UNITED STATES

ENVIRONMENTAL PROTECTION AGENCY

PESTICIDE PROGRAM DIALOGUE

COMMITTEE MEETING

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Conference Center - Lobby Level

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Arlington, VA 22202

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P R O C E E D I N G S

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DR. BRADBURY: Welcome to all the members of the PPDC and the public. I appreciate everyone here to join us for the next day and a half as we go through, I think, a number of challenging issues. We're looking forward to having a discussion with you, and I know you've all put in a lot of work in preparing for today and tomorrow.

Again, I appreciate all the travel, some of you traveling through the Beltway to get here, and the subway, and some of you flying across the country to get here. I appreciate the effort just to get here and to participate, and especially all the work that you've been doing ahead of time as we come into these meetings.

As we've discussed numerous times, the PPDC, when we all get together, is an important time for sharing information, but more importantly, getting feedback on next steps. To have feedback on next steps means the workgroups have been doing a lot of work in between our meetings, because that's where the real work gets done and the ideas get crystallized and brought

forward to the full committee. So, I appreciate that.

And just to sort of recap what we're all about in the context of the PPDC and the Federal Advisory Committee Act, this committee, as part of a process that flows from the Federal Advisory Committee Act, is a really important part to government in general, EPA more specifically, and what we all care about is the pesticide program. It's the feedback and the ideas we get from a diverse group of stakeholders that really is critical to advancing the program to help us see what we're doing today and what could be better.

And as important, if not more important, is looking to the future to see where we need to be as we move forward into the future and take on challenging issues. But to take on those challenging issues takes input and advice and ideas from a broad array of stakeholders who all have interests and equities in what we do.

So, it's really an important part of our program, everything from the registration and re-registration process that leads to label language, to stewardship and training, to enforcement, to the field

program. All of that intertwines in, hopefully, having a solid program that provides for public health safety in terms of pest control and agriculture, but also ensuring protection of human health in the environment at the same time. Your input is really important.

Obviously, we take on tasks and challenges that are pretty challenging, have a lot of different viewpoints. So, the goal of the workgroups and the full committee, as we tackle issues, isn't necessary to reach a consensus -- although that's great when it can happen, and we like it when it happens. Then, we may agree or disagree with the consensus, but that's a different point -- but also realizing that sometimes it's hard to reach consensus.

Not reaching consensus is not a bad thing because good hard work, constructive work, careful deliberation, brings out some of the challenges that may be associated with an issue. Not reaching a consensus, as I said, isn't a bad thing. Getting clarity around the different viewpoints and the assumptions and the analyses behind different viewpoints is very helpful for us as we ultimately have to make the decision. But understanding

the complexity or the variation in viewpoints is really important for us.

So, I want to just encourage the workgroups. We'll hear some things today where I think we are reaching some consensus or maybe some areas we're still struggling trying to figure out how to tackle some issues. I just want to make it clear that's okay. Continuing to kind of work and get clarity on issues is a critical step. Consensus is great, but it's not a requirement to make progress and to move forward.

So, we've got a pretty solid agenda, like we usually do. Hopefully, we've struck a balance between getting efforts out of the workgroups, which is our main engine of getting things done and getting feedback on steps for other workgroups to take on based on your feedback and our feedback from EPA.

Also, we've got some spots on the agenda just to get updates on activities going on. I notice there always is this balancing act between updates and digging into the details of activities. So, we'll see if we struck the right balance on that.

I just want to spend a few minutes going

through the agenda just to hit some of the highlights of the agenda. Then, what we'll do is just introduce ourselves. Although I think we're all getting to know each other pretty well, I think it's helpful just to go around the table again. Then we'll move in into the agenda.

So, what we're going to take on during the course of the next day and a half, the first session, after we do introductions, will be Marty and I reviewing a bit on our strategic direction setting and intertwined in that an update on our budget from the past, our budget today, and a little bit of a sense of what the future looks like for budgets.

We'll then have a session on pollinator protection, the workgroup. Those come together over several months and had a good meeting yesterday. I think we'll be getting some, I think, tangible suggestions or recommendations from the group on some next steps that we can take on. Don Brady will help facilitate that discussion with presentations from workgroup members as well.

Following lunch, we will then hear from the

integrated pest management workgroup and get some presentations from what the workgroup has been taking on, as well as a presentation from the USDA and some components of USDA's IPM program. That will take us up to after lunch, and then we'll take a break.

Then we'll get an update on the endocrine disruptor screening program from Karen Whitby, who is the acting director for the Health Effects Division, and Mary Manibusan, who is the new division director in the Office of Science Coordination Policy that leads the endocrine program. So, we'll get a snapshot of what's going on right now with the program and what some of the future looks like.

We'll then have a series of updates, trying to get that balance again with updates as well as workgroup reports. You can see on your agenda we'll be going through a number of topics that were based on info we got from the committee on areas you'd like to get some updates. We also reserved a little bit of time for sort of an open mic if there's a topic or a set of questions you may have that we didn't capture.

Then, near the end of the afternoon, Jack

Housenger will give an overview of some work we've been doing on the definition of minor uses, the economic definition of that. It's going out for comment, but we just wanted to give you a preview of what that's all about, not necessarily to weigh in on it but maybe help with some clarifying questions as that moves through the comment period. We'll get you up to speed on that.

Then, the last session will be an update on spray drift, where we are in our spray drift policy as well as some of the technology that we want to advance in terms of drift management.

Tomorrow morning Don Brady and Rick Keigwin will talk about the Endangered Species Act. That act still exists and some of the challenges still exist. But there's some progress and some steps we've been taking, so we want to give you an update on that and get some feedback.

We'll then spend a little time on registration review, but in particular, there are two aspects of bringing up registration review. One is just sort of to get an update on where we are in registration review and just reminding ourselves of the work we've got or the

ideas we got in terms of these focus meetings to try to help at the front end of registration review to make sure we're getting the most critical information to moving forward. It helps with ESA, but it helps generally with our risk assessment process.

Related to that, we want to spend some time on water quality. One of the goals going into registration review was to insure that we were getting the best available information on monitoring information and other information about aquatic systems. We finished registration review.

As we finished re-registration, we're getting a lot of comments on, are you sure that your re-registration decisions aren't going to inadvertently, perhaps, lead to future 303(d) listings or impaired water listings of the Clean Water Act. Obviously, we want to try to minimize the idea that we're registering pesticides that in the future could create a water quality problem through the Clean Water Act.

Some of the dialogue near the end of the re-registration process was hard because people were concerned where we're going and talking about monitoring

that, but we didn't have our hands on the monitoring data or the information behind impairments or potential impairments.

So, we want to spend some time tomorrow talking about that process and how to make sure we're getting the current information on monitoring data to help feed into the front end of problem formulation for registration review to tackle one of our major objectives.

Then we'll spend a little time with the PPDC workgroup on 21st century toxicology, getting updates on where they've been taking on some issues. We'll talk a little bit about -- have a guest speaker, if you will, from our colleagues in the Office of Pollution Prevention and Toxics, sort of giving a little update on how they're thinking about 21st century toxicology and the work they do.

Then we'll wrap up with a couple of short sessions on the Regulatory Cooperation Council and the efforts that Canada and the U.S. are undertaking to try to make sure not only in plant protection and pesticides but more bodily across the economy coordination between the U.S. and Canada and trying to harmonize approaches.

So, we want to give you an update on that. Then, there will be an update on sustainability issues within the agency and things that we've been taking on.

So, I think it's a pretty robust agenda. Hopefully, there's enough time for questions and dialogue and decisionmaking. Without any more of me burning up clock time, why don't we go around the table and just introduce ourselves. Then we'll get on to the agenda.

So, Marty, why don't you go first.

MS. MONELL: Marty Monell, Deputy Director OPP.

MS. KUNICKIS: Sheryl Kunickis, USDA Office of Pest Management Policy.

DR. KASHTOCK: Mike Kashtock, FDA, Office of Food Safety.

CAPTAIN BEAVERS: Good morning, everybody. Mark Beavers, Armed Forces Pest Management Board.

DR. CALVERT: I'm Geoff Calvert. I'm a physician with the Centers for Disease Control and Prevention.

MS. SMITH: Cindy Smith with the Gowan Group.

MR. DELANEY: Tom Delaney, Professional Landcare Network, Landscape Group.

MR. THRIFT: Jim Thrift, Agricultural Retailers Association.

MR. HANKS: Doug Hanks, National Potato Council.

DR. FERENC: Sue Ferenc, Chemical Producers and Distributors Association.

MR. GJEVRE: Eric Gjevre, Coeur d'Alene Tribe and Tribal Pesticide Program Council.

MR. BUHLER: Wayne Buhler, NC State University, coordinator of the pesticide safety extension programs and cooperative extension.

DR. GILDEN: Robyn Gilden, University of Maryland, School of Nursing.

DR. GREEN: Tom Green, IPM Institute.

MS. HERRERO: Maria Herrero, Biopesticide Industry Alliance.

MR. JACKAI: Louis Jackai, North Carolina A&T State University.

MS. STARMANN: Allison Starmann, American Chemistry Council.

MR. BARON: Jerry Baron, IR-4 project.

DR. KEGLEY: Susan Kegley, Pesticide Research

Institute.

MR. VUKICH: Jake Vukich, DuPont Crop Protection.

MS. SULLIVAN: Kristie Sullivan, Physicians Committee for Responsible Medicine.

DR. KEIFER: Matt Keifer, National Farm Medicine Center.

MS. LUDWIG: Gabriele Ludwig, Almond Board of California.

DR. ROBERTS: Jimmy Roberts, Medical University of South Carolina.

MS. LAW: Beth Law, Consumer Specialty Products Association.

MR. NYE: Ken Nye, American Farm Bureau.

MS. PALMER: Cynthia Palmer, American Bird Conservancy.

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

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

DR. LAME: Marc Lame, Indiana University School of Public and Environmental Affairs.

MR. SHEEHAN: Pieter Sheehan, Fairfax County Health Department.

MR. SCHERTZ: Scott Schertz, Schertz Aerial Service.

DR. CLEVELAND: Cheryl Cleveland, Dow AgroSciences.

MR. COX: Darren Cox, U.S. Bee Industry.

MR. McALLISTER: Ray McAllister, CropLife America.

MR. WHALON: Mark Whalon, Michigan State University.

DR. WILLETT: Mike Willett, Northwest Horticultural Council.

DR. VERDER-CARLOS: Marylou Verder-Carlos, California Department of Pesticide Regulations.

MR. SMITH: Steve Smith, S.C. Johnson.

MR. TAMAYO: Dave Tamayo, Sacramento County Stormwater Program.

MR. JORDAN: Bill Jordan, Office of Pesticide Programs.

MR. BRADBURY: Good, and again welcome to everybody. I've got to get my left hand on the right

hand side because Margie got me confused. Some of you aren't in the same places I'm used to seeing you. Cindy is over there so that part is stable. Hopefully, I won't get names and faces mixed up. Again, welcome and appreciate all the time and effort to join us today.

So, the first topic that we'll cover today is to give you a snapshot of where we are in our strategic direction setting as well as the budget picture. I know, over the course of several meetings, we've talked about our strategic direction setting, efforts that we've been doing in the program, and you've all been asking, so, how does this interplay with some of the budget issues that are playing out in the federal government. So, they play out with us well here in the pesticide program.

Let me just spend a few minutes kind of introducing the topic, and then I'll turn it over to Marty for the lion's share of the time. We'll also have time for some questions.

I think in a couple of our sessions I described an effort we undertook starting probably a couple years ago, a year and a half ago, when we did some self-reflection within the program. We're coming up on

cycles, three- to five-year cycles when you sort of sit back and take a look at your organization, what are its challenges, what are the dynamics inside your world and the world you interact with, and do that time when you decide is everything going pretty good and maybe just a few minor modifications is appropriate.

You don't really need to do a major shift in sort of how you tackle the challenges that your organization takes on, and you move forward for the next three- to five-year cycle. But sometimes you take a look at where you've been, where you are, where you're going and you reach a different conclusion.

Folks on the phone, if you can make sure that you hit your mute button, that would be helpful.

If you take a look at where the world is and where you're going, maybe it's time to make the conclusion that kind of doing the same old same old may not get you where you need to be in, say, five to seven years. If you want to be at the head of the class five to seven years or continue to be a high performing organization, you have to make some adjustments as you go forward.

So, we are looking at what are some of the drivers, what are some of the activities going on, and realizing there are a number of important drivers that we're starting to reach some critical points. Some of the drivers included changing technology, technology in the context of how information moves, both within our organization and outside our organization, and how information can come into our organization.

This technology had a lot of power to it. It could enhance not only efficiencies but also effectiveness in what we do. We realize that we need to change to start to really be able to harness that technology and use that technology to our advantage.

In reading about some of these things, sometimes it's the technology that's ready to go, but are the people ready to figure out how to use the technology and advance that technology for useful purposes? So, we felt that was an important change and we needed to start to try to learn about that and be able to start to advance some of that technology for ourselves and for all the folks that we work with.

We also were realizing that the science is

changing significantly, and it's changing fast, everything from what goes on inside cells with subcellular components up to the scales of air sheds and water sheds in terms of the science that we have to do to support our regulatory decisionmaking. Some of that is technology and some of it is just that science is advancing rapidly.

We realized that five years from now the information and the way risk assessments are done and whatever scale you want to talk in terms of time or space or organisms, it's not going to be the same five years from now as it is today. I think it's just a fact. There's just too much happening.

Having said that, do you want to be chasing that change in science or do you want to be near the front of that change in science so that we can take advantage of more effective ability to do risk assessments at whatever scale, whatever the question is, as well as the efficiencies that can be harnessed from, I think, some of the technology? So, we realize that that's changing fast. So, we need to be ahead of the curve on that.

We also realize that the resource base is going to be changing. So, we've got all these exciting events happening, technology is changing, the science is changing, how we communicate ideas in terms of labels or stewardship. There's all sorts of opportunities there. We also have another challenge, that the resource base by which we're going to take on all these challenges probably isn't going to be the same as it has been. It's probably not going to be the same because it's getting bigger. It's probably not going to be the same because it's getting smaller.

So, how do you blend the fact that your resource base is likely to be going down? It's not just us and EPA. It's across the federal government, our state colleagues and local government colleagues have been facing these challenges for quite a while. It just took a while for parts of the federal government to start to absorb the same changes that are going on.

So, realizing we've got these three or four different themes before us, we established some workgroups that have been taking on issues like how do we get to the point where our organization can get

information instantaneously. So, whatever you need at the snap of your fingers you can get what you need, be it information coming in from the registrants, which would mean if that can happen, hopefully we're making things more efficient for the registrant community, but also snapping our fingers and seeing what we want to see.

Most of our stuff is public. It's open to everybody to see, the outcome of our risk assessments or different ways our risk assessments are working. So, everybody can see information quickly and access it in different ways efficiently and effectively.

So, we've got groups starting to think about how to do that. Actually, a lot of that is what's your business process and how do you actually move information even if you didn't have electrons around to do it? So, we're spending time on that.

Also, there's a workgroup focusing on how do we communicate information effectively, not just by words but by pictures, by whatever technology is out there so that in the future we can communicate how to follow the label appropriately in lots of different ways, from information coming down from satellite to going into the

council and the planters so that maybe label instructions can be put right into the planter.

Here's where the buffer zones are and here's where that riparian zone is, combined with knowing what your nitrogen or phosphorus levels are as you do your fertilizer applications just as you need, where you need, in your field. There's other things that can probably be going on in that computer and that planter. We also realize in our country many people speak many different languages. So, how do you tackle that, you know, effectively?

The third workgroup is looking at how do we advance both the science of risk assessment and the science of risk management, if you will, and take that to another level in terms of information flow decisionmaking.

Then we have a couple workgroups that are focusing on the people that work in our organizations. All these things don't happen at once. There are people there to do it and the people there are able to take it on. So, how do we ensure that we're advancing collaboration and teamwork and constantly learning and

adapting.

The challenges that we're going to be facing are going to be evolving and it's not a world where I know one thing, I do it really well, and I get it done, and then I do the next thing really well. We're going to have to be adaptable and be able to cross disciplines and learn and be constantly learning and adapting as we go forward. So, there's some workgroups focusing on how do we do that, as well as how do we retain the best people that we can and how do we attract the best people that we can that are going to be part of this change.

Then, with all that going on, there isn't as much money in the checkbook as we had over the last few years. So, that's part of getting intertwined in that, because some of these things, though, we think will increase efficiency and effectiveness at the same time. So, how do we use the resources we've got as effectively as we can?

So, we were anticipating a change in the resource base, but we may not have been anticipating the change as fast as it happened this fiscal year. So, what we want to do is share with you a little bit some of the

changes that are happening this year as we deal with one of the drivers we knew we had to deal with, which was going to be a change in resource base. It came a little faster and a little sharper than we thought it might, but that's what this election setting exercise was all about, to be able to start to adapt to change that was going to be coming.

So, what I want to do now is turn it over to Marty. She'll give you a little bit of a retrospective and a current picture so you can kind of see where we are in the budget picture. Then we can open it up for some questions and discussions.

Marty.

MS. MONELL: Thanks, Steve. Just bear with my throat. I was up late last night watching a hockey game and I was screaming at the TV for hours.

Anyway, the first slide is a snapshot of our budget over the past four fiscal years. When people talk about the pesticide program, the budget for the pesticide program, it's a little complicated because we have three different appropriations and we have two fee accounts. The three different appropriations actually fund more

than just OPP. Part of the funds --

I don't think it's on a slide. You're going to have to use your paper. I'm on the first slide.

The pesticide program budget is the large number here depicted in blue. It includes all of the pesticide activities within our AA-ship. So, it includes a little bit of the AA's office that support the work that we do. It includes the regional activities and FPEs that support the work that we do, as well as OPP itself.

So, the red lines are the ones to really focus on because that's the money that comes directly to OPP and with which we have to maintain our payroll, maintain our contracts, grants, and any other activities. So, this is appropriated dollars only. This does not take into account any of the fees.

So, the next slide is the same information only it shows a change for OPP from 2011 to 2012. You'll note that again this is -- I'm sorry, this is OCSPP. For the AA-ship, the pesticide activities overall took a pretty significant cut.

Then, if you'll turn to the third slide, you'll see the cut to OPP from one year to the next. Now, you

might wonder well, couldn't you anticipate that? Didn't the president's budget give you a clue? What has historically happened in the federal government in the past four or five years is we have a continuing resolution. Congress takes its time passing a final budget.

So, usually for the first two quarters we have a continuing resolution which means you're funded month to month and it's based on the prior year's appropriation. Then, when they actually give you the budget, it's a full year continuing resolution based on a certain percentage of the previous year's budget.

So, yes, we have the president's budget and we have a number that that speaks to, but the reality is, Congress has historically given us continuing resolutions that are based on a percentage of the previous year's amounts.

So, while we knew there would be cuts, as Steve indicated, we didn't expect them so quickly and we didn't expect them to be so deep. As you'll see, there's a $9.2 million reduction from '11 to '12 that we had to absorb. Again, this is appropriated dollars only.

The same thing with the FTEs, the next slide shows the FTEs, full-time equivalents. This is the government's jargon for level of effort, the hours, the man hours in costing out of personnel costs. So, these are numbers that speak for themselves. Again, the red depicts what the Office of Pesticide Programs actually has received in terms of FTEs.

As a government agency, we are not to go over the ceiling that Congress authorizes for us for FTE. We have a little bit of leeway in the pesticide program because PRIA enables us to hire additional people to do the additional work without counting against our FTE ceiling. It's a very nifty provision in PRIA that to this day we thank Wesley Warren for because he used to be in OMB and he knew enough to make sure that we had that protection.

So, again, we go to the two-year comparison, the changes between '11 and '12. You can see it for the AA-ship there's a reduction in the number of FTEs. That's man hours to do our work. If you go to the next slide, it specifically addresses the OPP FTE summary. You'll see that for FY '12 we enjoyed a 14.6 FTE

reduction. So, in other words, our ceiling is reduced. We can only hire up to a certain point. We can hire with using the PRIA dollars but only if we have enough dollars in PRIA coming in to support the payroll.

So, then, the next page will show the payroll associated with the FTE. So, we have a reduction in payroll dollars of $1.6 million. We had a reduction in FTE that you just looked at, but we never get enough payroll to cover the cost of the FTE anyway. So, having a payroll reduction associated with the overall appropriated dollar cuts leaves us with additional payroll shortfall.

If you look at the first number that I talked to, which was the OPP -- what we actually got in ‘12, it’s the $95.7 million amount after the rest of the money is handed out to the regions and to the AA’s office. The actual OPP amount is $95.7. Payroll takes up $80 million of that, $89 million of that, leaving us with $6.7 million to run contracts, grants, and all other non-payroll associated activities.

Again, tight, very tight. Obviously, we can’t do. We can’t live the way we used to live. But we have

fees and they're not included in these numbers. This is just talking to you about the appropriated dollar aspect of our budget.

So, as Steve mentioned, we realized right away that we had to engage in some efficiencies, some significant efficiencies. How are we going to make up for this shortfall? So, we knew we would have to do some shifting around, covering contracts more, those that supported PRIA activity. Our core mission work would have to be -- we'd have to use a larger portion on that from PRIA and from FIFRA, the maintenance fee accounts, to help us with the work to get it done.

What we usually try to do is carry over a little bit in all of these accounts so that knowing we're going into a continuing resolution, we've got enough money to sustain ourselves for at least one quarter. Historically, we've done it for two quarters so that we can meet our payroll needs and we can meet our obligations under our contracts in extramurals, other kinds of grant awards.

This year we knew we wouldn't have that luxury. We wouldn't be able to carry over money, so we saved

about maybe $4 million by operating under that change paradigm. It's risky, but we didn't see that we had much choice. We had been operating for the first full quarter of the fiscal year under last year's numbers. Then, all of a sudden we had to absorb these cuts which were magnified because we had been spending as though we had last year's amounts of money.

So, slide nine depicts sort of where we've been at, where we've spent our money historically on grants and contracts, the kinds of activities broken out by infrastructure. So, our IT contracts have been historically funded at very significant levels.

We've done not as much as I know you all would like us to do, but we've done some pretty serious investing in e-submission kinds of activities, in building up our documentum, which is essentially our big library of all of the data studies and reviews that the program has conducted over the years. So, we've done some investment, but, clearly, we were not going to be able to do the same things this year.

The non-IT contracts and grants, historically, we've been able to fund some things that have been

helpful to grantees, to local communities, to states, and then, of course, covering our immediate needs vis-a-vis contracts, the mission support contracts. Then, we've broken out the worker protection and certification and training kinds of activities.

There's a lot in there that you will see. It includes the national associations, State Department, Agricultural Foundation, the Association of Farmworker Opportunities Program, a lot of different activities that we have historically been able to fund, in addition to the certification and then training that we provide through the vehicle with USDA.

The next two pages show the IT contracts. This is basically just to show how we spent appropriated dollars in 2011 for a bunch of different activities, in addition to the maintenance of our basic systems. Then, for '12, we expect to spend a little bit less, and it will be basically just to keep the infrastructure going.

We had one small investment to help with our strategic direction setting, sort of an alternative analysis, if you will, that we were investing a couple hundred thousand dollars in because we know the kinds of

things we want to invest in and that we need to make us sufficient, to make your lives easier, but since we can't do it all at once, we need experts to tell us how we should phase these, how we should stage them.

So, we are investing in that. But, other than that small investment, we can only do the bare bones, keep the machines and PCs and everything running smoothly, hopefully. Again, this number is no longer just appropriated dollars. We're having to use some PRIA money and some FIFRA money to enable us to just keep the machines running.

The non-IT contracts are laid out on the next two pages. You'll see that it was a substantial difference in amounts between '11 and '12. The '12 numbers actually only reflect amounts that we have allocated to date. So, it's not the final decisions; it is what we've done to date.

We're working aggressively internally on efficiencies. For instance, a lot of our product chemistry and acute tox work had been done in a combination of contract support and internal FTE support. So, we're not able to do the contract support anymore, so

we're rallying our resources to figure out the most efficient way of getting the work done in house. So, that's one area that we were able to absorb.

We're looking at a lot of different areas. Primary data review that we've shipped it all out in the past, more of that will be done in house. We've got folks that have solid science backgrounds that are now in regulatory positions and reg management positions that we may be pulling to do some primary data review, in addition to our existing secondary reviewers.

So, as I say, we're looking at all of our options because we just don't have the resources to continue to maintain payroll and our people, which is our number one priority, at the same time that we maintain the contracts. We just can't do it. So, we're looking at all of these. That's why the final decisions haven't been made on all of our contracting activity yet. We're trying to assess how much we can save and then figure out how much we'll have left and what the priorities for use of that remaining money is.

So, you can ask me questions about this afterwards. I'm just trying to give you the overall

picture.

That brings us to the slide that depicts the minimum appropriation. As many of you are aware, PRIA provides that the agency and Congress essentially provide the program with a minimum amount of appropriation before the fees kick in. This was an attempt by the coalition to, two-fold, first of all, a basic understanding that PRIA fees would never pay for the full cost of running the pesticide registration or re-registration program.

There had been experience with FDA and the prescription drug program and some criticism about the amount of influence that some feel the industry have when they are paying so much of the cost of running a licensing program, essentially. So, there was a great deal of interest in not replicating that model.

There was also the interest in, I guess, the understanding that in government, if there is a fee revenue stream coming into a program office, it's a very easy target for appropriators to cut, with the idea that the cuts are offset by fees. So, that was never the intention. This is called the Registration Improvement Act. That's the IA part of PRIA. It was to enhance and

facilitate the process rather than replace it. So, this minimum appropriate is there. As you can see, we're pretty darn close.

These numbers, by the way, represent the entire appropriation to our AA-ship for pesticide work. So, it includes the regional allocation and it includes the AA's office oversight. So, it is not restricted to just what OPP gets. So, it's more broad than that. But, even so, for '12, we're right on the button. There is a provision that it can go 97 percent of that amount. So, $122 million is the magic number for our planning purposes, and we're above that.

Then, the last couple pages deal with fees. We collected $11.6 million in '11. That's down. That's down substantially from previous years. We've averaged about $15 million. One year, I think it was 2008, we had $18.6, then it's been $15. So, last year was a slow year. It probably is reflecting the change in the economy, as much as anything. Thus far, in '12, we've collected about $8 million.

Maintenance fees, we've collected a little over the target. If you'll remember, we were authorized to

collect $22 million in maintenance fees each year under PRIA-2. We collected a little bit over in 2011. We're right on the button in 2012. What we do is for the five-year duration, we average them out because it's very difficult to ascertain exactly how many registrants are going to maintain all of their registrations. So, we come pretty darn close.

Then, you'll see the historical collections on the next two slides for PRIA. It was 2010 actually that we got the $18.7 million and then some maintenance fees. So, you'll see that while the picture is definitely not rosy in terms of our appropriated dollars, we've done a lot of work internally. I have to commend not only the leadership but actually right down to the staff because everybody has jumped on this opportunity to make things better and to absorb the reductions without doing damage to our basic programs. I think that's our ultimate goal. I think we're well on our way to absorbing it.

Do you want to do questions or shall I go into PRIA-3?

This is a good segue into the next topic, which is PRIA-3. It's an update on where we're at with

reauthorizing PRIA-2. As you may or may not know, PRIA-2 ends September 30th of 2012, which is right around the corner. In terms of our ability to continue to collect fees for registration, we can collect -- we have a 40 percent reduction in 2013 and then a 70 percent reduction in 2014.

This basically reflects, again, the wisdom of the coalition that, you know, if you hire up, if you get prophecies in place, it's very difficult to just stop them on a specific date. You've got people. You've got contracts in place. So, they allowed for this ramp down. What it doesn't do is maintain timelines, so you pay your fee but you get no time line. The maintenance fees end as of that date. There's no provision for extending or a ramp down in terms of the maintenance fees.

So, last June, the coalition, in its wisdom, asked EPA to start working with them to provide some technical assistance on PRIA-3. What can we do to make PRIA-3 even better, besides just getting more money? That would help. So, we started internally by updating our costing information. We hadn't done this work since the beginning of PRIA.

So, eight years ago we had done a lot of -- probably 9, 10 years ago, Pete Cawkins (phonetic) had done a bunch of costing on the back of an envelope. We hadn't done anything really since then. We've done some work around registration review, but that was before we actually began implementing the program.

So, we went back and did a lot of costing work in our science divisions as well as our regulatory division and updated the information for the coalition to consider when they were having their discussions about what the fee categories should be and what the amounts for those categories should be and what the amounts for maintenance fees should be going forward to support the chemical program.

So, we started with that. Then, we decided that there were a lot of -- again, we seem to be on this efficiency kick, so we thought there were some areas of PRIA that weren't solely related to money but that were related to processes that could be improved.

So, we came up with eight different areas. The coalition formed workgroups to address work with us on these areas, to hear what our concerns were or what our

suggestions were, and then to work among themselves to either discard our idea or to come up with statutory language that would help to implement our ideas.

So, I'm just going to briefly touch upon what the areas were. Then, if you've got any questions about them, we can go into a little more detail.

One was decision times. This is addressing the issue where frequently we will make a registration decision that essentially provides for comments on your label. So, we'll give you a label, but it will be with comments. So, you don't have and we don't have a final stamped clean label. So, when you go to your state without a final clean label, you're out of luck. So, you have to come back to the agency, file an amendment, get your clean label.

So, we thought that why not add a period of time. So, there are actually two timelines for this label cleanup exchange to occur so that on the second time frame, you've got your label and we've got a copy of that label and the states will have it. It's just a much more efficient process. So, we have to work through how that's going to be implemented, but that's one area.

The other area that was not well addressed, has not been well addressed, was inerts. The clearance of inerts in products other than the conventionals just weren't contemplated under the fee categories in the fee table under PRIA-2. So, we did a lot of work to incorporate the various scenarios where inerts clearance was important, the review and clearance was important to the registration process.

Screening process for technical deficiencies, this was to address the fact that the negotiation of due dates was on a steep increase. We did a lot of review of the reasons behind that and what we could do internally to improve upon it, what the stakeholders, the registrant community could do to improve upon it, but there were certain basic things that really jumped out at us that really drove the renegotiation rate.

One was product chemistry. Probably 60 percent of all of the renegotiations have something to do with product chemistry issues or CSFs not adding up or the kinds of things that if you had more than just the 21-day content screen, you'd be able to identify and either fix or start over again.

We also thought that it would be appropriate -- we've been talking for years, ever since the beginning of PRIA. If you all remember Arnold Lane (phonetic), he was talking about his vision of having this whole e-submission where it would be totally electronic, not just submitting things on CDs and having them scanned into paper and so forth, but really true e-submission. Well, we just haven't had the resources to make it happen both in terms of contract development and implementation.

So, we thought, well, if we could get some sort of an IT set aside for this work, we could make it happen because we would have to just use that money for that and nothing else. Of course, the NGO community was very interested in this idea.

As you remember, the coalition isn't just the industry. There's a lot of NGO representation on it. They thought, well, you know, we're really interested in tracking conditional registrations. What's the story with -- you know, how many do you have, what are the conditions, when were they imposed, when were they fulfilled, so forth and so on. Quite frankly, we don't have an effective database right now to produce those

kinds of reports. So, that's another investment.

Some enhancements around our endangered species database, knowledge base we call it, where we have to work with the services and we struggle back and forth getting information. So, we get habitat information and so we need to put it in a central repository so everybody has access to it and everyone can see our decisions and so forth. So, that's another area. So, we developed this whole concept of some IT enhancements and having an addition to the maintenance fee amount to support that throughout the life of PRIA-3.

The set asides from the registration service fees remain the same. So, all of the other kinds of enhancements that we're talking about, those are from the maintenance fee side. The registration service fees support the worker protection set aside, the certification and training set aside, partnership grants set aside, and they remain the same.

Other activities that occurred thus far is that the registering divisions have all met with their sort of stakeholder communities, worked on time frames of categories, additional categories, deletion of

categories. I'm sad to say that we're up to 180 categories now. We started at 90. Every year we seem to increase more. But that just really speaks to the complexity of the work we do and the nuances of dealing with what you folks are bringing in to us.

Then, there's an increase proposed for maintenance fees. Assuming it passes, we're going to have maintenance fees set at $27 million. That's a $5 million bump up for the next five years, in addition to an $800,000 set aside for the IT enhancements. That $5 million really reflects the increased cost of registration review.

As you know, we are implementing our compliance with the Endangered Species Act through the registration review program. It's proving quite costly. We've got experience now with registration review. When we first set the fees under PRIA-2 for maintenance, we had no experience. So, now we've got more experience. We're realizing that it's more resource intensive than we had thought. So, we will hopefully see an increase in the fees.

Last but not least, we have adjusted the caps,

the caps on the maintenance fees. This is the certain point -- maintenance fees are based on a per-product assessment. At a certain point, if you've got a certain number of products, you reach a cap, either a small cap or a large cap, small business/large business.

So, we adjusted them so that the $5 million increase in maintenance fees would be more equitably distributed. So, the larger companies, their caps would go up a little bit higher than the commensurate caps for the smaller businesses. It's something we hadn't done previously. It just seemed like it was the right thing to do. Apparently, Congress has agreed with us.

So, that's where we're at. Hopefully, this is a win, win, win. We'll get some additional resources and I think a very good structure around the work that we do. Industry gets its predictable time frames and when it's going to be able to bring the products to the market. The NGO community gets predictable funding for workers, partnerships, and applicator training. I think we're in a good place. We just have to encourage Congress to help us out.

MR. BRADBURY: Which we can't do.

So, we'll open up with questions from Cindy and then Mark, Tom, and Allison.

MS. BAKER: Thank you very much, both Steve and Marty, for the updates. I think they're useful information to break it out in that way. I guess I would just like to comment that I think, Steve, in some of your earlier comments about the PPDC in general, you were talking about consensus.

I think this is a nice example, PRIA-3 at least, of different stakeholders coming together for a common purpose to achieve some things. So, I think that's good if people aren't aware. It's a broad coalition of NGOs and other stakeholders that have an interest. I think it's positive that we can continue to go forward with a plan.

I'm just curious about the PRIA fees and/or the maintenance fees that you collect. Do you guys do a breakout of FTE and contracts for where those dollars go?

MS. MONELL: What we have is a time accounting system, TAIS. So, before we can charge anything to a fee account, we have to have the requisite number of hours charged by our people. So, that's sort of a guiding

principle of how many -- we historically have supported about 130 FTE with the maintenance fees and then about 50-ish with the PRIA fees. That goes to the people that are putting their time into the system.

As you know, we're audited, so we have to do that. Then, the leftovers, if you will -- it's really hard to predict with the PRIA fees because we don't know how much we're going to get, we allocate for contracts and grants.

MS. BAKER: And then, do you have a way to track, you know, submissions involving EFED, ATD, RD? Sometimes the maintenance fees have a big involvement with PRD. Can you track it that way by division? I mean, I assume with your time allocations, since it's coming from that person, you know where it's going.

MS. MONELL: We know what the workload is going to be for the year. So, in our annual planning process, we know, for instance, the conventional world. RD will have -- okay, we've got three new AIs we've got to complete this year. It's a two-year time period, but we have to complete two or three new AIs. We've got to complete 10 new uses, whatever the numbers are. So,

using that as a guideline, we allocate the resources.

MS. BAKER: Thank you.

MR. BRADBURY: Mark and then Tom.

DR. WHALON: Marty, at this time of the day, for you to give us that much information was remarkable. For me to absorb even half of it would probably be even more remarkable.

MS. MONELL: Imagine if I did it at 4:00. You'd be asleep.

DR. WHALON: Only over a beer, Marty. I would need note taking by a lot of folks. Statistics is awful difficult for me. Bear with me on this stuff.

You know, besides being an entomologist, I had the misfortune of having to deal with a lot of public finance and budgeting. The fellow who taught me that was a three-star general who was a comptroller for the Pentagon. He basically said, you know, when someone tells you what a priority is, if there's not a budget that accompanies that that's appropriate, then someone is blowing smoke up your dress.

So, I kind of looked at the budgets on the five years for contract and grant funding. First I want to

recognize that there has been a meaningful shift to the administrator's priority, and I might say America's priority, to make sure that our children are protected from environmental assault as far as their health goes. School IPM has certainly been recognized by the agency. They've shifted resources in a very meaningful way. I recognize that.

However, as I look at what my old professor would say, when I look at the numbers and I look at the percentages, it seems that the priorities must be for IT and for information management, which, of course, I think is important. I might say I think the agency deserves more for everything. Those people who have been punishing the agency, whether we've been in a recession or not, I'd like to see them go a month or two without clean water and see what they do with that while they're on the toilet.

What I'm seeing here, if my calculations are correct, is there's a 5 percent decrease in IT contracts, a 48 percent decrease in non-IT contracts, a 63 percent decrease -- and this is from 2011 and 2012 -- for worker protection, training contracts and grants, and a 60

percent reduction, which is the school IPM budget.

MS. MONELL: Just let me add a clarification, Mark. At the very bottom of that chart it says for this year it shows allocations to date. It doesn't show final decisions yet. The reason that that's the case is because we're still trying to figure out how much we can absorb in house, how much we're going to have available to put on mission support contracts as a result.

There are certain contracts, for instance, we use -- I forgot what it's called now. It's usage data. We can only get it from one source. So, it's not something we can absorb without. FTE can't do this work, provide us with this information. So, that contract, we've allocated that money.

IT, you'll notice, we've got that down. This is the bare minimum to keep our databases running. This is no frills. You'll see it reduced by 50 percent since 2008 because we were in a building mode, expanding mode in 2008 when we were fat, dumb, and happy. Now we're in the real world and we just can only support the basic functioning of our system.

So, the numbers you're looking at in terms of

reciting reductions to worker protection, C&T, IPM in schools, SAI, that's only what we've given to date. They do not reflect final decisions.

DR. WHALON: Which is why I'm bringing it up now.

MS. MONELL: Okay.

DR. WHALON: In hope, as part of this FACA, of advising, redressing and a closer look at the priorities. I certainly recognize and understand what you're saying.

Nonetheless, both in terms of real dollars and percentage-wise, there's an inequitable decrease at this time. I would say that as you are making decisions and the administrator is making decisions, particularly with her priorities and with regard to the mission of the agency, that there are things that maybe need to be redressed as far as the money goes. I would always say that one needs to say, well, IT, is that going to further the mission more so than the implementation of real programs for, with my bias, children?

So, again, I bring that up with the idea that I think it's very important for the agency to have priorities, but I think that there needs to be

commensurate and equitable budgets for those priorities.

MR. BRADBURY: Thanks, Mark.

Tom and then Allison.

TOM: Well, thanks. I also want to express my concern about the impacts on IPM and the mission of the agency under FIFRA to promote IPM and under FQPA as well, but to also lend some assistance. In 2010, a group of about 40 professionals, including a number in this room, formed IPM Voice as an independent nonprofit to speak up for IPM. We've been focused on the USDA budget primarily and been very successful in getting Congress to appropriate more dollars for IPM than the administration had requested.

So, if others in the PPDC would be interested in joining that effort, we would love to have assistance in addressing this serious threat to your ability to address your furthering IPM mission. What would help us would be to have access to grant reports and your thoughts on what your biggest successes have been in terms of IPM efforts coming out of EPA to educate policymakers about the importance of that investment.

We have identified some really open ears in

Congress, so I think that we can be effective. Maybe during the break, Marty could get the president on the phone and we could have that discussion. Tell him you're calling about the hockey game and maybe he'll take our call. Thank you.

MR. BRADBURY: Allison and then Caroline Cox.

MS. STARMANN: I just wanted to clarify that the presentation figures are just appropriated, so it doesn't include the pre-owned FIFRA FTE?

MS. MONELL: Well, it's noted. Like, for instance, on page 9, there's a table sort of showing the five-year spread. That includes the fee accounts as well as appropriated dollars.

MS. STARMANN: So, for the FTE summary for OPP, for example, that would just be appropriated. Are those the ceilings?

MS. MONELL: Those were the ceilings, correct.

MS. STARMANN: And were you at your ceilings?

MS. MONELL: We always maintain ceiling, yes. In that fact, we go over because we have the PRIA also.

MS. STARMANN: I might have missed it. You might have said it over there, but what did the PRIA and

FIFRA add to the FTE?

MS. MONELL: Well, the FIFRA comes with its own ceiling, if you will. That's down to about 150 now. We burn about 130 because we just don't have the money. Then, on the PRIA side, we average about 50 FTEs. That's what the TAIS, the time and accounting system, reports will justify.

MS. STARMANN: So, if the PRIA-3 negotiations proceed the way they are, would it make up or would you expect it to make up for the roughly, I don't know, 13 FTE shortfall between '11 and '12?

MS. MONELL: It depends on the receipts. So, in other words, if the PRIA receipts come in to justify additional work and additional billing of time, then yes, we can increase the number of FTEs.

MS. STARMANN: But based on the track record, would you expect it to change?

MS. MONELL: That's really difficult to say. You see the trends in our collections. I would have to say no. But there are, you know, another 40 categories for which we will get fees, not much because they tend to be just nuances of existing categories. It's really

difficult to predict, but the trend certainly is not going up.

MR. BRADBURY: Thanks.

Caroline and Ray next.

MS. COX: I think that my comments kind of mirror what Mark and Tom said, so I'll try to keep them really quick. But I know when budgets are tight, it's kind of a squeaky wheel that gets the grease. So, I just wanted to be the squeaky wheel a little bit.

I do think that the environmental stewardship grants, the IPM grants, and the worker protection grants are really, really important and central to EPA's mission. I'd just like to encourage you to keep being creative and finding ways to fund that stuff.

MR. BRADBURY: Ray, and then Mike, and then Kristie.

