UNITED STATES

ENVIRONMENTAL PROTECTION AGENCY

PESTICIDE PROGRAM DIALOGUE COMMITTEE MEETING

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Conference Center - Lobby Level

2777 Crystal Drive

One Potomac Yard South

Arlington, VA 22202

P R O C E E D I N G S

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MR. BRADBURY: Good morning, everyone. I want to welcome you to our Pesticide Program dialogue committee meeting. I'm Steve Bradbury, the acting office director for the pesticide program. I want to welcome you all to Washington. It's sort of a brisk morning, but that feels good when we think of the summer days to be coming.

I want to again welcome you all to our meeting. The next day and I half I think is going to be a pretty robust meeting and a lot to talk about, which I'll address a little bit in a few minutes.

Before I get started, I'd like to introduce Jim Jones, who is a deputy assistant administrator for the Office of Chemical Safety and Pollution Prevention, and ask Jim to give opening comments for us as we get started.

Jim.

MR. JONES: Thanks, Steve.

I appreciate the opportunity to be here today. A number of you have come up and said you haven't seen me in a while, and it has been a while since I've seen many of you. But it's really good to see so many people who I've worked with for so many years in my time at EPA.

Steve Owens, the assistant administrator, sends his regrets. He was planning on being here this morning but he had some travel that he needed to take, so he's not able to be with you here this morning. But he hopes to be with you the next time you all get together. So, he sends his regrets.

I wanted to first talk about the name change, as Steve mentioned. We are now the Office of Chemical Safety and Pollution Prevention, which I actually have to say the full name does roll off the tongue. As someone who has had to say the former name in multiple fora over the course of my career -- and I butchered it routinely because it really didn't roll off the tongue very well. It's not about the ease of senior officials being able to say the name of the organization, but it is nice when the

name of your organization aligns with what you do. That is what we do, chemical safety and pollution prevention here in this office.

That's the reason why Steve changed the name, because he wanted to see alignment in what it is that we're called so that when we're talking about who we are and who we represent and where we're from, it represents what we do. Chemical safety and pollution prevention is what people in this office do. Whether you're in the toxics program, the pesticides program, or you're doing science coordination, you're working on chemical safety or pollution prevention or both. So, that's why we've changed our name.

The acronym isn't exactly -- definitely doesn't roll off the tongue. As Margie said to me, when you say it, someone might say God bless you. But chemical safety and pollution prevention does fit together, so that's generally how I describe the name of this organization.

I'm going to talk to you just a little bit about the administrator's priorities for which chemical safety is very high on her list, and then just a little bit briefly talk about how the agenda of

this meeting lines up with that.

The administrator has articulated -- when she first came on board -- five priorities. In the last month or so, actually right around Earth day, she said, I've thought about it, I've been listening to both the stakeholders and working with the people within the agency, and she supplemented her priorities.

But they're fundamentally still the same, the first being action on climate change, ensuring clean air, ensuring the safety of chemicals, protecting America's waters, and cleaning up our communities, which were the original five that she articulated on Inauguration Day in January of 2009.

After being here for a year, she has supplemented them with two additional ones, both of which she has talked about consistently in her 15 months here. They are expanding the conversation on environmentalism and environmental justice and building strong state and Tribal partnerships. So, those are two areas that the administrator has said are also major priorities for this agency and for all of us who work here.

Your agenda today is a clear reflection of ensuring chemical safety is reflected throughout the agenda. When you look through what you all are going to be talking about, it largely is a representation of our efforts to ensure chemical safety; in particular pesticide safety in the United States.

It also brings another element of the administrator's priorities. The conversation you'll be having later this morning on NPDES brings in the priority of protecting America's waters. It also is a reflection of the way in which we've managed that process. It's about helping to ensure strong state partnerships, the way in which we've engaged our state partners in the development of that program. So, if you work through the agenda as we do our work here, ensuring safety of chemicals will continue to be a top priority for the Office of Pesticides Program.

The other piece, and I realize this is not an agenda item for you, but it is a major priority for this AA and for the administrator. I think it just warrants a minute or two of my reviewing, and that is around industrial chemicals in TSCA form. The

administration last summer articulated principles for reforming TSCA.

For those of you who have worked in the arena of pesticide regulation, it will sound somewhat familiar. That is that we need to have a strong science-based safety standard for industrial chemicals in the United States. The EPA needs strong authority to be able to manage risks associated with industrial chemicals. We need the ability to get data in a relatively easy way. Manufacturers have responsibility for demonstrating through data the safety of their chemicals. Kind of sounds familiar, doesn't it?

We are working right now towards achieving that through the reform of TSCA. There's a Senate bill that has been introduced and the House has introduced a discussion draft. We're actively engaging in discussion with stakeholders and the House actually on their discussion draft. We hope to see the reform of that statute, which I think is widely viewed as not having succeeded in its objectives of ensuring the safety of industrial chemicals.

So, with that, I will turn it back over to

Steve. I'll be able to stay with you through the first session this morning. I hope you have a really productive meeting. Thanks.

MR. BRADBURY: Thank you. Before we get started, I wanted to just express my appreciation for all the folks before me at this point spotting the table and chairing the PPDC meetings. Actually, Jim was the office director. And more recently, Debbie Edwards was the office director, and who you all know retired around the turn of the year. I greatly appreciated working with Debbie and all the advice and counsel she gave me and all my colleagues in OPP, as well as Jim and Marsha Mulkey before that.

So, I'm really honored to be in this spot kind of with the ghosts of Christmas past wooing around me and one actually right next to me. I hope I can contribute as they did to the very constructive relationship this committee has with the program in terms of giving us advice and counsel on a lot of challenging efforts that we have to undertake.

We undertake them in the context, as Jim indicated, of ensuring protection for the environment and

human health, but in the context of using these products to ensure safe food, and an appropriate safety from the pests in our homes and in our different settings around our country.

So, I want to start off first by again thanking all of you for the time and effort you've put in to the work of this committee, not only at these sessions but I think more importantly in the sessions between these big meetings where we have different work groups that are taking on a number of the challenging activities.

I think two or three of the work groups who are meeting this week, or they will be meeting at lunch today even, will be going over a lot of the work that goes on that really feeds into the kind of conversations we have at these sessions. Again, I want to thank you all for your time and effort.

Let me spend a little bit of time just walking through the agenda. I won't use a lot of time but just put a little bit of context in the agenda and what we hope to accomplish over the next day and a half. From the feedback we got from all of you, there was a lot of interest in a lot of topics. We had some topics that we

wanted to spend some time with you to get some feedback as well.

In part because of a lot of new activities going on, this agenda is probably a little bit more towards the information sharing than we typically like to do just because you all had so many topics you wanted to get an update on.

Having said that, we've also inserted topics where we do want to have some dialogue and some back and forth in terms of where we are and where we're heading. One of those first topics has to do with nanotechnology. Bill Jordan will be chairing the session.

We'll review where we're at in terms of nanotechnology and pesticides and also some dialogue around the relationship between what we're doing in the area of nanotechnology and pesticides and what's going on in terms of industrial chemicals and looking at nanotechnology and how to do the risk and risk management around that.

Then we'll take a break and then we'll spend some time working through where we are with the NPDES permit process for pesticides that can be applied to

water or over water including near water. We've had this topic periodically over the last, I think, three sessions, perhaps, with the PPDC. We're reaching an important milestone in our activities with the Office of Water. Alison Wiedeman will be joining Bill Jordan and Susan Lewis to discuss where we are in that process of developing the general permits.

This afternoon we have two update sessions which will be intense because we have a lot of information we want to get to. But, having said that, for most of the topics, you've received background information or some web sites that you could take a look at. So, our goal there is to provide some quick snapshots or key points, try to manage the time so that there will be some time for clarifying questions during those sessions. But those updates aren't intended to be a wide-sweeping dialogue around different perspectives but just to give you a snapshot of where we are.

If we have some time, we'll do some clarifying questions. We're always open to have other meetings with the office in terms of more detailed explorations of topics. So, I hope you'll bear with me if I start to be

the ref on the ice at a hockey game. I won't put you in the penalty box but I am going to watch the clock so that we can stay on schedule, again in the context of how we tried to set up the meeting today.

We'll also be spending some time this afternoon, more in-depth time, for some back and forth in terms of endangered species. We're particularly focusing on where we are and starting to work through consultations and how to try to take the best advantage we can with the time frames we have of getting public input as we have to move forward with the consultation packages and responding to biological opinions from the services.

Vicki Dellarco will then give a brief update on where we are with our PPDC work group looking at 21st century toxicology and give a report out on some of those activities.

We'll also be looking at the end of the day getting some update on our -- oh, we'll have a public comment period, sorry, at the end of the day to kind of wrap it up. By then, I'm sure we'll be ready for taking a break as we move into tomorrow where we'll be taking a

look at the issue of pollinator protection which is an area that I'm sure you all are aware of, everything from colony collapse disorder in honeybees to just sort of broader issues about native pollinators.

What we want to do in that session with our colleagues at USDA is give you an update of where we are, in particular get some feedback from you on how we can enhance our communication, not just in EPA but with EPA and USDA and others in terms of where we are in receiving information and how can we do a better job at communicating what the federal government is trying to work through with this very challenging topic that we're dealing with.

Lois Rossi will then spend a little time giving an update from another PPDC work group, a newer work group looking at public health issues and how to start tackling some of those issues.

Then, we'll also get an update from Rick Keigwin and Karen Whitby on where we are in issuing test orders in the endocrine disruptor screening program and give you sort of a snapshot of how that process is going and where we're heading.

Then, we'll wrap it up tomorrow talking a little bit about next meeting. Also, Margie will walk you through the process of getting new members for the committee as we move forward in the history of this August body and the great work you all provide to us.

So, what I'd like to do before we get started is spend some time going around the table so everybody can introduce themselves and your organization. If you're an alternate for another individual, if you could clarify that as we go around the table. Why don't we start on my left and start with Marty.

MS. MONELL: Marty Monell, Deputy Director, OPP.

MR. HOUSENGER: Jack Housenger, Director of BEAD.

MR. JORDAN: Bill Jordan, Senior Policy Advisor in the Pesticide Office.

MS. SHIMKIN: Martha Shimkin (phonetic) with the Office of Pesticides Programs.

MR. DWINELL: Steve Dwinell of --

(Break in tape.)

MS. ROBERTS: Amy Roberts sitting in for Maria

Herrero as representative of the Biopesticide Industry Alliance.

MR. VROOM: I'm Jay Vroom, President of CropLife America representing agricultural crop protection manufacturers, distributors and formulators.

I wanted to take a moment just to say thanks to all the farm organizations that are represented. Cannon Michael, I think, is the only active farmer with us here today. Being away at this time of the year from planting season is a special commitment, but I think all of us are well reminded to thank farmers every day but especially during planting season.

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

MS. LAW: Beth Law, Consumer Specialty Product Association sitting in for Phil Klein today.

MR. FRY: I'm Michael Fry from American Bird Conservancy.

MS. RAMSAY: I'm Carol Ramsay from Washington State University and representing the American Association of Pesticide and Safety Educators since Amy Brown was unable to make it today.

DR. ROBERTS: I'm Jimmy Roberts. I'm a pediatrician at the Medical University of South Carolina.

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

MS. BRICKEY: Carolyn Brickey.

MR. TAMAYO: Dave Tamayo, County of Sacramento and California Stormwater Quality Association.

MR. WEGMEYER: Tyler Wegmeyer, American Farm Bureau Federation.

MS. KEGLEY: Susan Kegley, consulting scientist and representing Pesticide Action Network.

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

DR. SCHELL: I'm John Schell, a toxicologist with ENTRIX.

MR. SCHERTZ: Scott Schertz, Schertz Aerial Service, representing the National Agricultural Aviation Association.

MS. SULLIVAN: Kristie Sullivan, Physicians Committee for Responsible Medicine representing animal protection and consideration.

DR. WHALON: Mark Whalon. Jay, I'm also a farmer.

MS. LIEBMAN: Good morning. I'm Amy Liebman from the Migrant Clinicians Network.

MR. JAMES: Allen James, Responsible Industry for a Sound Environment. We represent companies that manufacture and formulate products for urban use.

MR. THRIFT: Jim Thrift, Agricultural Retailers who represent retailers, distributors and applicators.

MS. RUIZ: Virginia Ruiz, Farmworker Justice.

MR. MICHAEL: Cannon Michael. I am a farmer also and here representing National Cotton Council, California Cotton Growers. My friend Tyler across from me is also a farmer.

MS. SPAGNOLI: Julie Spagnoli, FMC.

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

MS. BAKER: Cindy Baker representing the Gallon Group of which one company J.R. Date Growers. We grow dates.

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

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

DR. FERENC: Sue Ferenc, Chemical Producers and

Distributors Association.

MR. BOTTS: Dan Botts, Florida Fruit and Vegetable Association and Monarch Crop Farmer Alliance.

MR. ROSENBERG: Bob Rosenberg, National Pest Management Association and I eat farm products.

DR. SHAH: Hasmuckh Shah, American Chemistry Counsel representing manufacturers and formulators of the antimicrobial pesticides.

MR. BEAVERS: Good morning, everybody. Mark Beavers. I'm at the Armed Forces Pest Management Board. I'm representing the Department of Defense.

MR. KASHTOCK: Mike Kashtock, Food and Drug Administration, Office of Food Safety. I'm representing Dr. Nega Beru.

MR. CHIN: Teung Chin, USDA Office of Pest Management Policy. I have a good crop of dandelions in my yard.

MR. BRADBURY: Thanks. If any members of the PPDC on the phone, if you could introduce yourself as well, please.

(No verbal response.)

MR. BRADBURY: Okay. During the course of the

day and a half, I think there will be some members who will be calling in on the phone, so we'll check in periodically and make sure when they're on that they introduce themselves so we know they're there. I can make sure they can ask a question or get some feedback to us as they desire.

Why don't we start our first session which has to do with nanotechnology and some of the activities that we've been undertaking in the pesticide program. I'm going to turn it over to Bill Jordan who is going to chair this session. Bill.

MR. JORDAN: Thanks, Steve. Thanks, everyone, for starting your morning with us on nanotechnology. The agenda indicates that there will be three of us working together. Joan Harrigan-Farrelly, the director of the Antimicrobials Division, is unable to be here this morning. She's attending a funeral. But Joan, along with Jack and I, work on the interdivisional team of folks who are trying to make sure that we proceed in an coordinated fashion with the development of policies and making particular decisions on products that involve nanotechnology.

So, I'm very grateful for the support of the other folks on this front. The presentation that I'm making actually was drafted by folks in Joan's division. I crib liberally from their work as well as work of folks in the other parts of EPA.

So, the presentation today is the first one we've had at PPDC since November of 2006. A lot has happened since then. If you're like me, you probably didn't know much about nanotechnology and maybe you have learned a fair amount. Or, if you're like me, you've probably forgotten a lot of what you might have learned. So, we're going to start off with a basic review of nanotechnology and talk a little bit about how we in OPP are going to define nanoscale materials.

Then we'll move on to some brief discussion of why OPP is concerned about nanoscale materials and then describe in particular the kinds of products that we are beginning to see. Because we have a lot of questions and a lot of places where we need help from the outside, we convened a meeting of the scientific advisory panel in November. I'll tell you what we asked them about and the kind of advice that we got from them.

I'll wrap up with a discussion of some notice that we're going to issue, I hope very soon, on nanoscale issues and summarize some activities that we're engaged with across the agency and internationally.

So, let me start off by reviewing a little bit of the basics. Nanotechnology has often been referred to as the science of the small. We're talking about really really small, in the range of approximately 1 to 100 nanometers. That may not mean much to you. I'll try to put that in perspective in the next slide, but working with materials in that size range is extraordinarily challenging.

The people who are doing it have discovered that it's just a field that requires new technology and new skills. They are developing and creating structures that will have astounding applications potential benefits. I'll talk a little bit about them.

So, it involves the ability to control or manipulate matter almost at the size of single atoms and then to understand what that does in terms of the properties of materials. The field is growing very rapidly. In 1985, people filed for 125 patents. In

2005, the last year I have data for, there were almost 5,000 patents. That represents a growth of about 20 percent a year. There doesn't seem to be any signs that it's going to stop growing.

So, how big is a nanometer? It's one billionth of a meter. If you lined 10 hydrogen atoms up next to each other, that would be about a nanometer in length. A carbon nanotube, which is carbon atoms bound together in a single layer and then rolled to form a hollow tube, is about two nanometers in diameter. DNA is about two-and-a-half nanometers. A virus which is pretty small is 100 nanometers.

By contrast, a human hair -- I will digress here to day that the figures on human hairs ranged anywhere from 60,000 to 100,000 nanometers. It runs in the range of about 75,000 nanometers. Shaquille O'Neal, according to the web site, is about 2.1 billion nanometers tall. So, we're talking really really small stuff.

Why are people interested in materials like that? Well, the answer is that they begin to display novel properties. Almost every field of product that you

can imagine is looking into nanotechnology. It's being applied in semiconductors to make them faster, cheaper, and smaller for data storage, to process information more quickly. There are carbon nanotubes which can transmit electricity with less energy loss. There are sunscreens that incorporate titanium dioxide. So, instead of being the messy white goop that you may be familiar with from years ago, it's now possible to have it transparent and provide better UV protection.

There are sensors that can detect explosives, I think land mines or IEDs or terrorist bombs in very very small levels of explosive materials. Quantum dots are being used in lighting. A quantum dot is a kind of nanosized crystal that absorbs light and then emits photons. They can be much more energy efficient.

There are nanoapplications that involve self-cleaning surfaces so that you never have to wash windows anymore, also capable of repelling dirt on textiles, structural reinforcement. Adding carbon nanotubes can produce lighter, stronger car bodies or airplane fuselage that's making people safer, saving fuel. This is just the start of some of the kinds of applications that we've

run across already.

So, people are beginning to think about using nanoscale materials in pesticides. We are beginning to see products. This is how we are going to define nanoscale materials. It's an ingredient that contains particles that have been intentionally produced to have at least one dimension that measures between approximately 1 and 100 nanometers.

A couple of comments on that. The first is the use of the phrase intentionally produced. Nanoscale particles occur naturally. They may be produced inadvertently in the course of making materials. What we're interested in are when people intentionally or deliberately manufacture a material so that it falls into the nanoscale range.

People don't do that unless they are hoping to take advantage of some novel property. So, you'll notice that it does not refer here to novel properties, as some of the definitions currently do. That's because we want to have the opportunity to look at the materials and to evaluate whether or not there are, in fact, novel properties and how those properties relate to our safety

assessment.

Finally, you'll see that there is no particular percentage. We are interested in trying to understand this field and don't yet have enough knowledge to be able to predict what level or percentage of nanoscale materials will be enough to change the characteristics of a pesticide product. As long as somebody is intentionally producing nanoscale material, we'd like to know about that.

So, what do we know? Well, lots of research is going on in the area of nanoscale materials. What it demonstrates is that nanoscale materials behave differently from conventionally-sized counterparts. When materials get smaller, they begin to behave differently. Gold, for example, in wedding rings such as the one I'm wearing, is a pretty familiar yellow-colored metallic substance not particularly harmful. People are intimate contact with it for long periods of time, one hopes, when they're wearing their wedding rings.

But when it's nanoscale size, gold can have very different properties. For example, it's no longer yellow colored. It can vary in color from red to black.

It becomes much more highly reactive and more toxic. The same is true for nanocopper, much more acutely toxic than the micron-sized particles.

The literature is growing fast. It indicates that not only size is important but so, too, is shape and coating. The SIP, when they reviewed our consultation package in November, said that there are just very large gaps in our understanding and we still need and have a lot to learn.

So, I found this slide particularly interesting. It helped me understand a little bit better as a lay person why nanoscale materials are different. This is a depiction of the relationship between size and surface area. The smaller a particle is -- this is sort of intuitively obvious, but the smaller the particle is, the more atoms appear on the surface of the particle. The larger the particle is, the smaller the percentage of atoms that appear on the surface.

This chart shows that around 100 nanometers in diameter, the ratio of surface area to diameter begins to rise dramatically. In the 1 to 10 nanometer range, it’s dramatically different from a higher range. But once you

get above 100 nanometers, the percentage of particles on the surface goes down. This is important because in a lot of ways, what determines the reactivity or the rate at which things happen is related to the availability of the atoms to interact.

So, the more atoms that are available, the higher percentage of the atoms that are available to interact, the faster and greater their interaction goes. This raises the possibility that there are ways of assessing risk, which historically have been based on mass, milligrams. Material related to a kilogram of body weight, for example, which is familiar for most of you, I hope, in our risk assessment, may not be as important as considering the surface area phenomenon.

On the next slide, I talk a little bit about why OPP is concerned. The research that's been conducted suggests that at least for some nanoscale materials, dermal absorption is more rapid. It can pass into the body much more readily because of its small size and actually penetrate into cell membranes.

In terms of inhalation, small particles can go much farther into the respiratory system, deep into the

lung, enter into the blood supply, cross the brain barrier, and reach parts of the body that are not otherwise expected.

Those same properties also are a concern potentially for environmental effects. These materials may be more durable and, as I mentioned earlier, more reactive, raising questions about fate and what compartments they would enter. We really don't have a whole lot of information about the toxicity of these nanoscale materials to nonmammalian species compared to conventionally-sized materials. So, we have a lot to learn.

Let me shift over now to what's happening here in the Office of Pesticide Programs. Currently, we know of at least one product on the market that contains a nanoscale material; it's nanosilver. This product was approved by EPA without our knowledge that the product contained a nanoscale material.

The applicant did not identify the presence of a nanoscale material and simply suggested that it was a ME 2 (phonetic) version of an already registered product. In fact, it does have many characteristics that are quite

similar to other registered products. It's material is preservative. There are a number of other silver-based antimicrobial products that are used as materials preservative.

So, identifying that product has led us to think that perhaps there are other registered pesticides that contain nanoscale materials. We are taking steps to identify them. We sent a letter to the registrants of all silver-based antimicrobial products informing them that we would not only like to know but we regard them as having a legal obligation to identify for us the presence of nanoscale material.

That letter was sent under the auspices of FIFRA section 6(a)(2). We're currently reviewing their responses and other information in order to identify any additional products that may contain nanoscale silver. When we do, then we'll take appropriate actions under FIFRA to ensure that all of those products meet FIFRA standards.

Beyond currently registered products, we have pending before us a number of applications. All of them at this point are in the antimicrobials division. Most

of them involve products that would contain nanoscale silver. Again, uses as materials, preservatives, additives to textiles or plastics, coatings or other substances in order to protect the treated products from microbial degradation, again very similar to currently registered products.

But there are other products in the works. One of them that is not a nanosilver-based product uses a nanotube like clay substance, halloysite, which would be used as a kind of microencapsulization of the active ingredient and would provide better delivery in timing for the active ingredient. I've also heard about another product that's not the subject of an application as far as I know, but it could be coming into our registration division or by pesticides division as a mosquitocide.

So, with all of this activity going on, we decided that we were going to be facing fairly quickly the need to make our science-based decisions on the pending applications and the currently registered products. Because of the newness of this field, we thought it helpful to consult with the FIFRA scientific advisory panel.

We held that meeting in November of last year. They have since provided us a report in which they responded to the questions that we asked them about how to evaluate the hazard and exposure from nanosilver and other nanometal-based pesticide products.

We wanted to understand whether these products incorporate nanoscale silver. We're going to pose any kind of differences from other silver-based products in terms of silver ion exposure and in terms of the release of nanosilver particles.

The SAP wrote a very extensive report in which they cited numerous scientific articles. In spite of the lengthy bibliography, their bottom line conclusion is you need a lot more data in all the scientific disciplines in order to be able to have a comprehensive understanding of the affects of the nanoscale silver.

The kinds of data requirements will need to be defined on a case-by-case basis. For example, looking at materials preservative, you need to take into account differences between the kinds of materials that might be preserved. Are you talking about ceramics or caulks or insulation or textiles? Also, is it being applied as a

coating or is it a constituent of the ingredient. These will all influence the kind of day requirements.

The other sort of broad overreaching idea that they recommended was life cycle analysis, something that I think we've been doing intuitively in the pesticide program. But their recommendation is to make it more explicit, starting with the initial use of the pesticide. So, you're talking about a product that's being used as a fabric treatment in order to extend the life of the fabric and anything about how the exposure might occur.

Well, there's the exposure that workers might get when they incorporate that material preservative into a textile product. Then there's the exposure that workers might get when they're handling the treated fabric. Then there are exposures that people might get wearing the fabric.

For example, does the product leach out when it comes in contact with human sweat? Or what about if it's put into a piece of clothing worn by a child and the child decides to suck on the clothing. So, that would be dermal exposure, perhaps an oral exposure.

Then you'd need to think also about washing and

drying the treated clothing. Does the nanoscale material come out during the washing or drying process? What about different kinds of detergents or bleach or qualities of water? Where does it go? Does it go down the drain? Does it aggregate, that sort of thing? What happens when it's dried? Does it go out the exhaust fan in the form of lint creating a possible exposure by de-inhalation?

Then, finally thinking about eventual disposal of the treated fabric. Will it be burned? If so, what combustion products form and what's the potential for exposure by that route? Or, if it's put in a landfill, what are the potential exposures there? So, these are the kinds of things that would go into a life cycle analysis.

Shifting now to some of the upcoming policies, we are working currently on a Federal Register notice relating to nanoscale materials and pesticides. My hope is that we will issue it in June, but I'm happy to use this time to tell you a little bit about what it's going to say.

It will announce a new interpretation of FIFRA

and our 6(a)(2) regulations and propose a new policy. With regard to the interpretation, it will say that the presence of a nanoscale material in a pesticide product is reportable under FIFRA section 6(a)(2). The basic idea here is pretty straightforward.

That is that companies that are seeking to register product or companies that already have products in the marketplace need to disclose to EPA the presence of a nanoscale material and their product, if they haven't already done so. This isn't a new regulation. This isn't a policy statement. It is an interpretation of the statute 6(a)(2) and our existing regulations at 40 CFR part 159.

