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8 **Transcript of Meeting of**
9 **Pesticide Program Dialogue Committee**
10 **Sheraton Crystal City Hotel**
11 **1800 Jefferson Davis Highway**
12 **Arlington, Virginia**
13 **April 16-17, 2003**
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1 **COMMITTEE MEMBERS**

2 Jim Jones	Director, Office of Pesticide
3	Programs, OPPTS, Chairperson
4 Stephen L. Johnson	Assistant Administrator, Office
5	of Prevention, Pesticides and
6	Toxic Substances
7 Margie Fehrenbach	Designated Federal Officer, OPP
8 Daniel Botts	Director, Environmental & Pest
9	Management, Florida Fruit &
10	Vegetable Association
11 Robert Rosenberg	Director, Government Affairs,
12	National Pest Management
13	Association, Inc.
14 Bill Tracy	National Cotton Council of
15	America
16 Carolyn Brickey	Executive Director, Institute
17	for Environment and Agriculture
18 Adam Goldberg	Consumers Union
19 Kristina Thayer	Environmental Working Group
20 Dr. Richard Liroff	World Wildlife Fund
21 Aaron Coangelo	Natural Resources Defense
22	Council

1 **COMMITTEE MEMBERS (cont'd)**

2 Patti Bright	Environmental Defense
3 Edward Zuroweste, M.D.	Medical Director, Migrant
4	Clinician Network
5 Shelley Davis	United Farmworkers of America
6 Troy Seidle	People for the Ethical Treatment
7	of Animals
8 Dr. Beth Carroll	Stewardship Manager for Food,
9	Feed and Fiber, Syngenta
10 Allen James	Responsible Industry for a Sound
11	Environment
12 Stephen Kellner	Consumer Specialty Products
13	Association
14 William McCormick	Project Manager, The Clorox
15	Company
16 Dr. Hasmukh Sauers	Manager, Biocides Panel,
17	American Chemistry Council
18 Julie Spagnoli	Director, Federal Regulatory
19	Affairs, Bayer
20 Dr. Warren Stickle	President, Chemical Producers &
21	Distributors Association
22 Jay Vroom	CropLife America

1 **COMMITTEE MEMBERS (cont'd)**

2 Gary Libman	Director, Regulatory Affairs and
3	Quality Assurance, Emerald
4	BioAgriculture Corporation
5 Alan Lockwood, M.D.	Chair, Environmental Committee,
6	Physicians for Social
7	Responsibility
8 Dr. Nancy Lewis	Associate Professor, Department
9	of Nutritional Science and
10	Dietetics, University of
11	Nebraska
12 Phil Benedict	Director, Plant Industry,
13	Vermont Department of
14	Agriculture
15 Charlie Clark	Environmental Administrator,
16	Pesticide Registration Section,
17	Bureau of Pesticides, Department
18	of Ag and Consumer Services
19 Dr. Jose Amador	Director, Agriculture Research &
20	Extension Center, Texas A&M
21 Larry Elworth	Executive Director, Center for
22	Agricultural Partnerships

1 **COMMITTEE MEMBERS (cont'd)**

2 Winand Hock, Ph.D.	Professor Emeritus of Plant
3	Pathology, Penn State Pesticide
4	Education Program
5 Dr. Robert Holm	Executive Director, IR-4 Project
6 John Vickery	Principal, John Vickery
7	Consulting
8 Patrick Quinn	Principal, The Accord Group
9 Dr. Michael Kashtook	Office of Plant and Dairy Foods
10	and Beverages, FDA
11 Allen Jennings	Director, Office of Pest
12	Management, USDA
13 Dr. Gary Clark	National Center for Infectious
14	Diseases, Centers for Disease
15	Control & Prevention
16 Dr. Melody Kawamoto	National Institute for
17	Occupational Safety and Health,
18	Centers for Disease Control &
19	Prevention
20 Brad Bergen	Section Head, Formulants, PMRA

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22

1 Day One

2 April 16, 2003

3 **PROCEEDINGS**

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5 MR. JONES: Why don't we get started. I think
6 being on time is important. We all want a timely
7 government, we should all be prepared to be timely
8 ourselves.
9 I really appreciate everyone's efforts to come
10 to Washington. I know that this is a difficult time for
11 a number of reasons. We have a number of holidays going
12 on this week, there's spring break for a lot of our
13 children, and the nice thing it's a nice time of the year
14 to be in Washington, but understand that it's a
15 challenging time for many of you to be here and
16 appreciate the effort and can understand why some of our
17 members weren't able to make it.
18 When planning for this meeting, we had the good
19 fortune -- it's really the reason we are in this hotel on
20 these dates -- that an SAP meeting had been scheduled
21 previously and didn't need to occur. And, so, the agency
22 had already paid for the space and we took advantage of

that. As I know all of you expect us to be frugal with your tax-paying dollars.

The bad news, other than the conflict with holidays and spring breaks and whatnot, is that the SAP -- in our SAPs we generally do not accommodate with coffee and any other refreshments, and so we have to live with that arrangement and couldn't change it at the last minute. So, we don't have complimentary coffee, and I apologize for that. The restaurant downstairs, however, will accommodate take-out and you folks really need to get that fixed -- the Sheraton's restaurant is able to accommodate you.

I did want to recognize that because we actually have two new members to our PPDC. I'm not sure if either of them are here -- Christina Thayer from the Environmental Working Group has replaced Sean Gray. Christina is not here yet, is she? And Rich Liroff, who I also believe isn't here yet -- oh, yes, there he is -- hey, Rich -- from the World Wildlife Federation has replaced Sarah Lynch.

They are permanent -- I use that word loosely -- new members to the work group. None of us are permanent.

These are two-year appointments. And all of us who are here are on two-year appointments. I'm unclear how long my appointment's going to last.

(Laughter.)

MR. JONES: There are also a number of individuals around the table who are sitting in for a permanent member, and when we go around, after introductory remarks, if you can just introduce not only yourself but who you are sitting in for, I would appreciate that.

As many of you know, sort of segueing into change, transition, we have a number of -- there have been a number of new personnel changes or personnel changes in the Pesticide Program since we last got together. I think, probably, most obvious is the one that affects me, that Marcia Mulkey, the director for the previous five years, has left the Pesticide Program. She is now on an employment detail to the FAO in Rome and she'll follow that with a, what we refer to in the government as an IPA, an Inter-governmental Personnel Act, assignments to Temple University as a visiting scholar. Actually, Marcia has been very good about not,

you know, giving me too much advice over the last three weeks. She e-mailed me this morning with a very funny anecdote that I thought I would share.

She's putting together a kind of a best practices or a code of conduct for pesticide use. It's actually been drafted. She's sort of doing some editorial work around it. And she said one of the things she found in some of her research was it was advice to people doing water monitoring in Africa, and after it gave sort of some technical things you need to be focusing on about how to take the samples and things like that -- and be very careful about crocodiles and alligators.

(Laughter.)

MR. JONES: And, so, I said, well -- and then she follows, Generally just good advice for the Office of Pesticide Program Office Director.

(Laughter.)

MR. JONES: And then I e-mailed back quickly and I mentioned PPDC meeting, and she responded and said, That was one of the most favorite things I did and I know you're going to love it, too.

But, I thought I would pass that along from Marcia. I am now the Director of the Office of Pesticide Programs and I'm very excited and thrilled about the opportunity, at large, of being the Director of the Pesticides Program. I think it's one of the most interesting, compelling and important public service jobs there is in the Agency, and I'm pleased and proud to have this opportunity.

Likewise, I'm very excited about having an opportunity to chair the Pesticide Program Dialogue Committee. I think that the Agency has been a leader and OPP has been a leader in trying to bring stakeholders together, to understand the concerns and the issues of stakeholders to be aggressive about getting stakeholder input into what we do in the Office of Pesticide Programs and EPA at large, and it's very rewarding for me to have such a leadership role in an organization that listens to its stakeholders and provides stakeholders an opportunity to give feedback and advice.

The other changes, which some of them may be just a little more new to you because the individual is new to you, but at my right is Marty Monell, who is the

new Deputy Director for Management in the Office of Pesticide Programs; Joe Marenda (phonetic) held that position previously, and, I think, as most of you know, Joe took a mobility assignment where he's going through a Senior Executive Service Mobility exercise at the Agency to our Office of Science Coordination and Policy; and Marty comes to us from the Grants Division within the EPA. So, we're very pleased to have Marty. She's going to be giving a presentation this morning. She had the great opportunity to oversee the operating plan for us in FY-03, and helping to sort through some very challenging and difficult budget cuts. I'm sure she's thrilled with the opportunity to help figure out how to deal with a smaller budget this year than we had last year. She did a great job and we're going to go over some of that this morning, as well.

And to Marty's right, actually one of the so-far highlights of my job as the Director -- the first day on the job I had the great opportunity -- it was Marcia's selection, I have to say, but I'm behind it 100 percent -- Debbie Edwards has now been named as the Director of the Registration Division, which is very exciting for all

of us and I hope for Debbie, as well. Debbie will also be participating over the course of the next day and a half.

And, I think, all of you know -- or you all should know -- Anne Lindsay, who is sitting at my left. Anne is acting in the position that I held for the last year and a half as the Deputy Director for Programs. And, Anne is also going to have a leadership role, not only in the program management in OPP in the months ahead, but a role in the management of this meeting, as well.

We have a new organization chart with all of these names in them in your packet to sort of help you navigate our organization.

We have a full agenda and I want to spend a minute or two sort of going over the agenda, not so much to say what is on it, because I assume you all have looked at it, but to describe some of the thinking that went into the building of this agenda.

There are three basic ways in which we try to use this meeting to get feedback. Some of it is by giving you updates on some of the most interesting,

controversial, compelling work that we've doing, and we call those Updates. We used to call them Updates in a Minute, but we realized we couldn't explain some of these things in one minute, so we just call them Updates now.

They are largely us informing you about some of these kinds of ideas. And you'll see those spread throughout the day and a half. Hopefully, in each of those sessions we'll have time to get some feedback on these Updates, as well. But they're designed less to be as interactive as the other two types of interactions.

The second kind of session that we have, in a couple of different places, including the first session this morning, is what I sort of think is our way -- the Agency's way -- of trying to be accountable to the PPDC around topics that we've talked about in-depth previously. Now this one is getting a little trickier to manage, because over time the list of things that we have engaged you in, in a meaningful way, is getting longer and longer, and figuring out how to use our time wisely here to be responsive, accountable around those issues is getting trickier, and we may want to spend some time at the end of the meeting tomorrow talking about your

thoughts about how we can manage that.

There are a couple of places on the agenda where we've had hour, two hour, three hour or dialogues around a topic, and we're coming back now and saying here is what we've done since that last session.

So, that's sort of the second basic way in which we are trying to get feedback from all of you, so that we just don't talk about something in a meeting for two or three hours, get a lot of feedback and then just walk away from it and never come back and describe what's happened or how did we use the feedback we've gotten.

The third way is basically to put a new -- use that word loosely -- new to the PPDC -- new on the PPDC agenda a couple of topics where we're in development of an issue and we're asking for some advice and guidance about how we're working through the issue. And the two big topics in that category today are Mosquito Labeling -- Mosquito Labeling, as most of you know, in and of itself, is not a new topic, but our engagement with this group is new on this issue, inasmuch in-depth as we're going to be doing today.

And the second one being Registration Review,

which is a new requirement -- getting less and less new -- a requirement under FQPA that we pursue sort of a continuous review of pesticide registrations on kind of a 15-year schedule, and we really need to get moving on this program, and we're coming today with our thoughts, following an AMPRM that we did a couple of years back and we're looking for advice, not only about content, but on process.

These are the three ways that we try to use that agenda. And we've heard from you clearly over the last few years, this is a meeting that you're looking for us to use where we need advice, and we're trying to use the agenda in that way. We very much do own the agenda in the sense that these are the areas we're looking for advice. We also recognize that there is some need to get some information out in an accessible way to all of you.

The session at the end of the meeting, I really do want people to be thinking about over the next day and a half where we're asking for topics for the next session. I don't at all mean to say then you tell us what you want to talk about, but I think it's helpful to get a sense as to what you think are the most important

things to talk about and then we can figure out are they areas where we really need input.

That's a very sort of overview of the agenda without actually going over each item to try to give you a sense of what we're trying to achieve here.

Sort of an administrative reminder that the PPDC charter will expire in November; we are planning on renewing it as we really do firmly believe in this as a way of getting meaningful advice from our stakeholders and just part of that, some subset of you, your term will expire and we will, over the course of the next several months, do what we've done over the last six years, which is some subset of the expiring membership coming right back and some subset not to bring in new blood. It's usually been very simple, because some people raise their hands to not be renewed because they feel like they've served long enough or forever reason. It tends to be along the lines of who really is up for another term and who's not. We do need to make sure we keep in balance, so that's one of the over-arching decision-making factors that we're using.

As another reminder for those in the audience

who are not on the PPC, we do have built into our agenda some time for public comment and at the appropriate time we have some microphones. And if you do at any point during the day -- today or tomorrow -- want to make public comment, if you would just let Margie Fehrenbach -- sitting right over here -- know and we'll make sure that we have enough time for public comment.

With that, I would like to turn it over to Al Jennings from USDA, who is also going to make some opening remarks.

MR. JENNINGS: Okay, thanks, Jim. I will be very brief. First of all, Jim, I'm very happy to hear the explanation for the lack of coffee. I was worried that it might be a reflection of the regime change in OPP, so glad to hear you didn't make the radical change.

(Laughter.)

MR. JENNINGS: No, seriously, in thinking back over the initial years and the first six years of FQPA implementation, it's fair to say that the USDA/EPA cooperation has been there in one form or another and we've been through some difficult times and I think, in reality, if you look back, we've resolved some very

contentious issues, and we've worked out a number of kinks in the whole regulatory process and in communication process, so I think we've done a lot but we still have a lot to do, and I really do look forward to continuing that positive working relationship with Jim and the new teams. I enter this with a very positive attitude. I think we've done a lot of good things and look forward to more.

Certainly this committee and your role here and my role as a USDA observer or whatever I am, I do enjoy hearing your perspective on a lot of these issues. It certainly does help round out the perspectives that we do get in the Department. So, I appreciate your continuing input and, I guess, there's just one other item to mention and one of my roles in USDA has been to try to get the information and data resources in the Department focused and refined and put into a usable format for EPA to use in risk assessments, risk mitigation, those sorts of things. And certainly that effort will continue.

One of the real positive things that's happening right now is the merging together of our land grant resources and what used to be the Integrated Pest

Management Centers and, then, there used to be the PIAP or Pesticide Impact Assessment Program Centers. And we will very shortly with a new set of proposals, fully merge those into what we'll now call IPM Centers. So, I think, that is going to go a long way with getting more bang for the existing bucks that are out there with our land grant systems.

So, anyhow, the role of providing data information, a sounding board, impacts on agriculture will continue and I think it will become a little bit better in the future. So, with that, I will send it back to Jim.

MR. JONES: Thank you, Al. Now, why don't we go around the room and if everyone would just introduce themselves and their affiliation.

MS. LINDSAY: Well, I'm Anne Lindsay and I'm the Acting Deputy Director for Programs in the Office of Pesticide Programs.

MR. JENNINGS: And I'm Al Jennings, I'm the Director of Pest Management Policy at the USDA.

MR. KASHTOCK: Hi, I'm Mike Kashtock, Food and Drug Administration, Center for Food Safety and Applied

Nutrition, and I'm sitting in for the Office Director of our Office of Plant, Dairy Foods and Beverages, Dr. Terry Troxell.

MS. KAWAMOTO: Good morning, I'm Melody Kawamoto, I'm a Medical Officer at CDC National Institute for Occupational Safety and Health.

MS. FEHRENBACH: I'm Margie Fehrenbach, I'm the Designated Federal Official for the Committee.

MS. BRIGHT: Patti Bright, I'm a Veterinarian and Director of the Pesticides Program at the American Bird Conservatory, and I'm sitting in for Rebecca Goldberg from Environmental Defense.

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

DR. AMADOR: Jose Amador and I'm Director of Agriculture Research and Extension Center, Weslaco, Texas.

MR. GOLDBERG: Adam Goldberg, Consumers Union.

MR. BENEDICT: Phil Benedict, Vermont Department of Agriculture, also representing states.

MR. MCCORMICK: Bill McCormick, Clorox Company.

MS. REED: Virginia Reed, United Farmworkers of

America, sitting in for Shelley Davis this morning.

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

MR. TRACY: Good morning, I'm Bill Tracy, I'm a Producer/Member of the National Cotton Council.

MS. BRICKEY: Carolyn Brickey, Protected Harvest.

MR. ROSENBERG: Bob Rosenberg, National Pest Management Association.

MS. CARROLL: Beth Carroll from Syngenta Crop Protection.

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

MR. KELLNER: Steve Kellner, Consumer Specialty Products Association.

DR. LIROFF: Richard Liroff, World Wildlife Fund.

MR. SEIDLE: Troy Seidle with PETA.

MS. SPAGNOLI: Julie Spagnoli, Bayer Health Care, LLC, Animal Health Division.

MR. LIBMAN: I'm Gary Libman, Emerald BioAgriculture.

MR. HOCK: Win Hock, Penn State University, American Association of Pesticide Safety Educators.

MR. VICKERY: Good morning, I'm John Vickery, I'm an independent consultant.

MS. LEWIS: My name is Nancy Lewis from the University of Nebraska in Lincoln in the nutrition area.

MR. VROOM: Good morning, I'm Jay Vroom, President of CropLife America.

Could I interject a thought here, Jim, real quickly? Al mentioned FQPA, which many of us in agriculture kindly refer to as the Act that keeps on giving. Some of you remember a few years ago we had concerns about FQPA and we did a little campaign around this red water, and if you don't mind, Jim, perhaps you'd like to have one of these for your office, if I can pass it around here. We just discovered we have a little inventory of these left over, and the message is probably a little out of date, although it doesn't hurt to remember history, and one of my colleagues in the office has discovered the American Legion is doing a campaign to try to collect useful items of personal hygiene care for the troops in Iraq, and we're going to be sending this

excess inventory through the American Legion.

So, one more positive effect of FQPA.

(Laughter.)

MR. LOCKWOOD: Good morning, I'm Alan Lockwood, I'm a professor neurology and nuclear medicine at the University of Buffalo and I'm here in my capacity of the Environment and Health Committee of Physicians for Social Responsibility.

MR. HOLM: Good morning, Bob Holm, the Executive Director of the IR-4 Program at Rutgers University.

MS. EDWARDS: Debbie Edwards, Registration Division, Pesticide Program.

MS. MONELL: Marty Monell, Deputy Director for Management in the Office of Pesticide Program.

MR. JONES: Well, I had been wondering how I was going to sort of get this unruly bunch sort of under control for the next day and a half --

(Laughter.)

MR. JONES: -- thank you, Jay, appreciate that. Now I have the tool that I need. With that, why don't we get started on this first session, which, as I mentioned, is a follow-up to a session that we did at our last PPDC

meeting where we talked about how over the last several years we've spent our resources. We're now going to spend this time going over the -- and we did a little dialogue around the five-year plan -- giving an update on the five-year plan as well as our FY-03 resource issues.

MS. MONELL: Good morning. One of the things I quickly learned when I came to the Office of Pesticide Programs was that I knew absolutely nothing about pesticide programs. My experience has been totally in management and in the administrative arena around budget formulations, strategic planning, personnel work, human resource planning, and so forth, and it was quite an eye opened. I've been here for three months and I've learned more than I ever dreamed I would learn about pest management.

Fortunately, I have some great people that work with me that know all about pesticide programs and the importance of planning and budgeting for implementing the various programs that we're involved with. So, this presentation actually -- I'm giving it, but everybody else that works with me has been most instrumental in putting it together for me.

What you're going to see first is the old and new structures of EPA Strategic Goals. Initially, we're going to show you the September -- you have this, by the way, in your package. This is the old structure, the September 1997 Strategic Plan where our pesticide activities were, basically, spread across four goals. We have now -- facing through 2003 to 2008 -- we have a proposed Five-Year Strategic Plan, this is the Agency, where in 95 percent of our activity in the Office of Pesticide Programs is located in one goal. And this is Goal Four. We have a little bit in Goal Two, but primarily it's in Goal Four.

Goal Four, essentially, is helping communities and ecosystems and the goal is to protect, sustain or restore the health of people, communities and ecosystems using integrated and comprehensive approaches and partnerships. These goals were very carefully wordsmithed to really get across the notion of what our mission is.

Objective 4.1, we have the chemical organism and pesticide risks addressed, where our objective is to prevent and reduce pesticide chemical and genetically

engineered biological organism risk to humans, communities and ecosystems.

Under that objective, we have two sub-objectives. These, obviously, encompass a lot of activities.

Sub-objective One is through 2008, now this is a five-year plan, so, obviously, there are incremental steps that we plan to achieve in the process. Through 2008 we will protect human health, communities, and ecosystems from pesticide use by reducing exposure to the more toxic pesticides.

And, then, in the second sub-objective, through 2008, again, we will protect human health, communities and ecosystems from pests and disease by ensuring the availability of pesticides, including public health pesticides and anti-microbial products that meet the latest safety standards.

Each of these sub-objectives has a number of strategic targets that you've got in your materials. I'm not going to go through them all and you won't see them on the screen here, either. I encourage you to take a look at them, however, and then go to page 7, which is

the next slide, because this lays out the time frame.

This Five-Year Strategic Plan is actually a work-in-progress. In the end of December of 2002 we began the 30-day public comment period on the draft architecture and, then, in March we submitted the full draft plan to OMB, and on March 5th it was published in the Federal Register for public comment. The public comment period will expire on April 25th, so if you see anything in the strategic targets or in the overall plan itself that you wish to comment on, please do so. We have a URL -- I'm not sure that that made it into your materials -- but --

UNIDENTIFIED MALE: No, it didn't.

MS. MONELL: Oh, we're sure that it did not make it into your materials, but I encourage you to jot it down in case you are so inclined to provide comments, particularly on the strategic targets that you see under the Office of Pesticide's materials. If you see anything there, please, we encourage you to engage in the public comment period.

Now, we're going to turn to our budget. As you all know, probably, we have been for the past five

1 months, almost six months, operating under various
2 continuing resolutions. That is a very difficult process
3 to endure if you are trying to plan your activities from
4 month to month and against an unknown budget situation.
5 Finally, we do have an appropriation and we're
6 being able to, as Jim mentioned, we're being able to
7 develop our own OPP operating plan with the appropriation
8 that we finally received.
9 This year the planning, during the continuing
10 resolution period, it was further complicated by the fact
11 that the fees expired. Our authorization to collect the
12 maintenance fees expired September 30. So, we sort of
13 had to limp along with the uncertainty of what the fee
14 situation was going to look like for 03 in addition to
15 the incremental funding that was being provided under the
16 continuing resolution.
17 However, the good news is that the appropriate
18 bill that was recently signed that funds us for the rest
19 of the fiscal year contains authority for us to collect
20 $21.5 million in fees, and that is significant, as you
21 will see when I continue.
22 This $4.5 million increase from the $17 million

that we had from the previous fiscal year to this year will offset the reductions that were included in our appropriations. There is about $1 million overall increase in funding available to OPP this year compared to fiscal year 02.

That $1 million, in its entirety, is going to be needed to support our in-house staff. We've had to reduce contracts and grants by -- we're anticipating it to be between $3 and $4 million this year. That uncertainty, that $1 million, sort of leeway, basically, will be determined by the amount of fees that we are able to collect this year. I mean, we are authorized to collect up to $21.5 million, that does not necessarily mean that we will collect that much.

The net shift of resources from contracts and grants to extramural resources to payroll, basically, continues a recent trend that we've endured in probably through EPA but most specifically in OPP that reflects stagnant budgets and increasing staff costs.

Now, up here you see -- and this just, basically, is going to visualize what I've told you -- in '02 about 62 percent of our available revenue went to

salaries and benefits; working capital fund was about 4.5 percent; contracts and grants, the extramural resources, 21 percent; states and regions received almost 10 percent of the funds; administrative expenses and travel being, you know, minute.

And, then, in '03, salaries and benefits are up by 2 percent; contracts and grants and extramural money is down by the same amount, down by 2 percent; working capital fund, grants to states and regions, travel and administrative expenses, basically, stay the same.

What does this mean for OPP? We have a shrinking staff. While the rise in personnel costs is obvious, it doesn't reflect increased staff; in fact, it's just the opposite. The costs that are associated with existing staff go up each year. In 2003, actually, our FTE allocation was reduced by almost 1.5 percent; we used 821 -- do you know what FTE is -- full-time equivalent -- that's the authority to hire full-time Federal employees. We had authority to hire 821 in fiscal 02 and we're now down to authority to hire or maintain 810 in '03. And this trend continues -- you'll see it. It's not significant on the last few years, but

every, you know, 10/12 people, it has an impact upon our program.

The spike there in '89, I guess, is where the FIFRA '88 came in and that's why when we were able to hire folks under authorization of FIFRA. And, then, you'll see that that amount increases, then it spikes a little bit or goes up a little bit in 1998, related to FQPA.

What does this mean for OPP? Congress protects registration and re-registration activities, so most of the $3 to $4 million reduction for us will have to come out of our field programs. We don't exactly know how we're going to manage that. We're looking at everything very carefully, but, unfortunately, field programs such as Outreach, Pesticide and Environmental Stewardship, Certification and Training, Worker Protection, Negotiating with Partners, Endangered Species and Water Quality are all those kind of field programs that are not protected; therefore, we have to look at them to devise ways of accomplishing the savings that we need to meet our budget constraints.

And, then, the last slide basically shows the

non-personnel. In other words, this is the corollary to the FTE cost chart that you saw before. This is the non-personnel, so this is contracts, grants, other extramural resources, IAG, Interagency Agreement expenditures. And, you'll see again, that they -- following the '88 FIFRA, there's a spike. And, then, following FQPA there's a little bit of an increase.

But our ability to fund these field programs from the past few years is going down hill. And we're going to do the very best we can and I suspect Anne will talk a little bit more about this in her various discussions through the next couple of days, but that is the reality.

Does anyone have any questions? Comments? Yes?

UNIDENTIFIED MALE: As a grower, I'd like to say welcome to agricultural financing. This is what we go through every year. We spend it ahead of time and then we figure out if mother nature is going to help us pay the banker back. If you're from a community property state, your spouse also signs that note that you mortgage away your whole future, your whole life and your children's future, and that's what you bet against nature

every year. So, welcome to the club.

MS. MONELL: Thank you. Anyone else?

MR. AMADOR: Yeah. Would you explain a little bit on the Grasson contracts (phonetic), you know, how is that money used in Grasson contracting and what is the difference between stage and regional grants and headquarter grants in contracts? Can you explain that a little bit more? How they're going to use that?

MS. MONELL: The Regional Cooperative Agreements is a little bit different than the other kinds of assistance agreements that we fund.

MS. LINDSAY: The wedge up there, that's grants to states and regions, represents money that the Agency from the pesticide programs sent to our state partners. So, Phil Benedict gets, I don't know, 10 pennies from us every year to help run -- oh, he agreed -- oh, nine, nine pennies a year.

MR. AMADOR: He gets a lot of money, you don't have to give him any more.

MS. LINDSAY: No, he gets nine pennies from us to carry out his job as a regulator for pesticides for the State of Vermont. So, if you hear us ever talk about

stag money, that's money that goes straight out to the states, through our regional offices, for them to carry out their responsibilities that flow from our regulation of pesticides.

And that has been flat for a long time now, Phil, so even though the amount of money has not decreased, how far it goes has diminished substantially, and many states are contributing far more to the funding of their regulatory programs than they're beginning to get from EPA.

I'll also note that our Office of Enforcement sends money through separate channels for the same purposes that get merged in our regional offices, and that's to carry out enforcement activities.

So, a state that's running a certification and training program might use some of those nine pennies to help defray the expenses. I think we calculated in the worker protection area, we might send enough money to hire a single individual at the state level to do all manner of work or protection activities.

That other category that's called headquarters, contracts and grants is more discretionary and has more

flexibility. So, for instance, it would include the money that my division, the Field and External Affairs Division, sends to USDA for distribution through USDA systems, to the extension service to provide training to support the certification and training programs that the states are running.

It would also include, for instance, funds that we provide so that there will be worker protection, worker safety training in the field for ACROP -- and now I can't remember what ACROP stands for -- Virginia might be able to help me with that.

So, it goes for contracts and grants that go out for our environmental stewardship program, IPM and schools. So, they're not the same from year to year, but they're intended to support key areas where I think there's opportunity for risk reduction, health protection that supplements the evaluation that we actually do of the pesticide products. So, in my mind it's the backstop. We evaluate the products, put them out in the field, we expect people to use them, but these field programs are one of the backstops to that, to help ensure that users are using them right, that they're well

trained, that's the appropriate oversight and enforcement.

MR. AMADOR: Does the grant go to the state agency, like in Texas it would be TDA or can it go to a land grant university?

MS. LINDSAY: No, the stuff that's in that 9.8 percent would go to the State regulatory agency. Now, how they chose to use that, they've got a fair amount of discretion. But since it's only nine pennies, it's probably not going very far.

MR. JONES: A significant part of the headquarter contracts and grants for contract review work of scientific studies -- our science divisions often have that work reviewed under contract first and then brought in-house for Agency review.

MR. JENNINGS: First of all, I'd like to commend the presentation here of Marty and those who worked with you, because I think it's important, always, to kind of give us the perspective of, you know, a little bit of the past compared to the relevant either current or future, and I think you did a nice job, both on the plan and the fiscal side of this to kind of give us numbers not in a

vacuum, and I think that's very useful for this kind of discussion -- any discussion, really.

I wonder if you could ask that the slide with the URL address be put back up, because I didn't finish getting that written down. And one question around competition, efficiency for -- at least for profit contractors, I mean, I think in the pesticide area we all are aware, particularly after the most recent bulge of demand for contractor services, driven by FQPA, that there are probably less pesticide companies, less work being sought to be done by the industry on the outside, and I wonder but I'm sure that's the same sort of scenario based on the amount of money you have to spend for OPP. Is it more efficient -- is there more competition for less business overall for this kind of outside work from private contractors and is EPA, in particular, through all of the outside contract work, able to get more work for the dollar today or are other areas of contracting for a similar kind of scientific and regulatory expertise, say from Superfund or elsewhere in the Agency, sort of taking up that slack and keeping it more of a seller's market than a buyer's market -- do you

understand what I'm asking?

MS. MONELL: I know exactly what you're getting at. And I'll respond to it and then I'll ask Jim to weigh in also, but my observation is that there are sufficient private contractors available to do the type of preliminary review of data that we need. We also have interagency agreements with, for instance, the Department of Energy has allowed Oakridge that also has the capacity to do the kinds of reviews that we need.

I'm not aware of any possible contractors or vehicles to get --

MR. JONES: We're certainly not finding that there are fewer available, but I think you asked a good question and we should follow up on it. Are we seeing that they're becoming less expensive per output or more expensive per output?

MR. HOLM: I thought the presentation was excellent and I like your self-objectives. I'm kind of wondering on this subpoint under the 4.11, sort of the objectives by 2008 at least 11 percent of acreage treatments will be applications of reduced-risk pesticides. I'm just wondering how that number was

derived and whether that also includes row crops and, you know, specialty crops, and maybe make a suggestion, you know, possibly those two categories could be broken out because, as you know, the IF4 program has really been focusing on reduced-risk chemicals and biopesticides for minor crop applications, and certainly since FQPA has been more addressing children's exposure and risks to that subset population, might be a more sharper goal to look at, you know, fruits and vegetables and, you know, the dietary risks there and it may be a little higher target, which I think is attainable, versus maybe just the general overall acreage.

MR. JONES: That's a very good suggestion, Bob. I think we'll, ourselves, want to put that forward, whether you do or not independently.

I would, without knowing specifically how we came up with it, I would venture a guess that we've been tracking acre treatment to reduce risk products, and what we did was -- and I know that it's right now below 11 percent -- we tried to set a standard that was achievable yet moveable, meaning we would move forward from today would be my plan.

UNIDENTIFIED MALE: You know, the real challenge here, obviously, is when, you know, you've got 80 million acres of corn and 70 million acres of soybeans, it just dwarfs the acreage for the fruit and vegetable crops, yet those acreages are very important and, you know, have a real impact on our food supply.

MS. MONELL: Thank you. Jerry?

JERRY: Yes, I also commend you on an excellent presentation. I have a question regarding the $4.5 million increase, which was just approved. Those of you who pay maintenance fees got a little notice in January or December saying that these fees are going to be the first wave of fees and then we're going to be receiving something. Would you care to comment on the logistics of when we're going to be receiving the other shoe, or whatever you want to call it?

MS. MONELL: We're actually just working our way through that. I'm not sure if you're aware or not, but there is a provision in the supplemental appropriate that raises the tax by a certain percentage that will also change the formula for the second round of billings. So, we're at the point now where we're making those decisions

and we hope to get something out by the first part of May.

MR. JONES: It will be around May, and for a broader understanding of what we had to do this year, in the continuing resolution, we were actually authorized to collect fees at last year's rate -- last year's rate being around $17 million, which had been the amount we had been authorized for many years. And, so, although we knew that in the final appropriation effort was being made to raise that from $17 to $21-odd million, we also knew we needed the money in the first half of the year to fund our work. So, we made the choice of billing what we were authorized under the continuing resolution, back in November/December, knowing that there was some likelihood that we'd have to do a supplemental billing to collect the difference if we were allowed to collect the higher amount.

And, so, in the early billing, we did give -- and we tried to be very clear about it -- that there would be the potential for a subsequent billing, but since we didn't know whether we had that authority yet and we didn't get that authority until March, we

recognize that this was gong to create not just a financial hardship but the potential for confusion there. But the alternative would have been, potentially, to have run out of money prior to the passing of an appropriation, which would have been -- we would have been in really tight, tight straights if we had waited until March to have done anything.

So, in hindsight, I think we did the right thing, recognizing that it was going to create confusion and potential hardship.

JERRY: To be fair, some of us also represent companies that wanted to be invoiced before the end of the calendar year for, you know, just cash flow purposes and tax deductibility purposes.

MR. JENNINGS: For a little further clarity for me, the first billing was based on the $17 million, so we're going to have at least one second billing, assuming that the $21 million, the higher number, is included, and if we are successful in keeping the caps adjustment that's in the supplemental bill now, we would see a two-times larger bills the second time around -- the difference between half of the $17 million -- did you

bill for the full $17 million or half?

MR. JONES: The full $17 million.

MR. JENNINGS: So, it would be the supplemental amount up to $21.5 million and for some companies the increase in the cap.

MR. JONES: Right, it would be in one bill, but it would reflect two changes. That's right, Allen.

John?

JOHN: Yes, Marty, thank you for your presentation. I'd like to second Bob Holm's suggestion about that item, the sub-objective about the 11 percent acreage for treatments. It does make very good sense to break that into subcategories by commodities, not commodities or IR4.

The last item there regarding persistent organic pollutants, can you explain a little about where these inventories are? Are we talking about helping less-developed countries reduce their stocks? Where are these stocks?

MS. LINDSAY: That would cover, actually, the United States itself. One of the interesting things, if you would go to our website, we have a Clean-Sweep Report

and it's a report where we've compiled activities that the states have conducted to essentially gather up obsolete pesticides, and what fascinates me about the report is no matter how many years ago it was that DDT was canceled, there's still some more out to be collected, apparently, unless we're recycling our collections, which I don't think is actually occurring.

So, that goal would apply to the Untied States, although I actually do think that we're making progress and because of our states, in particular. This is not really an EPA-funded activity. We're in pretty decent shape, but then there are other countries who may, in fact, still be producers of some of these POPS, as well as other countries, African nations in particular, that have significant stockpiles. We've even been told in Iraq, for instance, that they found some stockpiles of -- I don't know whether they were official POPS chemicals -- but they were certainly, apparently, obsolete chemicals.

So, it reflects a global attempt, but it will also have a domestic FOCUS, as well.

JOHN: Thank you.

MR. JONES: Anyone else? Yes, Bob.

BOB: I also noted on the sub-objective 4.1.2 on strategic targets, about reducing registration decision times, and I wonder why there wasn't a bigger incentive for reducing the reduced-risk decision time versus conventional active ingredients?

MR. JONES: The quick answer is that because we have focused so much already on the reduced-risk time, there was, from our perspective, there's less far to go than are for the conventional line of reduced-risks.

MR. JONES: Anyone else? Yes.

UNIDENTIFIED MALE: I'm going to refer to page 19, where you're talking about reduced contract resources. I just want to make an observation, and, obviously, I'm a little biased in this area, but EPA gets a lot of bang for their buck when they do outreach programs. When they do C&T, when they do worker protection, and so forth. And, you know, I realize you have internal, shall we say, fiscal problems, at times, and the money can only go so many ways, but I just want to make the observation that from what I've seen, EPA gets probably more recognition and I'll say good recognition, positive recognition, from some of these

programs than, you know, maybe you realize here in headquarters, but it is a very positive approach to do things like your outreach programs. You get a lot of bang -- like I say, you get a lot of bang for your buck.

MR. JONES: Thanks, and we recognize that and one of the dilemmas that we are facing is that the way in which our appropriation was enacted into law -- it's a law -- is that we were constrained in terms of what we could cut; basically, registration and re-registration, which, basically, are about two-thirds of our entire program, if not more, were protected. And, so, that, basically, leaves you with this category available for us. So, we didn't have a lot of discretion about which category. We do have some discretion within that category, and what we're going to try to do in the next couple of weeks is be as smart as we can about how, within this broad category, we allocate these reductions.

UNIDENTIFIED MALE: Thank you.

MR. JONES: Thank you. Yes?

UNIDENTIFIED FEMALE: On page five it says by 2008 you're planning on reducing by 30 percent the 1995 level of the number of incidents involving mortality to

terrestrial and aquatic wildlife. I was just wondering, how are you going to measure that?

MR. JONES: Good question. I'm going to defer to my Deputy for Programs for that.

UNIDENTIFIED FEMALE: One of the reasons I'm asking is that I know that some of the states have been doing reporting and have had very serious budget cuts and, so, I know, for example, your state has not been doing the type of reporting that they've done in the past.

MS. LINDSAY: I think the first thing is that I'd actually like to solicit, on behalf of the program, help in figuring out the best way to do it with the resources that are available. You've asked a real on-target question.

We have sort of cobbled together, with a lot of input from the states and state collection systems for information of this sort, our own incident system, which serves the baseline. But I think what I'm hearing you're saying is that our information collection system is being eroded because of state budgetary problems and others.

So, I have to go back and look at that.

Nevertheless, it seemed to us it was sort of a good goal to set for ourselves and we'll be coming around to talk to you and others about how we can do it in spite of the problems that are out there.

UNIDENTIFIED FEMALE: Thank you.

MR. JONES: Okay. Why don't we move on to the next topic, and thank you all for your thoughts and ideas on the first topic for this morning. Those are very much appreciated.

I'm going to give a couple of brief updates around three program areas that we've been very actively involved in, some for quite some time and others for a relatively short period of time.

The first is methyl bromide, the critical use exemption. Many, if not most of you, may not be aware -- although some of you I know are acutely aware -- of the pesticide program's involvement over the last year, year-and-half in what is, in effect, an Office of Air regulatory activity. Under the Clean Air Act, chemicals with an ozone-depleting potential above a certain level were required under the law to be phased out by 2005, and the law also created, as does the Montreal Protocol,

authority for allowing critical uses of methyl bromide to occur beyond 2005.

The Air Program has been managing the phase-out over the last several -- actually 10 years now -- and the Pesticide Program's involved to date had been to make the registration of alternatives to methyl bromide our priority, and we have done that pretty consistently over time over the last 10 years.

About a year-and-a-half ago the Deputy Administrator, Linda Fisher, knowing from her past experience the wealth and breadth of knowledge that OPP has around pesticides, such as methyl bromide, she encouraged the Office of Air to look to us to help them to manage the Critical Use Exemption Program. And, so, although we were -- I frankly was excited about the opportunity of a cross-collaboration with another office -- we did it with no additional resources, and it turned out to be quite costly to us.

But over the last year-and-a-half, basically, what we did is manage the process for the Air Program. That involved first developing an application for users who felt they had a critical use. So, literally, this

was an -- and we do retail here in OPP -- but our retail tends to be with -- a term Marcia used all the time -- with pesticide manufacturers, who know how to fill out our applications, hopefully, who do it all the time. We were actually doing an application for methyl bromide users. Those are the people who felt they had a critical use. We developed an application, worked it through OMP, did a series of workshops in the field last year, worked a lot with user groups about getting applications submitted to us by last September.

We then pulled together a technical group within the Office of Pesticide Programs. We also, then, with the help of -- with Allen, Burleson, Smith -- pulled together, I think, a somewhat unique and something that we hope to use going forward, a group of USDA -- they were partly USDA employees, they were partly Land Grant employees -- people who had expertise and knowledge about the use of methyl bromide and the alternatives to methyl bromide. And the team in total is about 45 individuals, during its peak, which was last fall, evaluated the applications that we got in from the user community. That group did a technical review -- did the applicant

meet the standards laid out under the Clean Air Act and the Montreal Protocol to qualify for being critical -- a critical use?

We, then, forwarded the technical review to our colleagues in the Office of Air who then led an inter-agency review process with State Department, the Department of Agriculture, Department of Commerce -- others within the Executive Branch who have a stake in the issue, and ultimately out of that came a U.S. nomination for a critical use exemption. I believe the U.S. nomination ultimately asked for 39 percent of our baseline number -- the baseline being 1991 -- for 2005 and that's going down to 37 percent in 2006.

I just thought I would share sort of this exercise that we went through last year. We're going to continue to have engagement in this as this is a continuing process. There will be subsequent opportunities for applications over time. It has definitely affected our capacity in our Biological Exams and Analysis Division to do the support that they historically do for us in OPP, although I am hopeful that this rather innovative approach we used, collaborating

with the Department of Agriculture in sort of all it has to offer -- we literally had people from around the country in Land Grants and the USDA facilities themselves helping to give technical review to the applications we had -- that that may provide a model going forward, and we are in discussions with the USDA about that model and the programs that we operate, not just the ones that we're doing in support of the Air Office.

Next is the food residue activities. We have as a general principle, we try not to bring for sort of broad dialogue to the TPDC topics where other forums exist, and that sort of includes things like we don't spend so much time on things that fall within the category of the technical working group, but I just wanted to give you an update on this topic.

As we have heard pretty clearly from industry and growers, too -- who, I would say, are the two groups that spend the most -- who are most aggressive at participating in the TWG -- not because they're the only groups invited to the TWG, but they are the groups that have been most active in participating in our NAFTA technical working group, but as a reminder to those of

you who are not in industry or a grower group that there is an opportunity to participate, and if you feel the need to, you should.

They have been very -- the industry and the growers -- very vocal in their disappointment with the degree to which we have made harmonization of MRLs and tolerance priority. For many years, we had been saying that it's a priority to the extent that there has been -- the fact that there's not harmonization has led to a trade barrier in the sense that something was stopped at a border, because a tolerance didn't exist or it was over-tolerant.

The users, in particular, have been quite compelling in their argument that the fact that you're not treating something that's getting stuck at the border isn't the whole story. Users are smarter than they, they won't use something they know they can't export to a country, that doesn't mean it's not a problem that they can't export it there. And they'll also say to us that sometimes these are reduced-risk products that they can't use because they want to export and there's not an MRL.

And, so, we have attempted to refashion our

NAFTA TWG food residue activities to take broader consideration of what is a trade irritant in a sense, and take a hard look at where harmonization may or may not be a problem. More broadly, we have a couple of pilots that we agreed to do; one because the technical working group -- and this could be somewhat of a test -- the pulse growers -- I contend that this is a term that's used in Canada, but I'm told by some of my colleagues it's not, this is peas and lentils, dried beans -- but not soybeans -- pulse growers -- you heard it here first. And the tomato growers are piloting with us an exercise to be more inclusive of our analysis of where differences in MRLs or an example where there may be an MRL in one country and not another country, are creating trade barriers.

And, of course, the EPA's stake in this is about risk reduction, but I think we've heard some compelling arguments that U.S. growers or many growers are not using a product that's a reduced-risk product because they can't export it. We want to fix that.

So, we're re-engaging on this issue in a way that is different enough that I thought it would be

worthwhile, more broadly discussing and letting the PPDC know and we will have our next TWG meeting, full meeting, it's annually and it's in December and this year it's in Canada -- will be in Canada in December -- likely the first week in December.

The third quick update -- and this is something that we've actually brought to this committee before -- we went final on March 5th on a PR notice on how registrars can amend their labels to reflect that all the ingredients in it are allowed under USDA's National Organic Program. And this is an idea that came up through our dialogue with the USDA's National Organic Program that we thought had a -- it's sort of a nonregulatory mechanism of creating a marketing incentive for products that are generally reduced risk.

And, so, we're now allowing -- if all the ingredients of your product are allowable under USDA's National Organics Program, you can send in an amendment to your product to us that basically says that, that the ingredients in the product are all allowable under USDA's National Organic Program.

And that went through a fair amount of public

comments and, I think, we actually spoke about it in this meeting at one point, were finalized on March 5th of this year.

Those are the three quick updates that I have, if anyone has any questions or thoughts?

UNIDENTIFIED MALE: Jim, could you give us some idea how much methyl bromide is actually being used now in reference to the reference date and, of that amount, how much is slipping through under the critical use exemption?

MR. JONES: Well, slipping through wouldn't be the term I'd used --

(Laughter.)

MR. JONES: -- it's being authorized by the Government under the statutes that we're operating under. As I understand it -- and, again, this is not our program, but I've learned more about the Office of Air various ozone protection programs than I knew this time last year -- as I understand right now, in 2003 all of the signatories to the protocol -- or maybe it was just the developing countries of the protocol -- had to be at 30 percent of their 1991 baseline.

So, in this year, 30 percent of the baseline is what's allowable; beginning in '05, that number will become 39 percent and in '06 it will be 37 percent.

UNIDENTIFIED MALE: (Inaudible -- too far from microphone.)

MR. JONES: Oh, good point. The United States submitted its nomination to the party -- that's the part I left out. We submitted our nominations, we have not been approved -- we haven't been disapproved either -- but I believe we'll learn in November of this year --

UNIDENTIFIED MALE: Sometime this fall.

MR. JONES: -- sometime this fall we will get, from the parties, our allocation from the parties to the protocol. So, yeah, it's not clear what we will have in '05. I mean, we know what we've submitted.

UNIDENTIFIED MALE: That much has been submitted?

MR. JONES: The 39 percent and the 37 percent.

I think, Rob, you were up first?

ROB: Yeah, this is sort of a different take on the same question. I think in the last discussion that we had at PPDC on this topic, there was some question

about whether the process that had been developed, that had actually captured all of the potential critical uses, and I guess there's two parts to the question.

One, does the Agency feel satisfied that things that would have qualified have all been captured in the nomination; and, two, if there are things -- critical uses -- that weren't, there was talk of a second round, and I think, in fact, that at the last PPDC the timeline was something like last winter for a second round of applications. And, obviously, that slipped a little bit, but is there a new timeline?

MR. JONES: Yeah, there were potential applicants who just never got enough notice or there were applicants who felt that they didn't get, you know, a fair shake the first time or they're going to make a better case this time, they have an opportunity to submit their application.

Again, basically on the same time frame as last year, in the August to September time frame. The application, I think, has about cleared OMB. Is that right, Christine?

CHRISTINE: It's at OMB right now -- (inaudible,

too far from microphone).

MR. JONES: So, we're, as you would expect, we're a little ahead of where we were this time last year, but there will be a second round in the August/September time frame. That's when the applications will be due. Applications will be available much before then.

Larry, welcome.

MR. ELWORTH: Jim, two quick things. One is my impression from some is that OPP did a really substantive job along with the USDA on this methyl bromide criminal use exemption -- Christine and Denise and everybody that was involved in it did a really substantive job. So, I think that was very welcome.

And, secondly, I wonder if you or Anne want to talk and just briefly describe how broadly staff in the agencies involved in this, NAFTA working group after working with it -- because I think there's a lot of people from various divisions are involved in it -- and it might be useful for the committee to just know how many parts of the Agency that touches.

MR. JONES: One of the things that we've tried

to do since the December meeting is expand the participation and elevate the level of participation. Debbie Edwards and Lois Rossi, as well as Anne, are playing more of an active role than previously. But, certainly, not only the regulatory divisions and the field and external affairs divisions, but obviously HED is a critical player in the food residue activities. There are a number of other TWG activities that involve others within the office.

MR. ELWORTH: Is anybody from DPR involved in this, as well? I'm speaking of the other countries.

MS. LINDSAY: DPR is not involved as what we call a full partner, but they're not yet an independent nation. But they actually are a significant partner in an array of harmonization activities and that's one of the areas that Debbie and Margaret have actually spent quite a bit of time is sort of -- they're more -- I don't know whether you call them a silent partner or a --

MR. ELWORTH: Well, they're their own harmonization issue.

MS. LINDSAY: We did the easy stuff first, which

was Canada and Mexico, and then we turned to California.

MR. JONES: Yes?

MR. BOTTS: First of all, I didn't realize that Christine was behind me. I'd prefer to be on this side, but --

(Laughter.)