MR. McALLISTER: Marty, my last count was 189 categories. Getting where we are today with the PRIA-3 language, the legislation ready for introduction in Congress has been the product of sometimes tense and often very intense discussions and negotiations. We commend the agency for all of their work in bringing that

to fruition.

I'd also encourage all of the stakeholders on the PPDC to support the legislation. It doesn't require necessarily active participation, but if you're asked your opinion on this, whether it's from a congressional office or from the press or the trade press, I'd encourage your support so that it gets passed quickly and readily.

We all have a stake in this, whether it's the minimum level of support that Congress is required to provide in order to maintain PRIA for the OPP appropriations, the individual set-aside programs within those C systems, there's something in there for everybody. A unified support will make things happen a lot more smoothly.

MR. BRADBURY: Mike, Kristie, Gabriele, and then we'll stop this session.

MIKE: Thank you. Thanks, Marty, for pointing this out.

I just wanted to note there's one area where you're going to have significant information shortfall that you didn't know it because it's not actually in your

budget, but it's information that you use all the time. It's related to the NAS chemical use surveys.

You recall that in November, National (inaudible) Service decided they were only going to do their chemical use surveys every five years. In order to re-institute the fruit and vegetable surveys on an every two-year basis, the NAS folks say they need an additional $2.3 million a year. That wasn't provided in the senate budget for them in the farm bill. So, we're really concerned.

Those of us who use that data are extremely concerned that maybe there hasn't been quite enough response back to the department. We specifically asked them if the EPA had actually said anything about not having that information. The response we got from Dr. Clark was that they hadn't heard from EPA.

I understand there's all these federal family things that you have to make nice about, but I think it may be useful to find some way to communicate how important that information really is. Perhaps maybe a five-year interval is not the right interval. Of course, I'm echoing Ray's comments that everybody in PPDC who

thinks that fruit and vegetable and other chemical use survey information is important should make contact with those folks who might have input into that process. Thank you.

MR. BRADBURY: Kristie and Gabriele.

MS. SULLIVAN: Thanks for the information. I just wanted to say that I actually kind of like the idea of bringing more of the data and tox review in house. Admittedly, I don't know the details of these contracts, but on the tox side, the toxic side, excuse me, and the industrial chemical side with the HPV program in the 2004 to 2008 range, I had some experience with sort of data review being contracted outside the agency.

I find it to be more difficult from a stakeholder perspective to get information and have a dialogue with the agency because of that. So, I think that this could be -- given that it would be difficult for staff to take on extra work, I understand time issues, but I think having that process and having those reviews be more in house is much more open and stakeholder friendly.

MR. BRADBURY: Gabriele.

MS. LUDWIG: Just a quick question. I'm not sure I have this straight. But my understanding is if Congress doesn't get a certain percentage of cuts this year, then you get into automatic cuts that are 10 percent across the board?

MS. MONELL: They're Draconian, whatever they are. Our senior budget office is now looking at the impacts of that situation on us. We don't have the data yet. We haven't seen the precise language of sort of the drop-dead action.

MS. LUDWIG: Right. The reason I'm asking is just simply, if it were 10 percent, then I think you fall below the PRIA minimum, if I'm seeing this right. So, it makes the mess even worse.

MS. MONELL: Well, what has historically happened is during the budget formulation process and discussions with Congress, we always note -- and when I say we, I mean our chief financial officer -- always tells the appropriators we've got this anomaly here with the pesticide program where we have to maintain a threshold appropriated amount, 97 percent of it at any rate.

So, that would kick in. Those discussions would kick in. I'm not saying they'd necessarily be successful, because I think that by operation of law, they may not be able to have those conversations be effective. But that's what historically happens.

MR. BRADBURY: Okay, thanks. Good questions and we appreciate the input in terms of priorities from different folks on the committee. So, take a break until 10:30 on that clock, and then we'll start off with the pollinator protection workgroup report out. Thanks.

(Whereupon, a brief recess was taken.)

MR. BRADBURY: We want to get started now on the next session, which is going to be a report out from our workgroup dealing with pollinator protection. Don Brady and Rick Keigwin sort of co-chaired or helped guide the group along. Don is going to take the point. Don.

MR. BRADY: Well, thanks very much for, like Yogi Berra would say, making this day necessary. We wanted to just get a report out from the workgroup that was formed at the last PPDC meeting. Our format today will be that there were four sub-workgroups, we called

them, formed. The co-chairs of those workgroups will report out on recommendations to the full PPDC. Then, EPA will provide some initial reaction to the advice we get from the full PPDC in this session tomorrow morning.

So, I just wanted to start by putting one slide up, which is just to remind the PPDC. This was the charge to the workgroup in April 2011, that the workgroup look at initial, science-based risk management approaches, including appropriate labeling restrictions and training; development of information on state approaches and authorities; the transfer of lessons learned by various stakeholders to improve existing management practices; continuing international communication; and any other issues the agency wishes to bring to the workgroup's attention.

Mary (inaudible) was our lead staff person, who is sitting to my left. Mary and all the members of the workgroup did a very nice job of coalescing. It was a large group, somewhere in the neighborhood of 50 people, I think is what we initially ended up with. That's a large group to coordinate across phone calls and things of that nature, which was how most of this work was done.

But the workgroup managed to do that. The sub-workgroups very effectively met on their own and got together and came up with recommendations that they'll present here today.

So, what we'll do is we'll go to each of the co-chairs of the groups. Before we do that, we'll start with common issues that were identified across the workgroups. Marylou Verder-Carlos will just provide those for the group.

MS. VERDER-CARLOS: When we met yesterday, each of the subgroups also had reported out to the whole subcommittee to present their recommendations to the whole committee on each subgroup. So, the common issues we figured -- actually, we wrote these common issues after we had already written all the issues from each subgroup.

The common issues for each one was to really minimize pollinator damage while controlling pests to protect crops. It was laid out on the table that it would be impossible to say zero tolerance for each, you know. It just wouldn't work. Bees are needed by crops, and endocrops would need bees. But, at the same time,

there are also some issues that could be done to minimize the pollinator damages.

Also, provide residual toxicity information on the labels. So, labeling issues is really one of the big issues that we need to deal with and improve labeling language. Again, it's labeling issues.

Then, we also wanted to highlight success stories. There was one very good success story that happened in Yuma, Arizona, where there was a very good collaboration between the beekeepers, the farmers, and the industry. So, there was a nice story that Cindy Baker-Smith is going to talk to us about later on.

Then, also, it was very apparent that training of the pesticide applicators and communication is also one of the big issues that needs to be improved. So, each of the subgroups are then going to report out on what we would ask PPDC to have advice on.

MR. BRADY: Thanks very much. So, the first subgroup was the best management practices subgroup. Rich Briarly and Brett Aidy (phonetic) were the co-chairs.

Just for logistics, Mary (phonetic) has the

clicker up here. So, if you're presenting as a subgroup chair, just let her know when to advance the slide.

So, Rich or Brett? I don't know if Rich is on the phone. It's kind of early. There's Brett. He needs a microphone. If somebody can maybe just give Brett a shot at a mic, I'd appreciate it.

MR. AIDY: We came up with a lot of different ideas, but we tried to prioritize them to what we thought would yield the best results the quickest. Our number one idea was the timing of application. That's denoted up here. This was our highest priority.

On the timing of application, this wasn't unanimous by any means, but it was the majority that when products are used that are toxic to bees, they should be done while plants are blooming or producing nectar. These products should be applied in the evening or at night when the bees or other pollinators aren't foraging. So, that, we thought, could yield the best results the quickest with the least amount of change. Just applying the insecticide at the correct time of day to protect the crops.

The second issue we found would be very good

would be to standardize the training manuals. That came up in a lot of the other groups also. On the subpoint, we saw there in the training manuals, it should be to point out the importance of bees as pollinators, not only to the ECA (inaudible) but maybe to their neighbors crop that may need pollination or the crop that's going to need pollination down the road in the future months. So, I think the real take-home point on that was, you know, in the training manuals to point out the importance of bees.

Thirdly, we came up with the idea that best management practices are adopted faster by economic motivation than anything. So, we thought case studies of yield enhanced by good BMPs would be really good. That, again, goes to timing issues and a lot of the auto-pollinated plants in case studies where the yields are increased with bees.

So, if you can keep the bees alive while you're controlling your pests (inaudible) by timing, you're committed to get a small yield increase and that will adapt the good best management practices faster than anything if we can document returns to the growers.

Fourthly, we think that there needs to be good information on toxicities of the products so the growers, the PCAs, and the applicators can make good selections of the products when they're spraying a crop before bloom so they have the right residuals so it doesn't affect the bees or other pollinators when the plant needs them. So, good residual toxicity data is needed.

There's initial residual toxicity data we thought should be more specific for how the toxicities are affected by temperatures, humidity, winds so the applicators and the growers can make more informed decisions of how long it's going to be there, you know, high humidity conditions, windy conditions, hot conditions, cold conditions, so they can make more intelligent choices. So, that was our fourth recommendation.

Our fifth recommendation goes into the seed coatings and the planters that are applying. We highly recommend that the companies that make the seed coatings continue to develop better, more integrated products that do not make dust. Then, the planting equipment manufacturers need to work on mitigating the dust so the

exposure to bees and pollinators is minimized by both chemistry and stickers and by mechanical and engineering.

So, those were our five highest priorities that we thought would reduce the risk to bees and pollinators the fastest with the least impact on industry.

MR. BRADY: Thank you, Brad. It might be good to pause for just a second here and ask if members of the PPDC have any clarifying questions as to what's meant by the recommendations. My thinking on how to sort of get the full discussion going is once we get the presentations from the four subgroups, then people can have more general conversation. So, at this point, if there's any clarifications for Brad as to what he meant when he presented?

(Whereupon, there was no verbal response.)

MR. BRADY: I don't see any cards going up, so I think we'll just go on to the communication, education and training subgroup. That was co-chaired by Wayne Buhler and Ray McAllister.

MR. BUHLER: Thank you, Don. I realize that Mary and Marylou last night gave us one slide, and the

other three groups have two. So, I'm going to talk very slowly.

MS. VERDER-CARLOS: You were there, Wayne. When I was sizing it, you were there.

MR. BUHLER: Okay, yes, I'm sorry. I confess, I was there, all right. Thanks for straightening me out, Marylou.

I am with the extension service, however, so I do a lot of talking. In this case, I was very impressed with the input that we received and extremely thankful. It's been a number of years since I worked with bees, but we have a couple of beekeepers on our subgroup. They really helped in providing some insider type of information that was vital to, I think, coming up with about eight or nine issues that our subgroup addressed. It's been distilled, as you can see on this one slide, to four issues.

What I'd like to do is describe each one of those and then I'm going to ask Bill if he would help by going off Power Point and to a web site that I'd like to present better than talk about it. It's easier to see the web site as kind of an initiation to what we might

consider as a portal or repository for training and training information.

Much like the best management practices subgroup, we recognized the need for standardizing, training resources, but then we also realized that beekeeping and stewardship of bees is variable. It certainly varies by crop. We could get down to crop specific information, and we could get down to various products. We can talk about the different regions, humidity, mountains, whatever would have an impact, even the unique pollinator species of those areas would make it really difficult to make a one-size-fits-all package.

But we do realize the importance of at least getting the terminology standardized, such that if the label is making statements about extended residual toxicity, for example, we have common definitions that are used in the training. So, we need to see that parallel between labeling language and training to be standardized.

As Marylou has already indicated, there have been some successful case studies, if you will. The one out of Yuma is an example of that. I think Cindy is

going to elaborate more on that towards the end of our presentation. But, suffice it to say, that these kind of things would be excellent training tools.

Anything that has shown how beekeepers have worked with crop producers and advisors, extension services, all of those experiences, would be awesome to have as case studies that can be involved in training, making training, I think, more active in terms of bringing it to the people that it's affecting.

Number three, or bullet item number three, is really -- I don't think anybody in this room would find it hard to find some good information by Googling or whatever you might do to search it out. I know that with my program, I work as the statewide pesticide coordinator for North Carolina. Forty-nine other states have programs, too. Each of them probably has their own fact sheet on protecting honeybees.

So, there's no shortage of information out there. But I think what we need to do is kind of have a common repository, if you will, where people can go to these. This web site that I'll demonstrate later provides something of a portal for that. Certainly,

there would be good need to vet or validate the information that's out there and make that appropriate for interested readers.

One of the other issues that we grappled with are bee registries. Bee registries have been around for a long time. They're considered kind of a traditional means of communication between beekeeper and pesticide user. But they've been frowned upon by beekeepers simply because they haven't worked for at least the stewardship of bees in many cases from pesticides.

So, the question becomes, what is the intent of the bee registry. I think if it's not used as an enforcement tool or doesn't have that connotation with it, I think as a means of communication, we can continue to see value in it. So, we don't pinpoint that as the solution, but perhaps one of the solutions, if it can be integrated into a holistic approach to protecting honeybees.

There's been interest to do a pilot study where we can look at the bee registry as a communication tool. I think North and South Dakota, from what we've heard yesterday, has had a very successful program online where

that information is easily accessible. However, we recognized even that has some shortcomings in terms of preventing bee kills.

So, there's much more to be looked at with bee registries. I think we'll continue to grapple with that, but we certainly want to continue perceiving that as a possible way of continuing on with the communication linkage between grower and beekeepers.

So, with that, Bill has gone ahead and done the good work of taking this web site and having you see that, at least for those of you in the room here. Those that are on the phone, this is pesticidestewardship.org. It's a program or web site that has kind of been my baby for the past four years. There's a lot of information related to all kinds of stewardship, information that we don't have time to get into.

But, Bill, if you can perhaps go down on the left frame, you can see pollinator protection at the bottom. Again, this is kind of roughed in. I considered it a rough draft, but I just wanted to make it available for this meeting.

What we've done is create or break this down

into various subparts. Bill, if you could scroll down a little bit on that page, you can see where we deal with pesticide pollinator protection. Go back up a little bit, Bill, I'm sorry.

The pesticide may be toxic to the pollinators. You can see that at the left frame as well. Understanding pollinator habits, using an IPM approach, minimizing drift, the cooperation and communication, and symptoms of accidental exposure. So, you can click on any one of those subpages, Bill, and go to the site that would describe each of those features in greater detail. I do have permission to use this particular publication as the text. This is from CURES, Coalition for Urban, Rural, Environmental Stewardship. It has been reviewed and vetted and also has a number of resources.

Bill, if you could scroll down to the bottom subparts, you'll see a resources and suggested reading. There is something that we would consider, again, kind of as a repository, direct access to a number of PDFs, excellent brochures that are out there, highlighting, as you can see, NAPPC, North American Pollinator Protection Campaign, Project APIS-M, pollinator conservation through

the Zersi Society (phonetic), EPA, the CURES, all the way down the list.

So, again, a lot of work being developed currently, a lot that exists that's really good. We just want to make this as a portal to easily attain that information.

MR. BRADY: Wayne, thank you.

Is there anybody who has any questions about just understanding what Wayne was presenting as recommendations from his subgroup, just in terms of clarification? Darren, did you have something?

MR. COX: I would like to be able to point out that these bee registries that has been very historic in these regions was originally developed to prevent the spread of American European foul brood. It was not originally set up as a way of notification or communication between the beekeeper and the applicator. Many of these bee locations are set up and designed so there's not overforaging or overgrazing in the specific areas by having too many bees into the area.

We had also talked about having pesticide usage reporting to complete that circle, but at this time we

don't see how that would work.

MR. BRADY: Thank you.

UNIDENTIFIED MALE: On sort of an overlapping between Wayne's presentation and the previous one, basically, I see the registries as being a very useful tool to prioritize where additional, you know, safeguards need to be taken. You know, we really can't do everything that requires insecticides on blooming crops at night. I mean, that is just reality. It isn't a simple solution. Between the two, if you can prioritize it, can be very helpful. Thanks.

MR. BRADY: Okay, thanks.

So, let's move on to the labeling subgroup, Marylou Verder-Carlos and Dave Epstein (phonetic).

MS. VERDER-CARLOS: Dave is here right behind me. So, if I make a mistake, he's going to kick my chair.

So, our labeling subgroup started with exploring, actually, what the existing labeling is right now. We also explored how EPA currently determines what goes on the label. So, we reviewed chapter 8 of the label review manual and then we started our discussions

from that.

We found that our recommendations to go forward was to look really at the environmental hazard statement, because they are not consistent between each active ingredient, and they are difficult to understand. So, we were thinking that simplifying the language would be a good recommendation, although we understand that there is a science behind highly toxic, potentially toxic, and toxic.

So, then, what came about yesterday was to develop a labeling interpretation manual for clarity so people know what the highly toxic, potentially toxic, and toxic mean. So, from the group yesterday, the recommendation was to have that labeling interpretation manual much like the spray drift manual, if you will.

Then, also, we wanted to move forward with providing simple label statements on pesticide's residual toxicity. This was already discussed earlier with the best management practices subgroup. The RT-25, what does that mean? When it's on the label, for a beekeeper, what does it mean to them?

So, mostly what we intended to recommend was to

have those label clarifications. At the same time, we had actually two folks from the registration division to talk to us about label revisions. They said there is also room for improvement. So, we were happy to know that.

So, Eric Johansen (phonetic) from our group also came up with label review manual revisions to be more specific. So, we have drafted something and we've forwarded that to Mary and Don and Rick to look at that and see if we could do something with revising label review manual. One of the things that we looked at was that there was a big concern between crops requiring pollination by bees and crops that do not require pollination by bees, but the bees were there.

So, that was an issue that needed to be discussed more fully. So, with the label review manual revisions, we though that that would be able to be addressed. But, of course, there's also going to be more work done.

But we thank Eric for starting the work on that because there's issues with application timing, when the crop is blooming, drift minimization, and all kinds of

issues on that label review manual that we thought would be a good thing to start with.

John Scott (phonetic), also from my group, and I were in a class last week with 21 state-lead agencies. So, we asked for input from them about how to go about label revisions, on how they would think they would be able to enforce those labels. We found out that there was a mixed review, if you will. They did not think that some of the label revisions we proposed would be enforced, and some thought that it would be.

So, they asked that if we could forward them any label revisions before it becomes finalized, that would really help out the states as well. So, there's really a whole mix of reactions from the label review revisions, if you will, moving forward.

Like we said earlier, there's various label issues that overlap with best management practices, communication, education, training, and also the enforcement subgroup. As you know, the label is the law. If the label is not clear, it's going to be very hard to enforce it. So, that's where also the state-lead agencies come in.

If there's any other from my subgroup -- we actually had a very big subgroup. I think we were up to 30 people at one time on our conference call. I appreciate --

Oh, also from our subgroup, Susan Kegley and a group of our subgroup people had volunteered to come up with a survey that would be able to survey the beekeepers on a package that would be practical for them. She can pipe in and tell us more about the survey, but we will evaluate that survey for the data that we get as it comes in and see what we can come up to help us with the label recommendations going up to EPA.

DR. KEGLEY: The survey was mostly about crop specific label language. So, the idea of the survey was to figure out if there are particular crops that are more or less problematic for bees and what the focus should be in terms of modifying label language. So, it's out now. We're going to close the due date for getting all the surveys in at the end of May, but we're going to try to do it like a preliminary cut on the results sometime in the next couple of weeks so we can send those out.

We also have a few questions on enforcement and

a few questions -- most of them are focused on acute pesticide poisonings that the label could conceivably control. We have a few questions on kind of longer term (inaudible) that is really harder to pin down in terms of -- well, there's pesticides, there's mites, there's many, many factors that may be affecting that. So, our focus was mainly on the acute pesticide poisonings for that reason.

MR. BRADBURY: Folks on the phone, if you could hit your mute button, please.

MR. BRADY: Okay, we're getting a little bit of feedback here, but that's great. So again, just clarification questions from that workgroup's presentation? We'll get to the discussion mode as we finish.

Louis?

MR. JACKAI: I was just wondering, the labeling subgroup, I think one of the points was about simplifying the language in the example you gave us to eliminate some of the words, the terminology that has been used for a long time. I wonder if the group came up with some ideas and what that might be, you know, making it simpler? If

you look at the next bullet, develop the labeling interpretation, that seems to actually address the issue that you're raising in the previous one.

MS. VERDER-CARLOS: Yes. Our discussions started with, you know -- for a lay person, toxic, potentially toxic, and highly toxic is the same. It's toxic. So, we were thinking in the beginning that it should just stay toxic. But, like I said earlier, there's a science behind that. That's why the risk assessment and the tox findings would be very important for us to move forward on are we going to do this or not.

So, then, yesterday, like I said, what we came up -- the whole committee came up with the recommendation to say, well, maybe there should be a labeling interpretation manual to address that. So, you're absolutely right, that that's how we're probably going to be able to address it if we move forward with doing it that way.

MR. BRADBURY: Cheryl, did you have something?

DR. CLEVELAND: I heard a lot deeper discussion yesterday in the meeting. A lot of details were voted but not decided on. So, my question is, is the survey,

then, going to form the basis for some final label language? Right now, this is very high level.

The main thing that I heard is that you've got some very specific suggestions for revisions in this manual piece, but those aren't being brought forward here. Are you waiting to finalize those based on the survey and then you'll bring them back to the group? What's the process, next steps, for this subgroup?

MS. VERDER-CARLOS: So, we're waiting on the results of the survey and then we come again as a committee. So, I don't think that this is going to be the end all be all. The labeling issue really is a big national -- it's a big thing to do. You know, it affects everybody.

So, what we were thinking is if we could get everybody again back on the table and the pollinator protection workgroup before we even move forward, we have to go back to the state-lead agencies and see how they're going to be doing that. Then we have to go back to the industry to be able to get input. So, it really is a work in progress. But this is what we thought would be a good start to focus people on okay, these are the things

that we will probably move forward.

We're willing to forward all the label review manual revisions that Eric Johansen put up and we had already sent it to Mary. But it's an ongoing discussion. This is not going to be the end. But we wanted to focus people on things that we think should move forward, although it's not a decision that's already made.

MR. BRADY: So, I just want to thank Marylou for the answer, but also to point out that the question about what we do next and the sequence and who does what is what we will hopefully get some advice from at the conclusion of the session today. So, we want to finish the presentations. Then we'll have discussions and questions about next steps and what's a logical sequence, as we were saying yesterday in our workgroup meeting, who does what, you know, which agency or which entity, so to speak.

So, let's just finish this last report out and then we'll be able to get into sort of more general discussion about people's reaction to reportS from the subgroups as well as discussion and advice to the agency. So, thanks very much.

So, our last subgroup was the enforcement subgroup. Darren Cox and Gabriele Ludwig were the chairs. One of them will say something, I'm sure.

MS. LUDWIG: My turn. So, the enforcement subgroup really was dealing with the issues of how to improve state-lead agency investigations of bee kills that might be caused by pesticides. So, beekeepers have encountered some frustrations in that area.

Really, we have two main focus areas. One is what I'll call process improvements, basic ideas or steps that could be taken to improve how state-lead agencies do these investigations and just even step up to the table to do an investigation. The other one is how to engage state-lead agencies in this process, because it's very variable to what extent they are engaged on these issues.

So, going through the list, the theme of training came up again, develop and standardize training manual for investigations. But this is now training on how or what steps are specific related to a bee kill investigation. I should say at the moment, OWECA (phonetic) is in the process of revising the FIFRA enforcement training manual. So, some feedback has gone

into that.

Develop a method for tracking incidents and investigations. So, one of the issues that has come up is even when a call has gone into a state-lead agency, it's not always clear who is taking responsibility. So, if you call in three weeks later and say, okay, what's happened, you know, trying to find out who has done what, it's essentially like an audit trail that you can know so and so did this, so and so did this, so and so didn't do that, or this is what the decision was at steps along the process.

Developing criteria for states to convey information to EPA, this probably should come down later. But it's very variable when an incident investigation or enforcement action -- what the criteria are for state to send something on to EPA, either the regional EPA offices or federal EPA. So, developing some consistency around what the criteria are, when something should get notified or should not get notified to EPA as a bee kill incident.

Develop procedures to make it easier for states to determine when and where pesticides were used. This is coming back to the issue of when something happens, it

can be difficult to figure out who sprayed what. If the beekeepers had their druthers, all growers would be required to do pesticide use reportings.

I will say the beekeepers said that they would be willing to participate in pesticide use reporting on their own. However, EPA has made it clear they do not have the authority to mandate pesticide use reporting across the country, so we're not really sure how to move this forward. But just to say that is something that would help investigations, but we don't know how to do so.

Develop consistent and simple procedures for notifying state-lead agencies of possible bee kills due to pesticides. This comes to the issue I think Susan raised yesterday, and that had actually come up at other times, that in some states, it's very easy to know whom to contact and other places it's very hard to know whom to contact or it's inconsistent. So, again, making those procedures easier to at least say, hey, I think something has happened, can someone come out and take a look.

Clarify whether states have authority to obtain incident details. This is maybe some of our ignorance

for those of us in the group, but it's not clear based on what some states have said to beekeepers whether they always have the authority to do the full investigation and really ask growers in the area or applicators in the area what did you apply when. So, we need some clarification in that area and just make sure that that full authority is there.

Then, the other thing is just to develop a process for periodic review of investigation guidelines to incorporate either new technologies, new knowledge, things that have been learned throughout the time, so something every three to five years or some kind of review process for these processes.

The other side of it were steps that could be taken to get state-lead agencies to pay more attention to this issue because it's very variable from state to state based on beekeeper's experience. You have SFYREG -- and I always forget what that stands for, State Federal something something. But it's basically EPA and the state-lead agencies that do enforce pesticide issues. They meet every two months, three months at least, at least conference call meet, to talk about what is EPA

doing, what are the state-lead agencies doing.

We really think that that would be a good forum for EPA to take the lead and say to the state-lead agencies, hey, we have an issue here. We need you to pay more attention to it. OWECA has this (inaudible) manuals. Give your comments on it. Here's an opportunity to raise that issue.

Similarly, NASDA, which is the National Association of State Departments of Agriculture -- to many states, it's the Department of Agriculture that is the state-lead agency. That's another opportunity to raise this issue and see if we can get some more traction. Again, it's very variable from state to state how much engagement they show on the issues.

Anything to add, Darren?

MR. BRADY: Okay, thanks very much. Again, any clarifying questions? We have one more presentation and then we'll be able to -- everybody I know is anxious to get into the discussion. Okay, then, the last presentation that the workgroup thought would be valuable to share was results of a field trip that Cindy Baker-Smith was instrumental in arranging. So, she's going to

share just a few slides on that activity right now.

MS. BAKER-SMITH: Thanks, Don. So, after our last PPDC meeting and the workgroup discussion around pollinators, Rick Smith, who I don't think is here today -- he was here yesterday -- a beekeeper in Yuma, and I got together and said, you know, we've been able to find a way to make this work in Yuma. Maybe it's worth bringing Don and Rick to Yuma and showing them what we did and then seeing if there's any lessons that we can take from that that could maybe be applied generally in other areas.

So, just a quick little background on Yuma, because I know not many of you have probably been there, other than those of us who live there and work there. So, it's a long time agricultural community. Been in farming for over 100 years. If you eat lettuce or winter vegetables in the winter, they come probably from Yuma. Over 90 percent of the lettuce and winter vegetables come from Yuma Imperial Valley which is about 40 miles away.

It's a very diverse agricultural community. We have vegetables, melons, alfalfa, cotton, wheat, safflower, beans, all those you can see there. I put the

crops up there to show you there are some that need pollinators and some that don't need pollinators. But because you're in a 20- to 30-mile radius of agriculture, you know the bees are in that area, whether they've been ordered in to do a specific function or whether they're just there because that's where they reside.

The pollinators are needed and used in the crops. I think it's kind of a microcosm of the issues that we talk about here at PPDC, water, ESA, worker exposure, pollinators, et cetera. I put that there to say that when you talk about what are you going to do to protect pollinators, you have to factor in the other things that you are trying to do to minimize drift, to take care of workers, to be protective of the environment. All of those things are happening at the same time in any particular environment.

So, what we did, I just talked about, we brought Don and Rick down. Rick Smith really deserves the credit for organizing the day and a half. We visited pest control advisors, so in California and Arizona, the people who walk fields and make recommendations about what you spray and when you spray and how you spray are

certified licensed people by the state. They have to go through training annually to get enough credit hours to keep their license.

We talked to actual farmers who were there, so farmers who were ordering in the bees to pollinate their melons and farmers who are growing other crops right next to these guys who have to use the bees, and we talked to applicators. We saw and heard firsthand about all the different interfaces that go in there.

So, you know, the PCA is standing there talking about the white fly problems that he has in melons. The best product that he has today happens to be a neonic to help try to be protective of the bees. He applies it in the soil and then covers it up over the top to try to minimize the exposure. So, those are kind of real examples of what people are doing to try to address the concerns.

Then, this last slide is just kind of a summary of what I learned, because pollinator protection and concerns hadn't been high on my radar screen. So, it was very educational for me to go around with Rick and Don and Rick to look at all this stuff.

So, what I think we discovered was that local solutions can work and probably will be the most effective because one size doesn't fit all and there is no silver bullet here to solve this problem. The pests need to be controlled. The pollinators are necessary for ag production and for other important reasons and need to be protected.

We found that a champion helps a lot. So, in the specific case of the Yuma success story, it was actually Rick's dad I think who started this talking and reaching out to PCAs and to growers and trying to find a way to live together in this rather small agricultural community where all those factors had to be addressed. So, he initiated the work with PCAs and with growers and with beekeepers.

And so, it doesn't always have to be the same functional area that's the champion. In some areas, we were talking yesterday, it might be an NGO who is the champion because it's not high on the radar screen in that particular state or maybe that state has a predominant crop that doesn't need bee pollinators. So, it might be somebody other than the beekeeper or the PCA.

Creativity and flexibility are really important. Really good communication is the key. So, one of the reasons why it worked so well in Yuma is we are a small community. Everybody knows each other. The PCAs know the growers, know the applicators, know the regulatory authorities there, work closely with the university cooperative extension. So, it's a nice environment for good communication, which is really one of the key ways that we'll see success in this area.

MR. BRADY: Thank you, Cindy. So, we have about 45 minutes here.

Mark, did you have a question for Cindy? Okay.

But I think to help give some structure to the conversation, it might be good to start with the workgroup report outs. What we would like to hear from the EPA standpoint is some sense from the folks around the table as to a sense of priority in terms of what, for example, the best management practices subgroup committee members think is most important to take on initially or to take on first.

So, hopefully, if we walk through that discussion, we, in EPA, will get a sense of what the

priority feelings are from the group. We'll also, as we work through that, begin to look at common cross-cutting things that were identified. So, I would start then with best management practices subgroup.

Mark has his card up first.

MARK: Sometimes that's really a disadvantage, to have your card up first. I took it down. I put it up. I took it down.

MR. BRADY: We can go up here to Valentin if you want.

MARK: Well, one of the things -- first of all, I think the work that this subgroup is doing is really vital right now. The reality is that we are impacting pollinators significantly. I've been doing this project called functional ecology in orchards and road crops in Michigan for 11 years. We've seen a dramatic decrease in pollinators, not just domesticated pollinators but native pollinators and also natural enemies in these systems. It's pretty good data. We're still analyzing a lot of it. It's an immense amount of information.

One of the things that I think that I'd commend this working group for is just the communication, getting

the word out, a bunch of things like that. Education, absolutely essential. But there are a couple of things that are nagging at me. That is, we talk about pollinators but we don't talk about natives.

Natives sometimes give significant input in various pollination strategies. I know that makes it much more difficult, but there's quite a few of them out there in some ecosystems particularly. Some of those desert ecosystems are really important. That, again, relates to natural enemies, which have also really gone down.

But one of the significant things that we have seen is where almost any plant that's irrigated that has been treated with a systemic material, if that treatment and the irrigation process are close in timing, you can induce gutation (phonetic) in plants. You can induce the process whereby plants give off water.

A lot of people recognize this or look at it and they say there's a dew on the plant. No, stomata and other organelles on plants give off this water. When you build the water pressure in that plant, they compensate. In that compensation, if you have a systemic material

associated with it, you push that systemic material out into free water and you impact anything that's using that free water in the system.

There's hardly any work done in this area, more now focused in this area. But I think this is a broad impacter of beneficials in the context of agriculture. It really needs to be looked at. We're moving to more irrigation, not less, and the impacts on natives, as well as domesticated and as well as natural enemies, are significant.

So, I'd like to raise that as a major issue we really haven't pushed too hard, the correlation between irrigation, gutation and impact. Thank you.

MR. SANCHEZ: I'd like to just get some clarification. You were talking about the Yuma trip. I see here you guys talked to farmers, applicators. I guess my question is, when you talk about applicators, are we talking about independent companies that apply pesticides or are we talking also about workers who sometimes (inaudible)? Also, whether some of the applicators spoke Spanish or (inaudible) Spanish.

MS. BAKER-SMITH: So, there's a mixture in Yuma

of how crop protection products get applied. The actual application company that we went to was a company called Morris Ag. They are aerial applicators mostly. So, that was the specific field trip. But growers also do some of their own application in Yuma.

The distributors do a good chunk of the application in Yuma. So, somebody like Crop Production Services does application not just for their clients, but they also contract out their application services there. In the mix of employees in the distribution network in Yuma, because the Gowan Group has the Doom companies which are ag retail distributors there in Yuma, speak English and Spanish. So, I think that was your question.

MR. SANCHEZ: Yes, thank you, Cindy. In Oregon, we don't have a lot of aerial. Most of the farmers ask their employees to apply pesticides. So, I'm just thinking that we should consider including workers as well into this discussion because at least in Oregon, they're the ones that are working on this daily at the farm.

MR. THRIFT: I want to try to get this in perspective. I'm not a member of the workgroup but I've

spent close to four decades in a pesticide business and grew up on a farm in California where we used bees. I also want to say our association, Ag Retailers Association, represents about 45 percent of all the pesticide applications in the U.S., primarily ground applications.

With that said, and this has probably already been discussed in workgroups, but I wasn't in the workgroups, the original pollinator questions came up in the PPDC two or three years ago basically surrounding colony collapse. Evidently, we've moved other places, so that's fine.

A number of things I've heard this morning make very good logical sense, education. In the enforcement area, however, historically, bee regulations and restrictions were directed toward pesticides on colonies, not migrating bees. I'm going to make a point here because I must have missed a connection here that I think is very important to ground applicators.

I also want to state the fact that my background in agronomy and science really puts pollinators in a beneficial insect class. I think

they're important. They're necessary. But, quantifying that, I believe that USDA and NRS data says that pollinated crops are roughly a little over two million acres of which over half of that is actually located in one state.

The primary crop, as we know, is almonds, 850,000 acres, I believe, at last count. I believe at last count, USDA is using 400 million acres nationally of crop land. Actually, I think it's 397.5, but I wouldn't want to be picky on data. But I think now from something I just heard that Marylou said a couple of minutes ago, and I believe the quote was, "crops not pollinated by bees but bees present on the crop," I'm trying to figure out how my members would look at this, because I think we just went from 2 million acres of pollinated crops to crops across the U.S. or something like that. I'm not sure that I understand that.

Now, probably I've gotten lost here somewhere, but I think that 2 million acres, probably 60 percent at least -- I could probably provide the committee data if you'd like -- is in California, probably another good part in probably Florida and Arizona. So, that's what I

guess we're actually talking about. We're not talking about the Midwest corn crop or cotton in the south or other crops. That's one thing I want to quantify.

The other part is, I get concerned about label restrictions, but we would be open to discussing best management practices. I think that's a very logical approach. I also get concerned when we start talking enforcement and we haven't even talked about the protocol of the regulation yet. That makes me nervous.

Now, I can't tell you what I'm nervous about really yet because I haven't talked to my members because this is the first time I've heard about this. So, I don't know if I'm nervous or everybody is happy, but I think we need to quantify.

My first question would be, are we talking about U.S. crops and we're going to educate applicators, or are we talking about the crops where there are necessary pollinators?

Then, the next question is what Marylou brought up -- I knew about it but I hadn't thought about it -- is I don't think they build fences around fields where there's pollinated crops so the bees migrate. If the

bees migrate into a crop or my members are spraying because of pest thresholds, are they responsible for -- I hate to think of this -- dead bees? Do you understand what I'm trying to say here and quantify this thing?

MR. BRADBURY: Let me give a couple of sentences, and then I want to really encourage the rest of the speakers to focus on the best management practices subgroup, if you can give us some advice on next steps. Jim, some of your comments related to that (inaudible) half an hour. The agency, working with the PPDC, has created this group. We want to get some advice from the committee on where to go forward and try to tap into the various thoughts you all have.

Colony collapse disorder, yes, that was a discussion of two or three years ago, but clearly, through research from the USDA and just what we all know, going back to the NAS report of the mid-2000s, pollinators are in decline across the country and globally. It's more than just managed bees. So, the issue has always been bigger than colony collapse disorder and honeybees.

There are a number of issues that the workgroup

has been dealing with, some of them acute poisoning incidents as well as sort of just understanding sort of the landscape as a whole and how pesticides are integrated with lots of other stressors in the landscape. We want to get some advice on how we ensure that what we're doing in the pesticide program is reasonable and appropriate to I think strike the balances I really commend the workgroup on.

We have to have crop production and we want to minimize harm to pollinators. I really appreciate the group realizing sort of this tough goal we want to get to and how do we start to chip away at getting at that, realizing working with USDA this multi-factorial challenge will be tackled.

So, if we could go around with the folks that are up right now and get some advice on what you think for the best management practices group, then we'll try to get through the other three workgroups to start to get some feedback. EPA will ponder over the evening, maybe with or without a beer, and then we'll get back to you tomorrow and kind of give you our thoughts on where we think we'd like the workgroups to focus on in the next

cycle.

So, Scott, if you could go ahead.

MR. SCHERTZ: I just want to expand a little bit on my earlier comment and then also take an expansion basically on Cindy's explanation of what goes on at Yuma. The application protection of crops doesn't always fit into this nice little 8:00 at night to 6:00 in the morning time period.

Throughout the country, you know, she has the example of a very intensive ag situation. I think it would be very easy for many people to discount that as really being odd in those demands. Whether you're in a major crop area, you know, corn, soybeans, whatever, you still have similar things that may have a little bit different labels.

But whether it's (inaudible) corn workers and re-entry times and when they've got to get back in dictates when you can do the spraying, et cetera, it just isn't an easy piece, and you've got to take all these different things into account. That's why I think it is so important that it be kept under best management practices but be able to prioritize it to where the

active pollinator interests are and not a blanket recommendation. Thanks.

MR. BRADBURY: Susan and then Cindy.

SUSAN: I just wanted to comment on Cindy's statement about the Yuma situation which seems -- I agree that having people working together in a way that everyone can see the benefit of working together is really valuable. Ideally, that's where this would head.

I'm a little bit concerned that in a time of limited resources, that some states who don't really depend on pollinators for growing the crops that are present in those states are not going to be able to prioritize this activity. Relying on point people who are -- essentially, it's not their job to do it; they're volunteers -- it's hard to see how this is actually going to be effective in the long run.

I'm thinking that what EPA can do perhaps is provide some incentive to bring these people together. I do think communication is going to be a big part of the solution, but providing some incentives for making that happen, that communication happen, would be really, really helpful.

MR. BRADBURY: Cindy and then Tom.

MS. BAKER-SMITH: So, one of the things that happened in our workgroup yesterday, Steve, that makes this discussion kind of challenging is that a lot of these things overlap. So, (inaudible) the best management practices feedback loop because I really do think it's important for us to think about what can we do now and what has to take some time.

Just changing labels by their nature takes time. We're going to have to figure out what the right language is, what is the data and the risk assessment behind that language. The point about residual toxicity I think is an important part. The reality is that all that data doesn't exist today.

Getting it by crops, by products, by geography -- because there are things that if you're in an area that gets more than 25 inches of rain or you're in Yuma where your average rainfall is 2 inches is going to make different impacts in terms of how long something might stay on a lead surface or whatever. So, I think my recommendation would be for EPA to do the things that they can do today in the area of best management

practices and balance that with what you have to wait for science and data to do.

I think the other thing that was important for this workgroup -- and I actually think we made a lot of progress here -- I think it started out with a lot of emotion. I think the easy place for people to go was to go into their corner and say, I'm a beekeeper and I'm only going to -- and I'm not suggesting they did this -- I'm only going to protect my interest or I'm a grower and I'm only going to protect my interest or I'm an applicator and I'm only going to protect my interest.

The reality in a lot of these issues that we're dealing with is that we're not going to make 100 percent of the stakeholders happy. I know you know that. You live it every day. It just isn't going to happen. We're probably not going to get to a situation because of the things that Jim pointed out -- you can have bees in an area where nobody knows they're there.

If you have all of the registries in the world, you won't know they're there. So, we're not going to be able to get to a place where we say no bee will ever be harmed. But I think that we also can't say that there's

nothing that we're willing to talk about in terms of changing how we control pests.

So, I think there are some best management practices we can start putting in place. I would focus some energy around what are those today, where we have enough information, where you've got an agreement from all of the stakeholders that have to be part of that, where we can utilize some of the learnings that we have done with other communication things that I think have been successful. Get that information out to people so that people know what some of those things are.

MR. BRADBURY: Tom and then Marylou.

TOM: Well, Cindy's presentation about Yuma made me think about what partners need to be at the table. I don't have the workgroup membership in front of me. But the obvious ones would be the CCA program and then NRCS, who we're going to from this afternoon, had some program options around pollinator protection. Then, the ag retailers, I think it will really be important to have them participating in the next steps, whether it's the workgroup or EPA that goes forward with best practices and training materials.

Jim, there was a publication that came out of Perdue this winter you may not have seen that talked about corn seed treatment and the planter (inaudible) about reducing the drift of that broken up insecticide. That's where I think it's really important that we have the infrastructure that you're talking about involved.

MR. BRADBURY: Thanks.

Mark and then Darren.