In talking about this with some stakeholders, I've heard concern raised that this stigmatizes in some fashion nanoscale materials. That is not what we are hoping to do. We're simply hoping to get information. We don't think it is any more of a stigma than the existing requirement which requires registrants to report to EPA any newly identified matabolites that might be formed by their product, something that's been going on since the 6(a)(2) regulations were promulgated a long

time ago. Those metabolites, as far as I know, are not being stigmatized.

We're very clear in the notice and we'll be clear in any communications that we make that we are not convinced that all nanoscale materials are automatically dangerous or harmful. What we do know, though, is that they behave differently from conventional and sized materials. That fact, which is common across lots of different nanoscale materials, is enough to make it prudent on our part to look for additional information in order to be able to understand the effects.

The application of this -- I should point out that under our regulations, we also have a provision that says that any person applying for registration of a product must also report as part of its application any information that would be reportable under 6(a)(2). So, as a consequence of that existing regulation, this interpretation will apply not only to registered products but also to products that are submitted for registration.

This next slide simply summarizes what I just said. It places the burden of reporting the presence of nanoscale materials on registrants and applicants who

will continue to be responsible for proving the safety or continued safety of their products.

The other part of the notice will be to announce a proposed new policy. That policy is that when an active or an inert ingredient contains a nanoscale material, it would be presumptively considered a new active or a new inert ingredient even if there is a conventionally-sized active ingredient already in a registered product.

So, just to explain, we have registered lots of products with silver-based active ingredients. A company seeking to register nanosilver products, we would presume that that nanosilver would be a new active ingredient and would process it according with PRIA schedules and data requirements accordingly.

Now, I said that’s a presumption. A presumption is something that isn’t binding and can be overcome by submission of information demonstrating that the nanoscale material and the conventionally-sized material behave in comparable fashions.

I want to move on to a citizen petition in May of 2008. The International Center for Technology

Assessment filed a petition with us asking EPA to regulate products containing nanosilver. We have been looking at that petition in the context of the pending applications and also in light of the FIFRA SAP review. Among other things, the ICPA asked us to take regulatory action on what they estimated was about 600 unregistered nanosilver products. They claim that we ought to be regulating them under FIFRA.

I will note that the products are pretty diverse. Some of them clearly do have antimicrobial claims and would be regarded as pesticides whether they were nanosilver or any other ingredient, claiming that they are antibacterial or that they eliminate 99.9 percent of bacteria or providing antimicrobial or antifungal affect. But there are other products that are not FIFRA-regulated materials, soaps and personal care products and that sort of thing, and some that are clearly within the scope of FDA's jurisdiction.

With regard to the regulatory issues, another aspect of this that makes it challenging is that many of these are manufactured around the world, not necessarily in the United States. So, enforcement is facing some

pretty interesting and challenging issues here. Our goal is to answer this response in connection with and concurrently with issuing that Federal Register notice hopefully in June.

I'll wrap up by talking briefly about how OPP working with other parts of the agency, other parts of the Federal Government and international organizations. We, in OPP, are really not the leaders of this effort. The Office of Research and Development and the Office of Pollution Prevention and Toxic have been looking at issues related to nanotechnology much longer and know a lot more about the science of this area than we do. They are leading, appropriately, the efforts for the agency. We're very happy for their support and help.

The Office of Research and Development issued a nanomaterials research strategy with a lot of emphasis on understanding sources, fate and transport of nanomaterials, and understanding the human health and ecological effects. They are also spending time developing new testing methods which will be very valuable when we, in OPP, begin to require data on nanoscale materials.

They are serving another very helpful role in pulling together the information in the public literature in case studies on particular chemicals. They have case studies already available on titanium dioxide and carbon nanotubes. And very happily and gratuitously they are developing a case study on nanosilver which they hope to get out this year.

OPPT, our sister organization, in 2008 started a voluntary program called the Nanoscale Materials Stewardship Program in which companies that were making industrial chemicals of nanoscale were invited to provide information to the agency to assess them. We got information from 31 companies, 132 unique materials.

That's the good news. The bad news is that that probably didn't come close to capturing even the majority of nanoscale materials that we think are out there in the environment. So, we think more needs to be done. I'll say a little bit about that on the next slide.

In addition, the TSCA New Chemicals Program is looking at nanoscale materials. In the world of TSCA, the universe of chemicals is divided into old materials

and new materials. Old materials were ones that were being marketed when TSCA was passed. New materials are new chemicals that were developed since the passage of TSCA.

Over 100 new chemicals have been developed that are in the nanoscale range. TSCA requires those developers to notify EPA and provide us with information about them so that we can decide whether they should go ahead. This premanufacturing notice program has led to requirements on the release of the new nanoscale materials to minimize human and environmental exposure in many cases.

OPPT's future activities to deal with old chemicals will include a significant new use rule that says if you're going to take an existing chemical, an old chemical, and put it out and start using it in nanoscale form, you need to notify EPA such that it would go through the same kind of review process as a notice on a new chemical.

The TSCA section 8(a) rule would get existing information to characterize the use, production volume, exposure pathways, existing toxicity data on currently

marketed nanoscale materials. A TSCA section 4 test rule will be issued for certain nanoscale materials, probably a proposal by the end of this year.

With regard to EPA's role through the Federal Government, there is a national nanotechnology initiative. It has a complicated organizational chart that you see here. We play actively along with other federal agencies that are involved in nanotechnology research or regulation.

Our primary involvement is through NEHI. I should have printed this in purple or orange, but the NEHI one is at the bottom there. It's the group that focuses particularly on environmental and health implications which is a special concern to us and other regulatory agencies like CPSC and FDA.

EPA is actively working in international organizations. We took a lead role in the working party on manufactured nanomaterials established under the auspices of the OECD about four years ago. There have been a number of meetings. We've set up a number of working groups. We chaired the first five and now the responsibility is passed over to the EU.

This group is actually doing a fair number of interesting things with the overall goal of promoting international cooperation. This is such a fast growing field and there are so many countries trying to understand and take advantage of the important and exciting opportunities in nanotechnology that this kind of international cooperation is going to be very valuable.

The next slide and the last slide shows you an example of that. The working party on manufactured nanomaterials has decided that one of the gaps that we need to fill is getting more understanding of the toxicity of many of the widely used nanomaterials. They are listed here, single wall carbon nanotubes, multi-wall carbon nanotubes. The fourth one down is silver nanoparticles which is of particular interest to us. It indicates that there will be testing on all of these materials.

Various countries are volunteering to take the lead and others are participating in various ways to do parts of the research. The lead sponsors will design the research programs and the other countries will contribute

resources. As a result of this, we should be getting a lot of additional information in the relatively near future, next few years, to better understand the toxicity of these materials. It will be quite helpful, I think, for all of the regulatory agencies to be able to fill our responsibilities to evaluate safety.

So, that is a fast run through of what's happened since November 2006 on nanomaterials. I'm going to stop here and invite comments and questions. Jack and I will do our best to try and answer. The way we'll do this is raise your cards if you want to make a comment and we'll circle around starting --

Steve started on his left. Last time he started on his right. The first card up appears to be Joe Conlon. So, Joe.

MR. CONLON: We don't know what we don't know in a way with this product and given the fact that there's different toxicology profiles of nanotechnology vis a vis regular active ingredients and environmental fates, et cetera, et cetera, how does all of this fit into the risk cup?

MR. JORDAN: That's a great question and that's

one that frankly not only we in OPP are struggling to make sense of but so, too, are a lot of other regulators and scientists.

The SAP report, which is very dense, very technical, has suggested a variety of ways of thinking through those issues. I will tell you I don't yet feel I have the technical sophistication to be able to explain. I'm not even sure I come close to understanding some of their ideas. But they are suggesting qualitative approaches in conjunction with quantitative approaches that would be appropriate for assessing these materials.

We'll be working with our colleagues in the Office of Pollution Prevention and Toxics who have had to come to grips with these questions in the context of the PMNs on over 100 different nanoscale materials. I think the short answer is that we'll be using some of the basic principles of toxicology and using our best professional judgment, understanding potential sources of exposure and being careful and being transparent about it as we go forward, consistent with the notion that these are new active ingredients or new inert ingredients. They'll be covered under our transparency policy and we'll take

public comment on our assessments.

MR. BRADBURY: Caroline Cox.

MS. COX: I was speaking with an analytical chemist who said that nanomaterials are the one clear category that she flagged as there not being available analytical techniques to identify, I think, especially once these materials get out in the environment.

So, my question is, is there going to be a requirement from EPA that registrants of these products provide an appropriate analytical technique?

MR. HOUSENGER: Yes. That's one of the issues that NIST (phonetic) is looking into and certainly one that we're concerned about. How do you measure nanomaterials present out in the environment? How do you know what form they're in? Are they agglomerated? Are they individual particles? I wish I had the answer to it right now, but I think it's one that we're struggling with along with the other agencies in the government.

Certainly, when we're talking about nanosilver in textiles and other materials, we need a way to identify how much they leech out and also what's leeching out. I think we have identified some of the methods to

do that but I think it becomes harder as we get into how these materials get into the environment and in what form.

MR. JORDAN: I'll add that on the slide indicating ORD's research priorities, about half of their research funds are going toward identification of sources and measurement issues.

So, Cindy Baker next.

MS. BAKER: Thanks, Bill. Nothing like starting off the morning showing your ignorance. So, here's my ignorance question. If I think I understood you right in what you were saying, it sounds like it might be possible that there is existing products out there that have nanoscale materials. Even the registrants might not be aware of that by the nature of how some of these things could form.

So, I mean, your definition is very clear. If you're intentionally producing something to be a nanomaterial, then you come in upfront saying that. But, having this requirement under FIFRA 6(a)(2) is a different level, I guess, of awareness and responsibility and all that on the registrant, which I'm not saying is

right, wrong, or indifferent.

But, does this change the product chemistry requirement? I mean, how do you go about figuring out if you have a nanoscale material in something or one is formed if you weren't intentionally doing that in the first place?

The other is sort of a comment about just putting this under the umbrella of FIFRA 6(a)(2), because historically, what information comes in about a formulation and what's in it, comes in under a confidential statement of formula, which is, in fact, confidential information for a proprietary business reason which FIFRA 6(a)(2) reports are not covered under that. So, just kind of your thoughts a little bit around those two issues.

MR. JORDAN: One of the sort of bedrock principles of the 6(a)(2) reporting requirements is that it doesn't require people to develop new information. So, to address the first part of your question, if a company doesn't have knowledge that their product contains a nanoscale material that was intentionally produced, this interpretation would not in any way expose

them to any kind of failure to report liability.

The second part of your question relating to product chemistry data requirements, we are thinking about whether we need to change the prior chemistry information that we routinely ask for in connection with an application. My hunch is that we probably will ask for additional prior chemistry information if the applicant or registrant reports that they have intentionally put a nanoscale material in their product.

At least at this point, I'm thinking that it's not particularly likely -- but I could be wrong about this, pardon my ignorance as well. It's not particularly likely that somebody is going to manufacture something with a lot of nanoscale material in it by accident. So, I'm not sure where that goes.

The last piece seemed to relate to the CBI issues. The FIFRA CBI protections, I think, apply to material, to any kind of information submitted to EPA. That would include 602 if the claim is appropriate, it would not be released to the public.

Rather than my calling on people and since my eyesight is not great, I'll just let you all do it. So,

Julie, go ahead, please.

MS. SPAGNOLI: I wanted to clarify. So, under your OPP under FIFRA, if it's a nanomaterial of an existing active ingredient, it's considered a new active ingredient. But under TSCA, if it's a nanomaterial of an existing chemical, it's considered a significant new use? Is that how they're -- little differences in how they're addressing nano?

MR. JORDAN: What you said I think is correct. I looked over to Jim Jones who gave me a very subtle understated nod. Having said that, I think the differences arise from the differences in the definitions and structure of the two statutes. While they may sound different, in practice, I think they are really quite similar.

Under both FIFRA and TSCA, what we're saying is we want to know about new nanoscale materials so that the agency can assess the safety of these chemicals. I'm not saying that they're unsafe, but just that we want to know about them.

MS. SPAGNOLI: I just wanted to make sure I was understanding that.

MR. HOUSENGER: If I can just put a clarification, we actually aggressively explored, both in the last administration and again in this one, whether or not we could under TSCA say that a nanomaterial of an existing chemical was new, as we are and are allowed to under FIFRA. The statute just doesn't allow you to get there. So, we came up with the concept, which isn't a new concept and topic at all, of saying it's a significant new use and therefore we have to be notified.

MR. BRADBURY: Virginia Ruiz.

MS. RUIZ: I'm just wondering if there's also a consideration -- if you're looking into tools for detecting the presence in people, like the tools for physicians or to help protect health effects?

MR. JORDAN: I can't say that I know about all the research that's going on in this area. Measurement and detection, as I noted earlier, is a significant part of the research agenda for the Office of Research and Development. But I can't answer -- don't know the answer to that particular question, sorry.

MR. JAMES: Allen James. My question is a follow on to Cindy's.

If a company now reports a nanoparticle or whatever it's called, a nanoproduct, a nanoscale item in their product, and it is considered a new active ingredient, and they have distributed products nationwide -- it's in the channels of commerce -- is that company in violation of FIFRA for having that product on the market? If so, how will that be handled? Will they be subject to the extreme fines that are associated with marketing an unregistered pesticide?

MR. JORDAN: Steve, did you want to say something about the last question while I think about how I'm going to answer Allen's?

MR. BRADBURY: Virginia, we'll get back to you to confirm, but my understanding in the research programs and ORD and others that they're looking at a variety of matrices to the analytical methods, including looking in biological tissues. So, we'll get back to you, but my sense is that the research is going in the direction you were wondering about. There's analytical methods for a variety of applications and matrices. We'll confirm that for you.

MR. JORDAN: Thanks. The report of information

under 6(a)(2) does not change the status of a product's registration. If the product is registered, it may be sold and distributed in the United States in accordance with that registration.

I don't want to speculate about -- in the failure to have provided that or the fact that a person -- I don't want to say failure -- the fact that a person hasn't provided information about the presence of a nanoscale material does not constitute a violation until the person is on notice that we expect to receive that information, which we think, among other things, this Federal Register notice will clearly accomplish.

If we at EPA find out that currently registered products have nanoscale materials in them, that could lead to our decision to require additional data to assess the continued safety of those products. That would be imposed through a (inaudible) notice in all likelihood.

Amy.

MS. LIEBMAN: Thanks. Steve, you had clarified some of my question, but I just wanted to -- first of all, I'm very happy that you guys are taking this seriously and doing the work that you are to try to

understand.

I just want to reiterate Jack's answer to Caroline's, a lot about what's happening in the environment but the importance of trying to understand the human health effects even before you're allowing them to be registered. Then, once they are registered, the importance of trying to understand the human health effects and what the exposures are. I mean, I think that's part of the product registration from my understanding.

So, as we talk about environmental exposures, we really need to better understand what the human health effects are, particularly the bonable (phonetic) populations. You mentioned products that kids are involved with or baby products and then also worker populations that might be disproportionately exposed.

DR. WHALON: Mark Whalon. Bill, you mentioned your ring, your gold marriage ring there. One of the things that that brought to mind is that an old remedy for sties in the eye were to take a ring off and rub them on a sty which accelerated return to normalcy in that way. That suggests that nanotechnology has been around

for a long time. But now we know it has been around for a long time because a lot of Roman era stained glass used nanotechnology for affecting light transmission through the glass.

So, on the one hand, we don't need to panic. On the other hand, in the journal Cell a recent article pointed out that under evolutionary processes, symmetrical cell division is expected. It turns out that nanoparticles do create nonsymmetrical cell division. In other words, one of the daughter cells resulting from a division dies with all the nanomaterials which are redistributed after the death of the cell.

So, that creates a microevolutionary issue and one that could lead to mutagenesis and toratagenesis and opens up a whole new area where probably life cycle exposure and things like that will have to be addressed for some of these materials.

This article, by the way, is in Cell, 135, November '08. There's also a summary of it in Nano Today. That's a new magazine like thing that's come up around nanotechnology, volume 5, issue 2, April 2010. So, it's a real thing.

In the area of resistance development and in segregation of genetic material in cells, particularly microbes, it becomes really really important to look at short term and long term.

MR. BRADBURY: Kristie.

MS. SULLIVAN: This is another research question, I guess. The next slide on research allocation where there's 30 percent in the nanomaterials research strategy going to human health and ecological effects, from what I understand, some experts in nanomaterials have made statements about current toxicological testing methods and some of the properties of nanomaterials making it difficult to test them in, for example, an inhalation test.

So, I was just wondering if you could speak to what portion of your research strategy relates to determining the appropriateness of testing methods for tox testing of nanomaterials.

MR. JORDAN: Well, the short answer is I can't give you much in the way of details or specifics. I don't know that much about the particular projects that are being funded under these headings. From that said,

the first question that I think needs to be getting answered in any kind of assessment is to what are people being exposed.

Jack, in his answer earlier, referred to questions relating to agglomeration, are nanoparticles coming off of the treated substrate. If so, are they complexes, which are maybe nanosilver bound to other chemicals, or is it just nanosilver. Once it gets into the environment, does the nanosilver or the nanosilver complex interact with other substances? Do they interact with each other to form agglomerates?

Answering those questions is, in my mind, one of the first things that needs to happen in order to be able to figure out from a toxicological point of view, what are people in the environment, nontarget organisms, going to be exposed to. That's the reason why I believe it makes a lot of sense to emphasize sources, fate, transport, and exposure research as the threshold. Once that's answered, then I think we could turn attention to okay, what's the toxicity of those materials.

In the SAP, there were discussions about how difficult it is to maintain exposure to different

substances because of those tendencies to agglomerate and change character. That's a particular challenge that the methods part of the research is working on. That's about as far as I can go in terms of being able to give you an answer.

MR. BRADBURY: Susan.

SUSAN: I'm curious if any of the inert ingredients have been turned into nanoscale materials or nanoscale materials used in inerts? If so, are those reportable?

MR. JORDAN: The reporting requirement would apply to any nanoscale material, whether it's active or inert. At this point, I don't have any information on inerts.

MR. BRADBURY: Jennifer.

DR. SASS: First of all, thank you, Bill. That was a really good presentation. That was actually a very detailed overview. It was also very informative. So, thank you. There was some new information there.

There's one point that I missed and then I wanted to make a couple points. You said, I think -- I missed the slide because I was taking notes -- that when

you issue the Federal Register notice in June, that that will be responsive to that petition. Is that right or no?

MR. JORDAN: We are planning to respond to the petition and issue the Federal Register notice concurrently.

DR. SASS: I see, okay. Then, I'm going to make my two points first and then ask you a question. First of all, I actually want to very very strongly support what some of the other people around the table have brought up, that you could actually make the registration conditional upon the registrants providing you with monitoring or analytical techniques, because -- and this just doesn't apply to FIFRA but this applies to every statute that regulates any toxic materials -- if you can't detect it, you can't enforce the statute.

So, it's really important to have those techniques available both in biological media as well as environmental media. And only under FIFRA could you require that to be provided. So, I think that you should and I would strongly recommend that.

The other thing is, I'm going to sort of go

against the grain here and say actually, I don't think you need to reinvent toxicology to test these materials; you just need to test what's actually being used in the product or in the formulation. It doesn't have to be fully defined in order to be able to test it in a toxicological system.

I'm not the only one that's saying that. There's a whole lot of -- a lot of the people that own the patents for these materials are actually saying the same things. If they provide you with the actual material that's being used, not a purified or an artificial sample but actually what's being used in the material, in the formulation so that if it's altered in surface coatings or interactions in the formulation that you have that, then all you have to do is test it.

So, actually, under FIFRA, you have the ability to require that information. And although it would be nice to understand the materials and be able to define them at the molecular level better, like to characterize them, the fact that they're in products already means that we shouldn't have to wait. I know those toxicologists have like a 10-year plan. As an agency

that protects environmental health and human health, I don't think we can wait 10 years because they're already in products.

I wanted to ask you a question. Are you concerned that with your definition of 1 to 100 nanometers, you're locking yourself in, because everybody agrees, everybody agrees, scientists and policymakers, that there's nothing quite magic about the 100. So, if it's 200 or 150 or 250 nanometers, the important distinction is that the characteristics are altered in a size-dependent manner.

If the characteristics are altered in a size-dependent manner, it's very likely that the toxicological profile is also altered. That's what's needs to be tested. So, are you concerned about that? FDA didn't actually lock themselves into a strict size definition.

MR. JORDAN: I notice that we've used up the allocated time and the level of interest is great. I want to thank folks. We'll take the comments and questions from the four cards that are up, at least that I can see.

With regard to your question, Jen, the working

definition says approximately 1 to 100 nanometers. It gives us some flexibility to take into account variations above or below those values to the extent that they potentially affect the behavior or safety of the product.

MR. BRADBURY: Jimmy, I think.

JIMMY: One of the nice things about being last is that a lot of the questions I had were already asked. Joe Conlon and Virginia Ruiz and Allen James brought up several concerns that I had.

So, I did want to comment as one of the few health care providers on PPDC that if we've got some products out there that were registered but not identified initially as having nanosilver in it, then we really should consider suspending use of the product until you can assure that these products are safe.

I really echo and really strongly urge that as a health care provider, again, we don't have much of an idea of how to identify some of these people who may be poisoned. This need for analytics and diagnostic testing is brought to the forefront with this. I think this really kind of is exactly why some of us on the 21st century tox committee has been pushing for this.

MR. JORDAN: We'll be looking at the products that are currently in the market. I will note that I have heard that nanoscale silver is incorporated into surgical dressings which are used currently. So, at least, sort of intuitively to me, it suggests that that particular way of using nanoscale silver involves a greater level of potential human exposure than putting it in a piece of clothing. But we'll looking at the safety and trying to determine whether we need to take any further regulatory action.

MR. BRADBURY: Michael.

MICHAEL: I also agree that this has been an extremely informative session. I would like to reinforce Jennifer Sass's recommendation of testing the formulation rather than testing the active ingredient. That's not normally done in FIFRA. I would like to see that changed not only for nanomaterials but also for conventional pesticides and other products.

UNIDENTIFIED MALE: I have four questions, and probably they're all to different degrees and ponderable but just quick reactions and then maybe further follow up later.

Number one, would most individual pesticide molecules actually fit within the 1 to 100 definition? How do you address that?

MR. JORDAN: It's my understanding that molecules are generally smaller than one nanometer. I'll defer to scientists who can help me on that at some later point.

UNIDENTIFIED MALE: So, by definition, would then everything that's already registered under FIFRA --

MR. JORDAN: The molecules, as I understand it, are smaller than one nanometer. But, like I say, that's just my understanding. So, that would not implicate --

UNIDENTIFIED MALE: Okay. It's outside the bounds on the low side, then. I think the question about the pejorative concerns around the use of 6(a)(2) are interesting and important and I appreciate the fact that you acknowledge that and are looking for ways to work through that. Communications and language are important.

I think a parallel, if you remember, and Bill, I know you remember this very well, in the early days, in the early 90s, the approach to the regulation of plant biotechnology, when it was making a pesticidal claim, was

the development of a rule then known as the plant pesticide rule. There were a lot of concerns about that in the academic community and industry and elsewhere.

Eventually, we came around to the notion of relabeling that rule. It's now the plant incorporated protectant rule. That was prospective and forward looking as opposed to the use of 6(a)(2) in this context which is a little bit of a reaction.

Again, I understand the construct of where you're at but I would just suggest as we go forward that we think about the PIP rule experience as a way to fit the language to the regulatory construct and help with the avoidance of pejorative language. Again, I don't know that you need to respond to that.

Third, Dr. Chin, USDA, I'm curious to know whether the organic board has looked at these issues and whether or not, particularly given the fact that Bill had mentioned in his presentation that as an example, it's a known scientific fact that copper nanomaterials are much more active than non-nanoscale copper compounds and then how the organic certification of copper compounds be considered. Did that come up at all or do you know?

DR. CHIN: Teung Chin, USDA. I'm not aware of any conversations with the national organic program or the OMRI (phonetic) on that particular question about copper. I'll look into it, though. USDA does have scientists looking at nanotechnology and risk assessment in an international forum though.

UNIDENTIFIED MALE: Great, thank you. The fourth question is kind of back to at what point does regulation engage with regard to FIFRA requirements for the Environmental Protection Agency, and then overlay that with how does it engage with PRIA, fee authority (phonetic)?

Marty, I don't know. Again, we've got so many other complicated issues around PRIA right now that this is probably one for down the road a ways, but it is an important point of consideration for sure, both in terms of the allegation -- the burden on the industry, but also providing the appropriate resources to the agency eventually, and especially OPP, to be able to manage these responsibilities.

MR. DWINELL: Steve Dwinell, Florida Department of Agriculture. Will the notice that you're planning

address 25(b) products?

MR. JORDAN: I think the answer is no.

MR. DWINELL: Can I urge the agency to reconsider that?

MR. JORDAN: Okay. I think we'll look at that and think about that.

I want to just wrap up by saying thanks to everybody for your questions and comments. Feel free to get in touch with Jack Housenger or John Harrigan-Farrelly or me if you want to continue the conversation. We're happy to get feedback from any and all of the stakeholders here.

MR. BRADBURY: I'd like to re-echo Bill's thanks. It is very helpful to go around the table and get some of the various perspectives and insights. If there's some facts we can get to you before we break up in the next day and a half, we'll do that, especially with regard to some of the ORD research portfolio.

Let's take a 15-minute break. We'll start our next session at 10:55 instead of 10:45. Thanks.

(Whereupon, a brief recess was taken.)

MR. BRADBURY: Okay, thanks all for getting

back in time, at least those of you around the table, and the rest of them will lose out because they won't hear the beginning of this presentation.

