In the Matter of:

Environmental Protection Agency

October 12, 2011
Pesticide Program Dialogue Committee Meeting
Day 1

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UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY

PESTICIDE PROGRAM DIALOGUE
COMMITTEE MEETING

October 12-13, 2011

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: Welcome, everyone, to Washington. People have been traveling from coast to coast, and Susan Kegley from Paris. We appreciate jumping across the ocean to get here and join us for today's meeting and tomorrow's meeting.

Again, we really appreciate the investment you all are making in preparing for the meeting and getting here and visiting with us for a day, day and a half, as well as all the time you spend on the various work groups that we have associated with our Federal Advisory Committee, and all the advice that you provide us at these main meetings and through the work group meetings. It's really important to us as we move forward.

As you know, some of the topics we talk about are topics that we're throwing out into the ring, so to speak, to get you all to engage in. Many of the topics we take on are ideas and concepts and areas of focus that you bring to us. We appreciate that, because it is really important to take a look at not only what we're doing today, but a lot of our work groups are taking a

look at what's in the future. Some of it is near-term future but some of it, as we'll go through our workgroups, maybe five or seven years out.

But if we don't start talking about what the world can be like five or seven years from now, all of a sudden it will be five or seven years from now and we won't be prepared or ready to take on some of those challenges.

So, we appreciate the time and effort you spend on the near-term issues as well as the time and effort you're spending on the long-term issues working with your partners and your colleagues and the different organizations you present, as well as across federal family, state, and tribal family in terms of working on some of these tough issues.

We've got a pretty full agenda. A lot of work has been going on in the work groups. We've got seven active work groups with our Federal Advisory Committee. We'll be sharing over the course of the next day and a half activities going on from four of those committees. As I touch on the agenda a little bit, we can go through some of those areas. Again, as with the work groups and

as with the full committee, getting sort of a diversity of opinions and ideas that you all have is really important.

Steve Owens will be visiting with you tomorrow morning. He's on travel today. He's got some speaking engagements at the front end of the week and the back end of the week. So, he's going to be back in town, I think, tonight and be here Thursday. So, he'll be meeting with you Thursday morning and give you some thoughts over the last six months since we met with you last and sort of how things are looking, and probably share some time to talk with you about some questions you may have as well.

So, before we fully go through the agenda and touch on that, I think it is probably good to go around the big room here and introduce ourselves, what your organization is, and just kind of get reacquainted. Some of us don't see each other except for e-mails and phone calls over the course of the six months or so. So, why don't I start on my right and turn it over to Marty.

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

MS. KUNICKIS: I'm Sheryl Kunickis. I'm the

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Director of Pest Management Policy at USDA.

DR. CALVERT: I'm Geoff Calvert. I'm with the Centers for Disease Control and Prevention in Cincinnati. I head up the pesticide poison surveillance efforts conducted by CDC, along with state health departments in 11 states.

DR. VERDER-CARLOS: I'm Marylou Verder-Carlos, Assistant Director for the Department of Pesticide Regulation in California.

MR. BARON: Good morning. I'm Jerry Baron, Executive Director, IR-4 Project.

MS. SMITH: I am Cindy Smith with the Gallon Group of Companies. We're a basic manufacturer in crop protection. We have retail facilities, feed, and we actually grow some dates.

DR. GREEN: Tom Green. I direct the IPM Institute based in Madison, Wisconsin.

MR. TAMAYO: Dave Tamayo, California Stormwater Quality Association.

MR. THRIFT: Jim Thrift, Agricultural Retailers Association.

MR. BUHLER: Wayne Buhler with North Carolina

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State University, pesticide safety education specialist.

MR. NYE: Ken Nye, Michigan Farm Bureau, general farm organization.

MR. KRABILL: Ryan Krabill, National Potato Council.

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

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

MR. McALLISTER: Ray McAllister with CropLife America.

DR. GILDEN: Robyn Gilden, University of Maryland School of Nursing and also the Alliance of Nurses for Healthy Environments.

MR. SCHERTZ: Scott Schertz, Schertz Aerial Service and AAA.

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

MR. SANCHEZ: Valentin Sanchez, committee worker with the Oregon Law Center.

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

MR. DELANEY: Tom Delaney, Professional Land

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Care Network, lawn and landscape industry.

MR. VUKICH: Jake Vukich, registrations, DuPont Crop Protection.

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

MR. SHEEHAN: Pieter Sheehan, Director of Environmental Health and Protection for St. Charles County Government in St. Charles County, Missouri.

MS. STARMANN: Allison Starmann with the American Chemistry Council, biocides panel.

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

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

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

Dr. WILLETT: Mike Willett, Northwest Horticultural Council, Yakima, Washington.

DR. KEGLEY: Susan Kegley, Principal at Pesticide Research Institute and representing Pesticide Action Network.

MR. COX: Darren Cox representing the American

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Honey Producers Association.

DR. CLEVELAND: Cheryl Cleveland, Dow AgroSciences out of Indianapolis. I'm in the human health risk assessment group.

DR. WHALON: Mark Whalon, Michigan State University.

MS. HERRERO: Maria Herrero, Biopesticide Industry Alliance.

DR. KEIFER: Matt Keifer National Pharm Medicine Center.

DR. KASHTOCK: Mike Kashtock, Food and Drug Administration, Center for Food Safety and Applied Nutrition.

MR. BRADBURY: All right, thanks, everyone. If I could ask -- oh, yeah, on the phone, sorry. Anybody from the committee on the phone?

MR. GJEVRE: Eric Gjevre, Coeur d'Alene Tribe.

MR. BRADBURY: Thanks, Eric. Sorry about that.

If I could ask everybody to make sure you put your name tag with your name facing out. I think we've got everybody doing that, but just to doublecheck. Although we're all getting pretty good at names and

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faces, it's still sometimes a little hard. It's also very helpful for me. As you recall, when we have discussion, I can see your name tags coming up and try to keep order of that.

I also wanted to let you know a few changes since last time. Michael Frye no longer works for American Bird Conservancy. He's now a part of the federal family. He's joined the Fish and Wildlife Service and is a contaminant biologist in the Hawaiian Islands in the northern Pacific.

I was talking to him the other day. He's got quite a range of habitats to look after from the Hawaiian Islands, to midway, to all sorts of stuff in the Pacific. So, Michael is no longer part of the committee. Ann Law - I don't think she's with us today -- will be coming from ABC to sit in that chair.

Then, Marco Gusky also has a new position now, so he won't be on the PPDC in the future. So, a couple of changes there. Best of wishes to those colleagues as they go forward in their careers.

We can spend a couple of minutes walking through the agenda, and then we'll hit it. As I

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indicated in my opening comments, we're going to be focusing a lot today on outcomes and perspectives coming out of our work groups and have our discussions around, in many cases, some ideas and proposals coming out of the work groups, as well as updates out of the work groups.

Last April we formed two new work groups. One was in the area of pollinator protection, and the other work group was in the area of integrated pest management. We'll be hearing from both of those groups today, the first session, in fact, being a report out from the pollinator protection work group and some of the first meetings they've had.

That group is going to be reviewing its objective, provide us some information as they've sort of thought through what their goals and objectives are going to be. Again, a focus of this group is to help provide some advice on options for trying to mitigate risk to pollinators when that's an appropriate course of action, how to try to reduce exposures in the context of a risk perspective. Also, during the course of that discussion, provide an update on the science and some of the activities that have been going on terms of risk

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management efforts.

After we hear from that work group, we'll then move to session 2, which will be some brief updates. Again, our goal here, and most of the time with output from the work groups -- I'm looking at Cindy to make sure I'm tracking this correctly -- at least provide five-minute snapshots of some key activities that are going on. I'll look at the clock. If we've got some time for a quick clarifying question, we may do that. But I'll probably be very firm on the clock. Mostly it will be a five-minute report out.

There's also some information in your packet that isn't going to be part of any oral presentations but provide you some written updates of activities that are ongoing as well.

So, in session 2, we'll get an update on spray drift, an update on the work group that's dealing with comparative safety statements, inerts disclosure, and we'll have a discussion and demo that will spill over into the lunch hour on some new software tools that have been developed.

One tool gives some increasability to search

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active ingredients that cross different parts of our program so we can quickly see what's going on with a chemical in terms of its risk mitigation status or regulatory status, its science status. It makes it very easy to search chemical information. It's also a tool that makes it easier to keep track of inert ingredients and what some of the statuses are of inert ingredients. There will be a demonstration as well as a presentation on that.

After lunch, we'll hear from the integrated pest management group which met on Tuesday. We'll get some feedback from them. You can get some feedback to the group as well. Then, session 4 will be a follow up from the 21st century toxicology work group. They had a workshop all day yesterday looking at the state of the science and the application into our program in terms of biomarkers for exposure and effect and how that can play into medical diagnostics, to biomonitoring studies, to epidemiological studies for the complement to other aspects of the 21st century tox area.

Then, we'll close out the day with another update session which will include a brief update on

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status of the endocrine disruptor screening program, hear from the public health work group. They'll be meeting Thursday afternoon as well. Give you an update on the NPDES general permit for pesticides with Allison Wiedeman from the Office of Water, update on the human subjects rule, and an update from Wayne Buhler on the pesticide safety education program. We'll have a public comment at the end of the day.

As I mentioned, Thursday morning Steve will give us welcoming comments and give you some perspectives. Then, the big session of the day tomorrow will be with regard to endangered species and some ideas coming out of the PRIA process improvement group, in particular, focusing on some of the things we talked about last time.

One is how to take a look at the reg review process and how could that be adapted/enhanced to try to increase information flow into the process that could ultimately lead to consultation packages with the services, how to make that as efficient as possible, ensure we're getting the best information we can at the front end rather than at the back end of the process so

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that everybody has a better chance of getting everything done.

I think that gives you a pretty good sense of what we're going to do over the next day and a half. Of course, like other meetings, we'll wrap up with thinking about what our goals and objectives for the next six months will be and what are some of the main topics we want to have in that pool of potentials for the agenda when we meet the next time.

Assuming there aren't any questions on the agenda, which I appreciate everybody's input with Margie as we got started on this, why don't we get rolling. We're going to hear from Rick Keigwin, Don Brady, and other members of the pollinator protection work group to give us an update on their deliberations thus far, and get some conversation started with the bigger group.

MR. KEIGWIN: Good morning, everybody. Like Steve said, we wanted to cover two things. The bulk of the time this morning we want to spend on a report back to the PPDC on a series of work group meetings that the pollinator protection effort has had since the last PPDC meeting.

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But, what we thought we would do first is to help frame the discussion and maybe help to stimulate some questions and some ideas from all of you. We'd like to have Tom Steeger and Tom Moriarity come forward and give you all a brief update on some pollinator protection activities that are ongoing at the agency right now. So, Tom and Tom.

MR. STEEGER: Good morning, and thank you for this opportunity to speak. I'm Tom Steeger. I'm a senior science advisor in the Office of Pesticide Programs Environmental Fate and Effects Division. I'd like to give you an update on our understanding of the science relative to pollinator declines and pollinator protection.

It's the agency's current understanding that a number of factors and agents have been hypothesized as potential contributors of colony collapse disorder and pollinator declines in general. At this time, no factor, no single factor, has been identified as a cause. Rather, the available science suggests that pollinator declines are a result of multiple factors that may be acting in various combinations.

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Research is being directed at identifying the individuals and combinations of stressors that are most strongly associated with pollinator decline. While the exact causes of general declines in pollinator species and the phenomena characterized as CCD have not been determined, potential contributing factors, including disease, habitat destruction, urbanization, agricultural practices, monocultures, pesticides, nutrition, and bee management practices have to be considered.

Researchers at the USDA have hypothesized that CCD may be caused by many stressors, parasitic varroa mites, nutrition, and pesticides that may in turn cause honeybees to become more susceptible to disease.

Pesticides have been identified as one of the factors associated with pollinator declines. Based on national surveys conducted by the USDA, a broad range of pesticides have been detected in managed honeybee colonies. Based on these surveys, the most frequently detected pesticides and the pesticides detected in the highest quantity are those used by beekeepers to control mites. These include the organophosphates insecticide Coumaphos and the synthetic pyrethroid Fluvalinate.

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Although multiple pesticides are detected in honeybee colonies, these residues are not consistently correlated with the incidents of CCD or pollinator declines in general. While colony collapse disorder remains an issue and can result in sudden losses of large numbers of bee colonies, the focus of the federal agencies is on a broader picture of losses attributed to declining bee pollinator health.

As we have reported in several previous PPDC meetings, EPA staff participated in a Society of Environmental Toxicology and Chemistry Pellston work shop, which is a global workshop, entitled "Pesticide Risk Assessment for Pollinators." The workshop consisted of 48 panelists representing five continents consistent with SETAC policies.

The work shop included roughly equal representation from government, academia, and industry, regulators from the US, Canada, Australia, and the European Union, work with researchers from academia and agricultural industry, chemical industry, and with beekeepers and environmental groups to develop a risk assessment process for quantifying risks to honeybees,

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Apis mellifera, and non-Apis bees.

Similar to the process used by many regulatory authorities globally, a tiered process was proposed for fully early applied contact pesticides and chemicals which may be taken up into plants and act systemically via soil or seed application.

The workshop also identified the exposure and effects studies that would be needed to inform different tiers of the risk assessment process. These include recommendations for studies to document exposure through pollen and nectar and expanded testing to include larval honeybee studies and non-target arthropod studies at higher levels of refinement.

The workshop provided an opportunity to discuss the difficulties with conducting full field studies of free foraging bees that can forage up to distances of 10 miles. The utility of semi-field or tunnel cage studies and their limitations were also discussed.

The workshop provided an opportunity to examine the many sublethal effects that have been included as measurement endpoints and how they can or cannot be linked to different regulatory authority assessment

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endpoints which impacts the survival, growth, and reproduction that are known to impact populations.

As many of you are aware, SETAC published the executive summary to the pollinator Pellston workshop in September. This is available online. This is a hard copy of it. We can make more copies if anyone is interested in having a copy. The full proceedings of the workshop, we're currently working to get all the chapters completed, and we hope that SETAC will be able to publish the full proceedings in the spring of 2012.

One of the most promising chapters of the book will be the statistical analysis of actual laboratory and field data that will guide users or risk assessors, or serve as a guide to risk assessors, of how to move through these different tiers of data and make statistical inferences from that information.

The efforts discussed at the SETAC Pellston workshop expand on OPP's current process for evaluating potential effects to honeybees. At this time, OPP bases its assessment on contact toxicity, toxicity of residues on foliage, and full field pollinator studies.

However, this approach has not provided

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consistent measure of exposure to honeybees. Even the effects testing, the current battery of tests, is more appropriate for pesticides that act on contact rather than on systemic pesticides where effects may be due to ingestion of pollen and nectar.

The Environmental Fate and Effects Division, Office of Pesticide Programs, is developing interim guidance for the risk assessors to consider when recommending additional studies to inform the regulatory decision. These studies are required on a case-by-case basis and may include acute oral toxicity tests with young adult honeybees. These tests are regularly required in Europe: acute larval toxicity tests, semi-field studies at the colony level, and laboratory and field studies to determine residues in pollen and nectar.

OPP will present a proposed process for quantitatively estimating risk to insect pollinators to the FIFRA scientific advisory panel in the summer of 2012. This effort will be informed by the proceedings of the SETAC Pellston and by the research conducted by government and non-government organizations, both domestically and internationally.

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Tom Moriarity, my colleague on the pollinator protection team, will talk about efforts to advance risk management.

MR. MORIARITY: Hi, and thank you. As you know, following the last PPDC meeting, a work group has been formed to explore risk management options to protect pollinators. It's our hope that the work group and, in turn, the PPDC will provide advice to OPP on options that are appropriate in the short term while OPP moves towards the quantitative risk assessment process and options that are appropriate in the longer term when we move into that process and start quantitatively assessing risks to this (inaudible). As Rick noted, that work group is going to report out shortly.

OPP continues to coordinate and participate in the OECD work group on Pesticide Effects to Insect Pollinators, the PEIP work group. That workgroup is broken into four sections as well, risk mitigation, risk assessment process, incident reporting, and research. It's our hope that there will be synergism and sort of an exchange between that group and the PPDC work group on insect pollinators as the two move forward.

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While OPP works on various fronts to improve its risk assessment and its risk management tools, as Tom noted, we continue to stress that the best long-term solution was going to involve management, the multiple stress factors affecting pollinator health. This includes nutrition management as well as pathogen management and others.

Managing the different factors involves cooperation and coordination between fellow partners and stakeholders to find sustainable solutions that are going to integrate all these factors. To this end, EPA is working with the partners of the CCD steering committee, headed by USDA, to consider holding a national stakeholders conference towards the end of 2012.

The aim of that conference will be to synthesize what information and what has been learned by research and practitioners over the past several years that have affected the various factors and to identify practices and management means to improve on those factors and overall support pollinator health.

The conference will hopefully also identify new areas for action research to be undertaken by federal

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partners and stakeholders and continue to support pollinator health. So, I think that the hope is that the PPDC pollinator workgroup will integrate nicely and directly into that sort of effort.

So, with that, I'm going to turn it back over to Rick to walk through what the work group has been doing.

MR. KEIGWIN: Just real quick, if there are any quick questions for either Tom, we could entertain those now.

(Whereupon, there was no verbal response.)

MR. KEIGWIN: Okay. So, if we could have the next presentation pulled up.

UNIDENTIFIED MALE: The staff's analysis guide, will that be publicly available?

MR. KEIGWIN: The interim guide?

UNIDENTIFIED MALE: Yes.

MR. KEIGWIN: Once it's developed, that would become public.

UNIDENTIFIED MALE: Thank you.

MR. KEIGWIN: So, just a quick refresher on the

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work group charge, as Steve mentioned, we formed the work group on pollinator protection coming out of the last PPDC meeting. During that meeting back in the spring, you all charged the work group with exploring four basic areas of work.

One was to looking at developing some preliminary science-based risk assessment approaches, including potential changes to labels and training while the science that Tom Steeger talked about earlier continued to be developed and evolve.

The second charge area was to explore and develop information on state approaches and what different authorities might be in existence today to help with pollinator protection efforts.

The third area was one really in the area of technology transfer and applying lessons learned from various stakeholders, perhaps regionally or in different pockets of the country, and disseminate those more widely in order to improve existing management practices, and then to foster continued international cooperation.

Then, the final area would be a catch all of any other issues that the work group decided to explore

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and thought needed to be brought to the PPDC's attention.

To date, the work group has met three times. The first meeting was in early September of this year where we came together and discussed ground rules, had a further discussion of the charge and our work group's understanding of the charge. From that, we broke into four subgroup areas that I'll talk about shortly.

At the end of September, we had our second meeting where the subgroups had been formed and we then charged the subgroups to further explore how they would recommend efforts in those various thematic areas. Then, we had our most recent meeting yesterday to get broader input from the entire work group.

The work group, as you can see, is fairly large. There's about 45 people and growing. There's a good group of people representing a broad cross section of stakeholder groups, including growers, registrants, beekeepers from around the country, pesticide applicators, a number of state-lead agencies, cooperative extension and academia, as well as a number of non-governmental groups, and the Department of Agriculture.

As I mentioned, the group initially divided

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into four subgroups, the largest group focusing on management strategies, loss of interest in that area, and the smaller groups focusing on communication, enforcement and certification, and developing reliable data and databases.

So, what we wanted to do for the rest of the morning was for representatives from the work group to give you a flavor in our four thematic areas: ideas that we've discussed, approaches that we might pursue, some of the challenges that are associated with each -- pursuing protection activities in each of those areas, and framing both some short-term and long-term efforts that we might undertake.

So, the first group that's going to present to you is going to focus on best management practices. That will be led by Mike Willett and Marylou Verder-Carlos.

MS. VERDER-CARLOS: Okay. The best management practices work group had a very lively discussion about what management strategies we can use while we wait for the risk assessment process through the SAP will work out with USEPA.

So, one of the things that we had -- there's

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three main points that we discussed yesterday and concluded with. The work group is to explore information that currently exists or what works now for growers and beekeepers.

When we had the discussion yesterday, most of the beekeepers and growers were there saying that there are already best management practices out there that are being used by both groups that help them to make sure that the bees are protected, or the pollinators are protected. So, as a work group, we need to explore that and see what works and what doesn't.

Then, the next one is to explore voluntary registries. If you remember last April, we had done a survey on the different states, on what states had voluntary bee registries. There were about 9 or 10 of them that had both. So, most of the input from the beekeepers said that they would like to have it just voluntary instead of mandatory, and to see what models are out there that work. What are those registries that have been successful in making sure that their bees are protected, and is there an opportunity for communication and information exchange between the growers and the

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beekeepers themselves.

Then, the third one was to explore case studies where stakeholders work together for successful protection of pollinators and crops. There's examples from Washington State between pollinators and growers and USEPA working on labels, although it took some time. That was one of the things that we had talked about. Outside of working on the labels, there were successful stories about working between the growers and the beekeepers on what things that they could do mostly on communication.

So, those were the key areas that we had talked about and concluded from best management practices. So, there's still work to do for that work group. So, with 28 members in that management strategies group, I think we can come up with some more things.

MR. KEIGWIN: Ken Nye was going to give us a report back from the group looking at training and education opportunities.

MR. NYE: Well, training and education got quite a bit of discussion in our conference calls and work group yesterday. Obviously, I think everybody

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understands that the more education, the better. Some of that comes with expenses of other areas. So, we all have to be cognizant of if you spend too much time in one area, you lose something else. But the beekeeper and pollination part of this is very important.

We have various groups to reach out to that are part of this process, the users first and you get down to the certified users, commercial users, and so on. We also have homeowners, so we have some people that are fairly well versed in these issues. We have homeowners, some of which might not think of these issues at all.

So, we have a fairly diverse spectrum out there that we have to deal with. Obviously, we have the beekeeper's side of that also in terms of education and how we work together. User and beekeeper is very important.

Then, you look at that and you say, well, we have beekeepers that are relatively large and quite mobile. We have other ones that kind of stay home. We also have probably some hobby folks out there. So, the universe is fairly broad, and that makes a challenge out of our whole training and educational effort.

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In terms of training, we think, I guess primarily, of those certified users that go through some sort of core training effort to get certified. There is a process in place to help those people and to get them recertified. The training material has information in it. Is it the right kind of information? Do we stress that enough in terms of pollinator protection? Are the recertification credits -- the process put together so that we're providing the right kind of information?

Again, if you put too much time into pollinator protection, then you lose other things that may be just as important in worker safety or handler safety, and those kind of things. So, people have got only so much time. So, we have to do the best possible job of making sure that this information is put together correctly and as outreach to those that need it the most.

So, we have some challenges certainly on the training and educational side but a lot of opportunity because the systems are in place. There's a lot of information available. We just have to make sure that it's adequately provided.

We did talk a little bit about the label, and

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we have another work group that's going to report on that. But we kind of looked at it and said is the right information available on the label? Is it in the right place for the right people? Again, if you look at commercial applicators, certified applicators, and then homeowners, there's a fairly broad spectrum of users out there. We want to make sure that we're reaching out to all of them and they understand as clearly as possible.

Then, you get back into that discussion between the pollinators and the users out there. Do we have the system in place so that those folks can communicate? I think that goes hand in hand with the training and education also.

So, Rick, we had a lot of things that we had good discussion on. Have we solved every issue? No. You'll see in the report here that it says we need to explore and we need to continue to work. So, there may be others in the work group that want to make some comments on that, but we had a good discussion.

MR. BRADBURY: If you're on the phone, please make sure you've muted your phone. Again, if you're on the phone, please mute your phone or else we'll hear who

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you are talking to.

MR. KEIGWIN: So, the next area was enforcement and Gabriele Ludwig was going to (inaudible).

(Whereupon, a phone ringing over the sound system was muting out the speaker's voices.)

MS. LUDWIG: Enforcement, just to explain a bit about the issues from (inaudible) they feel like there's a number of times when they have had bee kills or their bees hurt. They (inaudible) get much follow up from the enforcement agencies within the state.

There's a couple of issues with that. The beekeepers don't feel heard. The growers get frustrated because there's a lot of accusations but no data to back it up. EPA or the other regulators are also (inaudible). Again, you have a lot of accusations and no data to back it up.

So, given that, it would also be helpful to have better information as to when is a bee kill really due (inaudible) try to figure out when we have real issues. The suggestion is to really encourage how do we

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strengthen investigations of (inaudible). Some of the ideas there is basically to just come up with a unified protocol that states can work with (inaudible) harmonize that. From my understanding, there are such protocols already in existence (inaudible) they would work.

Similar to that would be if there is (inaudible) encourage follow up in reporting an incident. So, there's also been (inaudible) all the way to EPA and understanding that.

In terms of communication, EPA has a regularly scheduled meeting with the state lead agencies called SFIREG (inaudible) EPA people for the translation of that acronym. It's like state federal something regulatory people. They meet every three to four months. So, I mean, it's already an institution. It's an opportunity for the states and EPA to talk about exactly such issues.

So, I think that's a place partly to explore why enforcement or just investigations have been lacking. Is it a question of time? Is it a question of money? Is it a question of training? Then, if a protocol is agreed upon, that would be the place to sort of move it into the state process.

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Part of the education side is whether to look at if there's a need to do education about how to do an investigation, how do you get information, and so forth. I think some of the issues are challenges. As I said, currently, at the end of the day, investigations are up to the state.

So, trying to get that more evenly done is going to be a challenge, especially in budget-tight times. Again, I think at least taking some time to understand what those challenges are and whether anything can be done about it is necessary.

Then, for example, if the desire is to do actual residue testing, let's say, on the honeybees, that is a definite expense and where is that money supposed to come from, just to give you some ideas of what that discussion has been about.

I don't know if anybody has some additions to my comments, or summary of it.

MR. KEIGWIN: There's a lot of cross efforts or ideas that sort of cross across the work groups. So, that actually generated a lot of discussion during yesterday's work group meeting about where to sort of

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bend some of these ideas. So, we appreciate PPDC's feedback in that area as well.

The last area is the area of labeling. Cindy Baker Smith was going to give us a report out on that effort.

MS. SMITH: So, what Marylou and I learned yesterday is don't leave early from a work group and don't show up for a work group that you're not on or you end up presenting the next day.