MARK: Just two short points. One is that we look at restrictions on products. This was more of a voluntary thing, and this was back in the 80s, doing resistance management. There's some of the same management techniques for saying this. We can do this but we can't do it all, so you need to, in fact, have some type of restrictions. Sometimes that's by government; sometimes it's by grower groups. That's something I just want to mention that there is a precedent for.

The other thing is, as Steve mentioned in his opening remarks, science is changing. Technology is just getting way ahead of us and stuff like that. We need to be looking at the things that have been brought out in

the literature about sublethal effects and really start paying attention to those and integrating that science into the best management practices, just like we would integrate the science of determining thresholds, damage thresholds, into the science of best management practices. So, I think it's time that we look more at the sublethal effects than we used to.

MR. BRADBURY: Thanks. Just real quick, I'm sure the workgroup members know, but there's been, on the science front and touching on what Mark and Cindy were saying, there's been a lot of international work at EPA as a part of -- we have a Scientific Advisory Panel scheduled for September 11th to 14th to get advice on moving forward with the risk assessment process. (Inaudible) is part of that effort. Canada is part of that effort.

As we learn some more about sublethal and other effects, hopefully the science will move along and we can integrate that with best management practices to training, to labels, to whatever. So, I appreciate the points, but we've got to kind of keep things moving together and integrated.

Darren and then Ken.

MR. COX: You know, on the beehives, we view them as environmental indicator species to represent the overall health in the environment. I'd like to commend the EPA for pulling this meeting together and being able to really just look at the pollinators, managed honeybees, and see how we can implement best management practices that's agreeable to all of us.

I'm very happy to see the level of cooperation that's been expressed here by all the stakeholders. There is some concern, of course, if you're in a state, for example, that you really don't need the honeybees but they're visiting your crop. I recognize that concern. In California, we understand the need and the desire for these almond crops to be pollinated by the mound of bees so that we can continue to have the proteins to feed our civilization and grow with. It's trying to find that proper balance that I think we all want.

One of the statements that was said was when your crops are in bloom, apply the products in the evening when the bees are not foraging, whenever possible. So, that wording in itself is a BMP statement.

I would like to say encourage that whenever possible, not because you'd like to watch the news at 10:00 instead of applying it at 10:00, but there is going to be some emergency situations that do come up.

But I'd like to just make sure that we clarify that as an emergency situation instead of just a general practice situation. So, I'd just like to extend our hand out as the bee industry that we're here to work cooperatively with the rest of our ag community families developing these BMPs.

As far as the bee registry locations, California has a registry for hives. They also have a registry for pesticides. I believe that's the only state that has a registry for pesticides. Wyoming, Montana, South Dakota, North Dakota -- Montana has apiary registration sites. We still have problems in there that can be improved upon for best management practices. We do not have a pesticide notification site in there for the beekeeper to gain that information for improving communication.

One other point that I still have a concern with is the ability of these states, especially in

today's budget crisis, of being able to have the funding to be able to go out here and do the proper training and be able to do the field inspections and work in the ag community to encourage BMPs in safer application and actually do some investigations on some of these sites. In many of the cases, states don't have the funding.

So, I would like to ask the EPA to try to work with the states to ensure that they have the means and ability to ensure the safety of our indicator species.

MR. BRADBURY: Thanks.

Ken and then Cheryl.

MR. NYE: Well, this is certainly an important subject because we need to protect bees and other pollinators. The importance of the services that are provided and the importance of agricultures is pretty critical.

Steve, I like the ideas here that have to do with training and education. Best management practices have suggested some of those, but there are some other areas also by the other workgroups. I think we can do a better job of making sure that the information is convenient and easy to use. We know we can improve those

things that make that better coordinated.

Allow the states to do a better job through the land grant institutions, the extension service, through the organizations, the farm organizations, and beekeeper groups also working closely together. I think we can accomplish quite a bit if we pay closer attention to this. I think too many of us have gotten a little complacent in terms of we need to understand that the consequences of utilizing pesticides on crops can affect bees. We've got to consider that. We've got to keep that in the back of our mind at all times.

I think if we do that, a little bit of help from the beekeeping industry and a little help from our educational institutions and so on, and from the agencies, whether it's EPA or USDA both, I think we can make sure that that information gets out to the field and is usable as much as possible. We're not going to solve 100 percent of the problem, but I think we can at least get people to think about it and understand the consequences of their action.

MR. BRADBURY: Thank you, Ken.

Cheryl and then Doug.

DR. CLEVELAND: This is a really hard subject. We've heard that. We've heard a lot of (inaudible) from all the stakeholders. I would say that in attending the full workshop yesterday, the information that is being presented here is at a higher level. So, the devil is still in the details. It's good to be respectful in this forum, but there's a lot here that still needs to be worked through.

But in terms of best management practices, again, I'm hearing balance is really going to be the key. I'm hearing that you want to have maybe some federal programs, but you want to give way to local solutions. I kind of liken it to my son. He's 19 and sometimes he's a man and sometimes he's a child.

The best that I can do is throw out, please do this. If he rises up and does it well, that's great. I would kind of make that akin to a local solution. When you can get that grassroots solution on your own, it's wonderful. But if he doesn't rise up, then I say, uh, I've got to come in and be the parent again. That's the minimum standard.

I kind of hear that that's the balance that's

needed even in these best management practices, because if you push -- this has been hard enough to get at this level to get this much cooperation. If you push this off to local systems which may not all be as motivated or may not all -- they'll have variable responses. You can't push this down to be completely local.

But, at the same time, you can't negate the good that could come from a local solution. I think that this is really important. It's more important when I heard that the labeling group was actually going to be mandating best management practices as part of their suggestion for label language. So, these things become intertwined. Again, I think that there needs to be kind of maybe even two goals, if you think about it like that.

MR. BRADBURY: Doug and then Cynthia.

MR. HANKS: Well, mine will be short. On the four areas of best management practices, communication, education, training, labeling, and enforcement, the last two would be compensated for if you can -- as EPA and USDA, we're doing a program called Gap Now. It's good agricultural practices. If that could be a page in the manual that we're doing on pollinator protection, it

would help the national and state organizations cover a little bit more of these items that we've discussed today. So, I would make that as a suggestion.

MR. BRADBURY: Cynthia.

MS. PALMER: This is Cynthia from American Bird Conservancy. I just wanted to make sure that as we discuss pollinators, we also include or think about birds and bats as pollinators. They are also important pest control agents. They do it for free.

With regard to best management practices, there are three areas that are particularly important to us. The timing of the pesticide application needs to be thought through very carefully. Songbirds migrate at night. On the other hand, bats fly around at night. So, we need to take all these considerations into account. As a bird group, we are very concerned about seed coating technology. We just have to be careful what we put on those seeds.

Yesterday, there was also discussion about encouraging the cleanup of spilled pesticides to avoid toxic puddles. I just want to make sure that that doesn't fall off the radar screen. Thank you.

MR. BRADBURY: Any other thoughts, comments?

(Whereupon, there was no verbal response.)

MR. BRADBURY: Here's what I think I'm gathering, and, Don, you jump in if you think I'm synthesizing differently, because we'll go back and brainstorm a bit this evening and then come back in and see if it feels right, thinks right.

One important concept that came out is a logical sequencing of activities. Cindy and others have obviously have formed groups that overlapped in certain themes. Some development in some areas will then create some foundation for moving into another area, depending upon what the specific topics are.

It seems like looking on best management practices, that the federal to the local level -- and that would be something for that group to work on to sort of get crystallizing those and seeing where they can play out and how that starts to advance, then, is an important concept that came out.

The education, training, getting information out to people seems to be a really important area of

focus. As Don said, it may all be there, but it's fragmented across a fragmented landscape or whatever, but there may be that there's better information to gather to get to folks.

It also may be there's really good information out there but it's just hard -- it's not efficient, it's not in the right places, or people don't know where to get to it. I don't know what the right words are. To me, that seems like low-hanging fruit that can start to move forward and maybe feed into the best management practice development and then could be a stepping stone into some of the other areas.

I'm getting a sense that there is work that can start on the labeling front. It may not be in the context of X numbers of days, weeks, months from now new labels would be developed, but to start to be prepared to take advantage of what may be learned through the education and training and through the BMP process to be poised to have good discussion about pros and cons of labeling.

I think it would be best to have people thinking about the state of affairs on the labels, how

noisy are the labels, how difficult are the labels to interpret. So, we kind of know what the universe is that we're dealing with, have a gut check, but we may not have a real complete understanding.

As the BMP and the education issues start to evolve, at least we'd be poised to think about what to do with the labels. It's sort of like getting ready, being informed and getting ready, but not to be jumping on something quite yet. That's sort of a third conflict I got out of it.

And then, a fourth conflict, and I don't know of the workgroups which clump it falls into, but it's sort of balance of retail versus wholesale and roles and responsibilities of us and EPA and USDA, states, and the community of Yuma. Concerns of how do we work at these different (inaudible)? I mean, EPA can't go around to every -- I mean, USDA probably can't get around to every single place in the landscape where you have different convergences of different cropping patterns and different kinds of communities and the roles of everybody in these different communities. That just isn't going to happen.

But what can we do at a federal and a state

level to work with local communities in terms of here's some things we've learned. They may not work in your place, but it may be a helpful starting point. So, it's not something that I can see to do immediately, but it seems like it's something to be thinking about.

How do you get these scales to work? I think the Yuma example is a good one, but Yuma isn't the same as parts of Michigan where cherries and apples are grown. But there could be some principles that are learned that the wholesale way we could start to help at the retail. The retail is going to be the local communities.

Again, I don't think that's an immediate one, but it's just sort of underneath all the discussions we've had. So, it seems like the BMPs, education, training seem to be high priorities and it could be a focus area.

I think labeling efforts, we need to get our heads around the issue so that we're ready to take advantage of some of the insights that come along. The science is moving, so I realize that some of this is tied into the science. I don't think we need to get ahead of where the science is going, but marry that up. So, it's

sort of like chugging in the background.

I don't know if that helped at all. But that's sort of how I was starting to synthesize some of the discussion. Somebody let me know that that's not what we meant or whatever. Don, is that sort of how you're pulling it together? Was that a rough attempt to try to synthesize, especially for the workgroup members?

MR. BRADY: It does seem, though, that once you start putting something on the label, it's got to be connected to risk assessment and science. I mean, I really think you may be getting a little bit of the cart ahead of the horse with what I understood of your summary of it.

MR. BRADBURY: Be clear. I think the first step with the labeling effort is what do we have on the labels now. So, it's understanding what our labels are saying now, because (inaudible) spray drift. We have sort of the same AI under the same scenario that's on multiple labels, and those labels are saying different things. The intent of the label may have been common across those three different labels, but the words sure as heck aren't the same.

So, to me, part of the effort is just sort of figuring out how much noise do we have in the system and kind of reflecting back. Those words are (inaudible) the following. So, at least we understand where we are today. As the science progresses or the DMP practices progress, they'll know where we're starting from, not so much to be doing anything yet, but to know what the universe is that we're dealing with.

Marylou?

MS. VERDER-CARLOS: I agree with you, Steve. Labeling subgroup, we knew that the science has to be there. But the last PPDC meeting we had the subgroups also report and we said that while the science is not yet there, could we do something with the labeling.

So, I think that the labeling subgroup should continue their work on looking at each label and each active ingredient to see where the inconsistencies are. So, in moving forward, we can tell the agency, well, see, this is the same active ingredient, but this has inconsistent language.

So, it would be hard to enforce it. So, I think that the work has to move forward with that in

mind, that it's not going to be a change all of a sudden. It's going to be a move toward a certain goal.

UNIDENTIFIED MALE: I would just like to reiterate on the best management practices. The quickest adoption is usually one that has a self interest. That being so, I think case studies that show a return to growers by keeping their pollinators even on autopollinated plants, like soybeans, canola, or sunflowers healthy and alive will be the best adaptation when it shows the grower a personal return.

That's why I highly emphasize that we need documented case studies that we can go out with the extension people and show the growers in their self interest the BMPs will give them a return.

UNIDENTIFIED FEMALE: Hi. Just to clarify, were you trying to synthesize the whole pollinator protection discussion or simply that on best management practices?

MR. BRADBURY: I was synthesizing across the whole presentation because I can sort of tell, which is fair enough, people were kind of bouncing around the various areas.

UNIDENTIFIED FEMALE: Okay, because I was holding back.

MR. BRADBURY: I appreciate that you were disciplining yourself. So, go ahead and if you have some other points, that's great.

UNIDENTIFIED FEMALE: I just wanted to talk briefly about a topic related to enforcement, which is incident reporting. I'm a little bit confused, and I'm new to this group, so maybe you can help me out here.

Why there's no national system for incident reporting for pollinators kills perhaps under FIFRA 682. Maybe that could be beefed up. You were talking about how EPA wants to be at the forefront of science and ahead of the curve, and I feel like we don't have the data at a national level. I know that that's a problem with the bird incident reports.

When we want information, we have to submit a FOIA to get that information on the incident reporting. That's not a cost effective use of government funds. I'm wondering about a more national system for birds and for bees incident reports.

MR. BRADBURY: Thanks.

Let Caroline go and I'll try to circle back around.

MS. COX: I had something I wanted to say about the enforcement slides. I like to dream the impossible dream, but I was struck by the one statement that the enforcement subgroup made about developing procedures to make it easier for states to determine when and where pesticides were used. I understand that there's some statutory and funding issues about full pesticide use reporting, which I would love to see and I think would be helpful in a huge number of arenas, including worker protection and ESA stuff and on down the list.

But I just think that this recommendation is really, really crucial. I hope that the agency will take it very seriously and do whatever creative things can be done to actually make that happen.

MR. BRADBURY: I appreciate the last two speakers of making sure we didn't lose track of some of the other areas.

David.

MR. TAMAYO: I think that your synthesis was actually right on. I think that the sequencing of those

is a good way to go about it, do the things that we can do now. I think those can really make a big difference.

Now, one thing about it, I think that the development of a set of a principles is really important early on because I think that's what's going to be sort of like the universal training. I think that's what you even need to do at a local level. The crops that are being grown are changing all the time. Even if it's the same crops, the conditions change from day to day. So, I think that's one of the things that whoever is applying these things needs to know.

I also wanted to say that part of the training or part of the work needs to address the need to accept responsibility. Jim said, well, are you responsible for bees that are migrating? Well, yes, if you kill them, you're responsible for them. There's a difference between whether that's an enforcement kind of a thing or just recognizing that we're part of a system.

It's your neighbors that's got the bees or that needs those bees. You might need the bees next year or whatever, but just be a part of the system and accept responsibility for doing what you can to avoid an impact.

I think if we move towards a system where people are trying to be more and more responsible for their actions and understanding that if we don't fix it through voluntary stewardship, that that's where it starts moving towards enforcement actions, which are very difficult to do and can have all sorts of unintended consequences or are less adaptable.

So, in answer to Jim's question, yes, you are responsible at one level or another if you end up killing them. You might be able to adjust and maybe you won't be able to adjust. But at least understand that you have a responsibility to sort of balance your actions and adjust them where you can to meet both your needs and your neighbor's needs.

MR. BRADBURY: We do need to break for lunch. We're going to ponder on the synthesis that we just did. I am going to add, hearing the last couple of speakers, that I think what's important, low-hanging fruit, no pun intended, but the continued coordination with the state-lead agencies and the state associations. There's no reason to not continue the dialogue we already have but continue to expand that, because as these things move

out, the coordination with the states is critical. So, we'll continue to push on that. But we'll set up some priorities on how to do that.

Also, maintain our conversation with OWECA in terms of the enforcement part, at least getting ourselves current in what's going on. We'll talk some more about incidents during the course of the next day or so and maybe update on some of the portals we have for getting incident information.

So, with that, I want to thank you all, in particular all the members of the workgroup. You've gone a great job. I really appreciate how you're trying to bring things together. I think Dave's comments nicely captured the spirit of the group in trying to come up with some approaches going forward.

So, we'll take a break now for lunch. We come back at 1:15 and we'll hear a report out from the IPM workgroup.

UNIDENTIFIED FEMALE: The 21st century workgroup, Jennifer McLain is going to meet you in the back of the room to take you up to your meeting on the fourth floor. You need an escort. Anyone who is going

to the 21st century workgroup meeting, can you just meet in the back because they're about to go upstairs? Thanks.

(Whereupon, a luncheon recess was taken.)

AFTERNOON SESSION

MR. BRADBURY: So, this afternoon, the first topic on the agenda is getting an update on integrated pest management from the IPM workgroup. Keith Matthews, Director of the Biopesticides and Pollution Prevention Division, is helping working with the group. I'll turn it over to Keith to kick off this session.

MR. MATTHEWS: Very good. Thank you, Steve.

We actually have a very full session to go through over the next hour and a half, so I'm going to keep my introductory remarks fairly short and try to get into the substantive aspect of the session very quickly.

So, as you recall, approximately this time last year, Steve asked the PPDC to establish a workgroup on IPM. I actually have to admit, working with the workgroup over the past year, I've been extraordinarily impressed with the dedication that the members of the workgroup have shown. We have a very impressive roster of IPM professionals and experts. They've done a great job in delving into the specific topics that we've asked them to work on.

So, the two charges that the workgroup received

was one, to help the agency develop metrics to assess the effectiveness of a new school IPM program, which I'm going to speak in greater detail about the new school IPM program later in this session. Also, number two, to assist us in determining appropriate ways to assess quantitative data benefits of IPM and agriculture, public health settings, and schools.

So, we had a workgroup meeting yesterday, and we have a report out from that workgroup meeting. The two subgroups are going to report out separately. If I have this correctly, Tom Green is going to report out first on --

Tom, are you reporting first or is it Marc?

DR. GREEN: Marc.

MR. MATTHEWS: Marc is going to report out first on the metrics for the new school IPM program, and then Tom Green is going to report out subgroup two work on assessing quantitatively the benefits of IPM.

So, Marc, why don't you just take it away.

DR. LAME: Thanks, Keith, I appreciate it. You just want me to tell you when to go to the next slide, and I'll just do that?

So, our contents, as Keith said, and there's a slight addition on this one, is that I'm talking for the next three hours on group one. Tom gets five minutes on group 2. Cindy is doing the general comments, and then Tom is going to have an additional report. Actually, we'll get this done pretty quick.

You know, folks, this time of day, this is finals weeks at IU right now and I'm skipping out to be here. I do have a 1:00 class, so I have people come in from lunch. I try to do things to keep them awake because their tendency is to drift off. Looking at the advanced age of a lot of people in here, I expect folks' heads to be on the table.

I do want to say something, and I'm sure Cindy will talk about this for a minute, I have a beef with the air quality folks. That office, I'm sure, pumped in some laughing gas into our session yesterday. We all got along. Not only was that not any fun, but we had a hard time getting things done.

So, this is what we want to do. We want to make this shift to integrated pest management, which is occurring in so many sectors, agriculture for sure, but

in so many other sectors which we'll talk about. But it's a shift from a scheduled treatment that is pesticide dependent to an integrated approach -- and this is in the built environment -- that, of course, includes pesticides, if necessary, but it is based on changing behaviors that cause pests to happen. So, that's what we're trying to do.

The reason we're doing this, particularly with school IPM, is to provide this safe learning environment for our most susceptible citizens. So, subgroup one, our charge is finalizing the development of metrics to assess the effectiveness of the new school IPM initiative.

Assess the effectiveness, essentially, that means accountability. So, we had two different types of metrics that we're really looking at. One is what I call management metrics, and the other one is mission metrics. Management metrics has more to do with how people do stuff, and mission metrics, of course, relate to the mission of protecting human health and the environment.

So, we have to figure out where to look. Of course, not every state is lucky enough to have a Roachdale. Indiana is.

So, management metrics, basically, there are three questions that have to be asked and answered in order to successfully implement. So, the charge is to have successful or effective implementation. The three questions are; what action is to be taken, who will take that action, and do they have the resources to take action?

What are the metrics that we're looking at for this? We have change in activities. The action that needs to be taken is moving from what they used to do to integrated pest management. As we discussed about it in our working group yesterday, we figure -- I think Tom was the one who was profane enough to say his wild ass guess was about five percent of schools in the United States. Of course, the idea is to take that to 100 percent of doing verifiable IPM.

So, change agent activities that can be measured are partnerships that are established, interactions with the school community, and the development of implementation and risk-based standards. Basically, those are the activities that we're doing, and those are things that can be measured for what we're

doing, because pest prevention is everyone's job.

I'm sure that's not Litchfield Park, Arizona, though. There's no possums there.

So, who will take that action? It goes to the folks who are charged with this new initiative. There are internal change agents, which are Keith's folks. As you guys are looking at this new strategic plan, these are regional IPM coordinators and folks from the Center for Excellence. Those are the internal folks. Then, there's external change agents which are the state-lead agencies, cooperative extension, not-for-profit organizations, et cetera.

So, those people, we can do some measurements with what type of folks we have by measuring the level of training for implementation. We can do that by degree, by number of workshops that they've taken. Many of you in other aspects of pesticides know that we do that with certification, for instance.

So, there's a level of training for both the internal and external folks, which are the technical aspects, the school IPM. Also, how do you get communities to adopt IPM? So, this is not a paper-

pushing exercise. This is getting with communities and changing the way they do things and getting them to adopt a new way of doing things.

For instance, IPM education for the affected community means that they have to become folks that understand that they need to know what pests are and their biology and conducive conditions, and the management alternatives.

There's a relationship that has to be established with these internal and external change agents to prevent pests, inspect for pests, identification, biology, all these things. Well, these can be measured, and these are things that the WHO is implementing. We can measure that person and their ability to do this kind of stuff. If they don't have that ability, we're not going to have successful implementation.

So, the final question is, do they have the resources to successfully implement risk reduction programs in school and beyond? That can be measured as well. That's a cost effective use of implementation infrastructure developed. So, what this initiative does

is develop an infrastructure to get IPM in schools, but once you have that infrastructure in place, you can measure the transferability with regard to other situations.

For instance, you can use that same infrastructure to move to childcare, to elderly care, to hospitals, and to public housing, basically implementing the same IPM innovation. The other way you can look at that as far as transferability is risk. You can look at risk from pests and pesticides, and you can use that same infrastructure, transferability, to deal with mold, lead, indoor air quality, et cetera.

That will be a function of the partnerships that have been developed. So, all of that is measurable and basically figuring out how we can get school districts to incorporate something that in many ways they're already doing, if you think about pest management, monitoring, keeping them out, same thing they're doing for energy conservation and that kind of stuff.

So, Tom, you can take it from here. I did add on that this is what I consider mission metrics, to

protect human health and the environment.

DR. GREEN: Thanks, Marc. Marc put my slides in his Power Point, but I'm sure that there was a land mine in there somewhere.

So, we did our group meetings consecutively yesterday, so we had the whole group there for both subgroup one and subgroup two. For subgroup two, our focus is on recommending ways that the agency can quantitatively measure IPM benefits and agriculture public health settings and in schools. So, how do we get some quantitative measurements in place?

Our agenda yesterday was to have a broad discussion on pests and risks and costs. Case studies that had been submitted over the previous months by e-mal to the group talked about environmental and economic benefits. It talked about who we'd see push back from. As Marc mentioned, there wasn't anybody in the room. We talked about partners, and then how does this fit with the strategic plan that was passed out. We'll be discussing this in this section.

So, deliverable? We haven't really refined what we're going to end up with yet. Presumably, it's

going to be some report to the agency that is going to list ways to quantitatively measure IPM benefits. We haven't settled on a time line yet either.

We have identified quite a few tools. We had Bill Coley (phonetic) from University of Massachusetts participate by phone. Bill talked about this multi-year, multi-collaborator effort to put together a set of logic models. The URL is up there on the screen.

What they do is describe all of these measures for different environments. So, there is one specific to schools and one specific to agriculture. They talk about short, intermediate, and long-term impacts or benefits, which is what we're after.

So, a short-term benefit might be just increasing the awareness of an IPM practice by giving a presentation to a group. An intermediate benefit might be that some of the people in that group actually go out there and do something differently on their farm or in their school as a result of participation in that session.

Then, a long-term impact might be that six months down the road that school has a lot fewer

cockroaches because of what they did differently by sealing up harborages in the food service areas and cleaning the drains. So, these logic models are in place. They really do a very good job of cataloguing these different benefits that we want to measure.

Then, we talked about best management practices and IPM elements and guidelines. We also have a good library of these at the web site. Then, Joe Conlon shared one to the American Mosquito Association that are really designed to help users measure how much IPM they're actually implementing. So, it's a checklist of practices that they could have in place.

Some of them are set up so that you can actually score yourself. The National Potato Council and Canadian (inaudible) Council and McDonalds just put together a survey that all the potato growers that grow potatoes that end up in McDonald's french fries completed this survey. Then, each grower was able to see where they stood within their own region and then also nationally and between the two countries in terms of how many practices they were adopting versus their peers. So, it was a good measurement exercise.

Then we have case studies also that detail IPM benefits. Joe provided one. Robin provided one from a healthcare project in Maryland where we worked with 18 different healthcare facilities and reduced pest complaints and pesticide use in those facilities. Another example was the great presentation that Peter Ellsworth made at the IPM symposium in Memphis during the closing session where he showed 15 years of history in Arizona cotton, a reduction in pesticide use and in pest problems like white fly in cotton.

We also talked about constraints to IPM adoption. Those are detailed in that first report, Ann Sorenson's report there. We talked about another recent report that just came out that talks about ecosystem services and the benefits that agriculture can deliver by providing habitat for pollinators and so forth.

Then, we have a number of state-specific IPM reports as well that IPM Voice has been working to collect to educate congress people representing those states. It's saying, hey, this is what IPM is doing for your stakeholders and voters.

So, our discussion, and Cindy will talk about

this some too, we talked about getting into the challenges and the constraints given that IPM adoption is well below potential. The NRCS conservation effects assessment program reports that Joe will mention a little later on in this session really documents that in school IPM or maybe about five percent of where we could be. Lots of constraints out there. Those have been catalogued.

We talked about having an extensive discussion about those next time after we've read that literature and then talk about some strategies to overcome those.

Here's some example measures that we talked about building off the presentation by Bill Coley, going from very simple measures like number of pesticide applications and number of complaints, to things like disease incidents and frequency of conditions that are rodent friendly.

One point that was made is there's lots of sustainability stuff going on. IPM is getting lost in the sauce where it has a real opportunity to be a part of these sustainability efforts and to document benefits towards greater sustainability for health and

environment.

We want to learn something about where EPA has been successful in getting adoption of best practices in the past that we might be able to use as a model. Collaborate with the public sector and, much like we heard with the pollinators, training is really essential. There are potentials to collaborate with others on improving access to training.

So, next steps, we're going to work on setting our agenda for our next meeting and refine our deliverable, what we want to see in that report, and set a time line. Then, after our group two discussion, we had a short presentation from Joe Bagdon, who is going to give that presentation today to this group after the school IPM session that follows now.

But, just in a nutshell, USDA/NRCS is the former soil conservation service. Works with private landowners to increase conservation and protect resources. I had asked Steve to add NRCS programs for IPM to the agenda for this meeting based on the work that we've been doing with Michigan State and others since 2006, focusing on getting greater access to this large

program that Joe will talk about in detail.

They invest about a billion dollars a year in conservation. IPM has been about two percent a year of that investment. We want to increase grower access to those programs as a way of increasing IPM adoption. What we discussed in the working group in terms of suggestions to OPP is that they could train EPA on these programs that NRCS has to offer. They can encourage grantees through the RFA process to use these tools.

EPA could host and co-host training events. NRCS uses private sector consultants to help deliver technical assistance to growers and provides financial assistance to fund that crop consultant time. We need more of those people, those TSPs to do this work.

So, the way it works in Wisconsin, I'm the only TSP working with apple growers. Apple growers come in to NRCS. They sign up for a contract, a multi-year contract to put an IPM program together. As part of the condition of getting that funding, they have to work with me, since I'm the only one in the state qualified right now to put together a plan and then implement that plan. I have a staff that helps work with the growers.

We're working with growers both in Wisconsin and Minnesota. It's just great to see the progress that can be made with these short-term contracts in terms of improving crop quality, because these guys are at the beginning stage. They're often doing a counter-based spray schedule that doesn't always catch the pests at the right time, and then reducing their pesticide application and pesticide costs as well. So, by the end of the five-year contract, they are just rolling and have a great IPM program and know lots about what the bugs are and their orchard and how to manage them effectively.

Another suggestion was growers could potentially get credit for the work that they do, potential with an exemption for regulations when they're already exceeding those expectations.

So, I will close with that, then, and we'll hear more detail from Joe in a little bit. But I think we're turning this to school IPM next. Thank you.

MS. BAKER: I don't have a Power Point. I have a nice one-page. This is my presentation. I wrote it out. So, it will be quick for you guys.

So, I think Marc kind of teed this up in his

comments. I use this as kind of the summary. One of the nice things about this workgroup is there is consensus in the group that the use of IPM is important and beneficial in schools and hospitals, in daycare centers, et cetera. It continues to be important in agriculture.

We talked about starting with the baseline for what you're going to measure from. Some of that baseline information already exists, and some of it just needs to be collected and refined. The metrics should be used, and some of those already exist, but they also need to be refined and finalized.

In addition to collecting information, though, for the metrics, we also think it's important to be sure to capture what works and why. So, in a number of these workgroups we talk about examples of let's learn from stuff that's already working and why.

We talked about brainstorming ways to improve adoption of IPM in more settings. So, identification of what the barriers are to IPM, sharing the case studies. So, Tom mentioned Robyn's hospital example, the NRCS apple example, Peter's cotton, and then, Joe, for sure, has some in mosquito control, which is nice because you

get some in public health and ag and in the private sector.

Developing user friendly communication options that are easily understandable, easily utilized materials, making them readily available and easy for people to implement would be a suggestion going forward.

In terms of some of the next steps, I probably jumped ahead of you guys and said that we should try to finalize some metrics for school IPM by the next PPDC meeting. So, because some of that information is already there, we didn't think that was such a huge leap. Maybe form a subgroup to work on ways approve the adoption of IPM, so that whole brainstorming session about what we could do there.

Tom, for sure, has this in his presentation about training EPA staff involved in this issue. We talked about what's in the strategic plan, the Center for Excellence, the number of FTEs that will be working on this. So, making sure that they have an understanding of what IPM is and what it isn't and maybe some specific examples of what it looks like in a school setting, for example. That's it.

MR. MATTHEWS: Thank you, Marc, Tom, and Cindy. Those are actually very helpful and very useful. Again, I'll just reiterate the fact that I think that the workgroup working on IPM has been extraordinarily successful and helpful to us already as we embark on this new initiative. I look forward to working with them over the course of the next year as we continue to develop metrics. Vote for school IPM as well as for assessing the benefits of IPM in general.

What I'm going to do now is go to a brief update on what's going on with the agency's school IPM program. We've been working very hard on that over the past more than two years now, and we've made substantial progress. There's still a lot of progress to be made. I'm just going to give an update in terms of where things are.

By way of a brief introduction, let me just say that this new initiative started in late 2009. It's consistent with the priorities of the administrator, the deputy administrator, and our assistant administrator at the time, Steve Owens. We've gotten substantial and strong support moving forward with this particular

program, both from Assistant Administrator Owens and our current assistant administrator, Jim Jones, as well as Steve Bradbury.

I think that the support that we've gotten is exemplified by the fact that we actually do have an IPM workgroup. PPDC was requested to establish an IPM workgroup to continue to enable the agency to move forward in this very important area.

Marc talked about resources and the fact that in terms of moving forward, that resources are a very important part of that. I'd like to point out that the resources that we as an agency are devoting to IPM, quite frankly, are substantial. We've got at least over 15 full-time equivalents that are devoted solely to IPM work across the agency. That includes an FTE that's dedicated to IPM work in each of the regions, as well as significant headquarters staff.

We're going to talk a little bit in a couple of minutes about the Center of Expertise that we're going to establish. So, we're going to have three FTE in the National Center of Expertise for school IPM, as well as headquarters staff. I've got two of my staff that work

effectively full time on school IPM issues, as well as the time that's devoted to the issue by the management team and the Environmental Stewardship Branch. So, the resources are substantial with respect to the FTE that we have.

So, some of the activities that I can give you an update on, we are currently finalizing draft strategic and implementation plans for moving forward with school IPM. You've received those. We have briefed the states on a brief outline of those plans. We're going to ask for a comment from our state counterparts.

We've got a lot of significant and substantial assistance and input from our regional staff working with our headquarters staff in developing these strategic and implementation plans. We think that they actually are in pretty good shape. We have distributed them to the workgroup yesterday. They're available to the PPDC.

MR. BRADBURY: Folks on the phone, if you could hit your mute buttons, please. Please hit your mute button. Folks on the phone, you really need to hit your mute buttons, please.

MR. MATTHEWS: I am going to try to speak over

the birthday discussion here and continue with my update. Just a little bit more on the strategic and implementation plans. You have a summary in your packet as well as the plans itself. So, we have provisions on the background, EPA's past involvement in school IPMs, the rationale for the current school IPM initiative, mission vision statements --

(Whereupon, the tape ended.)

MR. BRADBURY: So, for the rest of the afternoon, we've got a series of updates, some more extended updates than others. The first session that we'll be covering now has to do with the endocrine disruptor screening program. There's about a half an hour set aside. Karen Whitby and Mary Manibuson will give you an update on where the program is. I think we can manage the clock so that if there is some clarifying questions, we can weave that in.

If everybody is ready, I think, Karen, you're going to lead off. Thanks.

MS. WHITBY: Good afternoon. On August 3rd, 1996, congress amended section 408 of FFDCH that requires screening of chemicals using validated test systems and

other scientifically relevant information to identify chemicals that may have estrogenic effects. The amendment provided EPA authority to obtain testing on other endocrine effects as designated by the administrator. The Safe Drinking Water Act amendment also provided for testing chemical substances in drinking water.

The agency issued approximately 750 EDSP orders, starting on October 29th of 2009. Chemicals were selected on the basis of being present in either four out of four or three out of four exposure pathways, those being food, water, post-application worker exposure scenarios associated with high transfer coefficients, and residential use.

Responses to test orders were due 90 days for individual responses or 150 days if it was a consortia response after receipt of the test orders. Tier 1 data are due to the agency 24 months from issuance of the test order, unless the agency has granted an extension.

Orders were issued for 67 chemicals, and the agency will receive data for approximately 53 chemicals. There will be approximately 500 EDSP list one tier one

studies submitted to the agency. The data began to arrive late October of 2011 and will continue to arrive to the spring of 2013.

Instructions for how to submit data can be found at the EDSP website. Data may be submitted to the agency using formatted CDs similar to what is done for submission of new active ingredients. There is a new e-docier application that guides registrants through the process of assembling a CD using a question and answer format. This is very easy to use and can be done by non-IT folks.

The CD should be labeled PRDEDSP upon submission, and paper submissions are also acceptable. MRIDs will be made available to registrants on the website in advance. DERs for the tier one studies will not be considered as final or released until the agency has completed their weight of evidence analysis of the tier one data to determine which, if any, of the tier two data are required. The agency plans to begin to conduct the weight-of-evidence analysis in late 2012 to early 2013.

The agency has posted the revised weight-of-

evidence guidance document to the docket on September 27th of 2011, and the agency has also posted the standard evaluation procedures, data evaluation record templates, and raw data spreadsheets to the EDSP web site.

MS. MANIBUSAN: So, in addition to the work that's currently being done on the list one chemicals and tier one result tests, they're coming in, as Karen had indicated. The agency is also moving forward with a second list of chemicals that was proposed and issued in November of 2010.

That list of chemicals of 134 were drawn from three particular sources. That includes the National Primary Drinking Water Regulation list, as well as the Contaminant Candidate List, CCL3, and the 2007/2008 registration review scheduled pesticides.

We're also moving forward beyond the tier one assays for screening. We're moving forward with inter-laboratory validation of the four tier two tests. The Mammalian Two-Generation Reproduction study is, of course, validated already. We are also accepting the Extension One Generation Study, as it includes sensitive endpoints for the endocrine system.

We're moving forward again with inter-laboratory valuation for the Avian Two-Generation, the Japanese quail study, the Xenopus Laevis Amphibian Growth and Development study, the Medaka Fish Two-Generation study, as well as the Mysid and Copopod (phonetic) Invertebrate Multi-Generation study.

We're not only stopping there with respect to developing tier two tests, but we're also keeping our eye moving forward in looking to explore the use of advance computational toxicity tools. This title is applied to EDSP in the 21st century, as it is the impetus drawn from the NAS report that was published in 2007.

Here we're emphasizing the need to develop a more hypothesis-based approach, a more targeted testing strategy. Of course, the overall objective is to maximize our current knowledge base, using all existent information to do much more informed testing approach using a variety of tools, so thinking not only about the assays in terms of high throughput, but also looking at some inherent properties, as well as (inaudible), structure activity, as well as exploring the use of read across that we have today.

We're doing this in a very systematic and very incremental way, as I'll demonstrate to you a little bit later. Anchorage to all of this is the need to really understand the biological significance and the biological plausibility in terms of the toxicity pathways that we're interested in exploring.

This particular slide demonstrates the needs not only look at toxicity pathways but also consider mode of action and adverse outcome pathways as we link together not only the molecular initiating events but also exploring individual effects in going out to the population and community level. Again, this really demonstrates the need to increase our confidence as we move forward, making sure that the tools we use tomorrow are anchored by what we know today.

That particular confidence is reflected in the EDSP 21 work plan. As Karen indicated, that was published in September of 2011. There we reflect on three particular phases, which are kind of better illustrated in this slide. We talked about the phases in terms of how do we build confidence with moving forward on computational tox tools and moving away from the tier

one assays, if you will. It demonstrates that in three particular phases.

The first phase is use of high throughput technologies and again looking at other tools to help us begin to prioritize the universe of chemicals that EDSP is required to screen and test for. By doing so, we're building conscience as we move forward and establishing that level of conscience needed to move forward into the next phase, the second phase, which is the screening phase. That is to explore the use of toxicity computational tools to replace the current in vitro studies as part of our tier one battery of assays.

Then, the third phase, which is a long-term phase, is to ultimately do data replacement. As we move forward, we're thinking about things like uncertainties. What are the levels of uncertainty that are tolerated as you move through each of these three phases? Again, to try to build confidence.

Front and center, we're focusing right now on use of these high throughput assays and tools to begin to prioritize our chemical universe. Things that we're considering quite heavily are multiple tools. As we just

talked about, we're going to consider factors like exposure and exposure scenarios that are important as we begin to rank these particular chemicals. We're looking at the estrogen, androgen, and thyroid pathways and looking to the high throughput assays to anchor those key events that we understand and we know from the understanding of toxicity pathways.

We're again looking at the inherent chemical properties and QSAR with respect to structure activity and what we know about the receptor and what binds to that receptor to initiate activation and proceeding forward through the toxicity pathway. We're looking to the ER expert system for information, as that's been brought to the SAP and has gone through OECD reviews.

Information on structurally similar analogs help us in terms of read-across. So, we're going to bring that to bear, along with again an understanding of the biological mechanisms that we understand to interact with our endocrine system, our endocrine receptors.

Overall, the program is looking forward to making sure that we understand how we're utilizing these tools. Do we understand the clarity in which we choose

to use these tools to achieve our programmatic goal? We need to define the application and regulatory decision context that we're making. Are we using this for prioritization or are we using this for screening? Then, how do we think about these as we think about long-term data replacement?

But, all along that way, we need to build transparency, making sure we reach out to our experts, to our expert panels, for input, as well as our public at large in terms of public outreach, making sure that we engage with the public all along the way, insuring that we use scientifically valid and sound science as we move forward.

With that, I'll close and open it up for any questions.

MR. BRADBURY: Allison and then Kristie.

MS. STARMANN: With respect to list two, when is EPA going to be responding to comments and submitting an ICR?

MS. MANIBUSAN: I think there's a number of steps that we have to consider and that we're busy doing. From the November 2010 issuance of the proposed second

list of chemicals, we've been busy looking and compiling all of the public comments. We've received approximately 600 unique comments that range quite broadly from scientific issues to exposure issues and considerations of what should and should not be on the list, in addition to some regulatory consideration.

So, there's a lot of work ahead of us. There's also building the policies and procedures piece that goes along with that package in thinking about moving forward on the ICR.

MS. STARMANN: So, is there a when in there?

MS. MANIBUSAN: I think there's a lot of steps that we need to consider. It's very difficult right now to put a particular date on when. We're shooting for as quick as possible, but we're moving as quick as possible in terms of responding to the public comments. Some of those comments require really detailed analyses, as you can imagine. So, we're working very hard on that, in addition to thinking about policies and procedures that go along with list two.

The second list is different from list one in that it not only includes pesticide active ingredients,

but also broadening that range to be inclusive of the Safe Drinking Water Act chemicals and chemicals that really don't have a rich database. So, that's something that we're considering quite heavily.

We're targeting for some time in 2013, but we're not definite and that's no promise that we're going to meet that deadline, because there's a lot of steps in between. There's a lot of processes that we need to consider and areas of review that are outside of the agency, quite frankly.

MR. BRADBURY: Kristie and then Cheryl.

MS. SULLIVAN: Thank you, Karen and Mary for the update. First, I want to say that I really was pleased to come back from maternity leave and see the EDSP 21 plan. I think it makes a lot of sense to move in this direction because if we're ever going to get a handle on endocrinative compounds and where the universe is, it has to be faster and smarter.

But I do have a question about -- this is probably for Karen -- on list one. You said that the DERs will be released when you conduct weight of evidence on the data that you get in to determine whether tier two

tests are needed. Is that right? So, what is that process going to look like, do you know? Are there going to be any comments or drafts or how is that going to work?