What we're going to do now is spend some time giving you an update on where we are with the NPDES permit process for pesticide use applied to water or near, including overwater. Bill Jordan is going to chair the session and he'll introduce the members of the team that will be doing the presentation today and answering questions.

I think, as many of you know, this effort, which is lead by the Office of Water, reflects the area of close collaboration not only here in headquarters of the pesticide program and the water program, but also working closely with our colleagues in the regions and working closely with our colleagues in the states as this process has evolved and all the work and development of the proposed permit has come along. It's a very intense effort across a lot of organizations in EPA and outside EPA and a lot of input from the public to help us.

So, Bill, I'll turn it over to you.

MR. JORDAN: Thanks, Steve. In addition to the

folks listed on the agenda, we are fortunate to have with us today Linda Bernasian (phonetic) who is the director of the Water Permits Division, part of the Office of Wastewater Management responsible for the development and issuance of the NPDES pesticide general permit.

She's going to begin with some opening remarks and then turn it over to Allison Wiedeman who has been here with the PPDC before. Allison is the chief of the Rural Branch. It's Allison's day-to-day management responsibility to deliver the permit for proposal and final. That is no easy challenge. Fortunately, Allison has a really good team of folks working with her and led by Jack Faulk (phonetic) who is sitting behind me, along with a lot of other folks from the Office of Water and the Office of Pesticide Programs.

OPP's part of the effort is led by Susan Lewis who is the associate director in the biological and economic analysis division. This team I think has been really effective at working together. I'm happy to be a part of it from time to time.

So, let me turn it over to Linda to get started. We're going to set aside a lot of time for

questions, so be thinking about what you'd like to ask or comments you'd like to make.

MS. BERNASIAN: Thank you, Bill. I appreciate the opportunity to be here. In addition, I think I came about six months ago when we were only at the prototype phase. So, obviously, with all of the excellent work that our two offices have done, as well as we have held two different sessions with the states.

When we say the states, it's both the water, NPDES regulators, as well as the pesticide folks. So, I know from the water folks that have participated in those, they have appreciated so much the states that have come to those meetings and shared so that we can all learn in our knowledge as we continue and try to do the right thing.

Overall, the NPDES program has taken the approach that we're trying to recognize overall there is already a FIFRA system in place. As we look at it and we recognize that that's in place, we've been trying to think about how we can move forward and ensure that the appropriate pesticides are applied as they need to be applied to protect public health and the environment. We

do recognize that.

So, we've also tried to take a very common sense approach and ask what are the procedures out there that can really best fit within the water program so that you don't have to do additional activities to the extent that that's possible and really just adopt the good practices that a lot of folks are already doing.

So, as we move forward and just share with you the concept, we've tried to do a very open process. We have had a meeting with this group. We've had a webcast before the group. That happened. We're really looking forward to any thoughts today as we try to move to propose, hopefully within the next month. So, we are very close to really sharing in a very public way where we are. We take our public comment period very seriously.

We are planning to do, I think, four outreach meetings across the country. We do a lot of webcasts with those as well. So, there will probably be one webcast for people that can't travel to those meetings. Our permit -- and Allison will go into this in a lot more detail, but the permit that we're going to be proposing

is really for EPA.

We do have a lot of states that are authorized to run this program. They will be following by issuing and proposing their own permit. A lot of them are looking forward to seeing our version so that they have something to start with as they move forward.

So, overall, we are very happy to be here. We are still in a very significant listening phase, as we will be throughout the process. We look forward to hearing from you today. Thank you.

MS. WIEDEMAN: Good morning, folks. I think the way that we'll run the next hour, then, is that I will give a brief presentation, about 20 minutes, that goes over some of the requirements that we have in the permit right now ready for proposal and talk a little bit about the kinds of issues that we'd particularly like to get comment on during the comment period. Then we'll open it up for a general discussion.

Just to start off, the court's decision, which essentially results in the need for folks to get permits for discharges of pesticide in U.S. waters, will not take effect until April 2011. So, we have until then to

develop the permit, as most of you know. Until then, the regulation that we develop that says you don't need a permit is still in effect. I think that most folks know that industry asked the Supreme Court to hear the case and the Supreme Court denied that. So, we are moving forward with development of the permit.

The schedule hasn't changed since the last time I spoke with you, I believe. We are on course to develop or issue the proposed permit next month towards the end of May. Then we plan to have this permit finalized by December of this year. That's to give four months beyond that until the court's decision takes effect to provide outreach and education to the regulated community and also to get the state regulatory authorities in a position where they can have their permits final and begin accepting permit applications.

A little bit more about the schedule. We will be publishing end of May. There will be a short comment period. So, folks need to be ready as soon as this permit comes out in the Federal Register to take that permit and review it and provide us comments within 30 days. It's unfortunate that it has to be that short, but

we don't have much choice given the short timeframe of the court's decision.

We will be having three public meetings in June during the public comment period for the purpose of helping people to better understand the permit so that they can provide more knowledgeable comments. Those will be in Boston, Albuquerque and Boise. Those are the states for which EPA will actually be developing the permit. The actual dates for those will be published in the Federal Register.

We will also have one public hearing in Washington, D.C. As Linda mentioned, we will be having at least one webcast, probably two, where we can accept thousands of phone calls at the same time to hear about and understand the permit better.

I think you all are familiar with our efforts to date. It has been a fairly open process and it has worked well, particularly with our states. In order for the states to be able to develop permits pretty much simultaneously with us, we've had to be more open with them and have meetings with them, more so than we have in other permitting or regulatory efforts in the past.

They've actually seen the permit in draft and they have it and they have what they need to be able to start moving forward with developing their own permit. Certainly, they're very interested in finding out what the final permit looks like next month to hopefully begin finalizing their permit for their proposals.

This project has posed several major challenges to the NPDES program. One of them is indicated here where the permitted universe up until pesticides became a necessary permitted entity shows that the increase in pesticide permitees are those that we expect will need permits.

An increase from about 600,000 to -- increase by 350,000 permitees, which is almost a 60 percent increase in the permitted universe to the more traditional industries and manufacturing plants and then we went to vessels and stormwater and (inaudible). So, it has significantly increased the size of the permitting universe nationally. About 10 percent of that is for those permits that EPA will be developing.

I'm going to skip over state outreach. I think I covered that already.

Speaking of the permits for which EPA will be developing, the states that we still have NPDES authority for are New Hampshire, Massachusetts, Idaho, New Mexico. We will also be developing the permit for Alaska and Oklahoma because they don't have authority to develop a permitting program just for pesticides.

There are other places in the country, other regions. We've developed the permits for tribal areas and for federal facilities, particularly Washington and Colorado, and also for other regions such as Puerto Rico and Guam. Those will be the areas that really will be developing a permit. The permit that's proposed in May will be one permit that will apply to all of those areas.

Folks often ask if the states have flexibility to write different permits than what EPA develops. They do to a point. What we are telling folks and what is our authority is we review the permits that the states develop and we expect them to have permits at least as stringent as the EPA develops.

The way they go about doing that can be different. There might be site specific situations in other states where certain requirements can vary as long

as the overall environmental protection is the same. So, we are working with them to make sure that they are at least as stringent as ours. Many states also have the ability to be more stringent if they would like to.

A little bit about the actual contents of the permits. I'll talk first about the scope. In developing the permit, EPA has strived to maintain the coverage of the same (inaudible) situations that we envision covering in the 2006 rule. Those are for pesticide applications to or over near waters of the U.S.

Through research and talking with industry and other stakeholders, we've determined that these four uses are those that were primarily covered in the previous rule and are now uses that need to have permits. That would be mosquito and other flying insect pest control, aquatic weed and algae control. That also includes irrigation ditches and irrigation canals, aquatic nuisance animal control, and that use would also include invasive species, and forest canopy pest control for other pests than mosquitos.

There are certain things that this permit will not cover. We want to make clear that the exemption

that's in the Clean Water Act that says that irrigation return flow and agricultural stormwater runoff are not point sources subject to NPDES permits is still intact. The 6th Circuit Court decision did not affect that in any way. So, obviously the permit would not cover those situations.

We're also not covering in this general permit discharges to tier 3 waterbodies -- those are natural resource waterbodies, pristine water -- or discharges to impaired waterbodies for a particular pesticide that is being applied. What we mean by that is, for example, if malathion is a pesticide being applied but there is an impaired waterbody for malathion, we would say (inaudible) cover that particular situation.

We're also not covering terrestrial applications to row crops or agricultural crops or terrestrial applications to forest floors. We are also not covering under this permit spray drift. For the discharges to tier 3 waterbodies and for the discharges to impaired waters for particular pesticides, it may be that an individual permit would be necessary. Certainly, there still is an option to get individual permits. Just

because it's not being covered under a general permit does not mean that a permit is not available or a permit is not necessary.

The next huge challenge in regulating this industry is who should actually file for what we call a notice of intent to be covered under a general permit. In the general permit realm, the regulated entities would submit an NOI. It will be an electronic document about one or two pages that asks information on who they are and where they intend to be applying pesticides.

The Clean Water Act allows EPA to, under certain circumstances, not require NOI (inaudible) of the industry, although the industry would still need to be in compliance with the permit requirements. But because this industry is potentially so large, the number of permitees so large, and for a host of other reasons, we've decided that NOIs will only be required for the largest of the large applicators.

So, we are including a threshold in the permit that says for entities above this threshold. The threshold would be in terms of acres of areas, a treatment area, that they would be required to submit a

notice of intent. Other that don't again still have to meet the terms of the permit. So, in terms of the threshold, we will definitely be seeking public comment on the thresholds and its appropriateness in size and appropriateness to have such a threshold in this permit.

In terms of the technology-based effluent limitations, there's technology-based effluent limitations and there's also water quality-based effluent limitations. For the technology-based effluent limitations, we have determined that in addition to meeting the FIFRA label, which is not a part of the permit -- I want to note that the FIFRA label is required under FIFRA. We're assuming compliance with that label is already occurring. We're not requiring that to be met again in this permit.

Beyond the FIFRA label, we are requiring that all permitees should minimize their discharges. What we mean by that is that we recognize that a FIFRA label says that you -- many of them say that a certain maximum amount of pesticide may be applied. That's fine. We're not arguing with that, but we are asking folks to use the lowest amount of pesticide possible, to make sure that

leaks and spills are prevented, and to calibrate and maintain equipment. This is something that most folks do anyway, but we want to make sure that all folks do this now.

We're also concerned, though, and have heard many comments about the fact that if you don't use a certain amount of pesticide, that there will be a buildup or resistence. We don't want to interfere with the resistant phenomenon at all either, so that, of course, would be taken into account when you're using a certain amount of pesticide.

Then, for all permitees that are above a threshold or for the largest of the large applicators or those that have to submit a notice of intent, we're asking them to implement some additional IPM practices. The first is identify and assess the pest problem. This is where an action threshold is determined above which you would need to apply a pesticide, below which you would not.

The next one is to assess pest management alternatives. There could be mechanical alternatives to using a pesticide. There could be removal of the sources

of the pesticide, such as standing waterbodies for mosquitos. So, we're asking folks to look at the alternatives to pest management.

Then, follow appropriate procedures for pesticide use. This means that once this pest threshold is determined, make sure that a surveillance prior to pesticide application is done to make sure that the threshold has in fact been met.

Then, also ensure that the use of pesticides are done in appropriate environmental conditions, such as make sure that the winds are proper, that it's not too hot that the pesticides will volatize, and that kind of thing. So, we've laid out those kind of considerations in the permit itself.

The second effluent limit is water quality-based effluent limits. This would mean if your technology-based effluent limit did not meet water quality, then you may need to have additional effluent limits to meet water quality. We believe that because the requirements in the permit go beyond the FIFRA label, that they are IPM measures.

The data that we have seen so far does not show

significant water quality standard violations even without additional IPM measures. Following the requirements in this permit will allow the applicator to meet water quality standards. The fact sheets or the accompanying documentation to the permit will say your discharge must be controlled as necessary to meet applicable water quality standards.

We will then go on to explain in detail the reasons why we expect that compliance with FIFRA plus compliance with permit conditions would generally control discharges to meet those water quality standards. We certainly are interested in comments in this area.

The last few parts of the permit are monitoring. Then, after this is record keeping and reporting. For monitoring, we looked at several alternatives, including ambient water quality monitoring, visual monitoring that we have selected here, and also monitoring to make sure the practices that are required are actually being implemented in the permit.

The visual monitoring that we're requiring in this permit is monitoring that we're asking to be done while the pesticide is being applied. Also, if post

application surveillance is done by an applicator as a regular course of doing business, we would ask them to also visually monitor for purposes of the permit.

What we're asking for them to look for is in the adverse effects that may have occurred because of pesticide application, fish kills, unexpected vegetation, impairment and those kinds of things. If there is an adverse effect, we are asking that this be reported. This will be a good opportunity for regulatory authorities to know if and when adverse effects are caught.

In terms of reporting and recordkeeping, we're asking that for those that are submitting a notice of intent or those that are again above the threshold, that annual reports be submitted. Those annual reports will provide information to the regulatory authority that says where spraying actually occurred.

So, the notice of intent will say where the permitee is planning to apply a pesticide, but the annual report will say where they actually did apply pesticides, what kind of pesticide was used, and over what area it was applied.

We will also, as I indicated, ask for adverse incident reporting as any adverse incidents occur. The records that we're asking for for those that are again above the threshold or have to submit NOIs are that they develop and implement a pesticide discharge management plan which essentially implements the technology based effluent limits or the IPM requirements.

We're asking them to keep this plan on site. It does not have to be something that is submitted to the permit authority for review or to the public for review. We're also asking them to keep records of any other adverse incidents and corrective action documentation that may have been required as a result of adverse incident records that they would keep on site as well.

I wanted to talk just briefly about the particular areas where we would like to have public comment. The whole permit is certainly available for public comment and we want comments on the whole permit. But, in particular, there are some places where we have actually specified in the Federal Register notice that we would like to get comments.

I also wanted to point out that it can be kind

of confusing where these documents are. The thing that actually gets published in the Federal Register is the Federal Register notice that says that the permit is available for public review. It's not the permit itself that's published in the Federal Register, but it tells you where it is on our web site. The Federal Register notice has the actual specific questions that we want folks to particularly respond to. I'll just describe those briefly in the next overhead.

The pesticide general permit and its accompanying fact sheets will be on our web site. That's what we need to have reviewed and provide comments. The fact sheet is a document that explains our rationale for the permit requirements.

So, the kinds of questions that we're soliciting input from are the type, size and number of entities that are applying pesticides to US waters. That 350,000 permitees is an estimate by us, but we could use some more specific data. The appropriateness of entities not submitting an NOI is that threshold appropriate, is that site threshold appropriate, does that cover most of the largest of the large facilities, or are there other

types of thresholds that would be more appropriate.

The best way to cover entities where each are partially responsible for meeting permit requirements, this is a tough one because in this industry, you have folks that are making the decision to apply a pesticide. Many of them would be responsible for conducting IPMs. Then they would hire an applicator to apply the pesticide.

So, the types of requirements in the permit could easily apply to the pesticide applicator as well as the decision maker or the land owner. So, who should be responsible for what requirements in permit? We have developed a methodology in this permit and we'd like to see if folks could think of any other better way or what they think of the way that we are proposing.

We'd also like confirmation that folks are doing IPM out there. We think they are doing IPM. How small of an entity is actually capable of conducting IPM. Very small applicators or very small government agencies, can they conduct IPM as well as other larger organizations?

Other pesticide use patterns that should be

covered under this permit, are we missing some? I talked about the appropriateness of threshold sizes. The appropriateness of ambient water quality sampling, who should be required if we were to require that? What types of methodologies would make ambient water quality sampling, provide valuable data, and would be affordable?

MR. JORDAN: Thanks, Allison. This time around I'm going to work it slightly differently. We have about 35 to 40 minutes. I'd like to end close to noon so that those people who are planning to participate in a work group can have full time to do their work group work. The rest of us can enjoy a leisurely lunch.

This time again raise your cards if you're interested in making a comment. I will try as best I can to keep track of the order in which the cards went up. There are so many that I'm clearly not going to get that right. Steve is whispering in my ear that Bob is first. I'll just sort of call randomly on other people.

Because our Office of Water folks don't know everybody around the table as well as we do, please identify your organization when you introduce yourself, as well as your name.

MR. ROSENBERG: I'm Bob Rosenberg. I represent the National Pest Management Association. Our membership is pest management companies. Most of what they do is structural pest control inside of houses but they also do things outside. I have two questions.

One just really quickly, in answer to the question of what constitutes near water, is that some number of feet? Then I have a second one.

MS. WIEDEMAN: Actually, how near isn't as important as whether or not it contacts the water. So, now that permits are required, if there is an application of a pesticide that is say along a ditch tank for example and it actually hits the water, that direct contact means it needs a permit. If there is no direct contact, then a permit would not be needed. So, we're not really focusing too much anymore on the distance. It's whether it actually contacts water or not.

MR. ROSENBERG: In the initial application.

MS. WIEDEMAN: Yes, right.

MR. ROSENBERG: Okay. That solves a lot of my issues. Secondly, it seems to me from a small applicator point of view, there are advantages to not being in the

general permit and advantages to being in it. It provides something of a safe harbor from liability and litigation. What advice do you give to someone that thinks they may cross the threshold that require a permit but aren't included in the general permit?

MS. WIEDEMAN: First, let me just make sure that even if you don't submit a notice of intent, you're still covered. I wanted to make sure we're clear on that. So, now you're talking about something that is not covered in the general permit.

MR. ROSENBERG: Yeah. If there is a pest control operator that makes applications to pesticides for leads adjacent to river banks, for instance, but it's not for any one of the covered purposes and they don't want to run the risk of citizens or having to themselves get their own permit, what do you ask them to do?

MS. WIEDEMAN: At this point, they have the option to get coverage under an individual permit so they can go to their regulatory authority and be covered under individual permits. But we would also recommend that you submit comments letting us know if you think that is something else that we should cover.

MS. BERNASIAN: If you discharge a pollutant into the water of the United States from a point source, you do need coverage under the Clean Water Act. If a citizen or the government files suit, the penalties, I think, are $32,000 a day.

So, my advice, if you are above the threshold, you are required to file a notice of intent if you're in those categories. If you're not in those categories, then you should really seek coverage from the regulatory agency, whether they can do a different general permit, we could amend the scope of this general permit, or you do individual permits.

But the purpose of public comment is to figure out if we've missed people. So, if you're saying yeah, you've already missed people, could you talk to Jack afterwards and we can sort it out a little bit.

MR. JORDAN: Joe Conlon.

MR. CONLON: Joe Conlon from the American Mosquito Control Association. We've talked on a number of occasions. I'd like to express my thanks to the EPA for handling what is, at best, a sticky wicket for us. A few things.

The time line, I know you've spoken to the time lines but the time lines are really putting some people in a world of hurt, particularly the states, because even though it's been transparent to a degree, a lot of things have been kept close to the best. There was only, I believe, what, 27 or 23 states involved as stakeholders, so the other folks are generally --

I don't know how they're getting their information unless it's being purloined from someone. Once it is published, then they've got to go into some serious resource spinning up mode. Colorado has already said that they don't have the resources and they don't intend to put the resources towards it. So, they're putting themselves in a liability situation.

So, the time lines are really going to be difficult to deal with, particularly a 30-day comment period on something of this magnitude. I mean, we're really going to have to spin up some comments.

I notice that services, US Fish and Wildlife Services and NOAA fisheries, when are we going to hear from them, because they're going to have some significant input into this. Is that going to be when it's published

afterwards because that could change a whole lot of things with regard to the permit?

MS. BERNASIAN: I didn't mean to cut you off. It's just that I'll forget what the questions are.

MS. WIEDEMAN: In terms of working with the states -- actually, all of the states, we've been working with all 45 states, actually all 50 states. We're even working with those for which we'll be developing permits. They have been sent a permit. We have conference calls every two weeks where we talk to them.

So, I think you were referring to the number of states that attended our meeting. There was, I think, about 23 there. They're always included in the loop with our conference calls and all the information that was sent. The time line is tough. That's why we have actually developed a permit in record time, if I say so myself, and will be finalizing it by December.

The main reason we're finalizing it by December and not by April is to give the regulated community time to know what the requirements are and also to give the states time to finalize their permit. But, you're right, we have heard about those states that aren't moving

forward. Our focus from now through the comment period will be to work with those states to make sure that they are gearing up for this.

MS. BERNASIAN: Two more things. The 30-day comment period, if you extend it, then you get less time on the end. So, there's really a balance between trying to get our permit out as fast as we can so the states can follow. So, that will be a balance. I'm sure we'll get a request for more time, but we're really balancing here so we want to try for the 30 days. If people absolutely can't make it, they can always ask us for an extension. We may or may not grant it.

So, I do suggest -- we're trying to give everybody as much advance notice and be as open as possible through the process so that people shouldn't be surprised when the permit comes out what it may say.

The other thing I do want to say is this permit is not final yet. So, all the words that Allison shared with you are tentative at this point because we haven't gone through all of our different cycles yet.

So, while we're heading in this direction, there might be some differences when it's actually

published. So, I do suggest you read it as you go through.

Did we cover all your --

MR. ROSENBERG: Just one more. You did fine on that. With regard to the adequacy of the best management practices for integrated pest management, with the EPA's draft permit, who at the EPA is going to evaluate the adequacy of the pesticide discharge management plan? I mean, who there has the expertise to actually say, well, these are good, these are bad, you should do something else?

MS. WIEDEMAN: The pesticide discharge management plan will be something that the permitee develops, kept on site. This is not something that would have to be submitted to a permit authority for review.

MR. ROSENBERG: Okay, thank you.

MS. BERNASIAN: But we will, one, have to develop, obviously, training sessions. We do have EPA inspectors that go out to -- we are very fortunate to have pesticide agencies in each state that we were and are heavily relying on helping us best understand the practice. So, there's got to be some capacity built

there for us to be able to look at it when we do a site visit if we do a site visit. EPA can also request a copy be sent to them. Then we could also hire contractors that are trained in this area to help give us that expertise.

So, every state is going to have to deal with the capacity issue as they move forward. So, our job, once we issue a permit, is to make sure it's complied with.

MR. JORDAN: Tyler Wagmeyer is next. After Tyler is Susan Kegley.

MR. WAGMEYER: Thank you. Tyler Wagmeyer, Farm Bureau. This is a big deal for farmers. The end of May is an extremely busy time, if not the busiest time on the farm, whether you're a vegetable grower, harvesting strawberries, a row crop farmer trying to get soybeans in the ground, livestock producer trying to get your hay made.

Thirty days -- and I know it's been talked about. Joe took my question, essentially, but I just need to reiterate we need more time. I mean, that's almost impossible to expect a farmer to look this over

and to make substantive comments back to you.

MS. BERNASIAN: We appreciate that. I think what we're trying to share with you here is we've met with a lot of farming groups. What they have told us is that they believe they can avoid a line directly into water. So, we do not have the farming group as one of the sectors we're trying to cover in this permit.

MR. WAGMEYER: Well, to follow that up, what I was going to say is, has EPA -- do you think it's necessary or even possible to go to the court and ask for an extension? I will say that we have thousands of farmers that come to Washington, D.C. that care about what their government does every year.

This has been one of the top issues that they're looking at and paying attention to. They are looking at okay, let's put this into my operation. Do I need a permit or do I not? There's a lot of questions out there. It's not an easy answer. I mean, there's not really an answer for a lot of their questions that they have.

MS. BERNASIAN: Would it be helpful if we did a webcast just for farmers so that we can actually share

with them they have the two exemptions? If they are irrigating their crops and it runs off from that irrigation flow, that's exempt, and also stormwater?

MR. WAGMEYER: Only about 50 percent of farmers have access to high speed internet right now. So, web access is going to be hard. Like I said, they're in the field. So, maybe Cannon in his tractor has GPS enabled satellite systems that he can connect to the internet while he's driving, but the majority of farmers don't have that ability to do it. So, yes, theoretically, if you can get all farmers on the internet to do it, great, but I just don't think that's going to be a possibility.

MR. JORDAN: Tyler, thanks. We'll think about the comment period and what we can do there.

Susan Kegley is next and then Scott Schertz.

DR. KEGLEY: I'm more than a little bit worried about enforcement. You have the people who are doing the applications responsible for the monitoring and reporting. Then they're to report fish kills or some environmental damage or whatever and then they're going to get punished for it. That doesn't encourage reporting, really. So, I just wonder how the enforcement

is actually going to work.

Then, I'm also -- and maybe this doesn't fall under the -- maybe the labels preempt this concern, but herbicide applications to clear cuts, you have forested canopies in there but I know that some of the labels on the herbicides that are used in forestry say do not apply directly to water. But I'm not sure that that is true of every single pesticide that is used in that situation. So, I'm curious about what's going on there.

Three, the threshold limit doesn't deal with multiple applicators who might be applying at the same time. So, you've got the Alameda County mosquito control district and the Solano County mosquito control districts. Are they coordinating with each other so that the net treatment area is not exceeding that threshold if they're not going to get a permit? Maybe those are bad examples because those will be huge areas.

But farmers applying weed control in irrigation ditches, there's probably a season to that. When things start to really go in the spring, you might have all of your growers applying herbicide at the same time. So, I wonder how that's going to be handled.

MS. WIEDEMAN: Thanks, Susan. The first one, and I'm glad you asked it, about adverse incidents and recording them, having an adverse incident does not necessarily mean that a violation has occurred. We want the information. You're right, we don't want to punish them from reporting it to us.

We want to know so that if there's any corrective actions that need to be taken for that permitee, that there's an opportunity for the regulatory authority and the permitee to discuss that. We talk about how there needs to be communication between the two and the fact sheet to develop corrective action.

The second one about herbicide application to the forest floor, this is a situation very similar to application of pesticides to crops. The terrestrial applications are meant to be applied terrestrially for the purpose of eradicating either herbicides in forest floors or pests and other plants and crops.