MR. BOTTS: -- I like Larry's comments based on the information that was submitted in relation to the 52 individual commodity group or industry specifics with applications. The B Group did an outstanding job with the information they were provided to pull together a document which accurately reflected their understanding of the issues as presented in the data that was submitted to them. Now, recognizing that's kind of a loaded comment, I'd like to clarify a little bit -- and especially for Dr. Lockwood, some of the issues associated with this thing.

I would not characterize this as amounts of methyl bromide that slipped through the process or would be slipped through use of a product.

Methyl bromide regulations, under the Clean Air

Act, is taking a compound that is totally different than every other compound, with the exception of one that's regulated under the Clean Air Act, and it has a natural component it produces that impacts the environment as well as that that's man-made or released through use in agriculture.

And having said that, there's still a lot of questions relative to the actual sources and relationships and, in fact, the sources that have been identified naturally capture a much greater percentage of use than what was originally determined when the information was first listed. The listing was characterized based on laboratory studies of the potential of the product to deplete ozone. Nobody's arguing with that issue. The issue is whether or not the product that's used -- from an agricultural standpoint -- contributes significantly to ozone depletion.

Having said that as an industry and especially in Florida, we have spent millions of dollars since 1991 hunting alternatives. The petition that we put together for four crops requested 11 million pounds of material, which represents about 54 percent of the use that we had

in 1991 under the baseline.

You have to recognize that in Florida we're growing in a ball-bearing sand; we're not growing in clay. We're looking at a situation that we are already adopting most of the admissions reduction technology that's been adopted in the rest of the world -- or being proposed for the rest of the world. We bed fumigate, we don't broadcast, we cover with plastic tarp, we don't bare-ground fumigate, it's highly regulated, it takes special certification and application requirements for people to use it. That's probably one of the more regulated products that we use in Florida agriculture.

The petition that we submitted was based on the results of that extensive research program. We found out a week before the cue petition was submitted internationally by the State Department that one of the partners we had in our best alternative was no longer available. Because of the registrant non-payment of registration fees, the product has essentially died.

We don't have a herbicide partner for nut grass control and tomatoes. This gets to one of the issues on the need for additional submissions. The initial

submission that went in was based on having essentially a two-year window to be able to prepare for the 2005 phase out, which has not changed. The actual number that's allowable under the Clean Air Act, with the exception of quarantine and pre-shipment uses, it meets certain criteria defined by the international communities and those products that are manufactured in the U.S. for export to developing countries, will be the only methyl bromide that will be allowed to be manufactured in this country as of 2005, unless it's a CUE process as approved internationally.

This international process has started, the Methyl Bromide Technical Options Committee under UNEP (phonetic) met the end of March and they made a recommendation to the Technical and Economic Assessments Panel of the United Nations Environmental Program to come forward with a decision to go to the parties in November for an absolute decision.

Al, I think we'll know, basically, where things are probably by the end of the first week in May when the open-ended working -- or when the recommendations go to TAPT (phonetic) and they come forward with whatever

they're going to take to the Open-Ended Working Group meeting the second week in July, because they have to formally recommend what's going forward to the parties at the Open-Ended Working Group. So, they will pretty well know what's there.

It's just one of the questions I had and I think you've answered it. You all have not been briefed at all on the results of that initial MEBTOC (phonetic) review of the CUE packages not only from the U.S. but the other 14 countries that I understand submitted CUE packages, as well. And it's only developed nations that were allowed to submit.

You all haven't had any briefings at all, right?

MR. JONES: We have not been debriefed yet on the MEBTOC meeting -- is that right, Christine?

CHRISTINE: That's right.

MR. JONES: That's correct.

MR. BOTTS: So, right now we don't know what the status of that number is. Yes, the U.S. Government made a determination that based on the information they had there was a critical need for the amount that they requested because there were no alternatives that would

allow the continued production -- or non-economic disruption to the industries impacted. And that's a very thorough review that was done in the packages that were there. And I would, just based on the review of the petition that we submitted, they were much more critical in certain aspects and made some assumptions and decisions that I would argue were much more conservative toward biasing the number downward than they would have if they had done a review with more information in the process. But that's a subject for further discussion down the road with Christine and the rest of her group as they move forward.

So, it's a long-winded way of saying there will be an additional submission from the State of Florida to modify the request that we made last year because of the changing circumstances associated with those products that we currently were depending on being registered and available for use January 1 of 2005.

How large that petition will be, I don't know. I'm waiting for OMB review and you to tell me how to modify the petition and the form that was sent out. And as good a job as they attempted to do on that document,

it was projected to take 300 hours to compile the information necessary to submit it. We did four crops and the time that we spent on those four crops was a little over 4,000 man-hours, not counting all of the researchers who pooled their information together to help us document the needs in Florida based on a very sophisticated research program we had in place.

So, it's not a simple process; it's a very complex issue and in some regards it's been treated fairly cavalierly by people who characterize as a luxury industry taking advantage of an easy tool. It's not. And I would suggest that the issue is not resolved yet and won't be until we find out what the international community has proposed to go forward.

On the other issue, the NAFTA harmonization process, at a meeting earlier this year, Jim, we asked a question on the -- actually, the Canadian revocation and general maximum residue limits -- which those comments were actually due last Friday -- we got an extension to submit our comments for minor crop farmer alliance until -- actually today, they were due -- we submitted them yesterday. And I apologize, we forgot to send you a

copy, but I'll give you one, because I have them with me, as we speak.

One of our issues is we had hoped through this process of harmonization that we would prevent, in a very proactive way, the development of trade irritants. We're not saying they're absolute trade barriers, but when there's differential tolerances available for commodities and potentially differential registration periods after a tolerance is granted because of differences in the process, it does create very real and meaningful problems for those of us who grow specialty crop products, and it does create an issue.

One of the disparities and because of my crop farmer alliance having cross-border membership, we were being told by our Canadian membership that PMRA had projected a 12 to 16 month period of implementation of the proposed regulation to do away with the general maximum residue level in conversations with, actually IR4M, the agency, that timeline was predicted to be much longer than that.

Have you got any better feel for what kind of time frame we're talking about before the general maximum

residue level would be revoked?

MR. JONES: I don't, Dan, but we do have some PMRE folks that maybe during the break we can offline to get some clarity on that question.

MR. BOTTS: Thank you.

MR. JONES: All right, why don't we break -- I would say coffee break, but hopefully you all aren't going to get coffee or I'll never get you back here, you'll be qued up outside the Sheraton for the next 25 minutes, so if you could all be back at 20 of ll:00. Thanks.

(Whereupon, there was break in the proceedings.)

MR. JONES: So, we're just going to get started. The next session is a follow-up to a pretty lengthy session that we had at our last PPDC meeting around alternative testing. And this very much was a topic that a number of members of the PPDC encouraged the Agency to engage in at this meeting, and we agreed that it was something that we needed to focus on a little bit more. And I'll turn this over to Debbie Edwards.

MS. EDWARDS: Thanks, Jim. Actually, in this session, we're going to start with something other than

that, which is something we've been working on very actively and, also, it's a follow-up item to some of the PPDC meetings, and that is, on the Agency's efforts to expedite the experimental use permit process.

So, I want to give you a follow-up and status report on where we are with that. We think we've made significant progress. And to do that will be Mr. Peter Caukins, who's the Associate Director of the Registration Division.

MR. CAUKINS: Thanks, Deb. The expedited experimental use permit process, for those of you who may not be aware, it's an effort by the Agency to streamline our EUP process to allow for the approval of experimental use permits and the establishment of the appropriate temporary tolerances challenges that meet all of the FQPA safety requirements for a select group of all pesticides and accomplishing this without significantly increasing the resource burden on the Agency.

The chronology is pretty much -- we began looking into the feasibility of developing such a process during the summer of 2000. We have received quite a few comments from growers and from registrants talking about

the need for more EUPs. We discussed our intentions and our current thinking with the PPDC in November of 2000; we presented our draft proposal of the process at the PPDC meeting in December of 2001, a year later; we published, for comment, our proposed process on December 19, 2001; and the time period closed at the end of February, 2002.

At this point in time, we have revised the criteria; we have drafted responses to the comments; and the package is currently turtling its way through our internal ABD angecy review process. I think it's our expectation that we should be going final and public with this on or before the end of the current fiscal year.

Comments that we received came from registrants, agricultural commodity groups and stakeholders associated with university and extension services.

In general, the comments suggested the need for, one, greater flexibility in our selection criteria; and, two, more clarification of certain key terms, like the watershed.

In general, our response has been to provide more flexibility in our criteria. Some of the criteria,

which were proposed as must-meet, are now should-meet; we've also emphasized that our approach will be on a case-by-case basis. So, we think we have provided somewhat more flexibility.

Last December I used the analogy that what we're proposing to do is not a home run, it is not intended to meet all the needs for EUPs -- we cannot do that with the resources we have -- what we're trying to do, you know, is score a solid single, and I think with the added flexibility for a speedy runner, now, you might be able to stretch that single into a double, but that's -- it's not a home run.

In terms of being able to provide greater clarity and definition to key terms like watershed, we have provided a website where you can go in and, if you have the zip code of the town or the name or the river or the watershed where your UP is going to take place, you can identify the watershed; it outlines it so you can see exactly where your various plots are and what watershed is there.

So, we've addressed, I think -- and I'm not going to get too specific, but those are the general

comments and I think our response is that we've addressed them.

We have also piloted one EUP -- we tend to learn a lot more from actually doing something -- and the CARAT transition work with subcommittee helped to identify a critical transition need for eastern peach growers. Evidently with the cancellation of methyl parathion on peaches, second pests were becoming real problems since the alternatives did not control them as methyl parathion had, plum curculio and San Jose Scale were the most serious pests that eastern peach growers had to deal with. And, if uncontrolled, they were reducing the productive life of the peach tree by as much as 25 percent.

The Peach Growers Pest Management Strategic Plan identified indoxacarb as the potential alternative to control these pests and there was an urgent need for a EUP to evaluate, on a field scale level, indoxacarb's efficacy. We have granted that EUP, indoxacarb is a reduced-risk chemical and the Agency has worked with the registrant and the growers in issuing this EUP.

Anticipating some of the questions, let me say

at this point in time we are not officially open for business. Until what we hope is our final -- actually snakes its way through and goes through OMB and we actually publish it, I don't -- at that point in time we'll sit down with our staff, we will go through the process with our PMs and with our other staff members, so that we are implementing it as consistently and expeditiously as possible.

However, that being said, if you have a very critical transition need, not unlike this indoxacarb, we're certainly willing to listen and to have you come in and talk to us on a case-by-case basis.

But I think this program will be up and running by the end of this fiscal year.

That's it?

MS. EDWARDS: Are there any comments on that or questions? Buck?

BUCK: Pete, I can't remember, but in the initial proposal it seems like the acreage is rather limited. I can't remember whether it's 20 acres or 200 and I just wondered, IR4 had made a comment that particularly on perennial crops when you're looking at,

you know, wide scale programs, particularly for IPM management, whether the acreage was very restrictive. Is there any flexibility being built into that consideration?

MR CAUKINS: Yeah, the acreage limitation is 100 acres for a minor-use crop, and what we've done is that has become a should-meet instead of a must-meet criteria. The burden will be on the applicant to demonstrate why, even though it's more than 100 acres, the existing mis-assessment that we have will be adequate and there's no need to look at or revisit drinking water assessments or worker exposure or anything like that.

So, to the extent that these criteria are not met, then the burden is on the applicant to demonstrate that these accedence does not impact our risk assessment at all.

MS. EDWARDS: Okay, well, I think, then, we will go to the follow-on topic of alternative non-animal or reduced animal testing. This, again, as Jim said, was a follow-up report from a pretty lengthy session at the last PPDC meeting. I wanted to reiterate this morning that the pesticide program is committed to the adoption,

where feasible, of alternative test methods that reduce, refine or replace the use of animals in toxicity testing.

To give you a little bit of clarification or to refresh your memory on what that means, reduction is the use of fewer animals; refinement are procedures to eliminate pain or stress to the animals; and replacement, which to be truthful is actually the ultimate goal, is replacement with animals with non-animal or invitro tests.

An example of the Agency's commitment in this area is that we actively participate, through several offices, in the ICCVAM, which is the Interagency Coordinating Committee on the Validation of Alternative Methods, and we even have participation in that from within the Office of Pesticide Programs.

I would like to mention, also, that some guiding principles that we do have to keep in mind throughout the process for adoption of these alternative methods are that they most be validated to ensure their reliability as predictable tools and, also, that they must meet a risk assessment or risk management need for the Agency.

We're going to handle this presentation today

with a panel. We've gotten some agreement for several of yourselves, PPDC members, to participate. The panel will consist of Mark Perry, who is the Agency's OPP's team leader in the Special Review and Re-registration Division with oversight responsibilities for the evaluation of acute toxicity.

Also, I'd like to point that Debbie McCall, who is here, is Technical Review Branch Chief in the Registration Division and is also very actively involved in this initiative and is actually also a representative to the ICCVAM.

We also have three members participating here from amongst you; that's Bill McCormick of The Clorox Company; Pat Quinn from the Accord Group; and, also, Troy Seidle for the People for the Ethical Treatment of Animals.

So, to kick it off, we'll start with Mark Perry.

MR. PERRY: Thanks, Debbie. Let's start by providing a little history on this group. Back at the May 2002 PPDC meeting, the issue of alternative testing for acute endpoints was discussed and brought up, and some of the members expressed a real interest in

exploring this issue further through the PPDC forum.

So, in the following PPDC in September, we had included a number of presentations on this topic, as well as the panel discussion, and really of the discussions at the September PPDC, came the idea of forming a group.

Kind of what the goals of trying to get a handle on what alternative methods are out there for acute endpoints, what the status of these methods are and, then, kind of determine what can be done to facilitate the movement of some of the most promising methods into ICCVAM review.

And on the other side of ICCVAM review, what can be done to move them into Agency guidelines after they've had ICCVAM review. Really with the ultimate goal being replacement of all six acute endpoints with non-animal studies.

Shortly after the meeting in September, we put together a document detailing the status of numerous alternative acute methods. It's been referred to as the State of Play document, but it's actually entitled Alternative Methods of Acute Toxicity. You guys should have this in your handouts.

This document, basically, identifies for these methods exactly how far along they are in the process of becoming an EPA guideline.

And later on, in January of this year, we held a meeting to get feedback on this State of Play document and brainstorm ways to facilitate validation and use of these methods.

We had great participation at that meeting. We had reps from consumer and egg industries, the states, PMRA, animal rights and environmental groups. You should have a copy, actually, of the participant list for this January meeting, as well as the minutes, too.

But based on the feedback from the January meeting, we did make some changes to the State of Play Document. If you want to take a look at that document, you'll see that we divided the methods into three groups. We have three different tables there.

Table 1, basically, has methods that we consider to be immediately to meet EPA guideline requirements; Table 2 has methods which are likely to be available in the next one to three years, which pretty much means they'll probably either in ICCVAM review right now or on

the ICCVAM work plan; and Table 3 has methods that are likely to be available in three or more years.

So, this is pretty much where we are right now with this State of Play Document. It gives us a really good snapshot of all the methods that are out there, what the status is, which acute endpoints have methods kind of in the pipeline and which ones don't have any methods or have very few methods in the pipeline.

And one other note of interest, we have also started dialogue with ICCVAM to get their ideas on this whole effort because, clearly, they're going to be a key part of this.

Debbie?

MS. EDWARDS: Okay, Bill?

MR. MCCORMICK: I'm ready, but I'd like to hear Troy, first.

MS. EDWARDS: You would?

MR. MCCORMICK: Yeah.

MS. EDWARDS: Okay. Troy, is that all right with you?

MR. SEIDLE: All right.

MS. EDWARDS: Troy has a presentation, actually,

so --

MR. SEIDLE: Okay. And everyone should have these slides, as well, in your handout.

Okay, where we are today, as Mark has pointed out, we've had some discussions. The first point dealing with the acute toxicity six-pack, as it's called. The tables that are also included in PPDC members' handouts get into the individual methods that we've discussed. There are some gray areas in the tables, if you read through them. For example, some of these methods are accepted as partial replacements in other jurisdictions, such as Europe. They are listed in Table 3 here. It's an evolving document, so there's nothing etched in stone at the moment, and discussions continue.

But this is really just the very first step in the process. And looking at acute endpoints, while very important, because these are the achievable, short-term goals; as far as a body count reduction is considered for Part 158, Data Requirements, it's a drop in the ocean. Acute studies tend to involve very few animals and these are six out of, you know, as many as 40 separate studies that are required for the registration of a pesticide

active.

So, it's an important first step, but it's not the end of the process. As Debbie said in her introduction, the goal is total replacement, and what I'd like to do for the rest of this presentation is just share some of my thoughts in terms of what could be possible next steps.

As you can see, Part 158 gets very quickly into much more difficult types of test methods to replace, many of these are systemic toxicities, they're not the local skin, eye irritation. You have to consider metabolism and a lot of other factors. They are, typically, quite chronic and multi-faceted types of toxicity. So, there's a lot of very urgent need for R&D efforts, and, although there's a lot of money that's being spent in the U.S., as well as other jurisdictions, the coordination leaves something to be desired.

I'm going to spend a little time on this particular slide just to highlight some of the differences between the U.S. and Europe and the steps involved from the concept of the test method through validation and regulatory acceptance.

The left-most column goes through to individual steps as ICCVAM would conceptualize them from method development through pre-validation, validation, external peer review and, finally, regulatory acceptance.

In Europe, the first stages tend to be quite well coordinated, where an individual test method to address a regulatory endpoint is either developed by industry, through R&D, or through ECVAM, which is the European Center for the Validation for Alternative Methods.

In contrast to the United States and North America, we see these methods coming from individual Federal agencies and a lot of money going into extramural grants, whether through ORD STAR Grants or through NIHS' Small Business Grants. These tend to go out to academic researchers who may or may not have the necessary toxological background to develop methods that would be acceptable for regulatory agencies.

So, whether these types of grants are producing as much bang for the buck as they could, is very much an open question. Whereas, in Europe, having ECVAM involved in method development, pre-validation and validation, you

1 have the government regulators who will ultimately be the
2 users or the interpreters of these types of studies, who
3 are involved at every stage of the game, and it tends to
4 be much better coordinated and, even though less money is
5 being spent, dollar for dollar in Europe, versus the
6 U.S., you tend to get more bang for your buck simply
7 because you have the regulatory toxicologists who have
8 input from the very beginning.
9 In terms of ICCVAM, which has been raised,
10 ICCVAM, for the most part, tends to be involved only in
11 the latter stages. Once you have a method that has been
12 developed and gone through the validation cycle, the
13 question of whether or not it passes muster is ICCVAM's
14 responsibility. So, with very few exceptions, ICCVAM
15 isn't involved until almost it's too late -- for lack of
16 a better term -- where if a method hasn't had the input
17 of regulatory agencies until it's already done through a
18 $1 million validation study, and then ICCVAM says, I'm
19 sorry, it doesn't cut it or Federal agencies who
20 represent or who are represented around the ICCVAM table,
21 determine that it's not relevant for their purposes,
22 then, again, you get a lot of money and a lot of effort

being spent with very little end product.

So, the process in the U.S. could stand to be better coordinated at the earlier stages of the game, I guess, is the take-home message.

So, in terms of implications, the U.S. has no equivalent to ECVAM and this means that this scattered development and pre-validation activities are not as efficient as they could be and there needs to be greater interagency dialogue and coordination for the earlier steps in the process.

Currently, there is no mechanism for coordinating work on common end points. So, for example, if you have agencies such as EPA and FDA who require reproductive toxicity as regulatory endpoint, we have FDA working on great computational systems and there isn't, necessarily, the dialogue, within EPA's Office of Research and Development, to interface with FDA for this endpoint, and there you have similar examples for every endpoint.

There is a need for coordinated dialogue so that if a method, for example, is developed by FDA and in the case of the computational tox, they program these models

with FDA-type chemicals, except for pharmaceuticals, are these models going to be predictive for pesticides, if you don't include that data in the training set?

The answer is probably not; whereas, if these two agencies would interact, in the early development of these models, you'll have something that is more broadly applicable more quickly. So, it's just increasing the efficiency if we can get this kind of dialogue happening early.

And, secondarily, there's a lot of research going on for specific endpoints, but there are also a lot of gaps, and there's no coordinated effort to identify those gaps and come up with a stepwise strategy for closing them. So, that's another area that's needed.

So, the result, as I said before, even though more money is being spent in this country and on this continent than in Europe, we're seeing methods being developed and validated much more quickly in Europe simply due to greater coordination, which exists through the ECVAM process.

So, what's needed, in my opinion, is, number 1, effective interagency dialogue and coordination for these

test method development and validation activities, and the fact that OPP requires a wider array of these animal tests than any other Federal agency, EPA and OPP, in particular, needs to play a leadership role in spawning this type of coordination.

And, secondly, what I would suggest is a dedicated program within EPA to coordinate between OPP, OPPT, OSCP and the different offices that do require fairly similar endpoints, create a structured dialogue between the program offices and the Office of Research and Development, which ultimately is the science arm that would go about developing these methods, in response to a Program Office's need. And, right now, this sort of dialogue doesn't exist in a really formal way.

Secondly, determining the expertise needed to use and interpret the results of animal tests -- or of non-animal methods when these types of methods are brought on line to the individuals in the program offices who have to interpret them and make risk assessment decisions understand how the method works, what they're looking at and how that relates to the traditional types of toxicity data they'd be otherwise interpreting.

So, training staff is a major concern. And, in addition, establishing dedicated staff positions given responsibility for driving this type of program.

At the moment, through the commitment of individuals who serve in a voluntary capacity on ICCVAM, as well as the individuals in OPP, who have been real leaders in bringing this issue to the level that it's at, it's very commendable that they're adding this on top of their existing work plan. But creating a dedicated position that is identifiable, to say that this person is responsible for doing this on an ongoing basis, this becomes their job, would move it forward a lot faster and I realize, given the fiscal realities from Marty's presentation, that may not be a popular suggestion these days, but it's a suggestion, nonetheless.

And, then, finally, the group that met back in January. I think we had a very productive discussion and if there's some way that we can formalize that and make it an ongoing process, either a subcommittee of the PPDC or a committee unto itself, I think that would also be very helpful.

Thank you.

MS. EDWARDS: Well, thank you, Troy, I think that's a lot of food for thought for us, certainly, and a lot of good and interesting ideas. I don't know if anyone wants to ask any questions of clarification at this point or before we go on to the other panel members. No, okay.

What do you think now, Bill? Oh, I do have one, I'm sorry.

UNIDENTIFIED FEMALE: I'm sitting right next to Troy and I guess I could ask him, but what's the make-up of the ECVAM? I mean, what's kind of the representation on that organization?

MR. SEIDLE: ECVAM, structurally, is fairly similar to ICCVAM. It is a government -- it's an offshoot of the European Commission's Joint Research Center. So, it is government, and it's made up of -- it's fairly representative of the U.S. or the EU member states, and it essentially performs the -- it has the mandate to advance the development and acceptance of non-animal methods. Whereas, I guess, the distinction I would make is that ECVAM is proactive in this area; ICCVAM tends to be more reactive. So, that's part of the

difference.

ECVAM is better funded than ICCVAM is. There are a lot of these issues, but in terms of composition, it is individuals from the EU Joint Research Center who comprise ECVAM.

MS. EDWARDS: Anyone else?

(No response.)

MS. EDWARDS: Bill?

MR. MCCORMICK: Okay, now I'm ready.

MS. EDWARDS: Okay.

MR. MCCORMICK: I thought it was useful to have Troy's presentation ahead of my comments simply because I think he's assembled some good thought around what should happen in a broad scope of invitro alternatives to testing.

I want to make some comments about the effort that has been conducted to date, which is really around replacing acute toxicology test results within vitro alternatives.

And, to a point that Troy made earlier, we're really talking about -- we need to be clear about why we're chasing the acute tox package as a set of studies

to replace with invitro alternative.

There's been a lot of work around it, and I think one of the real positives of having the meeting back in January was that the meeting happened, and there were a lot people who had done a lot of work on invitro alternatives to acute tox endpoints, and it was useful to have all those people assembled.

I think, to me, there needs to be a clear goal established. Debbie, you talked about, well, the ultimate goal is to replace the six-pack with invitro alternative, which may be useful. But, to Troy's point, and I think EPA needs to maybe make their ethical commitment to or why do they want to chase those studies which really have limited animal use and the number of animals that are being used in those studies are going down. The use of waivers for inhalation are increasing and things like that.

So, you know, you're not talking about very many animals now, and is it useful to spend a lot of time and effort trying to replace those or could the effort be better used in looking at studies that involve a larger number of animals and maybe get those reduced? And,

again, I think there needs to be a sort of a principled basis for operation on that.

So, if you know ethically or by principle why you want to go after invitro alternative, than where you go makes more sense.

I think the group also -- I'm not sure that having toxicologists ask this question is all that fruitful -- I think there needs to be -- the group needs to have risk managers in there as well, because I think where we're headed in terms of why we do these studies, again, is for risk management purposes. It's just to warn the user of these pesticides of the acute toxicology that may ensue if they get exposed.

And where we're going with that, if we go to global harmonization of labeling as a very spare or kind of two signal word, kind of warning where the degree of the shades of difference that we deal with our current tests, are going to be eliminated. So, why are we going after those tests?

You know, my example would be, you know, if you're only going warning and danger, and you're going to wash the eyes out, regardless of what you get in them,

you know, what's the point of really doing the animal test?

So, I think there's some fundamental questions if why we're using the data is very limited and the way we're communicating gets more limited, you know, why do a fancy test? I think we can almost eliminate the test today.

Anyway, about the group. I would echo, again, Troy's concerns or that somehow this group can't just meet occasionally. It has to have some formal basis of being. And, so, if the agency is truly committed to replacing animals in acute toxicity, I think they need to commit to some formal either FACA or subcommittee of PPDC, and really say, this is a commitment, we're really going to go after this and these are the reasons why, and give that group more power than just having a group and talking -- you know, some defined endpoint.

So, my concerns about that, though, are -- and what's been raised -- is some of these invitro alternatives are very expensive. I'm concerned about, ultimately, level playing field issues; about companies, such as Proctor, who presented some fairly sophisticated

ways to look at eye irritation, that -- not deer tonight, which Debbie and I talked about -- a deer repellant. You know, those guys are not going to have the resources to do those kinds of alternative testing.

So, you know, on the one hand I'm advocating one thing and on the other hand I do think there needs to be a level playing field for all players; I think costs are a consideration here for some of the alternatives; and, finally, I'm going to pound this point until somebody listens to me about why are we doing it and what are the labeling decisions that we're making, based on these studies, and can that "why" drive what our alternative methodologies look like?

MS. EDWARDS: Okay, thank you. I guess, Pat, we'll end with you?

MR. QUINN: Thanks. Now, I'm wishing I went before McCormick, because now I get to echo many of the things he said.

I want to start, I guess, by saying that I think the Agency gets a lot of credit, Debbie gets a lot of credit for the leadership on the group, and Debbie McCall, I think, particularly for the work that she and

her staff did in cataloguing where alternative tests are in the validation and approval process right now. I think all of that was a great building block.

Secondly, although it's been said, for those of you who weren't there, the diversity of the group in the room that day and the level of common agreement, I thought, on goals, was really quite astounding. You had the environmental community, you had agricultural registrants, you had at least four consumer product companies in the room, you had a number of animal welfare groups in the room, you had significantly, I think, every office within OPP participating -- every division, rather -- and ORD there, as well.

So, I think the issue is right, and we've seen this issue ripen more quickly in the toxic's program with the HPD exercise, but for a number of reasons, it seems like the right time to go ahead and make some progress.

I would say that what we are challenged with here is sort of maybe a two-track approach. On the one hand, I think, continuing to monitor and increasingly support the progress of alternative test methods through the ICCVAM approval process is something the Agency

really needs to be involved in.

And given the new opportunities for the Agency to both sponsor and fund alternative methods that look promising and nudge them ahead in the ICCVAM process, that the Agency has a real opportunity to engage in that and push some things forward. And I think in a lot of ways the work group will have an obligation and a role in helping to track those methods and see that they make progress.

The ICCVAM process is, I've learned, you know, sort of hallowed ground. And I don't pretend to know more about it than the people in this Agency who have worked a long time on it. Having said that, it does seem that we also have learned that there may be opportunities to streamline what I'd call the process between ICCVAM approval and EPA implementation of a validated method. There seems to be some opportunity there maybe to achieve some efficiencies.

Finally, I guess, the second track is really the one that Bill has presented. And, to me, what's important is that we do go back and we ask ourselves why we're doing these tests. We're doing them, at least in

terms of the consumer product area, in order to determine precautionary labeling. And it may be that we've gotten to a point -- in fact, I think almost everyone in the room back in January would agree that those six particular tests are probably not the correct tests any longer to make those determinations. Science has clearly evolved; it's not clear that some of them are predictive; and I think it's time that if we're going to make progress in the short term, because I think what Debbie McCall's exercise showed is that one-for-one for replacement of the six acute tests, are probably several years away. So, we can't just pursue that track.

I think what we've got to do at the same time is get back to asking ourselves why are we doing the tests and can we make labeling decisions based upon other data sources, structural activity relationships -- other kinds of approaches that have been used successfully in the PMN process and that were outlined in Susan Wayland's letter that really resolved the HTD process.

I think we need to get back to those Whalen principles and see if we can apply them in real terms here in the short term.

1 MS. EDWARDS: Well, thank you. I guess right
2 now what I'd like to do is open it up for comments from
3 anyone else on the panel or questions for any of the
4 panel members.
5 Julie?
6 JULIE: I guess I'd just like to add further to
7 what Bill and Pat have said. I think while replacement
8 might be the ultimate goal, I think in a short term I
9 think a lot could be done to do, you know, reduction, and
10 mostly in the acute area, again, why are we doing these
11 studies, what information is available and what questions
12 do we have with regard to a product prior to initiating
13 any studies? I think if, by looking at information on an
14 active ingredient on a formulation, as far as decisions
15 for labeling, most of those decisions could probably be
16 made on all the available information. And, then, only
17 if there were particular questions that could not be
18 answered based on available data, you know, then, perhaps
19 some additional testing may be needed.
20 But, I really think, as they said, I think we
21 have to look at why are we doing the study? If what
22 we're doing the study for is to determine labeling, the

use pattern, the available data may give us the answers we need as to appropriate labeling without having to do additional testing.

MS. EDWARDS: Thank you. I want to make a comment myself right here on that point. I think that's absolutely true, and what we've actually encouraged various parts of industry and various fora to do for us is to come up with some case studies that give examples of how they believe, for a given product, we could make precautionary labeling decisions without the need for any data. If you see what I mean. So, we will keep making that offer, and I know that a couple of companies are actually, I believe, working on some of those right now. And we've used a little bit of that strategy, it's my understanding, in the biopesticides group.

But, so far in the conventionals we haven't really gotten much in the way to react to, but we know that consumer product companies, in particular, do make those decisions every day on nonpesticidal products, and we'd like to know what rationale and, you know, scientific logic they're using, you know, to make their precautionary labeling decisions.

UNIDENTIFIED MALE: And Proctor is not here, but I can say that I know that they have committed to do two case studies, different product lines, where they sold the products in a non-antimicrobial capacity for years and had done through what I'd call a non-animal hazard assessment or risk assessment to satisfy their own concerns. And, then, registered the product, subsequently, and hopefully that kind of case study will provide a good building block for both staff here at the Agency and other stakeholders to look at.

MS. EDWARDS: That's great, thanks. Larry?

MR. ELWORTH: I have the disadvantage of being totally ignorant on this issue, but for the benefit. But some of what -- I want to return to Troy's presentation, and while I don't know the particulars of this because it's not my issue, it reminds me a little bit about some of the stuff that we did that Al was real instrumental in at USDA in terms of USDA's development of information for making pesticide risk and risk management decisions. There had to be a lot of interaction of the regulators with the people at USDA, both from the Land Grants and in USDA to make sure that the information that they were

developing was actually relevant for the regulators. It was one thing to do a great research project; it was another thing for it to be used on a regulatory decision-making context.

So, I know there are benefits from that, but I was really curious when we talked about what's happening in Europe as opposed to what's happening in the U.S. Why isn't that same kind of interaction taking place in the U.S.? Can it be done within the existing institutions we have? And unless somebody is really against it -- unless it gores somebody's socks, why don't we do it?

UNIDENTIFIED MALE: I think it certainly can be done. I think there are historical differences where in Europe they have a EU Directive, 86609, so it's 1986 when this process began, whereas it's much newer on this continent, the awareness and the real driver to push forward is much newer, and in creating the ECVAM process we already have that institutional coordination from the get-go as they just had a leg up, whereas it has been very decentralized in North America. And I think agencies are certainly making an effort, but I think it's just a matter of taking good intentions and lots of money

and putting it to the best use. And there is, to some extent, the potential for coordination through what's called NICEDUM, which is the NTP Interagency Center for the Evaluation of Alternatives, which is supposedly an interagency mechanism a step up from ICCVAM, but in terms of actually coordinating the individual agencies R&D efforts, it hasn't evolved to that point yet.

So, the more we can move towards that, whether it's through NICEDUM or whether it's through simply key individuals in the individual agencies talking to one another, talking to ECVAM and getting the discussions coordinated to make sure that you're either not developing redundant strategies or that there aren't these huge gaps that could be filled.

So, I think there is definitely a need. I don't know that there's tremendous resistance, I think it's just it hasn't been considered in a really organized way by the individual agencies, so that's why the push.

MR. ELWORTH: So, then, can I follow up with Debbie then? So, then, what hurdles would the Agency or OPP face -- we're talking about pesticides -- we're going to face to increase the coordination on these issues, at

least on the research and the testing?

MS. EDWARDS: Well --

MR. ELWORTH: I mean, separate from resources. We know resources are always an issue.

MS. EDWARDS: Right. I think I'm actually going to ask Debbie to answer that because she's been the one that's been most active in working --

MR. ELWORTH: Using the Jim Jones method, that's a good move, yeah.

MS. MCCALL: That's a very interesting question. I believe, probably, the best answer I can give you is the way that ICCVAM is structured right now. As Troy was saying, we are a collection of Government agencies, as you know, and, so, individuals from each agency go and work on each like work group that is taking forward.

For example, if you were going to working on dermal, then you'd get a person that's used to working in dermal toxicology and working on that. And, so, a lot of the coordination of going and searching in the agencies, that involves some time. And since you are -- it really does come back to a resource burden, because you're coming back and you're adding on to the person's plate.

Okay, now, all of a sudden, I have this one thing to do that I didn't have to do before, and I need to get that done in the next six weeks. It just adds all the things together. ICCVAM, of course, doesn't exactly do the validation. We're looking -- when we look in the ICCVAM group -- we're looking at it as how did it get validated? Does it answer some of the basic questions? Do we think it's really scientifically valid? Did they do a good job at doing that type of an activity?

Whereas in Europe, those guys are actually -- they're in it from the get-go, so they're totally knowledgeable, they have it from the beginning all the way down to the end. We're kind of like coming in new and having to come up to speed and then coming out.

So, it's really -- it's the timing and it really does kind of come down to who can be there and do it at the time, when the time is needed, and how it's going to play out.

MR. JONES: So, this is --

UNIDENTIFIED MALE: Wait, let me give a little additional perspective to that. Obviously, you can tell from the presentations, we're not in charge. And when

you're not in charge, you have to use different tools. You can't just say, we'll do it on Tuesday and everybody show up and this is what you have to have done. You have to use more persuasion and sweet talking and compelling arguments and, so, that's the fundamental answer to your question of -- we would just have to use different tools and we'd have to employ them in those kinds of ways, because we're not in charge of the ICCVAM nor are we seeking to be.

MR. ELWORTH: Does anybody chair it?

MS. MCCALL: Bill Stokes --

MR. JONES: Who does he represent?

MS. MCCALL: He's NIHS.

MR. ELWORTH: Does the committee have -- does ICCVAM have staff, then, or not?

MS. MCCALL: Yes, they do.

MR. ELWORTH: They do, okay.

MS. MCCALL: They have committed staff.

UNIDENTIFIED MALE: Just to give you perspective, Larry, compared to ECVAM's budget, where it's -- I think it's in the 15 million Euros range, ICCVAM's is less than $3. So, they have two or three

full-time equivalent positions versus ECVAM's, you know, quite expansive transtyle. So, it does create a bottleneck at ICCVAM simply due to resourcing issues.

MR. ELWORTH: So, does it help you to have at least the discussion here to be able to take to the committee and saying that we have these stakeholders around the table, they thought this might be a useful thing -- does that help?

MS. EDWARDS: Absolutely.

MR. ELWORTH: Okay.

MS. EDWARDS: Kim?

KIM: Yeah, I guess I just come at this a little bit differently. I mean, I see that there are probably tremendous efficiencies and synergies involved in the European process, but I don't see that here, because you're looking at different chemicals for very different purposes, for the most part. I'm sure there are a few chemicals that overlap from one agency regulatory structure to another, but not that many. So, I think there's a lot more value in focusing directly on what OPP is doing to try to evaluate its own testing methods and, as was pointed out over here, look at the case studies to

determine, you know, what did we do? How is it different? Was it relevant? Was it useful? Et cetera, then spending a lot of time thinking about a, you know, regulatory structure -- I mean, a coordinating structure across a whole bunch of agencies. That's just my take on it. You know, if you want to get some efficient bang for your buck, this is where it is.

MS. EDWARDS: Okay, thank you. Betty?

BETTY: First of all, I want to commend EPA and the rest of the people that are working on this. I think it is certainly a very worthwhile goal. I'd kind of like to go back to Troy. Troy made a suggestion that perhaps there should be more coordination between EPA and FDA, particularly since FDA has models that they're using for pharmaceuticals. And I think that's something that EPA really should consider pursuing.

I know from a pharmaceutical standpoint when we look at things like dogs, certainly the anatomy and the physiology is fairly similar, so if you do it in a Collie chances are you're going to see the same thing in a German Shepard and a Dachshund with some minor changes. Not true in birds; the anatomy and physiology is very

1 different. Oftentimes when we do reproductive studies
2 for a pesticide, we look at mallards or we look at
3 chickens. The anatomy and the physiology are very, very
4 different when you get into the field and you're looking
5 at an eagle or a cardinal or a herring or whatever.
6 So, I think, you know, looking at some of that
7 potential for doing some modeling would not only allow us
8 to reduce animal use, but would also, perhaps, give us a
9 more accurate picture of what's going to happen.
10 MS. EDWARDS: Thank you. Bob?
11 BOB: Just a question: Is there any example of
12 -- and this is -- I so don't understand this issue that
13 I'll get this all wrong -- but are there examples of test
14 methods that have been validated and adopted by ECVAM or
15 even other Federal agencies but that aren't recognized or
16 adopted or allowed in the U.S. or by OPP?
17 MS. EDWARDS: And the answer to that is yes. I
18 don't know -- do you want some specifics?
19 BOB: Well, I guess where I'm going with that
20 is, I mean, does the U.S. think that the EXVAM process is
21 not a good process or is there some way that there could
22 be -- if they're doing it so well in Europe and we sort

of don't have our act as well together, that there could be some harmonization or some recognition by the U.S. of the work that's being done by the Europeans?

MS. EDWARDS: Right. Again, I'm going to ask Debbie to address that, but the first part of your question, I think that we don't think that the EXVAM is not doing a good job. That's really not the issue, I think it has more to do with being able to meet our needs in our regulations for what we're doing here. But let me let Debbie speak to that a minute.

MS. McCALL: I think just recently, in a conversation I had with Bill Stokes of ICCVAM, he just got back from a trip to Europe, so I believe that the idea of more coordinated efforts, looking at ideas in a similar time frame as they're looking at them, as ICCVAM would look at them, I think they're kind of working on that process. So, I'll just have to kind of leave it at that. I don't know where it's gone from there, but they are looking at it.

UNIDENTIFIED MALE: I'd just add to that that one of the subjects that the group talked about actually was having some of the ECVAM leadership meet with the

group at some point, have some dialogue on exactly the kinds of questions that you're raising. And, essentially, go to school and figure out what they're doing right, what they're doing wrong, what would we do differently. But I think that's part of the work groups plan in the future.

UNIDENTIFIED MALE: If I can just follow up on that just a bit. A case study, to answer your question, one method that has been developed and accepted in Europe and is an OEC guideline is an invitro method for dermal penetration, the dermal absorption rate. That's one method that is required or it's a conditional requirement under Part 158. It's not required all that often by OPP, but it's also something that's only relevant to EPA. It's not relevant to the other Federal agencies that sit around the ecvam table, but the current policy at EPA is that it can only get to agency review if it goes through ICCVAM, but if I was one of the other ICCVAM agencies and it's only relevant to one in 15, does this really -- is this an appropriate candidate to go through the entire ICCVAM process, expedited review though it is, and then go to the SAP and the, potentially, be accepted by EPA?

And, just to follow up on Pat's point regarding efficiencies, ICCVAM has really the potential to reduce inefficiencies if the method is relevant to multiple Federal agencies. And that way you can have one review rather than having to go through four or five separate reviews. So, it really can streamline the process.

But, if you have individual methods that are relevant to only one or two of the ICCVAM agencies, I would encourage EPA to revisit its policy and, potentially, if it's an OECD guideline or if it's been validated by EXVAM, be able to jump straight to SAP review. If it's relevant to an EPA-required endpoint and it's not necessarily relevant to all the other ICCVAM agencies and it has gone through validation, why do we need to go through that extra ICCVAM step, especially since ICCVAM is underfunded and it does bottleneck the process?

That's one suggestion that, hopefully, EPA will revisit that policy.

MS. EDWARDS: Okay. I think someone has had a card up down there. Melanie?

MELANIE: I'd like to thank the work group for

the work that they've done and I found the presentation very clear and intriguing.

One of the questions that was raised, I feel, by Pat and Bill, are really relevant, and, so, I was wondering -- I have a couple of questions:

One is that when an industry starts developing some of these tests, do they notify the agencies that would require it for their regulations? And what are the driving forces in the United States for trying to look for these alternatives? Who sets the goals, objectives, priorities and criteria for the development of these tests?

I think that, Troy, when you presented the differences between ECVAM and ICCVAM, I think some of these questions may actually get to the real reason for some of the differences and some of the questions that Bill and Pat had raised could probably be answered by the answers to these questions.

UNIDENTIFIED MALE: I think your questions are bang-on, and in the U.S. there simply isn't a single focal point for the development or the coordination, so individual companies may, for example, in the

pharmaceutical industry there's a lot of R&D going on and they have a number of in-house methods. The difficulty is some of them are patented, which makes them of limited applicability to a Federal agency for various reasons. You know, some companies are doing things that are strictly responsive to their individual needs for in-house R&D. For example, the weed-out (phonetic) products that are toxic early on in the development process. So, there are those drivers.

As far as what Federal agencies do, it's more than open question in terms of what drives them, why certain methods are addressed and others are not. So, I don't know if there is an easy answer to that question.

MELANIE: And those industries usually notify the agencies that they are developing these tests?

UNIDENTIFIED MALE: Not to my knowledge. I guess it's a case-by-case. Industries are working closely with -- for example, if a pesticide registrant is asked to go back and do a special study to answer a certain question, if they choose to do an invitro study and they present that data to the agency, there would be that kind of coordination. As far as advising the

agency, it's really the Office of Research and Development, in the EPA's case, that would do the hands-on development of these types of assays and whether there is a strong liaison between industries and individual companies and ORD on these issues, I don't think that's the case, just based on my meetings with ORD officials.

MS. EDWARDS: Thanks. John? I'm sorry, were you first? Okay.

UNIDENTIFIED FEMALE: Just to kind of follow up to my previous comments and your response. I think the Agency's been very good and very open to looking at, you know, registrant's rationales for bridging or requesting waivers of data, and especially in the area of bridging or re-registration and batching, I know I worked with Mark on putting together some different batching schemes, but I think, maybe, that for the registrant population as a whole they could use some more guidance as to what are appropriate bridging strategies or appropriate ways that data can be bridged. And I know that some years back there was a piece that was put into, I think it was one of the re-registration updates, where it kind of gave some examples of bridging schemes. They called like the

untroubled waters bridging or chain bridging, and it might be really helpful to registrants if something like that was maybe more officially issued, that kind of outline, the types of bridging strategies and schemes that the Agency will consider for those, you know, for registrants that maybe hadn't considered there may be available data that they could bridge, and I think that would be a way to help limit not only the number of studies but also resources going to review of studies.

MS. EDWARDS: I think that's a very good idea. Our goal, obviously, would be if there's no need to generate studies at all, we'd like to go there.

Dr. Liroff?

DR. LIROFF: I'd like to commend Troy for his insightful observations about the differences between the U.S. and Europe and some very thoughtful recommendations. I have a particular question. I notice in the meeting in January that there were a lot of OPP people there; there were two people from ORD; and I wonder if more can be said in this meeting about how OPP works together with ORD given the tremendous investment right now, the priority that ORD is giving to toxicology non (inaudible)

methods, in particular?

MS. EDWARDS: Part of the reason that there were so many more people from OPP in that meeting is that, at that stage, it was the first meeting and it was principally an OPP initiative, and there was an enormous amount of interest from our staff to participate, which was very encouraging. So, that's part of the reason why we had such good participation.

We actually got a couple of key people from ORD at the meeting, and I think, as time has gone on, we've had follow-up conference calls, and they're certainly very interested in participating and talking about it amongst their colleagues and management in ORD.

So, I think that, depending on how this group unfolds, we will have their participation, certainly in that group, and that we can use this forum, I think, to allow us to help set priorities within the funding constraints, you know, that ORD has.

But certainly I think that this -- if we choose it to be -- it can be a priority for the pesticide program to work with ORD on development of test methods.

Anyone else?

MR. JONES: Before we leave tomorrow, one of the things that I have heard on the table for our consideration is creating a PPDC subgroup, a working group on this topic, and before we leave, at some point, at the appropriate time, where we've got some time, I would like to get some broader feedback around that. I think I heard from all three of the presenters today that they were recommending that.

So, we'll find some time to get that kind of feedback, so be thinking about that between now and when we leave tomorrow, and if you, for some reason don't think you're going to be available, just make sure you touch base with myself between now and then and let me know what your thoughts are.

Thank you to the Agency staff who have worked very hard on this since the last PPDC, as well as to all of the panelists, and I also want to thank the committee at large. I think that was some of the most productive dialogue that we've had as a PPDC, frankly, over the years. It was great. Very well done. Thank you.

Okay, we're going to end the morning session with an update by Anne Lindsay on some of the most

compelling issues before us today at the Agency and OPP. Anne?

MS. LINDSAY: Okay. I'm going to start with endangered species, and there are really two areas that I want to focus on.

One is to give you just a very brief status report update on litigation and related consultation activity.

And, then, the second piece I've termed for myself, making systematic compliance with the Endangered Species Act -- A Way of Life in OPP, and sort of what we're doing under that broad title.

On the litigation/consultation front, there are three principal cases -- they're not the only cases, but they're, in my mind, sort of the big three.

The first was the plaintiff is Californians for Alternatives to Toxics, which we refer to as CATs. We don't actually have a dog case, we just have a CATs case.

This focused on plants, salmons, 19 active ingredients, forest operations -- sort of the Northern California -- not just Northern California -- largely California with a little bit in Oregon, if I'm

remembering correctly. That case has actually been settled with a Consent Decree in which the Agency agreed to make consultation decisions for the chemicals involved by certain dates.

And, so, for example, this last January we submitted a consultation package to the Fish and Wildlife Service that covered eight herbicides, 33 endangered plant species that would be found in forest operations. And, so, we're currently in consultation with the Fish and Wildlife Service around that package. And while I can't tell you all the details of it, it actually is going very well. We're very pleased with the progress and the level of interaction and the type of interaction we've having with the Forest Service -- I mean, the Fish and Wildlife Service.

And, then, the second of the consultation decisions that we'll be needing to make involves actually acrolein and, if I've got my dates right, we'll be making another consultation decision by the 18th of May. And, then, there will be some other decisions on out.

So, that case is not actively in litigation right now. Obviously, the decisions that we make around

consultation and how we, then, actually implement any recommendations from the Forest Service or National Marine Fisheries could, itself, at some future point, be subject to litigation, but the starting case is not in litigation at this point.

Washington Toxics Coalition is the second point of the second case, and this one is, actually, still an active case. What has happened is that we did get a court-ordered schedule last year in which the schedule specifies, it gives us a menu of 54 active ingredients, it specifies a number of chemicals and dates by which we need to make decisions, but it doesn't say specific chemicals by specific dates.

The species at issue in this case were salmonids. So, no plants, no other species -- basically, just salmon.

So far we have made decisions for approximately 20 active ingredients. I say approximately because when I count I'm never sure that I actually count right anymore. So, if you look on our website and you see 19 or 21, it's just a counting error on my part.

For eight of those -- just to give you sort of a

feel as to how those decisions are falling out -- we were able to look at the chemical and say for all the uses that are relevant to salmonids, there was no effect. When we make that kind of a call and decision, no consultation is actually required, and you can go to our website and actually see, if you want to go through in detail.