MS. WHITBY: Well, we'll start out by doing primary review of each of the assays or each of the studies. As I said, we're going to receive, I think, approximately 500 studies across the 52 or 53 chemicals. What we wanted to do to kick this off is to make sure that as we move through the data and start to make some preliminary decisions, that we're being consistent in our interpretation of the findings that we come upon.

So, we were going to, let's say, for the amphibian metamorphosis assay, for example, look at 10 chemicals and compare the various endpoints that are measured and make sure that we're consistent in our interpretation of the findings. But we were going to do that for all 11 of the assays for consistency first.

Then we were going to evaluate the chemicals across the 11 assays for each of the 52 chemicals. Some of the test order recipients have indicated that they plan to submit their own weight of evidence guidance on

how they interpret the findings. We would like to take that into consideration as well as we begin to develop our weight of evidence.

So, it's not something that we're rushing to judgment on. No, I was not planning on releasing any draft weight of evidence documents at this time.

MR. BRADBURY: Part of the process we'll go through, and we indicated that back in 2005 or 2007 with the policies and procedures with list one is using the Scientific Advisory Panel for some advice on some of the steps that Karen described in terms of assay performance, battery performance, how to use our draft weight of evidence guidance.

So, part of the idea of going final, if you will, is taking advantage of input from the SAP to make sure we've sort of got it -- we've tackled it in a reasonable fashion before we finalize a decision, some important steps of peer review, both internal and external, as we go forward.

MS. SULLIVAN: Real quick. So, that's all good and that's actually a piece I wasn't even thinking about. But what I was trying to get out was proposing the tier

two assays and how that will work.

MS. WHITBY: Well, the tier two is still under development and validation. I'll let Mary speak to the status of that.

MS. MANIBUSAN: Maybe I can take a step back and talk you through the review process and how it might look like. As Karen had articulated, the review of the tier one assays will be probably no different than how we look at all of our studies in terms of doing a primary review, a secondary review, and a tertiary review. The tertiary review is to ensure that we're consistently looking across all the assays consistently.

But, in a weight-of-evidence approach, we'll be not only considering the tier one assay results, but we will be bringing in knowledge that we have from our 158 studies. We'll be bringing in knowledge that we have through our other scientifically relevant information, all bringing to bear our characterization of that particular chemical, again, that characterization on its potential to interact with the endocrine system, not that it will.

So, it's not automatic that just because we

have a weight of evidence that indicates some concern, that we'll jump right into the tier two testing. When we think about the tier two testing, again, the distinction is that these tier two testing designs are definitive studies. They're not considered a battery. They're not considered screening level assays. So, it won't be that we will require all of the tier two assays to be targeted in our decision, but it will be made from a judgment based on the entirety of our knowledge base.

Is that helpful to answer your question?

MS. SULLIVAN: Yes, thank you.

MR. BRADBURY: Cheryl and then Mark.

DR. CLEVELAND: So, I hope that when you were saying that you were looking to get some guidance together, that that includes -- for the tier two to pause and get some guidance together before you issue the list two -- that that guidance and programming that you're referring to also includes an update from the lessons learned in the first round of testing. So, that would be encouraged.

I guess I'm still with Kristie a little bit to understand what the timing is for the communication of

the tier two tests. Is it implicit in what you said that you're going to wait for the full weight of evidence analysis for the whole list before you would go through and issue for the tier two tests or are they going to come kind of piecemeal?

I didn't get that out very well, but I have a follow up once I get that answer.

MS. WHITBY: As Steve had indicated, we will certainly make use of peer review as we go through the tier one data, develop the weight of evidence documents looking at the potential of the chemicals to interact. Right now we've been talking about taking certain taste studies, if you will, to the FAC and looking at them in terms of how we've applied our weight of evidence guidance documents to particular chemicals, looking for some examples that we might consider to be positive, that we would consider to be negative, and some that are somewhere in the middle that we would believe to be equivocal.

I would imagine that along with that, ideally, we would want to be able to say that if we think that this chemical is positive and shows potential to interact

with either the estrogen, androgen, or thyroid pathway, that we would then go on to say based on these findings, we would think that tier tests one, two, three, or some combination thereof would be required or needed to answer any outstanding questions about that potential to interact.

These data from tier two would then help to inform whether or not a risk assessment would be required or whether there would be an endocrine sensitive endpoint that would be appropriate for risk assessment.

DR. CLEVELAND: Well, my follow up would be that we're all interested in the timing and all this. I'm hearing you're not ready to commit to that, and that's okay. But I would like to mention that if and when you do get ready to issue a true tier two test, the management and the communication, that this is follow up testing not the new endocrine disruptor test. It's really important.

I'm sure you understand, and we've already stated that it's only follow up testing. But these types of lists can get circulated in an instant in a global world. There's other agencies that aren't as involved in

this whole process that could all of a sudden look at this new post and say, oh, that's an endocrine disruptor.

I would just encourage you that if it does come out in one bulk or even if it comes out piecemeal, to think through how to manage that as you go through that next level.

MS. MANIBUSAN: I really appreciate that sensitivity. We've heard that request from multiple stakeholders. I think the message that you should receive today is that the agency is looking to be systematic in our review. We're looking to take our time and do this right and be consistent about our approach.

We plan to check in with our external independent peer review panels to make sure that what we're doing in terms of looking at the assays by assays and, as Karen has indicated, how we're looking to approach the weight of evidence makes sense and that it's scientifically based.

At the end of the day, again, we are not looking to call a chemical an endocrine disruptor based on tier one assay results. We've been very clear about that. Even as we move forward, as we make decisions to

go forward with tier two testing, again, that would not be the message that the agency would be putting out, far from it.

As we look to explore and utilize all of the weight of evidence, we're being very careful to make sure that there aren't intermediate studies that could be done to address some of the uncertainties. So, again, it's not automatic that a chemical moves from tier one to tier two. We're going to take our time, do this right.

As Dr. Bradbury indicated, we've agreed to go forward to the SAP with some case studies to demonstrate how the agency plans to make its decision and characterize the totality of the weight of evidence that's in front of us.

MS. WHITBY: The only thing I would add to that, sorry, is again, that we would not be releasing the DERs independently without some context within which to consider the findings, which is why the DERs aren't being released independently but would be released with the weight of evidence document that brings you to the conclusion and explains what the next steps for the chemical would be.

MR. BRADBURY: Mark and then Caroline.

MARK: My question really is a little more theoretical in a sense. It deals with risk, certainty and uncertainty in risk. I know that you're very sensitive in a chemist or toxicologist mode when you describe how you'll know when you're there.

I'm backing up a little bit and thinking more in a system science approach. That is, a system science approach would basically ask the question, when are we going to see an alpha error or a beta error? So, an alpha error is that plausibility of an expected error, a beta error being the plausibility of an unexpected error.

If you work within a system where you're looking at partial features of cells, specific binding, coefficient, et cetera, and you do 500 studies with 52 chemicals, when you look at permutations of that, really, the statistical probability is pretty high that you would run into a type two error or a beta error, an unexpected plausibility at some point in the system.

So, I'm wondering if you're going to have to revert at some point to some in vivo testing even in the midst of your in vitro system that you're developing?

MS. MANIBUSAN: I think as we approach the EDSP 21 work plan, that's precisely how we're proceeding forward. It's in thinking about replacement of studies for in vitro assays first and then exploring the targeted need for additional in vivo studies. So, again, it's bringing to bear our knowledge of the adverse outcome pathways and making sure that we anchor it with the biological understanding that gives it that level of confidence to move forward. I'll stop there.

MR. BRADBURY: Caroline, Dave, and Susan, and then we'll move on to the next one.

MS. COX: My question was also about EDSP 21. So, I just wanted to make sure that I understood that flow chart correctly. Is the goal that within five years, the tier one screening assays would be replaced by tox 21 type assays?

MS. MANIBUSAN: So, just to clarify, the work plan is just that; it's a plan that we had foreseen in terms of how to approach this. But I think the message here is that the three phases are meant to demonstrate the increasing level of confidence as we move forward. So, making sure that we're doing this in an incremental

step-wise fashion.

So, I don't think I would pay a lot of attention to the dates in terms of the two years, two to five years, or five plus years. It's making those incremental steps forward and making sure that we're anchoring it with good science, sound science, and making sure that we have appropriate evaluations and a public process as we move forward.

But it's that incremental movement from prioritization, use of these tools to demonstrate prioritization, before you move into data replacement for just in vitro studies. Then you begin to even explore the use of high throughput and other computational tools for data replacement.

But, all along that way again, it's important to make sure that we're anchoring it with good science. The issue of validation is really key because validation is different for each of those steps. So, that's the challenge that we have in front of us in terms of how to use computational toxicology. The work plan is meant to just illustrate how do you begin walking through those phases.

MR. BRADBURY: Dave and then Susan.

MR. TAMAYO: I was curious as to where the data that comes from these studies is going to live and how accessible it will be. Is there a plan for that?

MS. MANIBUSAN: So, as Karen had indicated, we do not plan to issue the DERs or summary information publicly before we finalize all of our weight of evidence and characterizations of the data. But in terms of a database, we are in discussions about different forms of databases that we can make publicly available. It's something that we're still developing.

MR. TAMAYO: I don't know what a DER is.

MS. MANIBUSAN: It's a data evaluation record. It's an evaluation of each study done by the evaluator, the risk assessor.

MS. WHITBY: A DER is a summary of the study that's provided by or generated typically by the agency where we lay out test materials, materials and methods, the results, the conclusions that were drawn based on the study. It's a review of the actual study that's submitted by an industry.

MR. TAMAYO: I understand that maybe you don't

know exactly when and how it's going to be done, but I just encourage that the storage of this data is done in a way that maximizes its accessibility and also the (inaudible) to other investigators. Obviously, it's going to be a very rich source of data that people can do work on that you won't be able to do for your purposes but will be useful in a lot of other ways. Thanks.

MS. WHITBY: I would just add a caution to that, that the battery was designed to be a battery. No one study was meant to be taken in isolation to draw any conclusions about the potential of a chemical to interact.

MR. BRADBURY: Thanks.

Susan, and then we'll move on to the next section.

SUSAN: Two comments. I would just hope that the prioritization would also include a review of the literature that actually shows endocrine disruptors. It's not in here as the initial of why it would end up on the chemicals of regulatory interest list in the first place.

MS. MANIBUSAN: I think it's captured in the

read across as you look at structurally similar compounds and information that you have in front of you.

SUSAN: But if you guys are thinking about it, that's great.

MS. MANIBUSAN: There's a lot in the literature on these chemicals.

MS. WHITBY: Right. The guidance document that's on the web for how we will use the EDSP data for weighted evidence does address these with literature.

SUSAN: Okay, great. I guess I had a question regarding the comment that you weren't going to use the tier one study if you automatically assign an endocrine disruptor label to a chemical, but you are going to use the tier one studies to kick them out as not endocrine disruptors. Is that correct? So, from your flow chart, these go weight of evidence to the weight of evidence negative; therefore, they're out of the process. Is that correct?

MS. MANIBUSAN: So, the prioritization use of high throughput is meant to just prioritize what goes through the tier one assay battery first or in what order, not to rule out chemicals.

SUSAN: Different question. Prioritization was one. You made a comment that you're not going to call a chemical endocrine disruptors based on tier one results, but you're going to call them not endocrine disruptors based on tier one results, right? You trust those tests enough to tell you that it's not an endocrine disruptor but not to tell you that it is an endocrine disruptor?

MS. WHITBY: The tier one studies were designed to be sensitive enough to detect things that would be weak possible endocrine disruptors, yes. So, if it comes out negative and clean, then yes, we do have confidence that it is not an endocrine disruptor.

SUSAN: Thank you.

MR. BRADBURY: Okay, thanks, Mary and Karen.

So, we're going to move over to the next session, section 5, which will be a series of brief updates on about four or five topics. Then we've set aside some time to hopefully just have an open mic, if you will, if there's some specific topics you'd like to get some feedback on.

So, the first topic or presentation discussion is from the PPDC public health workgroup. Susan Jennings

is going to give us an update.

MS. JENNINGS: I'm going to provide a brief update today on the public health working group and what we've been doing. As most of you probably recall, this was established as an ongoing workgroup. As such, we have outputs from time to time. Right now, we're working on just looking at different issues that have been ongoing and trying to establish some sort of a framework and a structure for moving forward in the future.

Yesterday, we had an interesting meeting where initially we discussed with -- we had a representative from CDC on the line who covered a project that they have ongoing out there to combat Rocky Mountain spotted fever in Arizona. EPA had worked with them to expedite a registration faster than PRIA time so that they have that on time for April. Well, she came in and talked with the workgroup a little bit about what she was doing. We talked a little bit about the expedited process for public health pesticides when the need is urgent.

We also had an update from Kevin Sweeney (phonetic) of our registration division on the recent SAP on bed bug efficacy guidelines and revising them and

looking at them to be a little bit more specific towards the control of bed bugs so that we can have a little bit more detailed information about the efficacy of those products.

We also had an update from Carl Malmadrome (phonetic) from the IR-4 program who discussed a project that he has ongoing for the public health inventory. In his project, he's trying to go through and inventory the pesticides that are used against pests of public health significance.

His goal with that is so that we can have a better idea of exactly what is out there so that when we talk about our tool box, we'll know more about exactly what is inside that toolbox and perhaps have a way of identifying areas where we could use a little bit of growth.

We also joined the comparative safety statements or pesticide products labeling workgroup to discuss the repellant mark program, which you're going to hear about in a little bit.

Then, the last item we discussed yesterday was a very open discussion on 25 bee products and bed bug

control and some of the issues with those products trying to more or less brainstorm ways we can move forward and try to help people who are trying to combat bed bugs to be able to get efficacious products.

That's really the update that I have for right now. I don't know if there are any questions.

MR. BRADBURY: Questions, clarifications, or anybody else on the workgroup that has anything else to add?

(Whereupon, there was no verbal response.)

MR. BRADBURY: Okay, thank you, Susan.

Marty Monell is going to give an update from the workgroup on comparative safety claim statements.

MS. MONELL: You may remember about three years ago PPDC asked the agency to form a workgroup under the auspices of the PPDC to look at comparative safety claims, green claims, and things of that nature that would be responsive to what was perceived to be consumer interest in all things green, all products green.

So, there was some consumer perspective articulated. Clearly, the marketers in the registrant

community wanted to respond to the consumer interest. For the agency, if there was a way for us to assist in driving the market towards safer chemicals, then that would be a good thing as well.

So, we started the workgroup. You'll recall all of the machinations that we went through to ultimately get here with a recommendation that we proceed with two pilots, one of which would enable a pesticide product label to have a DFE logo on it.

The DFE is a design for the environment program run by our sister organization which does a different type of review than a FIFRA review for product safety. It is essentially a hazard screen, but it's designed to encourage safer chemicals on the market.

So, we have a pilot going where the pesticide product that's interested in obtaining this logo goes through the DFE screen and then some sort of a certification process. They bring that certification to, right now, the antimicrobials division with an application for an amendment to a product or just an amendment to a product's label to enable the placement of this logo on the label. To date, we have five products

that have obtained the DFE logo. Three of them are lactic acids. The active ingredient is lactate acid. Two are a citric acid.

The other pilot that we embarked upon is one to allow factual statements on product labels. What we agreed to was statements that could be factually ascertained. So, things like dye free and fragrance free were permitted to be put forth for inclusion in this pilot. In that area, we have 10 product labels, five each, five dye free and five fragrance free.

We also added in corporate commitment. What this means is that a registrant can come in with an application to put a web site reference on a product label that indicates that if you are interested in the corporate commitment to environmental and health matters pertaining to the product, go to X, Y, Z web page.

We have three of those kinds of factual statements that have been approved. Keep in mind that when you do this, the whole label that's on the web then becomes -- that statement becomes part of the label. So, it's not something to enter into lightly.

Last year, we expanded the factual statement

pilot to include determinations of biodegradability. We wrestled with this one for quite some time. There is guidance on the antimicrobial division's web site as to how and what sort of screening process you have to go through to be able to put a statement about the biodegradability status of your product, the entire product, which means all of the ingredients, or the biodegradability of the surfactant in your product. That, for us, is pretty easy to check because the DFE program has a list of biodegradable surfactants. So, we have two applications pending for the surfactant biodegradability claim.

Yesterday, at our workgroup meeting, we brought up the issue of allowing the use of the term botanical. This came to our attention because we realized that our registering divisions were in some instances all over the map. Biological pesticides, some more prone towards just allowing that because they have plant derived products many times.

So, they have allowed the use of the term botanical. It's also come up in a couple of other instances. It's not addressed at all. The issue is not

addressed in a label review manual. PR notice 9810 does address it, but it's in a very outdated fashion, I would venture to say.

So, the workgroup, we have decided that this is something that we want to look into further, perhaps incorporating it into another area that I'm going to talk about in a minute. But it's clearly something that we as a program want to clean up and have consistent advice through all the registrant communities, consistent standards so the public knows what it means.

It could very easily be conceived to be natural or safer or something like that. So, we want to just be careful how we proceed with it, but our intent is to come up with some proposed guidelines, guidance, internally and then bring it back to the workgroup and flesh it out for further communication.

Last time the farm bill was reauthorized, four years ago maybe, three or four years ago, there was a procurement provision in it to encourage the procurement by all federal agencies of bio-based products. A charge was given to USDA to set up a program whereby consumers and -- essentially, initially, it was geared towards the

federal government procuring officials that they would know which products had a certain percentage of bio-based products. It was an effort to wean us away from petroleum derived products and into more plant derived products.

This has become a very important issue in the federal procurement world because the procuring officials insist that upon certain standards and that you get this bio-based -- I think they refer to it as a certification mark. It's a logo, for all intents and purposes, but it is referred to officially as a certification mark.

So, in the pesticide world, we had a couple of registrants who were able to get their products through the bio-based program and receive the certification mark, which, essentially, indicates what the percentage is of plant derived products in its product within a certain sector, if you will. So, naturally, the registrants wanted to put it on their pesticide product labels.

This is our sister agency, this is something that congress wanted, this is something the president, subsequent to the passage of this provision of the farm bill, has issued at least two executive orders mandating

that USDA expand this program and that all agencies really pay attention and run our procurement by this program. So, this is not inconsequential matter for us to consider. Our concern is that it is a single aspect program. It's only looking at the derivative of the ingredient. It's not looking at the health or environmental or other safety kinds of data and issues.

So, we wanted to be very, very clear that if we allow this mark to be on a pesticide label, that there is some disclaimer language; in other words, a couple of sentences, in fact, that have been crafted by OGC that makes it very clear of exactly what this mark means, instructing the user to read the instructions carefully, and then it refers the user to the bio-preferred web site of USDA so that the consumer hopefully will go through those steps and realize exactly what it is, what the mark means, as opposed to making assumptions.

We think that this approach is legally sustainable and appropriate. Our next step is going to be to bring it to our states, the SFYREG, at the end of the May or early June and get some feedback from them. They clearly will have an interest in our doing this

because the state labels are as important as our labels in terms of the real world. So, that's the next step. As I say, the workgroup is generally in support of it, but I would say with some reservations because of the single aspect nature of the certification mark.

Finally, we talked about -- this was Kristie's recommendation to us, suggestion to us -- a way to perhaps incentivize less use of animal testing in the development of pesticide products that we allow statements as to the lack of or reduced nature of or something about the lack of animal testing in a particular product, to have a factual statement be allowed on a pesticide product label to that effect.

As you can imagine, this is not an easy task. It's very difficult to get your arms around the implications of that. Like, what about the ME2 community? We have a huge business practice, if you will, around ME2. Well, they don't do animal testing, but they're relying on someone else's product that did do animal testing.

So, the workgroup broadly supports this idea, the whole concept of it, but everybody recognizes there's

a lot more work to be done. We have to develop criteria. We have to develop the statements that could be used. Then, of course, the ideal would be to give some examples of situations that would warrant such an approach.

We noted that the EU is active in this area, XVAM (phonetic). It sort of has taken a larger leap than we have thus far, so we hope to learn from their experience and move forward.

Any questions?

UNIDENTIFIED MALE: Marty, are there any chemicals now outside of this ME2 that don't require animal testing?

MS. MONELL: We actually tried to think of one and even with a -- one was suggested by a participant on the phone that a simoil (phonetic) based product might not have used animals in testing of its development. Then, we took it a step backwards and I think in the manufacturing product sense, there was animal testing. So, I haven't heard of a product yet that has not had it.

UNIDENTIFIED MALE: Is that 25B, the simoil? Is it a 25B product?

MS. MONELL: No, no. This is an antimicrobial

botanically derived.

MR. BRADBURY: Maria.

MR. McALLISTER: I think I missed something in your explanation.

MR. BRADBURY: Sorry, Ray. Maria, Allison, and then Ray.

MS. HERRERO: I had a question because the pilot that you have going on the design for the environment has been limited up to this time on antimicrobials. There was some talk at one point of bringing in biopesticides.

MS. MONELL: Absolutely. I'm sorry, I overlooked that in my haste to make up time. Yes, we very much want to -- from the get go, it was always envisioned that we would not exclude products. We were trying to focus on a certain subset of consumer products in the antimicrobial world. But we have received interest from the biopesticide industry. CPDA has folks that are very interested in it. We are very interested in pursuing this.

Many of the biopesticides are living organisms with very low toxicity, so they would sort of lend

themselves to this kind of a program. Mike McDavit, on behalf of PPDC, is exploring it further with the DFE program to see how it would go through their screen.

MS. HERRERO: So, if you started a pilot, you would make that --

MS. MONELL: We would just include biopesticides in the pilot. The only thing we need to do now is to make sure that the screen that DFE now employs for what they're using for the antimicrobials is appropriate for the biologicals.

MR. BRADBURY: Allison and then Ray.

MS. STARMANN: I just want to thank you and the workgroup for showing the flexibility and for showing the dedication of trying to take these pilots. I think there's potentially a lot of value here. I think you were starting to touch on the DSE and exploring other active ingredients that might be able to be subject to it with the antimicrobials, the stalastic acid and the citric acid that has been able to go through that. Is there a consideration of expanding the universe of actives?

MS. MONELL: There actually is. The scientists

from the antimicrobial division have been working with the DFE program. They've identified some actives that they think might be appropriate. We're pretty adamant that it be only tox category three and four that would be eligible, so they've come up with some active ingredients that would fit that and other parts of the profile that they think that it might be appropriate for the screen.

We haven't come upon any yet, but we had a discussion yesterday about peroxide. Peroxide would pass through the DFE screen, but it wouldn't pass muster with the antimicrobial division because of its concentrated form. So, we think there's a way of working around that because many of the peroxide products may lend themselves to the DFE pilot.

So, we're trying to be flexible. We're trying to be more inclusive. I mean, the idea is to give an edge to safer chemistry.

MR. BRADBURY: Ray.

MR. McALLISTER: I think I missed part of your explanation about a product for which animal testing might not have been done directly but it cites testing for another product.

MS. MONELL: Right. So, ME2 comes in. Do you know what a ME2 is?

MR. McALLISTER: Yeah.

MS. MONELL: Okay. So, it comes in. It doesn't bring data with it. It relies on data that's been created by another product.

MR. McALLISTER: That would not qualify here.

MS. MONELL: Well, it would be a problem. I mean, technically speaking, there was no animal testing done, but is it fair to give them the edge when in fact the original product was very much involved with animal testing?

MR. McALLISTER: Yeah, I would think you should restrict any such recognition or designation to a product that does not depend on animal testing.

MS. MONELL: That's exactly what we're wrestling with. But, as I said, we have yet to identify one that has not had any. So, there's work to be done.

MR. BRADBURY: Okay, thanks, Marty.

We'll now move to kind of a related topic with Rose talking a little bit about insect repellency mark.

MS. KYPRIANOU: My name is Rose Kyprianou and

I'm with the Field and External Affairs Division of OPP. It's not really an update but more of an introduction to our insect repellency mark voluntary program that we have under development.

So, starting off with a question, how many know how to choose what kind of sunscreen you guys use? How many of you look at the SPF to choose that sunscreen? So, basically, the SPF is telling you how protective it is. It's right on the front of the label.

Now, how do you choose your insect repellent? How do you know how protective it is? Anybody want to read the fine print here? Well, currently, EPA allows this kind of information mostly in the fine print on the back of the label. So, what we're here today to talk about is that we think we can do better with this. Consumers are asking us to highlight information better.

So, we want to make this key public health information more prominent on the label of the skin-applied insect repellents by creating this mark that would be recognized in a way that is very similar to the way the SPF is recognized for sunscreen products.

So, today is more of an introduction than

anything else. We just want to let you know what we're developing and that we also may want to come back to one of the PPDC workgroups to ask for advice in specific areas.

We really feel there's an opportunity to provide consumers with better presentation of certain information on skin-applied insect repellent products, and we would like to create a mark that protects consumers from vector-borne diseases, in the same way that SPF number helps protect a person from the sun.

EPA has done some consumer research in this area in the past. Just to let you know, a couple of years ago we did a number of focus groups surrounding the insect repellent products. Last year, we conducted an on-line national consumer survey, which about 3,000 people responded to. The purpose was to better understand the behaviors and needs of consumers and also their understanding and preferences for various graphics that would represent efficacy of an insect repellent product against mosquitos or ticks.

We recently made these survey results available online. The URL is at the bottom of this presentation.

There's also a one-pager handout that we gave out that has that URL listed. So, you can get the majority of the results from that survey online.

But, one thing that really stood out is the slide that I put up here where we asked consumers what they look for on labels. There's really four answers that rose above all the rest. Two of those, the active ingredients and the safety warnings, we already have those clearly listed on the label. But, the other two answers, the type of insect repelled and the number of hours protected, this information is what would make up the mark.

So, what exactly is this insect repellency mark? It is an efficacy mark that could be used on the front of the label of an insect repellent, a skin-applied insect repellent. The mark will clearly relay standardized information about protection time for pests. The focus is on mosquitos and ticks since these are the pests that carry the vector-borne disease. There's two examples at the bottom of that slide there. These were two marks that were tested out in the survey, and those are the ones that ranked the highest. We'd be doing

something similar to this.

The basic approach we want to take with this is to make it a voluntary program so it will be applicant driven. EPA will control and approve the use of the graphic. Companies would apply to EPA to use the mark with the application they would submit or site specific data and also include any pertinent analysis of that data in their application. All skin-applied insect repellents will be eligible for this program whether they're registered or not.

OPP is also developing guiding criteria that will help people and their submissions for the application and also so that the mark will represent a very high standard backed up by good solid efficacy data. We're planning to let the public see a draft of this criteria that we're developing when we do an information collection request that we're planning to put out late in the summer.

We hope to launch the program at the beginning of 2013. We anticipate that we then see products in the 2014 marketing season.

So, to conclude, the mark has the potential to

improve public health protection. We're relaying information about protecting oneself against pests that may carry vector-borne disease. Research has shown that this really is important to consumers, and that this mark will represent a standard graphic that will meet the consumer demand to clearly inform them of the pests repelled and the duration. We also think that this may benefit companies in marketing their products. We're looking for feedback, if that's the case.

We also introduced this program to the PPDC workgroups yesterday, the comparative safety statements and public health workgroups. As I said before, we may work with them over the next couple months to get further input in specific areas. Thank you.

MR. BRADBURY: Open it up for some questions. Steve and then Dave and then -- okay, I'll go around. Steve, go ahead.

MR. SMITH: Looking at the cards, I'll try to be brief. First of all, NCJ supports any measures that clarify labels for consumers. We submitted a number of comments back in April on this program and had some basic concerns with the data behind --

UNIDENTIFIED MALE: Could you ask him to speak up? Could you move your microphone a little bit closer? I couldn't hear you.

MR. SMITH: So, we had submitted a number of comments in April on this program with some primary concerns on the data behind the duration claims, most of them based on field studies, and the variability of field studies is significant.

Looking at PPLS and NPEARS (phonetic), we see, just by means of example, products with 30 percent Deet with claims from one hour to eight hours and products ranging from 15 percent to 40 percent with an eight hour claim. So, the basis for comparison here I think is a little bit flawed.

I don't know if we need to agree on a standard test, arm and cage test in a laboratory or something. We support the idea, but we think the data behind it is a little lacking. So, with that, we'd welcome the change to talk at upcoming meetings.

MR. BRADBURY: Dave. I'm just going to do my best.

MR. TAMAYO: I'm going to go under the

assumption that you're going -- with input from the public, that you're going to be able to get a meaningful battery of data that's going to support these claims. I'm going to speak from the perspective of being on the mosquito control district board. I think this is a very useful tool for mosquito control districts that are trying to promote the use of a wide variety of insect repellants. It's really hard to communicate that to our constituents. So, I think this will be a really useful tool. Joe might have a different opinion, but it seems to me that if it looks like it's a good job, that industry-wide it will be very helpful.

Then, finally, I think it would be also very helpful to have -- once it's settled -- by the way, I really like the look. It's really easy to understand. But I also understand that the data is going to not really reflect the variability.

I don't expect the label to reflect that, but it would be very helpful if there was sort of a concise statement about the limits of that and really sort of saying that this is really kind of an index and people need to understand that there will be individual and site

specific variation, but somewhere like on a web site that's easily accessible to the public so that mosquito districts can help share that information as well.

MR. BRADBURY: Susan.

SUSAN: This was the first I'd heard of it honestly, so I would echo the points already made about variability across the region. My first thought, though, is a little bit different. This is kind of completely different than basically tanning lotion and your SPF. There's a single function of that, so the number is the number and you don't mix and match. I want 15 but I really want 25 so I'll take a 15 and a 10. That doesn't make much difference.

But, I guess as a consumer, I'd look at that and go great, I want six hours of protection from the one thing, but I also want six hours from another. So, does it make you start using a whole bunch of different things at once to get seven hours for everything? I mean, it's kind of like it sets up all these products that are very different, but I want seven hours coverage for ticks and I want seven hours of coverage for mosquitos, so I'm going to have to use this product and this product at the

same time or every two hours put it on if I want more tick control.

So, I think it's great as just general information, but when you think about there being two different numbers on here for two or three different pesticides, that means you've got to buy several products possibly and put them all on at the same time. I guess my first instinct is is that a good thing?

MR. BRADBURY: Ray.

MR. McALLISTER: I think I heard that if this program proceeds, it would be available for use on the products whether or not they are registered? Is that what I heard?

MS. KYPRIANOU: Yes, that's correct.

MR. McALLISTER: Well, we're talking here about public health pesticides. I thought there was some controversy about 25B products, whether or not they have to be registered if they made insect repellency claims. Has that been resolved?

MS. KYPRIANOU: Under this program, a 25B product would have to apply just like a registered product and survive the same sort of data and analysis.

So, they would have to meet the same standard to get the mark.

MR. McALLISTER: Okay.

MS. KYPRIANOU: Did that help?

MR. BRADBURY: Robyn.

DR. GILDEN: With both the insect repellency mark and also the design for the environment, since they're both voluntary products, or voluntary, do you think that creates an unfair advantage for the people that actually get the designation? Is that implying EPA preference or acceptance certification of these particular products over ones that might be very effective and safer just because they chose not to apply?

MS. MONELL: The DFE program has been well established for quite some time. It's voluntary. It's not required that any chemical company put their product through that screening program. It's essentially an incentive program to drive the market. It's proven to be effective. The consumers are the ultimate beneficiaries of that thrive, if you will. I think that it will be the same case with the insect repellency.

I do think that it's worthwhile having more

discussion within the purview of one of the workgroups, and that will be up to you as to what group it should be in, public health or the statements group. But, personally, speaking as an official in the organization, I don't have a problem with it being voluntary. It's pretty well established.

MR. BRADBURY: Pieter.

MR. SHEEHAN: I would like to preface my comments first to say that I'm in county service now and have been in county service for my entire career, albeit five different counties and four different states from one side of the country to the other.

I've always been fascinated and, to be quite honest with you, in awe when I look at my federal and state partners and how they are tasked out duties and how they complete those tasks missing a tool that we at the local have that it appears to us that you don't. That is our ability to immediately impact the community and communicate with them directly.

When staff comes to me and asks me that they want to change some of the administrative or regulatory procedures that we have in the division, I always ask

three questions. One, are the changes community based? Are they integrated? Do they illuminate the validity of the agency in some fashion?

So, if the on-site sewage program wants to change something, we ask, how is it going to affect the engineers, the soil scientists, the people who are going to put the on-site sewage system in, the neighbors, et cetera. Then, how can we use staff in the entire division to put these changes in and make it easier for everyone to do their job? Finally, does it help the agency shine at all?

I am utterly amazed that this idea is the first time I've really seen the federal government be able to meet those three requirements. I've never seen it in my career. I think it is an amazing feat.

UNIDENTIFIED MALE: Could you repeat those remarks? I didn't hear them.

MR. McALLISTER: When I listened to Rose yesterday about this, I was dumbfounded that this could be done because it's so difficult for us at the local level to communicate to staff how important this is. Yes, there's going to be holes in it, but when we

communicate to the community, we need something, some kind of tool that comes from a higher agency so we can help people understand the process.

Something like this gets us at least closer to the dialogue of pesticides and personal use of pesticides. I think it's an absolutely amazing idea.

MR. BRADBURY: Matt and then Joe.

DR. KEIFER: I don't want to repeat, but I do want to compliment this idea. I think it's a great one. The one thing I'd add is that given the budget information we were given at the beginning of this meeting, CDC seems like a very appropriate partner to help you out with some of this and maybe carry some of the load. They're very interested in vector-borne disease. So, I think they'd be an absolutely natural partner in this process and probably be very interested.

MS. MONELL: It was someone from CDC on the phone yesterday during our workgroup meeting who was participating and has been involved, if not directly, certainly indirectly, and we'll certainly follow up on that. Thanks.

MR. BRADBURY: Joe and then Jimmy.

MR. CONLON: Well, as someone who answers questions about repellency for mosquitos on a daily basis, I can certainly understand the impetus for this particular program. I don't think there's any more staunch proponent of repellent use than I am, as part of an integrated pest management program.

Nonetheless, I would urge the agency to exercise extreme caution when putting, in essence, their imprimatur on a hard and fast number for the following reasons. All of us in here realize there is a wide range of attractancy to mosquitos by individuals, and it's based upon eccrine emanations, skin flora, histoplasmic complex issues, all kinds of things. That will affect the repellency of certain products.

Number two, there's 176 species of mosquitos in the United States. Although there's considerable overlap in their bionomics, there are some profound differences. Some are more repelled by repellents like Deet or others. Deet is our primary product that we use, but it's ineffective against anaphalis albuminous (phonetic), which is the primary vector of malaria in Central America. So, there is some issue there.

Thirdly, and probably most importantly, there's a lot of research being done now and it's come up with some startling facts that the viruses that affect us, Dinghy, West Nile, Lacash or Cash Valley, also affect the mosquitos because they've got to go through the brain of the mosquitos and the salivary glands to get to us. It affects their behavior. They have found that there are certain plant viruses that mosquitos will pick up that make them more aggressive.

There's some research now that's showing that the mosquitos get a little bit more aggressive when they've got, first of all, West Nile, being one, and Dinghy fever. So, the people we're trying to protect from disease may be getting a -- that may affect the repellency; it may not. We haven't gotten to that point yet.

I'm just saying that if you tell someone they're getting four hours of protection from certain repellent and they're in an area where West Nile virus is prevalent and the mosquitos are not as repelled as they should be, you're asking for a lawsuit. Just a caveat there.

MR. BRADBURY: Thanks.

Jimmy, Beth, and then Jeff.

DR. ROBERTS: So, this is partly an effect of being one of the last ones to talk. Since some others have already said it's a good program, I'm going to keep it a little bit briefer.

Like Stephen, I am a little concerned about some of the data reliability. There are a number of studies out that we'll look at, like the arm in the cage method, and it's a controlled application of the product. But then there's other data to look at where the person themselves applies the product themselves and may not have quite the same variability or may be more likely to reapply or apply in some of the places that they don't need to apply. So, there needs to be good care in looking at the right data and looking at variability in the way that some people apply it.

As a primary care pediatrician -- and some may be surprised to understand -- the American Academy of Pediatrics does recommend insect repellent use. We really try to emphasize the need for the concentration for the time they're outside. So, for that reason, the number of

hours on the label is of use. That's all I'm going to say.

MR. BRADBURY: Beth and then Jeff.

MS. LAW: I just wanted to say that CSPA obviously supports the idea of trying to improve labels and make them more readable, more easily comprehensible by the public. This may help move the mark, no pun intended. But I just want to echo the concerns that others have raised here, the concern of variability. Different registrants do different tests.

The duration of protection of the repellent I think can vary. It's not clear to me that any of those factors are actually reflected in the numbers on this mark. So, we just think much more work needs to be done here. We urge that we do that. Thank you.

MR. BRADBURY: Geoff and then Virginia.

DR. CALVERT: So, I also apply this effort to make these labels more simple and understandable. But there's some insect repellents that aren't recommended for children; for example, products that have high concentrations of Deet. Would you have anything incorporated into these symbols that would advise parents

that these are not recommended products for children?

UNIDENTIFIED MALE: Well, we could look at that. I mean, it's open for consideration how to sort of differentiate what the products are used for based on the kind of comments you made.

UNIDENTIFIED FEMALE: I would just echo that concern as well. Also, did you say that a lot of this information is already on the label in the fine print in terms of the hours of efficacy?

MS. KYPRIANOU: Maybe not the exact information that we would put on the mark. The mark would maybe put a definite four hours, but you might have the label read up to four hours, up to six hours, something like that. There's a lot of variability on what you see on different product labels right now.

UNIDENTIFIED MALE: The other thing, have people here seen the focus group video clips? I think at one point you made that available to people. But it's sort of like a picture is worth a thousand words. These are focus groups who ran around the country.

Back to the comment about the label and what not, people had a really hard time figuring out what that

label means. So, the visuals we have here were sort of the kind of things -- really, I think, as Rose mentioned, the types of insignias that were up were ones that the group actually helped produce.

So, people had a real hard time. As a regulator, I could look at that label and feel proud that they had the right information. But, when you heard the focus group people sort of say, what does this mean, it really hit home. So, think about some night you're talking to your neighbor across the fence and trying to explain kind of what this stuff is. Those are the types of questions they ask about these products.

One of the things we want to do is work with FDA, too, because they've been down this road with SPF 50. We're going to work with them to kind of hear the process that they went through to arrive at where they ended up.

UNIDENTIFIED MALE: So, along those same lines, I was curious if there is any labeling statements regarding maximum number of applications? I was looking at tick repellency. For six hours, I'd have to reapply two or three times. Is that exceeding the dose for Deet?

MS. KYPRIANOU: I don't know the answer to that, but we'll take a look at all of that.

UNIDENTIFIED MALE: When EPA evaluates an application for a new topically applied insect repellent, we do not only an assessment of the efficacy but also a safety assessment. We make very conservative assumptions. That is to say, we assume that the product will be reapplied frequently. We take into account how much the typical consumer might apply. So, we will only approve the registration part if based on that risk assessment frequent application looks as though it's going to be safe for the user.

MR. BRADBURY: I'm going to move on. Again, this is the beginning, not the end. So, maybe ideas that came up will feed into the workgroups. I think what I'd like to have is this effort work across both groups, both the public health group as well as the comparative statement group, because both of these things are coming into play.

I think another aspect that came out of the discussion, which we realize, is that no matter what's on the label, paragraphs and paragraphs and paragraphs, or a

picture, there is the data and the uncertainty in the data. That exists regardless of what the words say or what the picture looks like. So, we'll have to kind of work it on both fronts.

But I just wanted to clarify that whatever the picture looks like, it's still based on the same kinds of things we have to deal with in terms of the variability of the data. That's real and sort of how do you translate the inherent variability of those data, what the data means. We're facing that as a challenge right now. Now it's just described in a bunch of words on a label. So, this is the beginning. We'll be working through the workgroups to see how we might approach this.

We'll move on to the last topic in this session. We'll see if we have time for open mic or not. We'll have to kind of play it by ear. So, Bob is going to give you a summary of some of the rulemaking that's ongoing. The specifics that he's going to talk about reflects some of the requests we got from members of the panel. So, it's not everything that's going on, but it gives you a sense of some of the topics that people asked us questions about.

MR. McNALLY: Thanks, Steve. Steve mentioned that I'm relatively new to this group, so I'll tell you a little bit about me. I'm the new director in FEAD. So, I just want to give you a quick sense of who I am in terms of what's important to me. Now, I could bore you with my resume, but it's late in the day and people have things to do.

So, I wanted to start this conversation with, do people know what was the biggest event in Washington, D.C. last night? Anybody? The hockey game, right, the Caps. So, I thought I'd tell you a little bit about myself in terms of how I am as an employee and how I am as a parent, because I think those are two important considerations.

I want you to know, as a good civil servant -- and we've heard about civil servants in other parts of the government who perhaps have been doing things they shouldn't be. I went to bed at 10:00 last night because I knew we had an important meeting with the public this morning. I wanted to get a good night's sleep.

The Caps game was almost over. I figured, I'll go to bed, what's the big deal. I'll see the score in

the morning. Now, as a parent, my kid said to me, hey, dad, can we stay up and watch the game. I thought, what's the harm. It's the third period. There's eight minutes left. What the heck, let him watch it.

Does anybody know how long the game went? Yeah, 12:10. So, basically, I'm in bed trying to get a good night's sleep and all of a sudden I hear my kids yelling and screaming. I come out. What's going on? They said, oh, there was almost a goal. I went back to bed. It went on and on and on. So, basically, all of a sudden at midnight, 12;10, everything got quiet. So, I figured, I guess we lost. So, I want you to know my heart was in the right place trying to get a good night's sleep.

Mark mentioned earlier about his students sometimes fall asleep at 1:00 in the afternoon. Well, I haven't checked my phone messages yet, but I'm sure the guidance counselors are calling in saying why are the McNally children dozing off at 10:00.

So, a little bit on the rules. I just want to give you a quick snapshot of kind of the ones that are important based on your feedback. The first one is the

worker protection standard. Now, this is the one that we're updating.