Our policy on this right now, at least just for the proposal, is that these are terrestrial applications that were not covered in the original 2006 regulations and they wouldn't be covered in this permit. But that is

definitely an area that we are seeking public comment on.

MR. JORDAN: Scott Schertz and then John Schell.

UNIDENTIFIED FEMALE: Quickly on the third question that had to do with maybe multiple applications to the same maybe water body, the way we have it currently structured is that the decision for a threshold is by the decision body. So, if you had two different counties making different decisions, the way it's written, there would be no coordination. Their threshold would be based on their application. So, I'd encourage you to look at how we set the thresholds and describe it and in your comments address that.

MS. WIEDEMAN: The other thing I'd like to add to that is if there is already a water that is impaired for that pollutant, it's not covered by this permit and we'll be asking folks to do more reasonable potential type analysis. Then you do figure out what the background is in the water and things like that. So, where it's already on what we call the 303(d) list, d is for dirty, then you do need to do more analysis.

MR. JORDAN: At the rate we're going, we'll use

up all available time with cards that are up. If we somehow finish early, then we'll entertain more cards.

Scott Schertz is next.

MR. SCHERTZ: Thank you. Just to repeat, there are a lot of concerns as far as the states being up to speed. I don't think that's new. It's just a reinforcement of some of the other comments. Also, the 30-day comment period that Tyler very adequately described.

The other issue, though, has to do with who falls underneath the permit the and notice of intent. When you look at a lot of the activities required by that, it really does need to stay with the party that has control over it, the land, of deciding it.

There is a subissue there of if an applicator does end up going over that threshold, how much, so to speak, retroactive activities would be required of the IPM, the monitoring, et cetera, and reporting? So, there's some real concerns. The impetus really does need to be on who has control over the initial operation.

MR. JORDAN: Thanks, Scott. John Schell and then Jay Vroom. Sorry, I misread the car. Jay, you're

next and then Amy Roberts.

MR. VROOM: Jay Vroom with CropLife America. First, I'd like to compliment Susan and Allison and the teams that have been working on this from both the Office of Water and the Office of Pesticides. I don't think any of us were really ready for this a year ago January, and while it's been a long time, it probably seems like it's been longer than it has been. But you guys have done a tremendous amount of collaborative work. We definitely appreciate that.

So, I'd like to ask questions related to slides 12, 14, and 16, and 17. But separately, I wonder if you could speak to whether or not this is a federal action subject to the provisions of Endangered Species Act consultation?

MS. BERNASIAN: Yes. We have initiated consultation with the services and they are really trying to work with us to come up with the actual scope for the biological assessment. We are hoping to work through it because they spray pesticides, too, and need coverage. That did help us in vessels when they actually had boats.

MR. VROOM: Yes. So, will that information

regarding work dealing with the services be part of the May Federal Register information or will that come later? If you don't know, that's fine.

MS. Bernasian: It's really a work in progress.

MR. VROOM: Okay.

MS. BERNASIAN: So, we might not have much in the proposal, but it is being worked on. What I want to do is try to see if I can really get buy in before we actually do the work so that at the end, they'll be happy with the work.

MR. VROOM: Great idea.

MS. BERNASIAN: So, we're spending more time up front there. So, I'm sorry if you might not get as much as you want in the proposal, but we will be sharing the information.

MR. VROOM: Good, thanks. On slide 12, Allison, you mentioned activities exempt. So, will the information in the May Federal Register announcement and web site have explicit language with regard to explicit exemptions or are the exemptions going to be sort of just silent, or have you thought about that?

MS. WIEDEMAN: We have been as explicit as we

can in the fact sheets to describe what I've just described to you today about what is in and what isn't. I think that it would be clear.

MS. BERNASIAN: The other thing that I want to highlight that wasn't on one of the slides is we did also consider an emergency provision that all of a sudden if you get something totally unexpected, then you can actually do the spraying and then file within a certain number of days.

MR. VROOM: I appreciate the fact that you've given thought to exemptions. This has more to do with applicators and growers where they may be involved having explicit legal protections if there are explicit exemption examples out there.

MS. BERNASIAN: Well, we are not allowed to exempt anybody -- we learned that in vessel -- by regulation. So, it has to be a statutory exemption. The two that we described here are the ones that we believe apply. So, those will be definitely discussed in the fact sheet in detail.

MR. VROOM: Okay, good. On slide 14, and I don't think this requires a response from you, but I just

wanted to reinforce that in referencing using lowest amount possible for avoidance of resistance management, et cetera, is a really important thought and I'm glad that you already caught that and expressed it.

On slide 16 and 17, with respect to visual monitoring, obviously, you know it when you see it, comes to mind, but -- so, it will obviously be important for as much definition for what applicators need to be looking for be conveyed in explicit writing as possible.

Adverse effects, I guess maybe, Susan, this comes back to OPP, how much convergence is there with adverse effects in this context and the 6(a)(2) requirements under FIFRA that you currently apply or will it be the same? Does this have to go into 6(a)(2) if it's separate?

MS. LEWIS: I think when you see the permit, you'll see how we define what we believe is an adverse effect in a report. We haven't worked out all the nuances of whether it comes under 6(a)(2) or the clean water.

MR. VROOM: But this will be a report that will come to the Office of Water, though?

MS. LEWIS: It will be the regional office.

MR. VROOM: Okay. I'm cognizant of the fact that 6(a)(2) reporting for OPP at times can be a significant burden for both the government as well as registrants. Now we're extending that responsibility to applicators. Presumably, you've already talked with regional offices about how to design systems to receive this information and manage it, et cetera.

MS. LEWIS: We have a national what we call our NOI database. So, it's electronic. It can receive annual reports and quarterly monitoring data. The one thing I want to share with you is we normally in the NPDES program do end of pipe discharge monitoring. There are costs associated. Sometimes we have people do them monthly, sometimes we have them do them quarterly and sometimes annually. They have to scan for priority pollutants and do all of this.

This is a unique universe. There might be some in public comment period that might want more ambient monitoring. We really are wrestling with that concept. We do need to have a whole cycle of feedback because we are responsible for making sure our permits achieve water

quality.

So, what we're describing here is that we have states doing monitoring. I really want to thank the states that have submitted the data to us from the pesticide folks, particularly Delaware and Florida have been so wonderful in all of their knowledge and sharing with us. I do want to recognize that. But we need to be able to show overall that our permit is protected.

So, one of the other things we're asking for is the cycle that we're creating, whether it's the state pesticide folks that are doing the sampling or whether we have the largest of the large do some ambient sampling, we need somehow to verify overall that the system is effective, or if the registrants are giving us ambient data.

So, this is our (inaudible) permit. As we move forward and try to really make sure that our system is effective, we do need to be careful of those things as we move forward.

MR. VROOM: So, it sounds like you're on a much different kind of time horizon for this reporting as opposed to FIFRA 6(a)(2) reporting. So, that's helpful.

Thank you.

MR. JORDAN: Jay, we'll look at that. Next person on my list is Amy and then Steve Dwinell.

MS. ROBERTS: Amy Roberts with (inaudible). I understand the scope of the pesticide uses that are covered. But if there's still any opportunity to talk about the scope of the pesticides, specifically pesticides that are exempt from (inaudible) residues, looking at them being exempt from the permit or --

MS. LEWIS: I would encourage you to make that comment. Right now it includes are registered and nonregistered 25 (inaudible).

MR. JORDAN: Steve and then Cannon Michael.

MR. DWINELL: Thank you. Steve Dwinell, Florida Department of Agriculture. First of all, I want to echo what several people have said and congratulate, thank, and whatever other good words I could use, the agency for engaging in the process they've engaged to in this. This has been really very productive.

I mean, when we first saw this thing coming down the pike, we were terrified. It's been very gratifying to work with the agency the way they've been

working on this. We've been actively involved right from the get go.

The other thing is that what this is doing -- and I don't know if it's fully sunk into everybody yet, but this is a really really major change in the way pesticides are regulated. What it has forced us to do at the state level and I think is going to continue for the foreseeable future is the water agencies and the pesticide agencies have to work together very closely.

Obviously, it's forced OPP and the Office of Water to work very closely together. That's been good. But it's forced us at the state level to do the same thing. We've been meeting with our water agency folks every two weeks on this since January of 2009 and have developed some pretty close relationships on this. States that are not doing that are going to be in a lot of trouble. It's just not going to work. So, we have to keep that in mind.

The last comment is on the enforcement issue. People have to keep in mind when you talk about enforcement of the objectives of the Clean Water Act relative to the pesticides applied to water, we already

have an inspection enforcement mechanism in FIFRA that's well developed and used daily when it comes to pesticide applications and water. We already do it. We do it every day. We have to keep that in mind.

We don't need to invent an entirely new regulatory structure and impose it on people who are applying pesticides in water. We just need to map it to the goals of the Clean Water Act, which I think is very doable. There may be some changes we need to make, but it is already a violation to violate water quality standards due to the application of pesticides in water. You can't do that, although it's pursued under FIFRA as opposed to the Clean Water Act. So, that's something to always keep in mind. Thanks.

MR. JORDAN: Thanks. Cannon Michael and then Caroline Cox.

MR. MICHAEL: Cannon Michael, National Cotton Council. Just had a quick clarification question. In some of the initial documentation about pesticide uses to be covered, there was an area wide category. I don't see that here. Was that replaced with the forest canopy pest control category?

MS. WIEDEMAN: Yes, that's correct.

MR. JORDAN: Thanks. Caroline.

MS. COX: The definition of IPM has been pretty controversial over the years. I wonder if the permit will actually have a definition of IPM. If so, what definition is it going to use?

MS. LEWIS: It's more concept. It's IPM principles. But an exact definition? Not at this moment, but it will give her guidelines of different areas we would like addressed.

MR. JORDAN: Speaking of IPM, Tom, you're next.

TOM: Carol asked my question. I told her not to but she went ahead anyway. I'm wondering what kind of work is being done to specifically look at these particular applications of concern to really define IPM for those applications more specifically rather than conceptually, so the permitee is going to put in there documentation what they consider to be the specifics for IPM that correspond to the general concept and then they may get that audited?

MS. LEWIS: We have outlined in great detail in the fact sheet as well as in the permit the four

different sort of areas and what needs to be covered in a draft. But we also wanted to leave enough flexibility so that not everyone is treated the exact same because situations change.

TOM: Okay, great. I'll take a look at that. Also, I hope to be able to contribute some information in terms of your question about how much IPM is already being implemented.

MR. JORDAN: That would be helpful. I have next on my list Dave Tamayo and then Jen Sass.

MR. TAMAYO: I really think it's important that you have pretty clear standards. I appreciate the need for flexibility with the IPM but it needs to be really clear to the people who are supposed to be enforcing it. Also, I'm assuming, since this is the Clean Water Act, that these things are subject to citizen's suit. So, if you don't have that clarity, then you don't have very much protection if you're the discharger in that case.

I'm sorry, I didn't introduce my organization. It's California Stormwater Quality Association. We represent a lot of stormwater permit holders, primarily municipalities.

My other question is, what sort of interaction is there between the urban permitees under this system and then the municipal stormwater permit holders that are responsible? We do, actually, a much more rigorous level of monitoring. So, if we find something that now we're kind of stuck with, you don't have monitoring of the discharges that are discharging into our system.

What's our recourse? Are we responsible, then, for their discharge that was supposedly covered under their permit. But now we don't even have the information because the monitoring won't -- they won't have a level of monitoring that we do to reveal problems that could very well have been caused by their applications?

MS. BERNASIAN: Thank you. That was a great question. The stormwater program is also an NPDES program. In the stormwater program safe for construction sites under one acre, you're not required to do anything. So, stormwater is a little different. The way that they've written the law is it gave EPA discretion how to create that program.

What we've done is we've picked some thresholds in that program that said under those thresholds, unless

we've designated you, you do not need a permit. So, the example that you're mentioning -- say if you had these terrestrial applications and then it washed off into the river, we consider those nonpoint source because it's stormwater and it's not designated.

So, that is not something that needs a permit. Nonpoint source pesticide application does not need a permit unless it's designated under the stormwater program or already captured. So, if somebody is spraying some pesticides on their lawn and it doesn't hit the water but then it rains and flows in, under stormwater that's a nonpoint source and you do not need a permit.

Now, if it's going into a municipality, again that is not something that is directly being applied to water. It's handled under the MS-4 regulations which is the stormwater regulations. We are looking at that question because we're also doing MS-4 regulations.

MR. JORDAN: Dave, why don't you and Linda talk at the lunch break which I hope will be coming up soon.

MR. TAMAYO: Well, okay. I'm going to be in the Tox 21 (phonetic) but --

MR. JORDAN: Okay. Jen and then Carolyn

Brickey.

DR. SASS: Mine is a fast one. The slides itself, I just wondered if some of those things will be publicly accessible like the pesticide discharge management plan?

MS. WIEDEMAN: As explained in the fact sheet and the permit, if the public asks for these documents, EPA will make them available.

MR. JORDAN: Carolyn and then Mark Whalon.

MS. BRICKEY: Question and then observation. Question, on slide 13 you talk about the pesticide application threshold. Will some options for what those thresholds should be be discussed as part of this document?

MS. LEWIS: We're going to be providing what we think are the best thresholds that we have been able to determine. So, it won't be options but they will be a different threshold for each of the four uses.

MS. BRICKEY: So, they'll be suggested for each of the four?

MS. LEWIS: Yes.

MS. BRICKEY: Okay. Observation, Linda

mentioned that there might be some options for emergency applications before the fact of having a permit. I just caution you about that because the pesticide program has a Section 18 program for emergency applications before pesticides are used. So, I would think long and hard about allowing people to use the materials before they have any notification or information into you.

MR. JORDAN: The Section 18 program will still apply, Carolyn. This isn't authorizing something that isn't --

MS. BRICKEY: To these uses?

MR. JORDAN: To these uses.

MS. BRICKEY: Okay.

MR. JORDAN: Or registration. They'll need to have either a registration or a Section 18-24©) external use permit.

Okay, Mark Whalon and then Allen James.

DR. WHALON: I just want to thank EPA for the general permit process because I think it's a big burden lifter for a lot of indirect users. It's a good strategy. I'd like to come back to this IPM thing, though. In terms of state lead agencies and the kind of

response that Colorado had, I can see a number of other states doing the same thing because a lot of these states in the recent economic times have been gutted.

So, if you look at a state like Michigan, look at MDA, Department of Environmental Quality, who would have a state lead agency responsibility, there's three people left. In terms of extension, cooperative extension in extending this information to growers, we're looking at a RIF of 50 to 70 percent in the state of Michigan.

So, some of these getting the word out, getting the response back, you're going to have kind of a no response deaf kind of thing in a lot of states given the time frame and also given the structure as good as it is.

MS. BERNASIAN: Well, we have 10 regions. I, in the next two weeks, am visiting three of them. This is on the agenda for each state for me to sit and talk with them exactly about where their states are and are they planning to use our permit or some iteration and when are they proposing it. So, what we'll do is we'll have a hot list of the ones that aren't moving forward and then we'll have to have a strategy for that.

MR. JAMES: Allen James with Responsible Industry for a Sound Environment. I'll make mine very quick.

On slide 14, you emphasized that permitees must use the lowest amount possible of pesticides in their application. I hope you will consider including in that statement using their best professional judgment, because if you don't allow them to use their best professional judgment, someone else's best professional judgment will be used. So, I hope you'll include that specifically, and I urge you to do that.

Secondly, I've been asked to express a concern for representation of some of our members which are utility rights of way. A number of them across the country are so large that they will certainly fall into the classification of the general permit. It has been the experience of a number of these that when pressure has been applied to them to move away from pesticides, they often do initially. That will happen under this program, I'm certain.

The problem with that is that the alternative methods of mechanical control have been proven to be far

more environmentally damaging through machine oil, other discharges, that would not be covered under a pesticide permit but would have a lot more negative impact upon the environment. So, the utilities are very concerned. The applicators particularly that do the work under contract for the utilities are very concerned about what this impact will be to them if they're required to do more mechanical use.

I have with me, who can't stay through the afternoon and give public comment, one of our leading experts in the nation on utility rights of way. He's done a marvelous job with protecting endangered species and bringing back endangered species where they have not been known to exist for some time. He's done it with the proper use of chemicals, to some degree mechanical but primarily through chemical. That program will be entirely lost on some of these utility rights of way under these permits.

The final thing is the question, although I know you're operating under a court order, the impact of this decision or your program is going to impact small business without question. It will be a large impact.

Are you required to meet the terms of the analysis of the impact on small business, the financial analysis, as part of your decisionmaking process?

MR. JORDAN: I think that the Federal Register notice and fact sheet will discuss our assessment on the small business impacts. My recollection is that it does not -- our assessment is that it will not trigger any additional requirements beyond the service threshold evaluation.

MS. BERNASIAN: First of all, they're already required to be covered, so I'm not doing anything other than trying to get them protected. So, right now, if they discharge without a permit, they could be charged $32,000 a day. So, in our permit, we don't have a regulation. This isn't a regulation so we don't have to go through some of those things. But we have really factored in and tried to pick things that are common sense.

So, you saw for the smallest applicators we're telling them they've got to minimize. We're telling them they've got to calibrate their equipment if they tell us if there's some adverse incident. That's what we're

going out with. So, we don't think that's a big burden on small business.

MR. JAMES: I'm not debating you on that part of it. But I will say that we're operating at this point in time and until the court order goes into effect under your rule that says these companies do not have to have a permit. They're not in violation if they do not have a permit today.

MR. JORDAN: Carol Ramsay and then I can't read the other three, so I'm going to ask you all to figure out amongst yourselves who goes next.

MS. RAMSAY: Mine is just a simple observation back to the ag impacts. If you look at slide number 12 and then the handout that you had, I think one of the concerns is the clarity issue that's already been brought up.

Slide number 12 up there says terrestrial applications on row crops and in your fact sheet it says agricultural crops. There's lots of crops that aren't row crops. So, I think that's a lot of the confusion of what's going on with people reading. What they're seeing is that the message is not coming across clearly.

So, I do encourage you to engage the agricultural commodities again before this May release to best define what crops may or may not fall under this. If it's going to be all agricultural crops are out, that's something. But if there are some agricultural crops that will be in, I think you want to define that.

MR. JORDAN: Thanks for adjusting the angle on the cards. Julie, I think you're next, and then Jerry has the last word.

MS. SPAGNOLI: This is with regard to the request and comments to if there are other uses that need to be a subject. Are you going to have time? I mean, if they identify four or five additional uses that they feel need to be under permit, how is there going to be enough time to develop thresholds and all the parameters around those permits?

I guess this goes to what Tyler said. If they determine there's that many more uses that need to be subject, would the agency consider asking for a further stay in order to have the time to develop those?

Then, I guess my second question is, and I think this had to do with what Bob said about individuals

getting permits. If people feel the need to get an individual permit because they're not covered under general permits and they're concerned about their liability, do the states have anywhere near the resources to issue those permits if thousands of applicators come in looking for individual permits?

MS. BERNASIAN: I really appreciate your question. Like say for a different state that has a whole lot of water throughout their state, they may decide that it's really not avoidable and they may include more categories. So, they're not restricted to what we do. We've just looked at the areas in which we're regulating.

The other thing is when we issue a draft permit, we could also do a supplemental permit modification a couple months later or things like that. So, we're not restricted to that. Or we could just start another general permit and that one may hit and not finish until four months. So, we wanted to really try to get this one to finish in case we've missed something so that we could have some amount of time to amend it if we needed to.

MR. BARON: It's always tough to be the person between lunch and asking one more question. In fact, Julie said a lot of my question. I thought I was going to make it through with all these cards there and no one coming up. It didn't happen.

Anyway, I applaud you for what you've done in very short order and tough conditions. The four areas are pretty clear cut. But what concerns me is the nebulous areas of those other crops. It was even implied before that people if they feel it's necessary -- and that's going to trigger in the time factor which I think our diminishing infrastructure at the state level will not have a chance to do it.

Two of the crops in my program -- I neglected to mention the IR-4 program -- that we deal with on a routine basis are watercress and cranberries. My guess is those two crops, if a grower was out there, they would probably want to think very strongly of submitting permits because they will likely require one.

That leads to the question. I feel that in some cases this is opening growers by not including them as part of this general permit to lawsuits. Again, I

applaud you for what you've done, but I think that you're giving some people a false sense of security that they're going to make it through 2012 after April 11th without having a lawsuit coming back to them. Thank you.

MR. JORDAN: Well, the scope question is definitely on the table, as Allison explained, in the Federal Register notice and a lot of other questions. So, thank you all for your comments. We will consider them carefully and we'll also be open to continued conversations outside this forum.

Steve.

MR. BRADBURY: I just want to repeat Bill's comments. I appreciate all the very insightful observations and questions. Some of that feedback already I think will have an impact for shaping aspects of the proposed permit going out.

The many other concepts and issues you brought up are actually part of what we want to get comment on once that proposal gets out there. So, again, I appreciate the thoughts now because it gives us some insight as to the stage we're at now. Also, if you didn't get an answer to your question, it's because, in

fact, we're asking for all of the public to consider these certain critical issues and get us some feedback as we go forward. So, I appreciate the very thoughtful input.

So, we're not doing too bad. Nobody is in the penalty box yet, no 10-minute majors or anything. So, why don't we shoot for a 1:30 start so we're only about 15 minutes off schedule. I'll work with our folks to see if we can pick up some of that 15 minutes after lunch. So, thanks, all. We'll see you at 1:30.

(Whereupon, a luncheon recess was taken.)

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MARILYNN H. McNULTY,
Transcriptionist

UNITED STATES

ENVIRONMENTAL PROTECTION AGENCY

PESTICIDE PROGRAM DIALOGUE COMMITTEE MEETING

April 30, 2010

Conference Center - Lobby Level

2777 Crystal Drive

One Potomac Yard South

Arlington, VA 22202

P R O C E E D I N G S

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MR. BRADBURY: Good morning, everyone. If you all could take your seats, we'll get started. Before we get started, I know there are a few folks that are serving as alternates for standing members of the committee. Those folks can introduce themselves, Pat, for example.

MR. DONNELLY: Hi, I'm Pat Donnelly (phonetic), representing Gallon Companies, sitting in for Cindy Baker.

MR. BRADBURY: Thanks. Also, introduce yourselves. I'm just asking people that are sitting in as alternates today if you just introduce yourselves to the group.

MR. BETZ: Fred Betz standing in for Maria Herrero, representing the Biopesticide Industry Alliance.

MR. BRADBURY: Thanks. So, we'll get started with this morning's discussion. We're going to start with the discussion on our pollinator protection activities not only here in the pesticide program in EPA but also in the context of our collaborative efforts with

the U.S. Department of Agriculture. I'll turn it over to the team in just a minute.

The goal of this session is to provide you some information. The team will be efficient in their presentation so we can get some dialogue. What we want to do is get some feedback on communication strategies. I'm sort of curious during the discussion what you all hear out there across the country.

Is the information getting out to you clearly about what the status of pollinators are, what some of the issues are, and to let you know that we're sensing that we could probably do a better job of communicating what we're doing, what's going on, just based on the kinds of questions we get or e-mails we get. So, that's the real focus of the discussion, get some feedback, some ideas going on how to improve communication.

Then we'll take a break. Then Lois Rossi will come in and do a snapshot on work she's been doing with a subset of you all on public health. Then we'll have a session giving an update on where we are in the endocrine disruptor screening program. Then we'll talk about next steps for the committee.

So, with that, I'm going to turn it over to Don Brady who will introduce the pollinator protection session.

MR. BRADY: We welcome you to this session. We think we have an interesting presentation. We hope to get some good feedback, as Steve indicated. So, the first presenter will be Dr. Mary Purcell-Miramontes who is with USDA and she will present on USDA's role in monitoring and research of pollinators. And then, Tom Steeger from EFED (phonetic) and Tom Moriarty from PRD (phonetic) will team up for a second presentation on pollinators in OPP. So, we'll get started.

DR. PURCELL-MIRAMONTES: Everybody hear me okay? Smiling faces. So, it looks like you heard me, okay. So, thanks, everyone, for the opportunity to come speak with you today. I work for the USDA National Institute of Food and Agriculture. I'm national program leader in Arthropoda nematode biology.

Part of this presentation and who are responsible for the material I'm going to present are Dr. Hackett (phonetic), also national program leader with the intramural research arm of the USDA and of course Dr.

Jeffrey Peduct (phonetic) who is the research leader (inaudible) Agriculture Research Service.

Just by way of introduction, the agency I work for in USDA, the National Institute of Food and Agriculture, is the extramural funding agency which funds competitive grant research, formula fund research, educational programs, and extension programs, issues of national agricultural interest.

So, I became intimately linked with Jeff Pettis and Kevin Hackett and Rick Meyer, also at NIFA, when the news about pollinator decline and colony collapse disorder hit the press in early 2007. We just beat the pavement continuously in the spring of 2007 going to congress to give briefings about it. So, we learned in a hurry what the issues were.

What is pollinator decline? Pollinator decline is a major issue impacting several kinds of organisms that pollinate plants in the environment as well as an agri-eco system. In January 2007, the National Academy of Sciences produced a report entitled, “The Status of Pollinators in North America.”

This reviewed the literature to date on

population declines of several species of pollinators, which includes bees, wasps, butterflies, bats, hummingbirds. The report also charged the USDA to enhance research efforts for this urgent problem.

Several factors are implicated in pollinator decline. The top lab European honeybee is a main pollinator but there are several species of native and wild bees that are also suffering significant decline. Several of these wild bee species are extremely rare and possibly extinct.

Several factors have been implicated in these losses such as the use of pesticides in large scale agriculture. Pesticides are known to kill bees and cause serious chronic effects on bee health. It reduces longevity, it reduces feeding, affects behavior, mating, and so forth.