But, seriously, I think as a plug for these work groups, it's hard to do justice in a presentation like this to all that transpires. In this case, I think it was a four-hour meeting where there was a lot of good dialogue and people outside of just the PPDC who participate. So, I think if you haven't participated yet in a work group, there really is a lot of value, I think, in doing those.

So, I'm not on this work group but I'm going to present labeling because I do have labels. So, basically, what we talked about here is a theme that I think you heard carried out through a couple of the presentations, which is there are some short-term

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immediate kinds of things that we think we can work on to help address the awareness of the issue and things that can be done easily.

There are some longer term things that are going to take some time for either data generation or risk assessment process improvements or other things that need to be implemented through the states and the agencies.

So, in the area of short term fixes for labels, the things that we talked about are that there's already some existing language on labels. In most cases, it's in the environmental hazards sections of the label. It says, in some cases, things like this product is toxic to bees. Do not apply when bees are actively visiting or foraging in the treatment area. Then, there are other examples.

So, one of the very logical things that the work group talked about was having some people come in from EPA and talk about how does that language get derived. What gets put on the label? What are the kinds of things that you look at? What are some of the examples that are there today?

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I think a next longer term logical step is to pull together some beekeepers, some registrants, some state officials, some folks from EPA, and talk about is there a better way to put this on the label? Is it going to be in exactly the same place on every label? Get some consistency across that.

Maybe there are ways to provide through information bulletins or web sites or extension programs some additional information about what that means. So, I think, like in the other areas that have presented, there's some opportunity to share additional information there.

There was quite a bit of discussion about the difference between a commercial agricultural product and a homeowner product. A homeowner product, just by nature, is a smaller product with a label with probably smaller font and more things on it. So, are there things that we could do in the labeling of homeowner products or in things that go out with those products to help sensitize people if there are concerns about bees with respect to the use of those.

I think that covers most of those points, Rick,

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that we shared there.

MR. KEIGWIN: Thanks, Cindy. She did get roped into volunteering as a non-work group member. So, that's not a plug for not showing up if you're not a work group member. There was lots of good conversation.

So, that sort of summarizes where our work group is right now. As we begin to pursue efforts in each of these areas, we wanted to get some input from you all and reactions to what you've heard this morning to help inform our course of action between now and the next PPDC meeting.

So, with that, Steve, I think we could open it up for questions and comments.

MR. BRADBURY: Why don't we try to organize this since you've got four thematic areas. It might be helpful to take a look at them. But why don't we first open it up for clarifying questions from the PPDC in terms of just things you've heard that you'd like to get a little more background or it wasn't clear to you.

Then, what I'd like to do is go through 1, 2, 3, and 4, and we can dig in a little deeper in terms of, for me at least, where the group is in terms of specific

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action items. Cindy gave a little bit of a sense of immediate action items for the labeling group. The one thing I'd like to hear is some ideas from all of you on what you think are tangible next steps for some of the groups.

First, are there any clarifying questions? Why don't we start with Jennifer, then Jim, Caroline, then --

JENNIFER: I think mine is a clarifying question. But if you think it's not, you can table it to Section 1, the best management. So, my clarifying, I think, question is, the second point on volunteer registries, you mentioned, whoever presented, that you guys were preferring at this time voluntary.

I just wondered two things. One, will that include also thinking about an incident reporting system in that? Then, the second thing is, what was the discussion on preferring voluntary? Is it just to test something to see if it works or is it voluntary forever? What was your thinking on that?

MR. WILLETT: I can answer that question, Rick. Marylou did a really good job, but she found out this morning that she had to make the presentation.

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The reason why the voluntary part of the registry was because there is not a clear agreement amongst the folks involved that registration of where bee colonies should be all the time is a good idea. There is some resistance to that because beekeepers have concerns about theft of colonies. They have concerns about people identifying foraging areas that they consider proprietary.

So, mandatory registration with bee colonies wasn't universally endorsed by everybody in the work group. So, that was the reason why it was left as a voluntary.

JENNIFER: (Inaudible) registry references referring to location of where bees are then.

MR. WILLETT: That's how we understood it, unless there's some other understanding within the work groups.

JENNIFER: No, I'm asking.

MR. WILLETT: That's how we understood it, yes.

JENNIFER: Okay, thanks. Then, I guess my second question was, is there talk about an incident reporting system or is that in a different section?

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Would that be on enforcement? So, under enforcement, they're saying the difference between an incident and an investigation. But is there a reporting system that you're talking about? I guess my question is, are you talking about an incident reporting system in here somewhere?

UNIDENTIFIED MALE: I think Gabrielle was going to -- we had put that under the enforcement theme.

MS. LUDWIG: The short answer is yes, it got talked about. The issue was we had so many issues that we felt like we were trying to figure out which ones were really top priority. So, on the incident reporting, several things got talked about. One is just simply, as I just mentioned, from a state perspective, making sure that whatever they learn gets transmitted to EPA. That's one aspect that got talked about.

Another aspect that got talked about in a subgroup is just simply beekeepers are still leery to use the existing incident reporting system. We need to explore more why. Again, I think it comes back to a bit like what Mike was just saying about their experiences with the government haven't been that great.

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So, there's a lot of details that are being asked in the system. Is that really useful to them at that point in time? So, there's some need to look into that. So, that definitely got talked about as something that needs to be floored more about how to do it better.

UNIDENTIFIED MALE: To build on what Gabriele was saying, too, just a reminder that there is a portal, via the EPA web site, for someone to report bee kills. Part of the discussion during yesterday's meeting had to do with maybe getting some consistency in terms of what information elements we ask people to submit through that portal now.

Right now, it essentially brings up an ability to send an e-mail to EPA. Some people were concerned that maybe because of what was being reported or what people didn't know might be helpful in reporting an incident, if we provided some clarity there, it might help with the enforcement investigation aspect of things.

UNIDENTIFIED MALE: Actually, taking off on Jennifer's question, I was going to start with that. So, I'll skip that part but go back to registries. At the last PPDC meeting, I mentioned that there are commercial

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databases available already that have the ability to overlay the data. The same things that Michael just brought up about some resistence, I have no problem with the voluntary registries.

My net point is, if the committee or work group would like any liaison with any of these groups that can do this type of data overlay that my members use on a regular basis -- Agran, CDM mass, several others (phonetic) -- do this already but they don't do it for pollinators unless they're given the information.

So, if there was a repository, my members would really prefer that it go to one place so they don't have to source multiple databases. The database uses right now, particularly Agran users, is actually you might call it danger zones. It could be schools or other environmental hazards. Pollinators would fit into that very very well. Some states actually require some of that information.

So, we like the idea of a registry. We do not like the idea of a new one. We think that it could be actually fairly easily recorded. For the simple reason why we like it, if my members know when they're making

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applications where the bees are, they can simply go to the beekeeper and say, look, keep a tarp around your bees. When we know we're going to make an application, we'll throw a tarp or a protective cover, or notify you, or something where we're working closer together.

I'm all for the label restrictions and the language and everything, but I think at least in the pesticide area -- and I'm not at all indicating at all that pesticides are the cause of the issue because they're probably likely not. But, in order to keep direct causes from pesticides on bee kills, we would be very interested in helping you with location. Now we're back to the registry.

UNIDENTIFIED MALE: Jim, one of the things we talked about in the work group yesterday was some of the existing programs that exist like Direct Watch where there is an ability to register into that system. We talked about exploring maybe having some of those organizations come in and give presentations to the work group on existing models that are out there.

UNIDENTIFIED MALE: Yeah, drift watch is one. There are already national organizations that are far

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bigger than the Perdue program. We have no problem if you want to put it in multiple places. But some of the national ones are far more used by CCAs and PTAs than the others.

MR. BRADBURY: Caroline.

CAROLINE: Are we still on the clarifying questions?

MR. BRADBURY: I'm hoping that's what people are trying to hold themselves to.

CAROLINE: The question I had was about the slide about the SETAC workshop. It said that there was no consensus about how to deal with sublethal effects. I was wondering if we could get some more details on that and more clarification of what that discussion was like.

MR. STEEGER: The intent of that comment was that multiple measurement endpoints are reported with studies. Some of them are sublethal effects that could not at this time be linked to agency or regulatory authority assessment endpoints. Behavioral effects, while they might impact individual bees, do they affect the colony as a whole and cause it to ultimately decline to the point of death.

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Making those linkages from endpoints in individual bees that aren't killing the bees but might be impairing them in some way, like the proboscis extension reflect (phonetic) that could impact feeding, that could in turn impact the extent to which nutrition plays a role in the decline of the colony, the SETAC Pellston Conference went through a number of those endpoints and decided that for some of these, we don't have clear linkages.

That doesn't mean that in the future those linkages won't be made. But it's just laying open the ground for further research that needs to be done in order to make those types of linkages clearer so that these endpoints could potentially play a role in a regulatory context.

UNIDENTIFIED MALE: I think this is a clarifying question regarding enforcement. I was in the work group meeting yesterday and I got the impression that most of the enforcement investigations and activities and reporting is done through or by state regulatory authorities.

I was wondering if EPA, either the national

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Office of Pesticide Programs or through regions, plays a role in investigation of bee incidents, either through funding, or off-state authorities, or directions to state authorities, or in sample testing?

UNIDENTIFIED MALE: I'm not sure I heard all of it because I was trying to get the slide back up.

UNIDENTIFIED MALE: I was just asking what role OPP or EPA's region plays in the investigations and reporting of bee kill incidents. Is there any funding of state authority specifically to do this or any role in testing of samples that may arise in the investigation?

UNIDENTIFIED MALE: So, we're engaged in an ongoing dialogue with the enforcement office as well as the regions on a wide variety of issues, including pollinator issues. It's becoming a higher priority for the regions and the states as part of those efforts.

In the area of support for enforcement, there have been instances where EFED has provided support to state investigations or regional investigations of incidents. We have had on occasion requests for OPP's laboratories to do some laboratory analysis of, you know, hives data, or pollen data, or honey data, or the bees

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themselves.

MR. BRADBURY: So, just to clarify, Ray, the enforcement activities are undertaken by the states. The EPA enforcement office, OWECA (phonetic), compliance and enforcement, we're working with them closely in terms of coordination across the states and engagement in the PPDC groups that have now been informed as well as prior to that. So, states have the primary authority. OWECA helps provide some continuity and some consistency in approaches.

Clearly, this has been one of the challenging areas in terms of people's perceptions and experiences in terms of what's playing out at the state level, the regional level, and then the national level. So, we're working hard -- and this work group will help -- in trying to knit things together a bit more coherently and effectively.

The states have quite a challenge, which I think some of our speakers have pointed out, in terms of enforcement and compliance, from worker protection to water quality to bees. So, what we're trying to do and what we have been working through with the states and our

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national program guidance from the pesticide program and aligning that with the enforcement office is to first try to make sure that the left hand and the right hand are working together so that the states aren't getting mixed signals in terms of priority areas. We want to try to make sure they're complementary.

We're working towards some flexibility with the states so that their national objectives in all states have to deal with that allowing some degree of adjustment to emphasis within certain areas, because some parts of the country may have different issues to deal with that are higher effort or challenge than other parts of the states.

So, that's what we're trying to work through. It's all kind of coming out of the same basic budget and set of resources. So, I think a number of you mentioned the importance of as we think through options, how to make sure that we're coming up with very effective and cost effective techniques to try out, try to make sure we're taking advantage of tools and technology that may have been used for another purpose but could be adapted to this area. That will be an important part of this.

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We'll want to maximize protection appropriately, science-based, and have it be as efficient as we can and as helpful to the states as we can. So, I think across these different work groups, some of the ideas that will come out will be helpful at the state level, at the regional level, and at the federal level.

Darren, you were next.

MR. COX: On the best management practices, we have a model that we kind of looked at with California. They do have the registry that's voluntary. The beekeepers can go ahead and register their locations if they are concerned about usage in the areas that may be a safety factor for their bees. There's a number of other states where they also will have registrations.

But, what seems to be the constant thing here is when the farmer needs the bees for that specific crop. The crop is protected with consideration of the bees. There usually is not a problem. Where we run into problems is where there's not that need by the farmer for the bees. As far as the voluntary registration, it's kind of like, as Steve mentioned, the right hand knowing what the left hand is doing if we have a farmer that does

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call us up, we can communicate to possibly say, okay, select a product with less residual.

That's one beneficial tool. But if we don't have usage reporting to where we understand what is being sprayed in our areas at many points, these products will get sprayed and the beekeeper will not be notified. So, it kind of turns into a two-way street.

UNIDENTIFIED MALE: So, my question has to do with evaluation. I enjoyed listening to all of these different actions and activities, but with these times of budgetary constraints and meager resources, how do we know which of these activities actually is effective? How do we know if the problem is getting better or getting worse? So, I'm wondering if there are systematic surveys of bee populations nationally and regionally, or are we tracking like numbers of incidents of bee kills?

MR. STEEGER: This is Tom Steeger. The USDA is tracking through monitoring of commercial hives the incidents of pollinator decline. Our understanding, EPA's understanding of incidents, though, depends on the willingness of the states and the public to report that information to the agency. That, we know, is not working

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effectively.

There is a resistance by the public to report to the agency. The web site that Rick alluded to, I've only had one person actually contact me using that web site -- it was Ray McAllister -- just to see what would happen if he contacted the web site. A few people are availing themselves to the National Pesticide Information Center, the NPIC portal. But the process that we recommend is that you report the incident to the state and the state will investigate it or report it to the registrant.

Only the registrant is required to report an incident to the agency. So, everything else is volunteer. That volunteer system, unless we can get engagement, isn't working effectively. I'll tell you, as a risk assessor, my ability to ground truth a risk assessment depends on incident data. That's our information of how a chemical is actually being used. Does it actually result in an effect? If no one is willing to tell us that, that means we're blinded to those effects.

UNIDENTIFIED MALE: But it seems like if you're

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basing it just on incident data, you're not really sure if you're actually winning the war because you don't know if -- if you see a decline in incidents, is that because there's truly a decline in the problem and bee populations are increasing, or is it just because people have decided not to report, or maybe there's barriers that prevent people from reporting. It seems like ideally you'd want measures of the bee population both regionally as well as nationally.

MR. STEEGER: You're absolutely right. There is a bias associated with the incident reporting system. We would like to improve that, but it will depend on cooperation. The USDA, though, has been -- congress noted that more needs to be done in terms of actual monitoring of colony losses from particular types of -- like CCD and pollinator declines in general.

They want to see it expanded from the current survey. But USDA is not sitting on their hands on this issue. They are actively trying to collect this information. Congress would like to see it expanded. Again, funding has to be provided. The reason why USDA did not do that is because the funds weren't appropriated

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by congress.

MR. BRADBURY: If I could sort of weave in a little bit and then step back as a chair. I think there are two aspects of getting information from the landscape. One is the effort that USDA is leading which is how do we come up with robust national surveys of the status of pollinators, be they managed pollinators or native pollinators, and what are the trends.

Set up a statistical survey design so that you can be tracking that. If done well or designed appropriately, maybe get some insights into potential associations between different stressors and the landscape and the trends in pollinator status. That's helpful for us in a broad context.

It's helpful for everybody because you can start to better understand what the relationships may be between different stressors and the landscaping status and what can be done in terms of individual stressors in the context of the milieu of pressures the pollinators are facing.

The incidence data can give us some information to complement what we have in our risk assessments for

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pollinators or fish or other parts of the ecosystem that we're looking at. So, we have the laboratory-based information. We may have field studies or semi-field studies associated with different tasks as part of the information base to make the registration decision.

The incidence data can be helpful for a specific compound and specific use scenario and gives us insights if we're seeing things that we didn't expect from the information that we collected or that was submitted to us during the registration evaluation process, or in going through registration review, taking a look at the incidence information that's out there, and is it consistent with what we were expecting or not expecting and how to go forward.

But, as Tom mentioned, that information one has to look at carefully because just because you don't get information doesn't mean it couldn't have been something going on as a function of whether or not it was reported or not. So, we have to take that into account.

So, I've got Cindy, Pieter, Ray, and Gabriele.

MS. BAKER: I just want to follow up kind of on your comment, Geoff, because I think that's where the

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work group went yesterday, not specifically to your point but to the point of how do we prioritize this and what are the things that will really make a difference.

It was interesting to me -- I think it was the guy from North Dakota who made the comment. We had something like a dozen things up on the white sheet and we said how do we prioritize, what are the things that really make a difference, where are the urgent things. He said best management practices and training is one of the things that he has found that really made a difference.

So, one of the overarching themes that I took out of that whole session and discussion was that there's a lot of information that is available today. It's a matter of compiling it and getting it to the right people. So, whether it be where the bees are, whether it be information that's already on labels, or whether it be information about products that we know, it's getting it out to people. That seemed to be the biggest single thing that people thought they could get some benefit from.

We have some examples of where it has worked

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well. That guy from North Dakota had a great testimony, if you will, about how that worked. I think there are some others. So, I think getting that information out into the hands of the people who can make a difference, the applicators, the beekeepers, the growers if they're a private application, I think is the real positive first step that would actually make a difference in what people are doing.

MR. SHEEHAN: I want to speak on the idea of information sharing between states and the EPA. It sounds like it would probably be characterized as not fantastic at the present moment. I'd like to offer two things.

At a local level, we deal with the federal and state governments all the time. There are two examples I would say you might want to look at in terms of how this communication from a very low level to a very high level rapidly occurs. What I'm talking about is the administration of that communication, their applications, their process.

The one that I'm most impressed with is the CDC's communication with local health departments when

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there's a recreational water incident, whether there's a disease being spread in a swimming pool, and how rapidly we can communicate to Atlanta with something like that.

Then, of course, retail food programs, restaurants, food-borne illness and how those forms -- and how the communication moved very quickly from the local level to the state level to the federal level through very simple forms, through an understanding of what the big picture is and how to gather that information.

MR. BRADBURY: Thanks. Ray and then Gabriele.

MR. McALLISTER: I think that lacking comprehensive surveys on bee kills or bee incidents and perhaps lacking the resources to find out the extent of problems or the extent of success is perhaps one of the most fruitful approaches we can do is look at case studies, like Cindy mentioned, where we know things have gone right.

In our discussions yesterday, we identified three or four of those. Apply the lessons learned there to additional (inaudible), additional circumstances. I think there's a big opportunity there for some short-term

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quick gains. We also might want to identify some negative case studies where things went bad, went wrong, and find out what we learned there what not to do in other situations.

I also just wanted to mention in my test of the incident reporting system, I found out that Tom Steeger is on the other end of that reporting line.

MR. BRADBURY: Gabriele, I think you put your tent down, okay. So, Caroline and then Cheryl.

MS. COX: I just wanted to comment about the sublethal effects. To me, this is like one of the most critical areas where we really need to move forward and make some progress. If there isn't consensus right now, I think that just shows how important it is to move forward and make progress and figure out how to come to a consensus.

I think that's at the core of this issue about pollinator protection as far as pesticides. It seems like a really critical area to make some progress in.

MR. BRADBURY: Cheryl, Scott, and then Gabriele.

CHERYL: So, almost back to that but in a weird

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way, I guess, I am intrigued by the labeling report that they're going to explore what exists today on the labels and how EPA currently determines what goes on that label. What I'd love to see and I think would be a really easy work group activity would be a polling and a survey of what is on the various labels, what works for applicators, and do a survey of homeowners.

Do they understand what this means -- applicators, commercial applicators, non-commercial applicators, farmers, whatever -- and really dig down into what is on the label today, what works, but take that a step further because you're also way over here on advancing the science, talking about what you might be asking for in terms of a case by case situation for additional data testing.

In that same conversation, say, if you ask for these additional tests, what are the outcomes of those tests going to look like in terms of new label statements? Kind of wrap that all back together. That would be really helpful, I think.

MR. BRADBURY: Scott and Gabriele, then Mark, and then what I'm going to suggest is that we take our

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break at that point. Then, after the break, I'd like to come back to each individual group and go through each of the four areas, get feedback from you all if the scope of each subgroup seems reasonable to you, if there's anything you suggest to broaden or restrict that scope. Then, get from the work group or your advice on specific action items.

I'd like to make sure we leave this meeting with knowing over the next six months what exactly each work group is going to do and accomplish before we meet again six months from now. So, clarity on scope. Make sure scope is okay for each of the subgroups. Then, get input from you all on immediate tasks to take on over the next six months so we give our work groups a clear set of instructions, if you will, on things to take on.

So, Scott, Gabriele, and Mark. Then we'll take a break. Scott.

MR. SCHERTZ: An observation of all this process and being a part of it, this is a very complex issue, a lot of crops, a lot of products, a lot of different stressors, et cetera. There is an interest in the short-term recommendations, but also the SAP is

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coming up.

Many of these, I think, are so complicated and interconnected that that's a huge interest. Some of these, particularly labeling issues, would take a while to get on and then they would be very difficult to get off if we get them wrong.

I would caution that we do need to take that into account. I would request a bit of an update of exactly where EPA/OPP is on the charge and possibly charge questions, et cetera, on the forthcoming SAP on this.

MR. BRADBURY: Gabriele.

MS. LUDWIG: Well, Scott's comments play into what I wanted to emphasize. I think this is partly in response to Caroline's request. I think one thing that we were very clear on in the work group is we need to figure out what we can do now with science progressing as it is.

Anything that is dependent on really sorting out the data is not something the group can deal with right now. For example, if you take labeling, I think we can talk about what's working, what's not working with

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the current labels, what are the inconsistencies, what are some ideas for improving the labels once we have more data available.

But, just to give you an example, some of that is going to be contingent on when that data is available. Sublethal is not something this group can tackle. I mean, that is just not something that we have the expertise and can tackle. It's not to say it's not important; it is on EPA's agenda. But that is not something we can deal with at this point in time. There's just not enough data to figure out how to do it with any consistency, any fairness across all the products. So, that's the rub.

So, I just want to be very clear that when we talked about priorities, and I think this is important for the discussion next, there are limits to what we can do because there's still quite a bit of uncertainties about which of these issues are significant enough to merit an action and which ones are not yet. We just don't know that in so many cases. So, that's the issue.

I realize there are those that believe in the precautionary principle, but that is not what we're

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working under in the USA. So, just be clear on that. As I say, I just want to be -- we've talked about that on the committees. Some ideas came up. What I suggested is that we come up with a list for research so that there's areas where we say this is where we need research so that we capture those discussions. They don't get lost.

So, I just want to be clear that we're not dismissing it, but there are some areas that we just don't have, from a PPDC perspective, the ability to deal with. I just want to be clear with that as we go into the next discussion, the continuing discussion.

UNIDENTIFIED FEMALE: I'm not sure what you mean by we can't do acute, but the incident reporting data -- or, sorry, we can't do sublethal and chronic. The incident reporting data is a really important opportunity to just make sure that you're capturing data that's not necessarily bee kills but other kinds of things and start to collect that important information. So, there's lots of ways to consider all these endpoints.

So, I'm not sure what you mean by that. But I would suggest that by keeping it front and center and keeping it as a main concern, you're thinking of it when

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you're doing the things that you can do, like the incident reporting.

MR. BRADBURY: Thanks. Okay, so let's take a break until 20 to the hour. We'll start sharp at 20 to the hour. We're going to go through work group by work group, clarity on scope and clarity on near term activities to be taking on over the next six months. So, be thinking about that. I'll look to the work group members to sort of help us through that conversation.

(Whereupon, a brief recess was taken.)

MR. BRADBURY: Before we get started, there are some folks that came a little bit after we got the meeting rolling. If they could just introduce themselves. Ann and Jennifer and Nancy, if you could just introduce yourself, your organization, and who you are representing.

MS. LAW: Hi, I'm Anne Law. I'm here with the American Bird Conservancy. I'm currently sitting in for Michael Frye who has, as many of you know, left ABC and is now in Hawaii.

MS. BECK: Hi, I'm Nancy Beck. I'm here in

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place of Kristie Sullivan, and we represent Physicians Committee for Responsible Medicine.

MR. BRADBURY: Thanks, Nancy and Ann. Jennifer is having tea. Jennifer Sass from NRDC also joined us a little bit after we started.

Okay, so what we'd like to do between now and 11:20 is go through each of the four thematic areas, the subareas within the pollinator protection work group. I'd like to get confirmation on the scope of the efforts, get some feedback, if any of the members think it's too wide or too narrow, if we could get clarity on that. And then get clarity on specific action items that each individual group will take on over the next six months.

I don't mean to imply that all these issues will be resolved in the next six months, but to get clarity on what specific tasks will get accomplished during the first six months. It could be, in some ways, actually tackling a specific issue and maybe getting, to some degree, a resolution.

It could be trying to set up the game plan for something that may take 12 months to get done but there will be a very clear plan prepared in the next months and

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make it very clear what's going to happen over, say, a little over a 12-month period.

So, I'm not trying to imply everybody gets everything done in six months, but there will be very specific tasks. We'll know very specifically what kind of communications will be coming out to the full group six months from now.

So, Rick, Don, why don't I turn it over to you and members of the work group and let's tackle the first area.

MR. KEIGWIN: Okay. So, as Steve indicated, let's start with theme one, best management practices, and try to scope out our activities over the next short term six months that Steve indicated that we can either do additional planning if we need to or action items that we can actually adopt and move forward on through the work group, and with EPA's assistance.

So, those were the three points that the work group identified as areas to make progress on. So, I guess I'd like to try and hear any thoughts from committee members as to where our priority might be or specific ideas that come.

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Mike Willett.

MR. WILLETT: Some people in this room are probably familiar with this publication. It's a 25-page publication. It's titled, The Specific Northwest. It essentially summarizes all of the known best management practices, including pesticide specific practices that can be used. It covers honeybees as well as solitary bees, bumble bees and osmia (phonetic) bees in terms of what are the impacts of pesticides.

One of the authors of this is on the work group, Eric Johansson (phonetic). He pointed out that this publication needs to be updated. It seems like this publication or information of this sort vetted across whatever sources of information that exists in the U.S. would be helpful not only to ensuring that we have best manufacturers compiled in one place, but also would feed into this OECD effort of building an international database for best management practices.

So, trying to do something like that I would submit to the work group might be a worthy effort and to the agency would be a worthy effort.