So, there's already a worker protection standard out there. It's been out there for a couple of decades. This standard is designed to protect the one to two million ag workers in the country. These are the people who harvest, let's say, fruits and vegetables, those sorts of people. We have a separate rule dealing with the people who apply pesticides. That's a different rulemaking.

Now, what this proposal will do is cover things like training, the content of training. It will cover things like the frequency of training where there's any notification and posting type efforts that should be put into place to better inform workers in things like recordkeeping.

Now, how did we go about making changes to this rule? Well, groups like this and other groups over the past, I guess, two decades, we've gotten their input about they would make changes to this rule. So, where we are now is we're sort of finalizing the proposed rules provisions, and we're doing the economic analyses

associated with that in terms of the cost and the benefits. Our goal is to complete that in 2012. We have a companion rule, as I mentioned, on applicator training and certification. That's going on a similar time line.

Let's go to the next one, 25B. We had a little bit of discussion on this in the earlier session dealing with the repellents. Like good civil servants, instead of having one rule on 25B, we have two rules on 25B. The first rule is called the clarification rule. That's more of some process changes, you might say, in terms of considering whether we should provide common names, whether we should provide things like cast numbers, whether we should make the rule itself more transparent to really help folks out in the field do a better job understanding what is or isn't a 25B issue. So, this has been a big concern among other groups of our co-regulators in the states. This proposal should be coming out relatively soon.

Now, the second one is a little more substantive in nature. Again, we touched on it with the insect repellent. This is the 25B reconsideration issue. What this would do is require efficacy data as part of a

rulemaking for 25B insect repellent products. Again, you've hit on it here today due to concerns about things like Lyme disease, West Nile virus. Just like our focus group showed, people want to know is this stuff working and, if so, for how long.

Now, before we embark on that rulemaking, one of the steps we take is to see if our Science Advisory Panel wants to weigh in. They wanted to weigh in on this issue of efficacy data, both in this rule and in the companion rule called the product performance rule. So, they're both similar in intent in terms of the efficacy data for insect repellent issues.

At the moment, the possibility of that SAP is probably in the first half of fiscal year 2013. So, we'll probably have an SAP sometime between October and March 2013. So, where do we go after that, after we get the input. See if there are any issues that come up through that process that we need to, pardon the pun, reconsider, and then we'll move forward with both the product performance and with the 25B rule dealing with the same set of issues but on the 25B products. The efficacy requirements would probably be the same for

both.

Now, having said that, I know there's a lot of interest in this. I think the comment made earlier about what does this mean for 25B products with the voluntary program that Rose showed the different labels and what not on, certainly, anybody can apply for that mark if we have that program. So, 25B products could come in under that. So, that's the status of that.

The next one people had some questions on were inerts disclosure. I think we have some of this on the slides. As most of you know, we received two petitions on this subject a couple years ago. We published an advance notice of proposed rulemaking in 2010. We got a lot of comments. Over 400 comment were received and analyzed in 2011.

Due to sort of the complexity of the issues here, both legal and policy issues, things like CBI and what not, our office of policy here at EPA decided to elevate what we call the tiering of this potential rulemaking to require more formal higher level decisionmaking process within the agency because of the public interest, the number of comments, and the types of

issues this potential rulemaking raised.

What does that mean to you? It means there will be a more formal process, probably a somewhat lengthier process, and require a lot more coordination across the office. So, in terms of what we're doing in OPP in fiscal year '12, we are going to be framing the issues and establishing project goals to help move this process forward, both within OPP and across the agency itself.

The next one is 682 that we had some comments on in terms of where that stands. What this proposal would do is, as you see, revise and update the regulations governing the reporting of risk and adverse effects provided to OPP.

The two issues they are grappling with is electronic reporting and what we call non-aggregate reporting, which I think came up this morning on some of the B issues. As some of you know, we've established an eco-porthole at NPIC to try to get data in on eco incidents. So, those are the two areas that this rule would address, the electronic reporting and the non-aggregate reporting.

Our goal is to launch a voluntary effort this fall for anyone who is interested in participating to sort of do a dry run with some of these ideas to see how it works before we go full tilt with the proposal. We're interested in letting you know if any group is interested in participating in that, to contact us. Ann Overstreet (phonetic) here in OPP is honchoing that effort. If you need to reach her, let me know and I can give you her information.

Last, but not least, there was a request about the Spanish labeling petition that someone raised. So, some of the facts on that is that there was a petition in December 2009 that came in from several groups. In March of 2011, we published an FR notice soliciting comment on the request. The comment period closed last summer.

Again, we had a whole series of comments, over 200. Approximately 60 percent were in favor and 40 percent were not in favor. We had all sorts of comments from all sorts of different groups. The public and the private sector groups were saying Spanish labeling is a good idea so that workers who predominantly speak Spanish can understand the label. Also, other people were

saying, hey, not a good idea because it's costly, there's different dialects, and maybe folks can't necessarily read the label, even though they speak Spanish.

So, where we stand now is in office. We're analyzing the comments, like we've done on other petitions, and we're trying to see what the appropriate next steps would be to address the issues raised in the petition.

So, with that, let me stop and see if there's any questions people might have.

MR. BRADBURY: Virginia.

MS. RUIZ: Could you be a little more specific about the WPS time line? The last information we had was it would be mid to late 2012. Maybe just a little bit more about the types of analyses that you're still doing?

MR. McNALLY: Sure. The time line is not too much different than that. Those are estimates. There's a whole series of things we have to do within the agency and then ultimately outside the agency. What we're doing now is like you do with any rulemaking, looking at the provisions that we are considering and then examining what the costs are associated with those provisions. So,

that's one of the steps that we're dealing with currently.

MR. BRADBURY: Susan and then -- Susan, go ahead.

SUSAN: Again, two questions. One, the worker protection standard update, can you, in just a few sentences, describe what the changes are that are being considered?

MR. McNALLY: I can't because we're at that point now that we're finalizing it. When we put it out, obviously, it will be available for comment. But there's general areas I talked about. Again, we had a very robust stakeholder process where people gave us comments based on their experience, saying, hey, maybe training needs to be more frequent than it is currently, or maybe the material has to be enhanced to include material covering safety for family members, because we find, based over the last decade or two, sometimes workers bring home their clothes, and their family members could be adversely affected.

So, those are the types of issues that have happened over the last decade or two, as well as others

that we're considering to see how we might modify it.

SUSAN: Thank you. Then, the second question, just real briefly, what was the name of the person chairing the effort on the incident reporting?

MR. McNALLY: Ann Overstreet. If you need to reach her, it's 703-308-8068.

SUSAN: Thank you.

MR. BRADBURY: Cynthia and then Matt.

MS. PALMER: On that topic, you said that you would be launching a voluntary effort this fall to do a dry run on the non-aggregate reporting. If you could just explain what sort of a dry run you mean, that would be helpful.

MR. McNALLY: Sure, and others can chime in as well. I think the goal is our colleagues and our information technology group in the office have kind of helped develop the infrastructure for that. So, what we'd want to do is pilot that infrastructure working with a small set of entities that would be interested in supplying that information to sort of work the bugs out to see whether, if and when we take it to a larger scale, that things, in fact, work the way we envision.

MR. BRADBURY: Matt and then Valentin.

DR. KEIFER: My question is the same about the electronic reporting. I didn't quite get it. What are you taking reports of, human, animal, everything?

MR. McNALLY: Any adverse effect data, for example, we're interested in. So, whether it's ecological in terms of fish kills or if it's human health in terms of those types of issues, that's the type of information that we would look to get. That's the type of information that we're getting in part through NPIC out at Oregon State currently.

DR. KEIFER: Okay, thanks.

MR. BRADBURY: Valentin and then --

MR. SANCHEZ: I just want to see whether there's a possibility that we can look at the 40 percent of comments that were against the Spanish labeling just to see what were their concerns?

MR. McNALLY: The question is, can they look at that. All that information is in the docket, I believe, that people submitted both for and against the idea.

MR. BRADBURY: Geoff, and then we'll move on to the next topic.

DR. CALVERT: I was also wondering about the worker protection standard and when that would be available. With the announcement last week from the Department of Label where they had some regulations to protect child workers and they withdrew those, I'm just wondering about what needs to happen so that we can see a draft of the revised worker protection standards?

MR. McNALLY: Well, I think what you're referring to are the OSHA rules that were pulled back dealing with -- associated with child labor. I mean, at this point, our goal of the next step is to propose them, in which case people will be able to see them. So, we certainly appreciate the interest in what the provisions are.

I think, speaking for those of us in the program who have been working at this for a long time -- because this process we've had to get input from stakeholders has been going on, as I mentioned, for over a decade -- I think we're looking forward to moving out from the stakeholder process to actually proposing the rule. Again, it's a proposal, so we're certainly interested in taking comments.

One of the things we've done in the proposal and the preamble is ask for advice, suggestions. Another option that we didn't select is to see what people think about those and to provide data. So, we still believe it's a very open process. The next step is to get it out on the street.

MR. BRADBURY: Thanks, Bob.

Let's move on to the next session, which is a discussion about economic definition of minor use. Jack Housenger will lead that discussion.

MR. HOUSENGER: Thanks. We drew a bad time spot, but we're going to -- I'm sure everyone is waiting for the economic minor use talk, but we're going to move through this as quickly as we can so we can get on to the last presentation of the day on spray drift with Jay. We weren't the unluckiest of straws, I guess.

We sent out some paper on this already, so hopefully everybody has gone over that. Just as a kind of summary, as we mentioned in that paper, FIFRA mandated, as amended by FQPA, that is, intended sort of a more coordinated approach for managing minor use pesticides, recognizing that growers in the U.S. may not

have sufficient access to the necessary pest control tools, including reduced risk pesticides, because of insufficient economic return on investment to an applicant from the registration of those uses, given the cost of registering and generating the data for those uses.

The term minor use is defined by FIFRA to not only include minor crops, that is both food and ornamental crops where production is less than 300,000 acres, but also uses in major crops where particular pest problems occur only in a specific limited situation or area, where the potential use is on too small a scale to justify registration of that use.

For growers, sustainable production can only be realized by the continued availability of crop production solution for pest problems. The sustainable production of food crops, especially those on high value and limited production area, is vital to our very nutritional and abundant food supply.

So, if you take a look at the FIFRA definition of minor use, the first definition, number one, it's pretty self explanatory. It's where a crop is grown on

less than 300,000 acres. We have data showing with USDA which of the crops fit into that category.

The second part of this definition isn't so straightforward, and it's what we're going to be proposing today. We're aware of situations where it may be desirable for a registrant to apply for an economic minor use status to control new emerging invasive pests in crops for production of more than 300,000 acres.

So, for example, the brown marmarated stink bug, an invasive insect not previously identified as a pest in the United States, has recently become a serious destructive agricultural pest in fruits, vegetables and ornamentals, including on apples. Apples are considered to be a major crop. It's grown on more than 300,000 acres.

Managing this newly introduced pest is challenging because there are currently two effective pesticides labeled for use against it. Researchers are looking into short and long term ways to effectively control this insect. We're concerned about the impacts of stink bugs on agricultural production, and we've been able to approve a number of pesticides under a temporary

basis under section 18 of FIFRA to deal with it.

However, there's a need for a more sustainable pest management tool box to control stink bugs. We envision the economic minor use guidance as potentially useful in instances such as this. We're by no means proposing to turn all major crops into minor uses, especially given that we collect PRIA fees. We are, as FPQA mandates, looking to provide incentives and reduce obstacles to registration of pest control products that have low expected returns, what are important to growers, subject, of course, to meeting safety standards.

I'm going to let T.J. Wyatt, our senior economist, walk you through what our proposed guidance looks like. Today, we're going to be asking for only clarifying questions to help better think about this. At some point in the near future, we're going to provide this up on the internet for public comment.

So, I'm going to turn it over to T.J.

MR. WYATT: Thank you, Jack. If you'll notice, in addition to the economic requirement under FIFRA(ll)2, there are some sort of biological and other criteria that may be necessary. We're not going to talk about those

today. Those crop up in a number of other places. In part of your handout is an explanation of how to apply for an extension of exclusive use. That will explain how we evaluate those alternatives, those factors.

Today, we want to talk about the economic incentives to undertake a registration and whether or not the future revenues that will accrue to a company will justify the investment in terms of undertaking the cost of registration. This work has mostly been done by two accountants in our staff, Michelle Ramville and Derrick Provalt (phonetic). Neither of them could be here today, which is why you have me.

In developing this approach, we wanted something that would be both rigorous and objective because we want to be able to make supportable decisions and we want decisions that can be consistent across different analysts, so that it's not sort of too subjective.

We also want to make sure that this is an open and transparent decision for all stakeholders so that A, that helps us make consistent decisions and 2, it helps inform people who want to apply for this sort of minor

use status to know what's expected of them.

Finally, we want to make sure that this is easy to implement. Specifically, we want to make sure that it can be done with a reasonable amount of data. One of the issues here is that people may be lacking incentive already, and to apply a bunch of more onerous requirements for information would be counterproductive.

Now, I'm going to run through an example to kind of try to illustrate how this approach would work. In doing so, I'm going to highlight some things in which we're still struggling and which we're looking for some assistance in answering.

So, as I go through this example, please bear in mind some of these questions. First of all, on the registration cost side, what costs should we include? Specifically, how should they be incorporated into the analysis? On the revenue side, we need to consider the fact that it costs money to produce a pesticide. It costs money to market it. Again, how are those costs going to be accounted for, and how do we incorporate them into the analysis?

Now, I mentioned that part of this is that the

returns to this investment accrue over time through sales of the pesticide. Big question, what time frame should we use? The farther out into the future we have to predict what sales are going to be, the less certain we are about the situation.

Finally, the two big ones. What is the best measure to use when we make this comparison of costs and revenues? How do we interpret that? What are the appropriate thresholds for determining what distinguishes a sufficient incentive from an insufficient incentive?

So, a hypothetical example we kind of dreamed up to do this, because we really have had no real experience in this so far, is an herbicide that would be used in soybeans. Soybeans is definitely a major crop. It's grown on 75 million acres in the U.S. But we can envision a case where maybe a resistant weed has been found inside just a small area of the country in North Carolina. It's currently a relatively small area affected, but, given resistence, it's likely to spread widely.

Our optimal policy, however, would be to try to confine it, control it, and keep it at a low level. So,

it may be that this market will never really develop into a large potential area of treatment. So, let's imagine that we have a candidate herbicide. It's also registered on cotton, a major crop, 10 million acres, and some other minor small acreage crops. So, there's a market already for this product.

But to register it for a new use could entail a significant amount of investment. Data generation costs alone, we are estimating, given what we know or what we're making up here, about $2.4 million. That would include revenue data, which, for soybeans, includes at least 20 field trials at about $2.2 million. The company would have to do some efficacy studies to support it. Those aren't submitted, but they have to be available. We're thinking that those might run about $200,000. So, we've got $2.4 million in data generation costs, plus the PRIA fee for an additional food use of $60,000.

Now, there are other costs associated with the registration of a chemical, just having to submit the data. If I were the registrant, I would be doing my own risk assessments. I'd be examining what the agency is doing. There's plenty of meetings and back and forth

about making sure that the labels are right. The question is, how do we account for all those costs? How do we know what those costs are? How do we verify them? How might we incorporate them in an easy fashion?

For the moment, I'm going to leave those aside and we're just going to look at this as an investment of nearly $2.5 million. On the revenue side, let's start with gross revenues. Gross revenues would be the price of the product times the amount sold. Well, like I said, this product is already on the market, so we might have a pretty good idea of the cost. To make things easy, we're going to say it's $10 a pound.

We might also have from the registrant the expected application rate. In this case, we're going to just say it's a pound per acre. That means it's a $10 per acre charge. So, if we knew how many acres were affected, we could make a pretty good estimate of gross revenue. We're thinking that in combination with USDA, in many of these situations we could figure out what extent the pest problem might be. We'd get the registrant to submit some of their information.

So, this hypothetical example assumes that we

start fairly small, 125,000 acres, because you have to get the product out. Plus, it's resistant. It's going to grow over time to maybe 325,000 acres by the third year. At $10 per acre, that nicely works up to $1.25 million in the first year to $3.25 million in the third year. If you total that all up, in three years you've got $7.25 million.

A couple things that we need to think about, though, in this is clearly there could be more years of sales. But again, the farther out in the future we have to go, the less certain we are. For example, there could be another product that comes on the market or something to that effect.

We also need to realize that what we really want are net revenues. This brings us to the question of marketing costs, manufacturing costs. How do we handle these? If I'm the registrant, I'm going to submit information that says I've got the cost of the raw materials. I need to pay my workers to do it. I've got the power to run my production line. I need to ship the stuff out. I've got advertising to do. I've got sales reps in the field. Oh, by the way, this is all

(inaudible).

So, as the EPA analyst, I'm kind of stuck here because I can't put this information out. I've got no way to verify it. I'm not even sure we've got the right numbers, because what we're really looking for are just those additional costs of that new product. So, we've got all this stuff already being made for cotton, being shipped out. You've got a distribution system in order.

So, how much truly additional costs are there for adding this new use? One way we were thinking of getting around this issue of cost we can't verify and we can't vet, is to think of some more categorical qualitative category. So, for example, in this case, our new use is probably going to be relatively small compared to the existing use. Cotton might have a big market.

So, just for this example, let's say that in this case, additional costs for the new use are 50 percent of gross revenue. That's basically covering your basic raw materials. That will give us net revenue. The second thing we need to consider in terms of looking at this investment is that money that comes in in the future is not as valuable as money we have right now.

If you think about it, there's all sorts of issues about money in the future. You may not get it. Because of inflation, you may not be able to buy as much with it. You may have other opportunities to use it. So, we need to do what economists call discounting. That's a little tricky because discounting is fairly personal. To the extent that it's tied to the inflation rate, it's also subject to variation over time. So, we need to think about what the appropriate discount rate is.

For this example, I'm going to use seven percent. That's kind of arbitrary but not as arbitrary as it might be. This is the value that the Office of Management and Budget has us use to evaluate the private discount rate when we're evaluating regulations and the costs and benefits thereof. So, that's a starting point, at least.

Now, if you discount net revenues over time, we come up with these figures. In year one, the money that's coming in is worth $.58 million; in year two, $1.2 million; in year 3, $1.33 million, for a total of $3.11 million over those first three years. Again, the

registration costs are about $2.5 million. So, what we call our net present value, the net between the return and the investment, in present value money, that is, future money evaluated as if it were today, it's $.65 million. Not bad.

But, one of the issues is that's just an absolute value. So, it's hard to say whether that's good, bad. One thing you might think about is whether or not that should be compared to the magnitude of the investment, because $650,000 against $2.5 is one thing; $650,000 against $5 million, that would be something else.

So, one other measure we might use are returns over cost. Then we'd have sort of a cost benefit ratio of $1.3. Now, how do we interpret that? It's kind of nice to think that anything greater than zero in terms of the NPV or anything greater than one as a benefit cost ratio is a good deal.

Again, we've got to take into account that we're probably missing things. I don't know how accurate our discount rate is. So, we need to think about what those thresholds actually are. As I said, we don't have

any experience at this time in making some comparisons, so we're looking for some ideas and possibly some case studies that we could run through.

Just as a quick example, I want to compare maybe two different situations to see how this would work. This is what we just went through where we thought of the new use as being fairly small in comparison with the existing market, where manufacturing costs were 50 percent of gross revenue.

Now, let's imagine a different scenario where this chemical is registered not on cotton but on snap beans. Snap beans are just over 300,000 acres total, so this is going to be a small market. So, an additional market in terms of soybeans, even though soybeans might be minor in this case, it's still going to be a major part of this new production scheme. So, you are going to have to ramp up production. You do need, perhaps, to bring on more people, more shifts.

So, as a category, maybe we'd say that manufacturing costs in this case are 80 percent of gross revenue. If you make the calculation here, you come up with -- even though we started with the same numbers --

quite a different outcome where the net present value is negative by over $1 million, and the benefit cost ratio is only 25. So, which category you fall into might be an important distinction in terms of how we interpret the results.

So, that's our example. Just to remind you, the things that we're still kind of struggling with are what is the appropriate measure and what would the appropriate threshold or thresholds be for insufficient incentive. In particular, we're struggling with how to incorporate the cost of manufacturing and marketing the pesticides. I mean, we've got the choice of relying on registrant submitted data. As I mentioned, there's some drawbacks to that.

So, our thinking right now might be some more qualitative categories with sort of set cost of proportion to just sort of estimate what those costs might be as a proportion of gross revenue. There may be other options we haven't thought of, so we're interested in ideas.

Finally, we need to think about the appropriate time period for this analysis. If we're too short, which

three years probably is, we're going to be understating total returns from this product. But, any longer and we're running into problems of a lot of uncertainty in our prediction. So, it may be that we want to just go with the shorter time period but take that into account when we interpret our results.

Thank you for your attention. I'd be happy to answer any questions. If you've got comments or ideas, please feel free to contact us.

MR. BRADBURY: So, we're just going to do Cindy and Matt. Again, it's just clarification. The point was to introduce what we're working on. So, we're not asking for answers to T.J.'s questions today. There will be a process to do that. But if there's some clarifying questions, that would be great.

So, Cindy and then Matt.

MS. BAKER: I have one clarifying question, and then I have one comment. What's the problem we're trying to fix here? Why do we have to do this? Is there a specific problem that's come up that you have to go through this? I'm just curious because I'm not clear why we're doing this effort.

MR. McNALLY: Well, I mean, this is a provision in FIFRA that we've never provided guidance for. That's number one.

MS. BAKER: Have you been doing it all along?

MR. McNALLY: We haven't been doing it, and we do have a few cases before us now to consider.

MS. BAKER: Okay. So, then, my comment is that a company like ours does this stuff all the time. Before you ever decide to spend money, you're going to an MPV. You're going to look at what's the expected rate, how many years you're going to go out, what is the percentage of acreage you expect to get treated, what are the costs going downward.

So, I think that you're right. I don't want to stick that in the Federal Register for everybody in the world to see, but I think it might be helpful to you guys if you had a couple of us come in. I'd be happy to come in and show you exactly the profits, because it's more than just the numbers part.

So, one of the assessments is go do the raw numbers and see what's the actual return on investment going to be, when are you going to go positive on your

MPV, what are the risk factors associated with all those numbers that you put in there, all that stuff we're doing and I suspect others are doing, too. I'd be happy to come in and share one with you.

But I think you've also got to factor in that it's more than just the return on investment from the things that you've identified here. The other thing that's unique, I think, about minor crop, as Jack pointed out, is their high value crops. So, it's more than just does the product work; you've got to do a lot of consideration of what are the liability concerns here. Is there any potential for FIDO? Is there any potential for damage in other ways to the pests because you're going to get a higher claim on that than you are on some other crops. So, that has to be factored in. It probably doesn't show up in an MPV type analysis.

So, I guess I just say those things to say I think there's some stuff that you can learn from people who are willing to come in and tell you how we evaluate this stuff on a regular basis. We do it all the time, and I'd be happy to share it.

MR. BRADBURY: Matt and then Jerry.

DR. KEIFER: I don't think my comments are going to be very much different than that. I just though that the experience with IR-4 in the past, doesn't that teach us an awful lot to answer the questions you pose? Hasn't IR-4 been a program that's been in place for quite a while now? Yeah. So, it seems like that information is current.

The only other thing I'd comment about your economic model was the one thing I learned in economics in college was supply and demand. I was wondering how when there's a greater demand on a limited product, why the price isn't going up? If there's a further demand than the product, why doesn't it go up? You assumed a static price?

MR. McNALLY: We are sort of in this example. Part of it would be if you've got a big market in cotton, you can't really mark up the price just for soybean without affecting your entire market.

MR. BRADBURY: Jerry and then Cheryl.

MR. BARON: Jack, I want to thank you and your team for putting this together, one, because it's needed. I'm not necessarily saying that this is the exact model

that's needed, but something like this is needed for a variety of reasons.

Number two, it gives me a break from what I've been doing for the last three months of trying to defend the IR-4 program. But that's another story.

One of the things I'd just like clarification on is, what type of involvement do you see of these models with the IR-4 projects? If the company decides that that doesn't meet their internal standard, their threshold for MPV approval, that's when it falls back on IR-4's lap. Would we need to twist the company's arm to provide this information to document this one or the fact that they said they're not going to do it, then we go on? So, that's just one question.

The second one is just the acreage figures. I'm a little uncomfortable. The acreage figures that I think you're using haven't been updated for quite a while. Just looking through some of the things of what the groups have collected, they're not easily found out there.

You also may have some crops -- and I'll use the example of tomatoes where tomatoes by itself is a

huge crop on an acreage basis. But there are subsets of tomatoes, for example, greenhouse tomatoes, that are totally different scenario, but the tolerants or the MRL would be based on tomatoes, not on greenhouse tomatoes, or field tomatoes, or processing tomatoes, or even post-harvest use tomatoes.

So, we have to be careful about that. I just give you that as a head's up. Thank you.

MR. BRADBURY: Thanks.

Cheryl.

DR. CLEVELAND: I would like echo some things that we heard in the bee discussion, actually. Simple is better whenever you can get there. So, I am concerned that you're trying to call in a lot of information that CBI -- you've already acknowledged it, but it's going to be more difficult in a process that already is something that a lot of people don't want to enter into.

So, you're looking to help the grower, not make a lot of money. So, make it as simple as possible for the registrant as well as yourself and the review and the whole process. So, I would just really encourage you to call in the minimal needed. Going down into all of this

might be a good case study to learn from, but I would hate to see you go there for your final process.

UNIDENTIFIED FEMALE: I just want to say thank you to FEAD. They've engaged USDA right from the start rather than at the end. I've engaged Dr. Glouber (phonetic), Joe Glouber's office, the Office of the Chief Economist. We've been working with FEAD and reviewed and had discussions with them, I think at least three meetings. So, we're a part of this. I appreciate that. I can only imagine that we'll continue this dialogue. But we're really glad to be in at the very beginning of this. Thank you.

MR. BRADBURY: Okay, thanks. Again, just an introduction. Good conversation. That's part of why I wanted to get it introduced. We'll have some process around getting feedback and input.

Okay, the last topic for the day is an update on spray drift. In particular, we want to focus on the drift reduction technology program. So, I'll turn it over to Bill Jordan first and then to Jay Ellenberger.

MR. JORDAN: It wouldn't be a PPDC meeting without our discussion of spray drift. It's always a

challenge to find something new and different and valuable to say. Jay is going to do that, and he's going to do it very quickly so that we meet our target of concluding by 5:20. He will reserve a minute for me to cover and update you on the PR notice.

MR. ELLENBERGER: Thanks, Steve and Bill. I guess I will try to get you out of here within about 12 minutes to get your margarita or whatever across the street.

As part of OPP's work to deal with spray drift issues, we've been developing the drift reduction technology program for the last few years. We're coming to what I believe is the end or getting close to it. I've been implementing it this summer. So, I wanted to just spend about 12 minutes to give you a very broad overview of what it is, where we are, and our plan to implement the program by this summer.

As many of you know, spray drift continues to be a problem for applicators, growers, and the public. USDA, OPP, extension service, state-lead agencies, and the private sector give quite a bit of attention to dealing with spray drift within the United States, as you

can imagine, and in all the countries, I think, around the world -- and I deal with a lot of them facing the same issues, both from sort of the real world field issues to regulatory science issues and so on and so forth.

Application technologies, different kinds of equipment, can be a major factor in causing spray drift. On the other hand, on the flip side of that, it can really be very helpful as a very important solution on minimizing spray drift.

So, the real goal of the drift reduction technology program is to accelerate the use of application technologies that have been verified to significantly reduce spray drift. We want to encourage manufacturers, both on the application equipment side, as well as the pesticide registrants, to voluntarily participate in this program. As you see there, this is a voluntary program. It's not a regulatory program, per se.

One of the important aspects of this is once it does get underway and equipment companies do start testing some of their application equipment, like

nozzles, so on and so forth, and pesticide companies make claims on their pesticide labels for using DRT verified equipment, OPP will credit the use of that as it would for any risk reduction measure when we do our risk assessments and risk management decisions for registration or registration review.

So, here's an illustration, very simple, very colorful at the end of the day here as to what we're trying to achieve. So, if you take a look at the very top illustration with aerial application, that's what we're going to assume is sort of a baseline. There's no drift reduction technology. Perhaps the aircraft is using nozzles with a fine spray.

So, you get a considerable amount, or a large amount, of drift compared to going down the slide there a good verified DRT piece of equipment, maybe 25 percent reduction in the drift, so on and so forth, perhaps all the way to equipment that might have potential of reducing drift 90 percent compared to a standard.

So, what's our motivation for doing this program? Why are we doing it? Well, let's take a look at that. As I mentioned, spray drift continues to

happen. There's about 2,500 reported incidents -- I emphasize reported -- to states every year that they have to deal with. They lead to risks of one kind or another, vital toxicities to other crops, to noncrops, the encroachment of residential areas and farmland, and effects on ecological habitats or species, including endangered species.

So, with the amount that's applied every year and the amount of about a billion pounds to ag and non-ag industrial sites, the percentage that can drift off target sites, that's a real motivator for us. We know that the equipment companies are continuing to produce better technologies of all different kinds. The science is getting better.

We continue to receive and actually participate in more and more studies, whether they're wind tunnel studies or field studies, to characterize spray drift. We continue to work with organizations like USDA and the private sector to improve our models that we use, risk assessment models that help us to estimate the amount of spray drift and deposition off the target sites.

Drift reduction technologies, we believe, will

lead to better drift and risk management, better efficacy for the applicators to keep more of the product on the target fields and less off of the field. It's a good cost management for applicators as well.

So, what we've got to do is verify these technologies. To do that, we've developed a test protocol that is almost complete, the verification of pesticide application spray drift reduction technologies for row and field crops. We've picked row and field crops because that's predominant acreage in the United States. It's where most of the pesticides are applied. It's where most of the applications occur. So, it just made sense to us.

We work very closely with our colleagues at USDA, ARS, at the aerial technology experiment station in Texas. They've got terrific experience in this kind of work. We've also worked with Andrew Hearit (phonetic) with Lincoln University and University of Queensland both in Australia and New Zealand, as well as the private sector, including registrants, equipment manufacturers, and academics in helping us develop this protocol.

There you will see below the title an

illustration of a wind tunnel where a lot of these kinds of studies will be done. Wind tunnels are great for testing nozzles at different speeds, including ground boom applications going at relatively slow speeds compared to an aerial, whether helicopter or fixed wing. To the right of it is actually a photo of a spray drift field study being carried out.

Below that, you can see, as I've already mentioned, that the focus is on ground boom applications, aerial application technology. That is a predominant ag and industrial acreage application method. I think the equipment companies will be testing mostly nozzles but also larger equipment like shielded or (inaudible) sprayers, as you can see pictured there on the bottom right.

Here's an illustration to show you after a study is done, particularly a wind tunnel study, that we would receive from the equipment company, we will take a look at the data. This is a table -- don't really pay attention to the numbers -- but it's just an example of the droplet size spectra of three different kinds of nozzles there. So, a reference nozzle, which is

important because you've got to have it to compare any other kind of nozzle to, and then two other kinds of nozzles that were actually submitted to us for a pilot study.

Our scientists would take that kind of data and then put it into one of our peer reviewed models to show in the graph on the bottom right. You can see the curves there. The top curve is the reference nozzle results. The bottom one are what we call a DRT, actually two DRT nozzles that fit the same curve. You can see over a distance the amount of pesticides that would be applied that would be drifting downwind.

To the left is just an example of -- although this is hard to see on these screens -- two nozzles side by side. The one on the left, you can see, is a lot more finer spray droplets, probably less than 100 microns, which is a little bit narrower than human hair, a lot more sort of drift potential. The one on the right has fewer of those kinds of small droplets.

So, once we would receive these kinds of studies, what would we do with them? What would OPP do with them? Well, we would review the studies, obviously,

to make sure they follow the protocol. It studies the QAQC. Take a look at the results. Carry out the kind of analysis that you saw in the previous slide.

Then, depending on the relative success, if you will, of that particular technology, we would determine is it potentially 25 percent less than the reference nozzle, 50 percent, 75 percent, and perhaps even 90 percent. So, we would assign what we call a star rating, one, two, three, or four stars. This is very analogous or consistent with what the United Kingdom has done with their DRT program. It's been quite successful over the last number of years.

We would then take that information, that rating information, and put it on an OPP website to make it much more available to pesticide registrants and applicators. I'll describe that a little bit more in a minute or two.

Then, the third thing, which I've mentioned, is as pesticide registrants make claims on their label to apply their product using perhaps a nozzle that has a DRT two-star rating or a DRT three-star kind of equipment, then we would consider that, how to credit that in our

risk assessment and risk management decisions.

Again, taking this a step further, here's a real example of taking those kinds of data that I just showed you in former slides and applying it to one of our models that we would use for depositions and buffer zone estimations for aquatic environments. So, using those different kinds of nozzles and the drift potential based on those studies, it would give these kinds of curves. The curves at the bottom obviously are the lower drift, the DRT kinds of nozzles.

Where those curves intersect the horizontal line, which is the level of concern based on the toxicity for a given pesticide for aquatic organisms, that intersection between the LOC and the drift curves, is where we'd have concern in something like a buffer zone. So, you can see, as the curves go smaller and smaller based on lower and lower drift nozzles, buffer zones get smaller and smaller.

So, that's quite a bit of detailed information. So, let me just quickly walk you through the major steps on the next three slides. Starting in the upper left, the program starts this summer. We'll announce it a

number of ways. We'll be working with the trade press, with applicator groups, extension services. It will be important to us to get the word out as they trade applicators over the coming years.

Then, technology companies, for example, nozzle companies, will decide to have one or more of their nozzles or other kinds of equipment that they make tested. So, they will contract with the testing facility such as the University of Nebraska which just built two big wind tunnels specifically for this kind of work, or perhaps USDA ARS, or some other top notch researchers in other countries.

Once those studies are voluntarily done and paid for by the equipment companies, we would receive those studies, evaluate them, as I mentioned, and then give the DRT rating for each tested nozzle or other kinds of equipment posted on our website, showing the company, the producer, their particular kind of equipment, the name of it, and a particular rating.

Then, these last few major steps, we would certainly hope that the pesticide registrants would take advantage of that and come to us with applications for

registration or mandatory registration with claims to use DRTs with the application of their products. So, perhaps in their directions for use, there would be a statement about apply this product with DRT two-star equipment, for example.

As part of that registration review process, again, we would consider that in our risk assessment risk management decisions. Once the product label is registered or amended and is out in the marketplace, growers would see that. They would know to go to either OPP's website to find out what specific nozzles have a two-star rating, or they can go -- after a while, I think, the equipment companies will also do a fair amount of marketing of that kind of claim. So, that's a way of getting information out.

Sort of finishing this up here, the incentives and benefits, we think there's a lot of incentives and benefits. We think it's really a win, win, win all the way around. We will be providing a standard method for validation of technologies. Right now, there's all kinds of methods out there. There's no way of comparing one against another.

We have a standard process that's been scientifically peer reviewed. The results will provide more information, better information to applicators, to the registrants, to growers, so on and so forth, to make better application decisions. It provides applicators with more options for making their applications and managing spray drift.

Also, it's obviously an opportunity for better pest control by keeping more of the product on the market, more on the application site and less away from the application site. It reduces their costs, reduces their potential liabilities for enforcement claims, lawsuits, so on and so forth. It reduces off target deposition drift, greater protection to people, bystanders, residential areas, and the environment as well. We want to move from what you see on the left to what you see on the right.

The next steps, as I mentioned, we want to take it on the road, essentially, this August. Finish the test protocol. We should have that done in about a month. We're having some last meetings with some of these spray drift research experts in a couple weeks.

We're going to put up a website. We will do a whole series of communications. We're hoping that that test will voluntarily begin as early as this summer. It's going into fall.

As soon as we receive those results, we'll start defining DRT ratings based on those test results of technologies. We're hoping that by this time next year, there will be labels on the market with DRT recommendations.

I went through that very quickly. I appreciate your attention, particularly at the end of the day. Thank you.

MR. JORDAN: Thanks, Jay. Let me just cover very briefly the status of the final PR notice. It's not out. You probably knew that. You would have noticed if we had put it out. It is in internal EPA review. This also should not come as a particular surprise to you, but when new people become familiar with the spray drift issue, there are a range of thoughts about it, ideas.

People need to go through a kind of education process. They want to understand how labeling fits in with other activities, product specific decisions, how it

fits in with things like the DRT program. Everybody thinks they can write it better.

We're still having discussions. I think I'm not going to make a prediction about when those discussions will reach a conclusion. So, stayed tuned. Maybe we'll be back at the next PPDC meeting talking about the status of the PR notice. We'll find out.

Steve, do we have time for questions or shall we go to public comment?

MR. BRADBURY: We don't have any public comments, so if -- we're supposed to end at 5:30, but if you all want to stay a little bit longer, we can go around and touch base with folks who would like to ask questions. Then we'll call it a day. Does that sound okay?

Why don't I just start with Mark and we'll just go around the table.

MARK: My question is the same kind of process for (inaudible) as regular application systems?

MR. ELLENBERGER: I think with (inaudible), you're looking at would we include (inaudible) technology in this kind of process? I guess we could. The protocol

is really written for wind tunnels and field studies. Whether or not any of that kind of technology fits in here or not, I don't know. I'm not saying no to it but we just have to give that a look.

MR. BRADBURY: Darren.

MR. COX: This is a little bit off, too, but autonomous solutions, in other words, unmanned equipment for spring, is that something you're looking at?

MR. ELLENBERGER: I'm sorry, say that again.

MR. COX: Would something like autonomous solutions unmanned spray equipment something you're looking at also for drift reduction technology?

MR. ELLENBERGER: Unmanned spray equipment? We hadn't really thought about that yet. The real key thing is -- I mean, nozzles are really highly important to this. I think that's where most of the work will be done because it's cheaper to do it. You can do it in wind tunnels as opposed to field studies. That again is something that we're willing to entertain and talk to you about.

UNIDENTIFIED FEMALE: A couple questions, comments. Given that the U.K. has already established a

program here, what thought was there to leveraging that information rather than kind of starting from scratch here? Also, this whole presentation is kind of focusing on nozzles. What about adjuvant as a drift reduction? Finally, the hurdle of 25 percent, what if you're at 20? Are you still going to get any credit, because you want to encourage getting to spray drift reduction not meeting certain big bucket --

MR. ELLENBERGER: Let me see if I can remember that. The U.K., actually, we've worked with the U.K. One of the leading equipment manufacturers in the U.K. helped us develop a protocol. We worked very closely with them. Our protocol -- actually, we looked at all of the protocols that are out there around the world, literally. We pulled the best into it. So, we aren't totally starting from scratch. We're making improvements on what's out there, number one.

Number two, things like drift retardant adjuvants, we've talked a lot to that industry. I'm taking to them again in two weeks at their annual meeting. So, they're very, very much involved in this. It's a little bit more complicated, more adjuvant because

there are other variables that make them work, including the physical characteristics of a nozzle, the chemical characteristics of a spray solution that they're mixed with, and other things. So, it's a little bit more complicated than just physical equipment.

Then, I think your last question, 25 percent -- these are really ranges. It doesn't start at 25 percent and then only to 50 percent, but you've got to figure out the ranges. If something is one percent better, it's probably not going to cut it. So, we've got to figure out sort of really where to start.

MR. BRADBURY: Scott and then Ken.

MR. SCHERTZ: Similar to Cheryl's comments, it seems like -- and this may be the example not the entire part of your program -- it was real heavy on the nozzle side of it. In particular, procedures and other (inaudible) smokers that aims on being able to -- and let me explain the aims as an airborne meteorological sensor. These are ways of basically using the wind to eliminate drift, not just prevent it, or minimize it. I just want to make a point of encouraging the consideration of very practical ways that are very useful and actually used

routinely.

The other comment is, obviously, the process needs to be valid. But it also needs to be readily accessible. At least some of the prior information on this program (inaudible) rural out of hurdles as far as accessibility of the (inaudible) techniques.

MR. ELLENBERGER: We're starting out with really ground boom and aerial, rolling field crops. We thought about the future, which could include other kinds of equipment. But we aren't just saying no up front to other equipment. We might, in the future, go into orchard and vineyard applications as well.

MR. BRADBURY: Ken and then Gabriele.

MR. NYE: Some interesting technology that could help solve some drift problems that we have. I think the comment was made that you've got a win, win, win. Remember, there is a cost that will be involved here. As the technology evolves, it's going to be passed on to users in equipment and pesticides. Let's all hope that what comes out the end is worth it in terms of the investment that people are going to have to make. So, we've just got to make sure that there's a payoff in

terms of what we're going to gain.

MS. LUDWIG: I have a question and a comment. I'm thinking you started to address the question, but when we look at spray drift, it's always sort of aerial, air blasts, and then ground. So, what are the plans for air blast applicators representing nut crops in terms of finding a protocol for that?

MR. ELLENBERGER: That's a good question. As I mentioned, we are putting off orchard and vineyard until later because that's not as well characterized to drift compared to ground boom and aerial. There's not as much data, field data, about that. We recognize that that's an area, application area, although much smaller acreage, relative to field and row crops. Those are application methods that can lead to lots of drift, off-target drift. So, that is something for us to work on potentially in the future.

MS. LUDWIG: I would like that to be more definitive than potentially.

Then, my comment is, and I think it goes along the line of what Ken is saying, from a grower's perspective, you also have the efficacy issue. So, just

to give an example, if the almond board refunds research and we had some research looking at just the efficacy side and we have some research coming in that wants to look at spray drift, and I said, guys, you all have to work together because my hope is that we can find the win, win.