But for the others, there are a mixture of decisions, and have led to the need to submit consultation packages to National Marine Fisheries Service. We submitted only to them because these are salmon and under their jurisdiction rather than the Fish and Wildlife Service.

More decisions are actually due -- seven more -- by the 1st of August this year, and then there's a schedule that will take us on out over, I think, roughly over the next year-and-a-half, until we get the 54 done.

What we have done, in addition to making these individual consultation decisions and sending packages forward to Marine Fisheries, where it was appropriate, we've also put on our website a menu. So, for the next six-month period, you can look and see, here are the

chemicals from which we are likely to be working, and we have tried to describe the types of information that would be valuable for us to get in advance of our making the decision.

We're using all of the data that we've got in-house on the chemicals and on the species inasmuch as possible taking advantage of work that we've done and the re-registration process, but if anyone -- whether it's the registrant, it's the user community, public interest group -- has additional information they think is pertinent to the decision, this menu is designed to sort of help you see what's next on our plate.

We put the first menu up in December, and it runs until June. And, so, we'll be putting a refreshed menu up in early June, and that's a practice we intend to continue.

It's much like the work plans that we have for registration and for re-registration, but focused on these court-ordered deadline consultation decisions that we have to make right now.

The last case I want to mention -- and I have less to say about it at this point -- was one where the

plaintiff is Centers for Biological Diversity out of California; the species at issue is the red legged frog, which I learned was actually the Jumping Frog of Calavaris County, for those of you who are familiar with American literature -- and the number of chemicals involved we find a little bit hard to judge, because in various different documents that are filed, the plaintiffs have identified somewhere between 60 active ingredients to 200. And, so, it's not clear to us how this will actually focus down.

There is a new judge that has been assigned to the case, and at this point I'm uncertain as to the precise schedule this new judge has set, but both we and the plaintiffs have filed various documents, briefs, pleadings and so forth, so the next action would actually be with the court, and I would expect that to be sometime this summer, but don't actually have a clear understanding of the new judge's schedule. So, that's it for the sort of big three cases.

Let me talk just a little bit now about Making Compliance with Endangered Species Act a Way of Life. One of the background things that at least I initially

had trouble understanding -- and I think it's because I'm a regulator and that's what I've done all my adult life -- in the case of endangered species compliance we at EPA and the Office of Pesticide Programs, in particular, are kind of the regulatee. Every action that we take has to be in compliance with the Endangered Species Act, so it's a sort of mental role reversal.

To give you a size of the actions we're talking about, we've got roughly 19,000 registered pesticide products that contain one of maybe, roughly, 1,000 -- one or more of roughly 1,000 active ingredients, and a product could have a single use on its label or it could have hundreds of uses on its label. And, of course, most of you know that a, you know, apples are not grown in one part of the country, they're grown in multiple parts of the country; multiple growing conditions. So, this huge variety, just looking at the pesticide part of actions.

When you then -- and it's not static -- because, of course, new uses are being developed, submitted for approval, we're running our old chemical evaluation program, making changes and adjustments where's it appropriate. So, none of that pesticide part is static.

In addition, species are not static. The number of threatened and endangered species changes over time. Some of them, actually, like the bald eagle, come off the list. I think, unfortunately, they're not coming off the list of threatened and endangered species in large numbers, but the list grows.

So, you've got sort of two sources of action that don't hold still and are very large, very complex. They are both national in scope, but they have very local -- extremely local implications. So, it's -- and all of those are actions of EPA. So, we have a continuing obligation to make sure that all of those actions are always in compliance with the Endangered Species Act, or as close to that as is humanly possible to get.

So, one of the things we're doing is looking internally within OPP as to how we need to sort of retool our existing programs, and our plan is, basically, to use our registration program and our re-registration program as the main driver for compliance. And, underlying that, to use the basic risk assessment processes that we've developed over the years for ecological effects as the sort of fundamental compliance.

But that also means is that we're going back and looking at test methods, data requirements, risk characterization methodologies, as well as basic processes, and figuring out where we need to make changes.

We're going to be doing this in what I think of as an incremental way. So, I would anticipate that during the course of this fiscal year and certainly next fiscal year, you will start seeing us make some decisions where we're much more explicit about the status with our compliance about the Endangered Species Act, but I think it will take us, because it is a very large job, a substantial period of time to get the entire program and all of those actions that I described to you in a state of continuing compliance.

So, it's a very large task. And I will actually note, since the last discussion was, in part, about animal testing and ways to move away from traditional approaches, some of the studies that were actually being talked about in the acute studies, are actually critical to our endangered species analysis.

So, I think the questions about what do you use

them for are real pertinent, and we need to make sure that we know all of the uses to which we put that data and, as we move to alternatives, figuring out how we do that in a robust way.

Consultation. Because of the complexity and, I think, unique characteristics that pesticides present, we -- and both the Fish and Wildlife Service and National Marine Fisheries and USDA -- are engaged in very intensive discussions about how we might appropriately redesign the existing consultation process to adequately deal, I think, with the scope, the sort of dynamics, of the endangered species process as it applies to pesticides, and still make sure that we're actually doing the job right and that we are ending up with protections for the species with as minimal an impact on agriculture and other users as we possibly can.

We are, as I think everybody knows, therefore, looking at the counterpart rule-making process that's allowed for in the current Services Regulations governing the consultation process, and would expect later on this year to come out with a notice of proposed rule-making.

Then, finally, implementation. Once you make a

decision that you need to consult, once we receive a biological opinion from the services that said, yes, there is an issue here, you need to take some reasonable and prudent measures, you have to have a way to implement that in the field.

We put a notice out in the Federal Register in December last year with a comment period that closed at the beginning of March laying out our ideas. I'm not going to go through all the details of that, but one of the principal things was the concept of the bulletin. So, where you need to put risk mitigation measures in place to achieve protection, you would use bulletins, they would be enforceable, because they would be incorporated by reference on the label of pesticide products, and that would be a main mechanism for ensuring compliance with necessary risk mitigation measures.

It also talks about state roles, and I want to just mention that briefly. All along we've had a few states, such as California, probably most predominantly, but also Florida, Wisconsin, Minnesota -- doing things at a state level, and we're very much encouraging states, where they think it's an appropriate way for them to help

us ensure compliance, to develop state approaches since it's got very local implications.

And, so, for example, Washington State has been in to visit with us. They're actively in the process of developing a state approach to endangered species protection for pesticides.

So, that is kind of a capsule; we're trying to keep everybody as current as we can on a continuing basis by putting virtually everything we've got on our website. So, any consultation package that we put together you can sort of see there.

Do you want me to stop and see if there are questions or do you want me to go through the other topics?

MR. JONES: Why don't you go through the whole presentation.

MS. LINDSAY: Okay. Spray drift. You always ask about it and we don't have it on the agenda, so this time we put it on the agenda for an update and you probably don't want to hear. But, essentially, we're following the same basic approach that I outlined to you last time.

We have certainly heard over the years the need to really improve consistency and enforceability of spray drift product labeling, and I think we've heard it, especially from our state partners, that they're expending a huge amount of their resources around drift issues.

Our early attempt, obviously, engendered a lot of controversy, a lot of, frankly, opposing comments, and we're sort of still back on the drawing-board stage. We've been having a series of meetings at senior management level, working with our regional offices, as well as with our state partners, and we're looking at both approaches for interim -- what do we do right now -- as well as in the longer term. And I would expect later on, and not too much later on, you will see the Agency begin to roll some of our specific ideas out with regard to interim approaches.

We will also be putting into place that series of public meetings that I've promised you, where we will start engaging in the longer-term dialogue; we'll be looking to those meetings; to the comments we got on the original draft PR notice. Whatever it is we do with our

interim approach, the results of the interim approach, to develop a new draft proposal.

So, we have what I now think of as a relatively long trajectory to get to probably not even a final resting place, but improved approach to spray drift labeling. Our goal is really to be both able to provide applicators with very good guidance about what is expected of them but that is also practical and acknowledges the realities that drift is not something that you can control to a zero level, but we also want to make sure that in doing that we're not disabling our state partners where they need to take enforcement action where it's actually really appropriate to do so, and where we would probably, all of us, want that enforcement to be taking place.

Section 18. This is a topic in Section 18 reforms that we talked about most recently at the August PPDC meeting last year, and that Section 18 Federal Register notice has been signed this week and is actually on its way to the Federal Register. Unfortunately, I can't actually give you a precise publication date. There apparently is a long queue at the Federal Register,

and until they're actually, literally, ready to put it up, you can't get an answer other than that you're in queue. So, now I know what it feels like to be a registrant.

(Laughter.)

MS. LINDSAY: It's like, I kept going, come on, I've got to know what the date is, I've got to tell people. But I would expect it to be within the next 10 days or so.

This FR notice announces a couple of things. First of all, a limited pilot to test two of the improvements that we've talked about; a streamlined application process for states that will allow recertification of emergencies for eligible emergency requests in their second and third year -- eligible being reduced-risk pesticides where you can expect the emergency reasonably to continue longer than one year and it doesn't involve new chemicals, first food uses or chemicals under special review. So, it's a pretty narrow, pretty limited pilot of this recertification approach.

The second is a revised tiered approach for

1 documenting significant economic losses. That would be
2 open to only reduced-risk chemicals.
3 So, the two pieces focus on reduced risk.
4 We'll be looking to see how that works, both in
5 terms of reducing burden, I think, principally for states
6 but also to a certain extent the EPA, without in any way,
7 I think, limiting the availability to Debbie and her
8 staff of the information that they need to make right
9 decisions about emergency exemptions.
10 The other thing we're announcing in the FR
11 notice is not for implementation as part of the pilot,
12 but a series of questions around resistance management,
13 and whether and how resistance management might, for the
14 future, become a basis for requesting an emergency
15 exemption.
16 And, so, we're very much looking for robust
17 comments there to inform our future decision making
18 around that issue.
19 And, then, finally, this notice also announces
20 that we will actually be starting actual rule-making to
21 amend the existing Section 18 rules to take these changes
22 which we're piloting and inviting comment on and

eventually fold into our routine Section 18 program, informed by the results of the pilot and the discussion.

And, so, I think you would see us putting out a notice of proposed rule-making -- our current plans are very late 2003, maybe early 2004. So, that's it.

MR. JONES: Tom?

TOM: Yeah, I just had a quick question about the endangered species process. If there's a -- at the end of the consultation process a finding that a particular product poses an unacceptable risk to an endangered species, the bulletins -- are these county bulletins or product bulletins or species bulletins or all of the above or --

MS. LINDSAY: As we've talked about them, they're county bulletins but would try to give a user very specific information. You can see some of the sample voluntary bulletins that we've developed over the years, and one of the sets of questions that we actually asked in our December FR notice was, what's the process we ought to have to actually develop the bulletins to ensure that they're as accurate -- and also sort of tailored and refined as they can be -- and useful to

users?

One of the other things we're doing is that we have an agreement with USGS because they have a very specific mapping capability. And, so, nowadays we're using USGS to help us do the basic mapping. That's a vast improvement over our early program, where I think we were going to AAA or something to get maps.

Larry? I'm just going to go around the table, because I can't remember which one of you came first.

MR. ELWORTH: Just real quickly, the endangered species issues in spray drift, I think it would be useful to have an expanded discussion with PPDC -- or maybe they'll probably both be solved by the next PPDC, so you won't have to deal with them.

(Laughter.)

MR. ELWORTH: But I think those are ones where I think we have a real interest in discussion. And one other quick thing on ESA, I know that it feels as if you're regulated in this situation, but I think one possible way to look at it, in addition, is that under the spirit of counterpart regulations you're also a regulator -- maybe a co-regulator -- and I think, as we

discussed on methyl bromide, the expertise on the issue to make some of the decisions -- a lot of the decisions really rest with the OP or OPPTS to make some of those. So, I would hope you don't get regulated too much.

MS. LINDSAY: Well, we're working on the partnership and I actually think we have sort of both of those roles. It's not a one or the other.

Jose?

JOSE: And, also, in spray drift do you have a feeling -- I guess complaints about spray drift don't come to you, they go to the state agency?

MS. LINDSAY: Generally.

JOSE: They make it so survey of anything of where we are on complaints because in South Texas, at least, we've seen a drastic reduction of the airplane and we, you know, we are only one or maybe two operators.

MS. LINDSAY: SFIREG over the years has actually done some surveys and one of the things that --

JOSE: Who has?

MS. EDWARDS: SPIREG -- that's an acronym for the state group that we work with. State and Federal Issuers, Research and Evaluation Group is what it stands

for. And --

JOSE: You know the acronyms -- I can't keep up with all the acronyms.

MS. EDWARDS: Anyway, they have -- the states have actually done a survey, at least twice now, to sort of try to get a fix on drift complaints, and one of the things that we're thinking about as part of our sort of roll-out on spray drift is how we can either update that survey or, otherwise, with our state partners, bring in more information from the field as to how labeling and other activities are currently working to address drift issues, and whether, in fact, you are seeing a decline. I have heard that about Texas. I don't think that I've heard that that's generally true nationally.

JOSE: Does anyone in the room have a feeling whether this is less of a problem, the same problem or more or a problem? Our spray draft issue has really quieted down a lot. At least that's my feeling.

MS. LINDSAY: Our state regulator is shaking his head. He's from Vermont, so he's often very silent, but he's giving me --

(Laughter.)

MS. LINDSAY: He's saying, no, I think, as I said. There may be things going on in Texas that we need to take a look at that may actually inform.

UNIDENTIFIED MALE: I think as the egg urban interface gets more and more complicated, drift issues -- I agree the plane is probably going away, but there's an awful lot of drift that's not associated with the plane.

JOSE: I would suggest that we do what Larry suggested, that we have a session on spray drift, because I think there's something important that we need to look into.

MS. LINDSAY: There will be a time, I think, tomorrow where Jim sort of helps focus on what should be the next topics so that's good.

Steve?

MR. KELLNER: Just a quick question. With respect to the spray drift PR notice, did you say that you've gotten to that or that's on a track that you will get to it?

MS. LINDSAY: We will be putting out another draft PR notice, or most likely a PR notice, around spray drift. I didn't give you a specific date for when that

draft would be, because there are a lot of pre-steps, including having a series of public, either workshops or other events, where we can take input. So, I very carefully didn't actually give you a specific time frame.

MR. KELLNER: Thank you.

MS. LINDSAY: Julie?

JULIE: Regarding the Section 18, the pilot program. I guess with this are you going to be soliciting comments on the program as a whole? And then, secondly, as far as the pilot program, kind of what is the objective of the pilot program? Is it to kind of examine the criteria for eligibility for this renewal process or is it to look at the process itself, to say that this is an appropriate process that then could apply to additional products outside that criteria?

So, kind of what are you looking for in the pilot?

MS. LINDSAY: Well, your first question, the FR notice really solicits comments on the two things that we're piloting and the future idea, although I don't think just because we tell people what we'd like them to comment on, that's stopped anybody ever from offering

other suggestions.

Your second question, I think -- and Debbie may actually want to supplement this because she actually is responsible for the Section 18 program. We're really looking at examining whether the process changes that we've thought of and are piloting here are going to work well and give us the results that we think. I think it's less so whether it should be, say, confined only to reduced-risk pesticides. But just how does this process work?

MS. LINDSAY: Yeah, I mean, I think that's right. Actually, there aren't a large number of chemicals right now involved in the process, just because of the way we've set it up, but we do hope to be able to just examine whether, for example, it meets the goals of the states that originally made this proposal for it to be kind of a streamlined way of evaluating Section 18s without, you know, compromising our need to make the safety findings, and so forth.

MS. EDWARDS: Gary?

GARY: For those of us who had a golf tournament last week, this is the young men corner right here. But

mine's a follow-up question on Section 18, and is there anything in the FR notice that's going to address the issue of the states looking more closely at the alternatives that are already out there and then the Federal government coming in and checking the states to see they've actually done an analysis or, really, is there really an emergency exemption or are there really alternatives?

I'm always -- we talked last time about the biological aspects sometimes are not looked at as alternatives.

MS. EDWARDS: You need to keep in mind the genesis of these ideas for reform came, actually, from a set of meetings and interactions without state partners, actually, back in 1996 is my recollection, and some of those are actually even older than that.

So, this FR notice focuses on sort of the remaining three areas where the states had proposed to us opportunities for change that they thought would help streamline the program or make it more responsive and, in some ways, perhaps more environmentally sound -- there I'm thinking about the resistance management.

The sets of recommendations that we got from the states for possible change, as I recollect, didn't explicitly address the alternatives question. So, this FR notice is not directed at that, although, obviously, the proposal or the set of ideas around resistance management will also raise questions about alternatives and availability of alternatives.

Win?

WIN: A question about the endangered species program. Many states have their own lists of endangered species that don't exactly coordinate with the Federal list. Is this strictly a Federal endangered species list that you're going to be working with and will it also include threatened species as well, as far as the county bulletins are concerned?

And then I have a question about the bulletins and the maps, specifically. I can relate back 15 or more years ago and thinking about the stacks of maps that I've had and the bulletins, and one of the criticisms, at that time, was that many of these were not very accurate; that is, the maps. And there was a reason for that -- at least what I was told. In that situation, people were

quite concerned about making the maps too accurate about the concern of collectors coming in. That was a real issue, particularly plant collectors, but it could have also been reptiles and a few other things, but the issue of plant collection.

How do you kind of resolve some of that in terms of the accuracy of the maps in relating to the concern that people might start harvesting those plants or animals?

MS. LINDSAY: Well, part of it is we're actually, like I said, taking advantage of USGS' basic mapping capabilities, which I think is a big step ahead. We're also looking at various different ways to access other sources of information about location of species to make sure that we've got very accurate information, and we need that not just for the bulletins, frankly, but for doing refined risk assessments. And there are, actually, some sources out there of good information about species location that, I think, we'll be able to tap into through one mechanism or another. And we've actually been having a series of discussions with pesticide registrants about ways to tap into that location information.

I think, though, in any given case, when we're probably going to -- just like every other aspect of this program seems to have a real local focus -- when you get down to brass tacks, around a particular use of a particular pesticide in a particular species, we may need to be working very closely with state officials, extension growers, local public interest groups to come up with something that works.

Wisconsin, for instance, has put into place land owner agreements, because that seemed to work well in Wisconsin with some particular plants, so you don't actually reveal the location but you've got a legally solid land owner agreement that serves to ensure protection.

So, I think there's going to be a variety of mechanisms that we're going to have to explore and many of them will be extremely local in order to make them work.

And, then, your other question was, we're really talking about the Federally listed, threatened and endangered species; although, obviously, if states have other species of their own that they've identified, I'm

sure that there will be opportunities over time to sort of piggyback on each other's efforts.

John?

JOHN: Yes, I wanted to make a few comments regarding spray drift. Air quality is a new area that's been given as a charge to NRCS and under the new Farm Bill perhaps an area of more emphasis than in the past, and, so, therefore, there are now funding opportunities for producers who want to address drift issues on some of the conservation programs like the Conversation Security Program and the EQIP, the Environmental Quality Incentive Program.

And, at the same time, on the technical side, NRCS is adapting some models of drift and vaporization risk and incorporating them into computer-aided decision tools that our professionals can use. So, coming together both the incentive, the funds and also the technical ability to actually define the risk in a particular area and identify where they could best be used, I think these are some good opportunities to deal with drift risk at this time.

MS. LINDSAY: Those are good suggestions.

Aaron?

AARON: I had a question about EPA's interim approach on spray drift pending more generalized guidance through draft PR notice or other mechanisms. And is EPA going to make a case-by-case determination on new spray drift label language for pesticides through new re registration or registration?

And, in particular, I'm thinking about azinphos methyl and fosmet. I had understood that there was new drift language in the works for those two pesticides and maybe for methamidophos, also. And, if so, has new label language been finalized on drift for those pesticides or is that pending a more generalized guidance?

MS. LINDSAY: It's not been finalized and I know you know but we're basically a licensing program. So, every decision that we make on a product and every product label is a case-by-case decision and we're going to have to look at the specifics of the particular product, which includes both the risk presented by the product as well as other key features that would impact the labeling.

Having said that, we're also, as part of our

interim process, looking at how do you have some generic language that would work for the interim as well as when it's needed for a pesticide that may pose a greater risk, risk-based measures that would go on a label that are really important to follow in order to keep risk at an acceptable level?

But the decisions for the particular pesticides that you have mentioned we've not yet made, but I hope that we'll be doing that in the near future.

AARON: Thanks very much. I had a question also about the endangered species issues. And in 1989 EPA stated in the ESPP that it was treating LOC exceedences as may affect findings, and you stated earlier that EPA is taking registration and re-registration as the main driver for ESA compliance right now. Given that, will EPA -- if EPA makes a conclusion that an LOC has been exceeded for a particular environmental endpoint or an endangered species, will that trigger consultation or is there some other trigger that the agency is relying on?

MS. LINDSAY: You know, I didn't actually read our '89 document before I got here. So, my memory might be faulty, but I didn't actually think we had ever said

that sort of exceeding the LOC, by itself, automatically moved to a may-effect finding. I thought that what we've always tried to say very carefully is that's a trigger that means we need to start refining our risk assessment to see whether or not that is actually the case, because you've got to bring -- you can bring to bear, usually in any given case, quite a bit of very specific, usually exposure information, that refines your risk assessment and tells you whether you've got a problem or not.

So, that's certainly what we're doing currently and that's certainly what I would imagine we would be doing for the future in our registration and re-registration programs.

AARON: Thanks.

MS. LINDSAY: Okay.

UNIDENTIFIED MALE: Yeah, I had a question about Section 18 reforms and I wonder if the proposed rules allow any flexibility for alternate pest control considerations or tactics as part of IPM programs, and the reason I'm asking the question is that in our RF4 program we work a lot with minor crops and there are very few, generally, only two or three, pest control tools

available for any particular option. And if resistance is a key issue, a lot of these newer products are very site-specific, and if you're looking at, say, disease control over a multi-seasonal program where you're putting on maybe six to eight sprays and some of the registrants are recognizing that, you know, resistance management is very key, and only wanting to put on, say, two or three applications during the season, is there some opportunity to look at maybe combinations of various chemicals, and even biological materials, as an add-on to Gary's, as part of, you know, a resistance management program?

MS. LINDSAY: Debbie, do you want to talk about that?

MS. EDWARDS: Well, it was my understanding that the -- first of all, the pilot does not include resistance management aspects to it at this time. It's principally the certification for three years plus the tiered system for economic impact.

The FR notice does, though, solicit comment on resistance management, but I think what the original proposal was that if it can be shown that resistance is

beginning to develop, although it has not yet caused an economic impact, that would be a potential candidate, you know, in this program, which may or may not include the kinds of things you're talking about because I'm not sure you're talking about where resistance has actually started to develop, if I understand it right.

But, anyway, that would be an area that actually we're hoping to get a lot of comment on because one of the things we need to understand better is how -- what are good criteria for determining when resistance is beginning to develop without it actually having had an impact on the economics of the product.

MS. LINDSAY: Patti?

PATTI: I don't know if this is relevant to Section 18, but I'm wondering is there going to be some trigger in there if there are management conditions that would take care of this problem? And I realize, from an agricultural standpoint, that sometimes making those management changes can take several years before you see the results, but will there be anything in the Section 18 streamline process to say, gosh, if there are management practices, are they going to be required to institute

those or will there be some cut-off where we say, well, three or four years down the road, we can't continue to issue the Section 18, because if you had done some management practices you could change that?

MS. LINDSAY: This particular notice doesn't get at those sets of issues.

MR. JONES: I'd say that -- and this is sort of Gary's special, too -- that we're always looking at are alternative practices available that could present an emergency, whether they are bio-pesticides or management practices, and that's included in our current evaluation for a Section 18.

To the extent that there are individuals or groups who sort of want to sort of sit down and talk with us about the robustness of how we do that, we'd be happy to have that dialogue at any time.

MS. LINDSAY: Phil?

PHIL: Can you tell us what the 15 species are on your priority list and what percent of the Federal list is that?

MS. LINDSAY: Are you talking back about -- actually, I'm not capable of that.

PHIL: Is that on your web page?

MS. EDWARDS: I don't think the 15 are, but I'll follow up.

PHIL: Can you get us a hand-out, then, because if we're going to comment on that, it would be kind of nice to know what those 15 species are.

Do you have any idea what percent of the Federal list that is?

MS. LINDSAY: The Federal list is relatively long, I believe.

PHIL: I was thinking it was several hundred or so.

MS. LINDSAY: Yeah, yeah. But it's not a large number.

PHIL: This goal, then, is kind of a real subset of the goal of the endangered species program?

MS. LINDSAY: Right.

MR. JONES: Okay, very good. I know that was a very rich, as Marcia would say, list of topics there for us to chew on on the update mode. And I think we got some good feedback about future considerations as more broadly.

Why don't we get back from lunch at 1:30, which gives us, according to my watch, an hour and seven minutes, but that ought to be enough time for all of us. Thanks.

(A luncheon recess was taken.)

AFTERNOON SESSION

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MR. JONES: Maybe an hour and seven minutes wasn't enough. On a day like today, it's hard to give people enough time for lunch.

All right. Why don't we get started. I know that we do not have everyone here yet, but we've got a lot in front of us and I really want to use our time wisely.

We're going to start the afternoon with another series of topics, and in the middle of the afternoon we're going to spend about two hours on a program area where we're bringing some early thinking to the PPDC on registration review to get your advice both on substance and process issues. Hopefully that will be a very meaningful dialogue for all of you, but more importantly, frankly, for us, as we're seeking a path forward in this program.

And, then, we'll end the day with a session on some follow-up to some earlier PPDC meetings. And we have a half an hour at the very end of the day for public comments. Again, a reminder to those of you in the

audience, if you want to make any comments, we have this time set from 4:45 to 5:15, and just let Margie Fehrenbach, our designated Federal official, let her know if you've got any public comments. And, so, we'll plan accordingly, based on the number of you who let her know you've got comments.

So, that being said, let's get right into the afternoon's agenda. Bill Jordan, do you want to give us a couple of updates?

MR. JORDAN: First update deals with human studies, and you should have no conclusions about the fact that it comes right after the discussion of alternative testing.

(Laughter.)

MR. JORDAN: I have really three fairly short points to make about what's going on here. In earlier sessions of the PPDC, I've reviewed and other folks have reviewed where EPA is with regard to its approach while the National Academy of Sciences looking at the ethical and scientific issues relating to third-party intentional dosing studies. And that approach is not changed.

So, the three quick updates are, first, the

National Academy of Sciences has finished the public phase of its work on the contract and will develop a report giving EPA advice or recommendations on how to address the ethical and scientific issues concerned with considering using third-part intentional dosing studies in EPA's regulatory decisions. They had three public meetings, the last of which was this past month, in March, and they have now entered into their deliberation and their report-writing phase.

Based on the conversations I've had with the academy staff and committee members, it looks very likely that they will deliver a final report to EPA on the schedule called for in the contract, which is in December of this year.

The second update is just to bring those of you who are not aware of it up to speed on the litigation that involves EPA's December 2001 press release. As most of you, I think, are aware, the CropLife America and two pesticide companies sued EPA saying that the press release by a regulation that had been improperly issued and, then, the Government engaged in all of the things that happen when such a lawsuit occurs, culminating in

1 oral argument, on St. Patrick's Day. Again, you should
2 draw no conclusions from the date or the timing here.
3 But the oral argument took place and that is the
4 last event in the case, as far as we are concerned, until
5 the judges issue their ruling in this matter. Although
6 there were representatives from the Government side, from
7 all of the interveners, the parties present and everybody
8 is quick to offer an opinion about what the oral argument
9 meant or when things might happen. I'm not going to do
10 that. I've been cautioned that it's always dangerous to
11 predict either what the court will rule or when they will
12 rule. So, if you want to ask other folks, you can talk
13 to any one of the number of people who are here today who
14 were also at the oral argument.
15 The third thing has to do with a point mentioned
16 during the oral argument by the Government's attorney,
17 and that is, during the arguments we said that EPA was
18 working on an advanced notice of proposed rule-making
19 relating to the subject of human research. And, indeed,
20 we are working on that and are very close to the finish
21 line in terms of getting it published.
22 The administrator has indicated that she will

sign the advanced notice as soon as it is presented to her, we're moving ahead to get that to her since we've cleared all of the internal steps with regard to EPA and OMB and other agencies, and hope to see that notice published sometime next month.

That notice will invite stakeholders and members of the public to comment on a large range of issues that are related to the human studies subject. We are hoping that you will look, if you're interested in it, you will look carefully at the kinds of questions that we've posed and try to think carefully about them and provide us a thoughtful, integrated response that takes into account the different sorts of ways in which this issue has arisen and angles on it, like does it matter what the purpose of the test is? Does it matter who sponsored it, and so forth?

So, look at the advanced notice of proposed rule-making, you'll have a generous period of time in which to think about it and perhaps your comments and send them in to the agency. We'll expect to use the comments that we get from the public as well as the materials that we get from the National Academy of

Sciences to develop our approach toward a more enduring way of handling these third-part intentional dosing studies.

Jim, shall I go on to the next subject?

MR. JONES: Yeah, why don't you take them both on.

MR. JORDAN: The other topic that I wanted to talk about today is the intradisrupter screening program, and particularly a Federal Register notice that EPA issued for public comment recently relating to criteria for selecting chemicals that would be among the first group of substances to be tested in this screening program.

But in order to make some sense out of that, I think I need to start back at the beginning, since we have not used this form, in particular, to let folks get up to speed on the intradent (phonetic) program.

I'll only do briefly and in a somewhat overview fashion, because of time considerations, and also because I'm not really the expert on this subject area.

But, in 1996, the Food Quality Protection Act amendments added to the Food, Drug and Cosmetic Act a

provision requiring EPA to develop a screening program for pesticide chemicals, to evaluate their potential for causing effects on humans that would be similar to the effects caused by estrogen.

Another amendment was added to the Safe Drinking Water Act in the same year that was, basically, of a similar thrust. And it is out of those amendments that EPA has been working to develop an endocrine disrupter screening program.

An endocrine disrupter is a chemical or some other substance or agent that interferes with any of the various processes related to the natural hormones in the body, not just in humans, but we're also concerned about other organisms. And these hormones are the ones that are really responsible for the maintenance of the reproductive, development, a lot of behavior effects and, basically, the whole balance within the human or other organism's system.

Part of our program is related to research. Our Office of Research and Development is responsible for that. They are doing a lot of very basic scientific work that is related to helping to understand the science and

the mechanisms of actions relating to endocrine disruption and to development of measurement methods in risk assessment models that would allow us to use data to get a handle on just exactly what kind of risks, if any, different substances might present.

The other part that is housed here in OPPTS is the screening and testing program. And at this stage we are developing a battery of tests that will be designed to serve as a screen for chemical substances and, then, if those substances, when tested, produce positive results, then there will be another group of tests that will help us identify exactly what the risks might be and give us the quantitative information that would lead us to have the capacity to do risk assessments.

The Office of Science Coordination and Policy, our sister office, is the leader on the development of the screening battery, and they have been working, first, with an advisory committee called EDSTAC, that's another one of the Washington acronyms, Endocrine Disrupter Screening and Testing Advisory Committee.

They gave us the basic blueprint for how we ought to approach the work. We issued a proposed policy

statement in December of '98 that summarizes not only the EDSTAC's recommendations but also EPA's plans with regard moving ahead on implementing them.

We're, basically, conceiving of a two-tiered system, as I suggested. Tier one system, which would be invitro and invitro short-term tests that would be used to identify chemicals that have the potential, based on their mechanisms, to interact with either estrogen, androgen or the thyroid systems. And, then, chemicals that are positive in this tier one group would then go on to testing in the tier two, which would consist of multi-generation tests in mammals, birds, fish, amphibians, perhaps other organisms, as well.

Faced in the Food Quality Protection Act amendments, a schedule for developing a program, and we believe that we have met that schedule and statutory deadlines, but I will note that Natural Resources defense counsel did not agree that EPA had done what it needed to do and sued us. We resolved that lawsuit through entering into a settlement agreement within our NRDC in which we promised to use our best efforts to move ahead and meet additional milestones beyond those contained in

the statute, including developing a list of chemicals that would go through the testing and to issue validated tests that would be applied in the Tier One group.

We have been working away diligently on both of those enterprises, and with regard to assay development, we're currently focusing in our nine different tests; they are going through a validation process using the ICCVAM principles, and we are working closely with an advisory committee under NACEP, which is another one of those acronyms, and I'm not sure what all of it stands for, but it's part of the outgrowth of the NAFTA Treaty, and it's the Endocrine Disrupter Methods Validation Subcommittee, and that is a group that is giving us scientific advice on our whole validation effort.

Validation of these methods is proceeding somewhat more slowly than we had hoped, and we've been outlining the difficulties that we've had in that, but it is still, nonetheless, making headway and we hope to be in a position to put those studies out as part of Tier One starting sometime next year.

The other thing that we have been doing, and this is circling back around to the item on the agenda,

is that we have developed a Federal Register notice in which we identify criteria for picking the first group of chemicals to go through the testing program in Tier One. And that notice was out for public comment, we received a fairly sizable number of comments, and, most importantly, a lot of very substantive comments from a diverse array of stakeholders, people who have commented come from across the spectrum.

We will be looking at those comments and our aim is, at least for time being, to make something available toward the end of this year in terms of revised criteria and a list, but we're also trying to be mindful of the need to coordinate the list issuance with the validation efforts. So, our schedule is still something that we're thinking about and trying to make the most appropriate choices how to handle our schedule.

The word about what we put in the Federal Register notice, obviously it speaks for itself, it's available on our website if you'd like to look at it. But the main thing is that we had, at least back in 1998, thought that we would be able to use various techniques to identify chemicals that looked like they were more

likely to be endocrine disrupters than other chemicals.

There were a variety of very short-term screening approaches that folks had suggested we use, there were other things that were based on structure activity relationships and analyses that we could use. When we worked through those, we discovered that really it wasn't as reliable as we felt we would like. And, so, the Federal Register notice we put forward emphasizes selecting the first group of chemicals using exposure as the primary discriminator in setting our priorities.

We've looked at cross, both active ingredients and inert ingredients, consistent with the FQPA mandate to look at pesticide chemicals, and identified various databases that we would refer to with regard to trying to get a rough handle on relative potential for exposure -- databases that would, for example, relate to pesticide residues in food or residues in water and that sort of thing.

We will, obviously, be focusing on active ingredients and inert ingredients, there's no precise number that we've picked for either category, but we do think it's important to have a balance of chemicals from

both groups, and we are looking to have somewhere between 50 and 100 for the first group of chemicals to go through the test.

Once we get the test results from the first group of chemicals, then the next stage will be to look at it and try to make some sense of it. Following the recommendations from the SAP, we are planning at this point to go back to the SAP, show them the results, tell them what we think they indicate, and, then, sort of use that opportunity to readjust and improve upon our approach, both with regard to the tests and perhaps things like selection criteria for chemical testing.

So, that's a quick overview of the endocrine program as well. Time for questions or comments.

UNIDENTIFIED MALE: Yes, thank you for that overview. My question, in terms of outcomes of these tests, are we looking to develop categories like we have for fossil carcinogens like from confirmed, probably, possible, unlikely, as an outcome of this process? And, if so, what would the likely decision or what would happen if you have a case where a confirmed endocrine disrupter was in use?

MR. JORDAN: Well, I think the process that I've described includes screening but then Tier Two kind of testing to give us a more empirical basis to do risk assessment.

I'm really sort of technically not able to answer the question other than to say it's my understanding that as we're going through this process developing risk assessment principles will be a big part of the work, and whether that leads us down the road of having categories or not, I don't know.

UNIDENTIFIED MALE: Thanks, that's really helpful to hear the endocrine disrupted issue brought to this forum since FQPA specifically identifies pesticide chemicals as being a primary target for this program.

And I'll phrase this point in terms of future issues for this committee to look at substantively, but I think there are a number of technical and policy issues that this group would benefit from a more in-depth discussion, looking at the composition of Tier Two, the fact that it is, as you pointed out, a multi-genre pro-study to look at human health effects, and the fact that every single pesticide active ingredient on the market

has already gone through exactly that study. So, whether there is value-added and how OPP would go about using the different tests and the different pieces of the endocrine tool box for different types of pesticide chemicals, I think that would be a useful discussion to have down the road.

MR. JONES: Yeah, I think one of the principles I had mentioned earlier about where there were other fora for dialogue around a topic, we would generally shy away from it, and that has been true from endocrine disrupters when we had this other advisory committee, the EDSTAC.

We are beginning to go, however, in this area to move from test design and starting to get into implementation. And, so, I think it's becoming more appropriate as we move from the test design into the implementation for a committee such as this to be potentially available for that kind of dialogue. So, I think that we're not likely to say we won't talk about it here because there's another place where it can be discussed because implementation is upon us. I think we'll sort of listen to the full committee and get their advice tomorrow and discuss the topic that we'd all like

to tackle a little bit.

MR. VROOM: Bill, one of the things that has been at the centerpiece of the clinical testing debate now, for whatever it's been, six years or so, is the component of ethics considerations, and I wonder if you could comment just briefly on how the management of the ethics issue has evolved not only within OPP but across various offices and is it or is it not being coordinated centrally within the Agency and, then, more broadly back to the sort of common rule across the Federal Government. How are these dots being connected or not and, you know, what trends do we see?

MR. JORDAN: Well, first of all, let me just start with a little background information for you folks that may not be as conversant in the terminology.

Mr. Vroom mentioned the common rule, and the common rule is a set of regulations that has been adopted by 17 departments and agencies of the Federal Government to govern the testing that the Federal Government conducts for sponsors, and it is designed specifically to provide protections for human research subjects who participate in the testing that the Government is either

doing or getting someone else to do.

The common rule has a lot of important procedural protections that are designed to happen before anybody starts testing to make sure that it is done in a way that is ethical and respectful of the participants in the program.

EPA has a central office in the Office of Research and Development that oversees EPA's compliance with the common rule for studies that EPA is conducting or sponsoring. And we actually do carry out -- I won't say a lot -- but a real noticeable number of studies that do involve human subjects. And that is a very valuable source of insight and understanding into ethical issues that involve human subjects. And that is something that every part of EPA works with to make sure that, whether we in the Pesticide Office or the Air Office or the Water Program, are aware of and making sure that we're following the standards that EPA has implemented in the common rule.

The question of what happens after a study's been done and it's not done by a Federal agency or sponsored by Federal agencies, one that, frankly, the

last six years have led EPA to pay more attention to -- and I think in a way that's actually fairly constructive -- the December 2001 press release represents one response and we were trying to -- not everybody, necessarily, is thrilled about that response, but we're trying to maintain a level of consistency across the Agency with regard to that.

There are other studies, frankly, that come to our attention that are not in what we call the "no fly zone," as described by the 2001, and we are paying more attention to the ethical issues that arise to that.

I will tell you that the experience across the Agency in the past has been uneven, maybe even within a particular AA shift, different times we've done different things.

What's happening in my estimation is that we're paying more attention to the basic principles of informed consent, voluntary participation and looking a little more closely at the studies as they come forward to us.

I don't think there's, you know, any set of principles that I could talk to beyond that, but I do think that it has shifted and we are paying more

attention to those things and trying to do so in a way that works across the entire Agency.

MR. STICKLE: First of all, I wanted to commend you, Bill, for your consideration of the real need to coordinate the list development, on one hand, with the development of the testing methodology on the other.

I think the last thing we need to have is a prolonged period between those two in which you lead to blacklisting of products and product de-selection and an adverse impact on the marketplace. So, doing those around the same time we think would make a lot of sense.

There's another provision in the Food, Drug and Cosmetic Act that provides for avoiding duplication of testing and developing cost sharing and, then, also developing protection for CVI -- all in one way or another leading to some kind of plan for data compensation for the data generated under the Endocrine Plan. And we hope that the Agency can work toward the development of that issue, just as they are in the area of inerts, so that by the time we get to the testing, in perhaps the spring of 2005 or whatever that date is, we also have a mechanism in hand to address the compensation

for that possible testing.

And, lastly, an issue that is as large and I think as important as Endocrine touches a lot of other parts of the Agency. It obviously has an impact on the data quality provisions, it has an impact on inerts, it has an impact on tolerance reassessment and, then, the tolerance reassessment of inerts. And I wondered if you might be able to comment on the potential coordination between various segments of the Agency on this particular issue?

MR. JORDAN: We are working closely with our colleagues in the Office of Research and Development on the research agenda; we're working with our colleagues in the Office of Water with regard to provisions of the Safety in Drinking Water Act.

The responsibilities for inert ingredients also overlap with what our colleagues in the Offices of Pollution Prevention and Toxics are doing in their HPV Program, High Production Volume Chemicals, and we're, basically, trying to make sure that we're all on the same page with regard to data needs and avoiding duplicative testing and so forth.

I believe we are going to proceed with the data that we have at hand, when we do our reassessments for inert ingredients for tolerance purposes. If we have data on endocrine disruptives, we'll use that; if we don't, we'll go ahead with what data exists and make a judgment about the safety standard in the Drug and Cosmetic Act.

With regard to your points about data compensation, yes, we are working on those; we'll try to have -- not only try to have -- we intend to have a system in place that deals with those issues.

MR. JONES: Carol?

CAROL: With regard to the human testing process, Bill, I was wondering if you could comment on what the scope of the NIS' report is going to be? Will it encompass ethical issues as well as scientific issues?

MR. JORDAN: Yes, it will.

MR. JONES: Okay. Margaret?

MARGARET: Good afternoon. I have two topics -- two updates to give you today. One is on the cancer -- Agency Cancer Risk Assessment Guidelines -- and an update on recent refinements in our drinking water risk

assessment approaches.

So, first, on the Cancer Risk Assessment Guidelines. If you don't know this already, in the cancer risk assessment world of EPA, two documents were published for comments recently. First was the draft final Guidelines for Carcinogen Risk Assessment. Several versions of this document have been through the public comment and several SAB reviews.

The second document, Supplemental Guidance for Assessing Cancer Accessibility from Early Life Exposure to Carcinogens, is a new document. It was developed in response to public comment and SAB reviews.

The next slide just gives you a short history of Cancer Risk Assessment Guidelines. And it was interesting for me to find out that even before 1986 we used guidance that was developed in 1976 specifically by the Office of Pesticides programs, and that particular guidance then was applied across the Agency.

In 1986, the Agency published the Guidelines for Carcinogenic Risk Assessment and you may be familiar with the alpha-numeric characterization -- A Carcinogens, B through C, D, and E.

In 1996, proposed Guidelines for Cancer Risk Assessment, there was a change. The alpha-numeric characterization was changed to hazard descriptors. An Office of Pesticides program, at that time, started using this particular way of characterizing cancer potential.

The draft Revised Guidelines for Cancer Assessment were published in 1999 after several SAB reviews. The hazard descriptors were changed, at that time, to carcinogenic defamation likely to be carcinogenic to humans, suggested evidence of carcinogenic potential, inadequate information to access carcinogenic potential and not likely to be carcinogenic to humans.

Again, that '99 version of the Guidelines were through public comment and SAB reviews, and the version that has been just issued recently, for comment, has a slight modification that may be of interest to you. There is a possibility of applying a combination of descriptors. For example, carcinogenic via inhalation; not carcinogenic via oral route; likely to be carcinogenic at high doses; not likely to be carcinogenic at low doses.

The 1999 version of the Guidelines is an interim and is the document that we use in conducting our cancer risk assessments right now.

I will just briefly describe to you the second document that was published for comment. That's the Supplemental Guidance Accessing Cancer Risk from Childhood Exposure. In the document, EPA describes the methods that we propose to use to access cancer risks from early-in-life exposures.

The document summarizes EPA analysis of results of cancer studies that investigated early life exposure. The document addresses cancers that manifest themselves in childhood and cancers that result from exposure during childhood.

And this is just a very brief summary of what the Agency is proposing. Four neutagenic (phonetic) carcinogenic where the Agency is using linear extrapolation to calculate risk. The Agency is proposing in the document that there would be a 10X adjustment factor used for exposure from zero to two years; a 3X adjustment for exposure between two and 15 years old; and a 1X for exposure over 15 years old -- for individuals

over 15 years old.

For non-neutragenic carcinogens, where we do not understand mode of action and, therefore, use linear extrapolation, the Agency proposes no additional adjustment be applied.

And for the non-neutragenic carcinogens where we understand the mode of action, we will do a nonlinear risk assessment and, based on the mode of action, make judgments about how the risk to children should be addressed.

Our next steps. We recently extended the common period to June 2, but note that the SAB, SAP and that Children's Health Protection Advisory Committee will meet May 12 through 14 to review, specifically, the Supplemental Children's Guidance.

If you can submit comments to the SAB shortly, they will be addressed and covered during those meetings. However, if you submit them following the meeting, the Agency and SAB will still consider them.

The goal is to publish the final Guidelines by the end of 2003. And, in the meantime, you will continue to use the 1999 Interim Guidelines.

So, before I move to what we are doing about drinking water risk assessment, I can answer some questions about the process, but the details.

UNIDENTIFIED MALE: Could you give us an example on the childhood supplemental proposal on how it might impact a specific pesticide label or maybe a couple of things -- maybe stepping stones on such a pathway for risk assessment that will result in a label change or a modification?

MARGARET: I think the changes that I describe really have more to do with the way that you would calculate the risk, so you would, perhaps -- perhaps there is a pesticide in a very small group of neutragens, so the way that you would calculate the risk would be different than we are calculating right now, because we don't have those adjustment factors. I don't know, and I don't know that we have discussed, whether there would be any impacts on the labeling. The discussion in the document is really about how do you calculate the risk.

UNIDENTIFIED MALE: So, it would sort of feed into the larger determination of whether a pesticide compound in its aggregate chronic risk equation meets or

exceeds the one in a million requirement that EPA established, but it also may, ultimately, have, you know, other fine tuning kinds of impacts on a pesticide's label uses if there are determined to be these differential kinds of cancer risk factors for childhood exposures.

MARGARET: No, I didn't say that.

MR. JONES: There are a relatively small number of pesticides that I think we've determined to be neutragenic, in the first place. So, you're talking about a relatively narrow universe that we would, if we adopt these guidelines as they're written now, would change the calculated number.

Now, if right now they're 1X7-6 or have less risk, they could, potentially, fall into the category of having more than 1X10-6, which would, then, potentially, lead to a change in the label of that product.

But I think that right now we think there is a relatively small number of pesticides that are neutragenic and that would be affected by this, but they would have their risk calculated differently if we were to adopt this.

UNIDENTIFIED MALE: Thanks.

MARGARET: Okay. Now, update on the refinements in Drinking Water Assessment. Many of you are familiar with the work that we have done in OP Cumulative Risk Assessment to refine drinking water risk assessment approaches. And we learned a lot during that time and decided that what we really needed to do as a next step is to apply some of that learning to the way that we conduct individual pesticide risk assessments for drinking water.

So, what we are doing now, we're still working in the tiered approach to drinking water risk assessment, but we are using model values for surface water residues and those are directly incorporated into the probabilistic acute food assessment.

The model values are applied to drinking water consumed directly or used in cooking, as reported in the Consumer Survey of Food Intake. And these methods were an effort of many divisions in the Office of Pesticide Programs, working together.

When do we use these methods? In our tiered scheme, when acute risk assessment for food alone is below a level of concern and when a conservative use of a

single high-end value, when considered with the food, exceeds level of concern. That's the time we would use the refinement.

What are the benefits? The refined risk assessment represents a more realistic range of surface water residues rather than a single high-end residue concentration. The range reflects seasonality of uses, duration of exposure, multiple peaks versus sustained pulse. The range is based on actual body weights and water consumption in CSFII, and the second tier provides additional information for the risk manager, so, to help them conduct risk management analysis.

And importantly, for the science divisions, both Environmental Fade Effects and the Health Effects Division, it conserves our resources. We still will do the first tier and only in certain cases do the second tier assessment.

Thank you. Questions?

UNIDENTIFIED MALE: What's the difference between a peak and a sustained pulse?

MARGARET: Well, okay. It's really a matter of degree. If you look at an electrocardiogram versus maybe

something more steady.

MIKE: Is a function of the ratio or mathematical exceedents of the maximum residues and the amount of time --

MARGARET: Well, it's probably a function of -- Mike, it's probably a function of the way that the particular pesticide is used, and the fate of that pesticide -- whether something is persistent, whether something has a short life.

MR. JONES: Carol?

CAROL: I guess I haven't looked at this issue for a while, but I have a lot of trouble understanding it when you don't give examples, so it's a little hard to follow this.

Is this modeled after what you did on the OPs?

MARGARET: Yeah, we are using prism exams. The same model that we used in -- yes, it is modeled after what we used -- the method that we used in OP cumulative risk assessment.

CAROL: You said "prism exams?"

MR. JONES: Yeah, that's the name of the model.

CAROL: Okay.

MR. JONES: The approach we took in the OP cumulative was --

CAROL: I thought we were doing Monte Carlo, I didn't know we had moved on to prism exams, so....

MR. JONES: Well, we use prism exams in our Monte Carlo.

CAROL: Oh, sorry.