The wide-scale planting of single crop types, called monocultures, could have questionable value to pollinators as a sole dietary source of pollen and nectar. Monocultures provide fewer field margins which make it difficult for bees to move in and out of the crop to find other sources of pollen and nectar to supplement

their diet.

In that National Academy of Science report, the report studied or collated the data on colony numbers in the United States. This is data provided by the National Agricultural Statistic Service which is a USDA agency. This slide shows data collected by NASS on honeybee colonies between 1945 and 2006.

Colonies began to take a precipitous decline from five million colonies in the 1940s to two-and-a-half million in 2005. In the 1970s when the varroa mite invaded the U.S. and infested beehives, this was responsible for the precipitous decline.

So, what is colony collapse disorder? Colony collapse disorder is a phenomenon which may or may not be a new thing. The symptoms of colony collapse disorder include the rapid loss of adult worker bees. Few or no dead bees left in the colony is pretty unusual in that bees that suffer pesticide exposure have a collection of dead bees just outside the hive. This is not the case in colony collapse disorder.

Another symptom of colony collapse disorder is that the colonies die and they have an excessive number

of immature larvae. But the reason they die is that the larvae are unable to feed themselves and quickly the colony becomes what they call dead. There is a small cluster of nurse bees that remain with the queen, but typically within a week or so the queen will die.

So, the USDA, in conjunction with the APRA inspectors of America have conducted surveys since 2007. The losses are ranging from 32 percent in 2007 to what most recently was reported by Jeff Pettis and Van Englestorp (phonetic), 34 percent in 2010. So, things clearly aren't getting better. Several beekeeping industries are seriously struggling.

So, the working hypothesis based on researchers that have been gathered to discuss and study the problem is that several factors are working in combination or synergistically to lead to colony collapse disorder. For example, some primary stress is imposed on bees to weaken them.

This kind of stress could be transporting bees long distances with adequate food or shelter. This leads to lowered immunity to secondary pathogens. Normally, they don't have a problem with these pathogens, but when

they're stressed, their immune response if hypothesized is compromised.

Secondly, the varroa mite, which I told you about, is a major stressor. Research is showing that the mite vector viruses to honeybee colonies and high levels of these viruses have been associated with bees that are unhealthy and have the CCD symptoms.

The ways bees are managed, their level of nutritional needs could be very inadequate. In addition, exposure to pesticides used to kill varroa mite and other diseases attacking bees are also important. It seems to be important that these management and nutritional factors and pesticides are associated with an increased susceptibility to a Nosema (phonetic) disease and various fungal diseases.

So, why do we care? Well, this is a problem of real concern to ensuring an adequate food supply in this country and perhaps the world. We have an ever-expanding population and increasing acreages of crops are needed to feed more people. A third of the fruit, vegetables and nut crops depend on pollinators for seeds and fruit production. So, bee shortages are linked with CCD and

other issues.

Consequently, growers are demanding ever more attention from beekeepers to provide pollinator services. Beekeepers are not keeping pace with the demand. Consequently, there could be food shortages. Certainly, it's not been well studied and there's a pressing research need to do that, to document whether yields are impacted by shortages and declines of pollinators and due to CCD.

So, what has the USDA's role been since the advent of these issues? So, the National Institute of Food and Agriculture has developed a coordinated agricultural project on colony collapse disorder. They provided $4.1 million to the University of Georgia and 14 other institutions to focus on research and mitigating the problem.

Secondly, ARS has an area-wide project to promote bee health. They're focusing on best management practices for beekeeping as well as basic and applied research on CCD and bee health in general. The research is highly complementary with the bee cap study being funded by NEFA (phonetic).

Thirdly, the animal plant health inspection service is initiating a bee health survey on the national scale. Federal, state and (inaudible) will collect samples and the ARS bees research lab will analyze them for pathogens and pests. Dr. Robin Rose and Jeff Pettis are the key contacts if you want more information about the national bee health survey.

AFIS (phonetic) is secondly providing funding for the problem of varroa mite which has invaded the big island of Hawaii and is threatening cona queen (phonetic) production on the west side of the big island. A control program is underway to limit expansion of the varroa mite from the east side of the island to the west side.

So, the Natural Resource Conservation Service has developed a conservation practice standard for pollinator species in conjunction with individual states and counties. They've developed planting guides which select plants can serve pollinators in natural landscapes. Doug Collee (phonetic) is the person that we work with the most and he's on the colony collapse disorder steering committee, along with EPA, Department of Defense, and two land grant universities. EPA is

developing new pesticide tests and protocols to better understand the risk of pesticides on honeybees.

So, I just want to give you some feeling for what's being done on these fronts of the managed pollinator cap and ARS area-wide study. So, as I said before, these two projects are developing basic and applied research on the causal factors. They're conducting monitoring surveys such as using sentinel beehives. They're surveying beekeepers and asking them what their losses are. There's a fair bit of extension and outreach being conducted that I'll talk about in the subsequent slides, and providing information to communities.

So, proceedings of the National Academy of Sciences paper written by Reed Johnson (phonetic) and May Berenbaum (phonetic) of the University of Illinois. They studied the genetics of bees in CCD colonies or colonies reporting CCD-like symptoms and colonies that were healthy and did not have the symptoms.

What they observed was there was a lot of variation in the genes that were expressed in CCD colonies. It leads to a question about whether different

stressors may be occurring on the eastern side of the U.S. versus the western side. So, there's no sort of set number of genes that are expressed across all regions.

Sixty-five gene transcripts were identified, however, as potential markers for CCD status. They also found that within the genes that damaged ribosomal RNA fragments were occurring much more frequently in the CCD affected bees.

So, again, these are very interesting phenomena and maybe ways we don't know what causes CCD but we at least can have a good handle on a marker for CCD. So, future research is going to be conducted to see if this is something that can be repeated over several regions. In this study, a final conclusion was that two viral diseases were associated with CCD. Those were Israeli Acute Paralysis Virus and Deformed Wing Virus.

Some more highlights were pesticide studies. University of Georgia did some testing of chemicals in the hives, for example, wood preservatives and various miticides used to control varroa mites. They found that it led to decreased feeding by the bees on supplemental sugar. So, as you know, to overwinter successfully,

honeybees need to feed on supplemental food and that seems to indicate that they just lose their appetite. So, these sorts of things are measures of strength of a colony and that beehives are incurring severe winter losses. So, that's an interesting finding.

Studies also at the University of Illinois and Nebraska have documented synergistic effects of pesticides when they are combined. So, when the pesticides Cumifa (phonetic) and fungicides are applied separately, they didn't find lethal effects. But when they applied them together, they observed synergistic acute effects or mortality effects on honeybees.

Then, most recently, a study by Chris Mullen (phonetic) and others at Penn State -- Jeff Pettis at ARS, a co-author, published the PLOS-1 that high levels of 121 pesticides and metabolite residues were observed in wax, pollen and bees from colonies which were termed unhealthy. So, these could be beehives that had both CCD and just heavy heavy losses. So, that's not defined.

What they observed were mainly miticides and fungicides in this group of pesticides. The highest residues they observed were in wax; the lowest were in

bees. What we need now are controlled studies to understand the biological effects of bees on materials and in particularly in combination -- applied in combination and their association with CCD and other stressors.

I wanted to also mention another study conducted by Jeff Pettis and a French researcher, Aloe Ettal (phonetic). Sublethal exposure of several pesticides indicated an increased level of pathogenicity in bees. They were able to document that. Nosema levels increased after exposure, for example, to Imiticoprid (phonetic).

So, outside the research front, there is a heavy component of mitigation and outreach. There is a community, a practice web site that is funded by the BECAP (phonetic) and ARS. It was publicly released in 2009. Here's the web site for any of you that are interested.

A big part of the mitigation and outreach part of what USDA is doing is to do beekeeper surveys before best management practices are adopted and after adoption of these practices. Members of the public can get on

this web site and put a question on and ask the expert. I'm observing bees in my yard much less commonly. What's going on? Any question and somebody within 24 hours will give you an answer.

Another part of this outreach is conducting workshops such as queen rearing studies or courses to show the public or beekeepers how to incorporate disease resistance trace in their bees.

In conclusion, what I hope I've gotten across to you is that all pollinators are threatened. That's what's meant by pollinator decline. The issue of honeybee health is a complicated one. It's not one that's going to be solved overnight. As you saw, there are several factors that are suspected as causing CCD or being associated with CCD. It's going to take careful research and good coordination between USDA and other research entities to really get a handle on it.

So, we've seen research that documents affects on bees with the miticides and other agricultural chemicals. There seems to be a very interesting interaction going on between pesticides perhaps enhancing susceptibility to pathogens that they normally would be

able to fend off.

With that, I'm going to close.

MR. STEEGER: Thank you very much. My name is Tom Steeger and I'd ask our slide presentation come up and we'll move right to slide 3. As we get set up, my presentation is going to include a brief overview, sort of touching on what Mary just talked about. We'll also describe how the agency is engaged in a number of fronts including monitoring research, enhancing the regulatory programs, and communication and outreach. Finally, we will present specific questions to the PPDC. So, I'm going to continue to go on here.

As mentioned by Dr. Purcell, the National Academy of Science did publish a report in 2006 discussing the status of pollinators in North America. That report concluded that there was sufficient direct evidence that indicated declines in North American pollinators, including America's most important managed pollinator, the European honeybee. The report also concluded, though, that species of insects, birds, and mammals associated with pollination are in decline but that there was insufficient information to determine the

causes of those declines.

Also, the NAS survey that Dr. Purcell presented on indicates that managed honeybee colonies have been in decline from a peak of approximately six million colonies in 1947 to roughly 2.8 million colonies in 2006. Some of the marked declines in managed honeybee colonies in the mid-1980s, though, were attributed to the introduction of parasitic mites which is the tracheal mite and the ecoparasitic mite, the varroa.

Historical trends monitored by USDA indicate a steadying decline in managed pollinator colonies in the United States, a typical loss of 15 to 20 percent since the introduction of the two mites. The marked colony losses, though, have increased roughly 30 to 36 percent since 2007 and present.

While USDA has been tasked with monitoring and reporting the number of managed honeybee colonies in the United States, beekeepers have voluntarily reported their experiences directly to EPA as well. The majority of the losses described in two EPAs had CCD-like characteristics and in some cases involved what could only be described as a staggering number of managed bee colonies abandoned

by their once resident bee population.

Beekeepers have reported increased difficulty in finding replacement bees and increased costs associated with reestablishing colonies through the purchase of new queens, packaged bees and nucleus colonies. Although a number of factors and agents have hypotheses as potential contributors to pollinator declines, at this time no factor has been identified as a single cause. Rather, the available science suggests that pollinator declines are a result of multiple factors which may be acting in various combinations.

Research is being directed at identifying individual and combinations of stressors that are most strongly associated with pollinator decline. While the exact causes of the general declines in pollinator species and in the phenomena characterized as CCD have not been determined, potential contributing factors such as those identified by Dr. Purcell include diseases, habitat destruction organization, agricultural practices, monocultures, pesticides, nutrition and demanagement practices have to be considered.

Researchers at the USDA have (inaudible) CCD

may be caused by a primary stressor such as a parasitic mite or poor bee management, nutrition, or pesticides that may in turn cause honeybees to become more susceptible to the disease.

In 2007, the director of the Office of Pesticide Program, Debbie Edwards at that time, established a multidisciplinary Office of Pesticides Programs pollinator protection team which included staff from various scientific and regulatory divisions within OPP. Since that time, staff participation in the team has expanded to include other offices within EPA and across EPA regions.

The multidisciplinary team is tasked with exploring possible approaches, tools, and resources for reducing the potential risks of pesticides to pollinators. To that end, the team has also been tasked with developing a strategic plan to guide its future work and direction.

The strategic plan, which is available on the EPA web site, identified three major goals. Goal one was to advance the agency's scientific knowledge and assessment of pesticide risks to pollinators. Goal two

was to improve risk management tools for mitigating potential risks to pollinators. Goal three was to increase and broaden collaboration and communication with governmental and nongovernmental organizations and the public in addressing pollinator issues. Over the remainder of the presentation, we'll discuss progress being made on achieving these goals.

As indicated by Dr. Purcell, USDA has taken the lead in the effort to determine causes contributing to CCD and serves as the lead on CCD steering committee. The committee developed an action plan which is available through the USDA ARS web site. The action plan outlines a strategy for addressing CCD and involves four main components, survey and data collection, analysis of samples, hypothesis driven research, and four, mitigation and preventive action.

EPA is a member of the CCD steering committee and is working with USDA to understand the factors associated with CCD and pollinator declines. As indicated earlier, pesticides have been identified as one of the factors that may be associated with the incidents of CCD and with pollinator declines in general.

Through its membership on the CCD steering committee, EPA is providing technical expertise in reviewing study protocols submitted to USDA for funding. It's examining the potential role of pesticides in CCD. The reviews provide EPA science staff an opportunity to learn more about the proposed research efforts, and the reviews provide researchers with an understanding of EPA's perspective on study designs and potential confounding effects on efforts to document the potential cause/effect relationship.

OPP science staff have participated in site visits to some of the facilities conducting research on the potential effects of pesticides and pollinators. OPP labs are assisting in pesticide residue analyses to support some of these research efforts and to potentially increase the utility of these data in a regulatory context.

In a cooperative study between USDA and the University of Maryland examining the effects of neonicatenoid insecticides on honeybees following a long term exposure, OPP labs have been conducting pesticide residue analyses on bees and bee products from that

study.

OPP labs have refined the messages in these analyses and have increased the capacity to detect both the parent compound and all of its major degredates in biological matrices and have historically limited detection on them. These refined methods have recently been published in the Journal of Agricultural and Food Chemistry.

Over the past several years, OPP has supported opportunities for EPA science and management staff to increase their familiarity with honeybee biology and ongoing research to examine the potential factors associated with pollinator decline.

For the past two years, USDA, in cooperation with land grant universities, have provided day-long training on beekeeping. These workshops not only increase staff awareness of bee biology but have also provided an opportunity to learn about the most recent research examining the potential factors, including pesticides, associated with pollinator declines.

In response to the uncertainty regarding the potential role of pesticides and pollinator declines, and

in CCD in particular, EPA is a member of a committee with representation from government, industry and academia that has written a proposal to the Society of Environmental Toxicology and Chemistry, or SETAC, for a global Pellston SETAC conference on estimating the potential role of pesticide or potential risks from pesticides to insect pollinators.

We are very pleased to announce that on Wednesday of this week the steering committee received notice that the conference will occur. The conference is intended to bring together the best available science regarding exposure and effects assessment methodologies for honeybees and native bee species.

The conference would provide specific recommendations for determining potential risks to insect pollinators from pesticides in a cost effective way. To these end, the conference has four focus areas. First, it is intended to produce tiered standardized test methods to assess exposure from systemic and nonsystemic pesticide products.

Second, the conference will identify hazard endpoints applicable to risk assessment for the honeybee

and a tiered standardized test method to consistently identify and measure hazard endpoints.

Third, the conference is intended to identify a risk assessment process that can serve as both a screen level and as a basis for more refined assessments where needed.

The fourth objective of the conference will be to evaluate information on risk of pesticides to nonnative pollinators.

To further increase our understanding in advancing the science of assessing potential risks, last summer EPA hosted a USDA sponsored meeting on acute and chronic laboratory and field toxicity study designs with honeybees. The conference included representatives from government and academia, and the conference proceedings will both inform the SETAC Pellston and will be part of the CCD steering committee annual report.

Over the past year, EPA has been coordinating with the California Department of Pesticide Regulation and the Canadian Pest Management Regulatory Agency on data needed to support respective efforts to evaluate the nitrochlonodine class of the neonicatenoid pesticides.

Also, in response to beekeeper concerns, the bee kill incidents were not being consistently reported to OPP's ecological incident information system under FIFRA 6(a)(2) adverse effect recording requirements. EPA has expanded the mechanisms to which beekeepers can report bee kill incidents.

At this time, bee kill incidents can follow a typical process whereby states enter a registrants file 6(a)(2) incident reports. However, beekeepers can also report incidents directly to EFED through contacts provided to the two largest beekeeping organizations. Beekeepers can also make use of newly expanded capacity of the National Pesticide Information Center portal, the NPIC portal, to report bee kill incidents.

Beekeepers, though, are encouraged to report bee kill incidents to their respective state agencies and/or registrants to better ensure that incidents can be properly documented.

My colleague, Tom Moriarty, will follow up on that. Tom is the chair of the pollinator protection team.

MR. MORIARTY: Hi. OPP has developed efforts

to develop the risk management. It can't be done in advance of a separate to develop the science. However, OPP is doing what it can now and is considering the best way to develop a tool to protect pollinators.

Current risk management is captured by honeybee warning statements on product labels which are based on acute contact toxicity data, not on the consideration of both hazard and exposure. Over time, the language has proven difficult to enforce and therefore perhaps not very effective.

Development of risk assessment methodology, as well as risk management strategies, is the focus of the pollinator protection team. Risk management for pollinators may turn out to be different than risk management for other taxa (phonetic) as pollinators, particularly managed pollinators, are different, say, than fish in a static water body.

So, approaching risk management for pollinators may present OPP with new challenges. To meet these challenges, the first and foremost step is the development of a sound risk assessment methodology. Second, OPP plans to engage its partners such as state-

lead agencies, beekeeper industries, applicators, and growers, and the like to understand what measures may or may not be effective to protect pollinators as well as the interest of growers.

Through dialogue with these stakeholders, OPP hopes to gain a sense of what management practices would be protective, feasible, and cost effective. Thirdly, OPP will share management approaches through its cooperative efforts with its international partners. While EPA knows that policy and management practices reflect numerous contextural variables, sharing measures and actions with the global partners may provide new ideas that may be adaptable here in the U.S.

Finally, possible changes to the spray drift language currently being explored through PR notice 2009X may also serve to provide a framework for protective language pollinators.

In the meantime, while it develops the science, OPP is being proactive to adopt risk management approaches where possible, such as reducing potential exposure from dust drift. Based upon events that occurred in Germany in 2008 where a large number of hives

were lost during the process of planting seeded tree and seeds, OPP engaged feed treatment manufacturers to adopt label language that would help reduce potential of a similar event occurring here in the U.S.

That event, pesticide dust drift to hives that are adjacent to a field that resulted from an environmental condition as well as failure of a sticking agent to prevent the pesticide from dislodging from the seed coat (phonetic).

Over the past year, OPP has met with technical registrants to discuss label language that would require appropriate sticking agents for certain types of seed. In addition to language regarding sticking agents, OPP has also met with equipment manufacturers to discuss engineering approaches that would further reduce potential dust drift.

In its registration review program, OPP is coordinating schedules in order to consider classes of compounds together. One class of insecticides that has received a lot of attention is that of the neonicotinoids.

The (inaudible) registration review was the

first to open in late 2008, and the rest of the neonicotinoids are scheduled to begin registration together in 2012. As was mentioned by Tom earlier, OPP is coordinating its review of Imiticoprid with Canada's PMRA and California's PPR. OPP will coordinate with PMRA on the other neonicatenoid compounds if the schedule of the two agencies align.

On a longer time line, OPP plans to revise the Code of Federal Regulations Part 171 which deals with certification of pesticide applicators. Updating Part 171 is a lengthy rulemaking process. Once complete, it requires additional time for adoption by an individual state.

Applicators, we know, are critical players in the safe use of pesticides. The originator of 171, which provides for public participation, will add requirements to the applicator and handlers certification program that deal specifically with pollinators.

The agency is also considering revising the core training manual which is a document that provides information to applicators on the safe use and handling of pesticides in accordance with the requirements of 171.

This again is (inaudible) potential cooperation and collaboration between OPP and stakeholders to provide guidance on protective practices for pollinators.

Communication and cooperation are key in the challenge that we all face. Need for good communication to bring about protection to pollinator species is apparent at different levels between agencies, between agencies and stakeholders, between growers and beekeepers, and so on.

The agency encourages and has gone so far as to stipulate the need for effective communication through labels. The pollinator protection team in OPP has strived to be open and available for stakeholders to request meetings who want to provide information to or who may be seeking information from the agency.

OPP believes that this committee serves an important role here as it seeks to develop consensus-based actions that rely upon bringing different parties together to exchange perspectives. As an example, during last year's North American Pollinator Protection Campaign's annual conference, which OPP hosted, OPP signed a memorandum of understanding with NAPPC to

further its relationship with the pollinator advocacy group.

OPP, like many, sees this issue as a global one. Part of OPP's global efforts is the SETAC conference. In addition to that, it has engaged with partners from the Organization of Economic Cooperation Development to find further areas where cooperation would advance the science and the management around protecting pollinators.

Specific recommendations from that survey include advancing the harmonization of science and risk assessment, which of course is the primary focus of SETAC conference; two, sharing risk management approaches where risk managers in North America, Europe and beyond understand the policy specific statutory requirements; and specific commercial agricultural profiles sharing information on risk management approaches could be helpful to spread ideas and continue to find creative ways to meet our respected demands.

Developing tools to share infinite information, timely and efficient sharing of information on causes, circumstances, effects and responses around incidents

that occurs in one country can potentially help other countries be proactive, evidenced by OPP's efforts to reduce dust drift. Finally, the survey indicated a need for index research relevant to pollinator health and protection.

As mentioned earlier, OPP is open to meeting and interaction with all stakeholders but it is also planning several presentations on its pollinator protection efforts to reach out and build bridges. Next month, OPP will present, in conjunction with the French Minister of Agriculture, at the SETAC European meeting and is also presenting at the Penn State International Conference on Pollinator Biology in July.

Finally, we encourage you to visit both the EPA and the USDA web sites which we and our federal partners here use to communicate with the general public on actions taken either respectively or together to protect pollinators.

Thank you for your attention. I'd like to ask if there are any clarifying questions before we move on to the charge questions.

UNIDENTIFIED MALE: You said that pretty fast.

What did you say that last part?

MR. MORIARTY: The slide regarding communication, the last slide, I mentioned that OPP is going to make a couple presentations, one in combination with the French agricultural ministry at the SETAC European Conference, and then we're also presenting at a Penn State conference in July.

UNIDENTIFIED MALE: You asked for feedback and if there are any clarifying questions. Then you said?

MR. BRADY: Let's start first and see if anyone on the panel has any clarifying questions from what Dr. Purcell, Dr. Steeger and Tom already mentioned. Then we'll go on to questions. Are cards up for clarifying questions first? I see Steve, Michael and John.

MR. SMITH: I see this all the time. Obviously, in Florida we've been dealing with this issue for a while. It's consistently reported that you lose about a third of your colonies every year. But it's impossible to lose a third of your colonies every year for four years running. Otherwise, you wouldn't have any colonies left.

So, there's an increase in colony procedure

that occurs in the spring or after the overwintering period. That's usually not explained to people. So, I think it's important when you're communicating with the public when you say you've lost a third of your bee colonies. What you've lost is a third of the colonies that you ended the season with. Then, at the beginning of the season, you've increased your colonies again.

So, obviously, whatever is causing the colony collapse or the loss isn't affecting the ability of the colonies to be increased. So, something is going on there. I mean, they're increasing the size of their colonies, the number of their colonies enough to continue to function and produce honey and provide pollination services. So, there's something going on there.

You just have to be careful how you describe that to people because I get calls from people -- this is a little off the clarifying question, but it's part of the problem. We get calls from people who have bees, Africanized bees, who have invaded their homes who are afraid to do anything with them because they don't want to kill any more bees. They're afraid all the bees are gone. So, they won't do anything to protect their

structures or themselves because all they've heard about from the media is the fact that there are no bees left anymore; they're all dying out.

So, we have to be real careful how we describe this. It's real easy for the media to take what you're saying and misinterpret it and run with it. So, when you say you've lost a third of your colonies, you need to clarify what you're saying, that you've lost a third of the colonies you started the dormant period with.

MR. BRADY: Thanks, Steve. Michael.

MICHAEL: Thanks. I think that was a really good update as to what's going on and a nice description of the problems.

I've got three questions, basically, clarifying questions. The first one is, is there a problem like the problem in the U.S. in other OECD countries? In Europe, is it the same kinds of colony collapse? If not, what are the differences?

MR. SEEGER: I think in our discussions with the OECD, it's become clear -- and with publications that are coming out of the group Co-Lost, which is Colony Lost, and out of the ICPBR group that researchers and

government officials in Europe that they are experiencing significant losses similar to those in the United States. Characterization of those losses, whether they completely overlap with CCD, is an uncertainty.

It was identified in the OCD survey that EPA participated in that there is a greater need to collect information to sort of standardize how these types of losses are characterized and potential ways of monitoring them and actually mitigating effects once causes are determined.

MICHAEL: So, there are losses similar to the CCD in Europe. Are the pesticide residues and residues in wax, that kind of stuff, similar as well? How many parallels have been looked at?

MR. SEEGER: First of all, let me reiterate what I presented in my slides. At this time, that I am aware of, there has been no correlation established between particular pesticides and the loss of honeybees as has been characterized as CCD. I'm not aware of any correlation there. The pesticides that are being detected in hives by various researchers, while there are many, the level of detection and the frequency of

detection have to be taken into consideration.

We need to have some ability to put it into context of how that spectrum has changed relative to the occurrence of these rapid losses. So, the type of pesticides that are being seen in Europe probably reflect the use pattern of chemicals and the extent to which chemicals are used specifically in bee colonies. But, at this time, the correlation between the losses and particular pesticides or even the presence of pesticides has not been established.

MICHAEL: It's not the primary cause I'm looking for, synergistic effects or other kinds of things. I'm just trying to find out what has been done.

I'm interested in the status of the reporting to the National Pesticide Information Center. Do you guys get feedback from the University of Oregon or Oregon State as to whether or not there have been incidents where honeybees reported to NPIC or what's the status now?

MR. SEEGER: The availability of the NPIC to reporting bee kill incidents has only just been made available. We will be monitoring that once some of the

initial difficulties have been worked out. I think beekeepers have tried to move through that system and have experienced some difficulty through the initial data testing of the portal as it relates to bee kill incident reporting.