MR. KEIGWIN: Thank you, Mike. That's a good

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suggestion.
MR. BRADBURY: Dave.
MR. TAMAYO: One of the things that seems to keep coming up is that there's some pesticide applicators that maybe are very motivated to protect the pollinators because they have a direct interest. Then, there's some pollinators that are less motivated because they don't have a direct interest in pollinators at that particular moment.
It seems to me that it would be great to find some cases where that sort of barrier to adopting best management practices or doing the right thing or whatever you need to do. Look at how was that overcome in a particular area or group of growers.
Maybe there are no good instances, but I suspect that there are some areas where people have figured out a way to do that and going beyond just legal requirements, just sort of incorporating that as this is how we do it in our area.
MR. BRADBURY: Thanks. Go ahead.
UNIDENTIFIED MALE: A late entry, sorry. I am not very much familiar with the pollinator partnership,

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but I just met Laurie at a meeting this past summer. Since I met her, I know a whole lot more about it within 15 minutes than I probably would have if I studied it online.
But she presented to me a module that is being developed. It's probably similar to what you had, Marylou, in California. It's kind of an overlapping, cross cutting thing with the education emphasis of another theme. But it seems to me like that would be a good place for contributions to best management practices maybe overcoming barriers.
Laurie, herself, is looking to interview growers in several areas of the U.S. that have developed programs or certainly shown care of the pollinators in their region. Maybe there are instances in which, as you were talking about, Dave, barriers could be overcome. This, too, can be brought to light in a video.
There is an interest in developing this for pesticide safety education, which is my particular vent. Having it as a re-certification tool for our private applicators and commercial applicators would be a welcome tool or item.

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Technical notes are going to be included maybe paralleling, which you have, Michael, with the BMP that you just introduced in a workbook, to try to engage the audience into something that's far more than just listening to a video and maybe tuning out, but actually becoming interactive in teaching it.
UNIDENTIFIED FEMALE: Is it possible, then, to maybe talk to growers and commodity groups that use these and see what their best management practices are and see what works and what doesn't? I'm sure there's commodity groups out there already, like Gabriele's almond board, that already have best management practices they're using right now to protect the bees. Maybe we can explore that on a more practical standpoint.
MR. BRADBURY: Darren.
MR. COX: In Western Farm Press about a week and a half ago, there was an article about soybeans producing heavier yields with the benefits of honeybees. I'm just wondering is it possible to look into some of this for research for just soybeans and canola and other various crops that farmers may not be aware of that they are receiving benefit.

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Once they are aware that there is an economic model that's here that's of value for them by having these in their communities and farm fields, then perhaps safeguards would be looked at more closely when it comes to applying the chemicals.
The last 30 or so years, the duck and cover, so to speak, that's been happening to the beehives, cover them up or move them out of the way, is really not working. The reason why we're here today is that the bee industry in many of us is really about money. We're here because pollenization costs continue to increase.
If we don't safeguard our nation's resources of pollinators, many of these crops could be exported to other countries where they can have cheaper pollenization costs and we will lose out on the big picture. So, I would encourage, if we can, to look at some of these costs that could provide additional benefits.
MR. BRADBURY: Okay, thanks. So, I'm just going to kind of reset everybody. What our goal is right now is to take a look at the potential scope of theme one. We've got to get through the other themes. Then identify some near term six-month activity. So, here's

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what I've heard so far, and then I'll go to Gabriele and Mark.

There may be a model, a document, that Mike brought up that could be at least a framework to consider these as a launching pad for the first goal within theme one, which is to try to (inaudible) collecting in one place information about best management practices that currently exist.

So, the proposal is to maybe use that document as a starting point. I'll defer to the work group to think how much you could get done in six months, but it may just be scoping out what kind of (inaudible) is before us to try to update it and get a sense of what's current, what's at stake, what's been (inaudible).

As far as the third thematic area, I heard working on the case studies. I don't think you can get the case studies done, but identifying what those case studies could be, and getting a sense of one case study around the cropping pattern where the crop is dependent upon pollination. See if you could identify a case study around the cropping pattern where, knowingly or unknowingly, that that crop isn't at least totally

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obviously dependent upon pollinators for its productivity.

Get two case studies going on those two fronts. Again, not to get the case studies done but to at least have scoped them out, identify players that could be involved in that case study. When you come back six months from now, you have identified the case studies, who the players are going to be, and what the time line is to work through the case studies. So, I'm trying to keep us focused on tasks.

Gabriele.

MS. LUDWIG: Well, you summarized some of the things I was going to say. So, to add to that, what I would suggest for number one is there are a number of EMP models out there. At least get all of them collected so we have the northwest protocol model, we have the blueberry model that I talked about last PPDC, and we have a bit in almonds, a bit on the ECIPM sites. NAPSI, or pollinator protection campaign, has also been working on this issue. Let's take a look at what they have put together.

Yesterday on the call, the Zerksi (phonetic)

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Society said they were working with NRCS on some best management practices that I also think need to be looked at for a variety of reasons. What I suggest for step one is to simply in the next six weeks pull together all of these different resources.

The other resource that needs to be pulled together as best management practices is for the beekeepers in terms of their pest management needs. I do know that between the cap grant and Project Aphis M, I think especially crop block grant in California, there has also been some BMPs put together in that arena. So, I think that would be something also to pull together just to see what we have.

I agree with the statements that the bigger issue is how do we motivate growers that are not dependent on pollinators to think about pollinators. I think I said that at the last PPDC in my presentation, that that needs to be a focus.

In terms of voluntary registries, I think, building on what Marylou has developed, look at what's working and what's not working, just figure that out, and have that discussion about what's all involved, what are

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the ways a registry would have to be built to make it acceptable, workable, what are the issues that would need to be resolved. I think that can be done in the next six months.

Then, as you say, for the case studies, based on these efforts, figure out which case studies would be modeled to look at more closely.

MR. BRADBURY: Thanks, Gabriele. On the phone, if you can hit your mute button, that would be helpful.

Mark, and then Jennifer, and then we'll move on to theme two.

MARK: Let me start with first an observation, Steve. It seems to me that there needs to be a way, actually, for the USEPA to get involved in another dimension. That is, to insent (phonetic) new products for varolla mite control. It's a really small market. There are huge risks associated with it, such that we're forced to use two really old insecticides to control varolla mites in hives; therefore, weakened broods, et cetera.

So, there must be an array of other insecticides that could be brought to the market. If EPA

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in some way could insent that process, but, right now, I would imagine that it's the last thing a registrant would want to do, is get a new varolla mite material right now. So, when it's really needed -- because you know that coumofos really weakens a brood. That's one thing.

The other thing is that in Michigan, we've seen some efforts in the area of foraging bee nutrients and probiotics, things like that. I don't hear best management practice around that. I hear some incentives and I see it advertised and promoted to beekeepers, particularly at the upper midwest expo. There's a number of them. But I'm wondering if there could be some standards of best management practices around that whole strategy that weaken boost hives.

There's a tradeoff. One is that if the bees are too well fed and doing too well, they forage less. The flop side of that is that if you keep them really hungry, they forage more, but they die easier. So, it's kind of a balancing. A best management practice around nutrients and hives I think might be another one.

MR. BRADBURY: Thanks.

Jennifer.

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DR. SASS: I think that this is going to be quick because I think that the working group came up with some good priorities and divided itself well. I'll identify just a couple main points. So, I guess I just wanted to sort of put my vote in. I think they're all really important. So, I think that our working groups are going really well.

The best management practices, theme one, the second one on the registries -- oh, wait, that's a different registry, sorry. Then, I guess it was the enforcement, the one with the incident reporting.

MR. BRADBURY: Can you hold that? We'll get to that one. I just want to make sure we can close out theme one and move on.

DR. SASS: We're just doing theme one?

MR. BRADBURY: Yes. Speaking for EPA, I'm pretty good with theme one. I'm sort of tracking on what Gabriele was sort of laying out as sort of the task. So, one goal is to pull together the documents that already exist in terms of best management practices for growers as well as best management practices for beekeepers. At least get the list together. Then we can figure out

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subsequent where the gaps were, things outdated, whatever it may be.

With regard to voluntary registries, a more detailed examination of what's working, what doesn't work, what would be the attributes of a well-oiled machine in terms of being able to have something like that work, both from the sociology of it as well as the IT of it.

Then, to at least identify six months from now two potential case studies, one in the cropping system where pollinators are critical in order to produce that crop, a cropping pattern where pollinators, at least on the surface, are not critical to production of that crop.

Those could be the two case studies to figure out how to help people work together to figure out how to solve problems. Again, don't do the case study but identify who the players would be and what would be the time line to execute those two case studies.

Cheryl.

DR. CLEVELAND: As you pull together documents, would you also post them perhaps as part of the -- if nothing else, maybe not sanctioning everyone, but you

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could post them as part of the work group documentation. Then it becomes publicly available as well.

MR. BRADBURY: I'll defer to the work group in terms of how much work they're going to get done. At a minimum, by six months from now, they'll have reported out here's what we've collected and it will be part of the public report they've got. I'm not going to make them do it two months from now, but they will do it at least a week or two before we meet so you can all see it. I've got to be somewhat respectful to people who don't work for me.

So, I want to move on to theme two. Indulgence of the chair watching the clock. So, the second thematic area is training and education. Any feedback from the full committee on the scope? Did the scope seem okay, too big, too narrow, close enough? Not looking for perfection, but ballpark.

Ken?

MR. NYE: Well, if we start with the basic training program that's already in place, then I think with some help from Wayne and others at the land grants, we can take a look at where this has come from, what's in

it, how is it delivered.

Each state is probably doing it a little bit different. How effective is that? Maybe with some things we can learn from the case studies and so on, we can figure out the best way that that system can operate. Are there some improvements that we can make in that in terms of trying to improve this pollination protection issue as much as we can.

The next part of that would then be, I believe, a concerted effort on the part of the user side and the pollinator side. Again, maybe there's some things that come out of the case studies and some other things that we can get from the pollinator work that has been done on what are some of the problem areas that we can have a concerted effort in the user groups -- that's both commercial, farm applicators, and so on -- to work together to try to solve these problems. Education, I think, is probably where it's at. Far more difficult to actually accomplish than it is to talk about, but we've got to start someplace.

The last part of that is let's take a look, with some help from the agency, as to what's on the

label, where it's at, how usable is it. I realize when we talk about making changes on the label, it gets pretty complicated pretty quick. But there are some things there that we can do that would help the educational effort.

MR. BRADBURY: Thanks. That last point may fold around to the fourth thematic area that (inaudible) outcome that you're looking at for sure.

Cindy.

MS. SMITH: So, I got corrected at the break that the North Dakota example wasn't a good example. But the reason why I thought it was a good example when he talked was that he had talked with the Department of Ag, that he had some interaction with applicators, that he was the beekeeper, and that there was some looking at labeling. So, I think this combination is a critical piece of this education component.

So, I think that if it's Eric Johansson at the Washington Department of Ag who is a common link of being a Department of Ag guy and having put together that document, Mike, and a couple beekeepers that Darren suggests and a couple of registrants, the real key to

success here is getting some people together in a room and working through a specific issue and then coming back and sharing it.

So, the components of that, I think, are what do we do to really make a difference to protect the bees while still being able to protect the crops and the enforcement component of it together. Then, can we scale that up? Can we take that out and can we apply it in other crops? Can we apply it in other regions?

What are the barriers that we're going to come up against, whether it's at the state side or the growers side or the labeling side, and identifying what they are. I don't think until we actually get our hands around one and try to do it, we're going to be able to identify what those are and do it. Then you can figure out how do we communicate the success.

Maybe ARA or some of Scott's group, the applicators, says this is the best way for us to get the information that we need. The beekeepers say this is the best way we need to get the information about these products. Understand is it a timing issue, is it five days we wait, the 24 hours wait, whatever. But until we

get everybody in the room and work through those on a specific case, I think it's going to be hard to make a lot of progress.

So, I would advocate in the area of training and education, put a group together of people who are ready to engage, have some experience engaging on these, and see if then we can duplicate it.

UNIDENTIFIED FEMALE: I just want to reinforce what Wayne said and what's actually already in there. I mean, one thing I will say for Lori Davis Adams (phonetic) is she knows about how do you change behaviors. That has been a focus of her life. So, I think that's an expertise we should tie into.

MR. BRADBURY: Dave.

MR. TAMAYO: I'd like to have a look taken at the training materials to see if there's information on how growers could be educated on this. This is the impact, economic impact on your area if we don't do this right. I know that there's probably sort of generic information. Oh, it's a bad thing for ag in general. But thinking about this is how it's going to hurt your neighbors whether you like them or not and the ability of

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your community to be successful.

MR. BRADBURY: Okay. So, let me try to synthesize what I think I've pulled together for theme two. Similar to the first theme, an effort to collect and document what's currently out there in terms of training materials, be it state certification and training materials, what NAPSI is doing that can augment that, but to get a good list of what's out there now and what's in that material so we can identify gaps that may be associated with the training materials.

Economic benefit, I think, is in the realm of things to be looking to see what's in the training, though it's not exactly about how to apply the product. But it's training about the notion of this product in the context of pollinator protection and crop productivity.

So, document what kind of training materials exist through the state programs, through NAPSI. Do a gap analysis in terms of what seems to be missing. Then, taking a little bit of liberty with the idea that Cindy had, which is maybe some cross talk between theme two and theme one as the case study starts to get thought about.

Theme two may be starting to be able to provide

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some insights. This will be really a critical set of concepts to make sure come out of that case study based on what we're seeing in the current training materials and what may be starting to evolve from case study option selections.

So, synthesize what we've got out there, gap analysis, and then be working with the group that's coming up with the case studies. That may transcend across all four groups, but does that seem like reasonable tasks for six months? Good, okay.

Let's move on to the enforcement theme. We'll turn it over to the work group, if you want to just spend a minute or two just sort of refreshing us on goals and objectives broadly. Then we'll see if the scope is okay with the folks.

UNIDENTIFIED MALE: So, a good part of the discussion during yesterday's meeting on this topic area had to do with looking at what type of guidance was currently out there across the states in regards to enforcement, what were some of the basis elements, and maybe should there be some standardization employed in terms of when you are looking into an incident or

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investigating an incident, the types of things that you look for. So, could there be some standardization that we bring, harmonization that we bring to that effort.

Then, the second area had to do with improving and standardizing the types of information that ultimately are reported. There also was some discussion about where the appropriate place was to submit that information. I think some groups had some concerns about information being submitted to certain entities versus others. I think that's another area that perhaps needs some further discussion.

MR. BRADBURY: Mark.

MARK: Sue, I want to follow up a little bit on a question that Ray asked. You got some of the answer that I was looking for, but I want to be a little more specific on my question. Regarding abilities of the agency to improve monitoring for compliance and enforcement, obviously, there's state agencies that are really good at it and are putting a lot of resources into monitoring for compliance and enforcement. Then, other states are not so.

So, there's the SFIREG which is basically a

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venue where the agency communicates and tries to convince and improve that monitoring for compliance and enforcement. Then, on the end of the spectrum, there's basically taking authority back from a state where they no longer have primacy for FIFRA.

In between there, what does the agency have as far as tools to do that? So, in other words, I'm talking about sticks rather than carrots.

MR. BRADBURY: Well, you've mentioned the biggest stick, which is pull it back, not a pathway of choice for a whole variety of reasons. It's working through how to define what the goals area, how to try to come up with effective efficient ways to do it. I think we all realize, and our state colleagues in particular, are struggling with reduced resources and less people.

So, clearly, as we go forward across the board on things we're working on, we're looking for efficiencies and we're looking for biggest impacts where the taxpayer dollars invest in trying to get as much harmonization and learning from each other as we go forward.

It's time spent with the states through OWECA

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(phonetic) and through our office as well to take a look at what they've got on their plate, how to set up the priorities, and certainly making sure we provide as much guidance and clarity and insight into how to go forward.

It's not that we know everything but in a collaborative process. So, it's partnership and trying to work together to realize they've got multiple challenges. We're all trying to get to the same place. I don't think the notion of pulling things back from the states is a very healthy way to go forward, given the struggles we're all facing.

So, we're working hard on trying to use the resources we've all got to get to where we need to get.

UNIDENTIFIED MALE: I agree with you. Is there anything between that? I mean, can you withhold funding? I don't know. That's why I'm asking.

MR. BRADBURY: Well, I don't want to spend a lot of time on this because I'd like to figure out what this thematic group can do as opposed to try to change the economy. But what we do is provide help through headquarters in terms of guidance and priorities and try to synthesize tools and techniques. The regional office

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will also provide assistance and work with the states.

We sometimes have to figure out where the regions can provide some assistance across the states to work through these things. I'm not going into it with the assumption the state doesn't want to try to do the right thing, but they're facing a lot of tough choices and challenges right now on how to try to work through the priorities and try to optimize the limited resources that we have available collectively as a country.

I appreciate the point, always do, but we want to try to see what we can get done in this third thematic area.

Darren.

MR. COX: I was wondering if our goal is to try to get consistency through many of these states? Is there any information that has been developed, like a pamphlet, that these states could go off of to where they understood what is the process of actually completing an investigation start to finish? That was one part of my question.

The other part is, could you give us a ballpark idea on the funding that these states receive? Is it

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standard throughout all the states or is it very much widespread? I know that some states have reported that they are not funded to do enforcement or investigations for beehives.

UNIDENTIFIED FEMALE: Through the guidances, we have our national program manager guidance that goes out to the regions and ultimately through the states. And OWECA also has program guidance that directly impacts investigations and enforcement activity. Contained within that guidance are overlapping priorities.

The approach that OWECA is now going to take is looking into the possibility of developing centers of expertise, if you will, so that every state wouldn't have to be an expert in every avenue of investigation and enforcement activity. They're not there yet. The current NPM guidance does not reflect that kind of an approach, but I think that we're all realizing, states and regions and ultimately headquarters, that we can't sustain everybody being experts in everything any longer.

So, I am not personally aware that there is a specific priority to deal with investigations and enforcement follow up on beehives or any kind of issues

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around bees. But it would fall within the purview of general FIFRA enforcement activities. So, it's not that it's not covered; it's just not right now listed as a priority. It's certainly something that we need to think about when we go forward with next year's NPM guidance.

UNIDENTIFIED MALE: Just so I'm clear on this, right now there is actually not an enforcement manual or some given direction that is consistent through the states for them to complete an investigation?

MR. BRADBURY: I would say probably not in the realm of a pollinator incident. Certainly, OWECA has general guidance across various --

UNIDENTIFIED MALE: Could an action item be to develop one of them for training for the primacy partners?

MR. BRADBURY: Yeah. What I was going towards, and maybe look to Marylou to maybe help with APCO and SFIREG to work with OWECA, OPP, and members of the work group, to get a survey across the states and with regional input. Region 9 is our lead region. At least tabulate or document what's going on across the states, or at the regional level at least, if not the state

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level, in terms of the variability there in terms of guidance at the state level, guidance at the regional level, guidance at the national level.

Again, at least we'll know what we're dealing with in terms of what's universe out there. Maybe at least start a gap analysis in terms of what do we see. At least that's information from which to then figure out what's the next most logical step. I throw that out as a proposal.

UNIDENTIFIED MALE: My comment actually is on the same lines but a little bit different approach. Is it possible, looking at bullet item number two about standard process, to set up a template for a 682 for pollinator protection or pollinator incident like that? Has that precedent ever been done for a template?

MR. BRADBURY: Tom will shake his head yes or no, but I think we do. It's on our website. So, one of the challenges is that there's so much information people don't want to enter it all.

Let's go Gabriele and then Mike and then move on to the last one.

MS. LUDWIG: Well, coming back to trying to

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prioritize what to do, basically, this whole discussion about coming up with standardized protocol. I think that's something we can make progress on between the entities you just mentioned and, as I say, it sounded like registrants also have some protocols they were aware of. I don't know if they are from the same source or not, but that came up yesterday in the discussion.

I think the other issue is also trying to figure out some more about what it takes for the incident reporting. That sort of falls into this as well. Again, sort of understanding what the issues are with the current systems. I like Peter's idea of looking at models that work for quick reporting. That's something I think we can also do, at least get that together and figure out some of what works and what doesn't.

MIKE: Very quick. I believe it was Ian Kelly from Bare (phonetic) who actually mentioned that there was a series of templates that he offered. So, I think we just need to make contact with Ian to see what those things look like for investigative purposes.

MR. BRADBURY: Cheryl, then Susan, and then we're done.

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CHERYL: Okay. So, I'm going to show a little ignorance. From a registrant's point of view, I know what 682 is. I also know that somebody has to have identified and told us as registrants before we are required to report in 682. So, if somebody has a bee kill, the first thing is what caused the bee kill. Somebody else has to figure out and then come all the way back to the registrant before you're going to get a 682 from a registrant on a particular compound.

Are there other requirements for 682? Otherwise, solving the 682 reporting issue doesn't do anything. It's figuring out how to do the investigation so that that information is communicated.

MR. BRADBURY: You're making a fair point and I think your observation is embedded in some of the tasks this group will start to do in terms of synthesizing the different components.

Susan.

SUSAN: Along those same lines, I'm not sure that the average pesticide user knows that they're supposed to go to the manufacturers to report incidents. So, kind of reiterating what we've already discussed,

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that reports to the states get forwarded on to EPA headquarters so that you guys have a chance to note them.

MR. BRADBURY: Okay. So, let me try to synthesize this group's efforts. So, one effort will be to try to tabulate or pull together documents, existing guidance on investigations and enforcement process, SOPs. We'll lean on our state colleagues to see if they can help sort of synthesize that information.

Look at techniques that may be in play by the registrant community. When they do get calls, they can go out and try to figure out what happened. So, we try to see what the state of the knowledge is or the state of SOPs are, for lack of a better word.

The other important task is -- I thank Pieter and Gabriele for reminding me -- is maybe our colleagues at CDC can help us in taking a look at systems that are in play that allow information to move quickly and effectively to the right people. So, you've got to let the registrant know if you think something is going on. Or, you can let the feds know or the state know.

Also regarding that is how do you let people know we've discovered that if these combination of things

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happen, we seem to be seeing something. We're not sure. How do you get that information out quickly to the interested or the important folks out there? CDC may be able to give us some advice on techniques you brought up. So, the CDC can join in on this area and maybe help feed some of that information in. That would be great.

Okay, let's go to the fourth thematic area on labeling.

UNIDENTIFIED FEMALE: Maybe we can do this one fast because, as you mentioned, I think that some of these components have come in to some of the other pieces. So, I mean, I boiled it down over the break to really two things. I mean, the work group has a specific charge in the first bullet that's under the charge that's related to label language.

So, I think it comes into two areas. What can be done to get label language enforced now? Certainly, there's an education component to it. There's a communication component to it. And then, what can be done to improve label language.

So, again, I think the best way for this to happen is to get a beekeeper, a registrant, an

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applicator, and a state enforcement person in the room and talk about it so it can come out of these case studies. We can take some examples of labels that exist today that have very specific language about bees on it.

We can take some examples that people raise that they think are not clear. And what needs to be done to improve that label language. So, I think there's some immediate stuff that can happen in the context of these groups that you're going to pull together anyway.

MR. BRADBURY: Gabriele.

MS. LUDWIG: I think I agree those are very good things to do. I would also encourage whatever group or group of people tackles that to also take a look at some of the court cases that have come up recently. Interpretation in the court of law is what's driving things in many cases. There's one incident where the bees were accused of trespassing, which seems a little odd. This is a case in Minnesota. So, there's some really interesting things that need to be looked at through the legal cases.

UNIDENTIFIED MALE: Is there any reason why you can't have supplemental material on a label, either added

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in or a sticker on, that might help. Of course, that's a nexus between labeling and education. But, it's a matter of partnership between industries to do that. Is there any prohibition on supplementing, adding anything onto a label that way, or in a label?

MR. BRADBURY: Yes and no, and it isn't easy as far as what's enforceable, what's not enforceable, what's advisory. Then, how do you make sure what's on the label people can focus in on? So, yes and how is sort of an issue.

Gabriele.

MS. LUDWIG: Just to build on that, where I think the discussion can go is talk about what kind of symbols or language would be useful. I'm still a little hesitant because there's still a lot of questions about when such a language or when such a symbol should go on the labels.

Also, just be very clear, changing labels is actually very complicated. This is not always the fastest route to get anything done. It doesn't mean we shouldn't be tackling it, but I just want to be clear. You're coming back to how you get something quicker.

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This is not the fastest route.

But I think some discussion about it would be useful. I don't know if I would put that on for the next six months because I think we're still at what's working and what's not working. Then we can get into how can we do it better, which would get at what you're talking about, which is, are there some simple labels. I think, particularly for the home uses, that's a big question mark.

UNIDENTIFIED FEMALE: I'm told by my beekeeper friends that there's a good symbol that would actually be very helpful here, a circle with a flash across it and bloom, no applications to bloom. That would be easily interpretable. You could also say that there are many toxicity properties of pesticides that would benefit from symbols or symbolic representation of toxicity rather than a big long string of words.

MR. BRADBURY: If you don't dismiss any of those concepts or ideas and formats, labels will be in the future. So, hold that thought.

But I agree with Gabriele -- and I think Cindy was saying it, too -- I think our first step is to see if

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we can, with EPA helping, get a cross section of some labels that are on products now. We've done this before. We'll do it carefully so that all that's okay.

Then, get some people together and start establishing what's on a label now that seems to make sense, and it's logical and it seems like people should get it -- I don't mean that in a negative way, but it seems clear -- versus where there are examples where, oops, that's pretty hard to figure out what EPA really meant when they wrote that down. Why was that there?

So, we can start again to get a better sense of what the world is like out there, which then could help us think about next steps, which could be, how does that feed back into the educational programs we're talking about, how does that feed back into some of the training education? You can see where it could then plug into even the case studies in terms of how that could play on the case studies.

So, I think surveying some labels -- Cindy, is that right -- and then (inaudible) at least some representative (inaudible) start to document what seems to be working, what's not working, sort of a gap

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analysis.

So, for myself, on behalf of the program, I think that gives us a pretty robust set of activities to do over the next six months, which will be challenging. But, with help from the work group members, I think it's doable and we can make some progress. Kind of getting our information base clear, getting our gap analysis clear, and then I think that sets up the launching pad for the next steps that we take on.