MR. JONES: We used the entire range of distributions of the pesticide's likelihood to get into water in the OP cumulatives, and since that time we've been asking ourselves -- and have been asked -- to think about how we could use that concept in an individual chemical and there were some barriers to that, some technical issues that we had to work out. And, basically, we've worked them out, and we're now going to begin using that process that we used for drinking water in the OP cumulative more broadly. I wouldn't necessarily say universally, but more broadly, but using a tiered approach so that we only use it when we need to.

CAROL: And you'd be looking at exposures over a period of time?

MR. JONES: That's right.

CAROL: Okay, got you.

MR. JONES: Okay. Thank you, Margaret. Tim?

KEVIN: I'd like to tell you a bit about three activities we've been involved in recently and in some cases in an ongoing way, in the area of pesticide worker safety programs, and in the light of this morning's discussion about extramural budget cuts, it's just some passing remarks about the need for something more than labeling which will make what we do here real in the field and make it protective for all that are working with and around pesticides.

The characteristics of good worker safety program are that it should be doable in the context of field realities, it needs to make sense in a number of levels as a policy and it has to benefit all of those who are involved, and it has to acknowledge that those that are involved have taken an active part in their own protection and the protection of the environment.

That all isn't going to be carried out simply by putting things on the label. It requires a very aggressive and vigorous presence in the field in the Federal and State agencies and through a number of

service organizations and commodity organizations.

There are field realities that have to be coped with, and I'm sure you who work in this area realize the range of these realities. There's real concern about the programs being able to be implemented when there is poor understanding about risk, so there's misconceptions about pesticides and their use. We have to deal with low literacy diversity in the populations that we're working with.

Some of the equipment that we deal with poses problems in certain environments, and there's always the potential for incorrect use, misunderstanding of how to apply and the rates to apply and simple management and business pressures that may force decisions that might not be in the best interests of the workers or protecting the environment or anyone around.

And there is great inconsistency in standards nationally. There's a state variance that is disturbing, I'm sure, to the states and to us, nationally.

Now, EPA's programs that we're considering as worker safety programs are driven by two regulations and a special initiative -- we'll start with the special

1 initiative. It's called the Health Care Provider
2 Initiative. It's something we started fairly recently
3 and it has over-arching concerns for the other two
4 aspects of the worker safety programs that are driven by
5 regulation. The Agricultural Worker Protection
6 Regulation, fully implemented in '95, and the Pesticide
7 Applicator Certification Program, which was instituted in
8 '74 and the regulation hasn't changed -- the Federal
9 regulation hasn't changed since, although states have
10 dramatically changed their programs and created some
11 concerns for them and for us as far as consistency.
12 The Health Care Provider Initiative is an
13 attempt to raise the awareness in the primary care
14 provider networks, how to deal with -- how to recognize
15 and manage pesticide illness and injury. There's an
16 awareness in the American Medical Association, they've
17 issued reports; the Institute of Medicine issued reports
18 about the inadequacy of primary care health provider
19 training in their initial stages in medical schools and
20 nursing schools about the whole area of occupational
21 health and safety, but certainly, specifically, about
22 pesticides. And there's some concerns about the

inadequacies of the retraining that they go through.

So, if we -- as we are really chided by GAO and others -- do not have a national monitoring system, there may be basic problems in what we have and even if it did have a monitoring system, there would be basic problems because the primary care physicians are not trained to recognize and manage pesticide poisonings. That's compounded, of course, by the nature of the symptoms that mimic other illnesses and, also, the fact that workers are probably reluctant to go to health care providers.

But the whole context of concerns that we have focused us on the need to try to address this with a special initiative. So, we began this special initiative -- in your handout package you have a one-page description and schematic that's put out by our extramural grantee, the National Environmental Education and Training Foundation, and it describes the initiative, the need, the target audience and the schematic indicates the framework in which we're pursuing this. And we, with them, developed a national strategy package, which was recently completed and published and is available from them and their website is given.

1 And, in addition to this, a number of competency
2 guidelines have been issued to address the concerns in
3 the nursing and to begin with pediatric care communities.
4 We are developing a resources website that primary care
5 providers can access; we're developing a national review
6 board to access the training materials and provide a
7 consistency nationally in how recertification programs
8 are put together for primary care providers. We're also
9 established a network of university champions, faculty
10 champions, to try to effectively change the curriculum in
11 medical schools and nursing schools.
12 Also, in your folder is a list of the various
13 people we have involved in this initiative. It's a very
14 large and a very impressive collection of people who can
15 effect change in the medical training arena. And we're
16 certainly heartened by their enthusiasm in participating
17 with us on this.
18 In June, we're having a national forum here in
19 Washington that will surface a number of these things
20 that are being done, these projects that are being done
21 under this initiative, and I'll use Margie's e-mail list
22 and mail you the background material on that -- the

1 invitation and the registration material, if you're
2 interested in coming to the forum in June.
3 Now, in the area of -- the area being driven by
4 the Agricultural Worker Protection Initiative and being
5 driven by some concerns coming out of CARAT for
6 transparency and how our analytical processes are done
7 relative to worker risk mitigation, and so forth, we've
8 had a variety of activities that focus on internal
9 infrastructure change in the area of -- I'm sorry, this
10 one slide is speaking to the review of implementation and
11 enforcement that we've conducted and the impetus for the
12 review coming from the Children's Health Protection
13 Advisory Committee, GAO recommendations, advocacy group
14 recommendations and the CARAT recommendation of a few
15 years ago, that the analytical process be made more
16 transparent.
17 Now, the components of that review and
18 assessment are -- the program element review of our
19 Enforcement Office was essentially looking internally,
20 looking into our regional offices and the guidance that
21 we give to our states as to how to conduct worker
22 protection and to see if that was adequate, and we found

it lacking in a number of ways and are correcting that.

Also, a number of workshops that we had in Texas, Florida, California and here that focus on various components of the program and the needs for change in these components, and the components are -- the focus was on training, communication, enforcement, compliance and retaliation in children's health. Now, a lot of these workshops where groups were formed to focus on specific projects to address these concerns in these theme areas.

In addition to that, we have workshops that -- last year and a few months ago, that focused on the worker risk assessment methodology and the worker risk mitigation methodology and tried to make them transparent.

Now, the work group projects that we've focused on, I'm going to be addressing hazard communication issues with a pilot in a number of states that tries to develop better means to communicate with the non-literary working population. How to communicate -- it's fairly challenging -- how to communicate relatively complex notions and protective information -- with symbols and colors and signs and so forth. But try to develop a

better way to communicate without relying on a reading audience.

We're also dealing with ways to change the way training is done -- basic safety training is done -- and developing a pilot based around a national -- the potential for a national trainer training program. We began something like this or we worked with Mexico on something like this and put some seed money in Mexico, that leveraged very nice at a 10 to 1 ratio for our commitment to develop a trainer training program in Mexico that would mimic the ones that we're developing here.

We're also working with CropLife, Latin America, and the Central American Ministries and a number of Central American NGOs to try to do the same thing there. So, that, in effect, where the sources of our labor comes from -- Central America through Mexico -- to here. They'd all be encountering similar basic worker safety training or training programs, and I admit it's something of a leap of faith to assume that then they'll all be trained to the same standard, but that's what we're working with.

We're also bolstering the compliance and infrastructure -- an enforcement infrastructure -- with, you know, regional offices in our states; increasing pesticide inspector training; the EPA State Project Office of Training; doing more interpretative guidance outreach to the states; and working with a number of recommendations and work groups to try to integrate pesticide worker safety programs and essentially try to create a more coherent regulatory grouping of like labor types -- labor types that might have similar health and safety concerns; such as, in one group being migrant, seasonal laborers as opposed to the mixed loader, handler, applicator group of labor.

As you can see, much of this will make what goes on inside the Beltway here real, but it's not going to happen just by label language, it has to happen by fairly aggressive presence by us and the states, all supported by extramural funds.

Now, the applicator -- I've passed out some material on the applicator program, and that is the cornerstone of what I think to be a good worker safety program. No matter what you do here and what you put on

labels, if you don't have a competent applicator corps, it's not going to end up being a safe environment for the workers because the applicators are their environment.

The Applicator Certification Program is an old regulation, it's old guidance on certifying pesticide applicators of primary restricted-use product. As I said, it was started in '74 and hasn't been changed since; there's wide variance state-to-state; we have broadening concerns -- there's a great deal of concern expressed by regulators, Federal and state, and by the Extension Service trainers as to this diversity, this wide variance across the country.

There are more than a million certified pesticide applicators and millions more apply under the direct supervision or work with pesticides in the technician/handler categories.

As you know, there's increasing sensitivity to pesticide worker applicator safety issues, and the occupational users of pesticides who are not certified as competent is of concern to us and to the states. There's growing, as you can see through any number of media outlets, growing concern for the whole range of who,

what, where and how pesticides are used. And on top of that, we in the program and in the Agency, have a mandate under the security -- the EPA security strategy to strengthen the security in the program -- the certification program -- by the end of '04 -- Fiscal '04.

We've worked with the Coalition -- you can't see it clearly in this slide -- the Coalition, which is in your package, of State and Extension Partners. It's called the Certification and Training Assessment Group, and it was formed to provide a forum to discuss and resolve program issues, and it seems to me these are some of the issues that we've actively been focusing on.

The need to raise national safety and security standards and create consistent competency standards. We've been working with Canada on this and establishing competency standards and core exam development that is a valid exam, that's testing for what you want to test for, the entry-level competency of applicators. We're working and circulating recommendations through the state agencies to build support for what you would assume to be a basic requirement if you're gauging competency, that someone is taking a written, closed-book, monitored

competency exam and that it is a valid exam.

There are no minimum age standards, nationally -- Federally. A number of sates have established them, but certainly that you'd assume to be some major step in establishing a degree of concern -- or it would create a degree of concern if you don't have that national minimum age standard, that's being looked at. And the whole question of restructuring the program so that it could integrate better with other safety programs is being discussed in that work group.

In your handout you have the annual report from the work group and you have the charter, the membership of the board and the various subgroups that are working on these issues. Now, I urge you to go to the website or certainly read the material in your packet, but go to the website and pursue the activities that are being conducted here, because it's very far-reaching.

It is, as I say, the network of partnerships of state regulators and state extension service coordinators that we work with here. And the conclusions and suggestions will dramatically affect the whole range of labor working with around pesticides.

So, the intent is to provide us with a plan that can span that range of labor, satisfy competency issues, mitigate risks and improve pesticide security through education, training and testing, all of which are supported by extramural funds.

I didn't mention that we do have the electronic -- the equivalent of an electronic proceedings from the workshops so that we had the three workshops over a month ago and will, again. I'll send that to you with an e-mail with a PowerPoint presentation. In your packet you also have the array of speakers that presented at the workshop.

Many of these speakers are working on projects that we're supported through grants and they provide a great deal of interesting information that we are going to pursue in the program as to -- and bring back into the program -- to better inform the decision making that's being done in the program.

At the conference, we also committed -- the program committed to -- on an every-other-year basis -- to create this forum to focus on pesticide worker safety issues. So, every other year, we'll have a workshop of

this type, and I urge you to look at the array of topics in that agenda and, as I say, the array of extramural activity that's going on that can significantly feed back into the decision making in the program.

MR. JONES: Thanks, Kevin. Any questions or comments for Kevin? Julie?

JULIE: Kevin, thank you. This is a lot of stuff that you're working on --

KEVIN: Well, maybe not, this year --

JULIE: -- well --

KEVIN: -- as you heard this morning.

JULIE: I think one of the questions that I have, given that, with all these various projects and the initiative, how are they looking at measuring the effectiveness of each of them or some kind of measurable goals, given, then, maybe, depending on what is most effective where you can further direct action? I mean, there's a lot of different projects; are some of them more effective than others and that being where you should put resources.

KEVIN: That's true. In the area of planning, we would establish for the trainer -- the trainer,

1 activity, for instance, a standard pre-imposed evaluation
2 tool that would give you some indication that the
3 training is working or it's not working.
4 The Health Care Provide Initiative, obviously,
5 is an array of concerns about establishing baselines to
6 gauge your effectiveness in preventing illness and
7 injury. We've worked with a number of state public
8 health organizations through a project called Censor,
9 which started out as a grant activity with NIOSH that had
10 eight states, now has more, but I devoted a couple of
11 years to establishing common definitions, common
12 reporting criteria and baseline measures that could be
13 used, and I believe it was last year -- I think it was
14 last year, we began to get data out of that system that
15 could function as a surrogate -- as a model for a
16 national system, but it's, obviously, not a national
17 system. It's focused on major ag states, so it could be,
18 you know, a surrogate for a national system to indicate
19 incidents and follow through on treatment of incidents.
20 Now, we have base data out of that. After we
21 get further into this Health Care Provider Initiative and
22 actually begin to effect change in the training of

primary care providers, you know, we can make some judgments as to how that affects reporting, how that reflects the incidences that are being recognized.

So, I mean, we're talking about behavioral change here in all these areas and getting good measures of behavioral changes is a challenge, which you know.

MR. JONES: Phil?

PHIL: I apologize, I was out at the beginning of your presentation, so if this is a redundant question, well, just tell me. It kind of reminds me when we had an animal husbandry class and a student came in late, they were giving the class on taking a horse's temperature and the student raised her hand and says, well, how do you keep the horse from biting the thermometer off? And the prof said, you don't stick it in that far.

(Laughter.)

PHIL: So, I should have learned my lesson from coming in late and asking questions. But I'll ask anyway. You mentioned the trainer pilot program, I was under the impression that we've had that for about 10 years. Is that not the case nationally?

KEVIN: No, we haven't. We've -- there are

states that have good sound train-the-trainer programs, but we haven't had a national -- an endorsed national program, no.

PHIL: So, that was a state program, that was not a Federally coordinated program in --

KEVIN: In California?

PHIL: California and, I assume, other states

KEVIN: Yeah, we're using two or three models, we're sort of taking the best of, and putting together something that we would endorse as a national program that other states could emulate. But, yeah, the California program is one of our good models.

PHIL: It's an excellent program, it's made tremendous inroads on the education of workers.

KEVIN: Yeah, we realize that and it's one of the reasons why we thought we should be marketing it -- marketing something like it nationally.

PHIL: And I would endorse that. It's made tremendous inroads on worker health and safety.

MR. JONES: Bill?

BILL: Yeah, Kevin, thanks for the presentation. I have a question about the hazard communication you were

talking about for non-literate people, and your using colors and icons or cartoons. How well developed is that and has that been sort of tested with people to see how it's going to work?

KEVIN: No, it's in the very early stage. We've just had work group meetings that are focused on the notions that we want to try to convey, and we'll be working with small focus groups in field testing of various things, and much of it will have to be conscientious of global, you know, activity in that area that we want to be in harmony with.

BILL: Do you have any kind of time table for this?

KEVIN: Oh, this next fiscal year.

BILL: Okay.

KEVIN: This year that we're in now.

BILL: And how can I get plugged into that? I'm just looking at broader applicability maybe to, you know, consumer products because it's an area we've struggled with is communication.

KEVIN: Contact me or my staff person working on it is named Richard Pont, and he's been working with a

stakeholder group, NGO advocates, commodity state folks, but just a small group that he's working with, but there's certainly room to participate still at the early stages.

BILL: Great, thanks.

MR. JONES: Thanks, Bill. Jose?

JOSE: Yeah, Kevin, thanks for your presentation. I'd like to commend you for the way you have dealt with these training programs. I guess being involved with you and the program for quite some time and the progress that the program and you have made, I think, are significant, and you've done a great job.

I've got two questions: Number one, what happened with the cards that the farmers -- the workers that were trained received?

KEVIN: We still have that, the training validation. Yeah, we still have that.

JOSE: Do they keep those or they --

KEVIN: We have them but the states distribute them. We issue them to the states and then the states issue them to training organizations to distribute, yes.

JOSE: One complaint that I have from one of the

farmers was that there's no proof that those people were trained. I mean, they've given the card but they lose them and, you know, after a year or two they don't know where the card is, and if somebody comes in and asks them, they have no way to show --

KEVIN: Well, I would maintain the more they lose the cards the better, because then they have to be trained again.

(LAUGHTER.)

KEVIN: No, that whole program, that's a concern we have. We have a concern and out of the assessment it surfaced in a number of grant projects we had it surface that the training -- the requirement for training is so infrequent that that's of concern. The nature of the training and the reception of the training is of concern, and how to validate it. You know, that is a -- the system that we have is as flimsy as that card.

JOSE: Yes, because when we first started out, you know, that was a big deal, everybody getting a card and they carry it, but after so many years, it seems like the card -- the ownership of the card has a lot of significance with the people that received it.

KEVIN: Well, I think in the worker are and in the technician/handler/applicator, the other span of labor, we do have to establish a good sense of professional competency, that you are a competent agricultural worker or handler/applicator/technician, and have some sort of sign of that. That does become real for them so that it's a valuable, professional chip that they have. And we're grappling with that.

Jose was a star of an earlier video that we did in training and in down in the Rio Grande, blazing sun, in which we had to keep shooting and reshooting and Jose's -- and then in the final product, Jose's face became magically changing redder and redder as the video progressed, since it took all day in the sun to film it.

JOSE: Yeah, for the middle of September, it was hot, yeah, I know that.

And the other question is, on these programs where you're talking about Mexico and Central American, are those countries contributing anything monetary to that program?

KEVIN: I said we put some seed money into the Mexican project. I think it was $50,000 we put into the

Mexican project and the Mexican Government has since put $500,000 in, so it was pretty well leveraged money we put there.

JOSE: What about the other countries in Central America?

KEVIN: In Central America it is still in the early stages. We were going to meet with Crop Life, Latin America at their annual session this month, but it was cancelled because of war and travel concerns.

So, when they meet again, we'll meet with them -- well, we'll meet with them, anyway, fairly soon to discuss the project there, but it's still in the planning stages in Central America.

JOSE: Well, I think it's a great idea because a lot people think why do we have to train people down there, but those are the people that need training and have jobs in the fields in California.

KEVIN: Like I said, we found fairly enthusiastic response in Mexico, and, you know, if you can put $50,000 in and get $500,000 returned, that's not bad.

JOSE: This has been a good program and I

congratulate you for your leadership on it.

KEVIN: Thanks.

UNIDENTIFIED MALE: Kevin, you're acquainted with the industry Annual Fertilizer and Ag Chem Safety School that has always been in North Carolina --

KEVIN: Right.

UNIDENTIFIED MALE: -- it's sort of run out of steam down there and, so, we're picking it up and moving it to Nebraska this summer. I just wondered if you and your team have had any dialogue with the industry folks that are --

KEVIN: We've talked to Tom, Tom Hall --

UNIDENTIFIED MALE: -- and are interested in talking further with --

JIM: Well, I think there's a lot of revitalization that needs to happen there from the industry side but also networking with Federal and state authorities, so that's good.

Since so much of the training activity has historically been done, and largely successfully, at the state level, with and without seed money from the Federal level, but now that we're entering this period where the

state governments, almost universally, are running deficits and are going to be cutting programs, that are important to all of us, do you have a monitor on kind of the resources and level of support that the states are providing?

KEVIN: It's plunging -- the funds are plunging and it's of serious concern for us and the states, obviously.

KEVIN: Is that something that maybe via Margie's list serve you could kind of give us an update from time to time on kind of what the trends look like, because there may be some state where, you know, any number of us around the table, you know, regularly try to influence state government policy. And, if we know where there are places of common concern, I know you can't tell us to lobby, but --

MS. LINDSAY: What I was going to offer, actually, is APCO has done its own analysis -- not of state of funding versus needs, both current and reasonably anticipated future needs -- and it would include the worker safety programs, but it actually goes beyond the worker safety programs, and I think we've been

very happy to take the latest iteration of the APCO survey and put it out so others can see what's going on.

KEVIN: I think we have to fairly aggressively work together so that there isn't duplication and that we can all leverage off each other's efforts. Crop Life, Latin America has done a great deal of very good training. It, perhaps, didn't get acknowledged because it could have been seen as industry by linking with us and with NGOs and providing some kind of entity that is clearly seen as only concerned with good worker safety training. A great deal more could be done -- can be done. I think that's similar here in the states, as well.

MR. JONES: Win?

WIN: Just a quick comment and a question. I know many of the states are suffering significantly, but just to give you an example, for the first time in my 30 years at Penn State, some of our country agents have gotten pink slips. And that's almost unheard of and that's because of tight budgets. It comes right to dollars and cents, and many of these people -- when I say many, a number of them who did get pink slips were

involved in these certification and training programs. If they didn't pick on those, particularly, they had other responsibilities as well, but it just shows you how tight things are getting. And, of course, many of our programs suffer as a result.

Kevin, just a question for you. I wonder if you care to share with the group, in light of the national security and safety concerns, what CTAG is talking about -- I won't say proposing at this time -- but in terms of positive ID, things like this, in the distribution and handling of pesticides, just make a comment on that?

KEVIN: It is discussed in the papers in the report and on the website, but it is -- there are a couple of groups in the certification and training assessment group network that are dealing with how to restructure a certification program. They're certifying as competent those that mixed-load (phonetic) apply, deal in, consult on the use of pesticides -- certifying them as competent but also building in security elements in the sale, the affirmation of who is buying and is having been certified, the physical security and so forth. And that's part of what we are charged with under the EPA

security strategy, to have that proposed by the end of '04, a full program, and we're, admittedly, broadening it to consider competency, but it's to address security -- we added competency, we feel that's a logical link to security to assume that people, if they are certified as competent, we'll have concerns for security, but we'll put that in there as well.

That's detailed in the annual report and in the website.

MR. JONES: Patti?

PATTI: This might be a little off-subject, because I know you're dealing more with the worker safety issues here, but along the lines of certification, is anything being done to kind of educate the public or outside groups, when you're hiring a contractor to do this type of work that they do, indeed, have the appropriate certifications? And I guess I'm kind of thinking back to, for example, what happened here at the National Zoo here recently, where they lost some red pandas inappropriately using rhodenticides and it appears that the company that applied those didn't have the appropriate licensure or certification, and I don't know

how much that truly weighed into the situation, but it appears that had they been certified, they probably would have been more aware of the risks.

KEVIN: There are states, usually, the programs are implemented at the state level, and, as I said, we have a Federal standard but it's a vintage '74, 1974, standard. So, the states have gone far beyond our national/Federal standard. Most states, I'm sure, have brochures, they should, to guide the consumer in dealing with REPPLICATOR companies. We could provide something generic, but it gets far more variable at the state level, so it's usually better as a state function.

MR. JONES: Melody and then Phil.

DR. KAWAMOTO: Thanks, Kevin. I wanted to just bring up a couple of comments. One of them has to do with resources. When I was assigned to Mexico in the Palo Office, I found that resources in the country were a big problem and my goal of training health care professionals was really limited by it, by the lack of, mainly, economic resources. But I found that there are quite a few physicians, clinical toxicologists in the

private sector and people willing to help participate in activities. So, I think it would be good to keep in mind in this country, as well, because I found I learned a lot about the United States by being outside of the United States. It would be good to take into consideration that, yes, physicians do need to be trained; and, yes, workers need to be trained; but there's also ways to use maybe clinical toxicologists in spreading out the message or engaging them in the training and not, you know, the surveillance of effects.

The other thing was that, I mentioned this also during the worker protection seminar, that Central America has a program called (inaudible) which has to do with pesticides within different countries and doing difference aspects of research, as well as training.

I also found that the multi-set collaboration is really important and the private sector can actually provide a lot of resources, not just in terms of monies, but in terms of some of the expertise to help put out information. For instance, in Mexico, the trade group is actually providing clinics throughout Mexico in agriculture areas; they're providing clinics with posters

and videotapes that they show in the clinics so that the families of the workers, as well as the workers, who come in can learn about pesticide training. And in these countries they also have done a lot with the literacy training of workers and communities.

So, there are a lot of models out there that are being used and the United States can actually learn from some of the things that are being developed in other countries.

MR. JONES: Thanks. Phil?

PHIL: I'd like to comment on Jay's comment for a minute. I don't know how many know it, but in the '60s USDA funded a program for pesticide education. And early in the '70s, because of the certification process that was created by FIFRA, those programs stopped doing general pesticide education and started doing certification for certified private and commercial applicators.

And, actually, at that point in the process, USDA dropped their funding for that program, and so the funding for that program kind of switched to EPA, which I think was a big mistake, because I think having the

general public totally uneducated about pesticides is not necessarily a good thing for the general public or the farming community.

In the late '90s again, or maybe even a little later than that, USDA started proposing, I believe, money to go back in to general pesticide education, but that money never seems to make it through the Congressional steps.

So, having your industry work to put some dollars back in to do general pesticide education, I think, would help with the pesticide safety issues and all kinds of things, and having pesticide coordinators only relying on the limited and diminishing funds that are going to EPA is not going to solve this problem, it's only going to make it worse.

MR. JONES: Okay.

UNIDENTIFIED MALE: Wait a minute, one more. Just want to follow up on what Phil said. Whatever pesticide training we're doing right now for the general public, if you will, to the consumer, to the homeowner, is really piggybacked, if you will, really on Kevin's program. I mean, that's the only way we can do it, and

we absorb people into programs. While we're doing certification training, we're also training, in many cases, just general pesticide users, homeowners and so forth.

So, we go through master gardener programs, we go through, again, our county staff, through our regulatory people, but a lot of it is really piggybacked that we try to get the maximum dollar out of the program.

But, Phil makes a good point.

MR. JONES: Okay. Jose?

JOSE: Just a quick question on the funding for this part of the program. Are you being funded at the level that you were last year, Kevin?

MR. JONES: He'll find out in about.....

(Laughter.)

JOSE: I see her going like that (indicating). I don't know what that means -- lower, more, lower, more.

MR. JONES: The division that Kevin is in took the brunt of the cuts that we're in. However, that division will have an ability to make choices. I'm sure Kevin's program will not come out totally unscathed, but it's not clear at this point, yet, just how much of a cut

Kevin's Work Protection Program will have to absorb of the cut that we've had to absorb. That will become clear in the next couple of weeks.

JOSE: I understand because we're going through the same thing in Texas he was talking about. We're going to have county agents laid off, too. And that's just the sign of the times, and we all have to adapt to it. But this is a program that has been very, very successful -- not that the others have not -- but this, in particular, is one that, you know, has done an excellent job.

MR. JONES: Thanks. Okay. I think what we'll do now is take a break. I want to thank the panel, Bill, Margaret and Kevin. It was a very informative discussion they gave and informative dialogue.

We'll take our break now and that will give us the entire time that we need to focus on the registration and review. Previously, we were going to take a break in the middle of that discussion; this will keep that conversation sort of whole and continuous. So, quarter after, if all of you could be back.

(Whereupon, there was a break in the

proceedings.)

MR. JONES: Okay, we will start without you. One of the things that we hear from PPDC members most offline and often at the meeting is that we need to use this as an opportunity for us, the Agency, to ask for advice in the things that we're most interested in getting advice in, and the upcoming topic is certainly one of those.

As I've mentioned a few times already, both substantive advice as well as process advice is what we're looking for in the upcoming discussion in registration review. At this stage in the game, actually process advice can be the most powerful because we're still very early in the process and, so, you can help us figure out the process going forward.

There will be plenty of opportunity, going forward, for substantive advice, so this isn't at all the last opportunity for the committee and others in the audience to be giving substantive advice, but we are comfortable receiving that today from committee members, as well.

But, again, giving advice on the process, this

early in the process, can be every influential in how something goes and how well it goes or how poorly it goes. So, the topic we're talking about next, registration review, definitely qualifies as an area where we are very interested in the PPDC giving us advice -- this doesn't mean to say at all that the topics to date and subsequent to this aren't important, but this definitely is.

So, with that, I'll turn it over to Bruce Sidwell.

MR. SIDWELL: I'm Bruce Sidwell and I'm the Chief of the Policy and Regulatory Support Branch, which is part of the Field and External Affairs Division in OPP. I am delighted to be here, especially on this particular topic.

The registration review topic, I think, should appeal to, in some way, everyone here, but especially it should be intriguing to the policy-walk side of all of us, since we want thoughts on a new program -- that should get you excited.

One key part of the registration review is going to be development of a procedural rule, and we're having

slides that we'll present on the background and the initial thoughts about this rule.

Leading the presentation, to my right here, are Luis Syuoma (phonetic) and Vivian Brenet (phonetic), both of whom have extremely broad experience in the program in various capacities and have been intimately involved in the workgroup development of thoughts in this area.

As Jim was saying, we especially want input on how you'd like to participate in development of the rule and, of course, your reaction of the efforts so far that we give you today.

With that, I think, I'll go ahead and turn it over to Luis.

LUIS: Thanks, Bruce, and good afternoon. This is my first time at PPDC, so, you know, it's really a pleasure to be here.

We wanted to talk to you about, like Bruce said, a new program, something that we're looking forward to have in OPP, and something that was also brought about by FQPA.

You know, in 1996 FQPA brought us many challenges and new requirements, new ways in which we

should regulate pesticides. But well known or in the spotlight has been, you know, items such as cumulative risk assessment, safety practices and, you know, the additional safety practices for children and other requirements.

Among the other requirements were also changes to FIFRA, and registration review actually qualifies as one of them, an amendment that was brought by FQPA in 1996.

So, what is registration review? And I'm going double duty, so excuse me for just a second. I know that many of you --

MR. SIDWELL: Excuse me just a minute. These slides are in your package and, I think, we've made sure that you have plenty of room to write down notes by each slide.

LUIS: I know that many of you carry a copy of FIFRA with you at all times, but I don't --

(Laughter.)

LUIS: -- so just in case, I have a copy here. And FIFRA was actually amended and section 3G was created, which deals with very special review. It's a

very short section. In a few sentences, I think, it captures the essence as to what is required of the Agency. And it says that the Administrator, by regulation -- so by a rule -- should establish a process or a procedure for accomplishing the periodic review of registrations.

And it also said that the goal of these regulations shall be the review of pesticide registration every 15 years.

In looking at the legislative history, there were actually two main factors as to why registration review came about.

One is the acknowledgment that science or scientific knowledge changes over time. And that we need to have that in the process as we review regulation of pesticides.

And, secondly, was the notion that we have learned so much about the challenges and the difficulties and how hard it has been to do all of the re-registration all at once, so what we wanted to accomplish is, you know, that our knowledge in that over time we will actually have the opportunity to review pesticide

products and keep them in line.

The essence of registration review is that all pesticides are covered, and when we talk about just the active ingredients, there are about over 1,000. We counted about over 1,100 active ingredients; 600+ are red chemicals and there have been also an additional 500 registrations since December of 1984.

So, just in the area of active ingredients, in the universe of pesticides, we're actually talking about over 1,100 pesticide chemicals. And that includes not just the conventional chemicals, but also the biopesticides and the antimicrobials.

In the key for a registration review, we have to make a determination as to whether the pesticide actually meets the requirements of FIFRA Section 3©)(5), which is, in so many ways, the registration standard.

So, every time we take an action -- you know, I work in the Registration Division -- and we take an action, we'll actually be measuring the pesticide up with that standard, which is FIFRA Section 3©)(5).

And, right now, under 3©)(5) we actually made decisions on the critical ingredients and we actually

applied them to the products, ongoing with the registration review process.

At this point, we don't have a policy as to how we're going to be addressing inert ingredients in the registration review process, but, of course, you're aware, as it was mentioned before, that we're actually looking at how we're going to be clearing all the inerts or reaccessing inerts, you know, because of the tolerance reassessment as well as the approach that is being developed by the Agency right now.

And under 3©)(5), the key to determination that we have to make is that the pesticide product that does not pose, if registered, an original adverse effect on the environment.

Now, we do that based on the assessment of past exposure data, the labels and all of the uses. So, we're looking at the entire package when we're reviewing the pesticide product.

VIVIAN: We started working on this a few years ago, and the first thing we did, as far as the public knew about it, was to issue an advanced notice of proposed rule-making, about three years ago in April of

2000. We got a lot of comments on that ANPRM and I'll go all over that in a minute.

Based on the comments, we've revised the approach to registration review and we've presented it to our management, and part of this process that we're doing within the program is identifying issues for the stakeholders to comment on before we issue a proposal. And we'd like to issue the proposed procedural regulations by early in 2004.

So, as we go through our slides, we'd like you to think about the approach that we're taking and also on how we can effectively conduct outreach in the time frame that we're interested in.

Comments. We got a total of eight comments, and the breakdown was one from USDA, two for private citizens, two from chemical companies and three from trade associations, and if your name isn't here, you know who you are.

There are basically -- we asked for 16 issues to be the subject of the comments. Of these 16 issues, five topics stimulated the most discussion, and I'd like to give you a very brief synopsis about the views that were

expressed on these five issues.

The first topic was the standard registration under FIFRA. And that has to do with the nature or process for reaching a FIFRA 3©)(5) decision, and there were suggestions made in the comments that the Agency should provide a checklist and this checklist, if everything on it was checked off, would constitute meeting the requirements of FIFRA 3©)(5). There was also comments that the Agency should not redo work that it had previously done.

The second topic was predictable schedules. With 1,100 active ingredients and a 15-year time frame, there's a lot of work to be done each year to make that goal. The comments were particularly helpful in this area. They said that we should be basing schedules on the date of the last comprehensive review and the other comment was that the risk-based tracking scheme that we had presented in the ANPRM appears to be unworkable.

The comments also addressed the issue of how should the Agency handle emerging risks. We had suggested in the ANPRM that we would use the presence of an emerging risk as one of the factors to consider in

scheduling something for a registration review.

And the commentators pointed out that there are other authorities under FIFRA for dealing with new risks that are coming out and that we shouldn't try to use registration review as the sole means of managing new issues as they come up.

We also asked for comments on the registrant's role in registration review. We were hoping that everybody would agree that this was such a great thing that they wanted all to go first and they would provide complete packages and that's what we wanted to hear, but that's not what we heard.

The comments were, basically, that the Agency should not expect registrants to provide data unless it asked for it. We had thought that perhaps registrants would like to anticipate DCIs by providing data voluntarily.

And the last topic that I wanted to summarize from the topics was public participation. By this we mean public participating in the registration review process.

Comments said, we want to be able to participate

in key points in the registration review process, whatever that might look like, and they also asked for an opportunity for error correction before a document is made public.

If you read the ANPRM, you will note that what we're about to present to you is a lot different from what we presented in 2000, and we changed our approach to accommodate and incorporate stakeholder comments and also to reflect some experience we had when we tried some pilots in-house.

So, you will see that we've revised our approach to the process and we've revised our approach to scheduling and we're seeking public participation to develop key elements of the process.

The newest innovation: The main way that the new approach that we have is different from the ANPRM is that we now have a five-step process that we believe, if we can do this, will be a fairly efficient way of getting a registration review.

The first step is to receive an application and to assemble the information. The application would initiate the registration review process and the

application might include new information to support the review. The public would also be invited to participate at this stage, possibly by submitting their own ideas about whether this chemical should remain on the market and, particularly, to submit information about how the chemical is actually used. We would like to hear from grower groups, particularly, at this stage.

And, then, at the close of step one, the Agency starts to assemble all the materials that it's going to need to conduct the review, particularly the existing risk assessments.

In step two, the Agency assesses the registration review information that has been -- that the registrants submitted, the material that the Agency had on hand and anything else that has come in from the public.

And in this assessment, we're going to do a couple of discreet things. First, we would confirm the data requirements that apply to this pesticide. Then we would identify any possible data gaps. The third thing we would do is that we would examine risk assessments, labels and use information and, based on what we learn

from this, we would assess the significance of any data gaps.

And these are the factors that we would consider in doing this assessment:

We would ask whether we should accept previous study reviews;

We would ask whether we should accept any previous data waivers;

We would ask whether we should accept previous risk-assessment methods;

Then, based on any new information that we have obtained by, for instance, from incident reports or from changes in use, we would ask if there's any change in risk;

Then we would ask if there's any potential change in the risk benefit balance;

And, finally, we would ask if we should accept labeling.

We believe this approach will work for both conventional pesticides and biopesticides and any other specialty chemical.

We believe that this approach builds on the work

that we've completed in tolerance reassessment and/or registration.

In step three, the Agency would decide if the existing information supports a FIFRA 3©)(5) decision. If yes, we would go to step five and we would include the registration with you. If not, the draft assessment would include a plan for completing the review.

The draft assessment would be available for public review and comment and we would apply the lessons that we've learned in the tolerance reassessment process to develop a public participation process at this -- for this stage of the work.

And, finally, I want to remind everyone that if we find an unreasonable risk at this stage or at any other stage in registration review, we would have the authority to act immediately.

I would like to talk about the completion plan. The completion plan sets out the work that needs to be done to bring a pesticide up to the standard of FIFRA 3©)(5); specifically, it would identify data gaps, it would identify incomplete risk assessments, inadequate labels and uses that appear to pose risks of concern.

The completion plan would also include schedules and priorities.

In step four, the Agency issues and implements the completion plan. The final plan might differ from the draft, depending on the kinds of information that are submitted as comments. Once the completion is issued, we would start implementing. That would mean issuing DCIs, as needed, and taking any other regulatory actions, as needed.

Then, it would be the registrant's turn. They would provide the required data and EPA would issue progress reports on each chemical as it goes through this process.

And I would like to remind people that regulatory actions might include changes in labels, voluntary cancellations of uses -- that king of thing.

Finally, we get to step five, and EPA completes the FIFRA 3©)(5) decision process. We review the submissions, we complete the tests specified in the completion plan and we publish a draft FIFRA 3©)(5) decision. We will take comments on the draft decision and issue a final registration review decision.

The other area that I'd like to talk about -- and it will be very briefly -- is the area where we got a lot of comments on the ANPRM. It's how do you schedule the registration reviews, how do you get through 1,100 active ingredients in a 15-year period? We certainly can't do it with the process we used for re-registration.

When we thought about the workload, we thought, well, if you want to do 1,100 ingredients in 15 years, what you do is you review 1/15th of the workload each year. A very simplistic way of putting it, but that's what we had in mind. That means that we have to pay some attention to how do we schedule these things.

As I said, comments to the ANPRM indicated that using risk-based criteria would be unworkable and it would be better if we went with a chronological approach. Chronology would be based on the date of the last comprehensive review, which, for working purposes, is either the date of re-registration or the date of original registration. This means that pesticides registered after 1984 will be going first.

So, we would have a fairly objective criteria for a schedule and we could come up with a draft schedule

fairly early in the process.

However, we need to keep flexibility because we want to be able to balance our workload and we will probably include in the proposed rule criteria that the Agency would use to move the chemical from one year to the other.

And, finally, I'd like to remind people, again, that we retain the authority under FIFRA 3(G) to conduct other reviews. We can conduct data call-ins, for instance, like the endocrine disrupter; data call-ins, we could do risk-based calling in of information, when that seems to be warranted; we could continue to do FIFRA Section 6(B) cancellations, if we come up with an imminent hazard.

And, at this point, I'd like to turn this back over to Luis and he's going to talk about how you can help us with some steps of the process and with organizing the outreach.

LUIS: And, you know, this is our first time that we have gone, actually, public and tried to get some input directly from, you know, a forum such as yours.

And what I wanted to show you, perhaps -- I am

more like a visual person, and I would like to see and actually develop like a flow chart and walk you very quickly and in very general terms -- and, again, please understand that nothing is etched in stone yet. We are in the process of actually thinking this process and developing the proposed rule. Okay?

If you take at look at our process -- and, by the way, Dr. Amador, is he here? We're also looking for a new acronym for RR, which we don't like it in there, but -- and to me RR reminds of my boyhood/childhood era was Roy Rogers and I don't want to expose him to pesticides any more.

(Laughter.)

LUIS: Although he lived to be up older than 90 years old, I think. So, if there is -- we'll take a suggestion for a new acronym for registration review.

If you take a look at step one, what we envision is that each year we will publish a list of all the chemicals that will be subject to registration review beforehand, so that you will know. And we will keep that process of that year with an application and at this time this is an area that we would like to see input from you,

because we would like to know what are the contents of these applications and the scope range from -- is this just an acknowledge letter that we'll receive from the registrant? What about if there's more than one registrant in charge, you know; if you're talking about a chemical that was registered in '85, it's very likely that you will find the basic registrants and also the generic registrant also in the market.

So, how that relationship is going to play in terms of supporting the registration review or be responsible for any actions that may be required out of this review.

We would also like to know what are the constant impacts of just this application process, you know, just along that component. And, then, what we will do is once that we start the process, what EPA will do is actually assemble or begin to assemble all of that information that would apply to that pesticide product, because that information is actually in-house.

So, in step two, we actually look at the data, you know, does it meet, you know, part 158? Now, remember that the data and risk assessments and all of

that could be a moving target over the years. So, in a given time there would be changes or there could be additional requirements that could be imposed.

We'll assess, you know, the current risk assessments. We are going to be working with our science divisions to develop a way for which we can actually determine at a given time or year the last risk assessment -- say it's dietary risk assessment -- actually meets the current standard, you know for that chemical. And we will look at the labels and we will also look at the use informations.

In step three, we will assemble a preliminary or registration review document and it will be made public, subject to public comment, and as Vivian said, if it needs Section 3©)(5), we'll go through step 5, complete it, issue our final research and review document, also subject to public comment. If not, then, we will actually have to implement an extra step, which could be very time consuming, and that would be trying to develop jointly with those responsible or those that are responsible for the registration, a completion plan. And, if it requires a DCI, which is a data collection

component, in some cases it could take maybe a year, may two years to develop that data, and they would have to develop a time table to complete that process, if there is a completion plan in place.

So, that's in terms of the steps. One of the things that we would like to hear from you is, you know, say, we talked about the application process, what might be some of the implications, or what might be some of the options that we could implement?

And, also, in terms of an outreach, you know, since we are getting ready to develop, by early 2004, the proposed rule, we would like to hear or share wherever, you know, we are with the stakeholders and get their input. And we can do it in several ways. We can contact each group individually and have them send information to us or share ideas, comments, to us; we can make presentations through stakeholder groups; or something else that has been done here in this PPDC forum, will be to work with the subgroup in your committee that could help us develop or further develop the ideas that have been presented so far in the application process, in the five-step process and in the public participation or

outreach component.

So, we will welcome your questions or comments that you might have at this point.

MR. JONES: Bob?

MR. ROSENBERG: I just had a question that just will have me understand this better, and then I've got some comments, but I'll save those for later.

Just one: What would the first registration -- or when would the first registration review be due if it was done 15 years after the last comprehensive review? What year?

UNIDENTIFIED MALE: I'd ask that question a little different way -- the same question. Do you consider that the 15-year review cycle started in 1996 or will it start in 2006 or 2008? I saw the chart earlier that said you were going to complete all of your initial reviews in 2008 under FQPA. Will the 15-year period start at that point or in 1996?

MR. ROSENBERG: Or if there was something registered that was not re-registered, but prior to '96, did the clock start running already before FQPA?

VIVIAN: Okay. We've thought of this and we

went back to the rule -- I mean, we went back to FIFRA Section 3(G), and nowhere -- nowhere -- in there, not even between the lines, does it say when a registration review program is supposed to start. It starts when the procedural regulation becomes final, and that has, obvious implications. If we never get it final, we never do a registration review.

But we are very interested in having a registration review up and running as soon as we can, really, so that when tolerance reassessment is over and re-registration is over, that this program is wrapped up and ready to go.

MR. JONES: Obviously, say, 2006 is when it's final, which is the goal of the Agency. We're already starting a little bit behind because there would be -- that's more than 15 years since 1984 when the first products were registered that are not subject to re-registration.

MR. ROSENBERG: But, now, presume that everything is reassessed -- everything needs to be reassessed and re-registered get done, then SSRD, at that point -- other than special review -- becomes the

registration review division. There's no other re-registration that's required at that point or tolerance reassessment?

MR. JONES: Once we complete 100 percent of our tolerance reassessments in 2006, on August 3rd, and industry registrations --

(Laughter.)

MR. JONES: -- right around the same time -- at that time their responsibilities for re-registration reassessment will be over. And, although we haven't made those decisions, it's likely that the division would then become the owner of registration review.

MR. ROSENBERG: What I'm driving at and just one more question, then, is: Does this look like -- I mean, I don't even have a sense of the scope of this -- is this like re-registration-like? Or does it look like a tolerance review? And does it require aggregate and cumulative risk assessments? And, I mean --

MR. JONES: Yeah, it is hard to get your head around that question. I think a couple of things are worth sharing.

We will have made modern decisions on everything

subject to registration review. Decisions will have been made since 1984.

In re-registration, that wasn't, necessarily, the case. There were dozens if not hundreds of pesticides that had not been registered or evaluated under a risk standard at all. Some of the earlier stuff, exclusively on efficacy. There were, you know, you had probably 30 years or more of pesticides that had been registered before they were even subject to a risk standard. So, the universe of what you're dealing with, although much larger -- we're talking about 1,100 compound, subject to registration review, versus about 600 for re-registration. The amount of work on any individual one should be much less.

Now, whether or not, in aggregate, it's going to cost as much, my gut is that it will basically cost about as much. You'll have twice as many chemicals with less work on each individual chemical because most of them -- well, all of them, have been at least evaluated in the modern era under a relatively modern standard, and a large number of them -- those which have been through solitary assessment, which will include a lot of them --

will have been under the most recent safety standard.

MR. ROSENBERG: I guess where I was going with this, was, you know, assuming this group of people that won't have any more work to do in 2006 and are looking for something to do, but you're still looking at, what, 80 actives a year? Ninety actives a year? Something like that. That's a pretty ambitious schedule, and, I guess, it almost seems as if the program needs to be designed to fit the resources that are available to meet that schedule or go back to the, sort of, 1986 era and be prepared to go up to Capitol Hill about 10 times a year to testify about why you're not keeping up with the schedule required under the statute.

So, I guess the point I was trying to make was it seems just overwhelming in nature, but that the key point would be to try to design it so the scope of the review matches the resources available to do it in a timely fashion.

MR. SIDWELL: I think I just stated it a little bit differently from the way you have, Bob, in that we have to design it to meet the statutory requirement, while keeping in mind the resources that we have

available to us. And if we find that we need more resources, we, as program managers, need to try to seek those resources, and in the event that they're not made available to us, that we use those resources that are available to us to do this in the most efficient and effective way to meet the statutory finding.

UNIDENTIFIED MALE: Is there an estimate of how long it would take to do a single registration review? How many FTEs or hours or --

MR. SIDWELL: No, I don't think we've gotten to that level of understanding of what the program will ultimately cost us.

Larry?

MR. ELWORTH: Well, first of all, I'd like to speak to the infinite wisdom of the drafters of this legislation.

(Laughter.)

MR. ELWORTH: But I think one of the things to do is to keep this in context. Remember this was written in '96 where everybody was still fighting with re-registration, where there was -- people were still very conscious of the backlog created from re-registration and

also there was a lot of concern from Ag and the registrant side about how to deal with changing science, both from the industry and ag side and also from people who were concerned about the risk.

So, the idea with this was to provide a simple standardized mechanism for dealing with changing science and avoiding what people in '96 and before thought was an unfortunate log jam created by re-registration. While you could argue that this was drafted very thinly, I think it was drafted correctly in that it provided the agency the ability to create a regulatory program that actually worked given the conditions under which it would eventually operate.

So, I think the drafting of this provides some flexibility. Now, of course, this provides a few dilemmas for the agency and how you actually draft this, but I think having drafted it with some flexibility for the agency is probably better than being as prescriptive as other parts of the statute were drafted.

And the other thing is that this gives people who are making registration decisions to be able to say, okay, we know we can go forward with this registration

because as -- in contrast to the way things were in the past, it's not a registration in perpetuity, that, in fact, we're going to regularly revisit these registrations and make sure that they still meet the standard and that the science is still current for them. So, I think this is a brilliant provision of law. But, also, I --

(Laughter.)

MR. ELWORTH: But one thing I would really encourage you to do, and I don't know exactly what the right mechanism would be to do it, is to actually -- is to engage in some fairly significant conversations with stakeholders, not just in sort of open forums, but have an opportunity to get a number of different people in the room at the same time to talk about this. There are a lot of questions that you would not have answered on this and whether it's part of PPDC or not, I'm -- I don't feel strongly.

But this is going to take a lot of work, and I think just putting out a rule and letting people shoot at it is one of the most inefficient ways of doing that.

MR. JONES: I agree. Steve?

MR. KELLNER: Do you have any kind of a template yet that would help us in terms of commenting? Any goals or anything like that that you -- not to shoot at, but to see where you guys are coming from so that we can get you back some good feedback?

MR. JONES: Well, I think what you see here today is right now what we've got. We are, as Luis mentioned, considering -- and some of the things we want to get some sense from this group is seeing if the PPDC is interested in having a subgroup work this issue with us. And it would be a fair amount of heavy lifting because we really need to get a proposal on the street in 2004 if we're going to be operatinG -- have a final rule in '05 or '06.

And I think we agree with Larry's assessment that the most inefficient thing we could do is work and work and work and work inside the agency and pop out a proposed rule and get all the fire coming on that. People really do believe you've made up your mind at that point. We'd rather have more participation up front before we go out with the proposed rule.

Right now, what you see is what we've got.

MR. KELLNER: So, we could work off the slides basically. What's on the slides is what we're your coming from at this point?

MR. JONES: Right. And, also, we're offering the opportunity of actually having a focused subgroup of this advisory group to work off the slides, but together. And it would have to be a balanced group of the PPDC representing all types of stakeholders.