So, it will be a tool, as our ecological incident information system is a tool from 6(a)(2) reports and as direct reporting of beekeepers themselves to the agency. All those are information that inform our risk assessment process.

MICHAEL: Have the beekeepers been using the EIS reporting directly?

MR. SEEGER: We have had a very limited number of beekeepers report directly to the agency on bee kill incidents, a much lower number than I would have suspected given the concerns that were expressed that beekeepers felt that their losses were underreported.

MICHAEL: Okay. The last question I've got is, what are current tests that are being done to look at in registration and registration review of conventional and other pesticides for honeybees? Do you do acute LD 50s or chronic or does anybody look at transfer of compounds

to brood? Are there any developmental studies done or disease resistant studies, this kind of stuff?

MR. SEEGER: For all outdoor use pesticides, the 850 guidelines, 40 CFR, define the studies that have to be conducted. They are tiered studies. The first tier study is looking at acute contact, toxicity to young adult bees. The endpoint is a 96-hour LD 50 value. Depending on the outcome of that test, if the study results in an LD 50 that is more toxic than 11 micrograms per bee, they are then required to conduct toxicity of residues on foliage.

Depending on the outcome of that study and if there's information that's indicating that there are actually field effects going on, field pollinator studies would be required. The studies we would acknowledge that a contact toxicity study is not that informative for a systemic pesticides where bees might be consuming pollen and nectar. That is a limitation of our current study design or testing paradigm and we hope to and expect to address those limitations in the SETAC health. That will occur either late this year or in January 2011.

MICHAEL: Thank you.

MR. BRADY: We've got a bunch of other -- we haven't even gotten to the charge questions yet.

DR. SASS: This is Jennifer Sass on the telephone. Can I be put on the cue somewhere and then you call my name when it's my time to speak?

MR. BRADY: I will, Jen. Dr. Schell.

DR. SCHELL: Just a couple of real quick questions. Mary, you gave the graph on managed honeybees. Is this collapse? Are we seeing it just in the managed colonies or are the wild populations seeing a collapse as well? Is there any regional aspect to this? Michael touched on it a little bit, but are we seeing this across the country or is it peculiar to certain areas of the U.S.?

DR. PURCELL: Colony collapse disorder is a phenomenon that is unique to European honeybees. The native bees, bumblebees for example, are experiencing declines but it's not a colony collapse disorder syndrome. And the second question?

DR. SCHELL: Is there a regional component to it?

DR. PURCELL: Well, it's been reported in over

35 different states. I mean, it may be overreported and a lot more careful analysis needs to be done. At least at this point we can say it doesn't appear to be regional.

MR. BRADY: I see another round of cards came up. Are we still in the clarifying question realm?

DR. PURCELL: Yes.

MR. BRADY: Okay. So, I see Virginia, Susan Kegley and then Jennifer Sass on the phone. So, Virginia.

MS. RUIZ: You answered part of my question in response to one of Michael's questions. I'm just curious about the expanded reporting mechanisms directly to EPA and to NPIC. Can you just explain that process a little bit better?

MR. BRADY: The National Pesticide Information Center has historically had the capability to report pet incidents that have occurred. That has typically been limited to people that are classified as professionals in that field. Like veterinarians would only be able to access the reporting mechanism of the NPIC. Now that has been expanded that beekeepers themselves can actually

report the loss of their hives through the portal system.

The other mechanism is where beekeepers -- we have people identified in the environmental fate and effects division that you can either send an e-mail to or call and report a bee kill incident. That information would be captured, then, in our ecological incident information system database.

Susan?

DR. KEGLEY: I have two kind of clarifying questions. You mentioned best management practices that are being promulgated to pesticide users. So, question one is, what are those BMPs?

DR. PURCELL: Good question that I probably am not equipped to answer that. It's something that the researchers themselves could provide answers to.

DR. KEGLEY: The second question is, this grasp, the thought of managed bee colonies in the U.S. over time, the source is NASS data, but how is that data collected?

DR. PURCELL: They're from honey-producing hives. So, NASS has collected data over the years, is tasked with collecting the data over the years about the

number of hives that are used to produce honey.

DR. KEGLEY: So, it's only commercial bees?

DR. PURCELL: It's just commercial bees, yes.

MR. BRADY: Then, Jennifer Sass on the phone.

DR. SASS: Thank you. Can you hear me?

MR. BRADY: Go ahead.

DR. SASS: Well, first of all, thank you for the very informative presentation. You covered a lot of information and also a lot of time. But I know you guys have been working on this issue. So, thank you.

I have one clarifying question and then one sort of more deeper question. The clarifying question is, is it true -- the way I understand it is once you determine that a pesticide is actually toxic or highly toxic or hazardous or whatever to honeybees, you don't actually regulate it differently.

The only thing it triggers is a bee caution statement on the pesticide. Is that right? You can't actually change the way the pesticide is used or cancel certain tolerances or uses knowing that information.

Then, my second question is, I'm really glad you guys are putting together a reporting database. I

want to ask if that's going to be a national reporting database and if it's going to be publicly accessible and searchable so that someone like me could go in and see how many reports there might have been associated with a particular exposure or set of circumstances?

MR. SEEGER: In response to your first question regarding the type of language that makes it on the label, we indicated the battery of tests that are used to look at the hazards that are associated with pesticides is used to inform the hazard statements on labels.

There can be, depending on what is available from a weight of evidence approach in terms of open literature and our toxicity studies that would include not only the laboratory studies but field pollinator studies as well, additional label language may be captured indicating potential risks to bees and mitigation to reduce those risks.

Regarding the question on the NPIC, I'm not familiar enough to know whether the NPIC results can be accessed. It's currently operated by a contractor. In this case, it would be Oregon State. But the accessibility of the data for analysis outside of the

operator, I'm not familiar enough with it.

MS. MONELL: Let me jump in here. It's Marty Monell. Part of our plan, if you recall, where we're dealing with the handling of incident reports holistically -- and part of the plan is to improve our reporting database so that we will have all of the incidents, human health, eco, and including the bee incidents reported funneled into our internal system -- ultimately, the plan is to have it available and searchable by the public.

So, it's a project in the works. We're not there yet, but that is the ultimate goal. Oh, gee, probably a year. It's resource dependent on a major IT project. So, those things take some time to develop the requirement, build it and then build the pieces that allow the external information to be fed into it. So, it's a good year.

DR. SASS: Thank you very much. I appreciate that.

MR. BRADY: We're very close to the end of our time limit, so I think what we'll do is -- Susan, did you have another set of questions?

DR. KEGLEY: Yes.

MR. BRADY: Wait. I was just clarifying whether or not your card was still up. I think we can take the ones that are up, so I see Jay, Susan, Mark and Lori. Then I think we're going to have to cut it off there for time reasons, but we can look for ways outside of the meeting, either through a teleconference or a webinar, to get at some of the other issues that have been coming up and circle back to the charge questions that we had.

So, why don't we -- Jay?

MR. VROOM: Thanks a lot. My guess is there's not time or available information to get into this, but I think it would be helpful for us in another setting to have a greater dialogue about Mary's third slide, the chart that Susan was asking about, the managed bee colonies. It's my understanding that many, if not most, of the colonies that are managed for pollination don't harvest much honey. So, I think we need to drill into a greater understanding of what's the available data, et cetera, but probably not for today.

Mary, I would just make a completely unrelated

plea. That is, the fifth slide that you showed which has the two photographs of a pesticide application and habitat destruction -- and the pesticide application is labeled pesticides and large scale agriculture. The accompanying photograph is a couple of people in a golf cart or an ATV spraying out of the passenger seat.

My guess is that that's a worker protection safety violation. So, I'd make that picture go away and find the people that were doing that. If they're USDA employees, then fix that. Thank you.

MR. BRADY: Okay. Let me go to the other side, Susan, and then I'll come back. Mark.

DR. WHALON: Thanks. A couple comments. From an ecological sustainability point of view, importing a species, propagating that species, and then becoming absolutely reliant on a foreign species to pollinate native as well as imported plants is probably ecologically speaking the height of (inaudible).

So, one of the things that is happening, at least in Michigan, is that we're trying to diversify our reliance on native pollinators and we know that there are a lot of problems in the genetic inbreeding, et cetera,

with domestic bees, parasite diseases, and things that we went over today.

When we look at native pollinators, there's a real challenge there because they're known but they're known obliquely, hardly known at all, hardly manipulated at all. So, an integrated approach to pollination is, I think, the future of pollination. We need some kind of focus on that.

We have an NRCS supported trial in Michigan that has a subscription up to 5,000 acres. It's designed to go with deciduous tree fruits. The whole approach is a companion planting approach. Historically, in orchards, you try to eliminate all pollinating plants in the ground cover and in the surrounding area so that you wouldn't have competition with bees to pollinate the crops. That may be an erroneous way of approaching pollination today, especially if you want to integrate native pollinators.

So, our approach has been to design a series of native plants that provide pollen and nectar reward at times that the deciduous tree groups are not in need of pollination. So, essentially, you feed them early and

you feed them after pollination but not during pollination, and you do companion planting.

It seems like a logical idea. We've done quite a few studies on what natives are available and what natives work, apples, cherries, peaches, plums, et cetera. There's an array of them. We don't know very much about a lot of them. So, the challenge is much the same way as integrated pest management.

I believe we should have an integrated pollination management system that tries to exploit native plants to feed native pollinators so that we can augment our weak European sister bees that we imported years ago with native bees.

So, the problem with this whole approach is NRCS, we got this through NRCS but the evaluation piece of it, does it work or not, is not funded. So, it's kind of typical of the way NRCS does things. They will fund a project to get it on the land, but they won't fund the companion evaluation stuff. So, we're trying to limp along and get that evaluated.

But it's a novel approach and it reflects what can be done in systems like tree (inaudible).

MR. BRADY: Lori.

DR. BERGER: I've just got a few points I'd like to make here. First to answer Susan's question about best management practices, those are being developed now. There's a big project in California. I know that the pollinator question and issue oftentimes does tend to be California centric because we have so many nut crops and tree fruit crops that are dependent upon this issue.

I can say, representing an organization that includes both growers as well as beekeepers, that these issues are very very important and we really need and request, as you guys develop all of this information, increased outreach at increasing intervals of time because it sounds like there's a lot of information being generated and people at many levels are extremely hungry for it, both from pollinator protection and crop protection.

We've had a very (inaudible) product that's been implicated in pollinator demise. I can guarantee you that growers and pest control advisors and beekeepers are all interested in drilling down into the real science

of this issue. So, increased outreach on your expanded research components. Webinars are a great way to meet with a diversity of people.

Also, question, is the NAS support as listed at 200,000, is that enough support to be monitoring the real picture with bee health? So, that's a concern.

And, let's see, something that Mark was just referring to, the NRCS support, as you all move through the process in learning practices and so forth, if you could increase the interaction with NRCS to get some of this information out into the field and practices, that would be very helpful. It does seem like that program has a lot of resource that could benefit pollinators and growers.

Finally, I just want to say that this is a really important issue. I was disappointed, even this morning, talking to one of my colleagues on the PPDC. There's really not recognition a lot of times for the importance of pollinators, not just to fruit and nut crops but to seed crops and to forage crops.

So, I think just your ongoing messages on the importance of pollinators to agriculture and the

environment are needed and important.

DR. PURCELL: I just wanted to respond to your comment about the NAS report of $200,000. That was funding that was provided by ARS to do the National Academy of Sciences report, not to be confused with the National Agricultural Statistics Survey.

DR. BERGER: Right. One of the things that we discussed in this committee is that report not having funding. That provides very important information for all of agriculture and environmental concerns. So, when I saw that number, it was a little bit of a red flag in reference to other discussions we've had about our concerns about that database.

MR. BRADY: Susan.

DR. KEGLEY: Pollinators, like many others, have been on our agenda for the PPDC meetings for several meetings now in the past. There is certainly a need for collecting more data, knowing more. We just don't know what's going on here exactly, it seems.

But I guess I'm wondering how far do populations have to decline before we call it an emergency and start to actually take action of -- make

our best guesses and take action rather than continuing to study it for year after year after year.

MR. BRADY: Nice way to end the conversation, Susan, in terms of some of the challenges. Clearly, I'm not going to give you the answer because I don't have the answer.

I think, because we've talked about the numerous stresses that are out there, everything from nutrition to habitat quality to the pesticide role, what I'd like to do as we wrap up this session is I've got two thoughts as I've heard the conversation.

One thought I have is that we and our colleagues in USDA need to do a better job of communicating what we're doing, what we're not doing, and making sure we've got incoming information, which was the idea behind the charge questions. But the fact that there were so many clarifying questions I think reinforces why I wanted to have some discussion about how information is flowing in and out of the Federal Government.

So, with that in mind, think about these ideas as we get to the last part of the morning when we talk

about actions for the future. One thought I have is through the PPDC setting up a webinar, telephone conference, or something with the pollinator protection team and the USDA colleagues and spend some detailed time exploring where we are in getting the word out, where we are in having -- a good receiving mode to get in information and give us some feedback. Then we can report that out in the fall so everybody knows what's going on, and/or thinking about what we might want to do in the fall.

So, I think we need to tackle the communication issue. We scrape the surface and just reinforce the challenge I think we have. So, think about something we might do in the course of the summer through the PPDC to get that feedback for us.

Now, I'd like to stop this session and move on to our next session. I know we had a break for 10 minutes, but we've only been sitting down for about an hour. So, I know you had your card up but I'm kind of doing a little bit of a Roberts Rule and we've got to cut off the conversation. Maybe we can catch up during the break and loop it back into the system.

Okay, go ahead, real quick.

UNIDENTIFIED MALE: Just to clarify, NRCS is developing a 799 monitoring evaluation standard that might be very appropriate. Now would be the time to get with them to make sure that that's incorporated next year.

MR. BRADY: Thanks. Okay, so let's move on to the next session which will be a report out of our new work group on public health pesticides and issues. Lois, thanks.

MS. ROSSI: I'm going to give an update on some public health initiatives. Then, also, on Wednesday afternoon we had the first meeting of the public health work group, PPDC public health work group, which was set up and blessed by this group at the last PPDC meeting.

Basically, I'm going to cover some background in public health initiatives at OPP, some current and recent public health projects, some collaboration that we're doing with other federal agencies. Then, last but not least, to give the results, a report out of the work group meeting we had and next steps for that.

By the way, sitting to my immediate left is our

OPP public health coordinator, Susan Jennings.

Very brief, as many of you know, in 1996, FTPA required EPA to develop a list of pests of public health significance, which we accomplished, and also to consult with HHS and the Center for Disease Control before taking any regulatory action on any public health pesticides.

By law, the law requires that public health pesticides are registered according to the same safety standards as agricultural pesticides. This is the one set of products that efficacy data is required for products used to control pests of public health concern. We also can take into consideration the benefits of the pesticide in controlling of public health pests before taking any regulatory action.

In dealing with the benefits, it can be quite an extensive process. A lot of consultation is routinely done with our federal partners and user communities. We definitely look at the availability of alternatives and looking also of whether any replacements in these alternatives is of concern.

CDC is the primary contact that we use to get information, but other sources are frequently used and we

involve our own biological and economic analysis division. Many of the projects, and you'll see it in a couple of slides, do not necessarily arise from risk concerns, but they focus on improving the use of these pesticides to maximize the public health benefits.

They tend to focus on application and encouraging appropriate use to improve exposure, obviously the pest control with IPM and efficacy and communicating and clarifying a lot of the policy issues and guidelines that we have for efficacy review, for example.

Some of these projects have a lot of components to them, namely, education and outreach, regulatory improvements, scientific updates, and label improvement. I think potentially more than any other of our group of projects, the collaboration is a very key factor in all of these public health projects.

Some examples of application specific projects include our currently ongoing repellant strategy, mosquito adulticidal initiatives including blanket tolerances and labeling for mosquito adulticides, the foggers initiative, and misting systems.

Some of our pest-specific projects to encourage appropriate pest control to improve public health include our extensive right now and very focused bed bug initiative, our PESP outreach and IPM projects, communicating the efficacy and the product performance rules, regulating prions and, of course, the rodenticides risk mitigation project.

Collaborating with federal partners, Susan actually has been very much involved in not only participating in the public health pesticide consortium but contributing a lot of energy to it. It's a common forum for federal agencies with different missions that are involved with public health.

There's a lot of acronyms there. But it's representatives from the Center for Disease Control, CDC, Department of Defense, DoD, EPA, HUD, Housing and Urban Development, NIH, National Institute of Health, USAID, USDA, the Agricultural Research Service, the IR-4 program.

This forum has been a very productive venue for partners to discuss problems and look at common approaches to solving these problems and just

coordinating the federal effort on public health disease control.

All of those federal agencies are definitely involved in public health. Many are involved in the pesticide use overseas. I think it's pretty obvious to say the impact of infectious diseases on people's lives and resources and that new diseases can spread very quickly, as we saw last year with the H1N1. Of course, we are currently engaged in working with DoD for their unique needs for protecting the troops serving overseas and the pesticides, the pests that need to be controlled and what's available to control them.

We also expanded recently our international work on public health to sort of parallel the work that we've done in agricultural international coordination. I think EPA, as definitely a leader in the regulation of pesticides, has a key role to play in this. Last year we had two workshops that were focused on looking at ways to increase the accessability and encourage development of newer public health pesticides both here and for use in other nations.

I think we've had very successful harmonization

and global joint review processes for the agricultural chemicals. I think the work done there can jump start the work on public health pesticides and not reinvent the wheel in many of the building blocks that we used and had to develop over the course of 15 years in global joint reviews. Certainly, that work can be applied to this and not concentrate on that, although there are other issues, obviously, unique issues, that public health pesticides bring to the table.

With those two workshops we did last year, we worked with WHO and the WHO pesticide evaluation group there and the secretary of the Stockholm convention whose main objective certainly is to find alternatives to DDT. So, we have been including them in a lot of our work. We look forward to working with them as they develop a framework in which we can play some role.

I think the results of the both workshops agreed that the harmonization of requirements for public health pesticides and coordination of reviews could potentially lead to a greater availability of tools to the user community and certainly save resources and make potentially the development of a public health pesticide

easier and more profitable for the industry so that we would have some newer potentially safer tools.

The public health workgroup under the pesticide program dialogue committee, it will provide us with a forum with some specialized skills that would allow us to come to stakeholders to seek guidance and advice on some of our initiatives not only in creating some of the initiatives, but once the initiatives get going, some advice on pathways forward. Some of these public health problems really present quite a challenge to all people involved. It will assist in the collaboration.

The purpose of the work group was to focus on issues specific to pesticides use to control pests of public health significance. We see that the issues may be regulatory, policy, programmatic. It can be a full range of things, as I think you'll see when I give the report.

We thought that having a work group that we presented I think at the last PPDC meeting, we thought that having a work group would be more efficient and effective. We could get participation from a broader group of public health stakeholders who we may not

normally deal with on a regular basis for most of the work we do, and increase representation of public health departments, communities. We did have some representation from communities and the environmental justice organizations and also proponents of children's health.

So, the work group will be ongoing. We'll probably meet regularly mostly by teleconference, although we probably will have -- and I'll get to that in a second -- a kick off session. Then, of course, we would take recommendations through the PPDC.

As I said, the kickoff meeting was held this past Wednesday afternoon. We presented our overview of public health activities. The public health activities pretty much involves most divisions in OPP and certainly impacts a lot of our regulatory decisions. The meeting was very well attended and we did have quite a cross section of representatives at the meeting.

We discussed areas of interest and priorities. The bed bug initiative was definitely surfaced to the top, which is an issue that a lot of people not only in this country but in the world are struggling with these

days. Of course, the concerns and the challenges are the lack of tools, the potential for misuse of existing pesticides, the need for education and outreach so that people who have this problem have a place to go to get good information. Then we also talked about further education on the OPP process for determining public health benefits.

Other areas we talked about was the 25(b) and public health pesticides. The workgroup expressed concern about projects that are proliferating during times of pest and disease pressure that may not work, that may not be efficacious. We talked about also the international efforts towards the global harmonization for public health registrations. The work group suggested that it could offer some help to locate some potential pilot projects that we could take forward.

Further, efficacy and communication for the products, developing a performance measure for public health, which is something we've talked about internally for many years now. This work group, I think, could provide some very valuable input into getting to a performance measure for public health.

There were concerns expressed about the new NPDES permitting process and its effect on the use of pesticides to control public health pests, vector borne pests. Coordination with EPA about an urban IPM, the misting systems and resistance concerns. I think that pretty much summarizes the main issues that people did in a little brainstorming session we had.

The work group is eager to work on these issues, provide advice and recommendation. We will develop a paper on the activities that were suggested. The bed bugs is very likely to be one of the first things we address. It was suggested that we try and have a one-day session in late June to put some concentrated effort into kicking off the initiative.

That's it. Thank you.

MR. BRADBURY: We'll take some questions. Dave.

MR. TAMAYO: At this point, can we do more than clarifying questions?

MR. BRADBURY: Sure. We can explore a bit. And then Amy.

MR. TAMAYO: Well, I've got a couple of hats

here. I'm on the board of our local mosquito and vector control district and then also I'm speaking from the stormwater quality perspective. One thing that I didn't really see up there is really sort of preserving the use of public health pesticides.

One of the things that we see, at least in the Sacramento area, is that there's a conflict between other urban uses of various pesticides and with the public health pesticides that are available. That happens in a couple of ways.

One is, I think because there's very extensive use of pyrethroids in the urban areas, that that's not really taken into account in resistance management. The district can do its own resistance management but you can't really do that in a vacuum. Because there's such extensive use of pyrethroids, for instance, in urban areas, at least in California, I think there's an expectation that that's going to lead to early development of resistance to pyrethroids.

We don't use pyrethroids at this point, but I think what we do use is pyrethrins. The mosquito district uses pyrethrins. I would suspect that there may

be some resistance crossover. Forgive me if I'm wrong on that, but I'm guessing that there's a very good potential for that.

So, I think I would expect that that's something that really needs to be looked at. How does the registration of pesticides in general throughout the country, how does that affect the ability to maintain or to reduce resistance or development of resistence for public health pesticides. I think a lot of the uses of these pesticides are basically either unnecessary or frivolous. I'm talking about some of the urban uses.

There really needs to be a look at how those certain uses are being allowed that really aren't that necessary and that will take tools out of the hands of the public health professionals where I think that's a higher use than certain other uses.

So, the other way that we've seen an impact is from -- there's ongoing toxicity in urban waterways. That's actually affected the ability -- you can even see it. We've created 303(d) listings under the Clean Water Act. So, those are impaired water bodies that now those types of water bodies, if the mosquito district needs to

do a public health application, they're not going to be able to get the general permit coverage.

Now, that may not be the case in California, but in the other parts of the country, if there's an existing impairment that's caused by other types of uses, then that takes, once again, a tool out of the hand or it makes it much more difficult to use those pesticides for public health because there's already an impairment either through synergists -- and there's also an observed problem with a synergist because there was already toxicity or there were already toxic levels of pesticides in the sediments in the creek.

A very small amount of synergists that was applied by our district actually caused the existing pollution in the sediments to become toxic. That's yet another way. So, that sort of interaction between very different types of uses that are in the same geographic area, I think that's something that needs to be looked at. I think in general, EPA needs to be able to look at the whole system rather than just use by use and chemical by chemical. Otherwise, you're going to run into conflicts like that.

MR. BRADBURY: Thanks, David, for the comments. Amy.

MS. LIEBMAN: Thank you for explaining what the public health work group was going to do. That was really interesting.

I'm just curious, given -- when we started off our PPDC meeting yesterday, we sort of heard about the administrator's priorities. I see that there's a very broad group of stakeholders involved in the committee. That's great. But what I'm not seeing, and maybe you can speak to this, is when we look at public health use of pesticides, where is the analysis or where is the input or concern for forebodable populations?

Let's take the example of substandard housing. You have poor low income people living in substandard housing. There's a lot of vector issues. There's an extensive use of pesticides to try and control that. So, I would love for you guys to address that and make sure that when you're looking at more efficient use of pesticides, regulatory issues, your outreach and education, that that rises to the top in terms of exposed populations that might be more vulnerable in your public

health effort.

MR. BRADBURY: Thanks, Amy. Let's see, Carolyn, Mark and then Pat. Pat, do you have yours up? Okay. We'll take those three and then we'll check the clock and see how we're doing.

MS. BRICKEY: I think the comments that both Dave and Amy made really bring out for me the importance of looking at public health pest management as pest management and not just focusing on the use of chemicals for public health pest management but also looking at all the innovative practices that have been developed to manage public health pests without or with reduced chemical use.

I really hope this work group can figure out what steps EPA can take to make sure that those pest management practices are developed and widely implemented and are as successful as they can be.

MR. BRADBURY: Mark.

DR. WHALON: Thank, Lois. Great presentation. Great summation from our meeting on Wednesday. I think it's also nice that we have the work group. I think it's long been needed.

My comment is more of a request than anything else. As you captured, we talked a lot about bed bugs. I don't want to minimize the importance of bed bugs or the rising importance of bed bugs, but we shouldn't lose focus on vector borne diseases.

There's another hot topic, dingy fever, also known as breakbone fever. It's named breakbone for a reason. Last year, there were 22 cases in Key West. Just last week there was another case, first case for this year. CDC just put out a health advisory this week talking about relief workers coming back from Haiti. Look out. And your differential diagnostic doctors for dingy. That is a rising issue.

We need to ensure that our professionals that are responsible for either controlling disease outbreaks or maintaining the minimal risk of vector borne diseases in general, that they have their adequate tools to be able to do their job and then taking into resistence as well. I think that's a very important point.

MR. BRADBURY: Thank you. Pat.

MR. DONNELLY: Thanks for taking on this topic and getting the work group up. I think it's really

incredibly important that that take place.

Lois, I was curious. I know you've been doing a lot of work and discussion with CDC and even DoD. Are they participating on the work group as well? Great. I'm glad to hear that.