I'll thank APCO and SFIREG ahead of time for jumping in, and CDC for jumping in as well. We continue to work closely with USDA on this as well as we go forward.

Thanks, everybody. That was helpful. I know we took quite a bit of time, but I think we made some progress. I thank all the folks on the work groups for that effort they put in, three meetings already.

We're going to move on to our first update session. Again, the idea here is to give you a snapshot update on activities. I'm going to probably be pretty firm when I see name cards come up and not recognize them unless I see that we've got time maybe at the end around

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noon. If we're doing okay, maybe we can come back to the specific topics. But, right now, they're just going to report out. The first update from Rick is on spray drift.

MR. KEIGWIN: So, in the interest of time, there is a five or six slide presentation, I believe, in your packet. I'm not going to go through that presentation, just give you a snapshot of where we're at, because spray drift has had much longer presentations at this meeting over the many years. Obviously, the work that has occurred, particularly over the past couple years, has been greatly informed by the efforts of the PPDC in the past.

So, as you know, a couple years ago we developed and issued for public comment a draft PR notice. We received several thousand, in some cases tens of thousands, of comments relative to that proposed PR notice. The biggest issues we've discussed here before had to do with the language about drift that could cause an adverse effect or harm. We acknowledge that.

Drift does occur. Small amounts of spray drift may, in fact, be inevitable, even under the most careful

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application scenarios. Many interpreted the "could cause standard" to be a zero drift standard. That was not our intention, nor does EPA believe that such a standard is currently feasible.

In response to that and after some discussions with many folks up here around the table, as well as some additional stakeholder outreach that we've done, the current approach that we are analyzing and pursuing is one that would prohibit spray or dust drift that harms people or other non-target organisms or sites.

As part of that, there's been a great deal of discussion with some groups about how harm intersects with the FIFRA adverse effects standards. EPA believes that both are wholly consistent. And there's a slide in your packet that goes through EPA's analysis of why we think the standard of harm or no harm is consistent with a standard of no unreasonable adverse effects under the statute.

As part of that better definition or elucidation of what we mean by harm -- and some of this was in the draft proposal that we put forward a couple years ago -- there's a series of examples that are being

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developed, or have been developed, that define what we intend by harm in the context of spray drift and focusing on not having a negative physical impact on humans, on the viability of beneficial insects and other non-target species damage to agricultural commodities, as well as other types of accedences, either water quality standards or tolerance levels.

So, we're in the final stages of analyzing those comments. We are in an internal agency review process at this point. Our current goals remains trying to complete this effort by the end of the year.

MR. BRADBURY: Thanks, Rick.

I'll turn it over to Marty now for two updates, one on the PPDC work group on comparative safety statements and then inerts disclosure.

MS. MONELL: So, as many of you may recall, about three years ago this committee, the then committee, asked the agency to consider the use of comparative safety statements or logos on pesticide labels. We had heretofore not consistently allowed it. A few slipped through, but we basically had taken the position that they were not appropriate for pesticide labels.

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But, in light of sort of recent consumer interest and demand for information about the greenness of products, we agreed that it would be the appropriate subject of a work group. So, we formed a work group under the auspices of PPDC.

About a year ago, we announced to this group the creation of two pilot programs. One is to permit the use of the DFE logo on pesticide product labels, where the product was able to pass our sister organization's DFE, Design for the Environment.

I'm sorry. I'm so used to acronyms. The Design for the Environment is a screen through which the chemicals and a product can be filtered and determined whether or not it's appropriate for obtaining the DFE logo.

Under this pilot, if a product makes it through that general screen, it is then eligible to have the logo put on the label if it also passes our requirements. This pilot, I guess the focus of it is on antimicrobial products. To date, we have had two products that have made it through the DFE screen and our process, two products that now bear the logo. There are four that are

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in cue.

We're also working on expanding this pilot to enable us to get a larger breadth of products and experience with the DFE screen. What they now go through is called the general screen. There are other screens that are more sector focused that we're going to try to work with them to see if other pesticide chemicals might be appropriate for including in this pilot, as well as possibly biopesticides.

The second pilot, if you will, is one we call factual statements. That is allowing pesticide product labels to contain statements that are factual. The first two statements that we thought were appropriate were die free or fragrance free, something that is easily determined through review of the CSF and something that we felt that consumers would want information about.

So, thus far, we've had eight products that have made it through the process in our screening or enable that statement to be on the product label. We recently -- and I believe we spoke about this at the last PPDC meeting -- where we were encouraged by work group members to look at biodegradability as a factual

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statement that perhaps ought to be considered for placement on a pesticide product label.

We did a lot of work. We consulted again with our sister organization, the toxics program that runs the DFE, because they have a screen for biodegradability. They keep a list of approved surfactants that we could use.

So, what we've recently posted, because we knew we wanted to go forward with this program, was a sort of web guidance on how a product could be submitted to the agency to enable it to make a statement about biodegradability either of all of the ingredients in the product, the entire product, or of the biodegradability status of the surfactant in the product.

So, that's up and running as of earlier this week, I believe. Several months ago, Kristie Sullivan of the Physicians Committee for Responsible Medicine, presented a proposal to our work group regarding animal testing. It would involve the allowance of a factual statement on a pesticide product label that the product met essentially the registration requirements of the statute while avoiding animal testing.

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The work group is very interested in this concept and have agreed -- because it's complicated. There's some nuances around. For instance, some of our guidelines require animal testing. So, we have to work around those kinds of issues.

So, we have a subgroup now that's going to be led by Kristie that's going to be looking into some of the options that we might entertain to go forward and present back to this group for further discussion, because we think it's a concept that is timely.

Lastly, we're looking at USDA's bio-preferred program. This was a program that came about as a result of reauthorization of the Farm Bill earlier. I think it was 2002. It provides for the use of a logo -- actually, it's called a mark as opposed to a logo, which is kind of interesting -- on products that have been certified as being bio-based according to very specific standards for both the products themselves and the packaging.

You can go on the USDA web site and find this. It's bio-preferred program. We're looking at a process where we could integrate this congressionally mandated program into our legal construct, if you will, for

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pesticide labels. So, stay tuned for more information on that.

The second item that I have to update you on is inerts disclosure. As you probably all are aware, I hope, in response to two petitions that were submitted to the agency that requested EPA require the disclosure of all inert ingredients that had been deemed to be hazardous under other environmental and other statutes, that we require the full disclosure of those inert ingredients on pesticide labels.

What we did in response to that was publish an advance notice of proposed rulemaking seeking comments on options for increasing public availability of the identities of inert ingredients in pesticides registered under FIFRA.

The comment period closed last spring. We've been sorting through the several hundreds of comments, while also considering our options under our statute. We received a lot of comments that provided us with legal analysis, on the one hand, of our constructs that precludes us from mandating full disclosure to yes, under the statute, you can require full disclosure.

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So, at the same time that we've been mulling through the comments, we've also been addressing or seeking to address the legal opposing points of view. Our plan has been, and continues to be, that we will have options for an approach that will increase inert ingredient disclosure.

I mean, I think that the ANPRM is clear that, as a matter of policy, the agency believes that we should be increasing public availability of this information. So, we're going to present some options to our office director later this month or early November with the ultimate decision on a regulatory approach to occur sometime early in the 2012 calendar year. So, stay tuned.

MR. BRADBURY: Thanks.

Now, I'm going to turn it over to Oscar Morales who is the director of Information Technology and Resources Management Division. He's going to give you a demonstration and update on some new tools that have been recently developed to help assist in what's going on in the program.

MR. MORALES: Good afternoon. Nicos (phonetic)

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and I are what is standing between you and lunch, so I'll try to make this quick. Since I'm the IT manager, though, I must tell the people in here from EPA that have been checking their Blackberrys, it's not yours or your IT guys, but it's down. Some of you got the message, and some of you don't. So, don't throw your Blackberrys away. It's down for the agency at this time. For some of you, you don't have anything. Don't know when it's going to be up.

I'm here to give you a quick update on some projects. As some of you may know, a couple of months ago, internally we started a strategic IT process in which we were going to first examine existing pesticides processes to see if they needed re-engineering and then to determine and to prioritize the IT that's needed for any of these re-engineered processes, even given the resource concerns that we have.

There are a couple of projects, however, that we had already begun that I want to share with you today. The first one is the electronic submissions. As some of you may know, since 2008, we had the ability to receive via CDs or DVDs electronic submissions. Roughly 10 to 15

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percent of our submissions are electronic. These are for section 3s, conventional, the UPs, tolerance partitions, renewed and (inaudible) submissions.

We are about to launch something we're calling e-DEL CA which is, in effect, a better version of what's out there right now. It's a downloadable, simple-to-use, program to help companies assemble e-submissions. Right now, there's about 12 industries or companies that are testing this software out in the last couple of months.

Once we collect their comments -- although there haven't been many negative ones -- we are going to make it available around the 20th of October for those registrants that want to submit their EDST test orders. We're trying to make it ready for broader use by the rest. The instructions are going to be posted on the web relatively recent.

Now, there are two demos that we are not going to show here. We're just going to give you some screen shots in a minute. But when you take a break or if you want to at lunch, for the next couple of hours in the break room, we will have a demo on chem search and on inerts.

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The first one is chem search. We created it because we realized we had so many public separate lists of pesticides -- there was roughly 25 plus -- and they were hard to find, difficult to navigate, and they didn't really communicate the whole story of what happened to AIs over time. For us, it was difficult to maintain so many static web pages.

Chem search is a simple-to-use, online search tool that provides users with a one-stop shopping for all publicly available pesticide chemical information. It's data that was published on the pesticide web site in regulations.gov. It contains roughly 20,000-plus documents, registration, re-registration, cleared science reviews, public participation, and open comments, roughly 800-plus links, and links to other important resources like the tolerance from ECFR and other agency's web sites like NIH's hub chem.

Nicos is going to just roughly go over --

NICOS: Just quickly, this application is not yet live. It is in the pipeline to go live very shortly. So, we hope to have it up on the web site within the next couple weeks. This is what you'll see as a simple

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Google-like search interface where we allow searching by chemical name, cast number PC code, if you happen to know that.

We've also collected a lot of synonyms, around 100,000 synonyms, to help drive this. So, if somebody knows an obscure, say, IU pack name or ISO name, it will help lead them to the right page. We have all these pages organized by common chemical name.

Then, when you get inside of it, here's an example for athrozene (phonetic). We can demo this for you over in the room next door. But a wealth of information about the chemical, a tab structure across the top of where you can find regulatory actions, the science reviews, section 18s and all the dockets that are associated with that chemical.

MR. MORALES: Okay. The second demo that we're going to have out there is what we're calling an inert finder. Our division and the registration division got together and posted this. This will allow a user to search approved inert ingredients dynamically to see if an ingredient has been approved for use, for food, non-food, or fragrance use.

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In inert finder, the ingredients are searchable by ingredient name and by cast reg number. The results also include status, approved status, synonyms, and food use tolerance information from 40 CFR. And, as of about two hours ago, it's now live on our web site. Again, if you go to our demo, we'll give you that web page.

NICOS: Again, here's what you'll see when you go to the web site. This is up live. Some background information there at the bottom, the ability to search again by the chemical name or the cast registry number, if you know it.

On the left, there are some quick links to dynamically-generated lists for the food use and non-food use, the non-food use only in the fragrance list. Then, if you went inside, you'll see, for instance, acetone here is approved for food use.

There are some details about that, including a hot link to the CFR site, which is sometimes a little difficult for people to navigate. Also, there's some information on approved for non-food use and a fragrant list as well.

This will vary depending on the status of a

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particular chemical. We're just hoping that this is a little easier for people to navigate. It does not replace the legal information that's published in the CFR, but as a way to help guide you to easier finding of that information.

MR. MORALES: Lastly, I wanted to remind you of something that we discussed in past meetings, and that's the new and revised PPLS. We've upgraded over 170,000 labels to make them text searchable PDFs. We've offered now new ways to search, including searching by product name or by company name. If you remember the old PPLS, you had to know numbers.

We're also providing information on the status of a product, whether it's actively registered or inactive, and information on product transfers. I strongly recommend if you haven't gone and checked out the new PPLS, that you do so.

If you want to take a look at the demos on chem search and inerts, my folks are going to be in the room next door for the next couple of hours. They can let you navigate and play around with it. Thank you.

MR. BRADBURY: Thanks, Oscar. We've got about

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five minutes. So, we can open it up for five minutes if there's some questions. Then, we'll break at noon and take advantage of the demos if you want. Then, we'll come back at 1:15.

Cheryl.

CHERYL: So, the inerts database, how does that relate to data compensation for approved inerts?

NICOS: Right now, we have a very simple flag at the bottom of the page, which we can demonstrate to you. It's just a big check mark. That check mark indicates whether you need to contact the agency on data compensation or not. It's basically a yes or no question. There's some help text there. But it doesn't have all the details, but it does indicate when you do need to contact the agency. So, we send you to the inerts branch for that.

MR. MORALES: Let me just add that we're going to be having the inerts, this particular inerts finder, as part of the chem search eventually. Right now, we just have the AIs. It's going to be a one-stop place literally by merging them together.

MR. BRADBURY: Caroline, Gabriele, and then

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Susan.

MS. COX: A quick question for Marty about the inerts disclosure time line. It seems like that time line has slipped a little from what you said in the past. Am I correctly interpreting that?

MS. MONELL: No. I said it has always been October that we would present the options to the decision makers. I did recently just say it might be the first week of November, if it's not by the end of October. That's because of things like this. You know, we just get pulled in different directions. But our basic time line is the same as it's been for the past six months.

MS. LUDWIG: This is for Rick in terms of the spray drift. You said by the end of the year it would be completed. Does that mean, then, you start putting the language on the label? What does completed mean, because I need a reminder?

MR. KEIGWIN: In terms of completed, what we're looking for is issuance of the PR notice by the end of the calendar year. The PR notice will go into an implementation or a description of how we would go about implementing and phasing in the new language.

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MR. BRADBURY: Susan, Matt, and Allison.

SUSAN: This is a quick one for Oscar, I guess. Will all of the old links break?

MR. MORALES: Eventually, of course.

NICOS: Well, not immediately. When we do launch chemical search in the future, we are going to have a transition period from the old static pages of the lists of fact sheets or re-registration/registration review, what not. So, we'll put a banner on the top of those pages which will indicate that you should try chemical search for a while. But yes, eventually those pages will come down and they will be redirected to chemical search.

For inerts, nothing is going to break. It's the same. This is a new feature. So, nothing will break in that area.

SUSAN: What about the documents that were archived on the CD? Will those be available? These were a lot of documents on the OPs and their re-registration process that got archived off of the EPA server and off of the docket even onto a CD that you have to ask -- I don't know what it is now, but you have to ask for it

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specifically. Will those documents be included in chem search?

NICOS: I will check into that. I'm not familiar with that. Right now, we are linking to the stuff that is live in the dockets. But if it's been removed from a docket, I think -- I'll have to check on that and see.

MR. KEIGWIN: There was a size of files issue that we had to a certain point remove information. As Susan said, people now have to request a specific CD from us. So, let's have a discussion about how to best make that available in a more user friendly manner for everybody.

NICOS: I think now we can do that, so we will look into that.

DR. KEIFER: I realize that this is probably anticipated to be used by people other than clinicians, but is there some way to link this information to information about the toxicity that would be useful to a clinician, or treatment, or the green book that Jimmy is writing, or something like that?

NICOS: We can certainly, and we've been adding

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links to other government resources such as you'll see in there. We've linked to EPAs DSS tox database. We're linking to the substance registry service. So, we can add more links. Generally, EPA's policy, though, is that we can link to other governmental resources, but we don't link to stuff that's privately published, as a generalization.

There are some exceptions to that. But if you have suggestions about things that would be useful to you, we can certainly add them into what we have now. But we have quite a lot of web services already set up.

MR. BRADBURY: Allison, and then we'll take a break.

MS. STARMANN: For Marty's presentation, the things that you're considering about the human or no animals testing and the bio-preferred, will those either pilot or consider things be available for public comment or how will that be rolled out for broader participation?

MS. MONELL: What we have historically done, since the work group is convened on the auspices of this committee, PPDC, we bring proposals once they're fleshed out pretty much, and that we have a unanimous

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recommendation, we bring them back to this group as being pilots, proposed pilots or extensions of pilots. So, we're not changing pesticide policy or regulatory guidelines; we're proposing pilots to see if these kinds of approaches to labeling issues or the like would make sense in the long run.

MR. BRADBURY: Okay. I want to thank everybody for a really good morning. I appreciate the input and the efficient, effective discussions. The demos are next door.

UNIDENTIFIED FEMALE: You should have some options to eat, meet, and play. If you don't have them in your folders, they're right outside.

MR. BRADBURY: Okay. Then, we'll be back at 1:15 based on this clock. So, see you in a bit.

(Whereupon, a luncheon recess was taken.)

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AFTERNOON SESSION

MR. BRADBURY: Before we get started, Virginia, if you could introduce yourself to the crowd.

MS. RUIZ: Thank you. I'm Virginia Ruiz of Farmworker Justice here in D.C.

MR. BRADBURY: Thanks.

Okay, so this afternoon we'll have two sessions that are fairly extensive report outs from a couple more work groups. The first one being a report out and get some feedback from the full committee on integrated pest management.

Keith Matthews, Director of the Biopesticides and Pollution Prevention Division, will kick it off. But, as I understand it, like the previous groups, we'll get report outs from work group members on where they are, where they're heading and get some feedback from you all. So, Keith, take it away.

MR. MATTHEWS: Thank you, Steve. Good afternoon, everyone. So, yes, I am reporting out on a work group meeting that we had yesterday for the IPM work group. We actually have a group of very experienced and

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IPM experts who are working with us on this work group.

What I'm going to do is we actually -- this is the first face-to-face meeting that we had of the work group. So, we had a fairly useful introductory discussion. Then we broke up into two subgroups. So, I'm going to speak to the introductory portion of our meeting. Then, we're going to have report outs from subgroup one, which will be Marc Lame, and then subgroup two.

Cindy, you and Dave are going to do subgroup two? Yes. Then, we'll have Dave Tamayo and Cindy Baker-Smith will report out for our subgroup two.

So, if I may, the first thing I'd like to do is just review for everyone the charge for this particular work group. So, this work group will provide advice to the agency on one, the development of metrics to assess the effectiveness of the new school IPM initiative, and two, on appropriate ways to assess quantitatively the benefits of IPM and agriculture public health setting and schools, and three, other issues relating to the promotion and use of IPM that the agency brings to the work group. So, at present, we're only dealing with

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charge one and two.

So, to begin, the work group meeting yesterday, I started off with a review of the work group mission and an update of school IPM activities at EPA. This was actually fairly important because, as was pointed out by more than one member, to the extent that we're asking for advice on the development of metrics to assess the effectiveness of the new school IPM initiative at EPA, it would be good to know what's going on with the new school IPM initiative.

I had to apologize somewhat to the group because, quite frankly, the development of that initiative is still in the formation stage. It's still fairly formative. We have a number of ideas that we are working on within the agency, both the headquarters and our regional offices, in terms of what's going to be the actual structure of the school IPM initiative going forward.

We don't have any final decision yet made in terms of how that is going to be structured, but we are moving forward. In fact, this morning I had a meeting with a number of our regional representatives on the

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school IPM front in terms of moving forward. Had some discussions to kind of look into different options for how we as an agency will organize this new initiative. I will report that we're making progress.

One thing that I did promise to our subgroup was that as soon as we actually have a plan going forward, a concrete plan going forward, then I'll share that with the work groups. Then, everyone will know kind of how we are planning to move that forward in the future.

So, once I had kind of explained that, then we got into -- this is the work group as a whole -- got into a general discussion of IPM itself. So, we began with the statutory definition of IPM, or at least one of the statutory definitions of IPM.

There's a definition in the Food Quality Protection Act which defines IPM as integrated pest management, as a sustainable approach to managing pests by combining biological, cultural, physical, and chemical tools in a way that minimizes economic, health, and environmental risks.

So, we had a fairly robust discussion in terms

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of, well, looking at that definition, are there things that we would add to it, are there things that we would detract from it? To the extent that we are asking the work group to help us develop metrics to assess the benefits of IPM, well, it's useful for everyone to have the same definition going forward in terms of what exactly are we assessing the benefits of.

So, the ultimate recommendation was to just keep it simple. Since we have a definition of IPM, it's a definition that's been codified into a statute, why don't we just keep that and just work with that as opposed to -- and this is after about a 45-minute discussion of different ways that we could alter or improve upon the definition -- why don't we just stick with the definition that we have.

So, there was also a bit of discussion in terms of what constitutes IPM. IPM, of course, is managing pests, minimizing health risks, reducing associated costs, how to measure risks or risk reduction. There was a definition given of social risk, which equals exposure times toxicity plus outrage.

We also had an enumeration of benefits that the

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work group perceives to come from the use and the utilization of IPM. So, some of the benefits that were enumerated were that it provides alternatives for conventional pesticides. These may actually result in a lower number of applications, fewer pest complaints. You can have IPM both before and after the utilization of conventional pesticides.

There are impacts, beneficial impacts, on non-target species. There may be decreased risks to non-target species, including humans from the use of IPM. One way to look at IPM is to consider acceptable practices such as monitoring, inspection, prophylactic treatments, eliminating food, water, and shelter.

A concept that came out is that IPM is a process, and that it must be verifiable. This is something that we actually are paying a lot of attention to in the school IPM context. One of the things that we want to make sure as we go forward with the school IPM initiative is that the increase in the utilization of IPM in the school setting is verifiable.

It's one thing to say that -- and this came out in our subgroup discussion, and Marc may get into this --

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it's one thing to say that we, we being an overall noun, use IPM in our school system. But the question is, how do you verify that? What constitutes IPM? Oftentimes, you get different definitions for IPM. IPM in one context may not be viewed as IPM in another context. So, verifiable IPM is going to be a very important concept for us going forward.

Other benefits include reduced costs. A very important benefit, which I think sometimes is not discussed as much as it should be, is that you can actually have reduced health care costs in the future. So, if you're looking at chronic diseases or chronic effects, the utilization of IPM, not using conventional pesticides, can actually have benefits further down in time from reduced chronic effects.

Something else that we as an agency are looking at more today in the present context is the resistance management. IPM can certainly be of benefit in resistance management.

So, I guess the last thing I will point out is that again another question that came up -- and this is actually a very useful question -- for our work group,

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given the charge that we gave the work group, is, well, what is EPA's strategic plan for school IPM? In the school IPM initiative, what is your strategic plan?

We don't really have a "strategic plan" right now. We have an overarching goal. That overarching goal is to increase the utilization of verifiable IPM in the K through 12 school system. In terms of a strategic plan for how we get there, that's coming. That will come as our organizational structure for the school IPM initiative is further fleshed out and established.

So, with that, I think I'll leave that as our introduction to our work group meeting and turn it over first to Marc Lame to report out on the discussions that we had for our subgroup 1. And then, after that, Cindy and Dave will take over.

MR. LAME: Thanks, Keith. Interesting group of folks, and they worked hard yesterday. Also, a few of them worked a little bit hard last night because they sent me some additions. So, there's one extra slide in here. Not any big surprise to anybody, but I did want to say that.

So, moving forward, what can we measure? We

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can measure state and district policies. But, of course, state and district policies have been measured before and have been used as an indicator. Well, they're doing IPM because they have a policy. I've heard this at the district level and I've heard it at the state level. It doesn't mean much, but it is one measure. Actually, MPMA has done a really good job of measuring the state policies, and they've been doing so for years. So, they have that together.

Implementation programs can be measured as far as educational activities, demonstrations, et cetera. Models of integrated pest management can be measured, not only that there's a model in place but what kind of model is it.

It can be an in-house model, where in a large school district, like a county-wide school district, they can -- Mike Page mentioned this -- that you would actually hire somebody that would just be in charge of running the pest management for the district as a professional.

Then, of course, another model would be using a contractor, a pest management professional, a firm on the

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outside. Those can be measured. As well can be measured is the procurement instruments, the contract itself. Do they have verification standards and are those standards being met?

Verified best management practices, such as monitoring, training, treat as needed, documentation, as well as other best management practices, those can be measured. In fact, a number of these things have been measured for years with IPM Star with the IPM Institute in their certification program. So, this has been done for a long time.

Risk reduction can be measured. We had a discussion on that. That's probably going to take a bit longer. Risk reduction, the technical definition of risk is toxicity times exposure. So, one of the things that we've been doing for years is measuring risk reduction just by looking at the number of applications as a matter of exposure.

Toxicity should and will be measured. Because it's such a hot topic, we can still look at risk reduction by looking at reducing the number of applications. That's just one of the measures. Then you

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can also measure degree of partnership, which I will explain later in this. There's more to come when we do have a strategic plan.

In all fairness to the agency, this is something that is in development right now. As Keith just said, when they have it, they're going to give it to us. That will help us more because it is difficult to really put precise metrics to something until we have it.

Shift to integrated pest management program requires added value for the school community. Our group talked about the idea that this is something that the school administration has to have the political will and desire to do. It's what I called, when I gave a presentation in our last meeting, demand side IPM. So, in order to make this shift to integrated pest management in schools, they need to see an added value, which there's a number of different things that would be added value.

Of course, this is, again, why we measure things. Reduced risk to school inhabitants, reduced administrative headaches -- for instance, pest and pesticide incidents -- more efficient pest management --

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that goes to time and money -- school community approval where the school community, in fact, approves of the administrative efforts to provide a safe learning environment.

Then, there are externalities. Every school district that I've worked in that has successfully integrated pest management has always mentioned that their buildings, in fact, are maintained in a better state than they were before. So, that's an externality.

I can also tell you that when it comes to bed bugs, schools that I've worked with that have an integrated pest management program in place are usually asked to be part of the leadership in a community regarding bed bug management.

It also requires partnership. So, you can see the different facets. I left out nursing. I wanted to mention that before you got me, Robin. In the school district, we've gone from the old PCO as an exterminator to a pest management professional that, in fact, is partnering with the school. There has to be a partnership. It's a two-way street to figure out the problem and to fix the problem. Pest prevention is

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everyone's job.

So, this partnership that can be measured and is required for integrated pest management is a documented and evaluated working partnership of a trained diagnostician/educator in the school community based on pest monitoring and information sharing regarding how to monitor, how not to attract pests, how to exclude pests, and how to control pests with the safest, most effective methods. All of those are measurable.