MR. KELLNER: I just had one other question. The Smart Meeting that's on slides, I think it's nine, I could hardly read it because it's so small, but Smart Meetings would be open to everyone. I mean, up to this point, I think there's been some controversy of whether they've been open or they haven't been open. But for people to decide what uses they're going to hold on to and what's going to happen with data, et cetera. That needs to be opened up pretty quickly.

UNIDENTIFIED FEMALE: The degree and the timing of public participation is one of the things that we're asking the PPDC and other stakeholders to help us develop. So, that would be an issue that we'd like to get some help on flushing out.

MR. JONES: Okay, Carolyn and then Troy and Julie and Bob.

MS. BRICKEY: Well, this seems to me like a tremendous opportunity to learn from all the mind-boggling mistakes and delays and everything else that happened in re-registration and tolerance reassessment. I don't say that to denigrate anybody else's efforts, but, I mean, there's a huge experience level here of work that you've done over the last 15 years as a matter of fact.

So, I hope that we won't forget that we don't want to do student body left, which is what this proposal really calls for, is moving, you know, 80 or 90 chemicals a year through the process without any regard to how risky they are or how serious it is that we look at them or anything else, particularly given what other people have pointed out here about the resources. You know, I would hope there would still be an opportunity to do some kind of risk ranking. I can't comment what you put out in the ANPR, but I would hate to see this just become another book function where we go through all this work and all this, you know, funding to deal comprehensively

with some chemicals that may not need that close a look and put off, at least chronologically, some chemicals that do need a look. So --

MR. JONES: That's the kinds of things that we're looking for some specific advice on. What we've struggled with in that, and actually, the reason we've gone with the chronological is, one, there is an administrative ease to it and, two, there is somewhat -- it provides somewhat of a proxy for not necessarily risk, but for what you don't know. The chemicals that were registered right after re-registration began in 1984 are likely to have more gaps in their database than those that were registered in 2002.

They likely are going to need more work than those registered more recently, certainly, anything registered since 1996. So, you have a little bit of a proxy for a need to fill your knowledge base. Whether it turns out ultimately to be risk-based is unclear.

MS. BRICKEY: Yeah, if you're talking about them as a group, that's true. But looking at some of the -- you know, if you could go through a list of chemicals, you could definitely point out some that need looking at

sooner than others.

MR. JONES: How you sort of do that without spending all of your time fighting over what that list is, we're open to suggestions. What we don't want to get into is we spend six years fighting over what goes first. We'd like to be able to sort that out relatively easily and get moving on it. And if there are ideas about how to do that in a way that we can manage, I think -- you know, our instincts initially were risk-based. That's just what we do. We're EPA. We do risk-based decision making.

And then we began to sort of have the dialogue internally about, okay, how are we going to do that. You can see what would happen. That we, inside the agency, would fight for a couple of years. Then we'd engage all of you and you'd keep the fight going for another couple of years. But it --

MS. BRICKEY: Just to come up with criteria?

MR. JONES: Well, that's what we were -- the road we were heading down. So, if someone can sort of help us think through how you do it in a way that we can get some degree of -- we don't have to have consensus on

everything, but some degree of people saying, yep, that would do it, we'd be open to it, absolutely. Because as I said, that's where our instincts were initially.

MS. BRICKEY: Right.

MR. JONES: We took a stab at it and we could just sort of see what was going to happen. But if someone's got an idea around that, that we could get consensus around -- or not even consensus, but enough to sustain it --

MS. BRICKEY: A rationale that people --

MR. JONES: A rationale that people could swallow. And, you know, that's the kind of thing that if we were engaging in a subgroup, we'd be completely happy to have that issue on the table.

MS. BRICKEY: Okay.

MR. JONES: Troy.

MR. SEIDLE: Thanks. Another question that I'd flag for discussion that I think really would benefit from broad-based stakeholder consideration is the issue of a checklist and the completeness of a database/data gaps. What constitutes a data gap? Are there ways other than a check the box exercise to demonstrate that a

chemical satisfies a current safety standard and, conversely, the concept of a new risk, who decides what that is, when it becomes a data requirement, does it get entered into Part 158 or does it simply be required under a DCI? And all of that has to, of course, comply with the requirements of the Data Quality Act and the ICVAM Authorization Act for test methods being validated.

So, all of those issues, I think, you know, before DCIs get even considered, they need to be thoroughly flushed out.

MR. JONES: Those are good points. Thanks. Julie?

MS. SPAGNOLI: I've got a couple of comments. Has much thought been given to how chemicals that are currently undergoing tolerance reassessment but aren't re-registration chemicals, how that could fit into the process? Because, currently, I believe they've somewhat merged the tolerance reassessment with the re-registration process and there are a number of post-1984 chemicals that will be undergoing tolerance reassessment and how -- I guess I'm throwing this out there as a thought -- how could that be put into the registration

review process? Can we get some synergy or efficiency in that way? In particular, I know chemicals like the pyrethroids, where there was a lot of those registered that aren't undergoing re-registration but are undergoing tolerance reassessment.

Second is, in the initiation of the process -- I guess I'm a little -- this whole idea of submitting an application, how that would be initiated? It seems that it would be better that the agency somehow starts to solicit the input that they're looking for, and I think as opposed to a -- as a Smart Meeting or that type of -- maybe a list of the type of information that the agency is looking for and that goes out to all registrants of that active ingredient, and that way, you'd solicit that formulator input and all use -- the various use patterns and not just rely on the basics or even the basics and the generic suppliers to get that information.

You might get a broader base of information to begin with, which has sometimes been a problem, I think, even in the Smart Meetings because sometimes there's confidentiality issues, whereas if that was just kind of collected at the front end, then maybe it could be

refined or questions could be answered via a Smart Meeting or some other mechanism.

But I think what we learned is -- I learned through the re-registration process, having been on both the side of a basic and a formulator, that the basics don't necessarily have all of the relevant information, especially about their formulator's products.

And then my last comment has to do with I think, also from an experience, the re-registration, I think it would be helpful to work right into this procedure some procedures for public health pesticides. I think we ran into a lot of difficulty in re-registration where there were provisions in FIFRA specific to public health pesticides but there really wasn't any mechanisms procedurally for enacting them. And so, there were data requirements that needed to be met. There were definite benefits or needs identified for public health pesticides, but we couldn't seem to get it connected.

So, I think that may be an area that if it could be written into the procedures, then we may avoid some of those problems in the future.

MR. JONES: Thanks, Julie. Actually, I want to

go to Jay and then come back to Bob.

MR. VROOM: I have two or three thoughts here, but one sort of over-arching reaction. I've tried to listen carefully and I don't think -- once this has been referred to and it seems to me to be the keystone to the starting point, and that is when will Part 158 of the Code of Federal Regulations be updated in final form? And off of that, then a lot of these answers will flow.

Jim, any sense of -- have you looked at that recently or --

MR. JONES: We're going to be going to OMB in the not too distant future, hopefully within about a month's time, and depending on how long it takes us to get through that process, which I'm confident it's not going to drag on too long, we'll then be coming out with the proposal. So, I think it will be this calendar year would be my expectation.

MR. VROOM: Great. Because that's about the same vintage as, you know, this 1984 break with regard to pre and post-re-registration.

MR. JONES: Exactly.

MR. VROOM: So, all the stars may be aligning

here. That's cool. Okay.

Vivian, I wasn't sure whether you were being facetious when you were suggesting that you thought maybe registrants would volunteer to sort of make up testing requirements before we got DCIs or were you serious?

MS. BRENET: Actually, we were, at one point, thinking that registrants, perhaps, would be interested in providing their ideas about what a risk assessment should look like.

MR. VROOM: Right.

MS. BRENET: And that would include new data that they had performed to support a risk assessment. Ultimately, though, the only way that the agency can be sure that it has the data that it really needs to make a risk assessment is to call it in under a DCI. So --

MR. VROOM: And that's another fundamental provision of FIFRA elsewhere in the statute, which is that data can't be protected and compensable unless it's been specifically and explicitly called for by the agency.

MS. BRENET: And that was a point that was made --

MR. VROOM: So, it's carting the horse --

MS. BRENET: That was a point that was made in comments.

MR. VROOM: Good.

MS. BRENET: Thank you.

MR. VROOM: I think the point Carolyn was making, and I would echo, it seems to make resource and time efficiency sense to consider batching within some reasoned chemical groups. And I think that's, Carolyn, one of the lessons that we did get painfully out of FQPA's tolerance reassessment experience is that there is efficiency in the agency focusing on -- and, by the way, the law still will be there in terms of the standard aggregate and common mechanism requirements and so, that all is going to drive part of this together.

Notwithstanding the fact that I'm sure I will have some members who will be registrants of chemicals that would fit into that sort of common mechanism box that will have significantly different original registration dates, and if you've got a later one, you're probably going to want to go later. But at the same time, there's got to be a way to make some regulatory

sense out of that for the value of the efficiency of the agency's resource time, and also application of evolving science will just make sense.

MR. JONES: That's actually a good point, Jay. You've reminded me of the part of our discussion that gets to Carolyn's point, that there are some simple steps you could take to a risk-based approach. Say if you have, in one given year of the 80 chemicals, five of them from different classes, you could say, well, you know what, this is the class we're most worried about, we'll pull everybody else up to it. These four classes, we're less worried about, we'll let them go back to some of -- there are some relatively simple risk-based approaches that are -- help you manage the resources as well as bring risk into the occasion that we have done some preliminary thinking about.

MR. VROOM: I think --

MR. JONES: And there may be other --

MR. VROOM: -- probably all of the (inaudible) herbicides fall into the Post 84 category. And yet, they probably have at least a decade between the first and the last AI registration and does it make any sense to sort

of do, you know, one in 2006 and the last one in 2016. I doubt it.

One specific idea on Step 2, maybe it's implicit, but we'd certainly want to make sure that there's a specific step where you would look at what else has been registered by the agency that may compete with this compound and change its use patterns in the marketplace and/or other things that have happened in the marketplace, new needs with regard to resistance management, anything that -- you know, or the fact that maybe by the year 2016, Brazil will be the nearly only soybean producer in the world and we don't use soybean herbicide in the United States anymore or whatever.

But those kinds of market-based factors, including the decisions EPA has already taken with regard to new and other re-registration decisions.

UNIDENTIFIED FEMALE: That's the kind of information that we'd like to see pointed out to us in Step 1. If there's things that you think that we ought to consider in making a registration review assessment, please point -- you know, there should be an opportunity in Step 1 for that.

MR. JONES: Thanks.

UNIDENTIFIED MALE: Jay, is your comment more related to including benefit assessments into that component? Is that --

MR. VROOM: I think our part of the industry certainly is satisfied with the way efficacy data is handled currently. So, I'd want to be careful about the way I answer that question. But that certainly is an ongoing consideration.

UNIDENTIFIED MALE: I don't even know how to say this, much less how to implement it.

(Laughter.)

UNIDENTIFIED MALE: It strikes me that the lesson of re-registration and tolerance reassessment is for each product that went through the process, it was a momentous, earth-wrenching event and it was very painful for everybody. If there was some way that this could be constructed differently so that it was something like an ongoing process rather than an event in time, like 2009 is the year that X chemical is going to have to do all this stuff, where there was a certain set of predictable requirements that could be being worked on and everything

just sort of falls into place just in time because you know that 2009, you're going to be the one that's going to be looked at and you just basically have your package ready and somebody kind of looks at it at the front door and checks it off and thanks you and gives you a license and moves on.

But just so it's -- I guess what I'm trying to say is, rather than a five-step process that starts, you know, October 1 and is supposed to be done in nine months, that it be thought of as a process that's sort of ongoing over the life of the compound.

MR. JONES: Well, I think that some of the -- when you're managing as many things as you have to manage in a program like this, you have to have some process or you just don't get anything done, it's been my experience. That being said, not every compound going through the process will have as many challenges and difficulties. This is the reality --

(End of Tape 4, Side A)

UNIDENTIFIED MALE: -- re-registration. Again, in re-registration, you are dealing with 600 compounds, most of which haven't been evaluated against a safety

standard. Some of them had, but not most of them. And so, there was -- virtually all of them got some kind of really, major, heavy lifting in terms of data generation as well as data review, risk assessment and risk management. In this program, there will be compounds, I'm confident, that sail through without much more work on anyone's part, and then there will be those that don't for whatever reason. You have a new data requirement around endocrine disruption. They sort of hit the first screen and they're into the second screen and it looks like something's going on there.

I think the fact that every chemical in this will have had a comprehensive assessment since 1984 will, for each chemical, make it easier than it was the first time around; otherwise known as re-registration or that registration that occurred between '84 and '96.

Patti?

MS. BRIGHT: Jim, I'm going to apologize to you and Anne because you've heard me say this many times before, but I'll repeat it again. Going back to just kind of on what Robert was talking about and your comments about some of the challenges that can happen,

1 particularly -- and we've seen this a lot in the re-
2 registration process where things are kind of moving
3 along, the registrant and other stakeholders are moving
4 with EPA, things are moving along. Then, all of a
5 sudden, some other stakeholders step into the process and
6 kind of throw up some red flags and there's a lot of
7 frustration on both sides, a lot of mistrust.
8 I really think it's important, both in
9 developing this process and once the process is up and
10 running, is to really focus on getting earlier
11 participation from all of your stakeholders and really
12 trying -- I know that you guys do stakeholder phone calls
13 and other things to try and get people to sit down
14 together. But I think that's a very, very important
15 thing to do. You know, maybe I'm being overly naive here
16 in believing that this process can run a lot smoother and
17 be a lot less contentious, but I really do believe that's
18 true.
19 I think that if all the stakeholders were
20 sitting down early, both the NGOs, both industry grower
21 groups, we might not always agree. We're certainly not
22 going to come to a consensus, but I think we would have a

better understanding of why the other side feels they need what they need. And I think not throwing up those obstacles late in the process would make things run a lot more smoothly for everybody.

So, I'm sorry, I know I've said that before, but I'll say it again. Thank you.

MR. JONES: Thank you. Larry?

MR. ELWORTH: I'm still sort of stuck on Bob's vision of the way that this would work. It sounded so nice, Bob.

(Laughter.)

MR. ELWORTH: It made me feel good, yeah.

UNIDENTIFIED MALE: But then there would be no jobs for any of us.

(Laughter.)

UNIDENTIFIED MALE: It was too nice.

MR. ELWORTH: One of the things that occurs to me, though, is -- that we didn't spend very much time on or not at all, is the whole issue of use information and I don't know if proprietary sources of use information are going to be continuing to generate data for a while here. And it's actually -- it really is likely to fall

as much to USDA or maybe even more to at least have some of the use information synchronized to be of use to this process as it goes forward, because, in fact, separate from DPR's PUR database there may not be any other regular use information except what USDA pulls together or maybe some scattered among the states.

MR. JONES: Let me come back to the -- one of the early questions I had asked. We really do want to have more participation in development than is often the case in the regulatory process. And the thing that seemed most obvious to us would be to use a subcommittee of this committee to be able to -- you know, frankly, if you're seeking advice from stakeholders, you need a FACA. This is our FACA.

Is there an interest in us -- in you, in enough of you, to use the PPDC work group process, which as I mentioned, will, I think, involve a fair amount of involvement on the individuals who volunteer to really sort of help us to shape what the ultimate -- not the ultimate, but the proposal will look like, and then that will sort of go through the standard APA process of notice of comment.

Any thoughts?

(No response.)

MR. JONES: And let me remind you that a subcommittee can actually include people who are not members of the FACA. It has to sort of just come back through the FACA. So, if you want to volunteer your colleague, this would be perfect. Just teasing.

(Laughter.)

MR. JONES: Julie?

MS. SPAGNOLI: Yeah, I think that that would be a good way and I think especially that there's a lot of people in this group and also maybe to look to some of the members of the old TRAC and the current CARAT that have gone through the experience of the re-registration and reassessment processes and use what we learned from those processes, what really was beneficial, what worked, where were the pitfalls and utilizing that basic experience to come up with a process that will be the most efficient.

MR. JONES: Others?

UNIDENTIFIED MALE: Yes. The one comment I hear more than any other from my members is the need for

consistency at the agency and how products are reviewed and the process that they go through and the understanding by all the stakeholders or what goes on, and even some of that's been said today. So, I believe if we started early enough through the process we're doing today and with a subgroup, the more we could put in place well in advance and debate it, discuss it and come to a consensus or something -- you used a better term earlier -- I think would be a process that we could support very strongly knowing. And given that, then the agency would be in a position to follow that process very closely once we get it into a working condition.

MR. JONES: Anyone else?

(No response.)

MR. JONES: Well, as we -- Steve?

MR. KELLNER: Well, I'd be willing to support that, too. I think it's a good idea and I think it would -- the fact that we could bring other people in, if we didn't have enough from within the group, to bring members in the group that are good registration knowledgeable people that would help, and I think we ought to give it a go.

MR. JONES: Anyone from the user community or the public interest community who I don't think we've heard from on this specific issue? I'm not asking for you to volunteer, I'm asking if you think that this is a worthwhile thing for us to engage in. We've heard from three people representing industry manufacturers.

Bob?

BOB: Oh, for sure.

MR. JONES: Okay.

UNIDENTIFIED MALE: Well, it seems like a reasonable idea to get everyone together to try to agree on some strategy, but it doesn't seem like that it would be all that hard to make some kind of prioritization that was based on factors, such as potency, persistence in the environment or a persistent environmental effect and the amount used per annum so that you wouldn't waste the agency's time or at least put at the head of the line something that might be very high potency but had a very small niche use while you ignored a product that may have a lower potency but was widely used and bio-accumulated.

MR. JONES: Patti?

MS. BRIGHT: I would agree. From the NGO

community side, I think it would certainly be a good thing.

MR. JONES: Okay. Well, I -- as you can tell, I want to do this, so --

(Laughter.)

UNIDENTIFIED MALE: It looks like a to me, Jim.

MR. JONES: number of people who also want to do -- not necessarily that you want to. We'll figure out sort of how to construct this. And, again, it does not have to be a PPDC member who is on this subgroup, but we do want to have enough of you to really make it feel as if it's part of our work. Yeah, Gary?

GARY: The only thing I would say to that -- I agree with you totally, by the way. But it needs to be a group that is not that big.

MR. JONES: That's right.

GARY: You know, something that can be working with a good strong leader who can -- you know, who can sort of do the compromising necessary (inaudible). So, you can keep that in mind. You don't want to have it look bad.

UNIDENTIFIED MALE: Yeah, I agree. It needs to

be workable and manageable, but yet representative.

Okay. Well, I think we're ready to close this session and thanks very much to our panel as well as to the members of the committee. And I think we have one last group of follow-up issues, issues that have been raised in previous PPDC issues. Anne Lindsay is going to lead us through.

MS. LINDSAY: Okay, this is a collection of three discrete topics focused on inert ingredients and I'm going to keep talking while the next presentation gets set up. But we're going to start off with giving you an update on implementation of the inerts risk assessment framework, which we had brought to you, I think, not at the last PPDC but maybe two PPDCs ago, and we have some real experience under our belts, so to speak, and we thought you might like to actually hear what it's like.

The other thing, while I'm waiting for Luis to finish off, I would just like to say it's not only Jim who is interested in having a subgroup of this committee to work on registration review, but you need to know that Vivian Brenet and Luis and just the staff in the program

came to me a couple of months ago and said, you know, we really got to go out and get stakeholder input at this point. There's no point in going farther without doing it. It would be stupid to write the rule.

So, I think actually one of the big learning lessons that we've incorporated from re-registration, tolerance reassessment and everything is the value of early and very balanced real discussion and hard work -- not just discussion, but hard work with our stakeholders, and it doesn't require the office director to tell folks, this is what you need to do. It's actually coming from the bottom up that, hey, you guys, this is the way we need to do our business. I was actually very impressed and I wanted to give Vivian and Luis a little credit for that as well as wanting to stall for some time.

(Laughter.)

MS. LINDSAY: But what I might do is just go ahead and talk about my own stuff and then Catherine can pick up. I was going to talk about two things. One was enhanced disclosure for inert ingredients. And this is actually an area where we did have a FACA subcommittee group and it was definitely a group that was not able, as

you'll recollect, to reach consensus. But it did actually put together, I think, some wide ranging recommendations for possible change that were good and will remain, actually, a piece of resource information for the agency and for others over the coming years.

There are three areas that, within the program, that we've decided right now we need to focus on and I wanted to give you just a very short preview of what they were. And I would expect that over the coming months and year, we will develop more concrete proposals around these three areas and that we would either bring them back to the PPDC itself or other appropriate venues that suggest themselves as we do our work. But we're not proposing to reestablish that subgroup for those of you who were members of it.

(Laughter.)

MS. LINDSAY: Just so you know. The first area was medical information availability. And when the subgroup looked at this, there was -- I think this may have been one of the areas where we came closest to having some kind of an agreement. That although there is information out there in essentially the health care

1 community around inert ingredients that's useful if
2 you're dealing with a medical emergency, it isn't as
3 routinely systematically, as easily available as you
4 would really like it to be. And, therefore, that's an
5 area that we think we need to work on.
6 There are a couple of, three ways that we might
7 pursue it. We could look at our own end pick, which I
8 still think of NPTN and what role they might be able to
9 play in providing this kind of information. You could
10 conceive of an EPA database that was made available to
11 health care professionals or there are already some
12 existing data service providers and we might look at how
13 we actually enhance the information they've got an ensure
14 that it's more widely available. And there may, as we
15 sort of explore those three avenues, be other things that
16 we haven't thought of. But those would be kind of the
17 directions that we would begin to do some exploratory
18 work.
19 The second area would be to establish what we're
20 now calling, in our minds anyway, and it's open to name
21 change, voluntary disclosure demonstration programs. And
22 we thought of at least three different kinds of

demonstration programs, one you might call the full disclosure in which labels of pesticide products would have virtually all information about the inert ingredients by chemical name and common name if available.

Something that's sort of a step down would be a label disclosure program that uses common names or descriptors. So, it might be dye, anti-foam or propellant, fragrance. So, a combination of chemical name, common name, descriptors, a full or partial listing of the inert ingredients. So, it wouldn't be the full set, but it would definitely provide more information than might currently be on a given product's label.

And then third, and I think this is definitely sort of a notch down, the idea of a releasable summary information program, and this is something that a number of, I think, individual registrants have developed, I think, frankly, from talking with them, out of their own needs to answer questions that they were getting. And so, that releasable summary information program could be pursued and enhanced in a number of different ways.

So, we're thinking -- and you could either do

one or you could do all three or a combination of these voluntary label disclosure programs. I think what you'd have to also probably pair with that is some mechanism to evaluate the, so, have you made any progress on this front, are the voluntary programs actually really working. So, after some period of time, when the demonstration programs are up and running, there would be a way to come back and assess the impact of those programs.

And then the final area that we think there's value in working, and I actually think this is an area where there was a fair amount of agreement, was in standardizing the nomenclature. So, this would be around alternative terms and common names for the inert ingredients themselves, around useful generic descriptors. This is the dye/fragrance kind of thing again. And we'd probably pursue it through working with various standard setting organizations, such as ANSI or the British Standard Institute or other organizations. And through all of this, both with the nomenclature and all of the other disclosure activities that I talked about, I think we would also be looking to work with some

of our other federal partners, such as FDA and OSHA, so that where it was appropriate, we were actually bringing our programs together and sort of standardizing and harmonizing. So, that's the inerts disclosure.

Are you ready, Catherine?

CATHERINE: Yes. Today I'm going to talk about the lower toxicity pesticide chemical methodology, and previously, this was brought to PPDC back in December 2001. And Carol Liefer and I discussed with you, essentially, a very broad overview at the time of what we were calling the inerts methodology, because that was the original intent, to develop a methodology for use on inert ingredients.

The methodology was actually released for public comment on June 7, 2002 and we have continued to use the methodology since then, but we have changed the name of it, the lower toxicity pesticide chemical methodology because we have also been using it on active ingredients. In the case of many chemicals, they have uses of both inert ingredients and active ingredients, and so, we have been assessing these on selected chemicals, chemical-by-chemical basis.

Now, what have we actually been using the methodology for? Well, for inert ingredients, decision documents that we have generated using the methodology, we used to establish tolerance exemptions for ethyl and butyl actate. That was published in the Federal Register and that document -- the decision document actually was put in Edockets.

We also used this for tolerance reassessment for the deadline last August. Approximately 450 chemicals went through the workgroup and were done with this methodology. At the same time that we were doing tolerance reassessment, we did the list reclassifications, our confirmations on them. Of those 450, approximately 100 of them went to List 4A and the rest of them, approximately 350, went to List 4B.

Now, for active ingredients, we had done -- for one of the chemicals that came through the focus group, a Section 3 registration has been done based on the document that the group generated. We have also looked for the basis of a RED or a TRED, propyonic acid (phonetic), urea (phonetic) and 4-CPA (phonetic), the decision documents, again, that were generated through

the group were the basis of these decisions.

For tolerance reassessment, we also looked at metheprine. Metheprine was actually the first screening quantitative risk assessment that this group performed. And it was done, again, for the deadline in August.

Now, as I said, we did release the methodology last June. The comment period closed on October 11th. We received 12 sets of comments. Trade organizations, companies, public interest groups and then one government entity were actually, you know, the classifications of those who comments. But actually, more than just 12 groups commented on it because in many cases the comments were signed by more than one company or organization. Overall, the response was positive.

Now, the comments have been organized and grouped and we've come up with about 60 comments that are currently, you know, being addressed, responses are being prepared. There will be changes to the methodology. It will be both as a result of the comments received and it will be, also, as a result of the knowledge that we've gained from actually using the methodology. But I'd also like to emphasize the changes that are being made are

still very, very consistent with what the original methodology that was published last June were. A lot of the changes are to provide increased clarification, additional knowledge that we can provide based on our experience now.

And so, the next steps are to complete the revisions and then to release the revised methodology. Our intent is to release it by the end of the year and then, also, we're going to continue with both using and developing the methodology at the same time. Most of our experience has been with a qualitative assessment. Right now, we're focusing on the screening quantitative assessments.

Any questions?

MS. LINDSAY: Let's do the last sort of update item and then we can see if there are questions across the board.

The last item actually deals with a set of data compensation as it applies to inert ingredients in particular. There's a provision of the Food Quality Protection Act, 408(I), that basically provides the data submitted to EPA for tolerance or exemption from

tolerances are entitled to data compensation and exclusive use to the same extent provided by Section 3 of FIFRA for active ingredients. So, I've taken to calling this the data comp for inerts.

We are publishing -- and I've actually got a publication date, it will be published tomorrow in the Federal Register -- a proposal soliciting comment on a proposed data compensation program for inert ingredients. And I'll leave you to actually read the Federal Register, but in essence, it picks up on some earlier proposals. We had come out with three options for how to interpret 408(I). One of the options basically said we should try to make this as much like the existing data compensation program that we have in place for active ingredients. So, that's largely what we're proposing.

We had some earlier stakeholder interaction last fall where we essentially, I think, shared our basic ideas. There have been some revisions since then, but, I think, in essence, that basically what we shared last fall with interested stakeholders is very close to what is actually being published tomorrow.

So, it will include data protections for studies

submitted to support tolerance actions, mechanisms for data compensation and exclusive use rights would allow tolerance data submitters to list studies seeking data compensation on our data submitters list. This is where the active ingredients go. 10G protections would be afforded to the data, as much like the existing program as we can make it. And it's got a 90-day comment period. So, there will be plenty of time to talk about it and I know that there are some opportunities already planned for further public discussion. So, those are the three updates on different inert ingredient activities.

Do we have time for a few questions, Jim? Shelley, I think you were first up.

MS. DAVIS: Shelley Davis, Farmworker Justice Fund. Well, I had the pleasure of being part of the workgroup, along with several of you here. Having spent about two years on this issue of what inert ingredient information should be released, I feel a little disappointed in where we are now because I really do think that the process, at least, underscored the importance of this information to a variety of stakeholders. That, for the most part, it really is not

available to people when they need it. And that voluntariness is not going to get us where we need to go.

At least on the medical side, which I think you're right, there was a lot of consensus that there's one thing that's probably the most important, that probably is it. Companies have had the ability to voluntarily disclose this information to poison control databases and they have not uniformly done so. And so, if they haven't uniformly done so in the area where there's the greatest consensus that it's absolutely essential, I don't -- I can't say that I'm too optimistic about anything else happening in any kind of consistent way.

And then I guess I just have to go back to where I saw this process because I think I came to it with not a great deal of knowledge and just kind of listened to what was going on. And I don't think the issues got too much narrowed. I think that although relatively early in the process companies said that there was a relatively small, discrete set of information that was trade secret in their view, it could never be defined as anything other than everything essentially, other than everything

except words of absolutely no value like fragrance and dye.

So, I mean, this, to me, really does come down to a place where the agency needs to take leadership, it needs to resolve this issue, not every issue involving FIFRA needs to go on for 20 years. And this one is ripe for really moving forward. And I guess my reaction to this update is that we've just agreed to sweep this under the rug, essentially, for another decade and another time. And I think we really could do better than that. And I guess I would like the PPDC to have another go at it and bring this to a resolution.

MS. LINDSAY: Thank you, Shelley. Julie?

MS. SPAGNOLI: I have some comments on both the disclosure and the methodology. I guess I'll start with the disclosure. I think there's still a couple of policy issues that -- and I don't know what the agency has done in trying to address these, but have caused, I guess, some hurdles in the voluntary disclosure and I think one of them was terminology or nomenclature and I think you addressed that. That until we really have some clear cut names and terminology that's universally accepted, it

1 does make for some difficulty for voluntary disclosure.
2 The second issue -- and this is one that we've
3 come up with -- is how to deal with alternate formulas.
4 And this could -- you know, whether it be done -- that
5 you have a terminology that's general enough to cover the
6 alternate formulas or whether alternate labels for
7 alternate formulas could be approved. Right now, it's
8 kind of limited in that technically an alternate formula
9 has to have the same labeling as the basic formula. And
10 whether there's some room there to make some kind of --
11 if you have an alternate formula and you're disclosing
12 ingredients, you can have an alternate label specific to
13 that alternate formula. I think that's one policy area
14 that needs to be looked at.
15 Let's see, I have one other issue. I'm trying
16 to -- oh, the last issue on it is, I think from -- and
17 this is one of the problems that we ran into, especially
18 if you get into -- you know, if you're really -- some
19 states are looking at it quite literally, as we ran into
20 with California, requiring ingredient statements on the
21 front panel. And if you get into a full disclosure of
22 all ingredients, that is definitely a problem. And,

also, I think from an incentive standpoint for registrants, especially of consumer products, to be able to put their full ingredient statement somewhere else other than the front panel would definitely create some incentive.

So, I think, again, that's one of the little policy barriers that could help facilitate getting more participation in voluntary disclosure.

I guess I just had one question on the -- I really commend the agency on their methodology. I think that's one of the best things they've done as far as tackling a very big problem and doing it in a very common sense way. But a question I have is, for new ingredients -- and this would not be necessarily a new tolerance exemption, just a new inert ingredients, how could this methodology be utilized and could a registrant basically use this methodology as a basis for requesting the use of a new active ingredient -- or not a new active ingredient, a new inert ingredient in a new formulation if it's not an inert that's currently used, but based on its similarity to an existing inert or some basis. Is there provisions in the process or in the methodology for

utilizing it in that way?

CATHERINE: Well, I'm assuming you're asking about non-food uses.

MS. SPAGNOLI: Correct. For a new -- not asking for a tolerance exemption, but just to utilize a new inert in, let's say, a consumer formulation.

CATHERINE: Essentially, actually, we just completed an action for one company. They wanted to use an inert ingredient in a non-food formulation and what they essentially did was they prepared a toxicity profile for us. The profile ran to about four pages and they just laid out what was in their possession and what they were able to find on the Internet and we just looked at it and did a little work on the Internet ourselves and then based on that, plus the use pattern that they wanted, we were able to say, you know, fine and approve it.

MS. LINDSAY: Okay. It looks like there are no specific comments. I've been reflecting, Shelley, about what you said and I guess my -- the other thought that I wanted to communicate about the voluntary disclosure is I think there are many ways that you can set up voluntary

programs of any kind, whether you're talking about inerts disclosure or the agency has a whole raft of voluntary programs. And part of it, I think, really depends on the level of energy that the agency itself puts into it as well as the incentives that are either there or can be found to be there by dint of paying attention to it.

And it's, at least, my hope right now that we'll be able to put together an approach to voluntary disclosure that has some real energy around it. But that was why I was also suggesting that I think we need to include in that some mechanism for evaluating success of a voluntary disclosure program, so there's an opportunity to come back and an appropriate point in time and to have everyone at a -- whether it's at a FACA committee like this or a -- I don't know, a future FACA committee and actually be able to judge, has the voluntary program really had an impact and a valuable impact and has it met what people believe the needs are or is there something that the voluntary program just has not come to grips with.

So, I think our intention is to make this a serious effort and not one of those, oh, yeah, you can do

it if you feel like it and then we all sort of walk away from it.

Sorry. Jay?

MR. VROOM: I had a couple of other points, but I think what you just said makes sense from my perspective, that it would be useful rather than continuing to have the issue of disclosure be a point of contention, to come back and understand what are the problems or anticipated problems in categories or specifics that may be the result of the remaining disclosure concerns in the community and then address it from that angle rather than just have this continue to e an open-ended issue for which, as Shelley, I think very correctly pointed out, seems to have no end. I would be curious to have a look at it from a problem-based area.

Two sort of sub-category areas of inerts that I'm kind of curious about are in the area of products that we would refer to in the trade as agivents (phonetic) that are designed to make the active ingredient formulation perform differently, preferably better for the customer, and also products that are additive inert ingredients that are designed to control

drift or are marketed that way. I'm curious to kind of know how the agency tracks both of those categories of inerts and their marketing claims and the degree of problems that may be indicated by way of state enforcement actions or complaints and that kind of thing, and is that a topic for some additional debate and discussion and advice from PPDC in the future?

CATHERINE: Well, agivents, we don't regulate at the agency. We do look at -- manufacturers who make an agivents, they do send us many times their formulation with a listing of what's in it. Essentially, we tell them whether or not -- they have a tolerance exemption for every one of the components of the formulation. After that, we have no contact with them.

MR. VROOM: And the same for products sold to control drift as additives?

CATHERINE: Again, if they would give us the formulation we'd tell them if they have a tolerance exemption for every component in it or not.

MR. VROOM: Okay. So, what about complaints or enforcement actions that the states might experience? Any tabulation on that or --

MS. LINDSAY: I'm not aware that there's an existent one. I was looking over at Phil and he's kind of -- I mean, I think because we don't directly regulate these products, since they're used after the product itself is formulated.

MR. VROOM: Right.

MS. LINDSAY: The level of knowledge is low. That might be a fair description of it.

MR. VROOM: Well, obviously, clearly I'm advocating --

MS. LINDSAY: I guess I would say, if you're seeing issues there, it would be interesting to understand better what issues you're seeing and then whether it became a topic for future discussion here or something else. But you may be seeing something from the industry perspective that we're not seeing.

MR. VROOM: Well, clearly, it's a trend in terms of the greater refinement of the product end use, both by manufacturers of active ingredients and formulated products, as well as others in the distribution chain who see market opportunities and are selling products that have some commercial benefit and either are performing

1 according to the claim or not.
2 And I'm not advocating that any of this be a
3 candidate for federal regulation or state regulation, but
4 it seems to me that there are some real significant
5 advances in science and commerce here that do relate
6 ultimately to a lot of the issues that we've already
7 talked about here today.
8 MS. LINDSAY: Okay. Shelley?
9 MS. DAVIS: First of all, I'm very glad to hear
10 you say that you're interested in working on a common
11 nomenclature because that does seem like a problem that's
12 resolvable, that everyone agreed was out there and might
13 help move the ball forward. So, I commend you for doing
14 that. I think that would be great.
15 But I've got to say I don't think that's enough.
16 I would certainly hope that you would be able to use your
17 existing authority to make this information available to
18 poison control centers. With that said, I don't think
19 that will be enough. I don't think that we can avoid the
20 problem or disclosure because we live in a world now
21 where many people go to an HMO or their own doctor and
22 are seen in six minutes and, trust me, in that period of

time, they're not going to get down to finding out the inert ingredients in the product. So, people have to be informed consumers and users and that means information has to be disclosed.

In the course of this workgroup process, we heard from other agencies, not only OSHA, through their material data sheet program, that if the agency takes an aggressive attitude toward -- and I would say -- aggressive is not the right word, a healthy skepticism towards claims of confidentiality, that it's amazing how many of them disappear. And that's what's not -- that's at least one element that's been lacking here at the EPA, that these claims are just accepted. In fact, it's presumed unless somebody really fights it and then ultimately it gets resolved.

But that puts -- what that means is that the public is the loser, which seems kind of a silly way to operate. And that means that people who have problems end up without the information that they need. So, I guess what I would like to see if, you know, you want some time to do voluntary stuff, okay. Let's make it a specified time, one year. And during that time period,

let's see what you can really do to get all three realms really moved forward. And if at the end of a year they really aren't, then I would say, you know, you really are faced with a rule-making situation. You know, this problem will not go away. And I would like you to act on it.

MS. LINDSAY: I think there's great value to setting deadlines and asking yourself at that point what you've accomplished.

Steve?

MR. KELLNER: I just want to echo the fact that I served on that committee, too. It was a tough one. I think it's a little unfair to say that the agency is not doing what it should be doing because of the statutory authority and the limitations thereof. That was all taken under consideration during this whole debate and I think there's been good faith efforts here on the part of virtually everybody. I don't think Shelley is going to be satisfied. She basically just said it. It's never enough.

I think the industry put its good faith together to try to come up with something and I think it should be

given a chance. I think that you're on target with where you're going with it and we'll just see what happens.

MS. LINDSAY: Okay. I think, Steve, you may have closed out the inerts discussion. You've had the last word for the afternoon.

MR. JONES: Thanks, Anne. I think we have one public commenter. Caroline Keeney, is that -- is Caroline here?

(No response.)

MR. JONES: Okay. So, perhaps we have no public commenters.

That being said, I think that we're ready to wrap up for today. We were off to, not necessarily, a slow start, but for a while there it looked like we weren't going to make it through the day before 6:00 or 7:00, but we caught up nicely.

I want to thank all of you for all of the great participation that you brought to this meeting today and the good advice that you've provided to the agency, and we'll be right back at it tomorrow morning at 9:00 a.m. See you then.

(The meeting was adjourned.)

CERTIFICATE OF TRANSCRIPTIONIST

I, Diane Quade, do hereby certify that the

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DIANE QUADE

Transcriptionist

1 Day Two

2 April 17, 2003

3 **PROCEEDINGS**

4 - - - - -

5 JIM JONES: Okay, we are starting right now. I
6 thought we had a good session yesterday. I think today's
7 is going to be up to matching it in terms of content as
8 well as dialogue. We're going to start this morning with
9 a topic that we think will provoke a lot of interest and,
10 hopefully, some feedback to the agency on next steps, and
11 that is improving mosquito control labeling.
12 Jim Roelofs from the Field and External Affairs
13 Division is going to lead a panel discussion on this and
14 then we will have some time -- I think a meaningful
15 amount of time to hear from the members of the PPDC.
16 Then we're going to have a session where we are
17 following up again on a previous PPDC discussion around
18 adoption of biopesticides, and then something that has
19 become somewhat of a PPDC regular, and that is, updating
20 the Committee on where we are on two of our core
21 programs, registration and reregistration tolerance
22 reassessment. And, hopefully, you all have been spending

1 some time thinking about agenda planning for our next
2 meeting. I think, actually, at yesterday's session, we
3 got a couple of ideas already floated and we'll spend
4 some time doing some agenda planning for our next
5 session.
6 So, with -- and, again, for those in the
7 audience, we do have some time reserved at the end of the
8 meeting for public comment. If you would like to make a
9 public comment, please reserve it until that time in our
10 agenda, and Margie Fehrenbach, who is out of the room
11 right now, but sits right in that corner, if you would
12 let her know and I'll remind you later on, let her know
13 if you have any public comments.
14 So, with no further ado, Jim is going to lead us
15 off.
16 MR. ROELOFS: Good morning, my name is Jim
17 Roelofs and my normal job with the Office of Pesticide
18 Programs is to deal with the Association of American
19 Pesticide Control Officials, our state lead agencies and
20 their working committee, specifically SFIREG , but I also
21 get involved in some regional work, which is what
22 happened. That's how I ended up here.

1 I helped to coordinate the workgroup, an ad hoc
2 workgroup, which I'll talk more about in a moment, that
3 put together the recommendations that we're discussing
4 here today, and I stitched together, from the workgroup's
5 comments, the recommendations, which are summarized in a
6 one-pager and also the talkier version, which tries to
7 put some context around those recommendations.
8 A few words about where these came from. It's
9 explained in the issue paper, but it's worth saying
10 briefly, in 2001, EPA's Region 2 Office in New York held
11 what they called an inter-regional mosquito control
12 conference and, of course, at that time, it was very
13 heavily driven by West Nile Virus concerns and their
14 first year of experience in planning and trying to deal
15 with that. And it was attended primarily by EPA
16 headquarters, regions and by state agencies, almost
17 entirely from the East Coast and the Southeast.
18 Many things were discussed at this conference.
19 Much information was exchanged. But one of the recurring
20 themes that kept coming out from the participants in the
21 audience was that labeling of mosquito control products
22 seem problematic in various ways. And so, by popular

1 demand, as it were, at the end of that conference, an ad
2 hoc group was put together to develop some
3 recommendations. And I want to -- well, let me just
4 briefly say there were five state representatives, two
5 regional office EPA, seven people from the Office of
6 Pesticide Programs and one from the Office of Enforcement
7 and Compliance Assurance.
8 Now, we had no specific project other than to
9 identify recurring problems, generic problems, if you
10 will, and to suggest some improvements as discussion
11 starters for a wider audience. And that is really what
12 we're doing here today, is starting a discussion with a
13 wider audience because we recognize perfectly well, there
14 are many stakeholders in mosquito control. Certainly
15 registrants, because we're talking about their labels.
16 Certainly vector control agencies, who weren't really
17 involved in the workgroup directly. The public itself,
18 because these are literally wide area public pest control
19 programs.
20 So, we have come up with some questions. We
21 generally have no specific plans, as far as the agency is
22 concerned, as to what to do next. That is what we are

1 asking you.
2 Kevin, if you could put up those questions.
3 Pretty straightforward. We're asking for
4 discussion and comment today on the recommendations we
5 put before you and we want to know what other
6 stakeholders we might be needing to involve and how to do
7 it. And most important of all, what is a practical next
8 step forward? Who would be involved? How would we
9 proceed?
10 Before we kick off the discussion, I want to
11 clarify several points. I've had phone calls about what
12 we were talking about that indicated some
13 misunderstandings. For one thing, we're only talking
14 about adulticides. Mosquito larvicides represent a
15 completely different use pattern and we decided early on
16 not to deal with them. The people at that regional
17 conference were most concerned about the aerial or ground
18 applied, ultra low volume adulticide products, and this
19 is a very high profile use pattern for obvious reasons.
20 It's almost a unique application. It's one of the very
21 few that I know of, maybe the only, that tries to kill a
22 pest, literally on the wing. It's also routinely used in

1 residential areas, so it's very visible to the public.
2 These products are designed to disperse over a
3 wide area, which means that there's both human and
4 environmental exposure concerns that are raised about
5 them, even though they are ultra low volume, which means
6 only a couple ounces of active per acre. But I'm sure
7 we'll discuss that more as we go along. So, those are
8 the products that we're primarily looking at.
9 Secondly, I want to emphasize, especially for
10 the registrants that are here, that this was not a
11 systematic review of labels. We were not trying to zero
12 in on specific problems and solve them. We were trying
13 to zero in on generic problems and make generic
14 recommendations. So, we're not picking on any particular
15 product or active ingredient as being a problem. After
16 all, if there's a problem here, it's, at least, partly
17 ours. EPA approved all of these labels with all of their
18 flaws. So, let's be clear that these are generic-type
19 recommendations.
20 Finally, before we start our discussion, let's
21 say that we are all well aware that there are other
22 issues looming over pesticide control and some of them

1 include mosquito control, such as the NPDES issue or,
2 more generally, the intersection of FIFRA and the Clean
3 Water Act. There are court cases involving this, there
4 are petitions before the agency. There is high-level
5 activity within the agency about how to -- what these
6 policies should be, how that interaction should work, and
7 all of those things are way beyond what this workgroup
8 can deal with.
9 So, we're really not -- we don't want this
10 discussion to go down the road of talking about stuff
11 that's unresolved and I think at a higher level of
12 generality than this type of problem. If the NPDES
13 decision was solved tomorrow, there would still be
14 unclear labels out there that need to be fixed.
15 Now, the procedure I have in mind, we have a
16 panel that tries to represent many different points of
17 view. I'm going to let the members introduce themselves
18 as it -- but they will -- we will go in the order that
19 they appear in the agenda. I have asked them to do about
20 five minutes, no more than 10 minutes, to explain their
21 perspective on these issues and I would ask that you hold
22 your questions until the panelists have made their

1 presentations. Then we'll have questions and open it up
2 for a discussion.
3 And I do want to be sure that -- I may break in
4 at some point as we approach the end. We really do want
5 advice about the next steps forward. I've asked that --
6 several of the people on the panel were members of the
7 workgroup, including the first two speakers, and I've
8 asked -- we thought that Kevin Sweeney from our
9 registration division would help to set the context in
10 which these recommendations were developed by describing
11 sort of the current situation. So, Kevin, if you will
12 start us off.
13 MR. SWEENEY: Good morning. My name is Kevin
14 Sweeney. I'm a Senior Entomologist with the Registration
15 Division in the Office of Pesticide Programs, and as part
16 of my duties at OPP, I'm responsible for reviewing a lot
17 of the data that comes in for product performance, for
18 public health uses and other uses, for reregistration and
19 registration. I'm also involved, quite often, with the
20 experimental design of a lot of the testing protocols
21 that are submitted to the agency for evaluation.
22 Then, lastly, I'm also involved with West Nile

1 Virus issues, insect repellent registration, a number of
2 PSP issues and some of the DoD mosquito and tick-born
3 disease committees.
4 So, in that context, I'll discuss the historical
5 perspectives that sort of help bring us to where we are
6 in brief. I think Jim did a pretty good job of giving
7 the generalities there. First of all, I think the one
8 thing that has probably led to some of the
9 inconsistencies that we've had is that we generally
10 haven't regulated these products as a class of products.
11 In other words, when we do labeling for these or approve
12 labeling by amendment or even for new registrations, we
13 don't look at these generally as a class or haven't. We
14 generally approve the labels individually over many years
15 and amendments are approved individually at the request
16 of the registrants.
17 And we have a situation, also, that's developed
18 over the years where we see mixed labeling, where we have
19 agricultural and mosquito control application uses on the
20 same label. So, as a result, you have crop and non-crop
21 uses and food and non-food uses on the same labeling.
22 And then to confuse the matter a little bit

1 more, we also have some labels that are mosquito control
2 only.
3 Some of the issues today, of course, we've
4 already laid those out in the position papers.
5 Recommendation number one discusses the restricted use
6 issue or other means to limit the users of mosquito
7 adulticide products. Recommendation numbers two and
8 three, we're looking at mosquito control only versus
9 mixed labeling issues. For number four, spraying near or
10 over water, which has been a very controversial
11 interpretation.
12 And then for four and five covers
13 recommendations for environmental hazard statements or
14 how to deal with those recommendations on mosquito
15 control only or mixed labeling. Also, referrals for
16 state agencies as far as knowing where sensitive habitats
17 lie within states, and then lastly, a brief discussion of
18 the improvements of directions for use. Since the
19 directions for use vary from label to label, some being
20 quite detailed, others being very general. And there's
21 also enforcement issues related to that topic.
22 Generally, with fogging, mosquito adulticiding,

1 of course, represents a different situation than we have
2 with agriculture applications or even agriculture area
3 applications in that we want the fogs that are applied to
4 disperse over wide areas as their target, compared to the
5 usual paradigm where the intent of such an application
6 would conflict with the applications to narrowly defined
7 sites like crop lands, where we want minimal dispersal,
8 we want it at the target and we don't want it to leave
9 the target area.
10 Just some of the language or some examples of
11 language that have been used as typically use limitations
12 are, statements like do not apply directly to water,
13 avoid drift and run-off, do not apply within X feet,
14 generally, of a water body and some of the labels name an
15 exact distance of, say, 100 feet. You see those in
16 permethrin labels. And then other limitations include
17 wind conditions and other temperature conditions,
18 temperate inversions. And then there's also some
19 statements on there related to not contaminating water
20 when cleaning equipment, when very often these
21 applications are made near water bodies or could disperse
22 over water.

