACA has been so successful over the years. So, thank you, Margie, very much.

(Applause).

MS. FEHRENBACH: Geez, this is a hard act to follow, too. Just briefly, many of you already know that the FACA -- the PDDC has a two-year life span and then we need to renew it, and that process is going to come up again. By this November, we need to have a new charter and new members.

So, sometime in June there will be a Federal Register notice that comes out that asks folks if they want to be considered for the committee to apply, and anybody currently on the committee would have to also apply again. The goal is to have broad representation with a balanced committee and the plan is to hold two or three meetings a year.

I'm also passing out a brief summary, it's called FACA Essentials, it's a little summary from the FACA law and it gives some general information, including your responsibilities as a member, and I just want to point out my favorite one is cooperate with your committee designated federal officer. That's me.

(Laughter).

MS. FEHRENBACH: And that has always been the case, so no problem there. So, that's all this really is about. We're going to continue with the work groups that are listed on this page that's coming around and we're looking to schedule the next PPDC meeting in October. If you have any dates that are not good for you, please forward them to me. We try as much as we can to work around, you know, major meetings and dates that don't

work. But sometimes we can't always accommodate everyone's schedule.

And that's it. If you have any questions, you know how to reach me. Both my phone number and my email is on the bottom of this sheet. That's it.

MS. EDWARDS: Okay, Margie, thank you again. We're going to have a short session now on the planning for the fall meeting where you can provide us with some of your ideas and thoughts on that. But before we do that, because I'm afraid you'll all get up and leave soon, I just wanted to tell you that this is my first meeting as the chair. I really enjoyed it. I think it was a great opportunity here for face-to-face dialogue and interaction, and I think that's what this committee is about. It's called the Pesticide Program Dialogue Committee.

We often seek comments through very formal mechanisms. We receive public comments and that's been very useful to us. We also have meetings individually with each of you where you come to us with issues and bring your agenda. But this is really the opportunity that we have to hear an actual dialogue amongst the

stakeholders with various interests and perspective, and we get a lot from that. I actually believe that you get a lot from it as well, being able to have a conversation with each other about some of these really difficult issues. So, thank you for that.

I also want to thank all of the presenters and the work groups. There's been an enormous amount of working leading up to this meeting and it showed. I want to thank the committee for all of your advice and counsel and input. So, with that, we can move into some comments that you may have on the next meeting.

Seth's card is up, but he is not here. Okay, Susan?

SUSAN: Just a quick -- do you guys have an idea of what might be on the agenda now?

MS. EDWARDS: Well, let me say a couple of things. I believe that by the fall, I'm guessing you'll want to get an update on how we're doing with the endocrine. If anyone agrees with that, you should tell me so afterwards.

I heard that you'd like to hear, some of you, an update on the measures and what is happening to actually

achieve them. I'm guessing that we will want to revisit some of the issues we've touched on today. We did make a commitment to let you know what we're going to do, our path forward with the spray drift report, and we talked about that. We'll probably have some of our usual short program updates. I would be interested, at some point, to hear if you find those useful. I know they're just basically a little bit of a talking head, but if you like them, we'll keep doing those. We could also just provide you with written information if that would be more useful to you and use the time for more of the dialogue.

I believe, although I heard some pushback on timing, that the work safety group may have some things to report out in the fall. I heard from a couple of people that they think they might need more time, so we'll need to look into that a little bit more. I'm guessing that the transition work group will have another update. I'm not certain about that.

We may have something to say, we're going to try, I believe, to have a registration review subcommittee meeting this summer. So, there will probably be a report out on that, and I think that's it

for what I had written down.

We'll start down there, Beth, and then move around.

BETH: I don't know if you really have a topic, but I thought -- I've found it helpful in meetings we've had in the past where -- and we did, in a couple of cases in this meeting, have actual questions that you guys want addressed because I think we got off track on a number of occasions and I was, perhaps, even guilty of that in spray drift. But if we knew exactly what questions you guys wanted answered from the presentations, then I think the committee itself could stay on track a little better.

MS. EDWARDS: Thank you, that's a good comment. Has?

DR. SHAH: I have a question about this afternoon. There's an electronic leveling workshop and -- or electronic filing leveling workshop at 2:00. I think almost all the PPDC members have (inaudible) that information. What's the process because we'll need the escort to go from here to the third floor?

UNIDENTIFIED FEMALE: Has, I think we'll have to

answer that after this meeting. If there are other folks who have the same question, collect yourselves with Has so we can figure out the answer and tell you once, hopefully, because you will need an escort, I just don't know who the escort is.

MS. EDWARDS: Okay, thanks. Dan?

DAN: It's been a while since we've had an update or briefing on the international coordination activities, especially OECD and EU activities and their attempts to bring products up to some of the standards that we've suffered through for the past 10 years in FQPA and some other things, and especially in the NAFTA context with their proposed revocation of the general maximum residue level. It would be really nice to get a briefing from the agency on how they are coordinating with those international activities because it impacts us on a daily basis.