Other partners for demand side IPM, that part of IPM that is value added for the school district administration, is that there needs to be state and local change agents, state lead agencies, universities, health departments, pest management professionals, and children's environmental health advocates. They would be examples of those types of change agents.

Federal facilitators would fall under that as well, but with the particular role of providing support and facilitating the partnerships. Within EPA, we discussed the idea that the Office of Pesticide Programs would work with children's health and Indian environmental programs. The USDA and the CDC also are

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working on school IPM. Again, there are opportunities for everyone to work together on this. This degree of partnership is measurable.

Existing tools for metrics -- this slide I don't believe is in your packet -- these are just -- school IPM has been going on for quite a while. I know that we have 16 years worth of project reports that were required and delivered to EPA as a funding agency for school IPMs. So, 16 years of those -- and we had to put down what did we accomplish and what were the outcomes. So, those are metrics right there. It's something to look at and go back and list what works.

Also, there are logical models for a number of different IPM programs, including school IPM, where they're looking at the short-term, the mid-term, and the long-term outcomes. They're evaluating those outcomes. Those are already out there. So, the point of the slide is so folks know that even though this is an initiative from the agency, the agency has been doing this for a long time. The rap book goes back probably 20 years. Folks have been measuring IPM for a long time.

There's a new tool that's out there, the iPest

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manager that Salt Lake City uses. It's an outstanding web-based program that not only monitors and teaches, but it also measures. It measures pest problems. It measures pesticide applications, both type and amount, that is available. Then, there was an attempt to do a school IPM report card, which there are good and bad parts of. But, nonetheless, they can take the good parts from that report card that was developed several years back as part of a metric program.

So, our goal is to move from what we believe is about 8 percent of schools in the United States that are practicing verifiable IPM to 100 percent.

MR. MATTHEWS: Thank you, Marc. Do we have any questions for Marc on the report out from subgroup 1?

Cindy?

MS. SMITH: I don't have a question for Marc. I would just offer maybe a suggestion, Marc. I think that putting on my school board hat, getting to school board members is the critical piece of this because they're the ones who approve the budget. So, they're the ones that are wrestling right now with do I put money into teacher staff and to books and to curriculum and to

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new playground equipment, or do I look at pest management.

So, I think that your point about what's the value proposition for schools is really an important point. I think if you included some school board members -- I don't know if National School Board Association is the right place to go, but I think if you could get them somehow engaged in your partnership discussion, because they're the ones who are going to adopt the board policies in a number of states and they're the ones who set the budget for these kinds of things. So, there might be an avenue there to talk to people about how they do it that way, too.

MR. LAME: I couldn't agree more. I mean, they are the elected decision-makers regarding schools, their policies, and their budgets. So, that's very important.

The group also discussed the idea of what is happening with school IPM. Most of us agree that it's really moving into an exponential phase. Part of that reasoning comes from the fact that in the past two or three years, we have gone to many more school business official meetings, plant manager meetings, and school

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board meetings, and association meetings. It's my opinion that when you go to schools these days, they know what IPM is; whereas, five years ago most of them did not. That's my opinion.

MR. MATTHEWS: Robyn.

DR. GILDEN: Real quickly. I don't know if this was discussed or I'm not even sure how it would work. But when you say K through 12, is it public and private schools or just public?

MR. LAME: For now, to begin with, we're focusing on public schools.

UNIDENTIFIED MALE: This question is as much for Geoff Calvert as it is for you two. Geoff, is there some way the censor system could be used to monitor decreases in pesticide reports from schools?

DR. CALVERT: As I said in my introduction, I kind of oversee the pesticide poison surveillance program across the country. We did write a report in the Journal of the American Medical Association back in 2005 that documented the numbers of pesticide poisonings associated with pesticide exposure at schools, both pesticide use at schools as well as off-target trips from agricultural

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operations neighboring the school.

So, we did that in 2005. We haven't updated it recently, although yesterday when I got back to my hotel room, I got an e-mail from a colleague saying that there was just a big school outbreak at a school in Cincinnati. They applied a toxicity one herbicide to the athletic field that drifted into the school and sickened like 50 people in the school.

So, as a result, the person who was the lead author in that 2005 report said, hey, should we update the 2005 report. So, I think we're going to do that, or at least try to do that. But our resources for our program are diminishing. Even the support that we get from EPA is decreasing. So, our resources are smaller and we can't do as much. With the resources we have, we'll try to do something with that.

UNIDENTIFIED MALE: As far as reporting goes, one of the things that we hope to do with the Salt Lake City instrument, the iPest manager, is to have that available to any school district that wanted it in the future.

Then, there would be reporting on that with

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regard to not only pesticide use, but it would be nothing to put incidents on there. So, that would also work with CDC, with NIOSH in particular. Also, CDC is doing workshops for county and state public health folks throughout the country on insect and rodents, and that includes schools.

MR. BRADBURY: Jennifer and then Tom.

DR. SASS: What's the ability of people that do that kind of work with schools, like what you're describing to us, to reach out to daycares?

UNIDENTIFIED MALE: Technically, it's the same as far as the type of pests. Of course, you're dealing with children and trying to protect them that way. So, there's a tremendous overlap. I would say this, that daycares are small businesses, typically. I mean, there are some like Head Start that are not. So, they have a different model of management. So, there is some difference. But as far as overlap and ability to do it, I would say yes.

What do you say, Tom? You've actually certified both.

DR. SASS: My question is to actually do reach

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out, like to do outreach to them and to contact them, to educate them, to get materials to them. With the school systems, you know how to contact them. But like the daycares are small (inaudible) all through the place. So, are you able to do effective outreach to them?

UNIDENTIFIED MALE: I don't know that we've really tried to any great extent, certainly not in-home daycares, probably California, formerly at Perdue, and now in Arizona. They've probably done the most extensive work in trying to figure out the childcare landscape.

MR. TAMAYO: Can I jump in?

MR. BRADBURY: First, Tom, did you want to let David jump in and then I'll get back to you?

MR. TAMAYO: I just wanted to point out that there's a recent program that was funded by a grant from California DPR to a group out at San Francisco that specialized in getting health information out to daycares. That was previous to taking on an IPM.

So, they were trying to figure out a model -- or actually, they were working on a model to deliver IPM information to daycares and then also to preschools, which are kind of different sorts of things, two

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different projects. But they're pretty far along. They should have some good information on what works and what doesn't work.

One of the things that they were doing was piggybacking on existing networks of providing health information and other types of information to that network of small businesses.

TOM: One of the issues that didn't come up in your presentation, Marc, and I don't know if it came up in the session because I was on the ag side, was the potential benefit of increasing consumer and taxpayer awareness and appreciation for IPM by getting IPM in all of our schools.

It's certainly one of the reasons that we got involved in school IPM back in 2000. Public awareness and appreciation for IPM is stuck in the mid teens, and it's been there since the early 90s, since Cornell has been measuring it periodically. You compare that to organic where nearly all consumers are confronted with organic every time they go in the store.

IPM was just absent in the marketplace because it has no currency there because people have no

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understanding of it or appreciation. That leaks out into our public funding as well. Public funding through USDA for IPM programs has declined by 36 percent since 2000 and by 29 percent since 2010. We really need to build the public base of support for IPM, certainly in support of organic and sustainable as well where funding has increased on USDA.

So, I think the EPA should think about that in their strategic plan as a real benefit. If we can get IPM in all of our schools, it potentially has benefits to agriculture as well down the road. If you want more information about the IPM funding situation, you can look at IPMvoice.org.

Then, my final comment, in terms of the timing for the EPA's strategic plan for school IPM, it would be great to be thinking about the IPM symposium in March in Memphis, the 7th international IPM symposium, as a place to showcase that. Assistant Administrator Owens is on the planning program for that. EPA has organized a session as well. That's the end of March in Memphis. The last time we had over 700 IPM professionals there.

MR. BRADBURY: We're plugged into this to

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planning and getting abstracts.

Caroline.

MS. COX: I just wanted to add to what Dave said about the California project regarding IPM and childcare centers. They did produce some really nice outreach material, kind of a handbook for doing IPM and a little IPM checklist that a daycare center can hang on its refrigerator. All of that stuff is available for free download.

So, if anybody has contacts with daycare centers and wants to send it out -- I mean, I think it's oriented around pests that are important in California, but it's probably applicable to the common pests in most daycare centers.

MR. BRADBURY: Robyn and then Mark.

DR. GILDEN: I just wanted to mention that the Children's Environmental Health Network also has a nationwide program called the Eco Healthy Childcare Program, and pesticides are a very big part of that and IPM in daycares.

MARK: I know that in my discussions with EPA on this, you can look at the funding. The funding for

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daycares for IPM in daycares goes back almost as far as IPM in schools. It was a choice to look at schools first with an idea of moving on to using IPM in other sensitive accounts, daycares, hospitals, elderly care, because so much of it is similar.

I can also say that EPA funded a program with the Indiana Department of Environmental Management probably eight years ago where they actually have a star rating program for different businesses. One of the businesses is daycare where IPM has to be part of it for them to get that certification, and with lots of outreach materials.

MR. BRADBURY: Geoff.

DR. CALVERT: So, I also wanted to make another point about daycare centers. So, in that 2005 report that I described that we published in the journal of the AMA, we looked at rates of poisoning for adults, for children over the age of five and for children under the age of five.

So, for adults and children over the age of five, the rates were pretty much stable, maybe decreasing a little bit. But for the kids under age five, the

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daycare center kids, their rates were actually increasing over time. So, I think that's another argument that maybe we need to focus more resources on daycare centers.

UNIDENTIFIED FEMALE: Were there classes of pesticides that rose or was it just in general?

DR. CALVERT: I don't think we drilled down to that level in that report. We could probably do that. When we update the report, we could explore that.

UNIDENTIFIED FEMALE: Because with the adult, what we're seeing, not surprisingly, and maybe good news or certainly a step forward anyway, is that the OP poisonings are going down, right. But then we see like pyrethroids and stuff sort of going up as their use is replaced. So, the poisoning is less severe. The endpoint is less severe, but we're still seeing that. So, I was wondering if that trend was also in daycare.

So, I guess, maybe to recommend that this get compiled, some of this really good information get compiled with your work group so that it can be available for us.

MR. BRADBURY: That was a good lead in. I was going to ask Steve, Marc, in terms of your next steps for

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this part of the effort -- I greatly appreciate the point where the strategic plan comes along. That provides some focus, clearly. We're working, as Keith said, with the regions and having meetings these last couple of weeks and starting to get the structure together which will help facilitate getting the function, the strategic plan and the tactical plan, in place.

But, in the meantime, to what extent are some of these sources you summarized at our fingertips, we, collectively? Just idle and wait or is there some effort that could be done in terms of cataloging, making sure we're up to date? I imagine there will be different aspects of these metrics you measure and will probably be all relevant to some degree as we get started.

So, I'm just sort of curious are we in a holding pattern or is there some effort that could be helpful even though you don't know exactly what the strategic plan is going to be yet?

DR. LAME: There is a lot of resources out there. The Institute has compiled a lot of them. The short answer is that I don't believe that we need to be in a holding pattern. We have lots of stuff we can be

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moving forward on. It depends on what Keith feels the work group can do. I know that anything I have anyone else can have. There's a lot of stuff out there.

I do feel that there probably should be some coordination with the measuring tools that we have right now, at least to get them to where they are up to where when the initiative really gets going, that they're going to be used and they have lots and lots of measurements. The work group can truthfully just catch up with that.

UNIDENTIFIED MALE: Actually, I think that's a very good answer, Marc, so we will make plans and make sure we're moving forward. While we, EPA, develop our organizational structure and our strategic plan, that we also involve the work group with making progress on the data and information that's already out there.

MR. BRADBURY: One of the things I'm thinking is insuring that this will all be public and posted and what not for everybody to see. Obviously, we've got to do some work internally to get the strategic plan together. We have folks across all the regions that will be part of that.

But if the work group can be helping to get

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pointers, examples, or illustrative activities that have gone on using the various tools that this work group defined to show sort of how it's working, that can help inform some of the strategic and tactical planning that will be going on.

So, I guess I encourage Keith and the work group to think about some ways that make it easier to drill into some good examples or some insights into how these different metrics complement each other or maybe sometimes confuse it because they're not --

I think you're getting at the point that documenting some things doesn't necessarily mean other outcomes are happening. It might be helpful to pull that together. I know this sounds a little amorphous but citing some real hands-on sort of cases studies or examples might be helpful.

UNIDENTIFIED MALE: I was just going to say that I'm pretty sure I understand what you're talking about. We can do that. I can even think of how to funnel it to Keith's group to where it's available to everyone.

But I also note, Tom, you just completed a case

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study, right, or is it in the works on the economics?

TOM: We just finished the business case for a school IPM document. That's on our website. We're also creating a three-prong measuring tool, the second generation of state report card in terms of what activities are going on in the state, what laws are present, how many FTEs in the state are working on school IPM.

There's a school district level survey that was piloted in Oregon last year and had over a 40 percent response from each school district. So, we've revised that and want to roll that out in every state over the next year.

Then, the third piece is the PSP program and the metrics for schools that want to participate in that program and earn the highest level participation. So, we have those three pieces that we can contribute immediately.

MR. BRADBURY: Anybody else on this specific topic? We'll have time if you could come back around and sit back and take a look at the whole effort before we wrap up the session.

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Keith, next group.

MR. MATTHEWS: Thank you, Steve. The second subgroup was actually looking more generally at how best to measure the benefits of IPM and agricultural public health and other non-school settings. The genesis of this charge actually came, I don't know, a year or so ago when we were sitting around talking.

I'll admit that I'm somewhat new to this. I've been involved with this for a couple of years, so I come at it with a different perspective. Sometimes it's a perspective of someone who just doesn't know. So, I was talking to my branch chief, Tom Brennan, about well, Tom, what's out there to determine or to help assess and calculate the actual benefits of IPM?

IPM is one of those things that's feel good. I mean, obviously, IPM is good. Everybody knows IPM is good. But why is it good? How is it good? How good is it? So, it turned out, in talking to Tom and to Frank Ellis, that as far as we know, there really aren't good metrics out there for really assessing the actual benefits of using IPM versus non-IPM approaches.

So, we thought this would be an area where this

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particular work group could really help us at EPA out because obviously, as I say, everybody knows that IPM is a good thing, but sometimes you have to be able to quantify how good it is. So, that's what this second subgroup is working on.

Dave Tamayo and Cindy Baker are going to report out on the discussions that our subgroup number two had yesterday.

MS. BAKER: So, thank you, Keith. Dave and I agreed that I'll do the first half and he'll do the second half.

So, the specific charge for subgroup two was to discuss the appropriate ways to assess quantitatively the benefits of IPM and agriculture, public health settings, and schools. So, we kind of carried into our work group meeting the three buckets, what I called them, that Keith identified in his introductory remarks, which were managing pests, managing risk, and assessing cost.

Then, we just started talking about what are some of the metrics that would target those three areas, so things like, first and foremost, pest control. Did you control the pests? What about resistance? What

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about treatment thresholds? What about training and education about the best way to manage pests? What about impact on beneficials? What about reduced exposure both to the pests and to the treatment of the pests?

In the area of managing risks, we talked about environmental impact. We talked about exposure. We talked about toxicity. We talked about risk of the pests to human health or crops or whatever the case might be there, and managing the risk to human health. So, it linked in quite nicely, I think, to the IPM definition that is in FQPA.

We also talked then about assessing costs, costs of controlling the pests, costs of not controlling the pests, costs of health care related events associated with pest control and ways to do that.

One of the themes that I think has come out in Marc's remarks and in the discussion that we had yesterday was let's not reinvent the wheel here if we don't need to. I mean, to everybody's point, we've had IPM around for a while. We've had some programs around for a while.

So, let's begin by looking at things like Tom

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talked about, the national IPM evaluation group and the logic models that they have there. Maybe start with something like that and say, now what's missing, rather than how do we start from scratch going forward with some of these things. So, I think that's kind of the flavor for how we try to put into buckets the different areas of metrics we could assess there.

Dave is going to talk about information sources and the rest of our discussion.

MR. TAMAYO: Cindy mentioned a number of different areas we'd want to look at. So, we kind of spent quite a bit of the session trying to brainstorm where we could get that type of information, who could we work with to help get us more information and interpret it, and, really, kind of like what's a meaningful way to use this information either to synthesize this or to communicate it out or really understand what the heck does all of this mean.

I'm going to reflect that we didn't really come up with some grand answer of how to do this, but we did come up with some ideas of existing places that we could go for information and tools to use and partners.

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Some of the very clear sources of information will be pesticide use data. Obviously, California identified the California Pesticide Use Report database as a very strong source of data. I expressed a frustration that maybe we're going to be hampered in our ability to do this on a nationwide basis because there's not comparable information. There were alternative viewpoints that there actually are some private -- I think it's Doane marketing research has some data available that can be used to support knowledge of pesticide use patterns.

So, the data that's out there obviously needs to be used. We need to identify whether we need additional data. So, that's a question that needs to be answered, and what level of effort do we need to go to develop new sources. That was just kind of left hanging.

Now, a lot of the information sources are going to be from partners, people who are already very much involved in this, or, say, for instance, people in the health professions. The National School Nurses Association would be one source of information.

Where is the data that indicates where there's

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some health impacts associated with either pest pressures or pesticide use or a combination of the two? The American Public Health Association and trade associations like the American Mosquito Control Association. Then, some of these organizations that we might partner with might have some already really good systems for evaluating how good their IPM system works.

So, the Golf Course Superintendent's Association of America apparently works pretty hard to evaluate the IPM efforts of their membership. I hope I'm representing that correctly. But knowing that organization, I wouldn't be surprised.

Then, the Loadi Woodbridge Grape Growers (phonetic) have a Loadi Roles program, a sustainable vineyards program, that could be potentially a very good source of information and methodology, really, for how to do this.

It came up once again that there's a national IPM evaluation group. Some members of the group -- and I'm not that familiar with it, but a number of members of the group thinks that's a really great starting point. That's a tool that may answer many of these questions on

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how to evaluate this.

Now, there may be a need to develop data sources to plug into that or to get people to use it correctly. But that's actually an existing set of tools that seems like there's a lot of good potential to use that. That's obviously an avenue that we should explore.

It was mentioned that there's a system called Prime which is used for assessing the potential for a particular pesticide use at a particular place that are causing impact. It will rate the different potentials. So, I think that there's a tool that's available to look at both retroactively and looking forward to evaluate impacts anyway.

So, other partners that might be involved on this are the CDC, commodity groups. The National Potato Council apparently has done some good work in implementing an IPM survey of their growers. They may have some information that would be useful.

Then, there's various types of ways of looking at the benefits. Some of the things we came up with were looking at benefits of IPM. Some of them were looking at level of implementation, which I think is still a useful

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thing to do.

These are some kind of specific types of things that we might look at to give us some insight into some benefits that may have accrued from IPM. It's not clear how we would use these in some ways. So, for instance, looking at sales of particular products or active ingredients going up or down, but within the context of what was going on with the crop at that point.

Looking at crop profiles over the years. Apparently, there's a set of USDA crop profiles that look at how were these things done 20 years ago. I don't know what the time scale is, but it sounds like it was at least 20 years. What's going on now? So, were there reductions in pesticide use, pesticide exposure? So, those might be some very helpful sources of information for us to look at for what the benefits would be.

Looking at trends in equipment that are coming out. Are there more types of equipment that are being sold and made available to the users that are associated with IPM or reduced risk? Looking at other ideas or looking at EPA reduced risk registrations and tracking how chemical manufacturers and pesticide products changed

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through the years with respect to reducing toxicity.

So, those are some examples of sort of looking at sort of more specific things. Then, I guess the one thing that seemed to be pretty clear to the group as a whole is that it would be really hard to just sort of mush everything together and say, yeah, there's an IPM benefit. You can't do that really on a national or regional basis necessarily.

But the most useful way to look at it, or at least to illustrate it -- I didn't even think about it -- is sort of like a commodity by commodity and maybe a reduced limited geographic areas, case studies. This is how it worked. These were the benefits. Looking at those in a fair amount of detail so that you understood that if a pesticide use went up or down, was it because of just the weather or a number of other factors, something to do with registration, or was it because people figured out how to do this better.

But looking at specific subsectors in a sufficient amount of detail and with some very deep understanding of what actually went on there. We came up with three likely candidates. It was actually kind of

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agreed that if you looked at too big of an example, that it would be too complicated. So, maybe corn wouldn't be a good example because it's just so big and so varied across the country.

So, we came up with potentially looking at almonds. There's a lot of information available on what's been going on with that -- so, we volunteered you to come up with a grand scheme of how to do that. Thank you very much -- and mosquitos and potatoes. Three of my favorite subjects.

I think one of the clearest sort of action items was let's really work on that idea of figuring out how we're going to pick a case study and what would that be. I think that was pretty clear that we needed to do that. I think the overall sense was yes, we got some good ideas. Some of these ideas we need to develop further and come up with a more concrete way of looking at that. But let's say we made some good progress.

I'd also like to say if that sounded a little rambling, that probably reflected the nature of the discussion, too. But we covered a lot of ground.

MR. BRADBURY: Thanks, Dave.

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Mark.

MARK: I actually think that USDA and USEPA have at their fingertips a lot of the kind of information that you're after in crops in the pest management strategic plan process, such that, for example, we just turned in one for apples and cherries this year. We updated our last one. They're very explicit, very detailed, have a lot of statistics, and identify a lot of the changes that have happened.

In fact, the changes may not be going the way you think they are. Reduced spraying may be going the other way in some crops, things like that. So, there's a template out there for you to look at anyway. With invasives and things like that happening, it is going the other way.

MR. BRADBURY: Robyn and then Gabriele.

DR. GILDEN: I just wanted to say if you're interested in IPM in hospitals -- I think hospitals and health care are like the fourth largest sector -- there's an example of an IPM project with the Maryland Healthy Hospitals for the Environment and the Maryland Pesticide Network. They've been doing it for a long time. They

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have advisories and technical assistance. So, they have a lot of information, too.

MR. BRADBURY: Gabriele and then Jerry.

MS. LUDWIG: Well, speaking of case studies -- and I have no problem with almonds being part of this, okay, because we do have a lot of information -- I think coming back to Mark's point, one of the case studies needs to be something where you do have a new pest coming in, whether it's apples on the East Coast or the wine grape situation, and how that got handled.

We are finding a bunch of IPM programs being completely scrambled by new pests. So, I'm with Mark that some of this underlying assumption that everything is moving towards less product or lower risk products and that that's the only measure of success, it doesn't account for the biological variability. That's always my concern in these discussions, how do we account for that biological variability. I realize it's a hard question, but I'm just saying, how do we do that?

UNIDENTIFIED MALE: One of the things that we discussed a little bit but didn't come to any conclusion on was the need to look at things on different scales.

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So, like, the example that you gave, there's a way of approaching invasive pests as integrated pest management. That's a larger scale than an individual commodity.

Then, the other thing is time, looking at things over time. Certainly, it's going to go up and down. Pest pressures are going to go up and down, some reaction, and the need to adjust. Oh, if we do this a little bit differently, then maybe we won't have that problem in five years, after you've learned there's this new pest or something else changed.

So, I think that's something that we really need to look at. I think your knowledge of the almond system could provide some really good examples of how scale makes a really important difference in how you look at things.

MR. BRADBURY: Jerry.

MR. BARON: As everyone else is making suggestions, I'll throw one at you as well. Shortly afer FQPA, there was a process started from the agency developing transition plans for a couple crops. I recall Hetch Mino (phonetic) spent a lot of time on peaches. There was a lot of collective effort put in, both by the

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agency registrants and USDA.

That may be one to at least track down that old document and look at it, because I think it will give you some real good baseline information of where we came from, probably even more detailed than some of the strategic plans, pest management strategic plans.

MR. BRADBURY: I've got a question, two actually. Oh, sorry, Louis, go ahead.

MR. JAKAI: I just thought I should mention that we need to talk a little bit about the fact that IPM, no matter how we measure it or want to measure it, is not static. It's a continuum. We look at time periods. This is important, particularly -- Marc, I think, mentioned something about turning in a new strategic plan for apples.

I would assume that in that particular case, even if they use a pesticide or saw a decline in apples, with the brown (inaudible) stink bug, it's going to swing back in the other direction. But that doesn't take away from the fact that at some point there was a decline.

One would look at time periods. That's the way we're going to have to look at it, not an indefinite time

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to make the point that there is a gain and there are benefits to it.

UNIDENTIFIED MALE: So, I was part of the work group with Cindy and Dave. You guys did a great job reporting out. But after we met, I thought more about the case studies and I realized that there's something like what Ray mentioned this morning with the pollinators, talking about the need for case studies, looking at both the model programs as well as the programs of what went wrong, what could we have done to prevent that situation.

So, I'm thinking with our case studies, in addition to writing up model programs, also write up situations where IPM wasn't present. This is what happened. Maybe if IPM had been adopted or used, we could have prevented those problems.

With our pesticide poisoning surveillance program, when we write reports, typically, one of our recommendations is the need to implement IPM. So, we have lots of case studies for the situation of what went wrong for here. We'd be happy to share those.

MR. BRADBURY: Michael.

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MICHAEL: I'd like to add on to what Gabriele said. Just a cautionary note. Mosquito control has been conducting IPM for over 100 years. We do it because it works, not because it lowers pesticide load. It's because it works.

Lowering of pesticide load in the environment is a welcome outcome of it, but it's not the reason why we do it. That's not a distinction without a difference, because once you go to where your goal is to lower pesticide load, that gets warped in a lot of ways. It's happened with mosquito control in the past.

Whereas, if you did an aerial application of nay lead (phonetic), which is a hot chemical -- I'll admit that -- at one time in the season, you might have foregone 8, or 9, 10 different applications of a less toxic pesticide later on.

I've also run into situations where in the race to utilize less pesticide or less adulticide, people are saying, well, we've got an epidemic going on, and we need a larvacide. No, you don't need a larvacide. You need an adulticide. So, it's just a cautionary note.