1 Just to give some examples, and to go back to
2 what Jim said, we're not picking on any labels here, we
3 just wanted to give an examples of some language, and
4 this is discussed in the recommendations and in the
5 narrative as well. For instance, on the Naled labels we
6 have a statement that says, do not apply directly to
7 water except when used over water for adult mosquito,
8 black fly or housefly control. And that's pretty much
9 similar to the recommendation number four that we have
10 here, although we modified it to be more applicable to
11 the number of labels.
12 When we look at some of the Resmethrin, for
13 instance, in the directions for use, there's a statement
14 that says, avoid direct application over lakes, ponds and
15 streams. And, of course, this is in conflict, for
16 instance, with the Naled label and some of the other
17 labels, and even when you look at ground applied ULV,
18 there's also a lot of confusion sometimes as to whether
19 or not -- if there's any dispersal or drift from that ULV
20 application, whether or not it really constitutes a
21 direct application over water, including lakes, ponds and
22 streams. So, these are some of the confusion that's

1 evolved from these labels and that we want to address in
2 these recommendations and in the discussion today.
3 Another point of confusion very often is the
4 referral statement for consultation. Some labels refer
5 to federal and state agencies, other labels have no
6 consultation statements and some refer to state only.
7 And in recommendation number six, we've proposed having
8 the referral be the state agency which would be most
9 familiar with the sensitive habitats within the state,
10 and very often, some states actually require permitting
11 on their own. I know Maryland does and others. But on a
12 more local basis, they can probably better look at where
13 the sensitive habitats are for endangered species or
14 other -- for instance, shellfish, et cetera.
15 And then, finally, with the directions for use,
16 the labels are -- there's a lot of variation on these
17 various subjects. For instance, calibration methods are
18 mentioned on some labels and not on others. Droplet size
19 determination is discussed on some labels but not on
20 others and it may differ from one label to another. Very
21 often, you'll see either VMD which is volume median
22 diameter or mass median diameter values given on mosquito

1 control labels when most of the industry and most of the
2 nozzles are really designed or at least sold with VMD
3 values on them. Mosquito control labels are really the
4 only ones that have retained MMD.
5 Another thing that varies is droplet size range
6 and distribution. For instance, you can have a VMD value
7 on a label, but that may not necessarily give you a
8 distribution of droplets that would result in an
9 efficacious mosquito application. I think some of the
10 very early labels that were approved for mosquito control
11 did have droplet distributions in the lower micron
12 ranges, say 6 to 18, that provided the most efficacious
13 mosquito control application because it resulted in
14 impingement on the mosquitos themselves.
15 Another point of discussion, we've discussed
16 this with the applicators, are the flow rates as well as
17 the registrants. And then, also, whether or not it's
18 applicable in some cases to mention pressure values for
19 certain machinery, as well as the revolution's permitted
20 values.
21 With aerial applications, again, the directions
22 here vary somewhat and I think what we're recommending is

1 that we see more specific directions to ensure efficacy
2 of application and also enforcement capability. I think
3 there's been a lot of discussion with a number of the
4 states, as well as the federal agencies, about the
5 ability to enforce some of this language on the labels if
6 it's very, very general.
7 And then, also, a mention of calibration methods
8 to be used to validate the nozzles and droplet sizes on
9 the aircraft and probably state when it's needed on a
10 seasonal basis. Of course, that's going to depend on how
11 much spraying you do.
12 Now, one other thing I wanted to mention was
13 that the American Mosquito Control Association has come
14 up with a proposal to use the Pesticide Environmental
15 Stewardship Program as a means for providing information
16 and input into this process on labels, in light of the
17 pesticide reduction scheme for the strategy.
18 So, that's all I have.
19 MR. ROELOFS: Thank you, Kevin. Next, we'll
20 hear from Mary Ellen Setting, who is also a member of
21 this workgroup. Mary Ellen?
22 MS. SETTING: Thanks, Jim. Good morning. I'm

1 Mary Ellen Setting. I'm Chief of the Pesticide
2 Regulation Section, Maryland Department of Agriculture.
3 As such, we're the lead agency regulating pesticides in
4 the state. And I wanted to give you some additional
5 background on how this came about and then a perspective
6 from a regulatory agency on these recommendations.
7 In the fall of 1999 when Hurricane Floyd came
8 through, many states experienced severe mosquito
9 outbreaks. New York City was experiencing West Nile
10 Virus. So, mosquito control programs started to kind of
11 ratchet up and get in gear a lot more than they had been
12 maybe in the past, and also, it became a lot more visible
13 to the general public.
14 As a result, we were getting questions from
15 applicators and members of the public on the use of these
16 particular products and the availability of them to be
17 used near water, as Kevin pointed out. As we started to
18 look at the labels and try to provide guidance to
19 applicators and members of the public and try to
20 interpret the labels, we realized we were having
21 difficulty ourselves. So, many at the state wrote to EPA
22 regions and headquarters and asked for interpretations of

1 the label directions when we received those. But then we
2 felt that wasn't really appropriate, that we would need
3 to have written interpretations of label directions that
4 should, in themselves, define exactly how a material
5 should be used.
6 So, state brought this issue to EPA through
7 SFIREG and asked that this become put on their plate of
8 an issue to deal with, and that's sort of how the
9 workgroup that was convened in New Jersey came about.
10 Once the workgroup started to put a plan
11 together, we decided to look at all the predominantly
12 used adulticide products and put a list of about 12
13 products, about 7 active ingredients, and just reviewed
14 those labels to decide what we thought was good language
15 and bad language in terms of what was easy to understand
16 and what was enforceable, and as a result of that, put
17 together the recommendations that you have before you.
18 That took about two years to put together, going
19 back and forth and getting input between the states and
20 EPA and we think we've got a pretty good set of
21 recommendations put together.
22 From the enforcement standpoint, the regulatory

1 agencies are trying to be sure that applicators are
2 confident and know what they're doing, and one reason we
3 hold them accountable to doing that is to require them to
4 follow the label directions. And we also provide
5 guidance on those label directions. But the label
6 directions also have to be easy to understand and be
7 protective of the resources they're trying to protect, be
8 effective, but also be able to be enforced and be used in
9 an appropriate manner.
10 So, that was part of what our biggest concern
11 was, the issues that Kevin pointed out, that labels were
12 all over the board, applicators were trying to look at
13 these label directions and pick out which products would
14 work for them just because -- so that those that they
15 could understand more easily, they would use. And we
16 were having trouble consistently enforcing the label
17 directions as well. So, we put the plea to EPA to try to
18 put a fix to this and that’s where we are today.
19 As far as some of the recommendations, I just
20 want to go through a couple of those. The one about --
21 the first one about possibly limiting the use of these
22 materials to certified applicators by restricting them.

1 We understand that the restricted use classification,
2 there are some concerns with that, some issues with
3 making it a voluntary process. But we wanted to make
4 sure that the individuals that were using these materials
5 were trained to use them, were aware of the precautions
6 that would be needed and wanted to make sure that there
7 was a process in place to make that happen.
8 Many states do not have the authority to certify
9 an applicator unless the product is a restricted use
10 product. Some states can have state restricted products,
11 but an alternative to a restricted use classification
12 would be the other proposal given in that the label would
13 state that the use of that product would be limited to an
14 individual who is certified to apply it under a mosquito
15 control or public health program, something that would
16 tie it to a group of applicators that we could identify,
17 and in that case, states that could only certify
18 individuals using restricted use would also be able to
19 certify these individuals. So, we were just trying to
20 make sure that individuals knew what they doing there and
21 that we kind of had a handle on that group of people.
22 The issue that Kevin mentioned about separate

1 mosquito control directions from -- label directions for
2 ag use, the one product we looked at was a Malathion
3 product and some of the ag precautions, like the
4 restricted entry intervals, individuals were calling us
5 up and trying to use the worker protection statements to
6 prohibit applicators from using products in residential
7 areas, and it was very difficult to explain to those
8 individuals that that these were was separate directions,
9 and it's just difficult to explain to people that there
10 are separate enforcement issues there. So, the need for
11 that either clearly on the label, that the directions are
12 for one use or the other, would be one option, or
13 preferably separate labels altogether.
14 And the label language that we came up with for
15 allowing the use of these materials over or near water,
16 which came about by looking at many of the labels that we
17 reviewed, and we're trying to recognize that the actual
18 method of mosquito control programs and how you need to
19 be able to use these materials near or over water
20 sources, but also to include some protection for aquatic
21 organisms.
22 And a lot of the statements are very vague there

1 as to what type of aquatic organisms you are being
2 protective of. So, we're looking for more specific
3 information on the exact species that you need to be
4 worried about during these applications.
5 And then the other statement about consulting a
6 state agency, again, the labels vary quite a bit. They
7 sometimes refer you to the state agency responsible for
8 protecting endangered species or the fish and wildlife
9 agency, and we felt that since the applicators are
10 familiar with the agency responsible for regulating
11 pesticides, they should go there first because these
12 agencies also would know what other agencies in their
13 state would have additional requirements for permits.
14 And with that, I'll turn it over to the next
15 speaker.
16 MR. ROELOFS: Thank you. And our next speaker
17 is from a Vector Control Program also in the State of
18 Maryland, Cy.
19 MR. LESSER: Thank you, Jim. My name is Cy
20 Lesser. I'm the Chief of the Mosquito Control Section
21 with the Maryland Department of Agriculture. I've been
22 with MDA for 27 years. Prior to that, I had experience

1 in the States of New Jersey and Delaware, also in
2 mosquito control.
3 We operate a cooperative program for mosquito
4 control in the state that interacts with 22 Maryland
5 county governments, plus the City of Baltimore.
6 Approximately 1,700 communities in the state voluntarily
7 participate in mosquito control services.
8 As a mosquito control professional, I've seen a
9 lot of changes in our business over the decades. Some of
10 the recent changes since 1999, as Mary Ellen referred to
11 earlier, with the increased awareness and attentiveness
12 to mosquito control products and techniques as a result
13 of West Nile Virus. Some have been very good. Some are
14 suspect as far as motivation.
15 I am very concerned that we're seeing a trend of
16 fewer products available for public health, vector
17 control for mosquito control. We were encouraged in 1996
18 when FIFRA was reauthorized that the presence of
19 mosquitos, just the presence could be considered a public
20 health hazard without the actual demonstration of human
21 disease or wildlife disease. We thought that was a step
22 in the right direction.

1 We are concerned, however, that other federal
2 laws make our job much more complicated. Also, in 1996,
3 the Clean Water Act, passed by Congress, required
4 pollution abatements. This led to creation of many
5 thousands of acres of artificial wetlands created for
6 stormwater management that are put in communities that
7 provide breeding sites for mosquitos. We also are
8 looking at more and more restrictions every year on where
9 vector control agencies in the United States are allowed
10 to conduct larval mosquito control. Certain state and
11 federal properties are off limits to local and state
12 mosquito control because of natural area characteristics,
13 endangered species, et cetera.
14 What we're seeing is an increase in habitat
15 where mosquitos are produced and increasing restrictions
16 on how we can reduce the larval populations. The bottom
17 line message I want to bring to you is that mosquito
18 adulticides, despite several disparaging references to
19 why they should not be used by certain environmental
20 groups, certain federal agencies, have been and will
21 continue to be an integral part of all or most all vector
22 control agencies in the U.S. dealing with mosquito

1 control, particularly when we're talking about protecting
2 public health from mosquito born disease. So, it's not
3 an issue that's going to go away. Mosquito adulticides
4 are essential.
5 We are very concerned about -- or I am very
6 concerned about discussions about placing all mosquito
7 adulticides as restricted use products. If the data is
8 there to show that they should be restricted use due to
9 environmental health or human health issues, then I am
10 all in favor of putting them on restricted use lists.
11 If, however, it's just a reaction to include all of those
12 products in that restricted use group, I am against it
13 without documentation.
14 The perception of our public, if you put a
15 product in a restricted use category, they logically
16 assume that if it was general use before, it's all of a
17 sudden restricted use. New data must have come forth to
18 make it seem as a more toxic product when, in essence,
19 what we're talking about here with the consideration of
20 moving them into RUP status does not reflect any new
21 data. It's a matter of almost a knee-jerk reaction to
22 put them in that group and make it easier for

1 enforcement. We're very much against -- I am very much
2 against that.
3 The questions that have been raised by Kevin and
4 addressed by Mary Ellen, we have additional -- we have
5 the same concerns at the user level. They were speaking
6 about regulatory level. Some of the labels that are
7 available now for mosquito control adulticides, they --
8 in ranking from best to worst from a user standpoint, I
9 would put the Naled labels in the best category. It's
10 well-defined. It's enforceable. The users know where
11 they can, where they can't use it. It's a good label.
12 The worst label, by far, in my opinion, are all of the
13 permethrin products that are labeled for mosquito
14 control. This also gets into the issue of, do we have
15 separate labels or do we have combined labels?
16 Permethrin can be used for agricultural products
17 and is one of the most widely used products in the U.S.
18 for agricultural. Apricots to zucchini, the whole
19 alphabet is covered. There are legitimate uses for
20 permethrin. When we get to the mosquito control label it
21 says, do not apply to crop areas. Now, how do you
22 justify that? You can put it out at 30 times the rate

1 for agricultural labels, but when it comes to the
2 mosquito control label, do not allow drift, do not apply
3 directly to crop land. It makes no sense.
4 It also has restrictions. You cannot treat
5 pasture lands or poultry ranges. Yet, permethrin is a
6 widely used insecticide labeled for lifestyle ecto-
7 parasite control directly applied to the animals at many,
8 many, many times the concentrations they would be exposed
9 to for mosquito control. So, frequently, in my
10 profession, we get calls from horse owners, they're
11 concerned about West Nile Virus, they're concerned about
12 Easterners, concerned about many diseases that affect
13 their animals transmitted by mosquitos. If we are using
14 Permethrin products to -- as an adulticide, we can't
15 treat their stables, their pasture land, their animals
16 that may be exposed to spray drift because it's not
17 allowed on the label.
18 Does it make any sense? Absolutely not. What's
19 the rationale for it? I've spent 10 years trying to
20 figure out why you can use it for one purpose at several
21 orders of magnitude higher, but not for mosquito control.
22 So, if anybody can explain that, I would be very, very

1 glad to listen.

2 The issue about water on mosquito control

3 adulticides, let me just put it on the bottom line. If

4 you're doing mosquito control and you don't have water in

5 the area you're treating, you probably don't have a

6 mosquito problem. Mosquitos need water. I mean, that's

7 the bottom line. Florida, the Eastern Seaboard, the

8 Coastal Plains, the Gulf Coast, they all have a common

9 denominator, low-lying areas, lots of standing water.

10 How do you define water on an EPA label? It

11 says water. Is that a five by ten pool that somebody has

12 in their backyard for a fish yard? Is it the Chesapeake

13 Bay, the Atlantic Ocean? Is it a roadside ditch?

14 They're all water. How do you -- you know, how do you

15 legally apply -- we hope that enforcement agencies have

16 common sense. When water means something, we interpret

17 it water means water bodies containing important aquatic

18 resources.

19 But if you take a strict interpretation where it

20 says do not apply or allow drift to water is virtually

21 impossible to use these products. There needs to be a

22 lot of attention paid to this language.

1 One other -- I know I'm running out of time,
2 Jim. One other issue, on the bee question, on the list
3 of issues that have been raised, bee toxicity is one of
4 the last. We have heard discussions about restricting
5 the applications of mosquito adulticides to times of day
6 when bee activity is non-existent. That primarily or
7 principally is the period between sunset and sunrise. A
8 couple of issues come up. If you're doing aerial
9 application, the Federal Aviation Administration
10 considers aerial spraying of pesticides, using an
11 aircraft as a vehicle to apply pesticides at low altitude
12 has a -- let me get the wording right -- a hazardous and
13 reckless activity which they are very well-founded. I
14 mean, you're flying at low altitude at high speeds and
15 their criteria is you only do that during daylight hours,
16 sunrise to sunset.
17 There are waivers possible for public agency
18 aircraft. Public agency aircraft does not mean an
19 airplane or a helicopter owned by a government agency.
20 FAA has its own definition for what a public agency
21 aircraft is and the one that we use in the State of
22 Maryland does not qualify for that. So, we are

1 prohibited by our controlling authority in Baltimore from
2 doing aerial application at night. Other counties, other
3 districts are able to do it, but only if they have a
4 public agency waiver.
5 So, again, there's a lot of things, if you
6 change labels, which seems like a minor and very common
7 sense change, it has unintended consequences down the
8 line. So, I ask that that be borne in mind. Thank you.
9 MR. ROELOFS: Thank you, Cy. Next, we will hear
10 from Adrian Krygsman from Bayer Crop Science.
11 MR. KRYGSMAN: Thank you, Cy. Good morning,
12 everybody. My name is Adrian Krygsman. I'm with Bayer
13 Environmental Science and I'm the Product -- Regulatory
14 Manager for the Professional Product Group. Bayer
15 Environmental Science is a worldwide leader in vector
16 control and we do have a number of the adulticides that
17 are being mentioned and discussed here this morning that
18 are registered by the U.S. EPA and we're here today to
19 comment as an industry representative on the state and
20 agency EPA recommendations that are being discussed.
21 As with all product labels, we understand and
22 recognize that product labeling improvement and

1 clarification is an ever green process. It's something
2 that just will never stop. And because of the high
3 profile of the mosquito adulticides that we currently
4 have registered, we have undertaken a program to modify
5 and improve and clarify the label language on a number of
6 our products. These are currently pending and have been
7 going through the process at the EPA and the effort that
8 we have undertaken is an effort to clarify the label
9 language, to make it more user-friendly and to address
10 and mitigate the risks involved with these products and
11 the environment.
12 In terms of the specific recommendations that
13 are being made by the EPA/Task Force/state agencies, we
14 believe and agree with a number of these recommendations;
15 that is, the separation of mosquito adulticide uses from
16 other product uses. We agree and encourage the
17 appropriate statements for the environmental hazards
18 section and that it be consistent with the scientific
19 data that is out there and available for these individual
20 products.
21 We also support the statement that was made as
22 far as the -- before making the first application in a

1 season, consultation with the state agency who has that
2 responsibility for addressing the regulation of
3 pesticides. And, finally, we are strongly in support of
4 the issue of updating and addressing the calibration of
5 the adulticides from the UOB standpoint.
6 With regards to some of the other
7 recommendations which we do have issue with, those
8 pertain to the issue of restricted use and, in many
9 cases, our comments mimic and mirror those that have been
10 mentioned previously. With regards to a voluntary
11 program for restricted use, we do not believe that this
12 will address the concerns addressed by the group. A
13 voluntary program will only lead to -- well, it will not
14 lead to a uniform consistent approach on labeling. As a
15 matter of fact, as was mentioned by Cy Lesser, there will
16 be a misinterpretation by the public as far as the safety
17 of that product, especially when it will be done
18 inconsistently.
19 There will be competitive advantages to those
20 products that are not labeled as restricted use and,
21 again, we don’t believe that this will serve the general
22 public.

1 If there is, we could support, as a company, the
2 mandatory classification of restricted use for all
3 products. However, this does cause problems to the end
4 users and small private applicators and we believe that
5 if this is a path that is undertaken, that there will be
6 federal funding necessary to address, number one, the
7 certification process and training for these small and
8 private applicators.
9 We do support the intention to modify the
10 language pertaining to the use over water. However, we
11 do believe that the whole issue of addressing water, as
12 you can see and hear over this morning's discussion, is a
13 greatly complicated issue. We do believe that scientific
14 data is currently available to address the application of
15 adulticides over water. We also believe that, as you've
16 heard, the whole issue of drift needs to be understood
17 and that is the area with regards to mosquito
18 adulticiding, is an area where you do encourage drift and
19 it's completely opposite and contrary to the notion of
20 agricultural drift.
21 But in order for all stakeholders involved in
22 this process to really understand the adulticide

1 applications, yes, it involves education, a continuing
2 education program. We think that the next step is the
3 creation of a workgroup, a task force to specifically
4 evaluate what's available out there, look at education,
5 outreach for this area, and to work up specific language
6 to address these concerns. With that, thank you.
7 MR. ROELOFS: Thank you. Next, we'll hear from
8 an actual member of the PPDC, which is why he's not
9 sitting up here at the front, and that's Adam Goldberg.
10 MR. GOLDBERG: Great, thanks. It seems like we
11 actually have a lot of agreement on this issue because I
12 don't have a whole lot of problems with what's
13 recommended here, either. So, it sounds like we're all
14 doing a lot of agreeing.
15 I think the first thing that I'd like to say is
16 that we would like to see the use of adulticides limited
17 as much as possible. Now, this doesn't mean that I
18 disagree with anything that Cy said, although I may have
19 some differences in degree. But it would certainly be
20 much more preferable to limit the use of adulticides as
21 much as we can to do other things and so on. So, I just
22 want to make sure that what we're doing here today or

1 these recommendations don't take the focus away from
2 trying to do other things as well, and I don't think that
3 they do, but I just wanted to bring that up as an issue.
4 And as I say, in general, we're supportive of
5 the recommendations. Our normal position in providing
6 more information is always good, and certainly, providing
7 more information that's more accurate and more detailed
8 would be good. So, for me, I think I want to actually
9 answer the questions, although I think the answers are
10 self-evident from every speaker.
11 We do think that the recommendations are useful
12 and reasonable. We do think that there should be
13 additional stakeholders asked for comment and input, and
14 perhaps, the next step for achieving improved labels
15 would be to implement these regulations. But I'd like to
16 talk a little bit more specifically about some of these
17 things.
18 One of the reasons we think that the
19 recommendations are generally good is that there are
20 certainly some public health concerns and providing more
21 accurate, more detailed labels will certainly help.
22 There have been a couple of studies recently linking some

1 of these products to Parkinson's Disease and some other
2 things, and Parkinson's has been linked to other
3 pesticides as well. So, labeling these products a little
4 more explicitly, I think, could lead to us being a little
5 more careful, number one. But, number two, lead to more
6 research, give us a little more guidance in the things
7 that we have to look at and do for human health. But
8 there's also, of course, the concern for animal health,
9 particularly aquatic species. So, these recommendations,
10 particularly with the more specificity, is really, you
11 know, very important and we support highly.
12 In terms of the specific recommendations, the
13 first recommendation about voluntarily classified, we
14 would prefer to see it be mandatory. I'm not sure that
15 the public would necessarily see this as some sort of a
16 step that -- well, they were safe and now we're
17 restricting them more so there's a problem here.
18 Obviously, people like us notice these sorts of things,
19 but I'm not sure it's an issue for the general public.
20 So, anything that we can do to be more health protective
21 would certainly be helpful and Adrian mentioned some
22 things that may have to be done if we move more towards

1 the direction that are in these recommendations or even
2 further, and perhaps we need to look at those things.
3 But we would certainly prefer to see something that's a
4 little more restricted so that there are tighter
5 controls.
6 On recommendations two and three, obviously, we
7 think it would be much better to have clearer labels when
8 you have a multi-use product because of the problems that
9 are mentioned earlier. So, I think definitely clearing
10 that up will help. I think some of the issues that Cy
11 raised are certainly a problem when the labels appear to
12 be contradictory. So, anything that we can do to help
13 that would be much appreciated.
14 And I would also agree that this is not the end
15 of the process. It really is an ever green process.
16 Whatever we do today to clear up these labels may look
17 good now, but will it look good five years from now, just
18 as when all of these labels were put in place in the
19 first place, you know, a process is created. But as we
20 do more, as we learn more, obviously, it's helpful to
21 continue to come back to the issue and readdress it as
22 necessary, but obviously, setting some good ground rules,

1 such as what's in here, will make that a lot easier in
2 the future, and in some respects, a lot less necessary.
3 So, in general, I would just say that we are
4 very supportive of the effort and anything that we can do
5 to make this much more clear; much less ad hoc is a good
6 thing and all of this guidance is very helpful.
7 Oh, and actually one other thing that Phil and I
8 were talking about just a couple of seconds ago about
9 drift, and as -- and I'll let Phil, later on if he wants,
10 expand on this, obviously, do so -- but he talked about
11 it in terms of the mosquito control not really being --
12 **(End of Tape 1, Side A.)**
13 MR. GOLDBERG: -- because of the way it's
14 applied, why it's applied, how it's -- how we want it to
15 act. And we had talked yesterday about the possibility
16 of doing a session in a future PPDC meeting about spray
17 drift, and it might not be a bad idea to add this issue
18 on. It may not be the same issue, but we are talking
19 about product drift. So, it might be helpful to also add
20 this in to get a clearer understanding of the nature of
21 the drift in this case as opposed to the nature of the
22 drift in the agricultural settings. Thank you.

1 MR. ROELOFS: Thank you. And our final panel
2 member is Dr. Gary Clark.
3 Sorry, Jack. Actually, Jack Neyland should be
4 next. I keep doing that.
5 MR. NEYLAN: He does that a lot actually. Well,
6 I guess we can blame Congress for us being in this fix
7 because if they hadn't amended FIFRA in 1972 and added
8 use inconsistent with the label, we wouldn't be around
9 here worrying about all this stuff, because prior to that
10 FIFRA was just a product compliance statute. So, all of
11 a sudden, in 1972, the label became the law and the label
12 language became very, very important. Thirty year later,
13 30 or so years later, here we are, still debating label
14 language and it's -- and I think for all those 30 years,
15 pretty much a very vexing problem for enforcement.
16 We get asked constantly, sometimes in the
17 context of enforcement of cases, sometimes just in the --
18 someone asking us a question about how would we interpret
19 label. I've been asked about how you would interpret
20 keep out of reach of children. Some people that means --
21 should be interpreted strictly, meaning that if you're in
22 the supermarket, everything would have to be somewhere up

1 there on the reach of an adult, not down on the floor.
2 So, all those pesticides ought to be off the floor,
3 probably not even at cart height because the kid can
4 reach in there. But that question has come up, that
5 label language, how would you interpret that?
6 Label language that says something like, don't
7 apply in coastal counties. Coastal counties, you know,
8 those waters, the Chesapeake Bay go up a long way and
9 cover a lot of counties in the State of Maryland.
10 Interesting one.
11 Here's one on several of the mosquito control
12 products, as well as a lot of others, do not breathe
13 vapor or spray mix. Some people would say that applies
14 to the applicator or should apply. That's trying to tell
15 the applicator be careful. But we've been asked, does
16 that mean that application is prohibited where anyone is
17 present that could breathe that vapor? So, label
18 language is pretty important from an enforcement context.
19 So, I guess I would say from a -- if we were to strictly
20 enforce most of the mosquito labels that are out there,
21 there wouldn't be any application of mosquitocides
22 because you can't apply these and not get them into

1 water. I mean, you're spraying over swamps and marshes
2 and so forth. While you may be directly spraying, or
3 directing sprays to vegetation, you tell me that
4 somebody's not going to get it in the water unless
5 they're standing with a handheld sprayer over top of a
6 piece of grass. It's just not going to happen.
7 Obviously, we don't like to have to deal with
8 this issue strictly through enforcement discretion, which
9 frankly is the way we are dealing with this. Mosquito
10 applications happen, pesticides get in water, we don't
11 take a lot of enforcement actions based on that because I
12 think you have to take somewhat of a pragmatic approach
13 to that and take enforcement where you see problems arise
14 from that, where you can demonstrate that the applicator
15 didn't use caution, where you have fish kills and things
16 that maybe demonstrate there's been over-application.
17 I looked at the recommendations of the panel. I
18 think, from my standpoint, they're some pretty good
19 recommendations. There are, perhaps, a few things that I
20 would change in terms of some of the language in some of
21 the suggested restrictions, particularly with respect to
22 trying to restrict the product to certain categories of

1 applicators. I think that might need to be a little more
2 tightened down. But generally, these are, I think, good
3 recommendations and I hope that the PPDC gives good
4 consideration to this and gives the agency some good
5 input.
6 With that, I'll turn it over.
7 MR. ROELOFS: Yeah, go ahead. Thank you, Jack.
8 Dr. Clark?
9 DR. CLARK: Once again, I'm the final speaker on
10 the panel, and as being the final speaker, I don't have
11 the last word because I understand there will be time for
12 public comment.
13 My name is Gary Clark. I'm with the Centers for
14 Disease Control and Prevention within the Division of
15 Vector Born Infectious Diseases. Our division is located
16 in Fort Collins, Colorado. Dr. Dwayne Gubler, who was
17 invited to attend, could not participate today and so he
18 asked me to come last night from San Juan and so I'm
19 here. He didn't ask me last night, he asked me to come
20 last week, but I came last night. I'm Chief of the
21 Dengue Fever Branch in San Juan. I've been there for 17
22 years. Prior to that, I was three years at USAMRIID up

1 in Fort Dietrich in Frederick, Maryland, six years with
2 the Illinois Department of Public Health in Chicago
3 working on arbo viruses and surveillance and control, and
4 I appreciate the invitation to be here today.
5 The Centers for Disease Control and Prevention
6 is not directly involved in mosquito control in the
7 United States. However, in this regard, we are more
8 involved in the surveillance of viral diseases of humans
9 that are transmitted by mosquitos, but we do provide
10 advice and consultation on mosquito control. We also
11 recognize the public health importance of mosquito
12 species that are nuisance or pest species and which are
13 not significant vectors of pathogens.
14 From our perspective, sustaining of mosquito
15 control in the United States relies on the state, county,
16 local and private mosquito control programs throughout
17 the U.S. to control mosquitos, ultimately in localities
18 where the problems originate. We regard these programs
19 as our constituents and make every effort to ensure the
20 availability of the maximum number of products and tools
21 needed for their programs to be effective and safe for
22 humans, the environment, including wildlife and the

1 personnel who apply these insecticides.
2 Our expectation is that properly trained and
3 supervised staff will use the appropriate products and
4 follow the label's instructions for application.
5 We view the recommendations that were provided
6 by the working group that met a little over two years ago
7 as a good beginning. As stated in the group's
8 recommendation, which cite numerous problems with labels,
9 we think it is imperative that the label on mosquito
10 control products be as clear as possible. We believe
11 that each label should contain the minimum amount of
12 required information and that it presents instructions
13 and guidance that are as practical, reasonable and
14 enforceable by responsible federal and state agencies as
15 possible.
16 The second question that panel members have been
17 asked to discuss this morning relate to the
18 identification of other stakeholders that we think should
19 be involved as this issue goes forward. A very important
20 stakeholder is the U.S. Department of Agriculture, which
21 relates to veterinary health and mosquito control much as
22 the CDC relates to human health and mosquito control.

1 A second stakeholder that we think should be
2 invited to participate is the American Mosquito Control
3 Association, the AMCA. The AMCA is almost 70 years old
4 and is composed of state, county and local governmental
5 programs and individuals that are employed by these
6 control programs as well as individual entomologists from
7 academia, other federal, state and local agencies, the
8 U.S. Military and the private sector. And there is a
9 significant number of international members.
10 We also recommend that either or both the
11 Florida Coordinating Council on Mosquito Control and the
12 California Department of Health Services be sought as
13 stakeholders since mosquito adulticides are widely used
14 in these two states. Another federal agency that might
15 have an interest is the Department of Defense, either the
16 Armed Forces Pest Management Board or the United States
17 Air Force. The latter agency has an important national
18 role in the application of mosquito adulticides often in
19 emergency situations, specifically following hurricanes,
20 floods and so forth.
21 And, finally, we suggest the U.S. Fish and
22 Wildlife Service might be represented, also.

1 The third issue relates to PPDC's next step in
2 improving the labels for mosquito adulticides. The CDC
3 recommends that once the input from this meeting has been
4 accumulated, that the newly selected stakeholders be
5 notified and advised about the issue at hand and its
6 current status. Next, the newly assembled panel should
7 be tasked with reviewing the workgroup recommendations
8 and determining if any of these issues or recommendations
9 should be deleted, modified or if new ones need to be
10 added, recognizing the comments at the meeting that
11 initially was held two years ago and it sounds like it's
12 been a continuing process that's brought us here today.
13 At that point, the EPA should utilize
14 recommendations from the stakeholders and incorporate
15 them into its prescribed label language for mosquito
16 adulticides. Time lines should be set for the
17 preparation and implementation of new guidelines for
18 improved labels. We suggest that this be accomplished no
19 later than May 1, 2004. Parenthetically, preferably
20 earlier, but this data obviously is subject to discussion
21 of the working group.
22 Following the availability of these new

1 guidelines, presumably they will be reviewed by the PPDC
2 and then approved by EPA. These guidelines will be used
3 by the manufacturer to prepare the new label subject to
4 EPA approval.
5 As for the seven recommendations from the
6 workgroup, time does not permit really an in-depth
7 consideration of all those. But subject to repeat, that
8 the improved label should bring clarity and not be
9 ambiguous, vague or subject to interpretation to the
10 products and thus facilitate enforcement activities.
11 In the recommendations, themselves, terms such
12 as public health applications, public health emergency
13 and restricted use products conjure up different meanings
14 for different people and we've heard that from previous
15 speakers.
16 It appears that all restrictions that are going
17 to necessitate enforcement should be issues that EPA
18 intends to enforce.
19 A few comments about the individual
20 recommendations, and these are just sort of questions to
21 be considered as they apply. First, do public health
22 applications include pests and mosquito species or not?

1 What are restricted use pesticides and could not the
2 inclusion of a statement such as, for use by personnel
3 certified in public health pesticide application only,
4 have the same effect and perhaps avoid raising the
5 public's fear about these products? And again, this is a
6 comment that's been made previously.
7 In terms of distinguishing mosquito control from
8 other uses on the label, will this distinction be applied
9 to both aerial and ground application routes or will they
10 be separated? Can these products be used for related
11 control of insects, such as biting flies, sand flies, et
12 cetera?
13 On to point number three, about terrestrial use,
14 again a statement sort of in the positive phrase,
15 something on the order of proper use according to the
16 label is not expected to result in harm to fish or other
17 aquatic organisms; for example, shrimp, oysters and so
18 forth as appropriate. This, again, might allay the
19 public's concern about the issue.
20 Some of the hazards to the aquatic habitat,
21 again, a statement like I made previously, sort of in a
22 positive statement, indicating that if the label

1 requirements that are clear and not ambiguous and so
2 forth and so on are followed, that there will not be a
3 negative outcome.
4 The issue of starting the season contacting a
5 state agency about having applicable permits, this
6 appears to be appropriate when state regulations apply,
7 and we think that the lead state agency should have
8 provided guidance on permit requirements during the
9 certification training for supervisors and applicators.
10 So, this might be a bit redundant.
11 Another possibility is, what if the operator did
12 contact the state agency or if a state agency did not
13 respond at all or in a timely manner, is there a penalty
14 and who will enforce? This is an issue that, I think,
15 requires a little bit of review, as all of them probably
16 require some adjustments.
17 And the final part, then, a couple comments,
18 there's the issue of do not contaminate under the
19 miscellaneous clarifications, and we think that the issue
20 of incorporating the concept of run-off into and from
21 storm drains that will eventually enter surface waters,
22 streams or lakes should be added to that. And, finally,

1 and I think Cy discussed this, the issue of bees. As
2 stated in the document we reviewed, while most adult
3 applications are conducted in the evening or at night
4 when bees are not at risk, the U.S. Air Force, which I've
5 mentioned previously, and I think Cy amplified this in
6 terms of aircraft and the FAA regulations today, they
7 only fly in the daytime.
8 There was discussion in the Louisiana situation
9 in the latter part of 2002, vis-a-vis, West Nile
10 concerns, should the U.S. Air Force be involved. And the
11 first statement was, we don't fly at night, and that's
12 when the culex mosquitos are most active. So, that's a
13 consideration.
14 We, as an aside, have done a major study in San
15 Juan with the U.S. Air Force and their C-130s, sprayed
16 the entire city of San Juan with Naled Dibrom-14, and
17 didn't have any bee problems because we worked it out
18 with the bee owners previously. Towels were placed on
19 the beehives and the bees didn't leave during the day.
20 So, that's more detail than you wanted. Thank you for
21 the invitation and these are my comments.
22 MR. ROELOFS: Thank you very much. At this

1 point, before we sort of open discussion on the specific
2 recommendations, does anyone have a question for a
3 presenter to clarify anything that they've said?
4 UNIDENTIFIED MALE: I wanted to be sure. I
5 think it was Kevin that said the AMA has made a
6 suggestion that it could work under the pest program. I
7 didn't quite catch the last comment.
8 MR. SWEENEY: That was the AMCA.
9 UNIDENTIFIED MALE: AMCA.
10 MR. SWEENEY: Yeah, they're partners.
11 UNIDENTIFIED MALE: Oh, AMCA, okay.
12 MR. SWEENEY: Right.
13 UNIDENTIFIED MALE: Would you repeat exactly
14 what you said?
15 MR. SWEENEY: What I said was that the Pesticide
16 Environmental Stewardship Program, in light of that, the
17 AMCA had made a proposal to perhaps incorporate
18 information and suggestions on labeling into their
19 strategies and means of improving labels, making them
20 more efficient as far as applications go and also in the
21 light of pesticide reduction.
22 MR. ROELOFS: Not having participated in this

1 before, I take it that when you put your name tent up,
2 that means you have a question. Am I getting it here?
3 I wasn't watching who put up first. Jay or
4 Alan?
5 UNIDENTIFIED MALE: (Inaudible).
6 **(Brief pause.)**
7 ALAN LOCKWOOD: Thanks. Certainly, clarity and
8 consistency are important positive attributes and
9 Physicians for Social Responsibility would encourage the
10 agency, as a part of its mission, to protect public
11 health and the environment to assume responsibility for
12 making restricted use classification rather than leaving
13 that up to industry.
14 We heard yesterday about the lack of success of
15 enabling of inerts, and we heard again this morning from
16 Adrian Krygsman about industry not voluntarily putting
17 itself at a competitive disadvantage and putting this
18 kind of restriction on a label. We think that this is
19 particularly important for the use of adulticides because
20 frequently political and public relations concerns rather
21 than evidence-based practice determine whether or not
22 adulticides are used in specific communities. That

1 having been said, we also recognize that there are
2 certainly, under many circumstances, lax supervision
3 under certified pesticide applicators. But nevertheless,
4 we think that this is an agency responsibility to make
5 this determination rather than a voluntary act on the
6 part of industry.
7 MR. ROELOFS: Thank you. Mr. Vroom?
8 MR. VROOM: Just one observation, and that is
9 that I think you've assembled, Jim, a really amazing
10 array of presenters that gave us, to me, a very credible
11 snapshot across a lot of venues of perspective on the
12 science and the practical aspects of mosquito control,
13 many of which I don't think I've ever even heard of
14 before, which says that there is an enormous amount of
15 intellectual capital invested across a wide array of
16 disciplines in this effort. I just think that, in and of
17 itself, is very impressive.
18 One thing -- one question that hasn't been
19 raised is resistance management. It's a growing issue,
20 obviously, for those in the agricultural community with
21 regard to the viability of products, particularly those
22 that are used in bulk agriculture and other use areas.

1 This one, in particular, because, as so many of you have
2 referenced, application of adulticide mosquito control
3 products, by definition, are designed to drift. How does
4 resistance management get factored in both from the
5 agency as well as from the perspective of all the other
6 interests that were represented by the panel?
7 And then one point to -- an item that Adam had
8 mentioned that I think probably was unintentional. He
9 said that some pesticides have been linked to
10 Parkinson's. That really isn't scientifically correct.
11 It's an allegation not yet proven and one that we
12 certainly, from the manufacturer’s standpoint, are
13 concerned about. But it is not a scientific fact.
14 MR. ROELOFS: Thank you. I think Mr. Vickery?
15 MR. VICKERY: Yes, thank you. I noticed that
16 none of the recommendations seem to deal directly with
17 health and safety of the pesticide applicators
18 themselves, the handlers, and there may be a very good
19 reason for that, maybe it's not needed. Along the lines
20 of what Gary Clark was saying, sometimes positive
21 statements are good, in this case, not necessarily for
22 the label, but for us here to understand why or why not

1 there is -- well, in this case, why there isn't any new
2 recommendation with respect to the applicator safety.
3 MR. ROELOFS: I guess that was a question if
4 someone could address that.
5 UNIDENTIFIED MALE: Well, as a member of the
6 workgroup, what I was trying to do was take what the
7 workgroup identified as problems and that did not come
8 up.
9 UNIDENTIFIED MALE: (Inaudible).
10 UNIDENTIFIED MALE: Well, let me -- Mary Ellen?
11 MS. SETTING: Well, I think the answer is we
12 didn't feel that that particular aspect of the label
13 language needed to be improved, that it was very clear
14 and well understood. As an applicator, Cy, you might
15 want to add to that.
16 MR. LESSER: Yeah. There are specific
17 statements on all of the pesticide products, certainly,
18 that early on in the registration process EPA recognized
19 that the single greatest group at risk from the use of
20 pesticides were the applicators and that's, I believe,
21 very well addressed on the labels as far as protective
22 clothing and avoidance of -- like Kevin said, avoid

1 breathing spray mist or coming in contact with. There
2 are statements on the label that are directed to
3 applicators. The public will -- I guess Jack said that.
4 The public will call in and say, I was exposed, so it's a
5 violation of the label, but it's -- I think it's
6 addressed fairly well at this point.
7 I don't know of any problems that we've had in
8 the industry from our applicators, our employees that
9 have had medical problems from exposure through not
10 adhering to label requirements.
11 MR. ROELOFS: Next? I can't read it, I'm sorry.
12 DR. HOCK: Win Hock.
13 MR. ROELOFS: Oh, okay.
14 DR. HOCK: If I could just elaborate on that a
15 little bit. Actually, I wasn't going to address that
16 first, but there were problems in New York City when the
17 initial spraying was done. Some of the applicators
18 complained about health problem almost immediately after
19 the initial spraying was done in 1999 and 2000. But I
20 would argue that many states already have requirements
21 for certification of public applicators, or if you will,
22 commercial applicators, even if they're using the

1 restricted use materials.

2 I'm sure, Mary Ellen, your state does,

3 Pennsylvania does, New York. I could probably list half

4 the states that already require certification of

5 applicators even though the product is not restricted.

6 So, during that type of training, during that type of

7 outreach program, the applicators are going to get a fair

8 dose, if you will, of health and safety concerns. So, I

9 think many of the applicators are already exposed to that

10 kind of information.

11 I would like to just use the argument and make

12 the recommendation that, in my opinion, all public health

13 labels -- and I'm not just restricting it to mosquito

14 control, but I'm talking public health now -- labels

15 should be singular. In other words, not mixed with

16 agricultural turf, ornamentals. I can't tell you how

17 many times we have gone through this in my program, in

18 trying to interpret labels that have mixed bags, if you

19 will, everything from traditional agriculture to turf to

20 ornamentals to mosquito control, dog dipping, you name

21 it. It gets a little out of hand at times.

22 So, I would suggest -- I would make that

1 recommendation and look very hard at singular labels for
2 public health products. And that would eliminate an
3 awful lot of confusion.
4 As far as restricted use products are concerned,
5 I would support the requirement that these products
6 actually are restricted use. I've been in the outreach
7 program in outreach education for close to 30 years and,
8 you know, most of our people, most of the citizens of --
9 I'm going to use Pennsylvania and I'm sure I can use any
10 state in the country, have been aware of restricted used
11 products for a long time. Certainly, applicators have
12 been and certainly many of the customers of these
13 applicators are aware of this. I don't think it would be
14 a major cultural shock, if you will, or any kind of other
15 shock if these products were actually classified as
16 restricted use.
17 I think we could use just the opposite approach.
18 We could assure the public that these products are
19 restricted use because we want applicators to be well-
20 trained, knowledgeable, well-versed in what they're doing
21 and this would assure these applicators of the training
22 that is required. It would expose everybody -- expose,

1 that's a bad term -- but it would require people to be
2 trained and trained well in public health categories if
3 the products were restricted use.
4 Like I said, I think we could use it to our
5 advantage rather than our disadvantage. We could
6 actually promote this as another safety factor, a safety
7 -- a public awareness program that these products now are
8 in the hands of competent, well-trained people. So, I
9 would use that argument that we could actually use it to
10 our advantage.
11 MR. ROELOFS: Thank you. Mr. Libman?
12 MR. LIBMAN: I'd like to first reiterate -- is
13 this on? I'd like to reiterate what Jay said also about
14 the panel. Very impression from what we've heard this
15 morning. I really appreciate it. Good job on the panel
16 this morning.
17 My question is the biological products tend to
18 be larvicides and one could argue that if more larvicides
19 were used, there would be less adulticides used. That's
20 by definition. Did you consider larvicides at all in
21 your panel discussion? Obviously, they're used in water.
22 UNIDENTIFIED MALE: Right. We decided not to

1 take on those issues because then we would have, in
2 effect, had to split into two because they're so
3 different in their use patterns and the issues around
4 them. So, that was a conscious choice.
5 UNIDENTIFIED MALE: Jim, could anyone on the
6 panel comment on the degree to which they believe the
7 same kinds of problems exist for larvicides or not?
8 MS. SETTING: Actually, in our decision to not
9 consider larvicides, a lot of the environmental hazard
10 statements that are causing a problem for the adulticides
11 are not present on the larvicide products. So, that was
12 another part of the reason why we did not. So, I don't
13 think the issues were there for many of the products.
14 UNIDENTIFIED MALE: And I agree with that.
15 MR. ROELOFS: Julie?
16 MS. SPAGNOLI: I've got two sets of comments.
17 I'll make my own comments first and then I have comments
18 from a stakeholder who was not able to attend.
19 As far as the questions posed to the PPDC, I
20 think that the workgroup has done a good job on
21 identifying the issues and putting together some
22 reasonable recommendations. I think probably the best

1 way to get the wide stakeholder input is to put these
2 recommendations -- you know, get the input from this
3 committee and from the workgroup, probably put together a
4 formal proposal of recommendations and issue that for
5 public comment. I think to ensure that they get full
6 stakeholder involvement is probably going to be best done
7 by soliciting for public comment.
8 With regard to the issue of the restricted use,
9 that's the one area that has been brought up by a number
10 of the panel members and commenters so far. The question
11 I have is really the rationale for that, you know,
12 according to the use pattern and just looking at the
13 legal basis for restricted use and I'll just read it
14 right out.
15 It says that to be restricted use is if the
16 administrator determines the pesticide, when applied in
17 accordance with its directions for use, in accordance
18 with widespread commonly recognized practice, may
19 generally cause, without additional restrictions,
20 unreasonable adverse effects on the environment,
21 including injury to the applicator or to the environment.
22

1 I think in order to make a blanket decision to
2 make all those products restricted use, we'd have to
3 determine what is -- you know, is there a -- according to
4 the current practices and directions for use, is there a
5 rationale that may cause unreasonable risk. So, I think
6 just to say, well, it's a way to ensure that the
7 applicators are properly trained, I don't really think
8 that's the rationale that should be used for making
9 products restricted use.
10 I also have comments from George Wichterman
11 (phonetic).
12 JIM JONES: Julie, can I just explain
13 to folks sort of procedurally how we're handling
14 (inaudible) --
15 MS. SPAGNOLI: Sure.
16 JIM JONES: -- which we've already worked out.
17 But George Wichterman, who we invited to sit on the PPDC
18 actually for this topic is a mosquito control official
19 from the State of Florida. I believe he's also the
20 President right now of the AMCA --
21 UNIDENTIFIED MALE: That's not correct.
22 UNIDENTIFIED MALE: No, he's not.