Just to align some comments with Mark, I hope that the work group does spend time dealing with not only sort of the existing problems right in front of us but sort of the future and emerging problems. I mean, we certainly can predict that if all the modelers are correct about climate change that we're going to see, increasing disease pressure from south to north, we're going to need to be prepared to deal with that.

So, I think taking the time to do some forecasting and scenario planning and understanding the what if scenarios, what if dingy really takes hold and moves quickly up north, are we prepared to deal with that? Do we have the tools? What are the regulatory constraints to make decisions and putting stuff out there that we need to deal with.

You may go so far into it thinking about what are deliverables from this work group. What most

companies have to do is emergency planning guides. So, they do the disaster scenario planning and then they sort of think through, if this happened, what would be our steps. They lay them our directly.

So, when stuff happens, they can read a book and say these are the authorities I have to do this under, this is what I need to do. Lay it out so all the future generations and all the people can sort of understand what the process is. That may be something that's warranted given the severity and seriousness of public health disease problems.

MR. BRADBURY: Bob and then Dave.

BOB: Is it all right to make a gratuitous self-serving comment? Everyone else does.

I just wanted to say, having been here for a long time -- and I understand the importance of agriculture. Yet, public health has always been a little bit of a back water. It's understandable. I just wanted to say that I appreciate the agency committing resources and shining light on something that's very important to a lot of us. That's all I wanted to say.

MR. BRADBURY: David, and that will be our

last.

MR. TAMAYO: I wanted to add that I appreciate that there's a recognition of the need to coordinate this effort with the NPDES. I realize that it may have met more coordinating with the NPDES aquatic pesticide permit stuff. I also think looking at the needs of the MS-4 and PDS permit holders and the potential impact of public health pesticides on our discharges -- and I already touched on that. I think if we remove some of the existing problems that public health pesticides are likely to be a lesser impact but they still could have an impact.

One of the things that we would greatly encourage is that EPA be involved in not just the chemical aspects of it but really supporting the development of a more integrated vector management program. I know that some districts are really great at it and some of them need some assistance. I think that the chemical part of it needs to be done as part of a broader program. Thank you.

MR. BRADBURY: Thanks. Lois, any closing comments?

MS. ROSSI: Just one thing that we didn't mention. We were able to get some funding and the request for proposal should go out very shortly. That is directed to developing educational materials particularly for EJ communities and addressing bed bugs. So, I just wanted to let everybody know that that request for proposals will be going out shortly.

MR. BRADBURY: Thanks, Lois, Susan, and members of the work group. I think it's a good effort that we've got started.

The next agenda item is an update on the endocrine disruptor screening program. Let me check in. Do people just need to stand up and stretch or sort of take a break on the slide. Is that working okay? Keep going. Take a break if you need it. Let's go that route, then.

So, Rick Keigwin and Karen Whitby are going to come up and give you a snapshot of sort of where we are in implementing the program and sort of manage the time so we can at least do a few clarifying questions.

We better not get into a debate about some of the science and other issues associated with the program,

but we certainly can clarify any questions about the processes that we're in right now.

I'll turn it over to Rick.

MR. KEIGWIN: I'll be joined by Dr. Karen Whitby to help with this presentation. We thought we would give you all a quick update on where we are with the endocrine disruptor screening program, focusing more on the process and much less so on the science that's developed to get us to this point.

Just by means of refresher, as part of the Food Quality Protection Act of 1996, we were directed by congress to develop a screening program to identify chemicals that may have estrogenic effects in humans, and that we were to test all pesticide chemicals. The statute also provided us with the authority to go beyond estrogen to look at other endocrine effects.

About the same time, congress also passed amendments to the Safe Drinking Water Act that also provided for testing of chemical substances found in drinking water, provided that a substantial human population may be exposed to the substance.

As we've gone about developing and validating

various screening assays, we've focused on two tiers of studies. Tier 1, which is the focus of the orders that went out starting late last year looking at in vitro and in vivo screens, focus exclusively on trying to determine whether there's a potential for that particular substance to interact with the endocrine system. Whereas, the Tier 2 studies, which we would subsequently call in through a test order process, would focus on providing data for (inaudible) response and hazard assessment.

I think in the past you received an update. There are basically five in vitro assays and six in vivo assays that are subject to this initial tier 1 screening battery. Those are listed here. I'll leave it to Karen to actually pronounce some of those names because I can't. Then, some of the tier 2 studies that had been validated are here. You'll see at least one of those is a core 158 data requirement instead of mammalian two gen.

So, 2009 was a rather busy year for us in OCSPP getting the endocrine program ready to launch. In April of last year, we issued the final list of 67 chemicals after a fairly extensive public comment process. The list contains 58 pesticide active ingredients and 9 high

production volume inert ingredients. None of these chemicals were selected based upon their endocrine disruption potential, but reflected solely based upon what their exposure was, either through drinking water or food or residential.

At that same time, we also published the final policies and procedures that we'd be following for issuing the initial test orders and how we would be screening those responses. We completed the Information Collection Act request requirements under the Paperwork Reduction Act in the fall of 2009. We published the final batteries the following week. Then, we promptly started issuing test orders. For one person on my staff, this is all she has been doing for the past seven months.

So, to date we have issued a total of 757 test orders requiring all of the 11 assays across the 67 chemicals. We issued the orders to the registrants for the pesticide actives and the known manufacturers and importers of the high production volume inert ingredient. The vast majority of the test orders actually were issued to manufacturers or suspected manufacturers of the nine inert ingredients.

The way it works is sort of similar to a data call in. In response to receiving the test order, the recipient has 90 days to let us know how they intend to respond to the order and if they are committing to do the studies or if they're joining a consortium. With the issuance of the initial test orders beginning in October, the first round of responses was due in early February. If they were responding individually or if they were responding as a consortium or they were intending to form a consortium, their responses were due in early April.

Then, subsequently, as they're progressing through developing the data, the test order recipient needs to provide us with a progress report at each one year interval. The orders themselves required the submission of the studies within 24 months of the issuance of the test order.

This is regardless of whether or not they submitted what we'll talk about in a few minutes, other scientifically relevant information and our progress in reviewing that information. Studies, as a result, are due beginning in late 2011 and then would go into 2012, depending on when the order was actually issued.

Order recipients had nine different options that they could choose in responding to the order. There were two options that were specific to inert ingredients only and three that were specific to pesticide active ingredients only. Basically, generate the data, site or submit existing data, form a consortia which then could result in either generating the data or citing existing data or claiming not to be subject to the order.

For pesticide active ingredients, an order recipient could also choose to voluntarily cancel their registration or to reformulate the product to exclude that chemical from the formulation or claim a formulated exemption, basically saying that they purchased the active ingredient from an already registered source. Then, for the inert ingredients, there were two other options. One was to discontinue the manufacture of those substances and/or commit to not sell that chemical for use in pesticide formulation.

As part of our policies and procedures, we provided for the ability to submit or cite existing data, along with a rationale as to how those data satisfy the order. This is what we call OSRI or other scientifically

relevant information. In a couple minutes, Karen will give us an update on where we are with the review of that type of information.

So, through the middle of the month, we have received responses for 24 pesticides. The heartening things in this is that a lot of consortia are being formed. To date, at least, many of the order recipients believe that a large of data that they had already submitted to the agency or may have generated on their own or they have found in public literature may satisfy a number of these testing requirements. The result likely could be significantly less testing, fewer animals being subjected to testing, and a much declined duplication of effort.

So, in terms of the total number of orders for the inert ingredients, there were 524 orders issued. A lot of these responses aren't yet due, so the numbers aren't going to completely add up yet. But for the inert ingredients, virtually everyone has either said that they're not subject to the order, meaning they haven't manufactured the substance in quite some time, they haven't imported the substance, or that they will be

committing to no longer sell that inert ingredient for use in pesticide formulation.

Then, for the pesticide active ingredients, we have had a total of six active ingredients or manufacturers of active ingredients. It indicates that they will be voluntarily cancelling that active ingredient. The six active ingredients are diselfaton, methamidifos, methidifion, methyl parathion, resimethrin, and propocor (phonetic).

Then, for some of the other active ingredients, individual registrants have indicated that they will be voluntarily cancelling their products. As I said, for every active ingredient that received an order for which there are multiple sources of that active ingredient, those registrants have been joining together in task forces.

I wanted to add here that just like with data call ins for the registrants, if they have questions about the process or how to conduct an assay or where we are with the review of their test order response, they should be contacting the chemical review manager.

About every week, if not every week, every

other week, we post an update on the test order responses on the endocrine disruptor screening program web site. We'll be including the names of the chemical review managers there as well for folks in the future.

With that, I'll turn things over to Karen.

MS. WHITBY: The agency will review the OSRI submission and cited existing data to confirm that the cited data support the rationale and that it is functionally equivalent to the tier 1 assay it is intended to replace. Test order recipients may also request that the agency consider an alternate test protocol or methodology for the conduct of the tier 1 assay that will require a science review.

The goal of the agency is to develop and provide a consistent transparent and defensible responses to cite existing data and OSRI rationale submitted by the test order recipients and the public. Evaluations of OSRI will be performed on the chemical basis rather than on the basis of individual responses or submissions.

Questions on the conduct of the EDSP guideline studies or requests for approvals of alternate test protocols should be submitted in writing to the chemical

review manager and the pesticide reevaluation division. OSCPP scientists will review these requests and provide a written response. Evaluations of OSRI will be very challenging in light of the diversity of approaches that may be used, as well as the volume and frequency of the responses that we've received to date.

MR. KEIGWIN: So, our next steps with the current orders, we expect for the next several months they'll be continuing to receive responses and will be processing those. Our goal is to get the other scientific relevant information packages into the review process as quickly as possible so that we can get those through the process so that if companies do not have to initiate studies, we can alert them of that promptly.

One question that we've been getting is when registrants will start to learn about the fate of their OSRI submissions. Optimistically, we're looking at probably the end of the May or early June when those responses will start to come out. Our intention is to publish the agency's responses as well as what the order recipients submitted for everyone in the public to see so that all can learn from how the agency has responded to

the OSRI submissions.

One other pieces that we're working on is that as part of the agency's appropriations for 2010, congress has required the agency to issue orders for a second list of substances of no less than 100 chemicals and to begin to issue those orders by the end of October of this year. The appropriations language talks specifically about including water contaminants and that we are to issue 25 orders, although we're interpreting that to be substances, per year for the chemicals that are on this list.

This list will likely be composed of substances that are either existing, drinking water standards, chemicals that are on the CPL-3 list that Pam Barr talked about yesterday, or chemicals that started registration review in 2007 and 2008.

We're working jointly with the Office of Water as well as our sister office, the Office of Pollution Prevention and Toxics, to develop a process. As I said, our goal is to meet the congressional mandate and to begin issuing orders later in 2010. We would expect that with the issuance of those orders, those data would start

to be received by the agency in late 2012 and into 2013.

So, I'll just end with a really helpful, I think, resource slide with a number of web sites to information on the program and where you can get regular updates as the order responses are progressing through the process. Thank you very much.

MR. BRADBURY: I'll take some questions.

MS. BRICKEY: As we all know, Rick, the legislation that authorized this program was passed in 1996 and it's now 2010, last time I checked. So, give me some feeling about where this program is in the scheme of life. Given that it's been this long and this is where we are, give us some feel for that. Are we playing catch up in some significant way to make up all those years when this program just kind of drifted?

MR. KEIGWIN: Well, I think it's important that we have started to issue the orders. There was a process, a scientific-based process that we had to go through to develop these assays and get them to the point that they are. Did it take longer than people had anticipated? I think the answer is yes. But it's progressed to the point enough that we have enough

confidence in these studies that we could begin to issue the orders. So, we're at that point.

The plan had always been for us to integrate this into the registration review program. That's what we're starting to do, particularly with the second list that will come out, to begin to fold in the chemicals that are in registration review and then as we progress, there may have to be a little bit of catch up to progress this to align this with the other substances that are going through the registration review.

MS. BRICKEY: Could you say a little more about the catch up and when you talk about the integration of this into that program? Talk a little more about that.

MR. KEIGWIN: Sure. So, this initial set of orders that were issued only covered 67 chemicals. So, our clearance under the Paperwork Reduction Act only covers those 67 chemicals. The next list will cover probably a little over 100 chemicals. It has to include both pesticides and nonpesticides. Then we'll have to get a clearance for that.

So, we're beginning to integrate with registration review to bring the chemicals that went into

registration review in the first couple of years in. At some point, there will probably have to be a third clearance through the Office of Management and Budget to factor in the other chemicals. At some point, we'll get to a point where this is happening in real time.

MS. BRICKEY: I know this is not your department, but as far as registration goes, how is this process being integrated into registration?

MR. BRADBURY: Well, with the first 67 inert ingredients, that's our first entre into that aspect of the registration division. What we're looking at right now is focusing on the registration review program as that progresses.

When some of the information comes in -- I think that was in the OSRI topic that Karen Whitby talked about -- I think that will give us some insight as we take a look at information requirements as you move forward with the new products. Right now our focus is to try to take a look at the existing chemicals and get started, invest the science and the resources to get that moving forward.

Susan.

SUSAN: I just have a couple of questions, clarifying questions. You're going to publish your determination of the OSRI material, but are you going to put out for public review or even be able to look at what your weight of evidence approach is going to be for evaluating all that material?

MR. KEIGWIN: We'll be publishing what our responses are. As part of our responses, it will be going through our reasoning for why we reached the conclusions that we did.

SUSAN: I think that would be very helpful obviously for industry because it would make it easier for you to do your evaluation if we knew what it was you were putting the weights on. We could present the material better for you that way. So, if you do at some point generate something that would appear to be the weight of evidence that you use, that would really be very helpful.

Looking at the time line for when you want to get your next set of orders out at the end of the year and sort of backing up through what that means for documents that are out for public comment and draft,

whatever, obviously, one of the things that comes to mind is the ICR for the first round of chemicals.

There was a fairly tightly written terms of clearance associated with the approval for that first ICR, including that a second ICR couldn't be approved until some questions that OMB had were answered. It's based on this, how are you evaluating other scientifically relevant information such that, for this question of yes or no, that these assays are pretty much telling you, do you have data already sufficiently available to do that.

Of course, part of that process then informs your next ICR whether or not it's mandatory doing all 11 assays or in fact you now would have a process for saying here's the other scientifically relevant information or here are other tests that give us the same information we need to make the appropriate decision on whether or not you do or do not have the potential to interact (inaudible).

So, I guess my question is, how are you intending to meet the terms of clearance when you won't have gone through all of the OSRI compared to all of the

data that you'll be getting in that's generated, which obviously there's much more OSRI being submitted than there are people looking to generate the tests. So, how are you going to respond to that?

MR. KEIGWIN: Well, obviously, we have a little bit of a competing mandate. We've got a directive from congress that says you shall do this as part of our 2010 appropriations language. Then we have the terms of clearance for the information collection request that says as part of either renewal or a new ICR, you need to report back on your experiences to date on reviewing OSRI.

Our plan is that as we gain experience with developing responses to the OSRI, we would integrate what we've learned to date and fold that into the ICR. These will progress through. I don't think the terms of clearance say you have to have reviewed all of the OSRI that's come in for all 67 chemicals before you go forward. I think it says tell us what your experience has been to date and include that in your report to us.

SUSAN: So, you're not going to write a report, then. You're just going to -- your response to the

writing report part that's written in the terms of clearance would be what you put in your next draft ICR.

MR. BRADBURY: I think, Susan, you raised and Rick summed it up, the beauty of our government. We have the executive branch and the legislative branch working through some issues. One of our challenges will be to work through these perspectives that the two parts of the government have raised for us. We've got to thread the needle to provide the information OMB is interested in but also the responses to the legislative branch that's handling our appropriations.

Kristie and then Scott. And then, after Patrick, that will be the last person.

MS. SULLIVAN: First, I wanted to ask a clarifying question on slide 15 where it talks about the orders. It says 100 chemicals by the end of this year. Does that mean then after that 25 substances per year? I'm a little confused about that.

MR. KEIGWIN: Well, we have a little bit of confusion, too. This is the congressional language, though. The congressional language says that you develop a second list of chemicals to be tested through the

program and it needs to contain at least 100 chemicals. Then it goes on to say that -- which we don't have on the slide -- that it has to include things beyond pesticides, so other water contaminants, substances that may be in personal care products, and the like.

Then it says once you've developed that list, the appropriations language says then for each of the next several years, issue 25 orders. Well, as you've seen, for 67 chemicals, we've issued 757 orders. So, we really don't think that what congress intended was 25 orders per year. We think for a list of 100 chemicals, that it would be at least 25 chemicals per year.

MS. SULLIVAN: So, it actually requires EPA to develop a list of 100 chemicals.

MR. KEIGWIN: Right.

MS. SULLIVAN: Okay, because the slide says issue orders.

MR. KEIGWIN: Yes. We first develop a list and then we issue orders.

MS. SULLIVAN: Okay, got it. Actually, I think part of the discussion was sort of answering my question anyway, but just wondering how the agency is going to be

able to review the battery itself based on your experience with the first stage, which was your plan, I think, a couple years ago when we've had briefings, but having to send out more tox orders at the same time. Is there still a plan to review the battery itself and the information you've gotten from that?

MS. WHITBY: There is a plan to go back to the scientific advisory panel with a rereview of the battery, but that won't be, obviously, until we get the data in from list 1 and get a chance to review it.

MS. SULLIVAN: Okay. Do you have any specific time frame when you foresee working in some of the work and techniques and information coming out of the (inaudible) ecology program?

MR. BRADBURY: I can't give you the exact year, but clearly that's part of the overall computational toxicology program. One of the things I was going to mention yesterday is that in fact ORD is thinking through some ways to consolidate a lot of the research program with computational toxicology as an umbrella with the endocrine disruptor program being part of it. There's appropriation language that also ask the agency to

continue pursuing new technologies, new assays, that can go faster, smarter.

So, I think in a way, getting back to Carolyn Brickey's point, how could you start to accelerate evaluating these chemicals and sorting out where you need to focus and get that done efficiently and effectively. So, it's part of an active effort.

Scott and then Caroline Cox.

MR. SCHERTZ: I have one clarification question. You had mentioned, I believe it was, six actives that essentially were not being supported. Is that correct? The question is, are those all of the uses of those products?

MR. KEIGWIN: Yes.

MR. SCHERTZ: Even with multiple registrants possibly?

MR. KEIGWIN: That's correct. In fact, for four of those chemicals, we've either already announced in the Federal Register that voluntary cancellation -- in the case of diselfaton and methamidifos, we've actually already issued the cancellation orders.

MR. SCHERTZ: Okay, thank you.

MR. BRADBURY: Caroline and then Jay.

MS. COX: I am also interested in the long term schedule for this testing. I was just doing some back of the envelope scribbles and I think if there's about 1200 pesticide active ingredients and maybe 3,000 inert ingredients, that's over 4,000 chemicals that need to go through the screening program, not counting the drinking water contaminants which would add something. If we're talking about 100 chemicals a year, that's 40 years. If we're talking 25 chemicals a year, that's 160 years or something.

I think both of those numbers are clearly to me much bigger than what the intent of the Food Quality Protection Act was. I mean, I don't think that anybody expected that that mandate was going to take centuries or something. So, do you have a plan for how to make this happen more expeditiously?

MR. KEIGWIN: Well, at least for the active ingredients, the plan is registration review. So, that's 15 years, I realize, but it's much shorter than the 100 that you mentioned. We do need to think about a plan for the inerts. Steve also mentioned the essential role of

(inaudible) as a way to help accelerate us through this process a little bit more quickly. But we're just not at that point yet.

MR. BRADBURY: If I can insert myself a bit, I think, Caroline, you captured the conundrum. The fuel and battery, if you do the whole fuel and battery, it takes two years because (inaudible) assays take essentially a year and a half to do. So, as you start to run the mathematics, you can start to see that you get sort of a disconnect.

That's part of the reason we have the 21st century toxicology work group as a piece of this puzzle. If on the one hand you're mandated to look through potentially 30,000 or 20,000 discreet chemicals and umpty ump inerts and 800 some active ingredients, there aren't enough labs in the country to run all those chemicals through in a short time.

But if we can develop some other technology to help us figure out where to focus, we probably could start screening through lots of chemicals in a relatively short period of time to figure out where to focus resources to tackle the most risky situations that need

to be tackled.

I think you've captured the challenge, which is part of the (inaudible) program. A lot of the efforts we're trying to do here with you all is to figure out if we can build a science, how do you use the science appropriately to make long protective decisions.

Sorry to soapbox a little bit, but I thought I'd take it up. Jay.

MR. VROOM: Staying on the mathematics theme and resource challenges, I've asked CropLife members that are working on this to try to come up with a standardized way that our members can keep track of resources they're putting in to interfacing and compliance. I think that's just as important as keeping track of the government side, which is very important as well.

So, one of my question is maybe for Marty. Have you put a GPRA kind of a matrix around this to be able to track resources that are being consumed in OPP and elsewhere? One of our member companies told me that their OSRI submission for getting out of the penalty box on all 11 tier 1 assays took him 250 pages to submit. That has to be a huge resource commitment to evaluate

that, just as an example.

MS. MONELL: We actually have. We've gone through an exhaustive ongoing process to evaluate our resources that we've expended thus far, as well as those anticipated for the future in terms of multiple fiscal years.

As you probably are aware, the bulk of the endocrine disruption resources that are given to the agency are given to OSCP for their testing and development. We're now hopefully at the end of that process for the time being so that more of those resources will come to the program office. It will be pesticide programs first but eventually it will be toxics and the water programs.

So, there's a huge resource need by the agency for this. I think congress is aware of it. We're spending a great deal of time, not only the planning efforts but also the (inaudible) resource needs.

MR. VROOM: So, that also applies to folks in HED and elsewhere in OPP?

MS. MONELL: HED, EFED, the managers, Karen, Rick. To the extent they spend time on this effort and

energy on this effort, it is tracked through the TIS system. That's our accounting system for accounting for people's time, what they're working on here in the program. So, we have a lot of details and data from all of the effected program areas.

MR. VROOM: I apologize. Maybe you dove into this when I wasn't in attendance on Wednesday, the PRIA work group. But did you go into that or can we get back together at some point to get a better understanding of what your measures are so far?

MS. MONELL: At the PRIA coalition meeting that was held on I guess it was Wednesday morning, we went into extensive detail about how PRIA resources are allocated across the program. What we agreed to do was follow up with that to put it in the context of -- because PRIA pays for about 33 percent of the cost of wanting the whole pesticide program. It pays for about 28 percent of the cost of just the registration program.

So, appropriated dollars, maintenance fees and so forth pay for the rest of it. So, we're going to provide the data that shows it in context. But to answer your immediate question, yes, we did drill down on the

PRIA expenditures.

MR. VROOM: Good. We'll look forward to staying connected on that. The last point relates back to potential duplication or redundant resources and trying to avoid having to do things over again. That has to do with the fact that while I think we understand on the industry side that the specific test guidelines are coming and the assays are described, one important piece that, as I understand it, is not articulated yet and needs to come from OPPT is the standardized evaluation protocols.

So, as companies design and execute the tier 1 tests, that they understand how the agency intends to evaluate so that when we get to the end and finish the test and discover that the test wasn't executed in a way to address the evaluation point. So, I know that's on the radar but I just wanted to reiterate that that's very important and something we think will help avoid a lot of wasted time at the end.

MR. BRADBURY: Pat and then I guess Steve. We'll sneak it under the wire and then we'll cut off this topic.

MR. DONNELLY: I just had a quick question. Looking at the timing, particularly that it's sort of first year, with test orders going out and people having to get responses and get the consortia together, et cetera, progress reports are due a year after issuance of the test order. So, when you add it all together, it doesn't leave much time for a progress report. So, what are the requirements or expectations of the progress report?

MR. KEIGWIN: I think it's just where are you in the development of the study, has the study progressed, have you contracted with a lab, those sorts of things. But we can be getting some guidance on what would be contained in that actual report.

MR. DONNELLY: Thank you.

MR. BRADBURY: Steve.

MR. SMITH: You mentioned that there were six actives that were going to respond with voluntary cancellations?

MR. KEIGWIN: There are six active ingredients for which all of the test order recipients have indicated they will no longer be supporting those chemicals.

MR. SMITH: So, would that be all the registrants?

MR. KEIGWIN: Those are all the technical manufacturers.

MR. SMITH: So, essentially all the uses for those things?

MR. KEIGWIN: Right.

MR. SMITH: I was just looking through the table and I'm counting seven. So, if you could just tell me which?

MR. KEIGWIN: The six are diselfaton, methamidifos, methidifion, methyl parathion, resimethrin, and propocor. What was the seventh one you saw?

MR. SMITH: Well, I got propargide but there might be another --

MR. KEIGWIN: There is an individual manufacturer who has indicated that they're not going to support it. In fact, we have an OSRI submission on propargide now.

MR. SMITH: From somebody else?

MR. KEIGWIN: From somebody else.

MR. SMITH: Okay, thank you.

MR. BRADBURY: Thanks, Rick and Karen, and thanks for the questions and the discussion as well.

The next part of our agenda is sort of twofold. I think I'll have Margie just spend a little bit of time giving you an update on the process about the membership renewal. When we do that, we'll ask (inaudible).

Then, the other topic to spend some time in discussion is opportunities for topics for our next meeting, start some of that planning discussion. I realize this typically goes on over the course of the next several months but at least we use this session to start to tee up some concepts or ideas that we can then adjust and tune as we go through the coming months. I've got some ideas but I'm going to hold my ideas to myself for a while and open it up to the group.

Julie.

MS. SPAGNOLI: I think it might be of interest now that the topic got the public health work group and just to maybe explore a little more of public health and what are the public health issues that we face. What are some of the vector borne diseases? How prevalent are they? I think just to get a little more wider grasp of

that whole public health area and what the implications are. I think we've touched upon it.