I'm not saying that we should use adulticide

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right off the bat or anything like that. All I'm saying is that if the reduction in pesticide load becomes the goal and not an outcome of what you're doing, you're going to run into problems sooner or later, at least in mosquito control. With cockroaches, I'm not familiar with that. But I'm dealing with potentially lethal diseases here.

When you serve at the pleasure of the public, you better be controlling mosquitos, regardless of how you do it. But the best way to do it, again, is integrated pest management. How we're going to measure that is going to be very, very difficult, because the ones that are not likely to be using integrated pest management is the guy who is on collateral duty on the roads department out in Lizard Thicket, Idaho.

We have no way of getting the information about that person anyway. Whereas, if you go down to Florida in the districts, yeah, they're very well represented and they all practice IPM because it works. That's why we do it; it works.

MR. BRADBURY: Caroline and Dave.

MS. COX: I'm part of the IPM work group but I

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wasn't able to attend the meeting yesterday because of the conflict with the 21st century toxicology meeting. I did have one thing that I just wanted to toss out, which is, if OPP would really like to make a significant commitment to IPM, I think that one of the really important things that OPP could do would be to consider IPM in the registration of pesticides.

A product that is a broad spectrum product and is being used and the use that's being proposed for it is a very non-targeted use for it, it really doesn't fit in an IPM program. I think EPA should consider that in the registration process and maybe with an eye towards promoting registration of products and uses that are really IPM compatible.

MR. TAMAYO: I just wanted to point out that I am from Lizard Thicket. Actually, I wanted to make it crystal clear that our discussion about IPM was not just focused on how does it reduce pesticides. It also was how does it provide better pest management. It's like a co-equal goal.

The fact is pest management is what we were talking about. The other things -- while reducing

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overall risks. I think it's risks from both pesticide use and from the pests.

MR. BRADBURY: Ken or Marc, if you could describe -- I won't get the words quite right, but the State of Michigan has a program where growers can -- and I won't have the label right, but the Minnesota Department of Ag or Natural Resources looks at all sorts of practices, worker protection practices. I think IPM is included in that.

They go through a fairly rigorous evaluation process, auditing process, to confirm that this cherry producer or this apple producer is following (inaudible) stewardship. I don't know if that's the right word, but it's a process to go through. I'm pretty sure, as I recall from visiting with you guys, that there is an IPM or some aspect of pest management tactics that are employed.

I was just wondering if you could share that with the group. That may also be sort of a --

UNIDENTIFIED MALE: We have a certification program in the state called MEAP. The MEAP program is a grower -- it was initially a state program but the

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growers and landowners in the state really appreciated it because what it does is that it puts them through a whole series of things. For example, I'll just give you an example out of cherries and the management of harvest of cherries and delivering them to the processor.

These people in their warehouses in their handling of water, in their pesticide applications, the residues resulting from that process, all of that stuff is monitored. They track it over a number of years. To get MEAP certification in that arena, they have to meet certain standards. When they get that MEAP certification, then they're reviewed periodically. So, that's an example of one.

Another one is, say, corn production. Such considerations as rotation, chemistries used, GMOs are not, what kind of runoff occurs, whether or not they're using sustainable practices in terms of cultivation, et cetera. So, that's another example.

So, MEAP certification is something that's handled by the state. The standards are manual stick by crop. So, to be MEAP certified, for example, I think in the apple and cherry industry in Michigan, well over 70

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percent of the growers are certified. That would be also targeting things like runoff, not only insecticide, fungicide, rodenticide, but nutrient runoff would be a real big target.

So, the standard is about 270 criteria long. It's adjusted variously by crops. I think in terms of (inaudible) crop growers in Michigan, a lower enrollment, but in terms of acreage, very significant. Well over 50 percent of the growers I think in major areas are certified.

So, it's a certification process across a whole series of things, including hiring/firing practices, management of people, et cetera. So, it's much more comprehensive, but there is the pest management component which is very important, and also the nutrient and water use.

MR. BRADBURY: Thanks.

UNIDENTIFIED MALE: The question is, what is the benefit to the grower? If you're MEAP certified and you're selling into a marketplace where a lot of export products today are run through a screening process and you want to get your product to market, being MEAP

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certified in Michigan is huge, a huge opportunity for you and market access. So, it's an assurance program put on by the state.

MR. BRADBURY: Thanks.

UNIDENTIFIED MALE: Well, it is a voluntary program. The State Department of Agriculture has a key role in making sure that people are walking through the process here. It is fairly rigorous in terms of what you have to do to become environmentally certified. There are different systems in terms of cropping, livestock, farmstead, and so on. Some growers have achieved all of those things; some have achieved some of them.

There are some regulatory advantages that you accrue if you go through the process. That would be along with some opportunities in the marketplace that our growers are visualizing there. That's the hook to get people to do things. It's a pretty rigorous program to go through. It is not going to be free. You're going to have to make some changes. It's a state program.

UNIDENTIFIED MALE: Another comment on that. That is that fuel storage and management are all part of that. Pesticide storage and management are all part of

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that. If you go into a meat certified farmer who is storing pesticides on his farm, not only does he have to have the fire end of it but he has to have the retention capacity. The refrigeration processes, all of that, it's a very comprehensive program.

UNIDENTIFIED MALE: I just wanted to mention that there are a number of systems like that out there in the private sector, too. The Food Lion, for example, is non-profit certifier that requires IPM practices for their participants. They certify millions of acres in the U.S. The Rainforest Alliance is another, certified mostly in Central America. Massachusetts Partners With Nature is a now defunct program. But all of these programs have measuring tools that help identify how much IPM you're implementing.

These days, everybody is doing some IPM. The question is really how much. These lists of standards really give you a measurement tool to assess the state of IPM in a specific crop and area, because all the key IPM practices are there.

You can say the industry is doing 80 percent of the available practices now; whereas, 10 years ago they

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were doing 40 percent. The potato industry is implementing a large on-line survey this fall for the first time using that type of model.

MR. BRADBURY: Gabriele.

MS. LUDWIG: A quick question to the Michigan guys. Who pays for it?

UNIDENTIFIED MALE: Well, the Department of Agriculture has some regulatory authority and they have a couple of people on the ground to do those things. So, there is some state money that goes into this training and so on. But the producer is going to have to implement some things on the farm to be able to qualify with these.

I guess I couldn't tell you, Gabriele, how much people spend to do this. Easily, in terms of some of the things you're going to have to go through with some of the engineering kinds of things and so on if you have to make some changes, it could be in the thousands of dollars.

MS. LUDWIG: I guess my question wasn't concise enough. I would say for almonds, when we explored certification, it didn't make any monetary sense. So,

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for us going with certification was just not an option. We do not see anybody paying us for the cost of doing the certification. What we do have is a voluntary program that is based on practices. The concept is the same as going through and defining what are the best management practices.

Actually, the pest management modules, rather than going by pest, is based on the IPM principles. So, what you do to prevent with a list of practices, what you do to monitor a list of practices, depending on what the issue is. Then, if you do need to treat, how do you decide when and how to treat a list of practices? So, the whole module is based on IPM.

It's also the same idea of best management practices, how many are doing what. But I just want to be very clear that for us, certification is an absolute no go because at the end, it comes out of the grower's pocket and we don't see anybody willing to pay for that substantial expense.

I'm not even talking about implementing any changes. I'm just talking about paying for the certification, someone to come on the farm and verify it.

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So, that's what I was trying to understand for the Michigan model, how is that working?

We are struggling with the question of what's in it for the growers, and would like to see some more tying it in with some of the regulatory issues. Certainly, in the marketplace it will make a difference, but that's definitely been, I'd say, one of our questions, what's in it for the growers?

UNIDENTIFIED MALE: Our program is not designed to be -- you go through a certification and so on, but it's voluntary. There's no requirement. We've got a lot of growers yet to go through this thing. Some of them don't necessarily resist but they just don't want to go through all of those things.

There is certainly a cost to the individual farm to be able to qualify with those. But again, it's voluntary and nobody is going to say you're going to have to do this.

USDA has some support systems for implementing various practices. With the marriage of the state system with the federal system for various conservation measures, fuel storage, sites where tractors are washed,

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et cetera, and capturing of the effluent from that process, there are federal dollars available in a competitive mode.

This MEAP thing shakes hands with that process. Some of the infrastructure resources come that way. But it's really true, as Ken said, that the growers are the ones who pay the price.

MR. BRADBURY: I didn't mean to divert us from the overall conversation, but I was just trying to explore some models that are in play that might have sufficient data, information, that can be part of those case study options we're looking at in terms of helping you take a look at some programs over time and get a sense of what kind of IPM practices were in place and how does that track with the various metrics.

People are talking about everything from effective pest control for resources invested and diseases averted to different patterns of pesticide use and how that all sort of lines up with different kinds of IPM practices or models that may be in play in different sectors.

I apologize if I diverted us a little bit, but

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it was a way to kind of probe about some other places where there may be programs and data that could be tapped to explore some of these.

The observation I had when I heard Cindy and David talk was at first I was going, where is this going. I was hearing all these different metrics from lower risk pesticide use to X, Y, and Z. I'm trying to think in my head about how all those things happened. How would we trace it back to trends in those parameters, including diseases averted or whatever, something like that, or productivity maintained and all these other metrics, and back to an IPM practice so you could sort of see how that plays out?

I was thinking some of the same things about over time pest pressures are going to change and systems have to be adapted. It's a combination of controlling the pests as optimally as possible and optimum from a lot of different perspectives.

Then, David sort of came around second base, coming towards third, and coming back to home plate. It started to kind of jell as to how we could maybe find some case studies that could get us some experiences and

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some insights as to how would you even do this and what are some of the maybe straightforward ways to do it and what would be some of the conundrums of trying to set up a set of metrics that are actually tracking some of these issues.

Tom and some others have been saying that some of these things are in play. The idea is you could maybe document people have done this following IPM practices but then being able to link that up to mosquito larvicide populations kept below a critical threshold or pests in cherries kept below the economic threshold with less dollars spent. I can imagine all the different metrics that can be in play to do that.

I think it would be helpful if the work group could continue to explore two or three different scenarios. Maybe you would have to look at a wider universe to figure out two or three that might be practical and doable.

I think the hospital scenario would be a good one to explore, as well as a mosquito control scenario, public health pests, and then picking an agricultural production system. Those three sectors seem like good

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sectors, the hospital and maybe something else, retirement homes.

But that's sort of part of the world. Crop production is part of the world. Public health pest management control is part of the world. Don't try to get the case study done over the next six months, but do some research, if you will, to figure out which systems have the highest probability of getting us the kind of information that we could explore, how close we could be to being able to track that, as well as what some of the challenges are in terms of the information that would be needed to link in IPM implemented, boom, boom, boom, but also what are the outcomes of that in terms of all the different components that IPM is all about, detecting the pests early, what kind of components were put in play to control -- at the end of the day, it's controlling the pests efficiently, effectively, and safely. Try to avoid pest pressure when you can. That's my spin on it.

Does that seem like sort of a reasonable charge to that group? They could come back and say, okay, we evaluated bing, bing, bing. For the following reasons, we think these are three case studies that could, as

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Geoff said, illustrate how it's struggled, but maybe complement that with some examples of (inaudible) can actually start to piece the story together. I think the time dimension is going to be critical.

UNIDENTIFIED MALE: A comment. I have a lot of faith that we can develop a number of different cases and scenarios that way. But, by way of advice to the agency, it's my recollection that not too many years ago, you all used to have a newsletter where different cases were put out in the newsletter. Sherry Glick (phonetic) did that with her interns some years back.

So, I'm one of these people that thinks if folks are going to work and put these things together, that they probably should be used. So, I would advise the agency to make sure that there's some kind of way to disseminate it appropriately. I'm not aware right now. I'm confident that you would do it, but I'm just not aware that that's going on anymore.

MR. BRADBURY: Let me make sure I understand. So, assuming we did some case studies, making sure that the outcome/results of those case studies were publicly and widely distributed?

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UNIDENTIFIED MALE: Right. They can always be thrown up on a web. But I know that there was some newsletters that used to go out to folks. I know that there was one on the economics of IPM in schools probably five years ago or so. So, I just want to make sure that there's an endpoint of the tunnel to where stuff actually gets used out there.

MR. BRADBURY: I agree.

UNIDENTIFIED MALE: Steve, with respect to the specific question that you asked, I wonder, Cindy and Dave, do you two feel comfortable taking the initiative and agreeing to that proposal for your subgroup in terms of moving forward?

MR. TAMAYO: It's kind of funny because people were deferring to us like we were in charge of it. I was just the messenger. I'm not responsible for any of this. It just really strikes me that that's kind of where we ended up anyway. I would say that that's very consistent with -- we didn't make an actual decision, but it seemed that was the direction we were going.

MS. BAKER: I think my recommendation is we threw out a couple of -- I'm not going to speak to the

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mosquitos or the hospital example because it's not an area that I'm most familiar with. I mean, I think those two should be in there because you want to get across the spectrum beyond agriculture for sure to get the other ones.

But I think we could take cherries, we could take peaches, we could take apples, we could take almonds, we could take potatoes. So, I think that the discussion now needs to be around what's the best examples to illustrate where we have some pros, some cons.

I think because this is for EPA, kind of to Mark's point, we're supposed to be giving you advice. What did EPA decisions impact, or policies impact, any of that IPM? So, I think we now need to take those and look at where's the best example to showcase that. Then, work with that commodity group to see if we can bring it forward.

MR. BRADBURY: So, that will be the charge. Let me ask Keith or any of the others on the work group, do you feel like you've got the diversity of folks with background in public health, pest control, or in the

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hospital setting?

You're in the group and Joe is in. Are you willing to pitch in? At this stage, it's just over the next several months to sort of identifying if there are places or programs that could be useful for this analysis, not necessarily doing it but just to do the research to figure out which examples may have access to enough data over a long enough period of time to sort of illustrate how this might play out.

UNIDENTIFIED MALE: Just on that point, I'd just like to mention the fact that this work group came together more or less. People volunteered for the work group. We did not go out and hand select folks. So, given the way that it actually came together, I've actually been very surprised and quite pleased with the diversity that we have in terms of people's expertise. So, for both subgroups, we have, quite frankly, a really good mix of talents and expertises here.

MR. BRADBURY: All right. So, that will be the game plan. We will revisit everything tomorrow morning as we kind of document exactly what we're going to do over the next few months. At least I've got in my head

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what the game plan will be.

So, thanks for the efforts of the members of the work group and their presentations and discussions. We'll take a 15-minute break, if I've got my agenda right in my head, and we'll reconvene at 3:00 with the report out from the 21st century tox work group. Thanks.

(Whereupon, a brief recess was taken.)

MR. BRADBURY: We'll be into our last session today that's based on work group activities. This work group is our work group that's dealing with 21st century toxicology risk assessment approaches. As its opening slide shows, a lot of the concept that this work group is dealing with flows from, in part, the National Academy of Sciences report of 2007.

This review was commissioned by EPA, although working in partnership with our colleagues in FDA and NIH. The backdrop to that effort in 2007 was taking a look at a number of different realities, realities being that everyone, the government, the public, and the regulated community, looking towards how the science was evolving, and the fact that as the science evolves, you

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can probably be able to harness tools that allow us to more effectively understand what the potential effects of chemicals could be, pesticides in this case.

In the process of advancing that knowledge, create the ability to more efficiently and effectively get insights on the information that's needed to make our risk assessments and to try to come up with ways that are more effective, more efficient, in how we do the business.

As a backdrop, all sorts of advances in molecular biology and genomics and (inaudible) and the tabalomics all starting to come into play about -- in 2005, even, we were starting to see how this was going to change and some of the work that led up to the proposal to go to the National Academy of Sciences. And colleagues in FDA, same thing, realizing how information that supports evaluation in drugs is changing rapidly.

This was going on in the U.S. and Europe, similar insights and activities were ongoing. So, at the OECD level, Organization for Economic Cooperation and Development, countries across Europe, Asia, Australia, North America were also seeing this change coming and,

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through OECD's efforts, were also trying to ensure that this international harmonization on the new approaches and techniques were going forward with toxicity testing.

This area is the very significant area of investment by EPA, not just the Office of Pesticide Programs, but also with the Office of Research and Development and with our colleagues in the Office of Water and other components of EPA that are realizing that the change is coming in terms of technology and the way to gather information and come up with more informed decisions about the potential risk of chemicals and maybe start to tackle some of these hard questions around mixtures and subtle effects and how they relate to other aspects of the biology of not only homo sapiens but wildlife and other animals as well.

We've been working on the science ones, if you will, with our scientific advisory panel and others in the scientific community. We had a peer review through the scientific advisory panel this past May in which we laid out our directions in terms of advancing the science. Our colleagues from the Office of Research and Development were involved and other parts of the federal

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government, either some presentations or some sitting on the review panels as well.

We sort of laid out sort of where we saw the science today and what we could start doing today as well as what the science was looking like several years out and how to approach that. The report posted on the scientific advisory panel's website was a very positive report in terms of the direction the office was taking and moving forward.

A very important aspect of that report was that -- well, the good news is OPP is thinking in the future and trying to be part of the future instead of chasing the future. There's clearly no way our office can do this by itself. It really can't do it by itself in EPA, so they were happy to see Office of Research and Development of EPA plugged into this and seeing the significant investment the administration is making in this effort.

But also, across the federal government there needs to be a partnership and collaboration beyond just the public sector in terms of the importance of collaboration and open transparent peer reviewed manner

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with the NGO community, with the scientific community at large, the regulated community, and the talents and expertise that are in all those sectors.

Clearly, this all needs to come together if you're going to make the breakthrough that needs to happen. We have to harness all these resources and talents in a coordinated fashion. Otherwise, we could have a thousand flowers blooming, but you don't really have the direction being set and the harnessing of the resources.

So, consistent with this area being a high priority in EPA and within our programs -- I just want to make that clear, that we're really making investments to go there. The change is happening. The question is, are we going to chase the change or can we help with all your input and advice, help make sure this change is effective, open and transparent and gets done what it needs to get done.

It was because the science was moving and we knew that we were going to be part of sort of the science (inaudible) part of this, that assuming the science is really neat and it's like the best thing anybody could

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ever envision, if that science isn't evolving with thoughts about how is this science going to play out in a risk assessment and how does it play out into regulatory decision making, it won't really matter if it was the best gee-whiz science anybody came up with.

If that science isn't involving by understanding the regulatory context of the science and then the regulatory context and the policy context evolving with the science, you could have real wasted opportunity.

That's why we created this work group, probably almost three years ago now, or at least the beginnings of forming this about three years ago. We were all talking about this in this context to complement what was going on in the scientific federal advice that we get so that as these tools evolve, we're thinking about how do you appropriately start to put these tools into practice. That's got to be in an open, and public, and transparent manner.

So, long introduction but just to sort of check in again about the importance of this, we think, across the board. What Vicki will be talking about with members

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of the work group is -- one of the important areas that our work group has been focused on came up at the SAP, and you'll hear more about it.

If you look at that figure that comes out of that NRC report, it really gets at this toxicity testing. I think a lot of people have in their mind that it was all about how we were going to come up with smarter ways to use cell lines or other kinds of toxicity testing paradigms to get the information to inform a regulatory decision.

But that outer circle in that figure has a component about population and exposure data. It's actually a key part of that report that actually brings the whole report back to where it needs to be in terms of a pathway going forward. It's the importance of this science and how it will help inform our understanding of what's happening in the human population. Or, if we take this to ecological, what's happening in ecosystems in terms of the kind of information that the systems feed back into our decision making?

So, how can this technology improve our understanding of biomarkets for exposure and (inaudible)

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advance diagnostic techniques and medical settings, how it could advance our ability to have more informed and effective biomonitoring, how it can help inform more insights, if you will, and I don't mean that in a negative sense, but more advanced epidemiological studies, because you'll have a better tool set of biomarkers that can give us information in the population, which is part of the overall process that the NRC laid out.

That workshop that we had yesterday was getting at some of those issues. With that, I'll turn it over to Vicki.

MS. DELLARCO: I think I've become a regular on the agenda to update you about what we're doing in this work group. On the next slide, this is the charge of the work group that we always put up. I've highlighted, by underlining, in the box there.

From day one when we were discussing our charge as a work group, it was realized among our members that if we're going to change the paradigm, it had to be holistic. So, we had to advance not only the science and being able to better evaluate hazards that also advance

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the exposure science, too. So, both the toxicity and the exposure are crucial components of the new paradigm that we're envisioning.

When we had our workshop last December, in sort of broadening the dialogue about out strategic vision in this area, that was one of the key points that was made during that meeting. We needed to have sort of a check system in place if we're going to change the way in how we evaluate hazards by using this new technology. We had to know that that paradigm was working. So, it was very important to put a population surveillance system in place.

Stressing the need for biomarkers and new biomarkers, simply stated, we need these biomarkers just as reality checks, a feedback mechanism. If things weren't working in terms of the new paradigm, we could go back and make appropriate adjustments.

So, one thing that we've been doing as a committee is sort of developing and holding these one-day FACA workshops on key areas. Yesterday, we had one on the topic of biomonitoring, looking at the state of the science, the challenges, the opportunities.

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Really, the important goal of that meeting was to stress the role that these tools play in different perspectives in the clinical setting or in the public health setting in terms of identifying what the pesticide exposure has been, to manage that appropriately as a surveillance tool, and the need for it in epidemiologic research so it can better make those linkages between exposure and disease outcomes that we see.

I would say that we had pretty good attendance yesterday. There was over 100 people either in the room or on the phone representing a broad group, people from different parts of government. We had people from CDC and OSHA, and, in addition, from EPA. There were people from different universities attending. We had several industries and various health advocate groups.

So, this is the program. The way the program was set up, there was a science program to discuss some of the critical issues around biomarker development and the interpretation of biomonitoring, how it's been used, the value of it, and what's on the horizon, what's new that's being developed. Then, after, presenting a discussion that science -- there was a panel discussion

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to begin looking at that science. How do we move this agenda forward in terms of a regulatory approach or framework?

So, let me just kind of highlight for you. It's difficult to summarize a meeting that was packed full of lots of presentations and discussions over our entire day. So, what I'm going to do is kind of highlight for you some of the messages I got out from the presenters that resonated with me.

We started the meeting with critical scientific issues. While biomonitoring provides a valuable exposure approach, the interpretation is not so simple. So, it's important that these studies are conducted appropriately and that the data is interpreted very carefully.

So, we started with some fundamental technical issues that cannot affect interpretation of biomarkers, particularly the toxicokinetic properties of the compound and how that can differ in different individuals and how it can affect the concentration of the compound in the body over time.

We also discussed some of the exposure issues around biomonitoring with respect to the critical windows

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of effect when you do samples and some of the issues about spot urine samples which is the common method that is used.

I think one message -- we were lucky to have two speakers who have a wealth of experience in this area and in interpreting biomonitoring. That was Lisa Elward (phonetic) and Dana Barr (phonetic). One thing that Dana Barr said that resonated with me is that you have to design these studies carefully, and you have to select your biomarkers carefully for the question that you're trying to answer.

So, it may not be the same biomarker or study design, depending on what your purpose is, whether you're a clinician and you need to diagnose overexposure or whether you're conducting an epidemiologic study and looking for causation.

She also stressed the need for repeated exposure (inaudible) exposure over time and how important it was to understand the impact of a variation within an individual and variation among individuals. In fact, that was something that kept coming up among the different speakers.

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After we talked about the technical issues, we moved to the next part of our agenda, which was the role and the need for these biomarkers. Jimmy Roberts, who is on the PPDC, gave a perspective from the medical management need. I think one thing that Jimmy said yesterday that resonated with me was that there's not very many biomarkers. I think cholinesterase is about it.

If we had more of a suite of biomarkers for physicians and a way of testing, it would likely increase the physician's ability to consider and diagnose appropriately. They would be incorporating this more into education programs. It was also important from a public health perspective that it allows the provider to reassure the patient or family that we can rule things out.

Lynn Goldman (phonetic) talked about the work that she has done with looking at poor blood samples in the Baltimore area for epidemiologic research. She stressed a number of important things. She was looking for markers of epigenesis changes that can be associated with outcomes in children. But she also was showing some

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of her results. We all know this, the reality is that you're going to see exposure to multiple (inaudible). That's the beauty of biomonitoring. It's more real-life reality situations.

We also had Asa Bradman (phonetic) from the Center for the Health Assessment of Mothers and Children of Selenas talk about the work that he's been doing on evaluating pesticide exposures in pregnant women and children living in an agricultural community.

He also emphasized the message that although people are exposed to many pesticides, they don't have biomarkers for many of the pesticides other metabolites. There's no laboratory method to measure these pesticide specific metabolites in biological samples. This really is a major limitation for the researchers who are essentially acting as our post-market evaluators.

He also emphasized the need to evaluate this intra/inter person variability in terms of exposure because we are complex as individuals and we do handle things differently. So, we can't look at average characteristics or responses.

Matt Keifer, who is sitting next to me, talked

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about a case study, the Washington Cholinesterase Monitoring Program, the value of that, and how that information has been used. I think one thing that I got from his talk is by having that program in place, it actually increased the hazard awareness and it led to improvements and overall workplace safety by guiding the ways that you could reduce worker exposure. So, monitoring can motivate change and practices.

The next part of our program was, okay, so what's new, what's out there that's promising. We had three different speakers. We had Dean Jones (phonetic) from Emory University. He talked about an approach that's called the Universal Exposure Surveillance as a Component of Personalized Medicine.

So, it was sort of a -- it's hard to explain technically, but I guess you would say it's a high throughput method to look for exposure, high performance metabolic profiling, where you can look at hundreds of thousands of natural chemicals in the body, antibiotics, in a very cost effective way. You can do this in 20 minutes. This is what we call metabolomics. Maybe that will be another topic we'll take in another workshop.

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Actually, I think that does have a great deal of promise.

We also had Michael Alavonya (phonetic), who is one of the lead epidemiologists in an agricultural health study, talk about his work, particularly the next phase that they're going into in terms of developing molecular markers of particular diseases or cancers, especially those cancers that are common in farm workers.

Then, we ended up with a speaker from NIHS to see what they're doing and what they're sponsoring. This was David Bowshaw (phonetic). They're funding a number of things. It ranged from wearable badge censors that you could put on people and protect what their airborne exposure is.