There are certain things, let's say, at the speed with which they apply or how they set up the nozzles will improve the efficacy and (inaudible) drift. So, I think that's an element that should be looked at, too. So, the more you can encourage also something showing that this improves efficacy, I think the faster you'll get adoption rather than just the stick of okay, (inaudible) lower buffer zones.

MR. BRADBURY: Susan, I think, is next. Sorry, Jake, I couldn't see you.

MR. VUKICH: A comment and a then a question. Comment number one, I think this is a very timely endeavor because I think as we get into endangered species assessments, I can see where buffers can be very much a part of the mitigation.

The question I had, though, is do you envision

being able to have kind of options for applicators so that if they use a DRT 50, they can reduce the buffer by 50 percent, if they use a DRT 90, they can reduce the buffer accordingly or are you thinking there will be just one DRT on a label and they'd be locked into that technology?

MR. ELLENBERGER: It's totally up to the registrant. I mean, if the registrant wants to put on four different DRT options, that's their prerogative. So, there would be relative risk mitigation measures with that.

SUSAN: Thanks, Jay. It's nice to see this work is coming to fruition. I have a question, though. I wonder how you envision it being enforced. So, if someone gets a DRT product, a special label that allows you to use it without a buffer zone, what's to keep someone from saying, oh, look, no buffer zone with this one, I'll just use it, and not going to the expense -- as you mentioned, it's going to be costly to change out all your nozzles. How do you envision this being enforced?

MR. ELLENBERGER: I've actually talked to states about that because they had sort of the same kind

of question. We worked through it. If, indeed, the applicator did use a DRT 2 nozzle or shrouded spray or whatever, if there is an enforcement case, they would obviously have to have that kind of equipment. Do they have records of that particular application using that kind of equipment, so on and so forth? So, that's a fair question, and we've had a dialogue with state-lead agencies about that kind of enforcement issue.

MR. BRADBURY: Wayne.

MR. BUHLER: As an educator, it's always a challenge to teach growers nozzle tip selection. I was just curious how this corresponds, perhaps the four tiers corresponding to maybe the different droplet spectra or perhaps the color coding of nozzles. Is any of that relative to the tiers or levels?

MR. ELLENBERGER: Yes, it is. The color coding having to do with different kinds of nozzles and high drift, low drift, medium drift kind of thing, and droplet sizes. I think there will be a relationship, obviously, between the droplet size, a very course nozzle, obviously, and a low drift nozzle, and perhaps a DRT four-star kind of product.

But, what we're trying to do is get companies to -- even though it's a nozzle that's rated as very course, get rid of all the fine droplets that also come out of that course nozzle so it's just course droplets and not a mixture. Again, we've talked to some of the extension folks and academics and nozzle manufacturers about how this is going to work out. In the nozzle manufacturer's catalogue, if you will, where it's color coded, how the DRT would fit in there.

MR. BRADBURY: Thanks. I'm going to close this session. Just make sure there isn't somebody on the phone that would like to make a public comment. Anybody on the phone, we're in public comment session if anyone on the phone has a comment you'd like to make.

MR. JOHANSEN: If you've got time for a very quick comment, I would like to make one. This is Eric Johansen, Washington State, Department of Agriculture.

MR. BRADBURY: Sure, go ahead.

MR. JOHANSEN: I listened in on the pollinator workgroup this morning, the discussion. I thought it was excellent. The one comment or the one concern I have, though, is it sounded like the EPA's take on it was that

if you didn't adopt significant revisions to the pollinator protection statements in the label review manual, that you couldn't do anything.

I guess I would suggest that if you're not comfortable at this point making substantive changes to the pollinator protection statements in the label review manual, you might consider making technical corrections only to improve clarity. In my opinion, it needs both, technical corrections and substantive changes.

I understand that the inclination is to let the CTAC process go forward, get the Scientific Advisory Panel involved, yada, yada, yada. That's fine. But I would encourage you to at least consider technical corrections. I could think of three right off hand if you're interested. Thank you.

MR. BRADBURY: Thanks. Anyone else on the phone for public comments?

(Whereupon, there was no verbal response.)

MR. BRADBURY: Okay, we'll close public comments, and we'll close it down for the day. I appreciate everybody's input. We're only 15 minutes off

schedule. Hopefully, we wouldn't have to renegotiate our PRIA for that. So, tomorrow we've got a lot of other very good topics coming up, so I'm looking forward to tomorrow's dialogue. Thanks and have a good evening.

(Whereupon, the meeting was adjourned.)

P R O C E E D I N G S

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DR. BRADBURY: Good morning, everyone. Why don't we get started. What we're going through this morning is ESA, an update on the Endangered Species Act activities. That's going to be more of an information sharing, maybe a couple clarifying questions, but that will be the primary part of that.

Then registration review, an update on that but with a focus on water quality. That will be some time to talk about where we are in terms of getting information in at the beginning of registration review to help inform especially the aquatic ecological risk assessments but also, to some degree, the drinking water.

We'll get an update from the PPDC workgroup on 21st century tox and a little bit on some coordination with Canada in terms of the Regulatory Cooperation Council and then some discussion on sustainability activities going on in the agency. Then we'll wrap up with thinking about the next meeting.

I want to adjust the agenda a touch, but we'll stay on schedule. One of the commitments we had from

yesterday was that Rick and Don would kind of synthesize the recommendations from the pollinator workgroup and then get to some feedback from the agency's perspective on next steps, working with the workgroup and things we might be able to do as EPA alone.

So, I'm going to ask Don and Rick to take about 10 to 15 minutes and let you know where we want to go next. We'll just eat up some of the ESA time, but we'll stay on schedule. We'll just use up some of ESA part of the agenda. So, I'll turn it over to Don and Rick.

MR. BRADY: Well, thanks very much. As Steve said, we just wanted to quickly share our thoughts on what we think next steps on the pollinator discussion we had yesterday was. Our goal here is to explain what we think next steps are and then re-engage with the workgroup in terms of the specifics of how we might accomplish these steps. Then, have a six-month goal of initiating and starting to make progress on these things.

This will be a busy six-month period for us in EPA and everybody who follows pollinator issues. As Steve mentioned yesterday, we've got an SAP that will happen in September, the Science Advisory Panel, on risk

assessment process for pollinators. We have an October stakeholder meeting related to pollinators. We have an ESA risk assessment protocol that we expect to see sometime this summer. So, we're just sort of piling on here in terms of these activities, but it's an important issue and we think we need to do it.

So, we sort of broken down the next steps we think that we can initiate into four things. The first one relates to the discussions that occurred in a number of groups around VMP success stories and documenting and fully disseminating those stories, the Yuma example and any other examples of best management practice. The goal here would be to enlist our partners in USDA in helping to provide those success stories, discover them, as well as to disseminate them through their channels.

This really is very consistent with sort of the impetus of the workgroup, which is practical things that are working for people in some places and just get them out so that everybody is aware of them. So, that's the first idea.

The second idea relates to the training thread that ran through the discussion yesterday. This is

really in our part here where we would work with workgroup members and others around this table to make sure that every place that we provide training we have an appropriate pollinator segment, if you will, or appropriate discussion of pollinator issues.

So, for example, we run prep courses, we call them, but we would want to make sure that we have a focus in those courses or in the next course on a pollinator module. So, every place that we participate in training, we would work to get the right message on pollinators for that audience in place and just keep the emphasis and the focus on that issue.

The third issue is sort of a specification of that idea. This one, we in OPP would explore with OWECA and the state-lead agencies the development of specialized training for inspectors and the enforcement arms of the agency. Should it get to the point of an incident occurring, the inspectors would have the latest training available to them to know what they should be looking for when they go out in the field.

The fourth thing is we would initiate a review to our label review manual and see what would be entailed

in crafting new language or appropriate language for pollinators. This is a complex area, so the main thing we would do first is try to go through and look at places and then see what it would take and where we think the opportunity target is, if you will, of the kinds of changes that we might initiate.

So, those are sort of the four key ideas. As I said, we would hope that we would take these ideas back to the workgroup for discrete next steps and time frames. I told Steve earlier I heard a lot of energy in the workgroup and a lot of commitment from members of the workgroup to stay working on this topic. It wasn't just we did our thing and produced recommendations and now we're going to walk away. If you listen to the workgroup discussions, there was an awful lot of what we should do next and how we should approach this after this meeting.

So, I would ask Rick if there's any -- okay. So, I just wanted to put that out as our idea of next steps, based on the discussion we had yesterday. So, that's the idea. Any thoughts? Steve, do you want to add anything?

MR. BRADBURY: Hopefully, I helped capture

realizing once the workgroup gets together, they can put a little more fine tuning to that. But clearly, I'd like to cross those four areas for the workgroups to identify discrete real steps that can be made over the next six months. For some of them, it may be a plan. For some of them, it may be actual accomplishments.

There may be over the next six months identifying key portals where we can accumulate the right information and be hitting the right targets between at the USDA or the extension service and making things up. Now, you all know better than I, for some of the areas, it may be what's the plan.

For example, in the label area, I'm not anticipating putting out PRNs to get labels changed, but I'd like to see in the next months what are some of the challenges before us. What are sort of the categories of areas that are going to need attention? Where are those areas?

Do those areas require new science in order to get it right, or are there some areas where the science is already good enough to figure out some things, but some things will need to wait until our science advances?

So, at least on the labeling front, you have a pretty good understanding of what the landscape looks like and what we need to focus on.

So, those are the areas that I'd like to see, but I think some of them have clear discrete outcomes that we could talk about six months from now when we meet again. Some may be a very clear plan of attack on others.

We'll do a couple of quick clarification questions or feedback, and we can move on to ESA.

Cheryl, why don't you go first and then Susan.

DR. CLEVELAND: It's not a question; it's just to add support to what Don just said. At USDA, I've already contacted some of our leadership about the importance of pollinators. Believe me, it is a high priority.

Like for brown marmarated stink bug, I worked two hours to get to our national (inaudible) to get the word out, as we have a presence in nearly every county and every state. We'll do this for pollinators, too. I've already scheduled to meet with some of the folks. I'll make a point to work with the other agencies that

have an interest. Have no doubt that this is an important issue at USDA.

MR. BRADBURY: Susan, then Jim, then Marylou.

SUSAN: I would love to see a number five on that list -- I like your list. Thank you for doing that -- in terms of improving the incident reporting system on the NPIC site to be really specific for honeybees or managed pollinators. Right now, it's not and you get stopped in the process if you don't know the name of the pesticides that the poisoning occurred with. So, it seems like an easy fix that wouldn't take that long.

MR. BRADBURY: I think that's reasonable. I think it's something that we could take on and figure out how to improve that quickly.

JIM: Thanks, Steve. I appreciate your tone this morning and a direction. That's very positive. On labeling, I think it's very appropriate at this time -- you've kind of indicated I'd rather have it called label review than label statements. It's just a nuance, but there have been statements on pesticide labels for at least forty years that refer to pollinators. I must admit they're all over the board.

It would be the same mindset that I've got -- and maybe you folks do, too -- as what we did with the spray drift thing. The statements are all over the place. So, unification there and making some sense in clarity, we're very supportive of that. That would help our members as well as the industry, enforcement, everybody, happen. I'd rather have us go there first before we start drafting new statements. Let's find out what's on the statement.

The second point is that we are planning, after comments yesterday, to become far more active in BMPs. I, frankly, think there could be a lot of agreement in the attitude on BMPs, particularly if we are going to look -- and I'm not saying we are, but maybe we are -- looking at non-pollinator crops. We're not even against that, particularly looking at non-pollinator crops for BMPs for consideration. There's probably some business logic there.

So, yesterday we were talking about labeling and then all of a sudden we were talking about enforcement. I'm going, whoa, let's talk about BMPs first. I think that approach is very logical. So, we're

supportive of that. I think there can be some agreement on some of the BMPs.

I also want to support what Cindy has said several times about local needs. There are different kinds of bees. There are wad cutters, leak, alcolide (phonetic). It's not just honeybees. So, there are different needs in different segments. I think it's going to end up being more of a local approach on BMPs than we're going to be able to have national BMPs.

DR. VERDER-CARLOS: Thank you for that list, Rick and Don.

So, for labeling subgroup, we would like to really ask for EPA's help on having EPA staff involved, because the conversation can't happen without your help. So, that's all.

MR. BRADY: Right. We're in this. We've got a lot of skin in this game.

MR. BRADBURY: Okay, good. I see no other comments. Now, we'll move into ESA and we will spend about 45 minutes on an ESA update and go from there. So, Rick and Don.

MR. BRADY: So, Rick and I will tag team this

presentation. We'll talk about the National Academy of Sciences review, what we call the usage pilot project, and then registration review in the context of process changes affecting endangered species work. Rick and I will tag team this presentation, as I said.

So, people are probably aware that EPA, the Department of Commerce, the Department of the Interior, and the Department of Agriculture requested the National Research Council to undertake an independent review of science issues that are related to best available data, mixtures, sublethal effects, inert ingredients, and geographic data sources and information.

More specifically, these are the kinds of questions that we jointly, as always, pose. What constitutes the best available scientific data and information? What are the best scientific methods available for projecting sublethal, indirect, and cumulative effects? What methods could be used to assess the effects of mixtures in formulated products or in the environment? What methodology might be used to project effects of inert ingredients?

What protocols might be used in the development

of assumptions associated with model inputs and the use of sensitivity analyses to evaluate the impact on multiple assumptions on interpretation of results? How might the federal government employ uncertainty factors to account for formulation toxicity, synergy, additivity, and so on? And, what constitutes authoritative geospacial information, including spacial and temporal scales that most appropriately delineate habitat of the species and duration of potential effects?

We're happy to say that the Academy initiated this review in spring of 2011. If you're looking for it on their web site, the key words to look for are ecological risk assessment under FIFRA and ESA. That will help you sort of navigate through to see what they are posting as part of their public process.

This is an 18-month process with 3 months for producing the final report. We expect the report to be published in spring of 2013. There are 17 committee members. There have been three public meetings up to date. There is an additional committee meeting only proposed in June. So, the committee is working hard on this topic.

One of the public meetings was a request by the committee for each agency to come in and provide a more detailed explanation in response to questions that they posed to the agency. There have been some follow-up conversations between committee members and agency representatives, not just EPA but the other agencies also.

So, we're letting this process work, obviously. We're looking forward to the report. We hope the report provides a firm basis for agreement among the agencies on some of the basic scientific approaches to bring to bear related to ESA analysis for pesticides.

So, that's our sort of update. Really, what I'm reporting is on another process, the NAS process, so that's why I encourage you to look and see what they've got up on their web site in terms of how they operate and what they are saying about what they are doing.

So, then, the next thing that we just wanted to update you on is what we call the usage pilot project. This project grew out of discussions between the agencies that occurred following the first two biops and thinking about the information that was used to develop the biops,

and whether there was a way to do a better job of us providing information on how pesticides are actually developed for use in either the biop or the development of the RPAs.

So, there were two pesticides chosen as pilots, oryzalin and diflubenzuron. Basically, it relies on the California Pesticide Use Reporting database. The idea here is to sort of try to get -- what this workgroup is focused on is trying to get sort of to that sweet spot between the maximum label rate and what we call the typical rate of pesticide application. So, we know that not all applications occur at the maximum rate all the time. So, the question was, can we get better data for use by all the agencies in doing so.

So, this project is ongoing. Cheryl's group has been heavily involved. I'll pause for a minute. Is there anything you want to --

DR. CLEVELAND: We started this process last year. I believe it's been about a year. It's an ongoing process. It's evolved a little bit from where we started. We have been looking at two pesticides, one an insecticide, denalin (phonetic), and the other oryzalin,

a herbicide. Two of my staff have responsibility. We've looked at use and usage, pulling the data from the California database. It's been very valuable.

What we've worked closely with the services on is helping -- well, for us, understanding how they're going to use the information, but helping to inform them how pesticides are used. For example, on one of the labels, I believe the label has about 30-some crops listed. We've worked with them to help show/demonstrate that it's actually only applied to about, I think, six or eight crops in the state. We talked about the differences. So, it's an ongoing process.

We have regular conversations with them. BEAD, Jack Housenger's group, is also quite engaged in the equal partner in this, I guess. They've provided the labels. I think you guys are doing maybe some of the modeling activities.

I will tell you, we've kind of slowed down a little bit because services had to get these next round of biops out earlier this year. So, they were a little bit swamped. They've got, I think, another one due very shortly. So, we've had a little slow down because their

efforts have been focused on that. But we continue to have, I think, a pretty good dialogue in helping to work on this issue. Thanks.

MR. BRADY: Thank you, Cheryl. I'm going to pass the microphone and the clicker to Rick here.

MR. KEIGWIN: Thanks, Don. So, the next thing we wanted to share with you all is to update you on something we've talked about at the last couple of PPDC meetings, but to reflect now some decisions that we've made relative to some changes that we intend to make to the registration review process starting this fall.

As many of you know, we began meeting with the PPDC subgroup on PRIA process improvements. We've done that now twice, once in July of 2011 and then again last fall, to explore might there be better ways that we could integrate ESA considerations and ESA consultations into the registration review process with the idea of trying to get the most/best available information into the process at an early stage, preferably when we're doing problem formulation on the front end to hopefully streamline and make the process overall more efficient on the back end.

This slide represents the front end part of the registration review process. What you'll see is we've inserted a new step in the process between when the internal team first starts meeting and our first team meeting. That typically occurs about eight months or so before the docket actually opens for each individual registration review case.

We're going to insert somewhere at that point what we're calling a focus meeting. The point of this meeting would be to bring together us and the registrants and others that might be interested to help us focus in more specifically on what the registration review will entail.

We intend to have these for most registration review cases. They would be specific to the chemical, not necessarily to a class. As I said, we want to do these as early on in the process as we can because we think that that will maximize the efficiencies that will come out of the process.

So, very soon, registrants, for each case opening up sometime this fall, should be getting phone calls from the chemical review managers. Some of you may

already have received phone calls from the chemical review manager to begin to schedule those meetings.

We anticipate that, for the most part, they would largely be meetings between OPP staff and the affected registrants. There may be on a case-by-case basis that a registrant wants to bring others in with them. That's fine.

Again, we want to try to minimize any rework that happens. So, figuring out what previous risk assessments said, maybe what work has been done by the registrant and moving towards getting reauthorization in Europe as part of Annex 1, what data might be out there that EPA isn't aware of but might have been generated to help address areas of interest.

I think now that we're about halfway through opening up a number of registration review cases, we see a number of areas, particularly like degredates or other types of exposure pathway information that we're finding that many registrants have because the Europeans, for example, have asked for those.

That can really help to address some uncertainties on the front end. If we can address those

uncertainties on the front end, we think we can have a more tailored risk assessment as we go through the process. In the long run, it saves resources for both the agency and registrants.

We anticipate that as a result, the basic topics that will probably be covered are what we think our data needs will be, as we've been starting our problem formulation, what the status of data that might have been required as conditions of registration. During our internal team meetings, we'll be looking at areas where there's some lack of clarity on the label, where there might be opportunities for increasing clarity, where there's some atypical uses, where getting better exposure related information might be helpful.

So, tree injections might be one example. It's not sort of a classic use, but trying to better understand. So, how often is a tree treated and how many trees on an acre, those sorts of things so we can have a more realistic risk assessment on the front end. As a result, going through that, if we can clarify labels and get better information on certain use patterns, there might be opportunities for some early mitigation in the

process.

One of the desired outcomes would be getting a better understanding of what uses the registrant intends to support going through re-registration or registration review. Some of the companies that we've begun to engage with have already submitted master labels outlining not only the uses that they intend to support but the use parameters that they are typical, that encompass a range of even those rare events where maybe a higher rate or more applications might be necessary.

Reaching agreement on what data will be submitted and generally what time frame. Again, understanding what data might already exist that could address some of our uncertainties. We also think, just basically, it's a good opportunity to commence a meaningful dialogue with everyone involved in the process.

So, some of the initial benefits, obviously, beginning the dialogue early, encouraging more communication throughout the process. Having something that will, for our dockets, when we open it up for broader public input, hopefully stimulate some more

comments that might come in.

Focus on risk assessments that might have recently been done in registration actions and see where we can tailor things for other parts of the label. Basically, get in front of ESA so that we're beginning to address some of those issues as early on in the process as we can. Again, ultimately save resources.

In terms of timing, depending upon the complexity, there could be the need, even, for multiple meetings. Sometimes there are multiple registrants who support different uses. Some registrants for some chemicals support the ag uses, others the non-ag. Maybe that fits in one meeting. Maybe we need to have multiple meetings, depending upon how that works.

We're going to try some different approaches over the course of the fall to see what might work better. There may even be opportunities for some of these meetings even during the public comment period as further information becomes available.

So, our next steps will be to pilot this approach beginning in the fall. We're encouraging the CRMs to be flexible, whether or not a meeting is needed.

We think we'd like to try to do them for all of them on the front end and then begin to develop some guidance on when one might not be needed. How many meetings we might have, the timing, attendance.

Our intention, and I think we mentioned this at the last PPDC meeting, is we would prepare meeting minutes relative to these meetings so that those who weren't able to participate would find those in the docket and they'd be available shortly thereafter.

Again, overall, the plan is to enhance transparency, get early engagement/early involvement in the process, focus on concerns that might exist on the front end so that we're not waiting for four, five, or six years into the process, and maintain flexibility. We do have a team now working on developing some guidance both for folks internally as well as for the registrants so that they know what we think would be helpful to have prepared coming into one of these meetings.

With that, let's see if there are any questions?

MR. BRADBURY: Susan, Ray, Cheryl.

SUSAN: I've got a lot of questions. I'm

really happy to see this going forward. It's going to be a nice change and very much needed. Bear with me.

I guess it seems like a lot of the topics for discussion in those meetings were all about labels and pesticides. I think it's going to be really important to have someone there who knows about endangered species, habitats, and where the issues are.

Maybe this takes the form of you guys getting together with Fish and Wildlife and putting together a one or two pager with issues that are going to typically come up for endangered species so that you have their expertise weighing in early on. Like, things to consider, does this pesticide get into water? Is it highly toxic to aquatic life?

The kind of basic things you need to think about so that you can start deciding about data needs and label modifications that might be needed. So, I would like to see some of that woven into what the review committee does, or maybe have a biologist from Fish and Wildlife Service be part of that committee.

I also know that you guys frequently have private meetings with the registrants, but you might

consider opening that to the public as well. I don't know whether that is possible, but it seems like people with knowledge of specific problems or specific species, chemical interactions, might have something to add to that.

MR. BRADBURY: Thanks.

Ray and then Cheryl.

MR. McALLISTER: My question is sort of related to that line of thinking. When do the services come into this process that you've outlined? Is it after that process is all over or is there any input at the focus meeting stage or shortly thereafter? I've understood that they've been involved after EPA has made basically a final decision on either registration or registration review. Then, there's these assumptions which aren't necessarily realistic. So, are they involved in registration review? At what stage?

MR. BRADBURY: There's a lot of different themes coming into play. Rick and Don talked about the National Academy of Science's effort. That's a huge component to going forward, because a lot of the discussions that Susan was touching on, sublethal

effects, mixtures, how do you integrate temporal and spacial components of an ecosystem into the risk assessment. These are some important activities that the NAS is focusing on.

Some of the challenges have been, how do you do that, and differences of approaches. So, as we go forward, the NAS can create some good insights for all of us to start using, and not just the services in EPA but others who are contributing to the science that needs to go forward. Some of the lack of efficiency and do loops may start to go away.

So, we'll also have an agreement on how to tackle some of those components. How do you interpret those responses for getting a probability of an effect? How do you interpret a sublethal effect with or without an adverse outcome path if we're going to use the NRC 2007 vocabulary? So, I think that will be important.

The services have also pointed out they don't have as many people as EPA has to be on top of 70 cases per year. So, that's something the services are going to have sort of work through in terms of when is it the most efficient for them to get into that process for a given

chemical.

Certainly, right now, we've been viewing it as we get into the proposed decisions -- and Rick and Don sort of went through that, I think, six months ago at the PPDC where you've been working with the services in a more logical spot to come in. It's still more at the back end, but I think the front end is going to somewhat be clarified as we get some agreement on the science.

We'd never preclude the services if they'd like to offer some opinions earlier on. Nobody is going to close the door on getting that input. But the first step that we're trying to get across here is sort of even beyond ESA, frankly. It's ESA related, but there's plenty of work and plenty of do loops that are going on just to meet the FIFRA finding where we look at a label that has sort of an open-ended use instruction.

It's pretty hard to do your problem formulation when you don't know how often, how many times a growing season is it used. So, getting that information, even if we weren't doing Endangered Species Act, that's cumbersome. That's a resource burn right that we don't have the luxury to wait three or four years to try to get

that figured out, when we probably already know the answers to those open-ended questions on the labels.

So, a lot of this is just to try to get as efficient as we can and get the information as quickly as we can. If we can clarify labels and clarify some of these things right at the beginning, then we can focus our resources where we need to focus and not be burning resources where we don't need it.

Cheryl and then Dave.

DR. CLEVELAND: A lot of what you just said is part of what I wanted to comment on. I fully believe that you've got to start somewhere. Starting with the clarification of these uses that drive the entire process just makes total sense. So, thank you for that.

It makes so much sense that I don't know why we need to call this a pilot, why we just don't do it, why we don't go backwards for the ones that have already opened up and do it better. This is the crux of where it all starts. So, clarifying those use patterns just makes really good sense. I know we spend a lot of time in do loops looking at old uses versus what today is really being used, maximum versus typical.

One suggestion I might have is you mentioned master labels -- taking a look at what's on the master label versus the commercialized label. It gets you a lot of information really fast. I don't know if that's part of what this project has been done to look at the pilot usage, whatever, clarification, but that's quick, simple. Then, clarification with the registrant would be highly welcomed.

MR. BRADBURY: Dave and then Cindy.

MR. TAMAYO: I guess I wanted to clarify. The focus meetings, are those only for products where you're anticipating the need for the ESA, or is that going to be sort of more general?

MR. KEIGWIN: It would be more general, because at that point, we wouldn't have even really started the risk assessment. But we think that there's high value in just clarifying labels, as Steve would say, of the FIFRA decisionmaking process.

MR. TAMAYO: So, I guess my point is, sort of parallel with what Susan brought up, and actually Ray, and everybody else, I think that from an urban water quality standpoint, there's going to be a number of

things -- our universe is a lot smaller than yours -- where we do have concerns about particular things.

It seems like early on in that process, and not necessarily that we need to be in all meetings where the registrants are, but maybe there'd be a bit broader meeting available, especially if it were something that we could call into.

A lot of times, or sometimes, we have particular information about how a particular use is impacting us. I think that might be very helpful to have that information right in the beginning rather than later on in the process.

I think if there were a more open meeting, not all of them necessarily -- I think they all really ought to be, but for practical purposes, if there were something where we were on the same call as registrants, we could find out more about what the constraints are and the broader picture of what you were trying to accomplish, that would be helpful to us.

MR. BRADBURY: Some of this will come up again in the next session when we talk about water quality and the concept of a focus meeting and getting early

information. As Rick and the other divisions that are handling registration review, we're posting our reg review schedules four years out. It's on the web site so you can see what's coming over the next four years. Right now you can get a sense of the scheduling that happens.

As we start, there's going to be a little bit of piloting to kind of figure out how to do some of the things you all have talked about. But, as Rick indicated, we'll definitely be posting minutes from the meetings. So, maybe with the registration only one, those minutes will get posted. That may also help people figure out where they -- oh, aha, this may be an aha moment and let's call up the agency to give them additional information.

But those are some of the things we need to work through because we want to make the meetings efficient as well so that we get the information in a tight time frame and then can work with it.

Cindy and then Joe Conlon.

MS. BAKER: Thank, Steve, and thank you, Rick and Don. I'm going to support what Cheryl said which is

that I think this is a very worthwhile change. I think that it is going to be more efficient for both the registrant and the agency and frankly for the stakeholders who want to comment on this. It doesn't do a lot of good for growers or NGOs to think that 20 uses and 20 different routes of exposure are out there when it might only turn out to be 15 or something like that. So, I think it is beneficial for both groups.

To Dave and Susan's comment, I actually think it's not all that helpful for you to attend a focus meeting. As I understand what you're presenting here, you're calling it a focus meeting, I assume, because you're focusing on what is it you want to put into the risk assessment. So, at that stage, there is not maybe a lot of input into habitats and all of that that would change what a registrant is willing or able to support.

So, I really think it would be more productive time for all stakeholders, as I said, to have the input come right after that. So, you know then I'm not going to have any urban uses. I'm not going to have any more residential uses or whatever the case may be so you don't waste your time chasing where is this product in terms of

those kinds of things.

I think realistically people have to understand a little bit that this is the business of the registrant, not that I'm the only one who has input but I'm not going to be really excited about sitting in a room like this and telling you what the (inaudible) are in every specific area and what I'm willing to keep and not keep, but I am willing to have an open dialogue with the agency about I don't want to waste my time and yours on a use pattern that's never going to pass one of your risk assessments. So, if you're telling me up front that you have a concern there, then that allows me to go back and factor that in.

So, I would support strongly the focus meeting. I think it's a good use of time for everybody. But I think to get the most out of it, the registrant is going to have to be comfortable coming into that meeting to have an open dialogue exactly about what those things are.

MR. BRADBURY: Joe and then Mike Willett.

MR. CONLON: I applaud the agency's attempts to provide some significant input into the NRC/NAS process.

It's really needed.

Over the years, the mosquito control profession has had some serious issues with risk assessments that have been done at the agency and elsewhere due to the fact that they're using ag models, like ag discs, that don't really accurately predict deposition on soils, but that was really the only thing that was available. So, we could understand that.

As of last week, a new model has been published that specifically addresses mosquito control aerial spray applications, ultra low volume applications, and it's been validated for each pesticide that's registered for that use. It's been published by Dr. Jerome Slyer (phonetic) of Montana State University.

I would highly suggest that in your discussions with the NAS, that you ask them if, indeed, a point of this whole exercise is to make it based upon best available science, that would be the way to do it. They really need to start utilizing that particular model. Thanks.

MR. BRADBURY: Mike Willett and then Caroline Cox. Joe, we will definitely track that model down, but

I would also encourage you to submit it to the NAS as part of the public (inaudible).

DR. WILLETT: I have a question and then a comment about the usage pilot project. My understanding is you're using the California DPR data to do that pilot project. Of course, that data set that you have is a data set that probably doesn't exist anywhere else in the United States, or at least maybe only in one other state.

How do you envision porting that approach to states that, say, are currently relying on the NAS agricultural statistics service chemical use surveys for usage data and maybe other types of monitoring for water quality? Have we thought about how that might work? I assume that most of the states in the country are in that other category.

UNIDENTIFIED FEMALE: It certainly is an issue we're fully aware of. We've talked to folks about identifying other data sources, other states that may have some information. We're aware that there is information in some states. That's one of the things we're talking about, data, the importance of data. With our NAS colleagues, I'm pretty vocal about the importance

and value of what they produce, especially when it comes to pesticide information. But yes, it's one of the shortfalls that we do have. We are talking about that.

DR. WILLETT: I guess I just would encourage you to think about how that's going to work and maybe run a pilot someplace where other sources of information are different than existing California. I think there is data, but I don't know that we'll know exactly how good it is unless someone actually looks at it.

MR. BRADBURY: Mike, that's part of the plan, try to start with California where they have the best you can get. See what you learn from that and then start to think about how do you extrapolate California information, other places that are similar, or, if there's other information, how do you think about the uncertainty in getting that information. That's some of the next steps after -- if the California data doesn't make a difference, there's not much point in going beyond that.

DR. WILLETT: I appreciate that. I guess I also would like -- one final comment is that if NAS decides only do their chemical use surveys every five

years, it's going to make it even harder for us to try to implement something like that. I've already been to NAS this week, so I'm encouraging anyone else who wants to go there to give it a shot.

UNIDENTIFIED MALE: I think one of the challenges we'll have is if California data does make -- what data can you use and how can you extrapolate to the other states, although that is somewhat dependent on how the service is used with data. I think the way they're envisioning it now is to look at it in terms of the RPAs and whether they will work or not.

So, in some regards, it doesn't matter if we get it right. If we get it right, how is that pesticide used across the country based on what information we have, whether it's through DONE or NAS, and what kind of impact that's going to have on growers, how that informs you in terms of the RPAs.

MR. BRADBURY: Caroline and then Gabriele.

MS. COX: I had a question about the NRC review. I was particularly interested in the question regarding inert ingredients, what methodology might be used to project effects of inert ingredients. Since

we're sort of a year into the NRC review, I was wondering if you could give us any information about what direction NRC is taking with that question?

MR. BRADY: I really can't at this point. Their process is right now in their internal review process. We won't really know what direction they've taken until we see their report. It makes me nervous, too.

MR. BRADBURY: They're collecting a lot of information right now, asking us and colleagues in the services lots of questions. I think they're starting to figure out what their recommendations will be.

Gabriele and then Mark.

MS. LUDWIG: Two questions. One is, having been around with FQPA when it used to meet with registrants and so forth -- I mean, I know when the docket opens, that's really the opportunity for any of us to provide comments on what we see the use as being or issues being. So, you have that step before you're doing the risk assessment. Am I understanding that correctly?

So, just to let everybody know, we all have an opportunity to put our input into EPA before they start

doing the risk assessment. I guess from a grower perspective, there's always a concern when the registrants decide to delete something. I want to make sure they talk to us.

The other question I have, and this comes back to Susan's point early on, is, have the services provided EPA with their maps, with their ideas of where endangered species are so that you have something to work with early on instead of saying, okay, there's a lot of usage of this product in California, and we see we've got these issues? Do you have that information in house?

MR. BRADY: Generally, we try to collect that information as part of our risk assessment process. As we do additional assessments, we collect that and hold it so we can use it the next time. We're also discussing with the services ways in which they could provide us maps that we could use in our assessments. But, as of the moment, we don't have a national database that incorporates all of the information that they have.

MR. BRADBURY: It is one of the topics at the NAS. It came up at the April meeting, the sort of challenge of how do you integrate all these different

knowledge bases. USDA has got data layers. Services has data layers. Our Office of Water has watershed delineation and all this. How do you bring this all together so that you can layer it down and what's sort of the state of that information.

I'm anticipating NAS will be giving some advice, but we're also having discussions inside EPA and with our colleagues to try to frame an approach. It's a massive amount of information. It's no knock on the services; it's just in different places across many, many different field offices. So, it's a challenge for everybody to try to get that information collected, digitized, and available. But it's clearly a big step.

Mark.

MARK: Thanks. My comments relate to a couple things. One is, as you know, in the recent past, there was a minor crop farmer alliance kind of organized stakeholder meeting out in Denver. It was attended by EPA and the services as well. It ended in a -- well, it ended, but nothing, anything.

It was one of the most discouraging meetings that I've ever gone to on this subject. It was

discouraging because I had the sense that -- services aren't here, really, to defend themselves, but they were just throwing their hands up. Yet, the freight train of ESA is coming.

So, I think for stakeholders and for those of us who are interested in it in an academic research kind of perspective, it was a situation where it wasn't hopeless, but nearly. I felt that coming out of that that the implementation mapping approach that EPA had trialed and put up was a real kind of coming together.

I'm wondering where you guys are going on that, and will we see more additions to that process? What's your plan?

MR. BRADBURY: Well, I think the minor crop farmers had their meeting in Denver. I think actually -- I'm not as depressed as you are, Mark. I think what came out of that workshop were -- in Denver -- it may have turned into focus meetings. It may have helped accentuate or refine what we're going to try to figure out from the pilot project.

There's issues of technological and economic feasibility that roll into the RPAs. That came out of

Denver. There's some work going on with services and USDA to get a process going. Everybody has lots to do to start to get some feedback. So, I'm personally not as depressed as you are.

MARK: Well, I don't see it; you do. So, that's why I'm asking. So, that's good. That's encouraging.

MR. BRADBURY: But I think you're seeing it feeding into some of it. I think getting people to talk is good. Yes, it's a problem. We've kind of know that for a decade or more. But if we can start to figure out, okay, what can we start to do to chip away at it -- and bringing people together like we do here coming from different places but all wanting to try to get to a solution, that's sometimes half of the battle.

MARK: Is it possible to get some sort of communication across the process?

MR. BRADBURY: Sure.

MARK: I think that would really help stakeholders and people like me who are interested in the research.

MR. KEIGWIN: If I can add, as Cindy was

mentioning, this was actually one of the big recommendations that came out of that meeting. But there were other things that involved direct engagement with the services. So, there are other activities going on. This is the one that was the ripest one to bring at this point.

So, I expect over the coming months that there could be other things that come forward. We're working with those with the services right now. It has probably taken a little bit longer, Mark, than any of us who were there thought, but even this has taken a little bit longer than I think some of us thought. So, I think probably at the next PPDC meeting we can give you some more information.

MARK: You guys have given me a lot of encouragement. That's good. No insight into that process, so this is insight. Thanks.

MR. BRADBURY: Let me wrap it up with Cindy.

MS. BAKER: I would just add one thing, Mark. It is unfortunate nobody from the services is here because I think what has happened is that EPA carried forward some of the action steps that they had out of

that meeting, which are the kinds of things that Rick and Don just described.

But one of the frustrations that I think still exists that came out of that workshop was a better understanding of how the services are doing these biological opinions. If you look at biop 5 and some of the comments that came out of that, there still is a significant lack of transparency in how the conclusions are reached in that for stakeholders.

So, we had two case studies that we did there at the workshop that I think MCFA is still thinking about some follow up steps to those. It's a matter of everybody's time and resources. I'm not going to speak for MCFA, but they've had a number of things that they've tried to get through and follow up.

So, the services left them with some action steps. We've tried to follow those up. I think they've tried to follow up with EPA, but I think this is evidence of what EPA has been able to do with some of that feedback. But we've still got to get the other side along, in my opinion.

MR. BRADBURY: Okay, thanks. I hope we'll do a

better job of trying to get the word out so people know what's going on. I appreciate comments and the questions.

So, let's move to the next topic on the agenda, which again is reg review, registration review. In this context, we want to try to focus on water quality issues in the context of the reg review process. I'll turn it over to Rick.

MR. KEIGWIN: So, I'll kick it off real quick, but the people who are really going to carry the ball on this are Tracy Perry (phonetic) from Pesticide Re-evaluation Division and Mark Corbin (phonetic) who, I guess right now, is with the Registration Division. But he's really permanently with the Environmental Fate and Effects Division.

Many of you who have been on PPDC before or who have participated in these meetings know that we've been trying to make a concerted effort as part of registration review to integrate water quality issues into the process. We did a pilot several years ago along those lines and made a presentation five or six years ago to PPDC.

We wanted to give you an update on where we are, some renewal of our efforts, particularly with the Office of Water in this regard. So, we're going to have Mark and Tracy come up and finish out this session.

MS. PERRY: Good morning. I'm Tracy Perry with the Pesticide Re-evaluation Division, and this is Mark Corbin with the Environmental Fate and Effects Division. As Rick indicated, we'll be discussing registration review and water quality issues.

We're going to do a joint presentation. I'm going to go over some of the background of our process for submission of water quality data, and how we develop this process, and our experience today in terms of receiving water quality monitoring data.

Mark is going to be going over the roles of modeling versus monitoring and how they complement each other. Then we'll be wrapping up with some of the actions that we're taking to improve our access to state and tribal water monitoring data. Then we'll leave some time for discussion and questions at the end.

So, to date, we've opened the docket for over 300 pesticide chemical cases out of about 745 in

registration review. When we initiate the registration review, the public process, we open a docket. We ask for feedback on our planned risk assessments and the data needs. In addition to that, we ask for information on several topic areas. One of them is water quality.

In our work plan, we note if there are impaired water body listings, and we put out a request for voluntary submission of water quality data. To date, we really have not received much in the way of water monitoring data. This is a bit curious to us as we actually have opened dockets for a number of pesticides for which states have indicated that they're cognizant of impaired water bodies in their states. As Rick mentioned, it's an important consideration, registration review is, to begin to address some of these water quality impairments and hopefully to prevent future water listings.

I wanted to give you a little bit of background. Rick alluded to this, that we actually did a pilot in 2006, which we reported to this committee on. When designing the registration review programs, states had asked us to reach out to them for their monitoring

data.

We thought it would be helpful to do a pilot. So, we worked with the Office of Water and with four EPA regions in seven states. We focused on several pesticides for which there were impaired water listings in a number of regions and states. This was very informative. It really helped shape our guidance to states on submission of water monitoring data, and it led to standard operating procedures that we developed in 2007.

So, just quickly, some of the highlights of the standard operating procedures. We said that states could either let us know, for example, if they put their data into STORET where the data was located, or send us links to their databases, or let us know that they had data and they'll be sending it in.

We identified some of the minimum data elements that were necessary in order for us to use the data in our risk assessments and risk management decisions. We also listed additional information that would be particularly helpful in terms of being able to increase our use of the data.

So, one important thing to note here is that it isn't mandatory that data actually be submitted during the comment period, but it's very useful if we're at least made aware that there is data that states have and a point of contact. Then, we can follow up later on how to get the data.

So, Mark is going to be continuing on with information about how we use the data and how it's related to monitoring.

MR. CORBIN: So, as Tracy and Rick said, I'm permanently in EFAD. I'm a branch chief there now. But, prior to that for 10 years, I did aquatic exposure stuff. So, I just wanted to give you a little primer on how we do our aquatic exposure assessments, not getting into the details of it, but just sort of the concept to keep in mind.

Then, I'll talk a little bit about modeling versus monitoring and how this data that Tracy is talking about gets used and the process for doing ecological and human health drinking assessments, because we also do drinking water exposure. But the primary focus of the impaired water data is for the eco.

So, on this slide, you'll see a couple of concepts to keep in mind. The first bullet there are the questions that we try to answer when we're doing aquatic exposure assessment, which is, what are the risks, who is exposed, where are they exposed, how much, and for how long.