We've talked a little bit about bed bugs. We heard there's an outbreak of dingy. There's still lyme disease. There's still the Hanta (phonetic) virus and some of these other things. I think just to kind of get an idea of what are all those potential public health and vector borne diseases and how prevalent are they.

MR. BRADBURY: Caroline Cox.

MS. COX: As you all start to evaluate the public comments that you received on the AMPR about annotes (phonetic) disclosure and then take the next steps, I would really like there to be an update and discussion in this group about that.

MR. BRADBURY: David, do you have yours up? No, okay. Susan.

DR. KEGLEY: I wasn't actually going to put a topic for it, but this is sort of the first time. I know that we've been talking about how the structure of the meetings are for the day and a half, whether it's lots of topics for 20 minutes each or this kind of approach. I just want to say I think that this -- obviously, it took

a lot of work to put this program together, to figure out which topics you were going to have sort of be front and center and a longer and more comprehensive report on. Personally, I think it went very well.

Obviously, you chose issues that everybody was engaged in and wanted to know about. You got good discussion on it and kept the updates to, you know, a pretty straightforward brief and still got everybody a chance to say something if they wanted to say something about it.

So, I just want to say I think, at least personally, I'm interested in what everybody else thinks too, but I think this particular meeting went very well given that you balanced those things, a couple of big issues that you spent a lot of time on and let everybody engage in and then the quick update.

MR. BRADBURY: Carolyn Brickey.

MS. BRICKEY: My reaction to the agenda for this time and the way that it went is that I think there were a lot of really interesting and important topics on the agenda. I thought they were jumping off the page. But I thought we had too many topics. I don't think we

had enough time to talk about them. I also didn't like some of the focus of the topics in that I wanted to get more to some options that you're considering on some problems that you're trying to solve.

I think this group can be a little more helpful in the problem solving mode than it has been. I'd like to be able to use all the work that the work groups have been doing to kind of bring it back to this group and give us more of an involvement and a sense of what's going on there.

I'm thinking as an example of the toxicology and the 21st century group. I'm not in that group but I don't from the presentation have a whole lot of understanding of what that group is doing and how it's going to feed back into us and how we can be more helpful.

Finally, I thought that the introduction of that topic yesterday, looking at non-FQPA protection policies was a big topic. Bob flagged it as something that he certainly wanted to spend some more time on and suggested having kind of an interim meeting to talk about that, which I think is fine.

But I think it ought to be a major topic perhaps on the next agenda. I think there ought to be time to really talk about some of the issues and really get into that, because that's a huge thing and could be very important and valuable for this program.

MR. BRADBURY: Bob.

MR. ROSENBERG: At the risk of sounding like a mutual admiration society, I was going to say, Carolyn, your plea to not drop drift, you and Jim Thrift, I'd say try to somehow revive that discussion would be a good use of time. I was going to talk about 10X. You've already said it.

Third, just playing on what Julie said, I think it's true in the world of pest control that we used to make broadcast applications of broad spectrum insecticides. We don't do that anymore as a matter of practice, and they're not so available. What's happening is things like bed bugs. We sort of didn't actually go out and try to kill bed bugs. We killed other things. Bed bugs were collateral damage. Now we're having problems.

I think one of the things Lois was trying to

say in her discussion is there's not any really good answers as to what the agency can do to encourage the development of products or strategies to deal with bed bugs. I think having an in-depth discussion about bed bugs would actually be a valuable discussion because it has implications for a lot of other things.

MR. BRADBURY: Carol Ramsay and then Susan Kegley.

MS. RAMSAY: I'll be brief. I agree with Susan. I kind of like the mix of topics and the allocation of time. When you've got a day and a half maybe, it's a real challenge to be able to give enough updates, get into some detail. So, it's always a challenge and I think the last five meetings have gone pretty well on target. You've kept things well in frame with sending people to the penalty box. I agree with four other individuals. Spray drift needs to be back on there.

You'll have your 700 comments you'll have chewed through and hopefully we'll be able to come up with some plans for some consistency, if not necessarily all the clarity and then probably with fumigants rolling

out, probably should have another update on that and an update is probably sufficient.

DR. KEGLEY: Along the lines of what Carolyn Brickey was talking about, by next October or this coming October, it will be almost a year since the scientific advisory panel meeting on volatilization drifts. So, it would be nice to have an update on what the agency has accomplished in that interim period. There were a lot of science issues to be thought about and dealt with. So, it would be good to hear what you've done on that.

Then, maybe this is too specific, but I would like to know a little more about the registration review process. We're just getting some chemicals into there. There's not been too many finalized yet but kind of knowing what the process is, where the avenue is for public input, generally how that works, would be useful.

Then, finally, one thing that keeps coming up is what can we do about bed bugs besides broadcast spraying of broad spectrum insecticides? I guess the broader rubric here is what is EPA's role -- where does EPA tap into promotion of integrated pest management that may not involve using pesticides? How do you interface

with USDA on that? Is there such a program? Is there a broad way of looking at that throughout the agency?

MR. BRADBURY: Thanks, Susan. Amy, Mark and Kristie. Bob, I did try to keep things mixed up but I think they all came up pretty close together.

MS. LIEBMAN: I thought the agenda worked really well this time as well. I know that you can't go into detail about every single topic that we discussed, but I do think that the brief updates are still needed. I think perhaps what can happen is as you see the interest or the questions that arise from some of the brief updates, the next meeting can follow them up. But if we don't get some of those brief updates, we're not quite sure what's happening or if there is a need for more discussion on them. So, it's a balance that you guys worked out really well this time.

I really particularly like the discussion on the nanotechnology because for some of us who aren't as intimately involved on a daily basis with EPA, it's very important to also look to you for just a little bit of education. I think the request for more on the public health involvement is an example of us needing more

information. So, I do like that you are able to take some topics and delve down into them.

So, I just second that because there was such discussion on some of the brief updates that we follow up with that. Also, I agree with Carolyn that in terms of what can we do to improve understanding what the work groups are doing. So that, as they report back, we can be involved with some of the discussions and decisions that they're making.

MR. BRADBURY: Mark and Kristie.

DR. WHALON: Thanks for the opportunity. I just took kind of a rough poll on the number of issues that we had that the agency relies either directly or indirectly on IPM information. So, the MP issue I thought we talked quite a bit.

The endangered species issue obviously we had in the breakout of issues there, certainly, spray drift and some of the other worker issues. Pollinator protection we talked about a little bit and the IPM link there is key, really. Certainly, with public health, it's front and center and needs more development and needs more implementation and needs some new tools.

So, I think that EPA, when you look at the history of EPA and its role in the development of IPM, I just remind the group that the Huffacre Project (phonetic) which transitioned into the Adkisson Project (phonetic) were the origins of IPM in this country. EPA was the one that funded a large part of the last end of Huffacre and the start of Adkisson and has facilitated a lot of that. So, I don't know where the star grant process is relative to IPM but I think it's nowhere, personally.

I think that PRIA 2 is doing some good things but not necessarily really focused on specific developments in IPM. So, if we look at EPA's role in IPM and creating programs and creating new tools and developing a transition matrix at a time when the public sector is beginning to back away from IPM -- if you look at land grant universities and you look at the erosion of IPM, it's very startling.

Right now the IPM centers are on the chopping block in USDA. Where's the commitment there? So, it may be a time when the USEPA steps back in a leadership role where integrated pest management is concerned and you

retake the mantle that you had under Heffacre and Adkisson and step out and maybe lead the USDA by its nose.

I hate to say that but that's where we're going. I mean, we're not funding IPM in the public sector today and who is going to train the trainers in the future when you look at your depending on IPM into the future where your partners and what's happening with them.

So, I think that we need to counter some of that. We need to look at and measure the erosion of public sector IPM and the transition to private sector IPM. We need to look at the interface so NASS, NRCS and USEPA as well as broader research agendas in USDA. Hey, how about that? Thanks.

MR. BRADBURY: Thanks, Mark. Kristie and then Tom.

MS. SULLIVAN: Well, the first thing is that I forgot to say during the endocrine program updates that I really appreciated the presentation. I'm sorry they're not here to hear it but there was a lot of specific information about the responses that you've been getting

which is really really helpful. So, thanks for that.

I was also wondering -- and maybe I've totally missed it -- but have you guys come out with a new part 158W testing regulation and I just didn't see it?

MR. BRADBURY: It's still in the works.

DR. GREEN: I had a couple things. In terms of the next agenda and also on an ongoing basis, I think it would be great to have NRCF participation. For the next agenda, a couple items that I think would be of interest to the group are the new conservation activity plan program that has $700 million in it this farm bill period. It includes an IPM conservation activity plan of cost share available to growers to hire a consultant to prepare a comprehensive IPM plan for their operation that could, I think, help with things like the drift issue.

Then, the other new element that they're developing that I mentioned before is the 799 standard which will be a broad evaluation and monitoring standard that could be applied to a number of different purposes. It's being developed initially for doing water quality monitoring in the upper Mississippi River base and around nutrients and sediments.

So, the NRCF would actually cost share growers to monitor water quality under operation. That would seem to have potential applications for the drift work and the pollinator work and the worker protection work that we're talking about here. So, I think the group might benefit from a presentation on those two developments.

Number two, I'm wondering in terms of input on worker protection poster. Bob had mentioned maybe organizing a couple hour conference calls with those who are interested in giving input on another issue. Looking at that poster, I'm thinking that it might benefit from input from those interested in a group and talking about audience and messaging and so forth.

Finally, I just wanted to echo Mark's comment about IPM and looking at more integrated and systems approaches in all the work that we do. I think we had a number of topics that should have benefitted from that perspective during the meeting here, including the worker protection and the pollinator protection. It would be great if we do a bed bug discussion to make sure that the integrated systems approach and IPM are included in that

discussion and not strictly pesticide management.

MR. BRADBURY: Thank you. David and then Pat.

MR. TAMAYO: I'm not usually referred to as David unless somebody is mad at me, so I'm sorry if I stepped on your toes in some way.

I think that the agency has done a lot of things recently in response to -- the stormwater agencies, at least in California, are concerned about the impacts of pesticides on our urban receiving waters. It kind of touches on what Susan brought up with the registration review.

I know there's been some significant changes in how you're approaching the pyrethroids. It actually would be kind of a good case study of how there is some information brought to the front. We've got a significant issue here. This is how we're responding to it, not just to the registration review process but looking at labels and early sort of mitigation measures, just different types of tools that you have to respond to things like that.

But the registration review thing is actually really important in how mitigation measures get brought

into that, how IPM and reasonable alternatives relate to product registrations and continuing registration, whatever you want to call it. So, it would be great to look at that.

Then also, how can EPA improve or what is it already doing to identify or least screen for potential problems or actual problems of urban water quality throughout the nation because there is a growing body of evidence that it's not just a California problem.

We're starting to see it in Texas, Illinois, and Atlanta. It would be really good to see what more EPA could do to more proactively identify those problems and forestall them in the future.

MR. BRADBURY: Thanks, Dave. Pat and then Steve.

MR. DONNELLY: Thank you. Just a quick comment on the agenda. All the topics, of course, are very interesting. I realize and can sort of sympathize how difficult it is to put one of these meetings together with so many potential topics and the diversity of stakeholder interests.

I just wanted to share with you some comments

that Cindy made to me yesterday about the agenda. I think she expressed some frustration that there were too many topics on there and she would prefer to have seen less topics and more time to get into them, less topics and more time to discuss them.

Specifically, since October, the agency has put out a number of policies, some of which seem to fall out of the sky. When those get relegated to brief updates, I think that would be an obvious source of frustration. This is new and important and we should be spending more time talking about it, particularly the implementation plan is pretty short.

MR. BRADBURY: Steve.

MR. SMITH: Thanks. One of the priorities that we talked about yesterday was the agency priority, to strengthen partnership with state lead agencies. That's a topic, obviously, that's important to us as the state lead agencies. We're under a lot of pressure these days and there's a lot of things that EPA is doing that have direct impact on our programs and our activities.

I think it would be useful for the other stakeholders to get a sense of how these initiatives are

impacting state lead agencies because a lot of the initiatives we're talking about today, unless they translate into activities at the state lead agency level, they're just ideas.

We're the ones on the front line doing these things. It just seems like there would be some useful information for the stakeholders that we could incorporate in and give some perspective to some of the ideas that are tossed around and the things people want to accomplish, how they actually get accomplished.

MR. BRADBURY: So, we'll go Beth, Lori and Virginia. I think that will be it.

MS. LAW: In the discussions yesterday afternoon about public health pests, one of the topics that came up was what is sort of the current status of the NAFTA labels and international labeling issues. How is that problem being handled in other countries? Is there anything in those countries that could inform our debate about the issue?

So, I think maybe if this is kind of two requests, one would be when we do bring the public health issues here -- and for this forum for the next

discussion, I think it would be great to be sure to include that international component because as we discussed yesterday, there may be some products or approaches used in other countries that could help us as we try to decide what to do here.

Then, secondly, I think having a discussion about the current status of harmonization would be good, again, not just limited to NAFTA labeling but labeling and also data requirements. Where do we stand with that? I know there have been some discussions with PMRA in Canada. If some of those discussions have been going on with the EU or you contemplate doing that with the EU, I think that would be very interesting and very helpful to know. Thanks.

DR. BERGER: Just to underline some of the comments of other people regarding the need for more discussion. I think that we had too many topics and the goal of this group, as I understand it, is to have more exchange from the stakeholders and the agency. So, I would encourage more discussion.

Also, the work group model has worked very well and we encourage you to continue that. We need to

continue the updates on ESA, drift, pollinators, endocrine disruptions of our core programs and initiatives that impact agriculture, something that I think would be very helpful on fumigants now that we've moved into a new area with the red. If you could give us a status report on how your outreach efforts are going, how the regional offices at EPA, how that's working as far as taking these programs out to the field.

With regard to fumigants, I believe it would be very interesting if we had someone from AFIS come and present some of the implications of the fumigants both on intrastate and international trade issues. I think that there's some things bubbling to the top on invasive pests, on international trade, that need to be discussed in terms of the fumigants.

Then, something that was just brought up by the last speaker was the topic of international harmonization and the many efforts that are going on at EPA and other regions of the world to bring about similar regulations or shared data, that type of thing.

MR. BRADBURY: Thanks. Virginia.

MS. RUIZ: One thing that I appreciated from

this meeting's agenda was the opportunity to learn more about some of EPA's upcoming regulatory activity or areas where you are going to be seeking public comment and participation, the nanotechnology and NPDES. So, I would encourage you to include similar topics in future meetings to sort of giving us a heads up and educating us about issues that you're going to be seeking public comment on.

MR. BRADBURY: Thanks. That's very helpful. The challenge of finding time to bore into a detail, finding time to give you some updates is always a constant set of recommendations to get from you and what we struggle with back home or here in this home. We'll continue to try to find that balance.

I agree this one might have been a little bit more information flow than dialogue. Sometimes it will be oscillating from spring to fall. I take that set of comments and diversity of comments very seriously and try to find the right balance.

Some of the topics I had on my list, which I'm having a fun time trying to integrate some of the thoughts I had. Of course, we're all going to talk about

it and we'll have some feedback as we go forward. I heard some of the conversations around, for example, registration review and how it interfaces with ESA and with water quality and with a number of issues, and how does that process work.

I think there might be something there in terms of getting feedback from you all in terms of is it working, is it not working, how to make it better, and how it might plug into a number of topics. We talked about something in my notes and we're quickly gathering that aspect about the worker risk policy which is very new and just beginning to get comments, hearing that -- and I'm not giving an exhaustive list, but seeing some of the threads that are starting to come out of the discussions here and some of the notes.

The other thing I want to explore with our group and then we'll get it back out to you is seeing about the idea of some webinars or some relatively short meetings on the phone, hopefully webinars, where we might be able to talk about some topics in between meetings. Of course, they'd be open to the public to listen in as well so that we could be very efficient then at these

meetings to be having the wider discussions.

Maybe we can use the work groups and maybe some interim webinars to get information flow going so that when we hit the spring meeting or the fall meeting, information flow has happened and we can focus more on how can you do it better, EPA, or EPA, how that I thought about it, I didn't realize blah, blah, blah. Here is something you should be working on.

I always try to think about some ways to do that. I know it takes time for you to do that, but that might be a way to try to strike some of that balance between dialogue here and information flow.

IPM came up and kind of bumped me back to some of the topics I heard. So, I think we've got a fairly robust set of ideas. I think there's some integration among many of these ideas which I'd like to spend some time contemplating with my colleagues. We'll get back to you, like we always do, to get feedback.

I'd also like you to be seriously thinking about topics that you think would be useful to have a one hour or two hour webinar or something in between as we kind of gel some ideas. I'd like to get some feedback.

Is there real commitment, significant commitment among the group that you'd make that investment to do something like that in between the meetings.

I think it could help balance information flow with in-depth discussion while we're here. Clearly, they'd all be public so everybody could listen in on those discussions as well. But it means some extra time for you to do that. So, you don't have to give me an answer now but be thinking about that.

What I'd like to do now is give Margie just a chance to let you know where we are in this process of the renewal, just in case there's any questions that you have for Margie on that.

MS. FEHRENBACH: I think I've talked to almost everybody individually, but I'll just review where we are. The deadline for submitting your applications was extended through this week. So, if there are any folks who have not yet submitted their renomination, please let me know. I know there's been problems with the regular mail. In fact, I received one the other day. The resume of the person was glued to the envelope. So, try to e-mail it if you can. It still goes through that process

where things are x-rayed.

The process will be, once we have all of the nominations, our program, the Office of Pesticide Programs, will put together a proposal. We will share that with our assistant administrator. Then, the package will go to the Office of Cooperative Environmental Management. They will review and make recommendations. Then it will go to our administrator's office and they actually have to approve and sign off on it.

So, our hope is to have a new committee sometime later this summer. We'll keep you informed of what's going on so that we can have our next meeting in November. That's about it. If you have any other questions, let me know.

Just one point, there's another meeting in this room at 12:30, so we need to ask everybody to please be able to leave by then.

UNIDENTIFIED FEMALE: What's the date for the next meeting, Margie?

MS. FEHRENBACH: We're tentatively looking at November 16th and 17th which is in conjunction with the one-day even that -- the work group on toxicology, 21st

century toxicology is going to have a meeting. I will send that out electronically.

MR. BRADBURY: Jay, Beth, and Carol.

MR. VROOM: So, I wasn't aware that you had extended the deadline. Obviously, as a PPDC member, I overlooked that. Do other members of the public know that also? If not, could it be extended another couple weeks so that we could get that message out to a broader community?

MS. FEHRENBACH: It will just delay the whole process. We have let people know informally that we were continuing to receive applications because some of the problems with information being sent to us. I'll let you know.

MR. VROOM: Okay. Then, I'm not aware whether you post on the web site the nominations that have been received.

MS. FEHRENBACH: You mean the individuals who --

MR. VROOM: Right. So, can we see who has been nominated in total?

MS. FEHRENBACH: We've not done that. I don't

know that that's -- I'll have to look into that.

MR. VROOM: This is the most open government in the history of civilization.

UNIDENTIFIED FEMALE: There's some privacy act considerations that we'd have to take into account with that. So, that's historically why we've not done it.

MR. VROOM: Okay. I'd still be interested in exploring that question, again, just from the overall context of how do you achieve balance, representation, and all the rest.

Obviously, the other question is, we've talked a little bit in the past about the six-year rule that apparently was overlooked for a long time and then also the various informal representations out of the White House Office of Ethics about the prohibition of people who are registered legitimately to lobby the congress of the United States being discriminated against in terms of participation and Federal Advisory Committee. So, do you have any information on either of those points?

MS. FEHRENBACH: Well, any questions you have about the lobbyist issue, we're being asked to refer you to our Office of Cooperative Environmental Management.

They've not yet put anything out in writing. I do know there's a lot of controversy over the government having that policy. But it has not been put out in writing yet.

The six-year policy, in the past six or eight years, we've had to justify any members who have been kept on. So, it is an agency policy and they're highlighting it this round as something that we're trying to encourage more new membership. But it's an agency policy. So, we still have the opportunity to maybe make justification.

MR. BRADBURY: Two things. We're passing around some information related to the questions around nanotech and ORDs, Office of Research and Development investments. So, that came around.

Also, there were related questions about what specific research is being done. The easiest way to probably do that is to give the web site and you can so see what's going on. It's www.epa.gov/nanotimes. You can see the specific projects that are going in the context of that budget.

We have one public commentor, so I want everyone to stay put. Our public commentor is Donna

Heppert (phonetic) from Oregon Toxics Alliance.

MS. HEPPERT: As Steven said, I'm Donna Heppert from Oregon Toxics Alliance. I'm here from Portland, Oregon. Also, I'm the board chair of Oregon Toxics Alliance. I also sit on the board of Northwest Environmental Defense Center there. I'm very thankful to be here today to have observed the proceedings and to be able to give this public comment.

To give you a little background about myself, I graduated in 1980 with a degree in botany and worked for 10 to 15 years as an ornamental gardener both with the Austin Parks and Rec Department and I was the head horticulturist at the Texas Governor's Mansion and also worked at several private estates in LA. All these times I worked using organic methods and found them to be extremely effective.

So, it was just natural that when I recently went to law school and became an attorney -- I'm also a public interest attorney. I should have disclosed that. When I went to law school, it was natural that I'd have an interest in working on pesticide policies. I get to have the last word today. My mom always used to accuse

me of wanting to do that, and maybe she was right. I'm sure she'd be glad if I told her that.

When I did go to law school, coincidentally, I was actually in the process -- we had been looking for two years for a piece of land suitable to become a commercial organic farmer. So, I was trying to be a farmer, at least. Maybe one of these days I will be able to stop being a bottom feeding attorney and go back to the exulted profession of farmer.

Anyway, I was also recently fortunate to attend Beyond Pesticides national conference in Cleveland, Ohio. At that time, we had a two-day meeting before that of the pesticide work group, which is a coalition of lots of groups that are working nationally on pesticide issues.

The sentiments of the group, folks are very encouraged by the progress we're seeing. A lot of that was gone over at this meeting with the risk assessment and the worker protection standards. There's also concerns and frustrations.

Part of the concern is about the rate of past progress, and some of that was brought up today, about the endocrine disruptor screening and how long it's taken

to get around to doing that. Now that we've got the momentum and the risk assessment and the worker protection standards, we hope that that momentum will keep going until we cross the finish line and actually put those protections into place.

The other reason for frustration is because we really feel that there are viable alternatives available that could be put into place instead of some of these pesticides. I overheard a conversation yesterday from some folks talking about us characters and how it was crazy for us to think that organic farming could feed the world. I won't point any fingers; you know who you are.

But the coincidence was that I was planning on bringing up an article that I read recently that talked about the U.S. Farm Bureau declares war on sustainable agriculture. This was on the Rodell Institute web site. But the interesting part of that article is that in there are two studies that are mentioned.

One of them is a UN study from 2008, a UN report, talking about how in Africa -- and I'm going to read to you some from there -- a 2008 UN report on organic farming and how it can feed Africa and bring

higher income to the poor. They found that food production rose and sometimes even doubled when farmers traded in chemical methods for more sustainable organic ones.

Then there was also a recent USDA 2008 organic survey that came out. It was the first major look at certified organic farmers and ranchers. It found that organic farmers who don't buy into agri-chemicals get a much higher return on their investment than chemical farmers do. So, I believe it is possible and I believe that we ought to look into promoting this more. That's one of the things that we like to ask for, is training.

There was the IPM center comment today, let's make sure those keep on getting funded. Let's see if we can get some training for organic farmers. One of the comments at this pesticide work group meeting is that there are farmers out there that would like to try organic methods, but they've been doing chemical methods for so long, they just don't know how to switch. So, some sort of program helping those farmers that want to try and make the switch would be very helpful.

Another thing is that organic farmers shouldn't

have to bear the burden of chemical drift and potential chemical drift. There seems to be a sentiment that if you want to farm organically and you're afraid of losing your certification with other people's residues drifting onto your crop, then you should leave a buffer on your land. Well, really, that doesn't sound too fair. So, the buffer maybe needs to go across the other side of the fence.

A couple of other majors asks and then I'll let everybody get out of here. I won't keep you here until 12:30 myself. One thing that would be great would be independent testing and research. It seems like we get into the war of the science and study results. You have to ask yourself if it's the chemical producers that are putting forward a lot of these research results. You have to ask where is the bias and which results might be more credible.

So, one way to do this might be to get the funding from the chemical companies but divorce them from the process of actually performing the studies and bringing forth the results. Let the chemical companies fund the testing but find an independent, the

universities, any kind of institution that's capable of doing that sort of research without the bias.

Today was brought up the national reporting database. That was something that we were very interested in seeing. It's good to hear that that's imminent, that that sort of thing -- the reporting, the usage and the incidence database where it would be possible for the public to even use that and find out what's going on.

Finally, the last thing I'd like to ask and comment on is oversight. The state programs are out there but a lot of times they're nonfunctional. In Oregon, for instance, we have folks calling in to the Pesticide Analytic Response Center and they'll say they've been sprayed and they're getting sick. The response often is well, you just have the flu. They just get brushed off. It never gets reported and goes up.

So, we need some sort of oversight from the federal agencies that these state agencies are actually doing the job that they're supposed to. Thank you very much.

MR. BRADBURY: Thank you. I want to adjourn

the meeting. Before I do so, I just want to again thank you all for your preparation before the meeting and during the meeting and in between sessions. I appreciate the dialogue and the information flow. I also really appreciate the comments at the end here, taking a look at the future and some approaches for topics in how to manage the meetings as we go forward. I appreciate that greatly.

I wish you all safe travels for those who are traveling short or long distances. Take care and thank you very much.

MS. MONELL: Just to reiterate what Margie said, we have to clear this room. There's another meeting here at 12:30. Thanks.

(Whereupon, the meeting was adjourned.)

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CERTIFICATE OF TRANSCRIPTIONIST

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