1 UNIDENTIFIED MALE: The first part's correct;
2 the last part's not correct.
3 JIM JONES: Thank you. He's a mosquito control
4 official from the State of Florida. He's also on EPA's
5 CARAT and we have -- which is another FACA group that
6 advises the agency. Periodically, we have allowed and
7 invited CARAT members to sit on the PPDC when there seem
8 to be an intersection and this certainly seems to be such
9 an example of an interaction.
10 George, we just found out this morning, that he
11 just couldn't make it today. He had been planning on
12 coming and he couldn't make it and so he asked if he
13 could have a statement read into the record which Julie
14 agreed to do. So, I just wanted to explain to folks why
15 it's sort of an unusual example of a PPDC member reading
16 a statement from someone who's not actually on the PPDC.
17 MS. SPAGNOLI: Again, these represent the
18 comments of George Wichterman. He split them up by the
19 issues that were raised and added his comments.
20 Issue one, mosquito control application should
21 be restricted to trained personnel. This is George's
22 reply: With over 30 years of experience involving public

1 health vector control in the country mosquito control
2 district and working with foreign governments in Asia, as
3 well as throughout Eastern Europe and the Caribbean, I
4 feel this action would be unwarranted for the following
5 reasons. First and foremost, those of us who directly
6 supervise and/or apply public health pesticide products
7 in the United States already undergo extensive testing
8 for certification, whether we apply restricted or
9 unrestricted products, to disperse these products in
10 residential areas over public controlled lands or bodies
11 of water.
12 Wholeheartedly, I concur with the assertions
13 made within the first two sentences of paragraph one
14 regarding treatment, correct use of equipment, training,
15 et cetera. This, and much more, is acquired through our
16 training for certification and continues post-
17 certification in the form of continuing education credits
18 under the auspices of maintaining these various
19 certifications.
20 Because of liability issues with respect to any
21 application of the public health vector product, one must
22 be prudent respective to the safety and to the purposes

1 of its use. The take-home message for this issue should
2 entail, do you understand the techniques of public health
3 vector control, how to accomplish -- and how to
4 accomplish a predetermined goal in the first place.
5 I have found throughout my tenure that if you do
6 not understand these very techniques, then the issue of
7 unrestricted versus restricted becomes irrelevant. Being
8 a restricted use public health vector control -- being --
9 is not going to be the best way for states to ensure
10 proper training and supervision when the perspective
11 applicator does not understand the science of mosquito
12 control.
13 Secondly, there is a public perception issue
14 with classifying what remains as a restricted use
15 pesticide. The general public does not understand the
16 complexities on what makes a pesticide restricted or
17 unrestricted. However, the properly trained applicator
18 who has the skills and knowledge of public health vector
19 control will understand this distinction.
20 My recommendation to this issue would be to
21 allow the current process of registration and
22 reregistration to proceed and then attach the restricted

1 and unrestricted labels, where appropriate, based on
2 sound scientific determinations.
3 Issue two: Many current products combine
4 mosquito control and other uses on the same label
5 generating uncertainty about which direction and
6 precautions are applicable to which uses. George's
7 comment is: Public health vector control officials are
8 in agreement with this recommendation. We have advocated
9 for a long time that pesticide labels discrete for public
10 health use should be specific for that purpose. It would
11 definitely reduce, if not eliminate, the confusion factor
12 between agricultural uses and public health uses.
13 Recommendation three: Qualify the term
14 terrestrial uses on labeling by adding after terrestrial
15 use statements, the statement, see separate directions
16 and precautions for mosquito control. He concurs with
17 this recommendation.
18 Issue three: Label precautions regarding
19 applications directly to or over water are inconsistent
20 among labels. Since time immemorial -- this is confusing
21 wording here. I think what he's saying is that this
22 issue with regard to directly to and over water has been

1 ongoing and confusing, not only to the applicator, but
2 also to the public. Within public health products used
3 in aerial and ground adulticiding, no two labels are
4 consistent with acceptable language. Having said that
5 and according to your discussion within the workgroup,
6 Naled currently has a label for adult mosquito control,
7 which would clarify this dichotomy.
8 The current label for Naled reads, do not apply
9 to water except when used over water as labeled for adult
10 mosquitos to target areas where mosquitos are emerging or
11 swarming or to treat vegetation where mosquitos may rest.
12 This does not appear exactly as stated by the workgroup
13 under recommendation four. What this current label
14 language allows us to accomplish would be to target
15 application utilizing an offset in order to drift the
16 material towards the desired treatment area.
17 If the current label language for Naled were
18 applied to the other public health pesticide products
19 used for adult mosquito control, then the issue will
20 become less complicated for the trained applicator.
21 With respect to recommendations five and six,
22 these are, indeed, appropriate. Labels need to have

1 detailed, up-to-date calibration instructions for ULV
2 mosquito applications. If this recommendation were to be
3 enacted, then the considerably less fenthion issues would
4 arise due to a lack of understanding of the importance of
5 maintaining an appropriate droplet spectrum for the
6 target species.
7 Miscellaneous clarifications. With respect to
8 do not contaminate water, indeed, it would be helpful to
9 specify what types of water should be avoided when
10 working with a pesticide product. Regarding hazards to
11 bees, I would concur with the suggestion that labels be
12 modified to provide an exemption from application when
13 bees are visiting the treated area in the event of a
14 public health emergency. Throughout Southern Florida,
15 local mosquito abatement districts maintain good report
16 with local beekeepers, thus avoiding the potential
17 problems associated with pesticide applications. As a
18 result, mosquito abatement districts are aware of the
19 placements of the apicultures.
20 However, concurrent events during the fall of
21 the year make the aforesaid more difficult. With the
22 onset of diseases, such as West Nile Virus, St. Louis

1 encephalitis and the influx of Northerners relocating
2 their agricultures to our warmer climates for the season,
3 oftentimes presents a problem to the mosquito abatement
4 district when Northern agriculturalists bring their
5 Yankee bees down here.
6 **(Laughter.)**
7 MS. SPAGNOLI: They are not aware of the ongoing
8 cooperation and education program underway between the
9 mosquito abatement districts and local beekeepers.
10 Sometimes their bees die and we are accused of killing
11 them. This allegation requires an inordinate amount of
12 time to resolve, thus precluding necessary applications
13 to affected areas during disease transmissions. Once
14 again, please include this exemption on public health
15 pesticide labels.
16 Upon investigation of the alleged bee kills,
17 generally it's been determined that the apiculture
18 operators have used pesticides to kill each other's bees
19 when they're found to be encroaching on the local
20 beekeeper's territory. Fortunately, they are not using
21 public health pesticides commonly used in vector control
22 programs. But all of this takes time to sort through the

1 issues and it is a great waste of our time when you have
2 arbo-viral (phonetic) transmission underway.
3 MR. ROELOFS: Is that it?
4 MS. SPAGNOLI: That's it.
5 MR. ROELOFS: Thank you.
6 **(Laughter.)**
7 MS. SPAGNOLI: Thank you, George.
8 MR. ROELOFS: I'm going to jump over to Ms.
9 Bright who put her tent up a long time ago.
10 DR. BRIGHT: Okay, thank you. Well, I certainly
11 think, obviously, this has been a very contentious issue
12 between industry and mosquito control and environmental
13 groups, I think, as illustrated by some of Cy's comments
14 about alternative thoughts and agendas, and perhaps
15 George's comments about Yankee bees. I would say I -- I
16 work for an environmental group, as many of you know.
17 I'm a veterinarian. I'm also an epidemiologist. I'm
18 also as concerned about my health and the health of my
19 family as are everyone else sitting in this room.
20 I think the important point that needs to be
21 addressed here, number one, is that those people who are
22 sitting on the other side from the environmental side, I,

1 personally, and the organization that I work for, I'm not
2 anti-pesticide. But what we really need to strive for in
3 this situation is judicious use of pesticides, and I
4 think it's really, really important that we continue to
5 work towards that goal.
6 In terms of spraying -- adulticide spraying, I
7 think it's very important that we step back and look at
8 the Centers for Disease Control and Prevention Guidelines
9 that are out there. Those of you who have seen those,
10 they have some very extensive guidelines. I know Gary is
11 well aware of them. I've spoken with Dwayne about them.
12 In those guidelines, the Centers for Disease Control and
13 Prevention state very clearly that adulticiding is the
14 least effective method. That's not to say that
15 adulticiding doesn't have a role. It does.
16 When you look at a situation like Louisiana this
17 summer, there are situations like that when adulticiding
18 is the appropriate thing to do. You need to get in
19 there, you need to knock down those adult mosquito
20 populations. But we also need to be looking more at
21 larviciding. I think, as Adam pointed out earlier, we
22 should be striving for things like larviciding, for other

1 types of biopesticides.

2 From an epidemiologic standpoint, when you want

3 to kill those pests -- you know, I'm not telling you guys

4 this, you all know this. But when you want to kill those

5 mosquitos, it's early in the season during the time those

6 larvae are hatching, which is March, April and May,

7 that's the time to get them. They're concentrated in one

8 spot. Once they start to hatch and you've got them

9 dispersing out into other areas, you have a much more

10 difficult job in terms of mosquito control.

11 One of the other things I think we need to look

12 at when we're talking about adulticiding -- and I've

13 talked to Gary and Dwayne about this as well -- one of

14 the issues that I think is facing mosquito control and

15 mosquito abatement districts is that there has been a

16 real cut in their budgets in terms of what they're able

17 to do. If you go back and you look at, for example, on

18 the Centers for Disease Control and Prevention website,

19 there's actually a map of the United States and it shows,

20 by county, those counties who have submitted mosquitos

21 for West Nile Virus testing. I would say probably about

22 60 percent of the counties in the United States have

1 actually submitted mosquitos for testing. So, they have
2 some idea of which mosquitos are turning out positive in
3 their counties.
4 Now, we do know to date there are over 90
5 species of mosquitos that have been identified as
6 positive for the virus. Whether all of those species are
7 actually competent vectors, we don't know. But what we
8 do know is that the species do vary geographically and
9 they certainly do vary in their life history. So, if you
10 are going to concentrate on doing adulticides, you need
11 to know something about the mosquito that you're going
12 after.
13 You know, we're dealing primarily with culex
14 species, but we're also dealing with aedes, we're dealing
15 with ochlerotatus; each of these species have a different
16 life history. If you are spraying in the morning, you
17 know, first thing at dawn when the mosquito -- the public
18 health mosquito that you're really concerned about
19 happens to be a mosquito that feeds late afternoon and
20 night, then you really don't have a very effective
21 program.
22 Then I think it's really important -- and I

1 realize that's not something that's going to go on the
2 label -- but I think it's really important that that's
3 something that we start to educate the public about and
4 we start to encourage mosquito control districts to do
5 and we start to encourage Congress to find funding for.
6 Because if you're going to adulticide, you need to know
7 what you're adulticiding for. If you're using
8 larvicides, as I said, you're doing a more concentrated
9 effort and you avoid some of these issues.
10 In terms of being restricted use, I would agree
11 with the other comments said here and actually, Dr. Hock
12 said exactly what I was going to say, which is, I don't
13 think that's a negative thing from a public standpoint.
14 I really think that that can be used from a public
15 relations standpoint to turn around and say, look, yes,
16 we realize there are risks involved, but we've got the
17 best-trained people who are doing it.
18 As far as Julie's comments about there having to
19 be an unreasonable risk in order to restrict it, I think
20 the fact that you are using adulticides on such a wide
21 scale suggests that there is an unreasonable risk, even
22 if it's low toxicity. When you're using it at that wide

1 a scale, you increase the risk that there could be
2 problems. So, I think encouraging increased training for
3 adulticide applicators is very important.
4 As George Wichterman pointed out, mosquito
5 control applicators have a lot of training. So do
6 physicians. You know, physicians go through four years
7 of medical school. But if you're going to have heart
8 surgery, do you want to go to your general physician or
9 do you want to go to a cardiologist? So, I think that,
10 yes, they do have a lot of training. But it is -- I
11 don't think there's -- I think it's appropriate in this
12 situation to require that there be some additional
13 training.
14 As far as -- somebody made the comment, I think
15 it may have been Cy who said that, adulticides are
16 essential for public health and that we are -- and
17 they're not going to go away. You know, I don't know
18 whether that's true or not. It may be, but we also, in
19 going back to the CDC surveillance and control
20 guidelines, they're really stressing personal protection
21 and source reduction, things like larvaciding. More and
22 more states are going to non-adulticiding. For example,

1 Washington, D.C. in the past year had two human cases of
2 West Nile Virus. They did no adulticiding whatsoever.
3 They did follow the other -- no, they didn't, Cy, I
4 checked with them.
5 They did follow the other recommendations and
6 many other counties are starting to move away from that,
7 too. That doesn't mean larvaciding is going away --
8 excuse me, that doesn't mean adulticiding is going away,
9 but I think we do need to use those -- we need to look at
10 those risks and try and figure out how we can reduce
11 them.
12 Again, going back one more time to something
13 that Gary mentioned, Gary was talking about some of the
14 stakeholders that should be involved in this. He
15 mentioned USDA, AMCA, the Florida Coordinating Council,
16 the Department of Defense and also the Fish and Wildlife
17 Service, and I think it is very important that Fish and
18 Wildlife Service be involved. I also think it's
19 important that NIMPS (phonetic) be involved and I think
20 we need to have some of the environmental groups
21 involved.
22 I actually sat as a member of the Florida

1 Coordinating Council, as did Julie and some other people
2 that are here in the room. I think that Julie would
3 agree with me when I say that it was a bit contentious at
4 times. I was the only environmental representative in
5 the group, so you can imagine I wasn't the most popular
6 person there. But I would also say that over the course
7 of those three meetings, even though we couldn't agree on
8 everything, it was very interesting because we were able
9 to start to see the other side. We were starting to
10 understand why mosquito control had to do certain things
11 that I might have been opposed to and they could
12 understand why I felt mitigation strategies were
13 necessary for some things.
14 So, even though there is a tremendous amount of
15 distrust on this issue and we're never going to come to a
16 complete consensus, I do think it's important that the
17 stakeholders start to sit down and look at how do we use
18 these more judiciously. I don't think you guys are the
19 evil empire. You may think that about me. I hope not.
20 But I realize that you guys have a very important job to
21 do and I -- as I said, I think public health is extremely
22 important and I think that we should be sitting down and

1 finding ways to protect public health, but also protect
2 the environment and protect wildlife and do it in the
3 most judicious way possible.
4 MR. ROELOFS: Thank you. I'm trying to do this
5 more or less in order. I think, Bob, it would be your
6 turn.
7 MR. ROSENBERG: Jim, I guess we're out of the
8 question-only phase.
9 MR. ROELOFS: Yes.
10 DR. BRIGHT: With my manifesto, yes, I think
11 we're out of that phase.
12 MR. ROELOFS: Yes, we're about to enter the
13 final phase. So, go ahead.
14 MR. ROSENBERG: Well, I just want to, one, echo
15 whoever said this, which I think is a bunch of people,
16 what a nice job the panel did. They've spent a lot of
17 time thinking about this and they clearly articulated a
18 lot of issues and I commend them for their work.
19 I only want to -- well, just a couple of things.
20 One, just for the record, there's a surprisingly large
21 number of PCOs who do mosquito control work, more than we
22 had even supposed. With the advent of West Nile and with

1 us polling our membership, we found out that there's an
2 enormous number that do it. I just kind of want to keep
3 that in the background of this discussion. There are
4 people other than mosquito abatement districts that do
5 mosquito control, including adulticide work.
6 Having said that, the two issues I just wanted
7 to comment on were first, the question about restricting
8 the sale of the products to training personnel. Four
9 quick thoughts. One, the RUP requirement, you know, I
10 agree with Adrian that if it's voluntary, it ain't going
11 to happen because the guys that I represent will not buy
12 an RUP if there's a general use product that's available
13 because that triggers a lot of other problems for them,
14 such as litigation, liability potential, record-keeping
15 requirements under USDA. It isn't going to happen.
16 Manufacturers are not going to voluntarily do it because
17 they won't be able to sell it.
18 Secondly, if the goal of that first
19 recommendation -- and I think it is -- is to require that
20 everybody be trained that uses adulticide products, we
21 support that fully. We think that's a great thing. As a
22 practical effect, there are -- even though FIFRA and EPA

1 only require the certification of people who apply or
2 supervise the use of restricted use products, every
3 single one of the 50 states require certification of
4 commercial applicators or the people who certify the use
5 of -- or use or supervise the use of all general use
6 products. And I think most states have a similar
7 requirement for public health applicators.
8 Having said that, I don't know if there's going
9 to be a whole lot -- it's going to be as much of a
10 supervision and training requirement if it's a general
11 use product as if it were a restricted use product. But
12 there's two issues that have come up that have to do with
13 labeling, which is not restricted -- which does not
14 designate as a restricted use, but does say that it's
15 restricted use or sale to certain classes --
16 **(End of Tape 1, Side B.)**
17 MR. ROSENBERG: -- of people and the two issues
18 are this. Now, I only mention these because I think they
19 need to be kind of kept in mind. One is, I think the
20 recommendation says something like, for use by public
21 health or vector control agency personnel and so forth.
22 There is a wide variety of state certification

1 requirements. In certain states, there are requirements
2 that you be certified in certain categories that vary
3 from state to state. I guess our thinking there is it's
4 not going to be easy to find one set of label language
5 that's going to fit all 50 states. And I guess we would
6 suggest something like, for use only by persons certified
7 by the state lead agency in the appropriate certification
8 category for the application of products to control adult
9 mosquitos has the same effect or takes into account the
10 variability among the states.
11 Secondly, and I don't know how you get around
12 this, it seems like there was an enforcement issue -- and
13 I don't know how you deal with it. Jack might could
14 comment on this. But something similar was tried on
15 termiticides back in the 1996 PR notice. It says, for
16 PCO use only and -- or words to that effect. For sale or
17 use by PCOs only. What happened was a couple of years
18 ago a PCO distributor took PCO use only products and
19 distributed them to a homeowner store, Lowe's, and Lowe's
20 sold for PCO use only products to non-PCOs and most of
21 the states in which that occurred, the general feeling
22 was that that was not enforceable label language.

1 So, that's kind of a tricky question. We
2 support the goals of what the committees come up with.
3 There's some tricky issues that have to be dealt with and
4 we'd welcome the opportunity to work with the workgroup
5 to try to address those.
6 MR. ROELOFS: Thank you. Dr. Holm?
7 DR. HOLM: I really do want to echo what Bob and
8 Jay said about the panel. Being a -- working in the
9 agriculture area and not in public health, it's always an
10 educating and refreshing opportunity to hear what's going
11 on in the public health area.
12 I represent the IR-4 Program, which is involved
13 with minor crop uses, and I think what I can add to this
14 discussion, I think, is a bit of a paradox in that we
15 track and work with registrants on a lot of new chemistry
16 and you have before you -- and I'll be discussing a
17 little bit in our biopesticide area -- our new products
18 transition solution list. I think it's a bit ironic and
19 interesting the fact that there are about 80 listings
20 that we have in there for insecticides, but none of them,
21 that I'm aware of, are really in the public health arena
22 for -- particularly for mosquito adult control.

1 And I think it's quite interesting to look at --
2 if you're looking at the products that you're using now
3 in your industry. I've been around for 30 years in this
4 industry and I think a lot of those products have been
5 around as long or longer than I have. Many of them are
6 in the class of organophosphates and I think that's
7 probably driven some of the recommendations to make them
8 restricted use. I also am aware of a lot of the products
9 that are on our list in the agricultural areas and many
10 of them that are reduced risk chemistries, also have
11 mosquito adulticide activity.
12 So, you've got to ask yourself the question, why
13 aren't the registrants of this -- or the companies that
14 are developing and registering this chemistry, why are
15 they registering it for public health use? I think there
16 are a lot of disincentives in the system right now, a lot
17 of them being public perception and barriers to use and
18 so on. And I'm just wondering whether the panel really
19 looked at this and also looked at the opportunities to
20 provide some incentives.
21 I don't represent the registrants, but I think
22 there's going to be a potential major disincentive if all

1 public health adulticides are classified as restricted
2 use for companies that are developing the new, cleaner,
3 reduced risk chemistry to try to go into that market and
4 then automatically be put in the basket of saying these
5 products are going to be restricted use, because that's a
6 label that those companies will not want to have on those
7 types of products.
8 MR. ROELOFS: Thank you. Ms. Kawamoto, I didn't
9 see your sign for quite a while. Sorry about that.
10 MS. KAWAMOTO: Thanks. I'd like to thank the
11 panel for clearly articulating a lot of the issues of
12 this very complex problem. I feel that in terms of
13 protecting workers and communities, it's very important
14 to have clear language on the labels, as Dr. Clark had
15 mentioned.
16 However, I'd like to readdress the -- or re-
17 raise the issues that John, Win, Patti and Bob had
18 touched on with regard to worker training or applicator
19 training. As Bob had mentioned, there's a lot of
20 variability of certification requirements among the
21 states, and even within states, there's probably a lot of
22 variability of training programs and what's included in

1 that. So, the final result of that is that there's a lot
2 of variability among training outcomes of the applicators
3 who are trained. Therefore, certified does not
4 necessarily mean that the applicator is competent or
5 well-trained, especially with regard to health and safety
6 issues.
7 I've found that when I've attended applicator
8 training, the content is mostly based on what
9 applications are being used within the workplace, such as
10 are they using insecticides and which types and how
11 should they be used and whether there should be fogging
12 or other kinds of applications -- application methods.
13 In effect, the health and safety issue ends up being a
14 very small part of the training, and sometimes even
15 though the applicators are certified year after year, in
16 which case they're supposed to be getting more and more
17 information and knowledge, that may not necessarily be
18 the case. Because when I've gone out to do evaluations
19 of workplaces, I ask the workers, the certified
20 applicators, how much do you remember of health and
21 safety in your training, and usually it's very little to
22 none.

1 So, I think that this brings up a point that we
2 need to address training probably as a separate issue
3 within the PPDC. I would also like to say that I think
4 it was Anne, but somebody said earlier yesterday that
5 there was another instance of the mis-application of a
6 certain pesticide for rodents when -- and I've seen there
7 before where insecticides were used instead of
8 rodenticides. And so, if the applicators are doing this
9 incorrectly, you know, how much do they really have to
10 know and how much do they really know? There's a
11 disconnect there.
12 I think we have to realize that applicators
13 really have to know a whole lot and it includes a lot of
14 different things about plants and insects and fungi and
15 herbs -- plants for herbicides. So, when we realize that
16 they have to also know toxicity to humans, to wildlife
17 and they have to know how to protect themselves, as well
18 as communities, that's asking them quite a whole lot.
19 And if they're just getting retrained in eight hours a
20 year, that's really little time to cover everything. And
21 you would hope that over the years, their knowledge would
22 increase, but sometimes they're just hearing the same

1 material over and over. So, you know, we're not
2 necessarily guaranteeing that the applicators who were
3 certified necessarily have the tools and knowledge to be
4 protective of themselves, as well as the community.
5 So, I think this issue has to be raised again,
6 and it's been raised before in the past, especially by
7 Win. So, it bears reexamination in the future. But I'd
8 like to say that I'm just restricting my comments to the
9 training issue and not really making any comments about
10 whether it should be restricted use pesticides or not.
11 But it's just another aspect of it.
12 MR. ROELOFS: Okay, thank you very much. At
13 this point, we really are closing in on the end of this.
14 So, there's one person who hasn't had a turn before and
15 that's Mr. Kellner. But before I call on him, let's look
16 at those questions again. I would really like to hear
17 comments about process. How should we move forward?
18 Literally, how should we make it happen?
19 Go ahead, Mr. Kellner.
20 MR. KELLNER: Thanks. I just have a couple of
21 remarks, I think. First of all, the public is very, very
22 interested in mosquito control. I think everybody knows

1 that. The public I'm talking about are individual
2 homeowners and the people -- individuals themselves.
3 We have -- at CSPA, we have a website. It's
4 called aboutbugs.com and we're getting over 10,000 hits a
5 month regarding the pests that are on that website. And
6 it shows that the public is extremely interested, and I'm
7 concerned that if all these products go to a restricted
8 use, that the public itself may be deprived of a useful
9 product.
10 I think that the criteria that Julie talked
11 about in FIFRA really needs to be taken a look at
12 anywhere we go with this. If the criteria is met, then
13 perhaps some things should be restricted use. If it's
14 not met, then it should not be restricted use. I think
15 we have to bear that in mind.
16 And, I guess, finally, I'm just asking sort of
17 to what you just raised, is this going to go by rule
18 making? Are we going to do this by rule? How -- you
19 know, have we thought about that?
20 MR. ROELOFS: We haven't decided. I think we
21 want to hear what the suggestions of the panel are and I
22 guess we'll have to take it back and think about what's

1 the best way to go forward. That certainly is not a plan
2 that we have at this point because we don't have a plan.
3 Let's see, Adam, did you have a --
4 MR. GOLDBERG: Yeah, just three real quick
5 comments. I accept Jay's clarification on what I had
6 said on Parkinson's. I'm sure we'll talk about the
7 medical evidence at other times, but he's right.
8 I also want to just say that I thought that
9 Win's comments on similar use labels was very
10 interesting, particularly the dog dips, but that's
11 another story.
12 And then I had said in my comments that, yes, we
13 should be consulting other stakeholders, but then I never
14 bothered to mention any of them. And it's my
15 understanding that when New York was first hit with West
16 Nile, there were some concerns expressed by the lobster
17 men up there. So, that's sort of who I had in mind, not
18 necessarily the lobster men, but just those sorts of --
19 the groups that are localized around places like that to
20 express those sorts of concerns. And that's what I had
21 in mind and I just didn't mention it. Thanks.
22 MR. ROELOFS: Thank you. Dr. Lockwood?

1 DR. LOCKWOOD: Just very quickly, contrary to
2 what Jay Vroom said, there is excellent case control
3 epidemiologic evidence that indicates that pesticide
4 exposure is a significant risk factor for the development
5 of Parkinson's Disease, including in-home use of
6 pesticides. There are two published animal models in
7 which all of the neuropathological features of
8 Parkinson's Disease have been replicated by feeding
9 pesticides, and sooner or later, the agency is going to
10 have to come to grips with this issue in its risk
11 assessment. Thank you.
12 MR. ROELOFS: Thank you. Phil Benedict?
13 MR. BENEDICT: With regard to your first
14 question, I think labels need to do a better job of
15 talking about the equipment that's being used. There's
16 equipment out there that tends to disperse and pick
17 mosquitos out of the air. Then there's other equipment
18 that tends to leave a residue. Treating both kinds of
19 equipment the same way on the label doesn't make a lot of
20 sense. The precautionary statements ought to be
21 different for different mechanisms for control. I don't
22 think the labels do a good job of that today. So, if

1 we're going to look at mosquito labels, we should
2 consider those things.
3 I would agree that we probably need additional
4 stakeholders, and I think most of the participants were
5 listed. I'm not sure what the next steps are for us. I
6 guess having people work on these issues a little more
7 and bring back a recommendation would be good. But I
8 also think that we need to have some changes to labels
9 and just putting that process off is not necessarily good
10 waiting for a study. I think there's been some things
11 identified today that would improve mosquito labels and
12 we ought to move forward with some of those issues.
13 MR. ROELOFS: Thank you. I've been ignoring my
14 own panel. I'm sorry about that. Dr. Clark?
15 DR. CLARK: Yes. I met Patti Bright two months
16 ago in a heavy snowstorm and I really like her.
17 **(Laughter.)**
18 DR. CLARK: She referred to me in the most
19 positive sense and my agency. Just very briefly,
20 comments on this. The way we view -- at least the way I
21 think we view, at CDC, mosquito control, the best way to
22 do it would be to eliminate the source. I work with

1 Dengue and comes -- is transmitted by Aedes Aegypti
2 mosquitos produced in containers. If we could eliminate
3 those containers, we don't have that. If they're
4 containers that we cannot eliminate, then there's a
5 necessity of using a larvicide, a bait. Temephos is
6 generally used. So, that's sort of the second step.
7 Recognizing that if we have a Dengue outbreak,
8 there is a need to use adulticides, and ultimately, then
9 we go to the use of personal protection, whether it's
10 screens or repellants or clothing and those kinds of
11 things. So, that's sort of, in my perspective, how we
12 present the hierarchy of being most effective. In other
13 words, absolutely 100 percent agreement. If we could
14 eliminate the larval sources, then we wouldn't have the
15 adults flying as she indicated.
16 The second thing about adulticiding, I would
17 suggest, is that many of the programs that control
18 mosquitos in the United States are based on political
19 boundaries and mosquitos. As good as they are for me in
20 my profession and my family, they don't respect political
21 boundaries. And so, they're flying from one location to
22 another location. And often, in a given area where there

1 may be transmission of West Nile or mosquito problems
2 coming without pathogens, there is a need to control the
3 adults because there is no larval habitat that we, in our
4 community, for example, could deal with.
5 One other thing I would add sort of
6 parenthetically for the entire group is that -- and she
7 talked about this, about mosquito control programs in the
8 United States. There is a movement afoot on the other
9 side of the Potomac to provide funds to the Centers for
10 Disease Control and Prevention to develop and expand and
11 improve mosquito control in this country. And the CDC
12 had a meeting in New Orleans, following the West Nile
13 conference that was held there, to bring together a group
14 of people to sort of provide guidance to the CDC on how
15 sustainable mosquito control can be improved and
16 developed in this country. And when I say that, I talk
17 about the issues of source reduction, larval control and
18 adulticides where necessary.
19 We're not interested in promoting programs that
20 are spray and squirt, in the negative sense of the old
21 way that sometimes may have been occurring, that somebody
22 sees a problem if I can get some machinery, if I can get

1 some insecticide, then we can spray and make it -- we're
2 not interested in that. We're interested in the
3 integrated programs that Cy Lesser talked about.
4 And, finally, in the most positive way, I
5 appreciate Dr. Bright's comments and the agency -- the
6 organization she represents and her comments about the
7 importance of sitting down in situations like this and
8 other situations in Florida to discuss our differences
9 and try to resolve them for the common good.
10 MR. ROELOFS: Thank you. Oh, I should mention,
11 I would ask the committee not to put up any more tents
12 and I'll just try to get to the people who have them up
13 now and then we're out and we'll have some closing
14 remarks. Jack?
15 MR. NEYLAN: I guess the point I wanted to make
16 with my remarks is that label language is often in the
17 eye of the beholder, and it's very important here. Bob
18 Rosenberg mentioned something that was a factual case.
19 FIFRA doesn't really permit the restriction of sale of
20 pesticides other than RUPs. So, we do see labels that
21 make that -- try and make that statement. It's a useless
22 statement.

1 So, I would applaud any efforts to -- I think
2 these products should be restricted for the purpose of
3 actually trying to get them into the hands of a specific
4 group of people that have been trained to do that.
5 Clearly, we can identify, we all agree who they are.
6 States know who they are because they have licensed them.
7 So, I really just wanted to clarify that point. I'll
8 pass it on to Cy, I guess.
9 MR. ROELOFS: Yeah, go ahead.
10 MR. LESSER: Thank you. I'd like to comment on
11 comments made by Dr. Bright. Factually, I believe there
12 was an incorrect statement made about Washington, D.C.
13 and West Nile Virus in 2002. I believe Dr. Bright said
14 there was two cases in the city. Actually, there were
15 over 30 cases of human West Nile Virus illness. The rate
16 of infection of people becoming ill from West Nile Virus
17 in Washington, D.C. was approximately six cases per
18 100,000 of population. That is one of the highest rates
19 in the country and is about 10 times greater than we in
20 Maryland experienced across the arbitrary line that's
21 between Washington, D.C. and the District of -- and the
22 State of Maryland.

1 We did aggressive adulticiding in many areas of
2 West Nile Virus problems in the State of Maryland. As
3 you say, Dr. Bright, they did none in Washington, D.C.
4 DR. BRIGHT: Right. And I'm sorry, I mis-spoke
5 when I said two. I meant to say two fatalities, not two
6 cases. I apologize.
7 MR. ROELOFS: Ms. Carroll, is it?
8 DR. CARROLL: I just have to make a comment on
9 Dr. Lockwood's discussion about Parkinson's. I have to
10 say the jury is still way, way out, the scientific jury,
11 that is, on whether pesticides cause Parkinson's Disease
12 or not. There's a lot of additional research that needs
13 to be conducted before any conclusions can be drawn on
14 that premise. And I'll just point out that recently I
15 looked at a paper that considered Creutzfeldt-Jacob,
16 Alzheimer's and Parkinson's Disease and it looked at
17 brain scans of victims of those three diseases and the
18 brain scans were very, very similar. Now, would we
19 automatically jump to the conclusion that BSE is involved
20 in Parkinson's? I don't think we're ready to do that yet
21 and I think the same thing is true of pesticides.
22 MR. ROELOFS: Ms. Lewis? Dr. Lewis, I'm sorry.

1 DR. LEWIS: I wanted to talk a little about how
2 do you decide what to put on a label and especially this
3 idea of restricted used and people are saying, well,
4 would the public be more or less concerned if it said
5 restricted used on the label? I'm wondering if anyone
6 has actually studied this, any kind of focus group on how
7 do consumers respond to what is on the label? What is
8 most useful on a label to a consumer and how do you
9 figure that out? It's just a question.
10 ANNE LINDSAY: Nancy, I can only speak here for
11 EPA. We've not studied the particular question at hand,
12 public knowledge and reaction to a restricted use
13 classification, but we did actually have a pretty
14 significant project, a partnership that involved a number
15 of pesticide producing companies, Consumer Product Safety
16 Commission and some others looking at how does your -- if
17 there is such a thing as an ordinary homeowner, what do
18 they do when they look at a label, how do they react, how
19 do they respond to it? And there was actually some
20 pretty extensive research done. The results of that,
21 we've made available on our website.
22 And probably more importantly for consumer

1 products that are really intended for somebody like me to
2 use around the house, there's been a significant effort
3 to really upgrade the labels. I think we did find out
4 what I would call our traditional consumer product label
5 didn't read very well to a normal homeowner and that we
6 had to have a lot more direct language. The placement,
7 the spacing, the kind of -- the whole design of the label
8 had a great deal of impact as to whether user would
9 really know whether or not they needed to pay attention
10 and why they needed to pay attention.
11 And at EPA, anyway, we're also following up with
12 campaigns directed at the homeowner. I don't know how
13 easy it is to translate that research into this
14 situation. I don't think it would translate real well to
15 the restricted use question, though I do think that there
16 are probably some general learning lessons that are
17 applicable to labels for public health products and
18 perhaps even for agricultural products, just about how
19 people learn and access complex information.
20 But one of my kind of broader questions is
21 whether there are other outside sources beyond EPA
22 because we frankly have not had a lot of funds to invest

1 in that sort of behavioral sociological resource
2 research, and I think it would be a valuable additional
3 tool. So, I'm sort of actively engaged in looking for
4 outside sources.
5 MR. ROELOFS: Bob?
6 BOB: I just want to comment on the next steps.
7 I'm on Adam's -- Adam's not here, but I'm on Adam's side
8 on this thing, notwithstanding the tangential references.
9 If you confine yourself to the narrow questions of
10 improving mosquitocide labels, it seems like there is
11 pretty much a consensus; at least enough refined thinking
12 has gone into the process to where I'm not sure you need
13 a whole other workgroup on it. I'd suggest that the
14 agency take what the workgroups come up with, draft a PR
15 notice, hold a half-day workshop to discuss it and I
16 think we're ready to move forward.
17 MR. ROELOFS: Thank you. That really brings us
18 to the end of our time. I have heard a heck of a lot of
19 things that we need to go back and look at, and I really
20 appreciate it. I think it's going to be a matter of some
21 discussion internally as to where we go, but perhaps my
22 office director has some thoughts about that. Jim?

1 MR. JONES: A couple of thoughts. I think it
2 was a very good discussion and some excellent dialogue.
3 I think we actually did get some advice on the three
4 questions that we had asked. I thought Dr. Clark
5 actually summed up pretty well the stakeholders who we
6 had not yet engaged and I think that Adam identified a
7 few others. I think we'll sort of capture those and make
8 sure that we do some more outreach with the groups that
9 we have not yet engaged and who are not here as part of
10 the workgroup.
11 There is a wide and rather long list of
12 stakeholders who we probably need to do a little more
13 outreach with. There were a few more ideas about
14 recommendations that we had not broached that we'll need
15 to sort of do some thinking around. But I think
16 basically our next steps are to do a little more outreach
17 with some groups we have not yet touched base with and
18 then, Bob, as you said, sort of take it inside and do
19 some internal vetting of this and make some decisions
20 about which -- which of these recommendations we want to
21 go forward with. And we'll have to think through sort of
22 is the PR notice or is rule making or some other vehicle

1 appropriate?

2 But I certainly think this is a topic we're

3 likely to keep this committee posted on our decision-

4 making as we move forward. So, I'd close it with that.

5 Thank you very much to the panel. You all were as on

6 point and did what we asked which was to sort of tee up

7 some issues and give us your perspective and

8 recommendations. I appreciate that very much. Thank

9 you.

10 JIM JONES: We are going to take a break right

11 now, 10 minutes.

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

13 JIM JONES: We're going to start our next

14 session, which, as I mentioned before, is an update of

15 previous dialogue that we've had at the PPDC around

16 biopesticides and biopesticide adoption. Janet Andersen

17 is going to lead us in this discussion.

18 MS. ANDERSEN: Thank you. In case somebody here

19 doesn't know, I'm the Director of the Biopesticides and

20 Pollution Prevention Division, and as a manager, I've

21 delegated these next updates to the PPDC people. I hope

22 that the last group was as successful as we have been

1 when we started to launch this about a year ago as a
2 topic here. It's really helped energize us on working on
3 the adoption of biopesticides. So, for sort of some of
4 the things that we've accomplished over the last year, at
5 least updates on two of them, I'm going to first turn to
6 Bob Holm to talk about IR-4 or research products
7 regarding biopesticides, and then we're going to turn it
8 over to Gary Libman, who will talk about some of the
9 successes we've had with biopesticides.
10 DR. HOLM: Thank you, Janet. I left a brochure
11 for all of you this morning. In it -- basically, it's
12 what we call our new products transitions solution, which
13 we -- basically IR-4 tracks all new technology,
14 biopesticide and traditional chemical in the major areas,
15 herbicides, insecticides, fungicides and plant growth
16 regulators, and this has just been updated in January.
17 To bring your attention to kind of the summary
18 table, which by the different categories, interestingly
19 enough, since last summer when we updated it the last
20 time before January, we added 16 additional biopesticides
21 that we were tracking. So, I thought that's quite
22 interesting because there's still active research going

1 on in this area from a company's perspective.
2 Technologies are being researched by the USDA in the Land
3 Grant University System and are being licensed for use.
4 It's interesting to look at the different
5 categories. Only six in the bioherbicide area, 27 in the
6 bio-insecticide area, including phermones, 39 in the bio-
7 fungicide area. That's where we're really seeing most of
8 our activity is in the insect control and disease control
9 area. Weed control area is very much more difficult
10 basically due to the fact that many of the pathogens that
11 control weeds are very narrow spectrum.
12 The next handout in your brochure just gives you
13 a little overview of the IR-4 Program involvement in
14 biopesticides. I won't go over it in detail because a
15 lot of it was discussed last summer at the meeting. But
16 just to remind you that we've had an active biopesticide
17 program for over 20 years now and we still have and will
18 continue to focus on helping registrants. I think a lot
19 of people don't realize that other than a few companies
20 in this industry, a lot of these companies are very
21 small, sometimes only three or four employees, and they
22 have very little capital and money to develop products,

1 let alone register them.

2 So, we spend a fair amount of effort in working

3 with Janet and her team in trying to help small company

4 registrants get these products through BPPD and

5 registered so that they can be used by agricultural

6 users.

7 What we have done more recently is a

8 biopesticide research program. Initially, we funded

9 projects which were kind of broken down into two

10 categories, early stage, which were products that are

11 more laboratory ideas, that are not yet commercialized or

12 have a commercial component to it, and then what we call

13 advanced stage. If you can see in the shifting of our

14 funding and our -- the number of projects that we funded,

15 we very heavily focused, in recent years, on what we call

16 advanced stage because we really feel the needs are to

17 demonstrate these products, work out in field conditions

18 rather than to support early stage research which hasn't

19 necessarily resulted in a lot of new products being

20 registered.

21 We've also sponsored some workshops and so on in

22 cooperation with BPPD and I do want to take this

1 opportunity to recognize Janet and her group for hosting
2 Michael Braverman, who is our biopesticide coordinator
3 this last year, and a very unique opportunity to speak
4 six months in BPPD, one week a month to help us -- train
5 us to be better submitters of biopesticides petitions and
6 also to help the industry through the Biopesticide
7 Industry Alliance, and I do think, that time, because
8 it's helped us be better submitters and I think we can --
9 hopefully, we can help the industry make Janet's job a
10 little easier in getting better quality petitions.
11 A year ago, we were very disappointed that we
12 had -- we increased our research budget to $400,000 and
13 we only got something like 42 grant proposals and we
14 funded, as you can see, 39 of them. We didn't think the
15 quality was that good. But this year, we put out a major
16 emphasis, and again, thanks to Janet and her group for a
17 lot of publicity, also the Biopesticide Industry Alliance
18 and IR-4s efforts, we got 108 proposals in requesting
19 about $1.2 million in grants.
20 So, we had much more of a challenge in selecting
21 proposals this year. As you can see, we funded nine,
22 what we call early stage, and 39 advanced stage, and if

1 you flip over that sheet, you may need your glasses, Bob,
2 for a little more detail, but it does show all the
3 projects that we funded by the stage. So, you can see,
4 the one column says advanced stage or down at the bottom,
5 early stage. And the title of the project being funded
6 and, again, a lot of bio-insecticides and bio-fungicides,
7 and the amount funded, and then the principal
8 investigator and the university or institution over in
9 the right-hand column.
10 So, I think you can see that the -- I think from
11 a research standpoint at the Land Grant University level
12 and USDA level, there's a lot of interest, there's a lot
13 of good researchers out there and we're seeing a lot of
14 very interesting and good products in the pipeline that
15 can be used.
16 Our focus of this year's research program was to
17 put biopesticides in IPM programs. I think one of the
18 difficulties and challenges of the industry, I think Gary
19 will agree with me, is that if you stack a biopesticide
20 against a traditional program, particularly under heavy
21 pest pressures, traditional programs usually win most of
22 the time. But if you integrate bio-control agents in IPM

1 programs, they work very well and very effectively, and
2 that's really the basis for one thing we're really
3 looking at now. Janet's group has come up with an IPM
4 bio-based demonstration program initiative. We're very
5 interested in partnering. I know Carolyn Brickey also
6 has some ideas there and we're really trying to look at
7 demonstration trials in California and other key states
8 to show that the biopesticides do work in traditional
9 programs.
10 Gary, I'm going to turn it over to you because
11 Gary has got some success stories from the biopesticide
12 industry that show that these products do work and they
13 are being utilized.
14 MR. LIBMAN: Thank you, Bob. I'd also like to
15 thank Janet and her group for really getting this on the
16 forefront. We had some excellent discussions last year
17 with the PPDC vis-a-vis the barriers and the use of
18 biopesticides and it seemed like the constant thread that
19 came through the 900 and something items that the EPA
20 BPPD put together on these click sheets was that people
21 were concerned about the efficacy, and in many cases,
22 that's been a problem. Well, I have a few examples here

1 just to show you that these products can be quite
2 efficacious as well.
3 First of all, from a key definition perspective,
4 you know, we could have put it in terms of dollars or
5 percent market share and so on. We thought the best way
6 to do it is to talk in terms of relative market share or
7 multiple-treated acres. And as you can see on this first
8 slide, what we're talking about for relative market share
9 is -- it's just the total acres where a product is used
10 at least one time divided by the total acres of that
11 crop.
12 So, for example, if you had 800,000 acres of a
13 crop, let's say tomatoes, in the specific area and it's
14 used one time on 80,000 acres, then that would be 10
15 percent. A more realistic number would be multiple-
16 treated acres because we know that the biopesticides are
17 not always used in every single spray and perhaps there
18 might be up to four or eight sprays of a particular -- of
19 a normal pesticide. So, in that case, we would multiply
20 the acres times the number of times it was sprayed, using
21 that 80,000 again, it would be 3.2 million acres, spray
22 acres, if you will, whatever you want to call it. And if

1 we apply it twice to 80,000 acres, then it would be a
2 more realistic number, perhaps 5 percent of relative
3 market share. Next slide.
4 A couple products that we'll talk about just for
5 a few minutes. We don't have very much time allotted
6 here, but I think it's very important to talk about some
7 of the successes. First of all, BioWorks, which has a
8 bio-fungicide called RootShield, the plant shield, which
9 has been on the market for about six years, used in
10 ornamentals for horticultural soil products. It's a
11 trichoderma harzianum product and they now have 10
12 percent -- BioWorks out of New York has 10 percent of the
13 relative market share of this product. A major success
14 story. They would not have this market share if the
15 product were not working properly.
16 Another one is the -- this is an example --
17 phermones have been a major success story right down the
18 line and this is one -- Sutera Company, also Pacific
19 BioControl, which makes the CheckMate and the IsoMate
20 products and these are both phermones, one used on stone
21 fruit, another one used on pome fruit. Been in the
22 market eight years or ten years and these phermones are

1 really doing very well. In the Western U.S., on
2 available acres, have up to 40 percent of usage on these
3 relative market share and then 50 percent on the pome
4 fruit, which is quite significant.
5 Eden BioScience has the harpin protein called
6 Messenger and it's been on the market for three years.
7 It's labeled for over 75 product -- 75 crops rather, such
8 as citrus, table grapes, melons, strawberries, tomatoes
9 and so on, and depending on the crop itself -- and again,
10 this product is not just for disease management, but also
11 a growth enhancement of PGR type product, and it's up to
12 1 to 10 percent, depending on the individual crop, a
13 major success story there. Next slide.
14 Valent BioScience is probably the -- well, not
15 probably, it is definitely the number one biopesticide
16 company. I, myself, worked for Abbott for about 20
17 something years before I joined my current company. So,
18 I know these products quite well. And there's been a 30-
19 year history of the BT, bacillus thuringiensis, the --
20 you can see the top one, Dipel and XenTari, which is --
21 Dipel is the kurstaki strain and XenTari is an aizawai
22 strain of BT. Used on vegetables and vine fruit and, in

1 some cases, up to 80 percent of available acres, these
2 BTs have been used for years, very successfully. Very
3 often, as Bob indicated, part of an IPM program and also
4 used as a stand-alone quite successfully.
5 If you go down to the bottom of that pile you'll
6 see 4-A which is the old Nobel Onortis (phonetic)
7 product, which is also a kurstaki strain used in forestry
8 and it's used on 50 percent of the U.S. forests and up to
9 80 percent of Canadian forests. And it's used -- I
10 remember traveling around the world several times on
11 these products and they're used globally everywhere,
12 whether it's Asia Pacific, Europe, Latin America and so
13 on.
14 DiTera is a product -- myrothecium verrucaria,
15 which is a nematicide product. It's been on the market
16 for four years and it has up to 2 percent of the relative
17 market share in the U.S. for killing anematodes in grapes
18 and vegetables and it also has 30 percent of the Mexican
19 anematode market, too.
20 We talked this morning about the adulticides
21 while the larvicides for mosquitos and blackfly control
22 are the BTI isrealensis strain and the bacillus sphericus

1 strain. It's been on the market for 10 years for vector
2 control and of the larvicide market, has about 40 percent
3 of that market, a substantial market. Again, mosquito
4 abatement districts would not use these products if they
5 weren't successful.
6 Emerald Bio, which is the company I worked for
7 right now, has a product called AuxiGro. It also has a
8 lot of microbials, too. AuxiGro is a plant growth
9 regulator. The active ingredient is gamma aminobutyric
10 acid and L-glutamic acid. For four years in California,
11 it's been used in -- on tomatoes and now have 10 percent
12 of the California acreage. Again, would not be used if
13 the growers were not happy with it. The last two years
14 it's been used on almonds in California and it has 15
15 percent of the California acreage of almonds and that is
16 for yield enhancement and just better product. It's also
17 used on onions and potatoes and various other things very
18 successfully in Canada.
19 The last one I have is -- next slide --
20 AgriQuest. AgriQuest has a product called Serenade,
21 which is a bio-fungicide bacillus subtlis, and it's been
22 used for two-and-a-half years in the market and these

1 things are kind of inverted, but they have relative
2 market share of 64 percent of the Florida fresh market
3 tomato acres and 12 percent of the premium wine grape
4 acreage and it's used on -- that's mainly for powdered
5 mildew and Botrytis and 11 percent of the California
6 lettuce acres, too.
7 So, this is just a very quick rundown, just to
8 give you a sense of the fact that these products, again,
9 as a stand-alone or as an integrated pest management tool
10 has been used quite successfully. We had a very good
11 meeting last week in Indianapolis, which Bob and many
12 other people from IR-4 were involved with, and also the
13 EPA, and we talked about how we can do even a better job
14 of these integrated pest management systems and maybe
15 biopesticides are biopesticides. One researcher got up
16 and said that he was very successful for diamondback moth
17 eradication by starting off with a Bavaria Bassiana
18 product and then finishing up with a bacillus
19 thuringiensis product.
20 So, you can do an IPM program with not just
21 synthetic chemicals and biologicals, but biologicals and
22 biologicals as well.

1 DR. HOLM: Thank you, Gary.
2 MS. ANDERSEN: Thank you, Gary. That was an
3 update. Shall we go ahead and move on unless someone has
4 a burning comment or question?
5 MR. JONES: Yes. Any questions?
6 (No response.)
7 MR. JONES: Thanks, Janet and to the panelists.
8 Oh, yes, Jose?
9 DR. AMADOR: No, I just have a comment. We've
10 been working with our fruit program at the (inaudible)
11 center for quite some time now and developed a really
12 good relationship. I just want to complement Bob and the
13 program because it's working very, very well. There
14 seems to be excellent communication between the field
15 people and (inaudible) in Gainesville, Florida and it
16 seems like everything is going really smooth. I hear no
17 complaints to none of them.
18 And I'm surprised about a variety of things that
19 are being checked and tested, and all I've got to say is
20 I'm very, very happy to participate, Bob, and we thank
21 you for your cooperation.
22 DR. HOLM: Thank you, Jose, and thank you for

1 your cooperation in the State of Texas.
2 MR. JONES: Great. The last session before we
3 get into some agenda planning and next steps is basically
4 the Senior Regulatory Management Team within the Office
5 of Pesticide Programs talking about something that we've
6 routinely used this forum to discuss and that is, how we
7 in OPP are doing as it relates to our registration and
8 reregistration programs.
9 So, I think we're going to start with Debbie
10 Edwards and then Frank, Janet and Lois will all then
11 speak to their respective division's responsibilities in
12 those areas.
13 MS. EDWARDS: Thanks, Jim. I hope that you can
14 find in your packets -- you should have a landscape piece
15 of paper that says, Registration Division, New Active
16 Ingredient Registration History. You should also have a
17 piece of paper that says, Registration Division,
18 Accomplishments for 2003 and also the report that we --
19 called the bird report here. It has a bird on it and
20 it's Registration Activities in the Office of Pesticide
21 Programs. So, I'll be talking from at least the first
22 two of those.