But that has to be balanced by some of these other points that are up there. We do hundreds of these a year. So, we try to do a tiered process that allows us to screen out pesticides that we hope that are not of concern so that we can move on to the ones where our resources are most efficiently used. That's an important concept to keep in mind.

Also, a key point to keep in mind is that the assessment is intended to try to count for variability both in terms of location, the source, the pesticide used, the environmental factors, and also the temporal aspect of that data and how the exposures are being handled in risk assessment. So, you'll see (inaudible) daily versus acute versus chronic issues. So, those are just some concepts to keep in mind.

The first question you might ask yourself is

why do we use a model. At its most basic level, a big reason why we use the model is for many (inaudible) we don't have any monitoring data. New chemicals, new uses that are recently on the market, compounded or not being looked for. But we use it to estimate pesticide concentration in water. Where we do have monitoring data, the modeling and the monitoring complement each other and they aid in interpretation of monitoring data.

It's a way that we can integrate the environmental fate data that we get into a conceptual model and test it with that model. Where we have monitoring data, they sort of link up together to sort of feedback on teach other. Then, one thing they'll give us that's a big benefit over most monitoring data is that we can predict daily concentrations. So, they give us an estimate of the frequency of pesticide occurrence and allow us to put that monitoring data in real context.

So, the next question you'll ask is where does the monitoring data fit in? When we talk about monitoring data a lot, and Tracy alluded to this a bit, the pilot project is the idea of context. So, it's not just the numbers we're interested in, but it's the

context of that monitoring data that's targeted to a particular use pattern.

Is the sample frequency appropriate for the endpoint that we're concerned about? If it's an acute exposure versus a chronic exposure, those elements are very important to help us determine how we use that monitoring data.

As I said before, in EFED, we look at the two approaches as complementing each other, not being opposed to each other. Generally, the more context we have behind the monitoring data, the better usefulness it has for us, particularly for quantitative or potential quantitative use for risk assessment.

So, the same theme comes across here. So, generally, monitoring, in most cases, not all but in many cases monitoring tends to underestimate the frequency of occurrence of acute exposure and peaks can also be missed, if that's what you're concerned about. Monitoring is generally a pretty useful estimate of a lower bound of exposure or it gives us a pretty good sense of what longer term exposures are when we're concerned about chronic issues.

For example, if you're looking for a peak concentration where you have an acute concern and sampling has been done four, six, eight times a year, it's tough to sort of link that up to that acute exposure. That's where the modeling fits in.

Monitoring doesn't always give us a sense of how -- there's not a lot of long term monitoring out there, so the issues of dealing with variability and weather, use patterns, pest pressures that have shifted around, those are elements that can't always be captured in the monitoring data, but we can with the modeling. So, that's where those two things link up.

Now, that's not to say there haven't been examples where we haven't relied on monitoring data for eco and human health risk concerns. There are examples out there. But there aren't as many of them as there are for most of the pesticides that we're dealing with.

So, just to wrap that part of it up, I think the important point, going back to this issue of the pilot is, if you've got monitoring data, get it to us and we'll use it in some fashion. Whether it's qualitative or quantitative will depend on how much of that

contextural information we get with it. But as a risk assessor or former risk assessor, we want it all. So, if you've got it, we want it.

We go out and look for some on our own. We look at some national data sets. The USGS Naqua data is a good example. We'll look at STORET. We'll look at state data where we're aware of it. But clearly, we're interested in more data, particularly if it relates to impaired waters and what we're learning about them.

Data varies tremendously on quality, so it really gets back to the context, and that's what's really important for us. Again, the ancillary data and how that data was collected and what we know about it really dictates how we'll use it for risk assessment purposes.

So, that's really it on that brief overview of modeling and monitoring. I just wanted to put the request for this process improvement that we're going through into context of how EFED uses the data when we get it.

As Tracy pointed out earlier, although we're halfway through it, we haven't gotten many inputs on available monitoring data. So, we've sort of ramped up

our efforts both internally and externally to reinvigorate this process. We understand everyone is burdened by dwindling resources, so we're trying to identify the most efficient and least resource intensive process to get more data.

A couple of things that we've done recently is we've been interacting much more with Office of Water through their regional contacts and their state contacts to engage the water agencies in the states who are doing the impairments and the listings. We had several webinars with them with a couple of the regions.

We're engaging with OW, Office of Water, wetlands, oceans, and watersheds. They have regular dialogue with the regions and the states. So, we're interacting with them more in terms of communicating our message of the need to get this data, how the reg review process is aligning, where their opportunities are to get that data to us.

I think, as Tracy said, the public comment phases are, how that pilot program was set up was to get that data. But there are several points in the process where I think data can be submitted to us and we would

generally be willing to consider it anywhere up until close to risk assessment time, because the more we know, the better informed our risk decisions are.

I think with that, that's about all we had for you on the process improvement.

MR. BRADBURY: Let me just provide a little bit of backdrop, going back to 2007, 2006. When we started registration -- as re-registration was ending and we were starting to think about registration review, there are a number of chemicals coming in near the end.

We're getting a lot of comments from water boards and others in states indicating their concern that our re-registration decisions could be such that it could lead to future impairments, because they had examples of the existing use patterns they thought were on the verge of becoming 303(d) listing impairments or were already 303(d) listing impairments for the given compounds.

The reaction from our program was we shouldn't be consciously creating situations to increase 303(d) listings. If that's really happening, that's not EPA; that's sort of the left hand not knowing what the right hand is doing. All we've done is handed off a potential

impairment to the states to incur the resource (inaudible) to deal with a 303(d) listing in the Office of Water. That doesn't make any sense. It just doesn't make sense.

But, having said that, we need the information that's behind the proposed or the actual 303(d) listing so we can figure out what to do with it. What can we learn from that information? We all know some of the 303(d) listing impairments are just for the word pesticide. In fact, there is no monitoring data that was associated with some of the listings.

On the other extreme, they're very robust 303(d) listings with highly sophisticated watershed level of mass-balanced modeling going on and where the chemical associated with the impairment is pretty straightforward. That's what was going on, and everything in between.

So, part of the backdrop to this was to make sure we were getting access to all the information that was behind, suspected, or draft or actual impairment so that we could do a couple of things. One would be, well, if there's an impairment in a certain group of receiving bodies in this or that part of the country, let's zoom in

there and figure out what's going on because we have the ability to make our label decisions national or down to subwatershed if we want to.

We've got the GIS capability. We have the ways to do that. Work through the risk benefit and everything that needs to happen. But the general principle is we shouldn't be registering pesticides that are leading to 303(d) impairment, but we've got to have this sign behind us.

Also realize if you saw some examples where that was happening, it may not be just for that specific place. There may be certain attributes about that place, soil conditions, cropping patterns, hydrology, that could be applicable to other places wherein perhaps you couldn't do the monitoring.

It gets back to Mark's point. You can't monitor every stream reach in this country, so how do you blend what you know with some monitoring some places and think about how you might extrapolate that to other places to have an informed process going in.

So, we thought we had things in pretty good shape. All the work with the regions and the states and

we figured out a way to do it. You don't have to send us anything; just tell us where that web site is and we'll go get it. If it's in STORET, we're cool. Just maybe make sure we know where it's located in STORET. No burn rate, no burn rate.

So, the first few cases in reg review come along and they're chemicals where you really wouldn't expect a lot of water quality issues. We sort of picked some early ones in reg review just to kind of get the system going, limited uses. So, at the beginning, that's not too surprising that we're not seeing much coming in to problem formulation because we just know enough about these chemicals. It's pretty unlikely that anybody is looking for them, much less would they be in receiving bodies.

Then the OPs start and the carbamates start and the pyrethroids start. We're starting to go, oh, this is kind of weird. At the end of re-registration, there was a lot of concern about the OPs and the carbamates and the pyrethroids about water quality and other things. Why aren't we getting any information coming in?

I think what happened is that we got a good

start in 2007 and then (inaudible) chemical that had a water quality connection. So, that was part of it. It kind of fell into the background. I think some of our discussion with Office of Water was that, to be fair to the state agencies dealing with water quality, they were feeding the information in to the region and the water folks in the region.

EPA sort of lost track of what we were doing, so the handoff wasn't happening, because some of the states said, what do you mean, I gave it to EPA. They did give it to EPA. We, in EPA, didn't keep track. EPA has got the different pieces and we didn't get EPA all flung together.

So, what we have been doing over the last month or so is trying to reinvigorate the principles of that 2007 SOP to try to get to where we wanted to get to make sure we get that information in. So, what we want to do today is certainly answer any questions if people want to know how we use monitoring data, but also any thoughts or impressions on what could work or what could work better. Or, if this is all news to you, that's helpful for us to realize that we haven't gotten the word out as to what we

want to do and how do we move forward and get that matter.

So, Mark and Cheryl and Dave will be the first three.

MARK: I really appreciate the challenge and understand the poor quality data and the consequences of model output. As a modeler myself, garbage in/garbage out, a real challenge, and how do you get around that when you have to make decisions.

It's interesting the comment about peaks. It's logical that a peak flow of a pesticide and the rate of a flow of a river or the half life in a lake or a pond can be modeled and you can get some reasonable estimates. But little data really hurts.

The comment I have is that there was a recent whole series of articles in the American Entomologist. It was really interesting because what this addition focused on was the citizen scientists. To just give you an example from bumblebees, there's a number of species of bumblebees in the U.S. They're not very cryptic. You can see them. They fly around. They're very noticeable. A lot of people are fearful of them. They have very

distinct patterns of yellow/black on their bodies.

So, the effort was to look at are we really losing some of these species nationally. So, they went out to basically people, and especially kids, who are interested in bees. They went out and they did these observation things. They just gave people simple little cameras and they went out and took pictures of these bees.

I'm not a taxonomist, but I could identify them immediately. I can even sort them by male/female. The constructed a little diagram and now we have almost a national picture of what's happening with those endangered and not so endangered bumblebees.

The illustration I'm making is that this citizen science thing in the context of arthropods and water as indicators is something that could be done clear across this country and could be done in such a way that you would have species identification and population densities if you train people on how to do this. This has been done before.

Actually, looking at the EMAP process, which EPA, probably one of the things EPA has, in my opinion,

done nationally, tremendous process. That experience, relative to these indicator species, could give you a lot of quality indicators on how our water systems are going.

I wonder if the citizen science approach to this -- just using high school kids who are interested in biology, teaching them how to do it, sending them out looking at the true quality of these streams and keeping longitudinal records over time, might be a much better approach than trying to guess what's going on. Just a suggestion.

MR. BRADBURY: I appreciate that. If you don't mind, from what Mark said, the Office of Research and Development developed the Environmental Minoring Assessment Program, which is a way to do a stratified statistical survey of the nation's waters. In fact, that is now part of the 305(b) reporting process. You have to do it under the Clean Water Act.

By and large, the states are using that stratified random design so we can say what percentage of the country's stream miles have aquatic invertebrates that reach this level of biological integrity. So, you can actually start to say what percentage of stream miles

are meeting different levels of biological quality. It's done for streams, it's done for lakes, it's done for wetlands.

Our office is plugging into that with our labs to try to at least get some representative pesticide information as part of that statistical survey. That gives you a good picture of what's going on nationally based on what percentage of stream miles, but it isn't necessarily a statistical representation of the percentage stream miles that are in low crop production. That's not how the sampling goes.

So, similar to what we're talking about here, I think it's complementary some of the things you're talking about, Mark, but it's how do you get data that's more specific to where the pesticide is being used. But your point is well taken, especially in how do we integrate different kinds of information.

Cheryl, Dave, and then Ray.

DR. CLEVELAND: So, there's a couple of things that it seems I need to comment on here. First of all, highly support calling for more monitoring data, absolutely. I have some concerns, though, about when we

call in monitoring data, how are you going to use it?

This posting that was in our packet, the little blue thing that you're asking for data, says OPP routinely considers water monitoring data and the PDP data in its human health assessment. As part of the dietary assessment working group with NCLA, we have looked very, very hard for examples for when monitoring data has actually been used in decisions for human health risk assessments. We can't find very much at all. It's like looking for a needle in a haystack.

So, it's good that when you talk about monitoring and modeling, that you say you want to use monitoring to help inform the context of the modeling or vice versa, but the real rub comes down to these peaks. The peaks are what drive the risk assessments.

If you always default back to conservative models because you might have missed a peak, and you keep looking for that information on an individual chemical, you're missing an opportunity to look across the body of the monitoring data that exists right now that could be used to improve some of these risk assessments.

The reason this is so important is we have a

real chasm in the way that the dietary assessments are done right now between food and water, drinking water. We have collected examples of where the entire dietary risk cut right now is full of modeled water information, modeled values, that aren't supported by any kind of monitoring information from a conservative screen model. It's 99 percent modeled water, 1 percent monitored food.

That is problematic in moving forward and continuing to support products. So, this is very important that we take the monitoring information seriously and we move it into a better way of using it through registration review.

MR. BRADBURY: Dave and then Ray.

MR. TAMAYO: I think some of the reasons for the (inaudible) of data is that I know that it's part of the regulated community. We're required to do some monitoring, but it's not -- I mean, it covered a lot of the things that might actually be in the water. We don't know and we're not going to -- so, our monitoring is actually very targeted on things that --

I know there's already a hint that there might be a problem. Fortunately, for us, monetarily it's a

narrow list. You're not going to find permitted agencies like us volunteering to expand that list because, well, quite frankly, we might find a problem, but the other thing is it's just too expensive.

I think that it would be -- and I already mentioned working with USGS and probably ought to be working with the states and figuring out what are the things that we really ought to be looking for and having ambient water surveys, really looking on a more targeted basis. Based on what you know about the chemicals already, the things that are most likely to be of concern in supporting a more concerted than targeted program.

The other thing is, the way that the requests are made, I'm wondering when -- there's a lot of notices that come out all the time in my registration review. I know the folks in our state water board, they're not monitoring those. As a regulated community, we kind of monitor those. We're aware of a fair amount of what we think might impact us based on focusing on things that have urban uses, best we can tell from our friends in the industry and also just what's on the label.

I really doubt that our state water board has

somebody that's looking at the federal register and looking at the detail that would be necessary and say, oh, okay, well, I think I know about that. Even if there was somebody in the Office of Water who was looking at that, they may not be the same person who is aware of the urban water problems that have been identified in southern California because they're not part of the stormwater program.

So, in your dealing with these bureaucracies that may not be -- they may not have the right person receiving the request for monitoring who is aware of in more detail about what the other problems are. So, it's sort of an organization problem. I think that in other states that may be even less proactive than our state, that you're even less likely to get that sort of information.

So, I think it might require some more detailed work and working with the states. Quite frankly, from a local agency's standpoint, we've made the effort and we had developed contacts within the regions. But I don't think that most local agencies are really working closely with the regional offices and letting them know here's

our problems.

I think, actually, most local permitted agencies really are kind of afraid to work with who they perceive as their regulators and folks who might want to use that to put more permit restriction on them. I think that that probably -- I've had trouble finding people in other parts of the country, even when I know that they have problems, to sort of buy into this idea of well, we really need to get OPP that information.

I think people say, well, we've submitted it. That's it. We're just going to wait for somebody to come get us. That hasn't been our strategy. I think it would be helpful for local agencies to understand that there's a good faith effort on OPP's part to try and fix that, the problem that you described. It just doesn't make any sense to be registering things that are going to end up being a problem. I think that would be helpful, too, because then folks might be more in a cooperative mode.

I mean, you're going to be coming in and saying, we're from the government and we're here to help. They're probably not going to believe you. I think you might be able to show them some examples of how it's

worked to at least our benefit in California. I'd be willing to help with that.

A lot of this is really just kind of a devil in the details and having somebody who is kind of directly working the problem. I understand that that's a lot of what Tracy is going to be working on, or has been working on. I realize it's a difficult problem, but that's what it's going to take, is sort of working through those details. I'm just talking about from the urban standpoint.

I think there's probably a lot less information on the ag side because they don't even have a permitting thing or a lot of state directed monitoring. In California, it's a little different because we do have some monitoring from the ag community.

MR. BRADBURY: Ray and then Cindy.

MR. McALLISTER: I feel fortunate in my job responsibilities that in large part I can let my colleagues worry about water monitoring. So, I use that as an excuse to ask what I think are some naive questions.

In the presentations this morning, we've heard

send it all in. We want everything you have. Here's how we use it. But I still don't understand what you use that data for. How do you use it? What do you do with it?

MR. BRADBURY: I encourage you, Ray, to read some of the SAPs that have been on atrosine (phonetic) over the last -- it was 2003 forward. I think it provides -- focusing on atrosine because the atrosine SAPs were actually fundamental, scientific input on how to use monitoring data, how to use modeling data, how to think about frequency and duration of exposure, how it links into different toxicological endpoints and how that factors into the dose (inaudible) interpretation between health and the environment. So, I think those documents are pretty darn clear as to how to use the information and some of the uncertainties we're facing.

As Mark indicated, if the risk assessment deals with an exposure, they can last a day or two. That's the critical window of exposure. Your monitoring data is based on sampling four times a year. We've gone to the SAP and they've agreed with our probability analysis. The odds of you picking that window, if you're only

sampling four times a year, is probably close to zero. So, that's pretty hard to use.

But if you're interested in a lifetime exposure because of a human health endpoint that may be associated with years and years and years of exposure, that monitoring data combined with some of our modeling data may give you some insight as to how to look at multiple lines of evidence to put that exposure together.

The record is pretty clear, I think, Ray, on how to use it. What we want to make sure is that if there's good information out there that we didn't know about, that's just a shame to lose it. If some of that information has been used to formulate a proposed or an actual 303(d) listing impairment for aquatic life, that's important information to see because it can give us insights into our problem formulation and perhaps down the road as we go into our risk assessment.

MR. ALLISTER: Well, I need a more basic answer than that. I assume you're looking at exposures to organisms that may be vulnerable to the pesticide toxicity. The aquatic organisms? People who drink water. The data you're asking for, how much of that is

finished drinking water residue samples?

MR. BRADBURY: I don't want to spend too much time on this. Sometimes we do have finished water. Working with USDA and USDS, we've got studies going on to take a look at to what extent does chlorination or oxidation of the water change the ratios of the parent compound of the metabolites in raw versus finished water. So, in fact, some of the monitoring data we're getting is giving us insights into how that changes or doesn't change as a pesticide goes through a water treatment plant.

MR. McALLISTER: You have 10 years or more of drinking water data from the PDP program at the request of OPP. Are you using that in dietary risk assessments?

MR. BRADBURY: Mm-hmm. We're starting to. A lot of the work with PDP was making sure are we sampling in the right places and are we sampling with sufficient frequency so that we can use it in the context of the toxicological information.

I'm sorry, Ray, I shouldn't be talking to you, but I do want to push back if there's a concept of EPA doesn't know what to do with the data if we've got it.

We've got a pretty strong scientific peer review record of how to use the information.

What we want to do is make it clear that we're not asking people to do extra work to send us information or to do new monitoring unless we can get USDA to do a little bit for us. We just want to make sure that if it's out there, we can get it.

Some of the information may be very valuable and spot on to the questions we have to answer; some of it may not be. But it's better to know what you know and not be wondering what you don't know as you go forward in the risk assessment, especially if that chemical has been associated with concerns due to either drinking water exposure or a chronic life --

MR. McALLISTER: Well, the concept of we don't know where the peaks are going to occur and sampling only with this frequency doesn't tell you that.

MR. BRADBURY: Well, I think --

MR. McALLISTER: But I want to make a comparison with food residues. You got all the peaks for the food residues? Do you have all the peaks for the food residues? I think there's some comparisons that can

be made here in terms of what you can use in connecting a dietary risk assessment from both food and water and make some rational decisions with the data you have in hand.

MR. BRADBURY: Cindy and then Gabriele.

MS. BAKER: You might not like me any better, but I'm going to give you a suggestion for what I think a solution might be. I think you heard it from Cheryl and you just heard it from Ray. I can tell you there's a disconnect within the registrant community about what you guys are doing with drinking water. Valid or not, there's a disconnect.

People don't understand how a risk cup could be filled with just a drinking water model. I've got what I would propose, and I didn't even ask Cheryl because she might tell me no, is that Cheryl and I -- Cheryl is the chair of the dietary working group for Crop Life. Both of us are PPDC members. Come in and I'll bring my two chemicals as an example, risk assessment you've already done, and let's walk through it and see if we can get to what the misunderstanding is.

I don't want a lot of time, and I'm not asking anybody to change their risk assessment or anything. But

I think it's in everybody's interest if we're not just sitting here and saying, we don't know what you're doing. You're all screwed up. You're not using monitoring data. We don't understand how you got to (inaudible). The two of us can sit down and walk through those two and come back and explain it. Then, maybe there's a way that we can move forward.

MR. BRADBURY: Gabriele and Mike.

MS. LUDWIG: I just want some clarification. You talked about the ancillary data that you would need. I don't know for this SOP -- did you in the SOP sort of say, here is all the ancillary data that we would love to have or give a model of here's our ideal data set? It's very clear to me that that seems to be the driver for how you choose or choose not to use the monitoring data.

I don't think that's -- I think that's maybe where some of the disconnect is, about what assumptions you make or what information you need and whether that exists to go along with these water data points. You just say ancillary data. I think there's actually a lot hidden behind that statement. So, if you could go into that a bit more.

MR. KEIGWIN: The answer is yes. The SOP did describe the types of things that we were looking for as ancillary data that would provide the context to the monitoring that would be submitted. We also described in there how we would use the monitoring data with and without that ancillary data and how it would feed into our exposure assessment. So, it is all there.

MS. LUDWIG: Can you give us some examples here right now?

MR. KEIGWIN: Sure. The objectives of the study that the monitoring was collected for, was it targeted to a particular use or was it a broad sampling across the landscape? That helps us understand whether the exposures that are seen are relative to the chemical use pattern that we're assessing. Detection limits, are they reported? What are they? If a detection limit is 100 parts per million and we're getting nondetect, it doesn't tell us a lot about it. So, that's some examples.

MS. LUDWIG: And where does pesticide use fit in?

MR. KEIGWIN: We'd love to have it. We'd like

to know specifically where use is in the field relative to where monitoring has been conducted. Sometimes we get that. Atrosine is a perfect example of that. The monitoring that's been done has been targeted specifically to pesticide use, to atrosine use. That's an example where the monitoring data is being used quantitatively for risk assessment.

It's difficult because, as you heard on the use pilot thing, there's not a lot of good use information out there. Oftentimes, the states would know better than we where their pesticides are being used and when. Timing is another example. A pesticide applied in the spring, monitoring in the winter might not tell us that the pesticide isn't necessarily there. So, those are examples of that. But usage is a limitation.

MR. BRADBURY: At least knowing where and when the sampling occurred can give us some insights based on what we know about the cropping pattern and pest pressure management.

Mike and then Caroline, and then we've got to move on to the next topic.

MIKE: First of all, I appreciate everybody

taking the time to go through this. Obviously, there's a lot of questions around it. I'm starting at a much lower level and trying to understand how the modeling and the data that's collected in the field is integrated. Probably a lot of people are.

One of the things that seems important to me to understand in terms of improving -- I work with growers in states where they are actually doing service water monitoring. They're trying to do it in a way that can be useful for lots of different purposes.

So, one of the questions I guess I would have, and I could probably get the answer in a sidebar, is -- obviously, the models used have been validated at some level. In looking at how those are validated probably in a number of different scenarios would help me understand how frequently you actually had to monitor in the field to see how closely it matched the peak issues that you're coming up with.

So, if there are some references that I could have and look at just for my own edification that would help me understand what kind of sampling frequency we needed in order to validate a modeling and catch those

peaks, that would be very useful to me.

MR. BRADBURY: We can definitely do that. We can provide to the PPDC web site the links to some of these SAPs I just described as well. These concepts came up actually with the NAS in the ESA meeting we had in April. We pulled together some of the validation information for the prism exam, the kind of models we're using and how that relates to validation evaluation of the model -- so, we'll get those on the PPDC web site and then people can get to that.

Caroline.

MS. COX: I think if you look over the long term past, there's been a lot of times with water quality when there's kind of been a confusion between lack of data and lack of a problem, so that there's been times when lack of data has been interpreted as there isn't a problem.

I just wanted to commend you guys for the steps you're taking to avoid that confusion and also just encourage you to keep moving in that direction.

MR. BRADBURY: Okay, thanks. Susan, I'd like to kind of keep us on schedule, if I can. You can go

quick.

SUSAN: Just a quick response. The USDS has a really fantastic study that they did in California where they monitored the plume of diazinon down the river in the winter with the storm. So, they did stormwater monitoring. I think they actually did catch a peak there. That's a really interesting study to look at.

But what that means is your water monitoring people need to be ready to go at the drop of a hat, day or night, weekend, or weekday. So, those studies don't happen very often.

MR. BRADBURY: Okay, thanks. I apologize if I got into that one a bit too much. I think it's an area we can solve, but it's complex. There's lots of layers to it.

So, we're going to get an update now from the PPDC workgroup on 21st century toxicology. Jennifer McLain is our associate division director for the antimicrobial division. She is going to lead this discussion, so I'll turn it over to Jennifer.

DR. McLAIN: Good morning. As Steve mentioned, I'm Jennifer McLain, and I'm a chair of the 21st century

toxicology and new integrated testing strategies workgroup. The PPDC has charged to this workgroup to focus on communication and transition issues as EPA phases in new molecular and computational tools.

In October, the workgroup put on a biomonitoring workshop, which was titled Diagnostic Tools and Biomarkers and Pesticide Medical Management Exposure Surveillance and Epidemiological Research. So, looking at the vision advanced by the NAS, which is graphically described behind me, the impetus for this workshop was to look at the tools necessary to implement the outer ring of this vision, which is the population and exposure data portion of the NAS vision, not just to have all of our discussions and meetings focused on the core of the toxicity testing, which we had looked at the previous year.

Since last October, we've been, as a workgroup, working to develop some project proposals based on ideas that came out of that biomonitoring workshop and the PPDC discussion that happened the next day. We have two subgroups that are going to be presenting project proposals today to you let by Cheryl Cleveland and Jimmy

Roberts.

In the interest of time, since we only have a half hour, we're thinking that it would be best to present them both back to back and then have a discussion about both of the proposals together. They're very interrelated.

Then, we're going to open it up for discussion. Near the end, when we have about five minutes left for this session, we're going to turn it over to Jeff Morris from OPP who is going to talk a little bit about stakeholder interaction with respect to 21st century science also.

So, the feedback that we'd like to hear from you today about these project proposals are whether or not the project goals that we're presenting are clear and the plans are clear, and then your opinions on the best way to accomplish the goals of these projects.

So, I'm going to turn it over. I think, Cheryl, you're going to go first, right?

DR. CLEVELAND: Well, I'm changing hats. My last comment was as a registrant. My comments now are to represent the consensus view of a group of people which

are listed. We decided not to make Power Points, but you have a handout from both groups. So, I would encourage you to pull out the 21st Century Toxicology Workgroup Project Proposal to the PPDC.

For the longest time, we were known as subgroup A. We finally got a name, and we are called CARB, which is the Clinician Access to Regulatory Data on Biomonitoring, but for a long time we were just subgroup A. So, the charge to our group was to look at data and information, identify it, how existing data relevant to diagnosing overexposure to pesticides could be made more accessible, and how you can use it better.

We had five members in our workgroup. Four are on the PPDC. We had the medical community, the clinician community, and the registrant community working on just this project proposal. The membership is there. What I want to do is switch over to the back of this sheet and talk about where we went before we get to the proposal, because we had --

This was a broad enough topic that we really needed to have everybody on the phone to make progress. So, we had three meetings over the course of the interim

period here. We first tackled this thinking that it was the five people on the phone that were going to actually kind of do this.

We quickly realized this is a very big and broad area. So, we then came back to we need to just outline what would need to be done to make progress on this. So, the first thing on the back page says that the project and the scope of the project is really going to determine how fast you can move forward with something very tangible on this, because it can get broad very fast.

So, where do we go? Well, the workshop was clearly a place where the clinicians were seeking improved methods to have diagnosis for human poisoning. That was part of the outcome of the workshop. So, that set the stage for this workgroup.

The other thing that was clear in the meeting last year was that registrants produce a large amount of data and information that's relevant to these questions on biomarkers. Is there a way to at least begin to close the gap between the lack of understanding within the medical community, clinician community, and what

registrants are producing.

So, we did spend some time in what I would call a pilot at this point. The five members on the phone got together. We talked through the test guidelines of what is typically called in under a registration process. I find that to be rather dry, so we spent more time working through an example and went out to what is publicly available.

The summaries that come out, the relevant information, you don't have to dig down into raw data from registrants to understand what's available in the metabolism studies from rats, what's being developed, what the target organism that comes out of tox studies. So, all of that is very accessible and comes through regulatory (inaudible). So, we spent some time there.

Some other things that we did is we clarified what biofluid methods are being called in for Annex 1 in Europe. I was misinformed the last time when I spoke that I thought pretty much Annex 1 was going to create biofluid methods for all pesticides in Europe for blood and urine. That was incorrect.

There are some categories for which they will

be produced, and that has to do with toxicity and/or if registrants are performing worker exposure studies and/or if they want to do it for product stewardship purposes. But not all EU pesticides (inaudible) will have urinary and blood methods, but there will be some.

We spent some time also talking around what is the process for EPA to collect worker exposure information. Again, that would be information really relevant to what biomarkers are available for clinicians and testing.

So, this back page is kind of where we all went. Probably relative to tox 21, this fourth bullet point is probably the place that ties in most with tox 21 and in which we would like to consider what other metabolomic or proteomic or other kinds of excretion products would come out of a more tox 21 testing to be used a biomarkers. We really didn't get very far on that.

Where we got to was this is very big and it needs focus. So, we turned it into a project proposal that if you're really going to make progress on this, you'd need to go through and dig deeper into these areas

and basically turned it into a project that says the key activities would be further explanation and specific exploration of what exists today.

We did a little pilot. We talked about one chemical. But, if you want to get a more comprehensive understanding of this, you're going to have to go deeper. Then, determine the existing needs. This doesn't mean do clinicians need more information. We've already determined that.

What specific information? One thought we had would be to possibly conduct a survey. You could learn through a survey process what are the needs and where are the gaps relative to what exists today. Then, it's really simple; it's not rocket science. You see what you've got, you see what you need, and then you try to make some decisions about how you could move forward and kind of close the cap for human exposure assessment.

So, we had different opinions across when we were working through this. First, we thought we were going to kind of do this, at least in a pilot way. Then we said this is too big. So, then we thought we were making a proposal for EPA. EPA said, no, we're really

making a proposal back to PPDC.

So, the bottom line is, we think there's a merit in exploring this quite a bit deeper. We think it needs to have focus, which I think Jimmy's group would help focus this project. Then, the question I have for the PPDC group is two-fold. Is there something missing that you don't see here? Would you support it? How would you support it?

It could be very resource intensive. It could continue as a PPDC subworkgroup. I don't think we've lost all our momentum. We could probably take on some of this, but if we did, we would need to add more people to this. We've listed a number of ESA needs. We would need to have some clearer boundaries around how we could move it as a subgroup versus how EPA might have other ways of moving the project forward.

MR. ROBERTS: We're going to move to the next handout in your book. The title is Pesticide Priority List Subgroup. We weren't quite as creative at coming up with an acronym yet, so we'll still have to work on that.

One way to look at this proposal is kind of narrowing down the list a little bit for Cheryl's sugroup

so that we can focus on a few pesticides of perhaps the greatest clinical concerns. So, besides myself, Matt Keifer, Caroline Cox, Erik Janus, Virginia Ruiz, and Valentin Sanchez are all in the subgroup. Everybody but Erik is on the PPDC. I didn't see Erik earlier.

Our goal is to develop a priority list of candidate pesticides to explore the process developing human health pesticide biomarkers. It says for research and clinical applications. It really is for both, but I really want to try to emphasize the clinical applications. Specifically, somebody might come in with acute poisoning. The clinician has got to figure out what it is. That was really the subject of our workshop in October, so I'm not going to belabor that point.

We do have our own list of key activities. I'm not going to read every single one of them, but I want to focus on a few. Certainly, we also need to expand the workgroup. It's a good bit of work, but we also want to broaden the expertise to make sure that we have everybody who would be the right people in the group. Included in that would be some folks from NIOSH and CDC, some other primary care docs, especially emergency physicians as

well. There's also some other folks in EPA that would be very helpful in this.

We also want to look at those acute and chronic situations, probably emphasizing acute first. Erik made a good point yesterday. We're probably going to end up with two lists, one for acute and one for chronic. But again, the other important thing is that we're going to look at the set of criteria to select the priority pesticides.

What I mean by that, for example, acute toxicity is certainly of importance. I think almost as equally important is going to be frequency of exposures, exposure incidents. I think everybody in this room probably knows that pyrethroids have pretty much replaced the usage of organophosphates. Most recent look at Poison Control Center data of human poisoning exposures, pyrethroids are now number one on the list and organophosphates actually moved down to number six, as far as human exposures.

The other important distinguishing factors could be method of exposure and then some of the other symptoms that we find. Specifically, with

organophosphates and pyrethroids, both of them, although somewhat different, do have a similar constellation of symptoms as far as how the patient might present.

It's very important to use the correct treatment for organophosphates poisoning, but it's also equally important not to be using a whole lot of atropine on somebody who has pyrethroid poisoning instead of organophosphates poisoning. So, it is important for the clinicians to distinguish between them.

So, on the back side, I want to emphasize this is an extremely preliminary list. This is just a starting point to begin to look at a list of our pesticides. I only have four groups listed. Our group has four groups listed, the organophosphates, pyrethroids, the neonicotinoids, and Fipronil. Again, this is where the selection criteria is really going to drive the process. We've sort of developed this little draft list to kind of test out our criteria and see how they really fit.

Again, same as what Cheryl said, we're looking for input from PPDC. Is there a major component that we're missing? Any other comments?

DR. McLAIN: Thank you very much, Cheryl and Jimmy, and thank you to the subgroups also. There was a lot of work put in just to making up these project proposals, as Cheryl mentioned. They weren't easy questions to tackle.

So, I guess I'd just like to open it up for comments and questions from the PPDC.

MR. BRADBURY: Susan and Marylou.

SUSAN: Thanks to everyone who is doing the work on this. One of the things, though, that strikes me as one of the factors that you would need to consider isn't just the frequency of the exposures and possible poisonings and the severity, but the number of times when someone presented with an unknown.

If you have frequent poisonings but they're always known, then the need and the utility of a biomarker for those seem less relevant than something that seems to be presenting with -- that is more often initially unknown poisoning problems.

So, that's another factor that I think you need to consider so that you're not wasting time developing biomarkers when something is always presented when it's

known, or more often.

MR. BRADBURY: Marylou.

MS. VERDER-CARLOS: Probably just a clarification question. So, you're thinking of the systemic pesticides more than the non-systemic pesticides because you're looking at biomarkers. Is that my understanding? Not the irritant pesticides, because with biomarkers, then it becomes a systemic group of pesticides that would go through the body and it's a biomarker.

MR. ROBERTS: Yes. Pretty much anything that's going to have some systemic symptoms is poison. So, for the most part, yes, it's exactly what you're saying.

MS. VERDER-CARLOS: Okay. So, actually, for chronic studies, you've probably -- I think in the last 21st century toxicology workshop we had, we had Brad from UC Berkeley working on the Chimako (phonetic) study for the organophosphates. Are you looking at incidents on a five-year scale from the time that they were exposed, because those are the chronic effects I would think? Then, for acute, that would be the peak and the -- you know, just a thought. Then, of course, California's

Pesticide Illness Surveillance Program, which works closely with Geoff Calvert's NIOSH program, has a lot of acute toxicity data that would be available. It's online.

MR. ROBERTS: All of the data you mentioned are things that we would be looking at to kind of help us distinguish our list and certainly to make the work go forward. Actually, I named Geoff by name in one of the key resources. That information is going to be very important.

MS. VERDER-CARLOS: So, I'm giving more work again to our department, but we do have a staff that works only on the illness surveillance program, which is probably more in touch with Geoff.

MR. ROBERTS: Okay.

MR. BRADBURY: Matt and then Caroline.

DR. KEIFER: Could someone wake up the slide? I just want to point out that these ideas which are starting to gel in these workgroups actually were introduced, it seems like, four years ago. I'm not sure. Can we date that, Steve?

UNIDENTIFIED FEMALE: Five.

DR. KEIFER: Five? Five years ago. I think they may have predated this particular report, but this particular report with the outer ring indicating the population and exposure data as an essential tool to validate the internal workings of the toxicological predictions that we develop in the new toxicological models, this fit right in with those.

One of the things that Jimmy and I have seen as clinicians working a lot with individuals who have been poisoned by pesticides, not having the tools to make accurate diagnoses or not having the tools to confirm particular exposures, both of us became very interested in this possibility and it was strongly reinforced by the NRC report.

It's a little bit like trying to do water sampling without having methodology. This is really what we as clinicians are asking, that the methodology be made available for us. We believe that it was literally in some of the dociers or the dockets that the materials -- the rudiments of those biomonitoring tools might actually be there.

I really appreciate Cheryl's presentation. I

think she did a great job of saying exactly what we were talking about in our workgroup. I just wanted to make an emphasis of the importance of this particular concept. Thank you.

MR. BRADBURY: Caroline and then I think Susan.

MS. COX: I just think it's incredibly exciting that the workgroup wants to move forward on the prioritizing biomarkers. I think it's something that probably should have happened a while ago. But, since it didn't, I think it's going to be a really useful and effective tool. So, I'm just really supportive of this process moving forward.

SUSAN: I am, too. I think it's a great idea. But something struck me as I was reading through this list of tasks, essentially. I'm wondering what the role of EPA is in getting some of these tasks done. Is this all work the committee is doing or is EPA staff doing part of this? This is starting to look like a real job for more than one person. I'm just wondering what you want the role of the PPDC to be in this.

MR. BRADBURY: Susan has been around the table long enough to know what we're thinking over here, too.

Why don't we try to loop back around. Jerry, then Virginia, and then maybe we can wrap it up and hear from Jeff Morris.

MR. BARON: I was just looking down at your draft list of pesticides. I guess the question back was -- you made a comment before about the OP's carbamates treatment would be much different than pyrethroids. I guess I was just wondering about the neonicotinoids and even Fipronil.

Would that be totally different treatments? In other words, I'm wondering if the treatment would be the same for, say, the OP's carbamates and the neonics. Would it matter that they have to be (inaudible)? Then, I guess my second question is, what was the idea of Fipronil on there? I mean, it's not exactly used (inaudible) in agriculture. So, I guess I'm just wondering.

MR. ROBERTS: First off, it kind of goes back to what most clinicians think of when they think of pesticide poisoning. I do this on a regular basis with my own residents. I talk about insecticide poisonings in a given scenario. As predictable, they all say, oh, it's

organophosphates poisoning. Okay, what else could it be? I get blank stares.

So, clinicians are just not in tune with what is currently being used. So, the purpose of treatment in terms of organophosphates, pyrethroids, and neonicotinoids, really, only one of them has the anecdotes, the organophosphates and the carbamates. I think why the neonicotinoids, again, similar constellation of symptoms as pyrethroids.

There's some differences, but there's enough similarities that any time a physician is going to encounter what they think is a pesticide poisoning, they're automatically going with organophosphates. So, the purpose of the others is to really be able to distinguish.

Why Fipronil? Again, we're looking at, first off, insecticides. All the three in the bottom of the list are actually highly used compared to organophosphates. Now, you mentioned Fipronil is not so much in agriculture, but it's certainly used a lot on the yard treatments and the pest coverage, and things like that. So, there's a lot of domestic human exposures that

are outside of the realm of agriculture.

Again, though, the list is really preliminary and it may end up having a completely different list of active ingredients on there. But we want to try to at least be able to distinguish the ones that we can treat and the ones that we have to use supportive care.

MR. BRADBURY: Thanks. So, I just want to do a time check. Virginia was up next. Tom and Cindy want to speak. We're going to try to wrap this session up at 11:15. We may or may not have 15 minutes of public comments, so I'm just checking in. If we want a little bit longer, we're supposed to get done at 12:15. If we don't get done until 12:30, is that acceptable? I'm just pointing that out. So, in terms of comments you want to make, I'm going to try to balance everything.

Virginia.

MS. RUIZ: I just want to say that I'm really encouraged by how far this has come. I'm excited that there's a possibility that we'll move forward. I think there's a real need in the community. The information that we would be able to get from these diagnostic tools would help to clarify and inform the incident reporting,

which I think is very important. So, I'm very supportive of this proposal.

MR. BRADBURY: Tom and then Cindy.

TOM: Well, I just wanted to say I'm really impressed by the working groups in general in terms of the willingness of people to step up and actually get some work done beyond just recommending what EPA should be doing. I think that's really impressive.

In terms of this discussion here, I just had a chance to review some farm worker or ag worker pesticide impacts data and want to be sure that we continue to think about the nonsystemic pesticide of sulfur as more than a quarter of total pesticide use in California and also the top pesticide for reported cases of farm worker illnesses. So, we shouldn't take our eye off the ball there, and we should be thinking about how do we reduce those cases.

Then, finally, pertaining to this discussion and also the water quality prior to this, NRCS introduced a couple years ago a monitoring and evaluation practice standard. So, yesterday we heard about the IPM practice standard where private landowners can get financial

assistance and technical assistance to implement IPM.

This monitoring and evaluation standard came about as a way of providing financial and technical assistance to private landowners who want to monitor and evaluate the outcomes of these practices that they're putting in place. I think the only use so far has been in setting up edge-of-the-field monitoring stations for nutrient management, so tracking nutrient losses from crop land.

But you can imagine it being also used pesticide losses or, in this case, as well too, grower actually using that to monitor and evaluate the impact of measures that they've put in place to protect the human resource.