Also, making antibodies to unique chemical adducted proteins or peptides. They had an immunological method. That was more of a dipstick method. One method they had developed is a dollar to do, and it was a very quick assay as a diagnostic kit.

Although there is a lot of promising techniques on the horizon being worked on, from what I heard and what I understood, they're promising but they're not sort of key-turn methods yet, off the shelf, anybody can do it

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and put it in practice. There's still some more work to be done.

After listening to all this science, we had a panel discussion. There's six people on the panel that represented different affiliations and perspectives. We had somebody from state government, federal government, FDA. We had industry representatives. We had academia and health advocates.

The purpose of that panel discussion was to share views on what could be the regulatory approaches and policies, advance this issue. What would be some of the challenges? In other words, we were trying to get at some of the solutions to move forward. Also, what can we learn from other federal agencies?

I think everybody who participated in this meeting and on the panel agree of the need and importance of biomarkers. It's a critical part of this 21st century vision. Some of the things that I captured in my notes that came out of the panel discussion is there is some existing information. Perhaps we need to harness that better. There's information that we have in OPP. There's also information that various industries have.

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Maybe it's not in user-friendly form, so we need to look at that.

I also heard that there's a lot of chemicals out there, a lot of pesticides. Perhaps we should think about a stepwise or triage approach, maybe prioritizing the things that are important to develop biomarkers. The point was made that EPA has no requirements for monitoring, and we needed to move in that direction.

But, on the other hand, the point was made that the technology is not ready for a data requirement today. There are issues about the complexities, particularly around some of the new actives and/or chemistries that we're seeing. So, there's more work to be done.

We also got the perspective from FDA who has been dealing with the issues of biomarkers like us for a very long time. They have a biomarker program. The message there is this takes a lot of time. It takes a lot of resources to move this issue. But the way that you move forward is through a collaborative effort. It's a collaborative-effort government working with academia or working with industry.

Let me get to the last slide, which is, are we

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done? Is this workshop it? No. I think we've just begun. There was a proposal yesterday -- I think it was a very good proposal -- from one of our PPDC members and also a member of our 21st century work group, Jennifer Sass, that we go back to our work group and redevelop a proposal to advance this issue of biomarkers and have it ready for the next PPDC meeting and put it to you for consideration for your input.

So, what we'll be doing is trying to schedule a special meeting to have that discussion about what the scope, the depth, and the shape of that proposal needs to be. It needs to be a consensus approach among all our members. We haven't had that discussion.

I have my own thoughts about what that proposal should look like. We need to talk about it as a group. I think it's going to have to be a multi-prong approach. There is a number of issues to consider. There is the scientific issue. There is the ethical issue. There is sort of a policy and legal issue. I think we have to think through the details of all of that.

What we will do is we won't do a summary. I gave you a very short version and probably a little bit

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biased because it resonated with me. But we'll do a workshop report and put it on the web site. I think we'll continue to do these one-day FACA meetings. There's already been some suggestions for the next fall of 2012 meeting.

So, what I'd like to do is -- there are a couple people from our work group that were at the workshop. Give them an opportunity if they want to add to something I've said or correct something that I've said or give a different opinion.

UNIDENTIFIED MALE: So, first off, I'd like to thank Vicki and the EPA for supporting and putting on that workshop. I think it was very important and necessary.

I did want to clarify a little bit about biomarkers versus diagnostic tools. They can be the same thing, but they're not always the same thing. So, for example, Enhanes (phonetic), has a lot of chemicals that they can test, a lot of pesticides that they can test. So that can be a biomarker. That's really well used for research.

But for diagnosis, it's not useful. So, that's

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where my comment resonated with Vicki. There's a lot of biomarkers but there's really not anything for diagnosis other than cholinesterase testing. The importance of that is a number of things.

Probably the most important from an educational standpoint, physicians are very familiar with diagnosing organophosphates poisoning. But the problem can be that a lot of these symptoms in times of organophosphates poisoning can also occur with other insecticide poisoning as well.

When they see somebody who might have seizures or some other sign or symptom, they automatically get cholinesterase testing and it's not really appropriate. They might start management for organophosphates on a poison that's completely unrelated to organophosphates. So, it's important to identify the poisonings, but I think it's also equally important to identify when it's not a particular poisoning.

There's also some educational issues that are important. We've touched on a little bit about what clinicians do know and don't know, CME, or continuing medical education, fix that. It can help. But CME is

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only as good as the people who attend the sessions.

For example, after our meeting, I was invited by the American Academy of Pediatrics to do a session at next year's AAP meeting on pesticide exposure. So, there's about 5,000 people that come to the meeting, the overall AAP meeting. But, on average, I'll probably speak to maybe 50 to 75.

So, while CME is great and it reaches some, it doesn't reach the masses necessarily. So, it's very important to get this into the medical education curriculum to an extent. We've already done some. It sort of depends on the teaching physicians who are at the institution.

So, if kids come into my clinic, they're going to hear a lot about pesticides, but not necessarily the same at all universities. So, that's one other thing.

MR. BRADBURY: Cheryl and then Jennifer.

CHERYL: So, it was a great session yesterday. I enjoyed it a lot. It was very diverse in the fact that we went over past history, future, and then where can we be today. I would like to reiterate one of the things that you named. I don't think we're making very good use

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of existing information, getting it all the way out to physicians.

I'm sure there's much more information that's held within the user community, within OPP, and within the registrant's data packages that could advance the science. I'm not saying all the answers that you need are there, but I don't think, from your description, that it's being leveraged as well as it could be. Particularly, if you're looking for biomarkers from a research perspective, I think the registrant packages have a lot of information.

It was brought out yesterday, but it wasn't resonated loudly, and that is for global products that are being developed in Europe, there are urine and blood methods right now, but they're not going to be down in a diagnostic kit. They would be available to start to answer some of these questions from a research perspective.

There's also, in some cases, additional toxicokinetic data being developed. Even within just the existing studies that EPA has within (inaudible) these studies and the animal testing that happens, you get a

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lot of research information that could take you a lot deeper than what was discussed yesterday in terms of all we have is cholinesterase. So, I think that's not being leveraged near as well as it could be.

Two other points. One point was that in the very beginning of the workshop, it was reiterated that having information on worker exposure, human, the types of things that the HSRB is looking at for studies, those same types of studies are very valuable in putting biomarkers and biomonitoring in perspective. Yet, right now, HSRB is sometimes a roadblock to getting additional information on new compounds. That was a point made that wasn't re-echoed here.

The last thing was that wasn't stressed very much yesterday is if we're talking about overexposure, in a lot of cases we're going to be talking about places where the label wasn't followed, PPE wasn't followed. Whose responsibility is it for enforcement? That never got brought up in terms of what are we going to do there. So, that's something that I felt was unaddressed.

UNIDENTIFIED FEMALE: So, Carol Burns raised the point about the packages that are submitted to the

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(inaudible) about developing the analytical methods, your chemicals and metabolites and blood and urine. Are we talking about the standard admin data that we get too, or is this something different?

MS. DELLARCO: No, it's not new.

UNIDENTIFIED FEMALE: When was it put into practice?

MS. DELLARCO: We're talking about analytical methods. Again, they're going to be (inaudible) or something along these lines. But we're talking about analytical methods and blood in the urine. I don't know if I can speak for all registrants. I certainly can't speak for -- I can't say that every compound has it, but I can say it's typical in our company. I think it's typical of those things that are going through the EU, that they will have those methods.

One other point I would make, too, is it's an operating principle for our company and our sciences that we don't guard our methods very tightly. There are times when the rest of our package for data comp or proprietary reasons we hold things kind of close to the breast.

But methods, analytical methods, we tend to put

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those out there as much as possible. We don't want people going off and misidentifying things. We want them to learn from our science. If they're going to do monitoring, we want to give them the best information that we have. So, methods are something that should be shared as freely and as broadly as possible so that it advances the science. That's my perspective.

MR. BRADBURY: Jennifer and then Jimmy.

DR. SASS: So, thank you. That was really great, Vicki, your summary. I'm impressed. I was there all day. It was really complicated. I'm impressed you can do such a nice summary.

It occurs to me in listening to your summary that I think we do need some kind of a glossary of terms for biomonitoring and biomarkers and diagnostic tests. I think I know what they mean, but actually, it would probably --

MR. BRADBURY: Jimmy and then Matt.

JIMMY: This is sort of a clarification question. In terms of the registrant packets that has a lot of that information and a lot of that data and a lot of the methods, how do we get that? Is that publicly

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available? I've used the reds for when I've worked on recognition of management of pesticide poisoning.

I don't really see that level of detail and that level of science in there. Is it somewhere else that's in the packet that stays at EPA? If so, how do we get that back out to the laboratories that would need to go on and take that information and put it into a clinically relevant test?

UNIDENTIFIED FEMALE: This is what I was asking Cheryl. Is this a new data requirement by the EU, because I haven't seen this. I've seen this from Dow because Dow has the corporate policy to do this kind of PPA work in all their studies. But is this a routine requirement in the EU, because I haven't seen this routinely?

CHERYL: I believe that it is. I'm 90 percent sure that that's true.

UNIDENTIFIED FEMALE: We're going to have to go back, Jimmy, and look into this more and get back with our work group on this, and see how we can make that available.

CHERYL: Can I just finish? I don't want to

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overcommit here, but what I do think is I know there's existing data here. Instead of going through and making a blanket cookie cutter requirement that everybody turn this in, what I'd really encourage you to do is explore what's there and see what makes sense.

Know that we'd be happy to share in the methods that we have. I think there's other companies that would be willing to do that, too. Instead of making it, okay, now EPA has got to go through and make this a requirement, too, step back and see what's there. See what makes sense to require.

MR. BRADBURY: Back to Jimmy's question, a couple different components to answering the question. One is that the data evaluation records or the summaries of the studies once the compound is registered, those are publicly available. Methodology, we've got to work through some of these issues as to what extent some of the detailed methodologies are claimed (inaudible) or not. It's just a detail that we've got to work through.

I appreciate Cheryl's point that many of the methods, analytical methods, many of them with regard to how the tolerances were figured out -- there's got to be

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methods for water quality monitoring. That's all publicly available in many of these (inaudible) techniques and adaptations that you're just applying the different tissue metrics. I don't think there's a big challenge there in getting that stuff open.

Then, the presentation you saw just before lunch was the chem search, that is part of the process we're going through to make it easier to get at this so that loading up of the risk assessments -- we can start loading up the DERs so it's easier to take a caste number or a chemical name to start drilling through it so you don't have to make a phone call for us to dig it up and get it out to you.

We can start to make it easier to get the information on the fly. That's part of this 21st century issue, just how to get your hands on the information. You don't do something you don't need to do because somebody already did it, or you're far enough along that you just have to adapt something that already exists and not have to reinvent the wheel.

I think part of this conversation is really important. I think it sort of creates a pretty

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straightforward next step, a scoping exercise that we can do in terms of where are we in the agency, in terms of things that are getting coded up in that chem search tool we described this morning. It's just time to get it linked and available.

There may be some aspects of the packages that we'll want to talk to industry and see to what extent can we clarify that this is okay to start loading up analytical methods. It may be a non-issue but it's something we just need to explore to start going there. So, anyways, I think that's a good snapshot. I think we've got an action item that we can start tackling pretty quickly in terms of some of the methodologies, analytical methods, and what not, we can make sure are available.

UNIDENTIFIED MALE: I wanted to compliment Vicki, too, for taking a very complex group of presentations and delivering them to you in a way that made perfect sense to me, much more than the presentations did yesterday, in fact.

It was actually pretty thrilling to hear so much of the work that was being done around biomarkers in

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various trends. Now, most of these were not about pesticides but the capabilities, particularly -- I don't remember -- from Emory, Dr. Jones, Dean Jones. Remarkable presentation. It was delightful to listen to that.

One of the things I wanted to emphasize, tried to emphasize yesterday, is the value of telling somebody they weren't exposed to pesticides. I don't think I can overstress how important it is to be able to tell a patient, that's not what happened. You have a virus. It's critical.

The difference between the person's perception of recovery between getting over a virus and getting over a pesticide exposure is day and night. You tell them they were exposed to a pesticide, they believe they were exposed to a pesticide. They're going to be months getting better. You tell them they have a virus, and they're going to be better when the virus goes away, they're going to be better when the virus goes away.

Believe me, this is one of the most valuable things we can do for a patient, tell them they were not exposed to a pesticide. So, the tool has an incredible

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value from that perspective in terms of worker compensation, in terms of patient's health, in terms of employer stability, because nobody is going to be suing that employer because they think they were exposed to a pesticide. Very valuable information. So, I just want to make sure that that's clear that that's on our agenda as well from a clinical perspective, because that's very important.

I agree with the terminology that we have to get the dictionary. When we had our guest from FDA talk to us about biomarkers, they were talking about biomarkers of tissue damage that were nonspecific. If the drugs they were testing did that damage, they knew that the drugs were toxic.

That's not at all what we were talking about. We were talking about the specifics of particular chemicals and how to identify them. I think that was a little bit lost in the shuffle, but that was important to point out.

The last thing I want to point out is the value for occupational medicine decision-making. One of the things that most people don't understand about

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occupational medicine is that we work not on the medical model of making a diagnosis, expecting 95 percent certainty that the disease is present.

What I mean by that is when, for instance, you develop a new test for some serum activity or some serum level, normally, what you'll do is you'll go out to a normal population and you'll collect 100 samples. You'll cut off the end of the curve and say the top 2.5 percent, two standard deviations above the means, would be the abnormal value.

So, medicine, when they make a decision about an abnormal value, they're actually using a pretty high standard for proving that it's an abnormal value and that the disease is present. In occupational medicine, because it's based on torte law, it's a 50 percent standard of reliability or a 50 percent standard of proof, which means it just has to be more probable that it's work related than that it's not, just 50 percent.

So, when we talk about the value of a biomarker for clinical diagnosis in medicine and clinical diagnosis in occupational medicine in determining whether something is work related, it's actually different. I can use a

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biomarker that if it is identified as being outside the Enhanes range for normal, it's likely that this person was overexposed in that event and related to their condition. That can potentially be a work-related claim. It gets me, as a physician, to the 50 percent mark in terms of probability.

So, I can use biomarkers and occupational medicine can use biomarkers in a way that general clinicians might not. It would help guide clinicians but it wouldn't necessarily cinch the diagnosis for them. So, that's just one other distinction that we didn't get to yesterday.

It was a great session, and you did a great job summarizing. Thank you.

MR. BRADBURY: Nancy and then Cindy.

MS. BECK: I just wondered if there's a more -- it seems that there are disparate approaches on the hazard pathway donation side and the biomarker development side. How do you get -- so, there's a systematic approach on the hazard side to sort of define pathways.

It seems like a lot of the information that's

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coming out of the definition of those pathways would be relevant biomarkers on the clinical at the exposure side. But I don't feel like that was being connected as much as it could be. Are these groups talking?

I mean, I know there's not like the Department of Biomarker Developers. That's not really a part of Tox Cast (phonetic) or some of the other EPA efforts that I know. But would it make sense to have it more, and I don't know if institutionalized is the right word, but part of the Tox Cast. So, there's sort of both sides talking to each other. You can take advantage of what's coming out of the hazard side.

UNIDENTIFIED FEMALE: Actually, articulated in the 2007 NRC report, that's part of their approach. As you understood pathways and biological events that are happening, that would lead to the development of these biomarkers. So, they are tied. You're right, it's important to try to make those connections in the research.

MR. BRADBURY: I think Vicki said it, and we talked about it in sort of the opening part of yesterday's workshop, that circle was intended to mean

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that all these different tools need to be interconnected. But yes, you start to figure out adverse outcome pathways and what are the key events along that pathway and the markers that could help interpret the experimental study, that same technology probably has --

I'm not in that business, but they're probably reasonably straightforward modifications that could be used to measure urine from the population as well as urine from the rats, that you were getting insights to make sure that pathway is really on or not on. So, I think as the research goes, they can be linked together.

I think you raise a good point, though, in terms of the parts of the organization that are trying to guide the research again to make sure they're not losing sight of the beauty of that vision. This is all interconnected. It isn't this and this. It's starting to be -- I use multiple lines and signs to reach a more complete understanding.

Cindy and then I think we'll let Vicki wrap up, and we'll move on to the next session.

MS. SMITH: Mine is just kind of a follow on to the conversation that Cheryl was having with Jimmy.

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Matt, I know you and I had this conversation once before when this came up. I guess I would just make a plea that I think this is a great example of where you pull a couple of us together, maybe somebody from Diagra Sciences (phonetic), an intoxicologist from Gowan (phonetic), and Jimmy, and Matt.

We could sit down and get a better understanding of what is it you need so that we don't go down the road of blanket data requirements and assumptions and things like that. We let this effort keep moving in the way that it does. This isn't separate from this effort, but it's a bit of a side issue that we've been talking about for a while.

It's an important issue and it's something that I think both of us recognize the value in. I think it's just a better understanding of what exactly is it that you need. What do we have? Are there ways to view what we have? So, I would suggest taking that kind of one off with a couple of us rather than going blanket out there and doing it, and seeing if we can't come to some resolution just talking about the next step.

MR. BRADBURY: Just to clarify, that's where I

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certainly was coming from. I think this could be low-hanging fruit in terms of what is it, what's always coming in the data packages. Maybe it's in the pipeline in terms of the search tool we all saw this morning, or we just add it to the list of stuff to get linked up so it's easy to get our collective hands on it. I think it can be a low-hanging fruit, fairly focused effort.

UNIDENTIFIED MALE: So, I wanted to make the point that these diagnostic tools, biomarkers, can also be a driver for -- or surveillance can be a driver for the development of these tools. A lot of pesticide poisoning is not pathoneumonic, meaning it can resemble many other diseases, like upper respiratory infections or gastroenteritis.

Thirty states require that physicians report pesticide poisoning. But a physician is not going to report that personally identifiable information to public health authorities unless that clinician is certain that that patient's disease is caused by pesticides. So, currently, they don't have that certainty without these diagnostic tools, without these biomarkers. So, we're not getting these reports.

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Also, there's the problem with false positives. So, sometimes we are getting reports of pesticide poisoning and maybe it's not truly a pesticide poisoning. Maybe it was a viral infection. So, we can maybe address the underreporting in our system, as well as do a better job with teasing out false positives in our surveillance systems if we had better diagnostic tools and biomarkers.

MS. DELLARCO: If we're done with this topic, there's another topic. We had a request to get back to this committee with the cost of studies. TJ did an analysis, so he's going to present that because they talk about making our paradigm certainly more reliable but more cost effective. So, what's the cost of the current paradigm?

MR. WHITE: Hi. I'm T.J. White from the Biological and Economic Analysis Division. I've got my colleague back here, John Faukner (phonetic), to back me up in case there are any questions that I can't handle.

As Vicki said, and Steve alluded to, part of this process is to make our system more efficient. There are a number of ways that might happen. It could be in terms of the cost of data, the number of lab animals that

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are used, the resources EPA puts into the review of the data. But in order to understand how we're improving a process, we sort of need to understand where we are now.

So, one of the things we can do is look at where we are in terms of some of these measures. I want to stress that this little analysis that I'm presenting right now is not the sort of detailed analysis that we would want to conduct to really understand where we are at this point in time.

These estimates were really developed in response to several questions that have arisen, several numbers that have been floating out in the media. So, it's more for communication purposes. So, it's a much more broad brush than we would really want to do. A more detailed analysis could be conducted if we thought that information was useful.

So, this is not an average cost of registration. This is really what is the expected cost, that is, the cost of any particular data requirement times the probability that that data would be required, given the use to which the pesticide would be used. I put up the little mathematical equation because I figured

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this was a group that could handle that. We're looking right now simply at conventional pesticides, and this would represent a single use.

Now, our tests costs have been obtained from a survey of various commercial labs that do these sort of tests. We maintain a database along with our colleagues over in the Office of Toxics on all the guideline studies that may be required. We collected this over a period of time for various purposes.

As you may know, we've recently revised a lot of our data requirements. So, as part of that rulemaking, we looked at the costs. We use these costs when we issue DPIs. So, they're maintained for a number of reasons. As we go through time, we may update them for various purposes.

The tests have all been obtained within the last, say, five to six years. As to the probability that they would be used, we looked at the CFR. As you may know, data requirements are tagged as either being required, not required, or conditionally required.

Just as a ballpark figure, we said if it's required, that's going to be 100 percent probability, not

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required zero, conditionally required 50 percent. So, again, this is a very broad brush. As you probably know, certain requirements can be waived. Sometimes the not required end up being necessary for a risk analysis. Conditionally required could actually be quite variable.

So, the results here show pretty much what you would expect, I would say, in terms of the difference between food uses and non-food uses, between uses that are in a fairly confined area versus those that may engender large amounts of exposure. They range from about $4.3 million worth of data for an indoor residential use to nearly $10 million for registering a terrestrial food product.

Going from non-food to food, as you can see from the comparisons, is about $2 million in additional costs. And say from a greenhouse that runs $4 to $6 million, as you go into a terrestrial environment, those costs go up to $8 to $10 million.

Just some points to remember about this study. This is for a new chemical and only for a single use. Now, if you have a second use, obviously these costs don't double because a lot of the product chemistry, the

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toxicology, those sorts of studies can be used for the additional use. You may, for example, need to do some additional residue chemistry for a second food use. Those sorts of studies can run anywhere from $450,000 to almost $900,000.

The other thing about this analysis is that we're assuming that all the data have to be newly generated for this registration. That's not a bad assumption for a brand new AI, but it doesn't take into account that some of the studies required aren't actually chemical specific. There's a whole group of human exposure studies that have to do more with the application method and the formulation than for the chemical.

So, a lot of those can be cited, even for a brand new study. Those are actually -- if you had to generate some all anew, it would cost about $975,000. I guess the other question that has come up a lost is simply the number of studies that are required.

For example, for a terrestrial food or feed use, there are 85 data needs that are required, according to the CFR. There's about another 50 that are

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conditionally required. So, for any given pesticide, new registration, you'd probably be looking at 110, 120 studies that may need to be generated or submitted. Of course, not all these studies are necessarily lab tests. Some of them are more narrative or product descriptions.

So, that's what we have right now. If anyone has any questions, I'd be happy to answer them.

MR. BRADBURY: Quickly. Jennifer.

DR. SASS: So, like, let's say you had a chemical like the old (inaudible) before SQP eliminated a lot of the residential uses. So, that was registered for approval in almost all these categories. I kind of think off my memory it is all of these categories. So, would I just like add up this list of numbers to get what it costs to register chlorpyrifos?

MR. WHITE: No. Like I said, this is just for sort of the first use. Additional uses, since they can count on existing toxicology data and other forms, you wouldn't simply add them together.

DR. SASS: So, then, it would be like $10 million for terrestrial, well food and non-food, so it would be like $17 million. Is that what you're saying?

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MR. WHITE: No. Say, for example, you registered for a non-food use at about $8 million. If your next one was a terrestrial food use, you would really only have to do sort of the additional residue studies that correspond to that particular use.

If you're going from a non-food to a food, you'd also have to establish another set of probably residue studies and that sort of thing. So, it would be like another $2 million for the additional food use. Every additional use thereafter might be a very narrow subset of the residue study, $500 to a million dollars.

DR. SASS: So, then, for something like a chlorpyrifos, which had a lot of uses in pretty well all these categories, it would be somewhere between $5 and $10 million plus these half million increments for these other uses?

MR. WHITE: Like I said, this is not really a detailed study. I would not want to talk about any particular chemical associated with this particular --

DR. SASS: Any chemical (inaudible) that has a lot of these categories.

MR. WHITE: If you wanted to think about

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looking at the cost of registering a chemical over a large number of uses, I mean, we could do that. We have the data. We could put together some sort of scenario.

DR. SASS: But this isn't it?

MR. WHITE: This would not really give you that picture of what all those various uses would have been.

DR. SASS: And then, my second clarification point, then, is going to be these probabilities here in slide number 2. So, it seems to me that if you conditionally require data, it's the probability -- you're guesstimating. You're just using a rough estimate that the probability requiring that data or not is 50 percent.

But it's a discrete variable. It's like if you require it, it costs the amount of the data. If you don't require it, it's zero, right? I mean, it's not like the data costs 50 percent. It's more like the probability of you requesting it is 50 percent, right?

MR. WHITE: Right. This is an expectation. If you were thinking about bringing a chemical to the market, you had a vague idea of what use you were going to do but you didn't know any particulars about the

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chemistry, this is sort of an expectation. It would be similar to an average if we looked at a large number of chemicals and said, well, some of them were required and some of them were an average. Here's how much it would cost.

DR. SASS: That's kind of my point. So, these estimates aren't really an expected data generation cost of a new conventional pesticide. It's more like the average expected generation cost over a whole bunch of pesticides. I don't know how to take out the 50 percent probability. I'd like to see the math without that.

MR. BRADBURY: Jennifer, I can jump in. I don't want particularly want this topic to consume our agenda. So, if people just have some clarifying questions, that's cool.

DR. SASS: I'd like to understand about how much it costs to register a pesticide for my own media communication ideas. I don't understand how to get it out of here.

MR. BRADBURY: I'm cool with that. We're just trying to answer one broad question with sort of a general sense. If people are really dying to know more

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and more, that's cool. We can help share information. We'll go around the table really quick. If this is a really burning issue, we can figure out a way to come back around to it.

So, Cheryl and then Maria, or was Maria first?

UNIDENTIFIED FEMALE: It doesn't matter because we're probably going to indicate the same thing. (Inaudible) are way low. There are a lot of hidden costs in doing this study, like doing the range finders, doing the analysis of the compound within your study, generating radial label material so that you can run this study.

So, to me, your costs -- yes, if I counted each study, just lean it at a lab, that's what the lab tells me. But then, they don't tell you that on top of that, you're going to have to add analysis costs. You have to give me the radial labels material. There's a lot of hidden costs which you're not covering.

UNIDENTIFIED FEMALE: There's Q/A and there's method development, there's all the range finding. It takes eight years, is our industry's model, two years of screening about 10,000 compounds before you find anything

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that you even advance, another three years to develop your full data package, and then three years to sit in a regulatory cue.

In conjunction with what goes into a regulatory package, there's a whole suite of biology testing and efficacy testing that goes on in the field. There's figuring out how you're going to do your manufacturing, how you're going to package, how you're going to supply. There's way more to this than what's here.