MS. EDWARDS: Thank you. Is it Dennis?

DENNIS: Just one thought. During the meetings this session, there was a number of comments about incident data and 682 reporting, that sort of thing. I don't know if PPDC has discussed that in recent times,

but a presentation on what kind of information the agency uses in acquiring incident information, what kind of databases you use and what kind of access there is to it, the guidelines that go into validating the data. That might be a topic of interest to some of us certainly.

MS. EDWARDS: Okay, thank you. Michael?

MICHAEL: Yes, I'd like to second Dennis' request for a discussion on incident reporting. Also, one of the issues that was tabled in the spray drift discussion was that of volatility or vapor pressure of compounds and I'd like to entertain bringing that topic up as a possible one.

MS. EDWARDS: Okay, good, we are actively working in that area and actually had a meeting yesterday on that. Diane?

DIANE: I think an update on endangered species, particularly whether you've heard back from the services on any of your formal or informal consultations.

MS. EDWARDS: Okay, thank you. Julie?

JULIE: With Dennis' recommendation on 682, I also think we need an update on 682 and probably an outlining of the changes that were made to the rule and

what the intent of the changes were and what impact it's had on reporting, because I think there's maybe some misunderstanding as to what was actually changed.

MS. EDWARDS: Okay, good. Carolyn? Karen?

UNIDENTIFIED FEMALE: We can't read your card.

MS. EDWARDS: Christie, sorry.

UNIDENTIFIED FEMALE: It's the typed side.

CHRISTIE: It's only on one side. I just want to support the request for an update on the endocrine disruptor program, and also, a report on the update with OECD-EU activities and both of those specifically related, as you might guess, to test guideline activities and alternatives for animal testing. Thanks.

MS. EDWARDS: (Inaudible).

UNIDENTIFIED MALE: Sure. I would like to, maybe not as part of the next PPDC meeting, but in some other forum, maybe just through submission of suggestions to Margie, find a way to offer some process improvement suggestions for the way PPDC operates. I agree with you, Debbie, and others who have said that this has been a useful meeting and it's built on progress and, you know, the open structure of dialogue is important and different

from a lot of other venues. But I think some additional improvements around process could be beneficial to the agency as well as the stakeholders.

MS. EDWARDS: All right. Well, I guess you'll provide some of your thoughts on that to Margie, is that -- okay, thank you. Okay, Dr. Amador?

DR. AMADOR: I think one of the questions that came up during the spray drift discussion was how is EPA or how the PPDC pesticide program is going to use the recommendations made and some of the suggestions that were made. Would it be too soon in the next meeting to get a report on how you may be using that or --

MS. EDWARDS: Are you talking about the spray drift report?

DR. AMADOR: Uh-huh, right.

MS. EDWARDS: Yes, that's what we're putting -- we are planning to do that. Well, we're not -- we may not actually have a complete plan by fall, but we're going to, at minimum, tell you our process forward on how we intend to use the report.

DR. AMADOR: So that will be part of the agenda.

MS. EDWARDS: Yeah, yeah. Okay, Lori?

MS. BERGER: You've touched on a number of things, but just a couple -- a few specifics, one with the transition group, I think that the case studies or drafts will be -- I think it would be good to have something along those lines. And then as Dan indicated on international issues, I think it's a very good time for a review of that. And then you had also mentioned, Debbie, the WPS work group and, in particular, the economic studies that are being developed, just the methodology and the results so far. I think that came up in our work group and I think that would be helpful at that point.

MS. EDWARDS: Okay, thank you. Bob?

BOB: I just wanted to commend the agency and the work group for the excellent presentations. I think this is one of the best PPDC meetings I've attended in a number of years, very enlightening, very good conversations and very good discussion, so thank you very much and the organization.

I also wanted to reinforce what Lori said about the transition group. I think the AZM transition project, in looking at those couple of crops, obviously,

is serving as a model from the work the USDA has done. But I think to raise it to this level and to look at challenges, because I agree with Al and Rick, I think there will be a number of those over the next three or four years that will face American growers as products are phased out or their uses are restricted.

I think for this group to look at the challenges that growers are facing with drawing these tools and then adapting a whole new IPM system, I think the concept is you can -- it was pointed out to me very well that you're not taking one tool out and replacing it with another, you're looking at systems and replacing systems and to get growers to do this. IR-4 was involved in a program in Michigan with Gerber Foods and Michigan State to remove all insecticides, OPs and carbamates, from baby food pear production, and it's taken about five years to implement a program where you get growers to increase the uses over larger acreages in a demonstration program over time.

So, I think the group needs to realize that these programs take time and a lot of effort and planning.

MS. EDWARDS: Thank you very much. I appreciate it and congratulations to all of you. It was a great, great meeting. And Anne has the room information.

MS. LINDSAY: You're in luck. You don't need an escort because the 2:00 meeting will be down here.

MS. EDWARDS: Thank you. This meeting is adjourned.

(The meeting was concluded.)

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