So, I think that's a resource that we should be thinking about in terms of pilots and maybe using that to work with private landowners on evaluating some of these efforts.

MR. BRADBURY: Cindy.

MS. BAKER: I just wanted to say I'm really encouraged by what I'm hearing about biomarkers and the work that's being done. I'm impressed that we're taking

an international view, looking at what's being done in Europe. I'm particularly curious what the group will come up with with respect to first and second generation of enticides (phonetic).

Both are tricky areas, just thinking about, for example, bromethaline (phonetic), recommended as a reduced risk pesticide, rodenticides (phonetic) by EPA, and at the same time, some of the pesticide makers are saying it's too dangerous for them to sell, even though they are selling it. So, there's a lot of contradictory information, and it would be interesting to see what you can come up with.

MR. BRADBURY: Okay. So, we're going to take the input from the committees and the subcommittees and get back to you. But my initial impression is one that is broad in terms of the 21st century tox workgroup that we have with PPDC. We knew this PPDC wasn't going to do science, but hopefully this workgroup can help, on the one hand, communicate and think about how the science as it evolves will fit into the regulatory process and policy development.

I think also this effort is bringing out how we

see where the research needs to go to develop the kind of tools that are needed for some of the things we described today. So, my initial impression is focusing on aspects of defining the universe of chemicals or endpoints that are of greatest concern and prioritize that.

Then, I think an output of that will be how we can be working in EPA's research and development things we know are going on like in DARPO, looking at some of these same challenges in terms of folks in the military that may get exposed to chemicals. How do you rapidly diagnose what somebody has been exposed to or things that may be going on in NIHS?

So, my thinking right now is to help crystallize what we think the needs are and then how do we link up with different research arms across the federal government to see if we can't nudge them or excite them to take on some of that, along with whatever the registrant community's research labs are figuring out as well.

So, that's sort of my first thought. But we need some time to ponder that. So, we want to keep it moving forward. I think, as Susan said, even if we had

all the resources in the world, we don't have the skills to actually build these tools. But, what can we do to help influence those who can build the tools for a common good?

So, thanks, everybody. I want to reinforce Tom's point about the hard work the workgroups are doing, not only in this group but across a number of groups to go forth.

What I want to do with the last part of this session is turn over the mic to Jeff Morris who is the associate office director for the Office of Pollution Prevention and Toxics, to talk a little bit about 21st century toxicology and how that is starting to fit in to some thoughts in the Tosca (phonetic) arena.

DR. MORRIS: Thanks, Steve, and good morning. Thanks for giving me a few minutes on your agenda to give you an update on an activity that we've started across the Office of Chemical Safety and Pollution Prevention, and to put on the table an idea in the form of a suggestion to you all that came out of that activity.

Last year, as the three offices that comprise OCSCP, the Office of Pesticide Program, the Office of

Science Coordination Policy, and my own office of Pollution Prevention and Toxics, looked at the state of the 21st century toxicology approach as another integrated approach. It's for testing (inaudible). We looked at how we are considering moving those into our own programmatic activities.

It became clear from both the resource considerations as well as just good government and good science that we should find a way to coordinate among our three offices in terms of encouraging the development of the science, as well as coordination on looking for approaches for implementing our programmatic activities.

So, we formed a committee, a steering group comprised of senior scientists and managers across our three offices to facilitate that coordination, really in three areas. The first is in looking at coordination across the different programmatic activities areas. We were trying to move these approaches forward.

The second is in looking at how we can coordinate and plug it into international activities, both through the OECD as well as other bilateral arrangements we have with organizations like the European

Commission and the Joint Research Center.

The third, and the reason why I'm here, is how we can better coordinate on stakeholder engagement. So, out of the third area of activity in our discussion, we thought it would be useful to come to you all with an offer to, as we move forward both collectively as an OCSDP and individually in our office, to bring to you things that we're hearing from our respective stakeholder communities for information purposes, as well as to get your feedback on your impressions of what we're hearing.

I'll give you an example from my own office. This summer, we're engaging our stakeholders in the industrial chemicals arena in a discussion about how we make broadly our data both useful and useable to them as they make their decisions.

As part of that discussion, we want to talk about how new information that's coming out of our Office of Research and Development, the Tox Cast Program (phonetic) and other areas, of how we bring that information into the discussion of how the body is scientific information that informs our understanding of chemicals, how that should be presented and discussed

within the community.

I'll give you an example of, say, an industrial chemical where maybe we have some weak indication through the -- not a whole lot of data, which, if any of you know Tosca -- industrial chemicals typically don't have very much -- give some sort of weak indication of developmental toxicity.

Well, if that industrial chemical will run through the tox cast assays and none of the pathways lit up for developmental toxicity, what would that tell us about that chemical? Would that lead us to a greater confidence that in fact developmental toxicity is not a priority concern? What do we do with that additional 21st century tox information? How do we use it? How do we present it, et cetera?

So, that's the type of dialogue that we're going to be having this summer in the industrial chemical arena. I'd like to offer that when you all would like, to come back and give you a sense of how that discourse went and what our stakeholder community is saying. I would suggest that as you, who now have four or five years in discussions, come up with ideas on most

effective ways of bringing that information into discourse about understanding chemicals, that if, in fact, we could hear some of that and share that with our stakeholders, that would be extremely useful.

Indeed, while we each have our own particular statutory and programmatic ways that we deal with scientific information in making decisions, the issues that I think we face in just discussing the development and presentation of this new information are often common issues.

So, a few minutes to lay on the table and to get any initial reactions and hopefully continue the dialogue as we move forward with this. Thanks.

MR. BRADBURY: Just a real quick summary. So, PPDC goes from FIFRA and FQPA. So, our 21st century hot group as part of this, we're thinking about all these issues in terms of how they apply to what we have to do in the pesticide world.

As Jeff indicated, folks that are working through how this science could evolve in the context of evaluating industrial chemicals are starting to think the same things we've been thinking. Tosca is (inaudible)

how that will all play out. It's going to be different. We're not trying to mix the statutes together or mix FACAs together.

At the same time, we want to be efficient. If our group has started to have some aha moments, if that could maybe avoid them from going down a blind alley or think about if they want to go down the blind alley, we say go in with their eyes open. Or, as they start to grapple with some of these issues, they may have an aha moment that may be helpful for us.

So, the offer is, if you all think it's reasonable, once Jeff and his crowd can kind of set up some structure and some process, to just keep lines of communication open and maybe keep each other informed of activities we're doing so that we can avoid doing things twice. We can, but definitely this is for FIFRA and FSCCA and what Jeff's group will do is for Tosca.

So, initial reactions? Bad idea, don't do it, or that seems like a reasonable thing to do.

Matt, Kristie, and Dave.

DR. KEIFER: Brief? Good idea.

MS. SULLIVAN: Some of us are in the same

stakeholder community, but not very many of us. So, not only is it a good idea, I think it's extremely important to make sure that the offices are working together and the stakeholders from both communities are aware of what the other offices and the other stakeholder communities are thinking and doing. Because you have different approaches historically to data and testing, you have different experiences. You can learn from those different experiences as well. So, definitely a good idea.

MR. TAMAYO: I think it's a great idea. I think one of the benefits will be if you can make sure that the technologies or the data that your offices pursue are compatible as possible. In my world, we're dealing with whatever this whole soup of inputs from consumer products and pharmaceuticals and industrial chemicals and pesticides and whatever else happens to be in the water.

There's folks now that are starting to use molecular tools in environmental monitoring. I think that the more consistent your data sets are and the more tied in they are with the types of environmental

monitoring tools that are being used, the more useful those tools will be for sort of getting at what the real causes are.

Right now, we're just kind of wow, yeah, there's -- we've got pelagic organism decline and we don't know to what extent that's chemical or what. But there probably are some chemical signals. Is it pesticides? Is it mercury?

One thing I really encouraged all of the offices to do is to really start looking at what's going on in the environmental monitoring using these tools and examining how best to support that and coordinate with that. Actually, there's some researchers that are very interested in what's going on here. I'll get them in touch with you. Hopefully, they can be part of that process. Thanks.

DR. McLAIN: Thank you all very much.

MR. BRADBURY: Thanks, Jeff. Thanks, Jennifer, and everybody that was contributing in the workgroup.

The last two sessions are going to be designed as information sharing to sort of update, extended updates. One is on what Kimberly Nesci and Jerry Baron

are tag teaming on which has to do with an effort with regard to collaboration between the U.S. and Canada on pesticide registration. I'll give you the details. Then, we'll have a brief update on sustainability efforts at EPA.

Kimberly.

MS. NESCI: Thank you. I'm here to give you an update on the U.S.-Canada Regulatory Cooperation Council, as Steve just mentioned. What this is, the U.S.-Canada Regulatory Cooperation Council -- we're calling it the RCC -- is a bilateral initiative announced last year by Prime Minister Steven Harper and Barack Obama.

In December of 2011, the RCC released a joint action plan at www.trade.gov/RCC and it discusses 29 areas or 29 initiatives or areas for alignment between the U.S. and Canada. Those 29 areas are not just (inaudible) protection products or pesticides. They address four sectors; agriculture and food, house and consumer products, transport, and the environment.

At the end of January of this year, there was an outreach event (inaudible) to allow an opportunity for stakeholders to learn more about the RCC and to provide

input to federal regulators on the work plans as we were finalizing these work plans to address each of the 29 areas.

So, those work plans at the end of January were made available -- or early February, I think, were made available for comments. So, we accepted comments on the crop protection products work plan. The work plan itself discusses four action items. Under each action item, there are specific tasks to accomplish that action item. The overall goal of the crop protection product work plan is to facilitate equal access to products and uses in both countries, and to align MRLs where possible.

In order to do this, the work plan then identifies mechanisms to encourage registrants to submit applications for joint regulatory review to Canada and the U.S. that include increased numbers of minor uses.

So, I'm going to briefly go through the action items but not the specific tasks under each action item. I'm hoping to be able to bring you all a copy of the most updated work plan for crop protection products. It has not yet been released by OMB, but I understand from correspondence earlier this week that it should go out

any second now, really. So, again, that will be available at trade.gov/RCC. In the revised work plan, these action items have not changed. I'll talk about what has changed between the work plan that many of you were sent and the new work plan shortly.

So, the first action item is to encourage joint submission of use expansions and fully aligned labels. The objective of this action item is to address the technology (inaudible) and trade irritants between products available in Canada and the U.S. In order to do this, the approach is to obtain simultaneous receipt of application packages and fully aligned labels, and to develop one joint work plan for all actions related to use expansion.

The second action item is to develop guidelines for joint residue trials. The objective of this action item is to move towards each country or agency accepting the other's review of residue data, helping to result in concurrent and aligned decisions. The approach to get there is to maximize a reliance on an acceptance of food safety data generated in either the U.S. or Canada to support regulatory decisions and again to develop joint

guidelines for residue trials.

The third action item is to address obstacles to joint registration. The objective is to eliminate regulatory obstacles preventing the joint submission and registration of pest control products, applications into the U.S. and Canada. In order to do this, the approach here is to identify flexibilities in the regulatory processes and procedures in each country, to enhance the use of existing tools to measure progress, and to develop new opportunities to align the work and work plan.

The fourth action item is to align data collection processes and procedures for residue trials for PMC and IR-4s -- PMC is the equivalent of IR-4 in Canada -- to lead the generation of residue data in each country or agency who would then accept data generated by either PMC or IR-4. So, the approach here is to align data generation priorities, reporting processes, and the work plan, again between the two countries.

So, we received comments on the work plan. The comments were received from Canadian grower groups, the Saskatchewan Ministry of Ag, the Canadian Federation of Agriculture, CropLife Canada and America submitted a

joint comment, and BARE.

Generally, the topics we received in the comments on the work plan were requests for more stakeholder involvement and more regular monthly calls and meetings with the stakeholders on the work plan and on the RCP actions, a need for transparency, a need for global harmonization to address codex MRLs and not just alignment between the U.S. and Canada. Generally, the comments were supportive of what we're doing under the RCP work plan.

Those comments have been incorporated into the work plan that OMB has and is almost ready to release. Again, it will be at trade.gov/RDD. The work plan under RCC is really the next step in a lot of the work that Canada and the U.S. have done towards joint reviews.

There are a couple of projects ongoing right now under the RCC, one of which is we're working towards aligned -- the U.S.-Canada confidential statement of formula or product classification forms. So, we're actively working with Canada to have a joint form for the composition of products.

We have a pilot submission in house that we're

evaluating under the RCC. We understand that PMRA is considering the PRIA 3 time line and code structures, and considering streamlining their value assessment to focus more on value rather than efficacy specifically.

Does anybody have any questions?

MR. BRADBURY: Jerry, did you want to --

MR. BARON: Good job, Kim. This has taken a lot of, I would say, prosthesis have been incurring between EPA, PMRA, IR-4, and the Pest Management Center in Canada over the last five to seven years. Not only institutionalized these agreements but probably more importantly take them to the next level of cooperation to save both governments a substantial amount of resources.

No one can afford to be doing duplicate work and have it being done. So, the whole concept is it would be a win win saving both countries resources as we go through this process. So, there's great value. At least from our end of it, we see great value in this process.

MR. BRADBURY: Ray, Cheryl, and Dave.

MR. McALLISTER: I've watched this closely since the meetings in January. I think that the

pesticide programs have had a strong advantage over the other programs in government under the Regulatory Cooperation Council because of a long history and a strong culture of collaboration between OPP and PMRA. We come in before that.

In light of our discussion during this PPDC meeting, I realize that your work plan is well down the road, and it's focused over a few years' time. But I would like to strongly recommend consideration of another area of cooperation which has high potential for benefit. That's in the area of drift reduction technology.

They're doing some exciting things in Canada that could benefit the U.S. and vice versa. It's something where it doesn't take a lot of additional extra effort to get a strong collaborative effort going.

MR. BRADBURY: Thanks, Ray. We might be able to tackle that through the NASTA and/or the RCC.

DR. CLEVELAND: So, submissions are always good. Rework is good when you can get them. One of the bigger problems with U.S. and Canada MRLs is there's a lot of crops that are grown in the U.S. We have uses. We have registrations in the U.S. They don't grow those

crops in Canada. They're not always that interested in establishing MRLs when they're not going to get the registration of the use in Canada.

So, I'm just wondering if this project has done anything to think about bundling. What you need to reduce trade irritation is you need to have MRLs established in Canada as well so you can move crops up there. That seems like a no brainer, but, for some reason, there's less emphasis in their overall process on the import MRLs. Does this process help shore that up at all?

MS. NESCI: Yes, I think so. I think especially as we're working through the pilot, we'll be able to identify areas where we can help to bundle. Also, I think the crop grouping will help in that effort as well.

UNIDENTIFIED FEMALE: Just so that you're aware, part of the pilot that we're working on, the specific chemical, one of the issues is we are working where there are uses where IR-4 submitted that are not going to Canada and we're going to try to get import tolerances in Canada at the same time and vice versa.

There's a use that Canada has pending that we don't have pending in the U.S.

So, the idea at the end of the process is not only will you get the joint uses registered, but both countries want to establish import tolerances. So, that's part of what we're trying to work through on this pilot that's different than our normal joint reviews.

MR. BRADBURY: Dave.

MR. TAMAYO: Well, I'm glad we're finally moving towards peaceful relations with Canada. I just had a real simple question. I don't know if the answer will be simple. You mentioned at the very end that you're moving towards, I guess, looking at value versus -- I can't remember the other term -- efficacy. I didn't really know what you meant by that.

MS. NESCI: Well, right now, Canada requires submission of specific efficacy data to support their application. So, I can't speak for Canada, but what we understand Canada is doing is they're taking a look at the needs for those specific data.

UNIDENTIFIED FEMALE: -- fundamental difference of why that's significant is because as a registrant, if

you make a submission to EPA for five crops, you don't have to actually submit the efficacy data to EPA and have it formally reviewed. You're required to have it, but they don't go through a formal review process. California does, but EPA does not.

In Canada, you have to submit the efficacy data in addition to submitting it, they will also review it and they'll pick the rate that they think is the most efficacious rate on your label. So, you can get into a situation where you have a pound per acre registered here by EPA and three quarters of a pound per acre registered in Canada because the pest pressure is much lighter in Canada. So, a lower rate is much more efficacious there. So, that's right now the inconsistency.

MR. TAMAYO: I guess I was really curious about the use of the term value. I wasn't quite sure what you meant by that.

MR. BROWN: That's a terminology that they use for efficacy data and product performance. It's a generic one, value of the product in agriculture.

MR. TAMAYO: But it's essentially the same concept. Okay, thanks.

MS. NESCI: And Miriam Law from PMRA will be speaking to the CropLife Canada meeting in just a couple of days up in Canada.

MR. BRADBURY: Thanks, Kimberly and Jerry.

Let's move to the last session that Mike McDavit is going to lead. That will be an update on sustainability activities undergoing in EPA and, in particular, how the pesticide program fits into some of those activities.

MR. McDAVIT: Good morning. Mike McDavit here. I'm going to be a speed talker, so get ready. I have exactly one minute to do my presentation.

A little preface, and I will go through these slides quickly. They were in your packet. If you had a chance to look at them, you'll see that it's the high point of the day and they saved the best for last. All kidding aside, it really is what you've probably been talking about for the last few days. This presentation sort of just puts things in a different context. But it's what we've been talking about already. That's my preface.

So, I'm going to talk a little bit about the

green reports. I'll flash it in front of you in a second. Then, about what the agency is doing with this advice and the next steps we'll be taking. Then, we'll give a tiny bit of time for you to address your thoughts to us.

So, we charged the NRC to take a look at what EPA does, how we run our decision making processes, and to give us an idea of how we could operationalize sustainability further into that framework. We wanted them to think about, to recognize, that our work is rooted very much so in the risk assessment process right now.

This is not a this or that; it's really about how do we incorporate what we're currently doing into a sustainability framework further. Then, what kind of tools should the agency use to do this to move the ball forward? What about internally? What kind of expertise should the agency have in order to do this?

The definition, like most topics, it's a slippery slope when you get into definitions. In a way, we're fortunate because even though there's been a zillion different reports written over the last 30 years

about sustainability, the advice we're getting is to look back to the National Environmental Policy Act. That's sort of the genesis of the idea for the United States. So, it's a pretty straightforward, simple to understand hard to do definition.

These are the key recommendations, and I really want to run through these not doing one at a time but just to mention a couple of key concepts. I sort of really want to move to two main ideas, one, the paradigm under which EPA operates and secondly, how risk assessment fits into that as an element within our sustainability toolbox.

So, let me kind of boil down this slide just to say number one, the advice we're being given is that we should be moving towards an optimizing benefits paradigm versus a reduced risk paradigm. I don't think this is written down officially anywhere, but we basically operate under a reduced risk paradigm now when we're looking at the choices before us.

Instead, the advice we're getting from NRC is that why don't you look at that as more of an optimizing benefits paradigm. In some cases, the decision would be

identical. It would be the exact same outcome. But in other scenarios, there might be a slightly different decision. That's kind of the underlying idea. This is a little theoretical, so forgive me for that.

Over time, we'll see how this plays out and see how it makes more sense. The examples I'm going to give you in a few minutes, too, about what we're already doing within this whole thing will maybe help illustrate this point a little bit further.

So, kind of a tangential related idea is risk assessment remains a really important tool for us. We suspect it will remain so for years to come. When they presented the report to the agency, they analogized to the old red book, which was a 1983 publication that many of you know around this table called *Risk Assessment in the Federal Government: Managing the Process*. This is where we were given very clear instructions on what risk assessment was, what are the components, the four step process, et cetera.

In 1983, a lot of people already knew what risk assessment was, so this wasn't like rocket science. But it sort of put the agency on a track of well, this is the

official view on it. Now, continue further. Do great things down the road, which, for the last 30 years, that's what we've been doing, a lot of innovation, a lot of improvements in the risk assessment process.

What they do is they analogize the green book, which is the report that I'm referring to, as something that may experience a similar track. It may take many years to fully realize the vision here of this report, but the idea being that we're not going to stop doing what we're doing, just as we didn't stop what we were doing 30 years ago in 1983.

We're already doing a lot of what this book talks about. So, that's kind of an embedded message. Yet, in 30 years from now, it won't be me sitting here but somebody else may be saying -- the pages are yellowed in this book. The pages are still nice and white in this book -- may be reflecting on the journey of the last 30 years.

So, again, I'm going to just run by this quickly. It's in your packet. This is advice we're getting from NRC. We're not bound by the results. We're developing a response right now based on a number of

listening sessions that we've been holding with stakeholders.

We would have had done something sooner with this group, but the timing of the report is it just didn't kind of click. This came out in, I think, November of last year, and we weren't scheduled to have a PPDC meeting until now. So, we sort of missed the boat in one sense, but I don't think that that's a correct way to think about it. Again, as I get through this, you'll see we're already doing a lot of the things the report recommends.

So, I'm just going to move through here quickly, so forgive me for just moving along. Again, the basic concept here is sustainability is sort of a verb and a noun. It's a process and an outcome. So, when you think about sustainability, don't think of it as just an endpoint. It is a continuum. That's the kind of division that we're getting from our management.

There's other sources of advice flowing into the government from NRC. Here's another example about sustainable agricultural systems. Just to point out, in the case of the green book, this is advice that we

sought. We commissioned NRC for this advice. The genesis of this report I think is somewhat different, but the point being that there's a lot of advice flowing to the government now about what does sustainability mean in various sectors. In this one, it's kind of an overarching paradigm type report.

Let me just jump to kind of the thesis here for us. So, what does sustainability mean to the Office of Pesticide Programs? Well, regarding ongoing projects, things we're already doing, one could easily argue that the application state of the art risk assessments and the constant continuous improvement of them is an example of sustainability. You're basically using the best -- not just the best available information; you're using the best way to get to the best information. You're really squeezing everything you can out of what we know about pesticides.

Another example is the streamlining process that we've been using for many years for bringing both reduced risk conventional pesticides to market, but also the whole biopesticide fund, which is sort of being fully codified in the law under PRIA with reduced time frames,

reduced costs, reduced data sets.

So, the streamlining process is actually in place and operating with bringing a new generation of products to the market. Again, remembering that, to me, the overlay here is the idea of optimizing societal benefits. So, these are all things that sort of fall into that niche.

Then, we're also doing other things like managing pesticide resistance to a degree by using mode of action labeling voluntarily on pesticide labels. In the case of plant incorporated protectants, we have more formal requirements for insect resistance management measures that are required.

Another example of things we're already doing is allowing for the organic production mark on pesticide products. That was kind of a watershed moment when we started doing that, but I think now that we've been doing it for a number of years, I don't think we've experienced maybe some of the unintended consequences that some might have feared, that it would be misunderstood, misleading. I think it's well understood by the ag community that this is information that helps them to make the right

choices so they can remain compliant with the national organic program.

As far as new ideas, new things we've been piling, a lot of this stuff you're very familiar with. In fact, it just hasn't been framed this way. The previous conversation we just had a few minutes ago about 21st century tox efforts, employing these new technologies as a way to reduce not only the costs of testing but probably getting at more core questions faster. So, that's a huge undertaking and will take many years to roll out, but we're kind of going in the right direction already.

The pilots we've been running, including the one for the design for the environment mark for hard surface disinfectants in the antimicrobials divisions, is an example where we're trying to get to meeting the demand of the public but also again maximizing benefits of society of how do people make choices about the product types that are out there. So, we're still experimenting with that. We're looking at expanding that, as you heard this week. So, I think that's another example of kind of aspirational direction that we're

heading.

Then, there's a lot of areas that we could speak to in the area of integrated pest management. A more concrete example is we've been effective in recent months at working with the green building council's draft LEED certification in incorporating better IPM language into those standards.

So, when they certify a building in the future as being a green building, there's going to be a little bit more legitimate, more robust recognition of the role of IPM in the running of that building and not just as a sort of an afterthought. So, that's sort of playing out right now, but that's kind of directionally a good thing.

So, as far as next steps go, there's been a whole bunch of stakeholder meetings. Some of you may have been involved in some of those. I was involved in a briefing with the Office of Water. Recently, I was in a briefing with OPPT regarding the DFE program. Some of you may have been involved in those meetings, I don't know. But we've been trying to collect input from stakeholders across the agency in all the different offices to inform how we'll respond to this report and

how we'll embrace or not embrace the recommendations.

So, this session here is yet again, I think, an opportunity for you to learn more about this report and provide some input to us on what we should be doing more of or less of with regard to sustainability. The response to the report, the green report -- it's always good to have visual effects here, particularly at the end of a meeting.

We're going to be developing our response to that. So, I would say stay tuned for that. But because it is a continuum, regardless of what we say in our response, it is a continuum. We're going to continue looking at ways to embrace sustainability and how to fold it into our basic operational decision making processes.

That was pretty fast.

MR. BRADBURY: Do you want to go around and do a few questions? Maria?

MS. HERRERO: Since I'm from the biopesticides group, obviously sustainability is something that we're heavily involved in. My only concern, and what I would like to leave EPA with is don't lose the baby with the bath water. I think you already to a lot of

sustainability. What I would like to see is more of invigorating the programs that you already have rather than creating a new one so that you lose a lot of what you've already done.

When you look at benefits, that is a catch 22 because benefits are not always equal. You kind of judge one against the other. My group is the first one who is involved in the organic products, but I don't want people to leave with the idea that organic necessarily means sustainability.

Some of the inerts that I am permitted to use in organics, I have to mine, whereas I'm not permitted to use a waste stream from sugar beet processing. So, I don't think people always understand the underlying scenario. To really get a benefit, you have to look at it really deeply.

MR. McDAVIT: Can I make a comment real quick? I kind of ran by this, but the three pillars of sustainability, for those of you not familiar, are economic, social, and environmental. So, you're optimizing the benefits of those three pillars. If any one of those three pillars was way off, then it would --

using the metaphor, it would fall over.

MR. BRADBURY: Jerry and then Mark.

MR. BARON: Just a brief comment. This last day and a half we've been talking a lot about resources or, better yet, lack of thereof. Everyone is being pushed, squeezed, tightened, and all that. Yesterday, we made a quick mention about IPM in schools and what USDA is funding and doing there. Hopefully, there will be connections made so they're not reinventing the wheel in two different areas.

I'd like to offer you this same opportunity or same suggestion. There's a very large sustainable agricultural program in USDA. I think there needs to be a connection made. So, knowing that not everything that you're doing is agriculture, but where you are doing agriculture, there should be good connections and maybe sharing some resources or saving some resources.

MR. BRADBURY: Mark and then Caroline.

MARK: Thanks. I just want to drill down a little bit and focus on this issue that in terms of sustainability, it's really a good and appropriate focus, and that is this insect resistance management requirement

for incorporated protectants. But it's not just there. I mean, it should be herbicide protectant product as well. So, you know that.

But the point I would like to make is that in that particular arena, as in many arenas, we really need a systems view because if you put out genetically engineered plant product that leads to higher inputs of X, Y, or Z, what's the probability of resistence development? Pretty high, probably, for the non-targets as well as the targets.

So, in terms of sustainability and that process, I think a more holistic view of this, including the ecology of that system, is a really important thing to do long term.

MR. BRADBURY: Caroline and then Virginia.

MS. COX: If we haven't already gotten a copy of the NRC report, would you be able to e-mail that out to the committees?

MR. McDAVIT: I think in your packet was a fact sheet. I hope there's a web site. It's available on line. So, I believe it has a web site. If it doesn't have a web site, you can Google it and you will land

right on it. So, it's available right now on line.

MS. COX: Okay. I had a question about the organic production mark for qualifying pesticide products. Can someone give us an estimate of how many products actually have that mark on them?

MR. McDAVIT: I don't have the estimate. I'm looking at IR-4 down the table here. You have a database that lists all of these. Maybe that's some homework we could deliver to the committee because I don't know off the top of my head.

UNIDENTIFIED MALE: I don't know the numbers. I can give a link to the group, if you'd like.

MR. BRADBURY: Follow up with either a link or get the information.

Virginia and then Louis.

MS. RUIZ: Well, I'm encouraged to see in there that one of the goals is enhancing the quality of life of farmers and farmworkers. I hope that that will translate into a cost benefit analysis, for example, greater consideration of some of the social environmental costs to workers and farmworker communities, a greater look at alternatives as well.

MR. JACKAI: Mike, I'd like to commend you and EPA for doing this. Essentially, you mentioned (inaudible) that EPA has been doing. Everything we've talked about here is actually along the lines or should be along the lines of sustainability. I would just like to echo the point that Jerry made here about hooking up with USDA which has a well-grounded program, an emphasis on sustainability, particularly in agriculture.

Also, the discussions from the IPM working group on school IPM and the ag and public health IPM, these are all grounded in sustainability. When we find it difficult to put forward the benefits of IPM, it's in part because sustainability was not in focus. Otherwise, it would be quite easy to look back and say, well, these are the benefits. But I'm happy about what EPA is emphasizing at this point.

MR. BRADBURY: Good points.

Susan and then Darren.

SUSAN: A request for the data team. If they can add a field to the PPIS data set to flag the products marked for use in organic production, that would be great so that that comes down with that data set.

MR. BRADBURY: Darren.

MR. COX: As I looked over the sustainability and the EPA and farming, what Lois said, it's starting to work within the USDA to try to make some of these programs more possible. I guess I just keep going back to IBM and (inaudible) management. The industry is really coming up against the constraint for decreased forage. If there's any way we can start working towards progressing that, that would be well served.

MR. BRADBURY: So, thanks. Good feedback.

Oh, Beth, sorry.

MS. LAW: It's late. I just wanted to echo someone on this side of the table who said that they hope the current efforts underway at EPA will not be sort of supplanted or deluded by bringing on some new initiatives. In particular, I just really encourage you to continue to work with DFEs on the antimicrobial pilot and, in general, make it to enable more products to successfully pass the screens for DFEs. I think that's a great program and a good thing for pesticides.

MR. BRADBURY: Mike, in his presentation, is definitely trying to take these principles, what are we

doing already and how do you kind of keep on keeping on. Look for advantages to leverage to move forward. We'll do the best we can to ensure that DFE process is scientifically rigorous and sound, and look forward to your research and development folks to create those structures that can get through the screen so we can get them out into the marketplace. I know you're all working on that, too, so we'll work together on that.

Why don't we switch to the last session, and that is to talk a little bit about what we want to take on for the next meeting in the fall. We'll do that for a little bit and then Margie can give you some windows that we're starting to look at in terms of calendars. Then we'll do public comment at the end.

So, some of the things I wrote down are sort of easy, no brainers, in terms of the next time we meet, some of the report outs from the workgroups. Clearly, the pollinator protection groups will be telling us all sorts of cool things that they've already started to do over the last six months and keying up some things to get some feedback to take to the next step. Cindy has lots of time now as the thunderstorms roll through the D.C.

area. So, I imagine a fairly robust pollinator protection session that we'll do. I think everybody is sort of anticipating that.

The IPM group also -- it will be an important window in time not only to report out on where we are with school IPM, because we've all had several national meetings and other work going on, but some of the other -- I'm not going to list everything I did yesterday, but there are a number of action items on the IPM front that we'll be putting out.

We'll probably do some aspect of an ESA update just because there's always so much going on. It's just a way to make sure everybody is aware of what's happening. I don't know exactly how we'd frame it because some of what we talked about with registration review and the focus effort, it's more than just ESA. It's got a lot of different connections. But I'm thinking some report out, and it may be short, of how that's working so far.

Some of you around the table or the groups you represent that are around the table through you may have experienced some of the early steps of trying out some of

those focus meetings and sort of getting some sharing amongst all of you, because some of you may not have gotten plugged in yet because of the nature of the chemicals or the scenarios. We'll do some initial checking on how that process is going.

So, there is some, like three or four, things that are probably taking a fair amount of time. Why don't I stop and see what thoughts you all have and sort of get a list going. Then, Margie, through e-mails and you e-mailing in, will communicate to kind of zero in on an agenda as we get closer to the fall.

We'll open it up to the committee for any other suggestions.

UNIDENTIFIED MALE: (Inaudible).

MR. BRADBURY: Where we are in spray drift and DRT, that sounds good. Margie is helping with notes.

Kristie.

MS. SULLIVAN: I think it would be really useful to hear an update of where the agency is with replacing some of the shorter term toxicity tests. There's some in vitro methods off the top of my head, skin irritation, eye irritation, skin penetration.

Sensitization is now coming up for being validated. So, I just want to hear about what the agency is doing about those.

MR. BRADBURY: What I'll do -- Jennifer and Vicki aren't here -- I'll kind of roll that back into the tox 21 group and maybe have you guys sort of work -- share at that level and then figure out how to synthesize and bring it up to the whole committee.

MS. SULLIVAN: That works because I was going to bring it up there, too.

MR. BRADBURY: Good.

Susan and then Mark.

SUSAN: It's been a while since this group has heard about fumigants. It would be nice to get an update on -- at that point, the new labels should be fully in place, I think. It would be interesting to get an update on how that's going and what you're finding out.

MR. BRADBURY: We'll do a fumigant update. It may be paper update or it may be a 15-minute or 5-minute thing, but someway or another we'll get that in. That's very reasonable.

Mark.

MARK: I'd really like an update on international MRL harmonization processes.

MR. BRADBURY: Beth.

MS. LAW: Actually, I was going to suggest a general international update on -- there's several initiatives under the RCC that EPA is involved with, in particular the notice of arrival project. So, that was one suggestion. Hopefully, by the time of our next meeting, we'll have some resolution on PRIA 3 and perhaps an update on where that finally shakes out would be a good idea.

MR. BRADBURY: You're very optimistic. We'll hope. As you're coming up with some of your concepts right now, and Margie will do some loops back in, let's make sure we keep track of topics that you want to engage on in terms of a two-way, if you will, or multi-way sharing of information as opposed to just a bunch of talking heads up here. We always want to do a little bit of that, but the big part of this meeting is challenges to take on. So, for example, the international MRLs, there's a lot of complex issues there.

So, be thinking about if you just want to brain

dump from us or if there's something you think a subgroup, even if it's an ad hoc group to get ready for a meeting, could help us maybe (inaudible). You don't have to tell me now, but just sort of think about that.

Now, I've kind of lost track. How about Wayne and Cheryl and Cynthia.

MR. BUHLER: Sort of gobbled together. It's kind of compiled with global harmonization also with labeling, signal words, anything that is in the plans to coalesce with the global harmonization initiative.

MR. BRADBURY: GHS.

MR. BUHLER: Yes.

MR. BRADBURY: Okay, we might put that in a quick update mode.

Caroline and then Cynthia.

MS. COX: The general topic of incident reporting came up in several different contexts during this meeting. It would be worth maybe a little more focused discussion of that.

MS. BAKER: My topic was related. I'm very interested in EPA databases and what is becoming public, what is the intersection between the various databases.

It seems like there's a lot that's coming on line now, and this is all very important in EPA budgeting as well. It's a huge chunk of your resources that go into databases. So, a general theme of databases as well as the incident reporting as one of them.

MR. BRADBURY: Okay. Not for this topic but for some of the others I've heard, in addition to -- just be thinking about what it is beyond just telling us stuff. We're happy to tell you stuff. We'll manage it between some written updates or five minute snapshots, but if there's something behind those phrases that you think we all need to dig into, that would be helpful to kind of tier the agenda.

Matt and then Dave.

DR. KEIFER: I don't mean to be redundant, but it's along the same lines. That is, a number of federal efforts have been underfunded or defunded in terms of data gathering that might have added to EPA's knowledge base about pesticide poisoning episodes, human episodes, and incidents, and things like that. I think it would be helpful to discuss how EPA is going to adapt to the missing information that is going to be missing as a

result of these defunded and underfunded efforts.

MR. BRADBURY: Dave and then Darren and then Mark.

MR. TAMAYO: One of the things that seems to cut across a lot of different issues is a lack of use data. It would be great if maybe EPA could come in and talk about well, here's some things where it would be really useful to have use data in states other than California. I'd like to have other members weigh in on that and why isn't it happening.

I realize that EPA doesn't have the authority to require that, or maybe you do, but I'd like to find out what people think about that idea of moving towards a more universal set of data, at least nationwide, and why that's not a good thing, or why it can't occur, or why it can occur.

MR. BRADBURY: Got that jotted down. My thinking is we might roll that concept maybe into some of the ideas of registration review and some of the information. I want to think about that a little bit. Again, that one I'd like to have a conversation around solutions or possible solutions or tiers of solutions as

opposed to just talking about it would be nice to have the data. But what would be some different ways it could be done. I don't know what they could be.

Susan, Darren, Cindy, Cheryl.

SUSAN: A continual theme here is how difficult it is for enforcement of label conditions to occur. It seems to me that a role that this group might play would be to think about how in a time of limited resources, how that can be enhanced so that labels are being enforced and protections are being implemented. It would be nice to explore some pathways to get there.

MR. BRADBURY: Okay.

Cindy, Darren, Cheryl.

MS. BAKER: Mine will be fast, Steve. It's just in response to your comment. So, maybe a consideration of a workgroup around registration review and the -- what are the data needs and opportunities? It will go at your international, it will go at Dave's questions, it will go at a number of different things that we talked about. So, it could be a brainstorming session among the people who are engaged in that to see what are all the avenues and possibilities that are

there.

MR. BRADBURY: Sounds good. Maybe we can tap into the PRIA improvement workgroup that I think we've used some reg review topics out of that group.

MR. COX: What Susan brought up I'd like to just say also I agree. I think that's a good point that we have to understand. If we have expectations, we have to be able to expect that we're going to be able to find a means and a way to create the funding in order to achieve those goals.

One thing that we went through, the IPMs, I thought it was a little deluded that we had so much information in the IPMs and the IBMs mixed up. I think there's a pathway that we need to look at on these IBMs for habitat modifications because of the challenges going on now to our pollinators. I'd like to see that expanded a little bit more into opportunity on public easements and byways that our projects could be geared towards for improving that for sustainability.

MR. BRADBURY: Thanks, Darren. We'll work with USDA on that one in terms of just keeping track of where we've got a direct line versus where you may be a partner

with another federal entity. So, we'll have to sort that out a bit, but point taken.

Cheryl.

DR. CLEVELAND: I'm not sure if the full PPDC wants this, but I would refer you back to our project proposal. One of the places that we thought that the EPA could provide some more clarity for that project, and it may be useful for other pieces, is on this outline. It talked about just really clarifying what the process is for when and how EPA collects worker exposure information. That was to be used to inform the biomarker conversation, but it may also be useful for the broader PPDC.

MR. BRADBURY: Maybe we can -- I don't want to lump too many things, but it might get back to what data is there and how does that feed into the -- okay. Margie has got that.

Okay, good. We're not going to do all of that, but we'll figure out different ways to maybe pull some things together, some written updates, some short verbal presentations, enough time for an in-depth discussion. Margie will be sharing with me.

Matt, you had something.

DR. KEIFER: One final comment. Someone came and presented to us about the worker protection standard being updated. I don't remember that ever being discussed in this group, the worker protection standard, updating, making suggestions, and changing it.

MR. BRADBURY: Oh, yes. That's sort of a painful part. It's been going on for so many years to try to get the rule.

DR. KEIFER: I know it's a slow process.

MR. BRADBURY: Really slow.

DR. KEIFER: Well, I was just --

MR. BRADBURY: We can certainly, hopefully, provide whatever new info we've got in the fall. We definitely can include that in the recent updates.

Mark, go ahead.

MARK: Sorry. I know you wanted to minimize the number of updates, but we just recently implemented the NPBS in January. So, it would be nice to get an update on NPBS and any issues associated with that.

MR. BRADBURY: We can either provide a written update or a link or have somebody from Office of Water

come over and give an update on that. The real snapshot is it's moving out into the states, the states that have delegated authority. They've pretty much got it running now. I think Hawaii was the one that was scrambling at the end, but they're doing individual permits until they can get their general permit process up.

The states that EPA is running, we're chugging through those. That brings up ESA again starting to work closely with NIMS in particular to do the consultations they need to do in the states that don't have delegate authority.

Margie.

MS. FEHRENBACK: We were looking at possible dates for the next meeting. It looks like October is a really busy month. There's a lot of big meetings and this room is pretty much booked almost every week. So, we're looking at the week that would be November 7th, 8th, and 9th. It's a Wednesday, Thursday, Friday, assuming that the first day would be workgroup meetings, or November 27th, 28th, 29th. You all can e-mail me directly if you know of any conflicts.

UNIDENTIFIED FEMALE: NBL meeting is that

Tuesday, Wednesday, Thursday of the first week of November, the methobromide alternatives.

MS. FEHRENBACK: Okay.

MR. BRADBURY: So, if you all hold on for a little bit, we'll turn the mute off and see if there's anybody from the public that has any public comments they want to provide.

MR. TAMAYO: I had a quick question as far as the reappointments. I'm thinking our appointments are up now. The last time it was --

MR. BRADBURY: This is Steve Bradbury with the pesticide program. Just checking to see if anybody on the phone would like to provide me public comments for the PPDC meeting.

(Whereupon, there was no verbal response.)

MR. BRADBURY: Okay, thank you.

Margie, one question that Dave had about appointments.

MS. FEHRENBACK: Membership. We're going to actually have to start the process for the next two year cycle probably around June because it's about a six-month

process and requires papal dispensation. Just kidding. It's harder. It's easier to get an appointment with the pope. So, you'll see that, but you all are good for the rest of this year.

MR. TAMAYO: So, it's not going to affect the fall meeting?

MS. FEHRENBACK: No.

MR. BRADBURY: I apologize that we ran a little bit long, but not too bad. I want to thank all of you for a really good set of meetings, good input. I think we made some progress. We've still got a lot of work to do, but we're moving forward.

So, safe trips. Hope you dodge the thunderstorms, those that are flying. We'll see you again in about six months or so.

(Whereupon, the meeting was concluded.)