1 The first table there on the landscape piece of
2 paper gives you the new active ingredient registration
3 history in the office of the last, I don't know, almost
4 10 years for conventional pesticide registrations, new
5 active ingredients. You can see we start there with 1994
6 and go through 2002, at least, letting you know how many
7 chemicals were submitted each year, how many new active
8 ingredients were submitted per year and then how many
9 were actually registered each year.
10 If you look there onto the right, there's an
11 average given and it's pretty interesting. We had no
12 idea how this would turn out when we started, but we are
13 averaging a receipt of 12.1 active ingredients per year
14 and we have, on average, registered 12 active ingredients
15 per year. So, that's right on target there.
16 You can see out at the very far right it has the
17 2003 statistics. To date, we have seven new active
18 ingredients in-house since October 1st of 2003. We're
19 expecting one more in May, which would take us to eight.
20 And to my knowledge, we're not expecting any more after
21 that this fiscal year. So, what you're seeing there is
22 actually a little bit of a -- at least in the past two

1 years, what may turn out to be a decline in submissions
2 of new active ingredients, at least for a period of time.
3 There will be nine in 2002 and probably eight in 2003.
4 If you go on down the page, we talk about the
5 summary of the pending new conventional chemicals. We
6 have 38 pending at this time, but 15 of those are
7 actually on the FY 2003 work plan for this year and 13
8 more we've actually placed already to be worked on in the
9 FY 2004 work plan, which only leaves 10 more to be
10 scheduled, some of which are, at this point, trysals
11 (phonetic) and other more problematic chemicals.
12 And, finally, there if you see in the eight
13 pending new conventional chemicals, those are for import
14 uses only, so we're tracking those separately, and of
15 those eight, we, at this point, have one on the FY '04 --
16 **(End of Tape 2, Side A.)**
17 UNIDENTIFIED FEMALE: Debbie, is this 38 then a
18 backlog?
19 MS. EDWARDS: Yes, it's a backlog, but only 10
20 of them are not scheduled. So, I would call -- the 10
21 would be the backlog.
22 UNIDENTIFIED FEMALE: Okay.

1 JIM JONES: (Inaudible) backlog (inaudible) been
2 in-house longer than we would like it to be. If it's on
3 this year's work plan, it's not necessarily clear that
4 that's backlog. But frankly, if it's on next year's work
5 plan -- as Debbie said, I think we would consider the
6 backlog to be those that are not scheduled for this year
7 or next year.
8 UNIDENTIFIED FEMALE: Okay.
9 MS. EDWARDS: That's correct. On the next piece
10 of paper you'll see, Registration Division
11 Accomplishments for 2003 -- FY 2003 to date. If you read
12 just across there, our goal for the year is a
13 registration of -- or decisions, actually, on 12 new
14 chemicals. We had 17 as candidates this year. We've
15 registered two so far, and, actually, I'm expecting we'll
16 have three more registered by early May.
17 For new uses, we had around 350 candidates. The
18 goal was to make decisions on 230. The number here says
19 28, but that's actually -- last night I signed tolerance
20 documents for 14 more. So, it's actually 42 new uses.
21 Those uses will come out probably next week. And then
22 for food use inerts, the goals was 10 to look at and

1 we've completed one.

2 Going down to the fast track and non-fast track

3 activities, I think there what you can see is that -- if

4 you look at the turn-around times, we're still doing

5 reasonably well with the turn-around times. On fast

6 tracks, it's 64 days for new products and 66 days for

7 amendments for this year so far. We do have a number

8 still pending in all of the categories, fast track and

9 non-fast tracks.

10 One thing I wanted to bring your attention to,

11 though, was in -- if you see submitted in FY '03 in

12 particular for fast track amendments, it's 1,553 that

13 have been submitted in the first six months of the year.

14 In FY 2000, we only had around 1,300 submitted for the

15 entire year. So, our receipts are dramatically

16 increasing in the fast track amendment area. We're doing

17 a little bit of an investigation into why that would be

18 and the impact on our resources and it's looking like, in

19 part, at least, it could be due to the first date

20 statement submissions that are coming in this year and

21 late last year.

22 Finally, there, in the bottom table, you'll see

1 the Section 18s, those are pretty much on track as usual.
2 Actually, I think we're down a little bit from last year.
3 We've had 231 submitted. There are six that have been --
4 come in as crises. We've granted 140 and our average
5 turn-around time is staying pretty stable at 35 days.
6 MR. SANDERS: My name is Frank Sanders and I'm
7 the Director of the Antimicrobials Division and I'm very
8 pleased to be here. I don't get an opportunity to
9 venture out to the PPDC very often. However, let me give
10 you -- I think in your package, you will see a chart that
11 talks about new active ingredient antimicrobial history.
12 The Antimicrobial Division has only been in existence for
13 a few years. I think we first started in 1997, but then
14 begins in 1998 until to date.
15 On average, we do about -- we get about 4.6, and
16 sometimes more than that registration applications and we
17 do about, on average, about 2.4 of those are completed.
18 As you can see, from 1998 to '02 -- from '03, when we
19 first started out, there was an increase in submissions
20 of seven in 1998. We do anticipate that this may -- we
21 do anticipate that we may get more submissions of new
22 active ingredients in the future because for a variety of

1 reasons.

2 Let me direct your attention to the next chart
3 that deals with fast track/non-fast track actions in
4 2003. As you can see, our fast track new products, we
5 have about 153 and we did 128 decisions. The average
6 turn-around time is also significant. Average turn-
7 around time is 72 days. That's significant because for
8 most of the fast track, you try to achieve at least a 90-
9 day turn-around time according to FQPA deadlines. So,
10 we're doing fairly well in that category. We have, to
11 date, pending 25.

12 Fast track amendments is a significant -- has a
13 significant increase from last year. We expect that to
14 continue for the second for the same reason that Debbie
15 pointed out. First date statements are beginning to come
16 in and we have to react to those as well.

17 So far, we have submitted -- we have received
18 1,279 of those fast track amendments. We've made
19 decisions on 1,069 and that's an average turn-around time
20 of 61 days.

21 Non-fast track new products, you can see in that
22 particular chart, we have 154 that's been submitted, with

1 the average turn-around time of 93 days. I'll put out
2 (inaudible) for these, the typical turn-around time is
3 120 days. We have 40 pending.
4 And for non-fast track amendments, we received
5 about 196 this year, we've done 109 and the average turn-
6 around time is 140 days, and we have pending 87. We
7 expect to be able to complete all the pending ones within
8 the time frame that we normally are required to do so.
9 With respect to our accomplishments for '03, so
10 far, we have a projection of one new active ingredient,
11 but that's not accurate. We've probably received a lot
12 more active ingredients because of alternatives to the
13 (inaudible) alternatives to other types of situations
14 like with (inaudible). So, that number may increase.
15 To date, we've done two, we've completed two.
16 And with respect to new uses, we've gotten 10 to respond
17 to. We have not made a decision on those at this point.
18 We do expect to make the decision within the time frames
19 allotted. And that's pretty much where we are with
20 respect to antimicrobials.
21 MS. ANDERSEN: So, then, one more chart,
22 biopesticides and this may give you a bit of flavor of

1 how the three registering divisions, as we call
2 ourselves, are different. We started in November 1994,
3 so our chart starts in '95, and on average, we have 13.6
4 submissions and 12.5 registrations a year for new active
5 ingredients.
6 But one of the things that we're having --
7 struggling with and spending a lot of time with right now
8 for biopesticides is that they actually are -- not that
9 many of them are passing the screen. And we have
10 certainly identified over the last year that one of the
11 things that's really slowing us down is that we're
12 dealing a tremendous amount with deficiencies and sending
13 back deficiency letters and waiting for products to come
14 in. So, we have instituted a new process and are
15 actually just, as I told the staff, kicking it up a notch
16 in the way we're doing it. And we are sending packages
17 back and not even considering them in -- for the year
18 until they really do pass both an administrative and
19 scientific screen.
20 We've worked with the Biopesticide Industry
21 Alliance and other groups. There's a phermone group and
22 we have their support in being able to do this, so that

1 we really have good quality packages and can move them
2 forward much faster we think.
3 And that's why our submissions are really down.
4 We have several pending that have not completed their
5 whole package. But we have registered three new active
6 ingredients to date. They are -- a little bit about them
7 are listed at the bottom. Two microorganisms and a --
8 what we call a plant incorporated protectant that looks
9 like it will be quite effective at reducing reliance for
10 chemical pesticides to control corn root worm.
11 So, we really -- you can see in the next chart
12 that we have 31 right now pending. That means they've
13 passed the screen. Our goal for the year is 12. We've
14 done three to date. Debbie and I should have coordinated
15 on this. I was going to say three in the next 30 days.
16 I've got several right on the cusp, so Jim's going to be
17 real busy as office director concurring on all of these
18 packages in the next little while. I am very assured
19 that we're going to meet or exceed that goal of 12 for
20 the year.
21 But notice as you go through and look at it, we
22 have, other than fast tracks, where we also are seeing a

1 huge jump in them and our analysis says it's not just
2 first date statements. So, we're not quite sure what
3 else is going on, but we're looking at that. But we've
4 really seen a jump in them. We are either on track or
5 ahead on almost all of our goals for the year and we see
6 very few, actually, fast track new products in the
7 divisions. So, that's why we tend to say we're not going
8 to do too many of them.
9 But we have seen, certainly, an increase in
10 experimental use permits. We have a number of these that
11 are for PIPS (phonetic) and that's partly why the number
12 is so high this year. But we've also approved them.
13 We've got one sort of set of PIPS with eight EUPs pending
14 right now that -- where decisions are going to be made in
15 the next month to three months. So, we'll have a lot of
16 activity in that area.
17 The one thing I want to say that sort of sets us
18 apart, we do a lot of new active ingredients compared to
19 Antimicrobial Division. They do a lot of amendments and
20 new products and new uses. So, the nature of our work is
21 actually different in the three registering divisions to
22 just give you a sense of that. I had a little statistic

1 run for them the other day. We have one new active
2 ingredient -- for every active ingredient we have, we
3 have six products for it, and I didn't ask my colleagues
4 to do that, but their numbers will be significantly
5 higher. They have a lot more products for every active
6 ingredient. And, partly, that is because for every
7 microorganism, every strain is handled as a new active
8 ingredient because there can be such variation in them
9 and we require the health and safety data to really be
10 there for each strain of a microorganism. So, that's
11 Biopesticides. I'll turn it to Lois.
12 MS. ROSSI: This is just a quick update on
13 reregistration and tolerance reassessment. You have, in
14 your packet, a handout entitled, Pesticide
15 Reregistration, Tolerance Reassessment Progress, April
16 2003. Just a quick overview of reregistration, our
17 universe is constant, 612. We are still showing 231 of
18 these canceled and completed decisions as of today, 215.
19 That leaves us with 166 REDs to complete, of which
20 approximately 40 are assigned to the Antimicrobial
21 Division.
22 Also, we have 22 IREDs that are pending

1 completion and being called REDs and the tolerances being
2 counted pending cumulative decisions. Many of those are
3 the OPs, as you all know.
4 We've scheduled work on another 55 and we've got
5 about 47 left to schedule, which we're in the process of
6 doing for 2005 and 2006. On your second page, you will
7 see the candidates that we are currently working on for
8 2003 and 2004 and as soon as we project what we'll be
9 doing for 2005 and 2006, we'll put those up on our
10 website.
11 With regard to tolerance reassessment, where the
12 count is at 6,501 out of 9,721 with 3,220 to go. Your
13 last page of your handout today gives you what we've done
14 so far in 2003. Our biggest, most labor intense
15 decision, obviously, was atrazine that we issued in
16 January, the IRED. We also issued a RED, Thiophanate-
17 methyl, and a TRED, 4-CPA.
18 Also, in our handout, it gives you the status of
19 the organophosphates, and you'll see we have four
20 decisions that we're currently working on. We're hoping
21 to issue Methyl Parathion this month. And that is
22 reregistration tolerance reassessment in a nutshell.

1 MR. JONES: Okay. Any questions for our
2 regulatory management panel we have here? Win?
3 DR. HOCK: I just have one. I'm really curious
4 about -- in the one that has the nice picture of the bird
5 on it, the great blue heron, the very first thing on the
6 second page, acetaminophen. If I recall, that's Tylenol.
7 MR. JONES: That's right.
8 DR. HOCK: And I'm just wondering, is that for
9 like rodent headaches or just what is it for? I'm just
10 curious. What is it registered for?
11 MS. EDWARDS: That is for -- to control the
12 brown tree snake in Guam.
13 DR. HOCK: Oh, okay.
14 MS. EDWARDS: We've had Section 18 use of that
15 for a number of years and what happens is you put a
16 couple of acetaminophen tablets in a dead mouse and then
17 you put them out with nets often in the canopy of the
18 forest and then the snakes climb up and eat them and die.
19 DR. HOCK: They die from the acetaminophen?
20 MS. EDWARDS: Yes. It's very toxic to these
21 snakes.
22 DR. HOCK: Let there be a warning to everybody

1 then, you know. Okay, thank you.
2 MR. JONES: (Inaudible).
3 UNIDENTIFIED FEMALE: Yeah, I forget what an
4 IRED is. Is that Interim RED?
5 MS. ROSSI: Yes.
6 UNIDENTIFIED FEMALE: Okay. On the last page
7 with the OPs, can you project when you're going to finish
8 those for OPs?
9 MS. ROSSI: Yeah. Methyl Parathion, I said
10 probably will be this month, by April 30th. Malathion,
11 we're expecting the revised risk assessment May 1st, so
12 we'll begin to work on evaluating all the comments that
13 have come in on phase five. Dimethoate, we're currently
14 working on and hope to make some decisions on by this
15 summer. And DDVP may be a little later.
16 UNIDENTIFIED FEMALE: (Inaudible).
17 MS. ROSSI: Probably into next year.
18 UNIDENTIFIED FEMALE: That's my chorus there.
19 Dimethoate, do you expect an announcement this summer?
20 MS. ROSSI: Probably a decision.
21 UNIDENTIFIED FEMALE: Okay. August?
22 MS. ROSSI: I'm not sure which month. It could

1 be sooner or be later.

2 **(Laughter.)**

3 MR. JONES: Jose?

4 DR. AMADOR: I noticed on your cancellations you

5 have, what, 231, and they were all volunteer?

6 MS. ROSSI: Yeah, and that -- let me explain

7 what that 231 means. Because if you look at the list of

8 completed REDs, which is 215, you'll also see some

9 asterisked with voluntary cancellations. That 231 really

10 reflects the early days of reregistration when people did

11 not support a lot of the chemical cases. And then as we

12 started going through the process and we would get a

13 voluntary cancellation, if we had put in a significant

14 amount of work on that and the end result was a voluntary

15 cancellation, we actually started counting those as

16 completed REDs. So, that 231 is pretty much -- yeah,

17 it's voluntary cancellations. It wouldn't include any of

18 the ones that we took action on.

19 DR. AMADOR: Do you have any idea what the main

20 reasons for the voluntary cancellations are?

21 MS. ROSSI: A lot of them -- the majority of

22 them, if you -- actually, we're getting ready to put on

1 our website, probably within the next month, the list
2 that is associated with these 231. If you looked at a
3 lot of them, you probably wouldn't even think that they
4 were pesticides. They were really a lot of the ones
5 that were canceled during the -- like the early '90s when
6 we -- for those of you who remember, we had lists of A,
7 B, C and D and lists B, C and D went through phases where
8 registrants had to declare support and show data
9 requirements. And many of those did not support the
10 active ingredient at that time. That comprises the bulk
11 of that number.
12 DR. AMADOR: But in relation to time, are the
13 numbers of cancellations now diminishing?
14 MS. ROSSI: Yeah. I mean -- yeah, we're not
15 getting massive ones, but we're still getting some. But
16 it's oftentimes after a long period of time of going
17 through the process.
18 DR. AMADOR: Are they all voluntary?
19 UNIDENTIFIED FEMALE: Sometimes.
20 MS. ROSSI: Sometimes.
21 DR. AMADOR: Sometimes.
22 MR. JONES: Pat?

1 MR. QUINN: Janet, not to put you on the spot,
2 but any idea what the turn-around time is per action on
3 those you've got listed here? And just for all three of
4 you, any idea sort of what the trends are over two or
5 three years on these time frames?
6 MS. ANDERSEN: Well, the trends have gone up in
7 how long it's taken to get a new active ingredient
8 registered. I often talk about the one case where we
9 have -- we did one in five months last year. It came in,
10 a perfect package, it sailed right on through. It was
11 not a food use, but it was one that actually is used to
12 control an evasive species. So, we considered it pretty
13 significant.
14 And this is why we're instigating this --
15 putting this program in place because our numbers have
16 continued to go up in the time it takes to do an active
17 ingredient. The last time I actually did a calculation,
18 it was on the order of about 20 months.
19 MR. QUINN: For an active?
20 MS. ANDERSEN: Right.
21 MR. QUINN: And then the amendments and shorter
22 term actions?

1 MS. ANDERSEN: Yes. There is -- actually, most
2 of the fast track amendments are biochemicals. There's a
3 fast track team and they usually do those very rapidly.
4 They're -- right now, nobody can keep up with fast
5 tracks, I think, as fast as they're coming in right now.
6 But those are -- are very rapid. I don't actually know
7 those numbers off the top of my head, Pat.
8 MR. QUINN: And, Frank and Debbie, would you say
9 your turn-around times on those actions, the shorter term
10 actions, are going up, going down?
11 MR. SANDERS: Well, Pat, what drives the turn-
12 around times, for the most part, would be the number of
13 applications we have, the resources and a number of other
14 factors.
15 MR. QUINN: Yeah, I know. That's what I'm
16 getting at.
17 MR. SANDERS: And I would suspect that, if
18 anything, it would -- we, at the Antimicrobial Division,
19 as you know, are required to complete those applications
20 within a certain time frame, and we continue to intend to
21 -- we intend to meet those deadlines. It is more
22 challenging today to meet those deadlines than it was,

1 perhaps, two years ago. But we still intend to meet the
2 deadlines. So, our turn-around times, respectively, are
3 about the same.
4 MS. EDWARDS: I believe the turn-around times
5 shown here are pretty much on track with the past, but I
6 would say what we are seeing, especially in the fast
7 track area and the Registration Division, are increasing
8 backlogs at this point and they're higher than normal at
9 this time of the year. Even though we've done an
10 analysis recently and actually determined that the per
11 capita output per year of fast tracks is going up almost
12 as much -- you know, per person working on them, almost
13 as much as the number of fast track receipts that have
14 been going up. But they're starting to fall apart at the
15 high ends of the tails of those curves. So, we need to
16 find a way to address that.
17 MR. QUINN: Thanks.
18 MR. JONES: Jay?
19 MR. VROOM: I have one sort of generic or
20 overview question and then a specific one. The specific
21 one is for Janet. The EUPs that you review and
22 authorization for plant incorporated protectants also are

1 coordinated with APHIS (phonetic) at USDA, is that
2 correct? Could you sort of refresh my memory on the
3 overlap there or are the APHIS experimental use
4 authorizations everything except for pesticidal
5 qualities?
6 MS. ANDERSEN: APHIS does a notification system
7 for non-pharmaceuticals and industrial compounds and some
8 -- and most of the PIPs and food uses. There are some
9 where they're very, very early stage research where they
10 are actually requiring permits. So, it is a notification
11 system that they do with USDA. And the requirement is
12 that you need an experimental use permit for any
13 pesticide. You need an experimental use permit when you
14 get to 10 acres of land or one acre of water. But there
15 is also the stipulation that you must have -- if there is
16 any potential that the pesticide residue would end up in
17 the food or feed supply, you have to have a tolerance or
18 tolerance exemption under FFDCA.
19 So, with those caveats, we do talk on a regular
20 basis to our colleagues at APHIS so that they know where
21 we are, we know where they are, especially related to the
22 PIPs; obviously, not so much the other compounds. So, it

1 is much more coordination. I would be very confident in
2 saying that I don't think anybody has an experimental use
3 permit where they don't also have an APHIS notification.
4 But notification is a pretty routine kind of easy thing
5 for someone to get compared to an experimental use
6 permit.
7 MR. VROOM: Okay, thanks. And then the kind of
8 macro question was, I think it was in Marty Monell's
9 presentation yesterday around the strategic plan. I
10 believe there was an explicit reference to 1,100 active
11 ingredients as sort of the overall work base for OPP.
12 And I'm trying to figure out how you get to 1,100 because
13 I sort of seem to remember that we're sort of in the
14 range of there were some 600 active ingredients that sort
15 of went into the mill under reregistration starting in
16 1988/'89 and obviously, as Lois has mentioned, a number
17 of those were not supported by registrants and even at 12
18 or 15 active ingredients a year, you know, coming new
19 into the front end, just trying to get the math
20 altogether here.
21 I think, by the way, the presentation of all of
22 you in this panel, short of my being able to do the sort

1 of final math step, is very helpful and it really paints
2 that picture. But I'm trying to get the closure in terms
3 of that top-end number.
4 MR. JONES: Jay, we'll get back to you with the
5 math on that. That's something the whole committee -- as
6 I recall from our discussion of registration review,
7 there have been 500 plus active ingredients registered
8 since 1984, which is the -- that's the cut point. So,
9 assumably, there would be 550 registered before that are
10 still in play and maybe that's the part that's not adding
11 up. So, we will do this -- do the calculus and get it
12 back to all of you as to how we came up with the 1,100
13 number.
14 Okay, thanks very much. At this point in the
15 agenda, we are going to talk about -- oh, I'm sorry. I'm
16 sorry.
17 DR. KASHTOOK: Okay, I'll be quick. I'm Mike
18 Kashtook from FDA. I just wanted to make you aware of an
19 activity that's, broadly speaking, related to the
20 tolerance reassessment that we're about to publish, a
21 guidance document that will detail FDA's procedures for
22 handling foods where residues of FQPA revoked pesticides

1 show up in the food in our monitoring activity after the
2 tolerance has been revoked.
3 This is the so-called channels of trade
4 provision, Section 408(L)(5) of FQPA where we have to
5 afford the responsible party an opportunity to show that
6 the presence of the revoked pesticide is the result of a
7 lawful application of the pesticide, and if that can be
8 done, then the food is not subject to enforcement action
9 that would normally ensue when a pesticide without a
10 tolerance coverage is found.
11 We've done a couple of these on a chemical-
12 specific basis. The one that we're about to publish will
13 be a generic one that we hope will cover any potential
14 FQPA pesticide revocations from here on out. This will
15 publish as a guidance for comment. We call it a draft
16 guidance. If anyone is interested in getting a copy of
17 this document, e-mail me and I'll make sure that you get
18 a copy of the guidance. I don't want to predict exact
19 publication times, but we're anticipating that probably
20 earlier or mid-summer at the latest, this draft guidance
21 will publish.
22 MR. JONES: Thanks, Mike. Mike, if you provide

1 it to us, we can actually use our electronic means to get
2 it around to the members of the committee.
3 UNIDENTIFIED MALE: I'm proud to see that the
4 FDA works a lot like EPA in those regards.
5 MR. JONES: Predicting publication times.
6 Thanks. Oh, Dan.
7 MR. BOTTS: One quick question for Mike. You've
8 got a draft available potentially right now? I've got a
9 meeting with Minor Crop Farm Alliance. We provided
10 comments to the notice on when you all published
11 initially, a notice on how you all were intending to do
12 that. Did you address the comments that were submitted
13 in relation to the initial channels of trade guide? And
14 if there is a document available, I need it sooner rather
15 than later.
16 DR. KASHTOOK: Well, what is available now are
17 the final guidances we've done for Methyl Parathion and
18 vinclozolin. If you don't have those, I can make those
19 available to you.
20 MR. BOTTS: I've got both of those. Okay. So,
21 there's nothing other -- is a draft available of what
22 you're going to publish for --

1 DR. KASHTOOK: No, when it is published, that
2 will be how we make it available to the public.
3 MR. BOTTS: Okay, thank you.
4 MR. JONES: Actually, let me just reflect for
5 one second on the previous panel and give some insights
6 into why we do this every time. Part of it is that this
7 really makes up about 70 percent or so of our work and we
8 feel the need to be accountable for it and this is a
9 mechanism for being accountable for the corporate
10 activity that we do in the Office of Pesticide Programs.
11 And another is just sort of to increase the awareness of
12 the magnitude of the work that's in front of us. At any
13 given point in time, there are literally over 1,000
14 actions before the agency for decision-making, and you
15 get to see that as we go through, sort of what's with us.
16 So, both for accountability purposes and just
17 raising awareness of sort of the scope of the
18 applications before us is really the reason why we have,
19 for seven or eight years of the PPDC, always sort of had
20 this on the agenda, which is a segue to our next topic,
21 which is agenda planning for the next meeting.
22 Julie, did you have something you wanted to

1 speak to before that?

2 MS. SPAGNOLI: Yeah. I just -- since you said

3 that, I did want to say how much I do appreciate these

4 updates and I think for those of us that work in this

5 area, this kind of information is very helpful for us,

6 because, often, we are questioned by our upper management

7 to kind of -- sometimes to get a crystal ball or to get

8 our assessment of how long actions are going to take or

9 what are the issues.

10 So, this kind of information is very, very

11 helpful in being able to make those kind of -- to answer

12 those kind of questions to our management. So, I just

13 wanted to express my appreciation for this.

14 MR. JONES: Thank you. As of right now, we

15 don't have any public commenters. So, we have a little

16 flexibility in our agenda and we are going to be out of

17 here at the scheduled time, if not a little before. Let

18 me just briefly go over something I started with

19 yesterday as we talk about agenda planning. When I -- to

20 give you sort of the how we have approached agenda

21 planning for this meeting, and not just this one, but the

22 past several. There's sort of three different

1 categories. Getting some feedback from you, do we have
2 the right mix first?
3 The categories are, as I said yesterday, updates
4 on issues that are just of interest and we know they're
5 of interest to a number of you. Some because you've told
6 us or others because we just know. They're sort of no-
7 brainers. They tend to be very timely, relevant, a lot
8 of public interest in them. Sometimes the interest may
9 be somewhat narrow in the group, but usually they're
10 broadly interesting. Those we've been calling updates.
11 Sometimes I feel like we're spending too much
12 time on those because they're all of us talking heads
13 kinds of things. I'm a little bit anxious about having
14 us do too much of the talking and not doing enough
15 listening. So, that's a sensitivity we've gotten around
16 the updates. Are we over-updating you?
17 The second category is what I would call
18 accountability. This last presentation was about
19 accountability. We had two other sessions -- I think two
20 or maybe three -- where we talked about, at this meeting,
21 something that we've discussed in a previous meeting. To
22 me, nothing worse than coming every six months, giving

1 your advice and never hearing again from the agency what
2 happened. And so, we tried to -- we don't do it on every
3 topic, but we try to do it on topics where at the
4 previous meeting or the previous two meetings, there was
5 some recommendation to sort of move forward in a certain
6 way. So, we've spent some time here today, and we've
7 done this the last couple of meetings, where we bring --
8 you know, we hold ourselves accountable, well, here is
9 what we've done. I think the big issue this time around
10 that we were doing that had to do with the alternative
11 testing, the biopesticide update would similarly fall in
12 that category.
13 So, there's this accountability where we're sort
14 of trying to hold ourselves accountable to previous
15 commitments made at the PPDC.
16 Then the third category is the one for which I
17 think we feel the most -- we gain the most out of, and
18 that's when we sort of bring a topic for the first time
19 in a somewhat comprehensive way to the committee.
20 Registration review is one of them and the second one was
21 the mosquito labeling. Sometimes we do it by having a
22 number of stakeholders present. Sometimes we're sort of

1 saying, here's what we're thinking. But in those, we
2 carve out a chunk of time where we're putting something
3 before the committee for the first time and are asking
4 for some advice, usually about both substance and
5 process.
6 So, those are the three categories that we have
7 and we tried to build this meeting around. We tried to
8 do it in a balanced way, balanced both in terms of the
9 types of topics, as well as -- and this, I think, is
10 actually the harder -- balance, and I'm not sure we've
11 nailed this one, balance in terms of making sure there's
12 enough opportunity for dialogue and listening and not
13 just us talking.
14 So, if we could spend a few minutes talking
15 about the structure. Is this structure working for all
16 of you? And then we'll spend some time talking about are
17 there some things that you'd like to propose that we tee
18 up for our next meeting. So, why don't we start with the
19 former? Any thoughts about that structure? Silence, of
20 course, will be considered to be you love the structure.
21 Thanks, Jay.
22 MR. VROOM: My sense is that you've hit a pretty

1 good balance around those three topics, broad categories
2 and good information. There was relatively good advance
3 information, but there probably were a few areas where
4 information sort of came out that maybe could have been
5 provided in advance for us to be a little bit better
6 prepared as a committee. But, generally, I thought that
7 those three categories are correct and that this meeting
8 represented a pretty good balance of that.
9 MR. JONES: Okay, I appreciate that comment
10 about advance materials. We do need to get better at
11 that. Margie is on us constantly about it and, as usual,
12 Margie's right.
13 MS. FEHRENBACH: (Inaudible).
14 MR. JONES: Carolyn?
15 MS. BRICKEY: Yeah, I agree with Jay that I
16 thought the three topic areas had a pretty good balance.
17 I thought, in particular, the discussion about
18 registration review was difficult because I didn't feel
19 like there was enough punctuation points for us to get
20 into, I guess. It was presented sort of generically and
21 I thought, you know, maybe we'd want to talk about it
22 again in the future after your workgroup works on it.

1 But I just thought, for future topics, to have a few
2 punctuation points where you say, okay, this is the
3 dilemma or these are the three alternatives or something
4 that we're looking at would be helpful.
5 MR. JONES: Thank you. Jose?
6 DR. AMADOR: On the accountability section, I
7 agree with the balance on the three, but I think -- it's
8 done sometimes and sometimes it's not done, when you
9 respond to some requests, it would be good if you give us
10 a background first. You don't have to identify the
11 individual or anything else. But as a result of this and
12 this and this and that, they would like to (inaudible)
13 that (inaudible). Because sometimes we might be getting
14 the response, but don't know why it's being done. I
15 think it would be a good idea if you can give us a brief
16 background of why we're doing this report.
17 MR. JONES: That's a good suggestion, thanks.
18 Dan?
19 MR. BOTTS: Jim, I think the mix was really good
20 this time. In fact, it was overwhelming, the scope of
21 the material that was presented. One thing I would like
22 to recognize -- and I didn't raise my card during the

1 mosquito labeling issue, but having been a charter member
2 of this group and been involved for longer than most
3 people probably would have liked me to have been
4 involved, that panel discussion was one of the best jobs
5 that I have ever seen done at this meeting where there
6 was an effort to actually frame the issues to the point
7 of giving this committee guidance in the meat and the
8 recommendations to come forward.
9 If that could serve as a model, even on the
10 reregistration review workgroup for those kind of things.
11 I mean, you all have a job to do. The issues have been
12 raised and it would be helpful to us to frame it to the
13 point that we can more efficiently utilize the time that
14 we're here together. That discussion was probably one of
15 the best processes. You had enough diversity in the
16 presentations to really flush out the issues and
17 understand them. I would suggest you probably need to
18 have the same type of panel on agricultural pesticide
19 labels as well as mosquito control labels at some point
20 down the road.
21 But if we could focus in those kind of areas to
22 tee up the issues, it would be great.

1 MR. JONES: I had the same sense myself, that
2 that served as a model. And I think we will take that to
3 heart in the future. Thanks. Julie?
4 MS. SPAGNOLI: I agree with Dan and I think that
5 the format was very good. To just kind of further what
6 he said, I think when the agency is specifically looking
7 for particular inputs from a committee, it's very helpful
8 when it is clearly identified, the questions that the
9 agency has and what they're -- what kind of inputs
10 they're looking for, as was with the mosquito labeling,
11 because I think it helps us focus our answers to the
12 agency.
13 MR. JONES: Thanks, Julie. Anyone else before
14 we talk about specific -- and this isn't the only
15 opportunity to identify specific topics you think may be
16 useful for us to engage in. For the next three months,
17 actually, any time you have an idea, feel free to send
18 them e-mail to Margie or use the PPDC forum if you want
19 to sort of get a broad discussion. I'll say, though, to
20 get better at -- along the lines that Dan and Julie
21 mentioned, and I completely agree with that, we need to
22 decide the issues early enough that we can do enough of

1 the work that is necessary to bring it in a mature way,
2 the way the mosquitocide labeling was.
3 So, we really need to have our big issues
4 identified in the next three months to have an
5 opportunity to do that. So, this isn't your only
6 opportunity, but that opportunity sort of closes about
7 three months from now. It's too late really to tee
8 something up for real intense discussion the month
9 before. Now, certainly not for an update it's not, but
10 for the kind of in-depth dialogue we're talking about
11 here.
12 So, that being said, does anyone today have some
13 ideas? We identified a few on the agenda that we had
14 heard from members amongst you previously, one being
15 environmental marketing claims and the other being
16 certification and training. I also heard, during the
17 course of the meeting, spray drift, endangered species
18 and the endocrine disruption program as all being
19 candidates for some significant dialogue at a future
20 meeting.
21 Thoughts? Jay?
22 MR. VROOM: One that I think was recorded

1 yesterday during Marty Monell's presentation and the
2 dialogue was contractor dollar efficiency and capacity in
3 general. And I might even lump in there, capacity of the
4 -- and ongoing activity of inter-agency contract work and
5 also grants, efficiencies, so states -- maybe these need
6 to be parsed out over several meetings.
7 But I think that's -- in terms of resource that
8 the agency's spending and the available capacities out
9 there, particularly in the private sector consultancy
10 arena, it would be really interesting to know more about
11 and, you know, to get a sense, as a country, are we sort
12 of dummying down our capability or is it being supported
13 out there.
14 A couple of others that I think have been also
15 mentioned, (inaudible) and oils topic that sort of flows
16 kind of beyond the inerts ingredient area, as well as
17 spray drift control additives. And then two things that
18 I'd like to offer that I believe have been mentioned
19 previously in this meeting, one would be a session on
20 industry and grower/other user stewardship initiatives.
21 There's a lot of stuff going on out there. To my
22 recollection, there's never, in my PPDC experience, been

1 an agenda topic focused specifically on that array of
2 things and we could probably pick out just a handful to
3 kind of feature over several meetings. It would be
4 useful, I think, to do some sharing there. And then the
5 other area that hasn't been addressed came up -- I
6 actually asked Margie about this a little over a week ago
7 -- on a specific enforcement issue that I thought surely
8 had been resolved by now. It turns out, in talking -- in
9 follow-up with Jack Neyland earlier this week, it's still
10 ongoing and is in a criminal phase with the Department of
11 Justice and couldn't be addressed at this particular
12 meeting. But it kind of made me think that it would be
13 useful to hear from OECA (phonetic) about all of their
14 kind of ongoing trend line experience with regard to
15 enforcement and compliance.
16 Just like this last panel on registration-
17 reregistration activity sort of gave us a score card, it
18 would be instructive for us, as an advisory group, to
19 sort of see what OECA is doing, what kind of coordination
20 is going on with OPP or not and, you know, what we might
21 be able to do to help bolster and improve government
22 efficiency in that area.

1 MR. JONES: Thanks. Win?

2 DR. HOCK: I'd like to first say that this has
3 been a great meeting. Jim and Anne and your whole staff,
4 you deserve a lot of compliments for a job well done.

5 Now, Jim, you may have to practice a little bit
6 your flamboyancy and your accent to match up with Marcia,
7 but you're working on it. I like what you're doing.

8 I really like the idea of having a certification
9 and training program scheduled for the next meeting. I
10 think it's a very broad, major area, involves, obviously,
11 several million people in the United States. I think
12 this is an excellent topic. I would hope you would also
13 have something as a follow-up on the mosquito labeling
14 issue. I know we threw it into your lap, but I really
15 would like to know what has been done, because I suspect
16 by the next time we meet, we'll have gone through another
17 mosquito season, and I think a lot of things could be
18 happening in the interim. So, you know, I would like to
19 have a follow-up on what EPA is doing or what they're
20 planning on doing or has been done.

21 And the other thing is, now that we have an
22 official Department of Homeland Security, I wonder if you

1 could give us a brief update. It doesn't have to be a
2 major topic, but I think a brief update of how EPA, and
3 specifically OPP, is interacting with the Department of
4 Homeland Security and what role we might play in that as
5 well.
6 I think this is a new area. Like I say, last
7 time we met, I don't believe it was an official
8 department at that time. It is now, and I suspect
9 there's probably some activity going on. I would find it
10 -- at least, personally, I would find it interesting to
11 know what you're doing. Thank you.
12 MR. JONES: Thanks. Julie?
13 MS. SPAGNOLI: I'd just like to clarify the
14 topic that I had suggested, which was identified as
15 environmental marketing claims. I think environmental
16 marketing claims indicates kind of a rather narrow scope
17 of types of claims, and actually, I think what I am
18 proposing is really looking at the agency's policies with
19 regard to label information as it falls under the
20 definition of false and misleading and the policies that
21 the agency has had in place.
22 As we've moved into recommending and encouraging

1 people to use safer products and -- the agency on its
2 website refers to safer products, also, that as new
3 products are being developed that are alternatives to
4 existing products. We're faced with a difficult
5 situation as marketers in being able to communicate some
6 of these attributes to the public, and it really becomes
7 a public information issue as there's somewhat confusion
8 out there.
9 A new product is introduced, but it's -- there's
10 no way of distinguishing it from an existing product.
11 And while it may be difficult to just make a claim of
12 general safety for any pesticide product, I think we need
13 to look at are there ways to communicate the specific
14 information to a consumer as to what is -- you know, a
15 safe use of a product, that a product is safe for a
16 particular use and, therefore, help the consumer in
17 making the product choices that are important to them or
18 that they are being encouraged to make. In particular,
19 with respect to risks to pets or wildlife, whether a
20 product is safe to use on certain sites. I think we need
21 to look at ways of trying to communicate that to
22 consumers accurately without being false and misleading,

1 but not by withholding information.
2 MR. JONES: Thanks, Julie. That helped. Beth?
3 DR. CARROLL: You mentioned yesterday the ESA
4 topic and I think what was said was expanded. So, I
5 would just like to perhaps suggests that within that
6 topic, we discuss how the agency is going to integrate
7 the EFED and ecological assessments into that process.
8 That would be interesting for us to understand and you
9 may not know yet.
10 **(Loud microphone feedback noise.)**
11 MR. JONES: Is everybody okay?
12 DR. CARROLL: I'm taking that as a sign. And
13 then along with Jay's suggestion on industry and
14 stewardship issues, I think that would be a good
15 springboard to also discuss resistance management and
16 resistance management labeling, which I think we have
17 various perceptions of, including within our industry.
18 And that would be something that could be folded right
19 into the stewardship process, as well as integrated pest
20 management discussions.
21 MR. JONES: Thanks. Bob?
22 DR. HOLM: I just wanted to follow up on what

1 Julie said on environmental marketing. I understand what
2 Julie's saying to refer to -- I think it's the agency's
3 charge to deal with questions relating to product-
4 specific environmental marketing claims.
5 There is, however, a second set of issues which
6 is commercial applicator's ability to make claims on
7 behalf of the services they provide, which is not a
8 central issue for the agency. Yet, it's the agency's own
9 document on that subject, which has become a de facto
10 standard.
11 MR. JONES: Right.
12 DR. HOLM: And my problem --
13 **(End of Tape 2, Side B.)**
14 DR. HOLM: -- about what the agency's view is on
15 what ought not to be said. But it's been very difficult
16 to construct things that people can say if, in fact,
17 they're doing things in a safer way, if they're doing IPM
18 or using reduced risk products, how they can characterize
19 that in a way the public would understand and that the
20 agency would approve of.
21 MR. JONES: Right.
22 DR. HOLM: And that states would buy into. So,

1 I hope if that comes up, that little subset of the
2 equation could be taken into account.
3 MR. JONES: Thanks, Bob. Warren?
4 DR. STICKLE: First of all, I want to commend
5 you, Jim, and your staff for both the content and the
6 structure of the meeting. I think it's gone very well.
7 Concerning the next PPDC meeting, I thought Anne
8 did a really good job of breaking out the inert issues
9 from the perspective of the methodology and inert
10 disclosure and then also data compensation. And by the
11 way, the data compensation did appear today in the
12 Federal Register. As a sideline, CLA and CPDA will be
13 putting on a workshop on data compensation on June 5th so
14 that it's in the middle of the comment period.
15 But I think in the next six months, each of
16 those issues will, I think, become really very, very
17 ripe, and a further opportunity to discuss some of those
18 developments, I think, would be appropriate.
19 Secondly, we talked yesterday about spray drift
20 and the issue of drift in general. If we're going to
21 discuss that, I'd recommend that we also look at it from
22 the new technological perspectives, from the point of

1 view of polymer technology on one hand and what that
2 means, as well as equipment technology on the other.
3 And, thirdly, you've already mentioned the
4 endangered species issue, and clearly, over the next
5 three to four months, many of the legal issues have an
6 opportunity to be resolved, so that within six months, it
7 might be appropriate to come back and look at that aspect
8 because the issue may be a lot clearer then than it is
9 now.
10 MR. JONES: Thanks, Warren. Phil?
11 MR. BENEDICT: I think the plate is full, but
12 I'm going to throw something else out anyways. I'm kind
13 of curious about the atrazine RED and how you're managing
14 water quality in the pesticide there. And I really think
15 it would be useful for the PPDC to have a discussion
16 about how water quality ought to be managed as part of a
17 pesticide issue. I'm not talking about the (inaudible)
18 thing. I'm talking about just how to regulate pesticides
19 with -- that have water quality concerns.
20 I'd be curious to know if the agency, in six
21 months or so, thinks that the strategy we're using is the
22 right strategy or the wrong strategy with atrazine. I

1 think we could use atrazine as a model to be perfectly
2 honest, because you've got that RED out there. I think
3 that would be a real interesting debate, just kind of
4 looking at it from a registration point of view, a
5 compliance and a field point of view of having a good
6 discussion about whether it's going to work or not.
7 MR. JONES: Thanks, Phil. Pat?
8 MR. QUINN: Well, just to congratulate you on a
9 very successful maiden voyage here in a leadership
10 capacity. But what I want to do is to second Jay's
11 suggestion about enforcement.
12 I think that would be a very productive
13 discussion. I consistently feel that OPP does not get
14 the support from OECA that it might and I think we ought
15 to explore what the reason is for that and how they're
16 setting priorities. And I think sorting out
17 institutional roles and what issues can be resolved
18 sensibly by the program without referral to OECA, what
19 sort of authority the program ought to have might also be
20 a good set of subjects to get into.
21 MR. JONES: Thanks. Troy?
22 MR. SEIDLE: Thanks. Two issues that were

1 raised yesterday with respect to, not so much PPDC
2 meeting topics for the next meeting, but discussions that
3 should take place between meetings, whether it's through
4 a formal subgroup. I'd like to second your suggestion
5 for a reregistration review. I think that's a subject
6 that needs to be discussed and flushed out in some
7 detail. So, I'd personally throw my hat into the ring
8 and be interested in participating in that discussion.
9 And, likewise, with the alternative test
10 methods. That's an extraordinarily dense topic that, I
11 think, needs to be flushed out further between meetings,
12 and then for more periodic updates down the road. But I
13 think that's an ongoing type of discussion.
14 But one issue that I think is ripe for PPDC
15 discussion for a panel would be the endocrine disruptor
16 issue again. I recognize that it's been discussed in
17 some detail from certain perspectives on the Office of
18 Science Coordination and Policy side with respect to the
19 tool box and the test methods. But what hasn't been
20 flushed out in any level of detail is how the program
21 offices who would require the testing for the substances
22 within their jurisdiction would actually rule that out.

1 And I think it would be interesting to hear how
2 the different registration divisions would plan on
3 deploying this kind of program for the different types of
4 pesticide products. I know there are stakeholders around
5 the table who are very actively engaged in this issue who
6 would also have perspectives on it and I think it would
7 be useful just to get the discussion going because before
8 the program is actually implemented, I think this kind of
9 discussion needs to take place in a very public forum.
10 MR. JONES: All right, thank you. All right.
11 That is very helpful. It sounds like the format,
12 generally, people are comfortable with and I think we can
13 expect that we'll stick with that format. The --
14 actually, Troy, you gave a good segue to one of the first
15 things I wanted to wrap up with and that is that we will
16 be doing -- we will be having PPDC workgroups for
17 alternative testing, as well as registration review.
18 Debbie Edwards and Jack Housinger have been
19 leading the alternative testing and will continue to do
20 so and we'll figure out how to, with Debbie and Jack,
21 reach out to the people who have been participating with
22 them already to make sure that that group constitutes the

1 right individuals to see if there may be the need to
2 supplement those individuals with some others. But we do
3 want to keep it at a -- with a size that allows us to be
4 effective. But recognizing that you don't necessarily
5 have to be a PPDC member to be on a FACA subcommittee
6 that reports back to this FACA committee.
7 So, Debbie and Jack will be working with those
8 of you who have been participating on that to sort
9 through the next steps of that working group.
10 We also are going to have a registration review
11 subgroup or working group of the PPDC and we'll figure
12 out, in the coming -- next couple of weeks, how we'll
13 solicit you for either your participation or if you have
14 -- if you want to recommend someone to participate.
15 Again, we have to -- it's very important that we
16 have -- in my mind, there are a couple of factors you
17 want to make sure you've got. You got to have balance in
18 the group. You have to have a group that's not too big
19 to get something done. And I believe that although it's
20 not required, you do need enough actual members of the
21 PPDC -- it doesn't have to be half the membership of this
22 workgroup, but it needs to be three or four and not just

1 one for it to be, I think, effective.
2 So, we'll figure out how to do some outreach to
3 all of you on that in the next couple of weeks and we'll
4 get back to you.
5 I think today is an interesting day to note that
6 -- today, the indoxycarb tolerance actually -- is it
7 today, Debbie, that it's -- yesterday. It was a PPDC
8 meeting that we had been hearing it sort of in
9 discussions we had had with individuals that -- but it
10 came to us in a PPDC meeting that, you know, the agency
11 really needs to do something about EUPs to help with
12 transition. And we basically sort of vetted the issue at
13 first to the PPDC and have subsequently kept this
14 committee posted. But it was advice we got from this
15 committee that sort of led us to realize that we needed
16 to do this.
17 I think it's sort of appropriate that on the day
18 of one of our meetings, we're actually issuing a -- we're
19 proposing a tolerance that's directly related to the
20 advice that we get from this group, which I think is just
21 how we want to use this committee. We want to get advice
22 on things that we are doing or not doing or there's a

1 sense that we need to be doing better so that we can be
2 better at what we do.
3 We think that one of the most effective ways to
4 get advice is to do it with a broad group of stakeholders
5 and I think that the trick for us is trying to figure
6 out, you know, where are we on various issues that are
7 really ripe for advice, which is why, I think, we're
8 pushing hard for this registration review to be something
9 we focus on. It is in the perfect place for there to be
10 advice being given, which is going to allow it to be
11 shaped in a way when it's proposed that the likelihood of
12 it having a success will be much, much higher.
13 Recognizing, as Carolyn pointed out, it's a little bit
14 sort of hard to get your arms around it because it's not
15 quite flushed out.
16 I think mosquito labeling is another one where
17 right now is -- you could argue we could have done it
18 five or ten years ago, but it's an issue that is primed
19 for the agency to get advice before it chooses a course
20 to go down. So, we really do want to -- and the mosquito
21 labeling wasn't one that we identified as a registration
22 review one. It was one our state partners identified as

1 you people need to get your act together on this.
2 And, likewise, it's not -- these aren't -- it
3 isn't just for us to decide what do we need to get advice
4 on, it's also part of what we're asking you and that's
5 this balance of where do we think we need advice, but
6 having our ears opened to where you think we need to get
7 advice, which is why it's important to ask you, what do
8 you think we need to be talking about?
9 There's this balance of us having a sense of
10 where do we need help, but listening to you as to where
11 you think we need to get a little help, where we need to
12 focus on something we're not focusing on or stop focusing
13 on something that we're focusing on. So, that is how I
14 think we have tried to use this committee and how we'd
15 like to use the committee going forward.
16 Finally, I would just like to thank all of you
17 for your public service that -- I recognize, just like it
18 is part of our jobs to do this, it is part of your jobs
19 to be here today. That being said, I realize it's a big
20 inconvenience for you. It requires you to be a
21 meaningful participant, which I think you all are, for
22 you to invest before these meetings. It requires you to

1 invest between these meetings.

2 But for the system to work the way we like it to

3 work in this country, it requires citizens to participate

4 in government, and I think that that's what all of you

5 are doing here over the last couple of days, and frankly,

6 what you're doing in between meetings when you're

7 participating in the workgroups or just giving us some

8 advice or suggesting things that we work on.

9 So, thank you very much. This is a very

10 important part of how, I think, this government likes to

11 operate.

12 That being said, we are now -- Margie, can I

13 adjourn this meeting? Is there anything else official I

14 need?

15 We are now adjourned. Thank you very much.

16 **(Whereupon, the meeting was concluded.)**

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22 CERTIFICATE OF TRANSCRIPTIONIST

1 I, Elizabeth M. Farrell, do hereby certify that
2 the foregoing transcription was reduced to typewriting via
3 audiotapes provided to me; that I am neither counsel for,
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13 ELIZABETH M. FARRELL
14 Transcriptionist
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