So, when you call this data generation, this must be contract study costs for a minimal package. Ray can probably quote the number better, but CropLife America has done some of its own surveys of people. I believe the cost to bring something new to the market over those eight years, when you screen through all the rest of that, is over $200 million.

MR. BRADBURY: Just to clarify, clearly there's a spectrum from screening 50,000 structures in the computer to bringing a specific structure and all its data to the agency. Somewhere in there it's R&D costs the company is investing. It may or may not pan out. That's truly not a cost to EPA. You're clearly going to

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get to a certain gray zone where you're still sort of --

UNIDENTIFIED FEMALE: But you're saying this is a cost to register a chemical.

MR. BRADBURY: Right, and we're just getting at some of the --

UNIDENTIFIED FEMALE: Literally, I'm just trying to understand. You had a word for it. You said the contract study cost. I would like to understand (inaudible), not R&D, not three years of sitting in cue, not your secretarial, your air conditioning, your heating, your computers. I just want to understand what does it cost to do these tests? So, you're calling it the contract study cost.

UNIDENTIFIED FEMALE: But even beyond that, there's going to be some other hidden things just to do the research.

MR. BRADBURY: All right, folks. Enough. Stop. You two, stop.

Jerry, did you want to say something?

MR. BARON: I'll say it real quick, Steve. Just one other point on that is for these additional crop uses, that does not account for crop groupings, which is

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using data developed on a few crops to support registration on many. So, when you ask the number about, let's say, a chemical like chlorpyrifos or oxystroben (phonetic), or whatever, large registration, crop groupings reduce that cost.

UNIDENTIFIED MALE: Well, Cheryl and Maria have clearly explained that this is a small slice of the total cost of developing a compound from scratch knowing nothing and taking it clear to market. In general, the food or feed terrestrial use listed here is the most expensive.

In general, the data generated to support that use will cover most of the other uses. So, if you got that one, there's generally not a lot more data to support those other uses. That's a very general statement. It doesn't hold in all cases. Like they said, there are many more costs associated with these studies than just the contract cost. This is a small slice of the total picture.

MR. BRADBURY: Thanks, all. Thanks for letting me be a little belligerent to try to keep this moving. So, having said that, if overnight there's something that

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could be helpful from the PPDC in terms of information sharing, ponder that. Tomorrow morning, we kind of go over objectives and topics for future meetings. I'm not saying that we can't explore this, but I just want to kind of keep track of the clock as we go forward.

So, let's move into our last session of the day, which will be a series of updates, session four. The first update will be from Karen Whitby on the endocrine disruptor screening program.

I wanted to announce, because I don't think we've had a chance with the group, that Tina Levine retired a few months ago. Karen Whitby is now the Acting Director for the Health Effects Division. Karen has worked with the program for a number of years, a risk assessor and branch chief in the Human Health Effects Division. Karen also is spending some time in the Environmental Fate and Effects Division. So, she sort of sees the signs from multiple perspectives.

She spent the last few years in the immediate office helping OPP working with our other colleagues in our agency in advancing the endocrine disruptor screening program and working through everything from some of the

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scientific issues to how it gets connected into the regulatory processes that are part of our program.

So, with that, I'll turn it over to Karen. I think you folks have a handout in your folder so you can kind of follow with that while we get the Power Point up.

MS. WHITBY: Good afternoon. Due to the limitations on the amount of time on the agenda for an EDSP update, I've provided background slides on the EDSP, its scope, the tier one assays, and proposed tier two tasks, and an appendix that's included in your handout.

As most of you know, FQPA required the agency to screen pesticide chemicals for endocrine (phonetic). The agency issued approximately 750 EDSP test orders for list one chemicals starting October 29th of 2009. Chemicals were selected for the first list on the basis of being present in either four out of four or three out of four exposure pathways, those being food, water, post application worker exposure, and residential exposure.

Tier one data are due to the agency 24 months from issuance of test orders unless an extension was granted. The agency expects to receive approximately 500 EDSP tier one studies for 53 list one chemicals. The

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detailed response and status for each chemical and test order may be viewed at the agency web site, which is provided on the last slide.

List one data may be submitted to the agency using formatted CDs similar to what is done for submission of new active ingredients. A web-based tool is available to expedite formatting to create the CD. The CD should be labeled TRD-EDSP upon submission.

Paper submissions are also acceptable. MRIDs will be made available to registrants on the web site in advance. The agency is actively developing web-based e-submissions. As we get closer to implementing web-based e-submissions, we will be encouraging industries to participate in the testing of the applications.

The agency published a notice of availability and posted the revised weight of evidence document to the docket on September 28th of this year. The standard evaluation procedures, data evaluation record templates, and templates for raw data spreadsheets have been posted to the web. If you go to the EDSP web site, there are links to all of these documents in the highlights box on the right hand side of the page.

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To evaluate variability of key endpoints and promote consistency in agency interpretation, the agency will consider several studies for each EDSP tier one guideline as a group before we begin the weight of evidence analysis.

For some of the chemicals, it was necessary to grant extensions for individual assays for reasons such as contract lab capacity. Therefore, all of the studies for a chemical may not arrive on the same date, which will impact the timing of the weight of evidence analysis, since the tier one assays are considered to be a battery.

Once all of the studies have been submitted and reviewed, then the agency will conduct the weight of evidence analysis for each chemical to determine if the chemical has the potential to interact with the estrogen, androgen, or thyroid hormonal pathways and which, if any tier two tests will be required to further characterize potential hormone interactions observed in tier one screening, and to establish a dose response relationship for risk assessment.

The agency weight of evidence analysis will

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consider tier one results and other sources of scientific and technical information submitted as relevant to tier one screening. Such information may come from any number of sources, including pesticide registrants and published or publicly available peer reviewed studies.

To develop a second list, the agency identified candidate chemicals that are either contaminants regulated by the Office of Water with the national primary drinking water regulation or are unregulated contaminants that are listed on the third chemical contaminant list.

The agency included pesticide chemicals that were scheduled for docket openings for registration review during fiscal years '07 and '08 that were not included on list one. The agency published Federal Register notices with information on the proposed second list in November of last year. The agency is working on the response to comments received on these documents, and the next step will be to submit our revised documents to the Office of Management and Budget.

EPA is considering development of efficient use of computational toxicology methods in high throughput

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screening to allow the agency to more quickly and cost effectively assess potential disruption of hormonal pathways. These tools may be used to prioritize chemicals for screening and testing, where the longer term goals may include possible enhancement or replacement of current tier one assays.

For additional and more detailed information, I would encourage you to visit these web sites. Thank you.

MR. BRADBURY: What I'd like to do is go through all the updates. If we've got some time left, we can hit the specifics.

So, the next update will be from Susan Jenning on the PPDC Public Health Work Group efforts.

MS. JENNING: Lois Rossi is ill today, or she would have been here herself to deliver this information.

I know we've had some change over in the members of the PPDC since we've generated and formed this work group about 18 months ago. So, I'm going to do a little bit of background. So, if you all can just -- for the people who have been here, it won't be long.

The public health work group was created about 18 months ago specifically to address issues that involve

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pesticides and pests that impact public health. It's a very broad area and it tends to have a fairly distinct stakeholder work group, stakeholder set. So, we wanted to generate a work group that would work on these issues specifically. Many of these issues can be regulatory, policy, scientific. The work group is designed to do any of that.

The work group itself has defined three critical roles for its interaction with the EPA. The first one is as an advisory panel to seek FACA advice under FACA for input into some of our processes and projects. I think this is especially important because a lot of what we do is more -- we have a lot of federal groups and work with federal agencies on these types of issues. Under the FACA umbrella, it allows us to again seek that broader input from non-federal participants and interested parties.

It's also a portal for stakeholders to bring issues of concern to us. So, if there are issues that perhaps we have not realized our issues or need to have a little bit more focus put on, this is a portal for people to bring these into the EPA. Lastly, it's a forum to

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discuss items of common interest.

What we try to do is when we hold our meetings, we try to kind of touch upon each one of these three roles within those meetings. Again, it provides us with broader stakeholders. The stakeholders for public health are up there. There's a whole host that aren't up there. Lastly, it provides us a venue for collaboration with the public.

The kickoff meeting was 18 months ago. The work group itself has been working in identifying issues. Each work group we identify and discuss different separate issues.

The four key areas of interest that the work group has identified are improving the toolbox of pesticides used to control public health pests. As Ray McAllister said earlier, if you have that terrestrial use, you might be able to add a public health use for little to no additional data generation. We're always looking to try to improve that toolbox for various public health tests.

Blanket tolerances for mosquito adulticides, this is a funny little issue because depending on where

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you are in the nation, they look at tolerances for mosquito adulticiding differently. So, when they're doing an adulticide, it's difficult for them to target non-crop land. So, if you've got an adulticide label that says not to be used over crop lands, you're going to get some restrictions.

So, IF4 is working and some of the other -- Joe Conlon and the MCA, they're trying to establish blanket tolerances for some of these. The work group provides a way for other groups to have input into this process as well. Efficacy issues, people are always ready to discuss the efficacy of pesticide use for public health.

The last issue that we had identified, that the work group had identified, is IPM in housing, schools, and communities. Now that there's a new work group that's specifically targeting at least a generation of metrics for measuring the impact of IPM in these areas, we're going to be discussing how we can work together with that group so that there's no overlap between the two. I don't think there really will be a whole lot.

Additional areas that the work group is interested in is again, efficacy, product performance

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standards, the communication of efficacy to the user community and to the public. There's a lot of discussion about resistance, pesticides that work, pesticides that don't work. The bottom line is some of that is just communicating.

Efficacy and resistance is a very complex topic. I think that it is difficult for the public sometimes to understand that when they sprayed and it didn't kill it, therefore, the pesticide didn't work. Well, you might not have sprayed the right place at the right time. It's not always as simple as that.

Some of the issues are very pest specific. So, bed bugs, tick-borne disease efforts are some of the more recent things that we're covering and bringing to this group. Development of performance measures for public health. This is an issue. Concerns about the NPDES permitting process and its effect on public health and pesticides and how they're used.

Coordination with EPA about urban IPM and community IPM and how IPM -- IPM and public health are linked inextricably together in most cases. In an urban setting, if you're not doing IPM, you are not going to

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get long-term control.

These public health pests are pests that are living with people, on people, eating their food, drinking their water. If you do not control their food source, their water source, their habitation, you're not going to get good control of that pest no matter what pesticide you use. So, that's an issue that's ongoing. And lastly, resistence concerns, which ties to the number one issue, which was efficacy.

So, the next steps for the work group, I think by focusing only on public health initiatives, we're able to work more effectively and efficiently with the stakeholder community. The work group is a very valuable resource for OPP. Again, the fact of the umbrella, it gives us access to a broader stakeholder group.

We're going to be having a meeting tomorrow afternoon from 1:00 to 4:30. Most of the meeting tomorrow, I'd say three-quarters, will be focused on bed bug initiatives and next steps. We'll be talking about next steps for the work group itself. For the bed bug initiatives, we'll be talking about -- some of our members of the federal bed bug work group will be there.

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We'll be covering some of the work that we've been doing to establish a federal strategy for bed bugs control.

So, that's all I have.

MR. BRADBURY: Thank you, Susan. Susan will hang around if we've got time at the end and you have any follow-up questions.

So, Allison Wiedeman, you're on the phone, right?

MS. WIEDEMAN: Yes, I am.

MR. BRADBURY: Okay, Allison, thanks. And Susan Lewis from OPP is coming up to the table. Allison, with help from Susan, will give you an update on where we are with the NPDES general permits for pesticides. So, Allison, take it away.

MS. WIEDEMAN: Thanks, everyone. I'm assuming everyone can hear me. I first want to say I extend my apologies for not being at the meeting. These are very important meetings to us. I've tried to be or my senior managers have tried to be at every one, but this one we just couldn't make it. I'll do what I can over the phone.

So, this is an update of where we are in the

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pesticides general permit. I'm sure folks are wondering if we're really going to make the October 31st deadline, which, in fact, we will be. So, we do plan to have a final permit by October 31st, which is in just a couple of weeks.

It will be published both in the Federal Register as well as on our web site. The items at that time that will be released on our web site include the permit and its accompanying fact sheet, which is a document that describes in more detail what the requirements in the permit mean and why EPA developed them that way.

We also will be putting up accompanying forms that are either required to be completed by the permit, such as notices of intent to be covered under the permit, or are available to assist permitees in documenting their compliance activities.

We also intend to have our electronic NOI database up and ready for permitees to use which will make it easier to get coverage under the PGP. We also plan to have an updated what we call decision tree web tool to assist permitees in determining whether they need

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to apply for permit coverage. If so, what permit requirements would apply to them. So, all of that will be up and available.

Of course, the agency's final permit will cover operators who apply pesticides that result in discharges from the same four use patterns that we've been dealing with for over a year and a half now, which is mosquito and other flying insect pest control, weed and algae control, animal pest control, and forestry canopy pest control, where those activities result in a discharge to water (inaudible).

The EPA posted a version of its permit on April 1st of this year. That version of the permit has everything in it except for any provisions that would result from our consultation with the services under the Endangered Species Act. The requirements that were permit for everything but the ESA related provisions have not changed. So, the permit that folks saw up there then is the same permit with the same requirements in it, except for the ESA provisions. I'll talk about ESA consultation in a moment.

We recognize that this is going to be

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problematic in our timing in a number of ways by publishing a permit by October 31st, which is essentially on the effective date of that permit, or essentially on the same day that folks are required to comply with it. It's been unable for us to avoid that. What we are going to do is to allow notices of intent to be covered under the permit.

They do not have to be submitted to the agency until January 12th of 2012. So, while requirements of the permits still need to be met, the notices of intent to be covered do not. That will give permitees time to get into compliance and do what they need to do to submit the notice of intent.

We're still covering the same things that we said we were going to cover and not covering the same things we said we weren't going to cover. So, for example, the PGP does not cover, nor is permit coverage required, for pesticide applications that do not result in point source discharges to waters of the United States, such as terrestrial applications for the purpose of controlling pests on crops and forest floors and range lands.

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Agricultural runoff and irrigation return flows continue to be exempt from permitting under the Clean Water Act. So, these will also not be requiring permit coverage. The PGP will also not cover non-target spray drift or discharges of pesticides to water bodies that are impaired for a particular pesticide.

That latter part of the sentence means that if there is an impairment in a water body in the U.S. for a given pesticide such as malathion, this permit would not cover -- if an applicator wanted to spray malathion, this wouldn't cover the application for that pesticide, but rather the operator would have to seek coverage under an individual permit.

Turning to, for a moment, the ESA consultation, folks know that we are in consultation with the National Marine Fishery Service. NAMFS has submitted a biop that we made available on our web site. We asked for public comment on that biop. We received them and submitted those comments to NAMFS for consideration and development of their final biop and the reasonable and prudent measures that they've also included in that document that they believe EPA needs to implement in the permit and

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order not to cause jeopardy to the species or their habitat.

We are still in consultation, nearing completion of it. So, NAMFS plans to issue their final biop, and we plan to incorporate what we believe are appropriate provisions to protect the species into our permit. That will be in there, of course, with the version that will be published at the end of this month.

A couple of other things about that. Remember that this permit only covers six states, and I can name them if folks ask me a question on that, the District of Columbia, certain U.S. territories, an Indian country, and some federal facilities.

For the 44 states that are authorized to issue NPDES permits, they have had since we posted the pesticide permit in April the information that they need to go ahead and complete development of their general permits. They are issuing a state permit that is not a federal action that would be required to undergo consultation as we are, because this permit that EPA is issuing is a federal action.

So, the 44 states not conducting a federal

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action are not bound by the same requirements under ESA. States can certainly include ESA requirements, but they are not required to include the ones that we will have in our permit.

States are able at this point to go ahead and finalize their permits. In fact, we know that 35 out of those 44 states will have final permits by the October 31st deadline, and we're working with the others to get them on board as well.

We believe that the provisions in the permit that are related to consultation are not going to be significant enough to warrant public comment. So, we will not be engaging in another round of public comment. So, we will be moving forward to publishing the permit then, on October 31st.

I think some folks would also ask, well, what is the status of consultation with the Fish and Wildlife Service? We are in consultation with them as well. Frankly, the outcome of that is to be determined. We will actually not be able to discuss it until the permit is finalized.

I'll stop there and see if anyone has any

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questions.

MR. BRADBURY: Allison, can you remain on the phone for a bit because I'd like to get through two other updates and then open it up for questions. Do you have some time?

MS. WIEDEMAN: Okay.

MR. BRADBURY: She does now. Kelly Sherman is going to come on up and give an update on the humans studies protection rule. Then, the last update will be Wayne Buhler, who is going to talk a little bit about pesticide safety education. Then we'll open it up and kind of go through the topics and field some clarifying questions.

Kelly.

MS. SHERMAN: Hi, everybody. This will be really short, just a brief update. As many of you may know, last year EPA entered into an agreement with NRGC to settle litigation over the 2006 human studies rule. As part of that agreement, EPA is committed to propose several revisions to the rule.

In accordance with that, in February, we published a Federal Register notice announcing the

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proposed revisions and opening a 60-day comment period. That comment period closed in April. We received a total of 10 comments. Four were from industry task force groups, two were from NGOs, and four were just from interested citizens.

Most of the comments related more to the underlying rule rather than the specific revisions that we were proposing. We reviewed the comments and are now moving forward with finalizing the amendments. Our current plan is to finalize the amendments exactly as they were proposed.

We finished the intra-agency portion of that process and the rule-making process. We're now beginning the process of talking to other agencies and also beginning OMB review. So, we're targeting to sign the final rule before the end of the year. That's where things are.

MR. BRADBURY: Thanks, Kelly.

I'll turn it over to Wayne to give an update on safety education.

MR. BUHLER: Thank you, Dr. Bradbury. You should have a one pager, both sides, for reports

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submitted last night to Marty. Thank you for including it in the packet. This was 18 pages but I wheedled it down to 2, since I was the last speaker of the day.

I have compiled some material here actually that came from a Weed Science Society of America press release that was done last month, and also some notes from the president of the professional society for which I belong, the American Association of Pesticide Safety Educators, or AAPSE.

Just a short intro with the first paragraph to explain who we are, the PSEP program has been around for more than 40 years now. We were formerly known as the Pesticide Applicator Training Program. I just received in this case acknowledgment or what I refer to as a commissioning from congress with EPA directing the uses of the state cooperative Extension Service to inform and educate pesticide users about accepted uses and other regulations.

There is a person like myself, or a person that does work like myself, I should say, in each of the states, with the exception of three states, I think, now, in the U.S., five trusts in territories. We're all part

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of the University Extension Service. The primary mission is to educate pesticide applicators that need to become certified either as private applicators, commercial applicators, and the like.

Just from the standpoint of some data, in 2010, there are 488,000 certified private applicators, 405 certified commercial applicators, 105,000 newly certified, and 227,000 applicators that participate in recertification programs in the state.

So, short of living my dream of becoming a professional baseball player, I have a wonderful captive audience in North Carolina. We have about 36,000 certified applicators there who come to programs from all over county-based programs and receive their continuing education credit. We also have a pretty good outreach to others that are non-certified audiences, such as master gardeners. We're highly involved in IPM school programs.

The table that's included under Federal Funding Decline is just a short history of the funds that we've received from the EPA. We've been very grateful for it. I know it's been extremely helpful and critical in my program.

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In recent years, the support has hovered around $1.2 to $1.8 million. That was up until 2007, in which case all funds were discretionary. Then, beginning in FY 2008 through 2012, Pesticide Registration Improvement Act, or PRIA 2 funds, which are earmarking $500,000 annually, come from company pesticide registration fees to be dedicated for the pesticide education program.

On the flip side, the funds, you can see a little bit of description about how some of these funds have, in this case, decreased and the impact it has had. There have been a number of obvious budget constraints and other challenges that EPA has faced. So, the discretionary funding is no longer possible for at least this year. The PRIA 2 funding is really the only thing that our programs are receiving from federal level.

So, what that means is there's about $10,000 that's distributed to each state. The universities now can take their cuts through distributions, in my case upwards of about $2,000. So, I'm really working on an $8,000 federal budget this year.

You can see that that's had an impact of 20 to 75 percent reduction to each state, and an 83 percent

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reduction compared to 2008 funding levels. The bad news then, of course, is that if PRIA funding were no longer in existence, the PSEP funding would also go to zero starting in 2013.

So, in response to these reductions, the executive committee of the AAPSE, or the board of directors, rather, conducted an on-line survey of my colleagues throughout the country. This just describes some of the conditions that they face.

Nearly 50 percent of state programs suffered serious setbacks in recent years. Federal funding reduction this year and next will be hard on many programs. Many of our states generate additional funds through education fees, sale of training manuals, and securing outside grants and contracts, as well as partnering with other organizations.

Some of the states lack the infrastructure, the support, or legal capability of pursuing those funds, however. So, lack of sustainability has directly resulted in decreased staff, reduced pesticide manual production, reduced education, and realignment to other non-PSEP educational work.

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In the case of myself, I do find myself writing more grants, but that's the life of a faculty member. More than two-thirds of the coordinators felt that they would have to seek funding in areas not related to pesticide safety education in order to make up for the federal funding shortfall.

Survey results show that national funding is certainly an essential part of the PSEP program in many states. One state in particular no longer has a program due primarily in part to the PSEP program not being able to fund it to the extent that it did in the past.

Pesticide users obviously are becoming more and more diverse, including those with organic production who don't think that they use pesticides. With growing complexity of pesticide labels, the public need for and demands on PSEP are also growing.

On behalf of AAPSE and the pesticide safety education program, I just wanted to kind of keep this on PPDC radar to help ensure that adequate federal funding is available to our programs for the foreseeable future. It is certainly our hope that PRIA funding will be renewed and authorized for supporting the pesticide safety education program.

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MR. BRADBURY: Thanks, Wayne.

Why don't we open it up and go through the menu of topics we just went through. We can field some questions. With respect to Allison hanging on the phone, why don't we first start with the NPDES permit and see if there's any questions, which there are, Allison. Susan, why don't you come up and you can help as well with questions on the NPDES permit.

I think Susan Kegley was first and then Caroline.

DR. KEGLEY: Hi, Allison. I guess I don't quite understand the ESA thing. So, there is an ESA requirement in the permit if you're under the federally-issued permit but not if you're under a state-issued permit?

MS. WIEDEMAN: Yes.

DR. KEGLEY: So, what will protect the endangered species in those cases?

MS. WIEDEMAN: That is up to the states to decide. The ESA is a law that requires any federal actions to consult with the services to protect species.

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So, the state actions are not federal actions. So, any time EPA issues a permit, which we're doing for these six states, we need to consult.

DR. KEGLEY: Okay, thank you.

MR. BRADBURY: Caroline, then Ray, then (inaudible).

MR. CONLON: I'm masquerading as Caroline. This is Joe Conlon from the AMCA, Allison. I heard you say that an NOI would not be due until January 12th. If so, what is the discharge authorization date going to be? Is it going to be November 1st that you're going to be able to discharge?

MS. WIEDEMAN: Yes. I'm glad you asked me to clarify that. What we are saying is that the effective date of needing to meet the permit requirements is November 1st. So, operators need to be in compliance with the permits requirements, but they do not need to submit an NOI until January 12th.

MR. CONLON: Now, is the permit requirement for a PDMP to be on hand?

MS. WIEDEMAN: The permit requires a number of things, and it requires different things for different

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parts of the industry. We have applicators and we have what we call decision makers, which the decision makers are those that are hiring applicators. There's different responsibilities in the permit for each of those groups to meet. I don't think we have enough time for me to go over that in detail.

Applicators under this permit are not required to submit notices of intent to be covered, although they are required to comply with the provisions of the permit that pertain to them. The decision makers are required to submit notices of intent. Those are the ones that are required, in the effluent limitation guidelines part of the permit, to conduct IPM-like practices, which have been outlined in the permit. They are also required to document those practices in a PDMP or a pesticide discharge management plan.

MR. CONLON: That's going to be by November 1st?

MS. WIEDEMAN: Yes. Again, those requirements have all been up since April. So, the industry, as well as regulators, know what they need to do to meet all of those requirements, and have since April.

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MR. BRADBURY: Ray McAllister, Allison.

MR. McALLISTER: I have to say that I feel very uneasy about this "just trust us" attitude. Frankly, I don't, in terms of we don't need to ask for your additional comments on what we're doing.

I'm particularly concerned about the total lack of visibility of the Fish and Wildlife Service in this process and the assertion that, well, we just have to do it this way and you won't know about it until the end, and things could be a whole lot different.

We've long said this is a train wreck in the making, and it's happening. What's really happening with the Fish and Wildlife Service? Why are they not in the picture?

MS. WIEDEMAN: I can't speak to the details of the consultation at this time. We have been able to move successfully through consultation with them. We are still trying to do what we can with Fish and Wildlife. So, it has been more challenging with Fish and Wildlife Service. I know there's a number of aspects to getting a permit out without a lot of lead time. I don't want to minimize that. But that, unfortunately, is the situation

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we're dealing with.

MR. McALLISTER: But you do have the option of requesting additional time from the court, and the court can say yes or no.

MS. WIEDEMAN: Yes, and the agency has decided not to do that.

MR. McALLISTER: Is Fish and Wildlife Service expected to provide a biological opinion at some point?

MS. WIEDEMAN: Well, the chances of having that done within the next two weeks are rather slim.

MR. McALLISTER: Don't they have a legal obligation to do so?

MS. WIEDEMAN: I'm not the attorney. I can't speak to that. But I can say that we want to make consultation successful. We are trying to work with them in the same vain we have worked with Fish and Wildlife. We are still working it out.

MR. BRADBURY: Any other questions on the NPDES permit?

(Whereupon, there was no verbal response.)

MR. BRADBURY: Thanks. Any questions on the

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endocrine disruptor screening program?

MS. WIEDEMAN: Steve, I'm going to hang up then, if that's okay.

MR. BRADBURY: That's great. Thanks a lot, Allison, for hanging on.

MS. WIEDEMAN: Thank you. Bye.

MR. BRADBURY: Any questions on EDSP? Going once, going twice.

(Whereupon, there was no verbal response.)

MR. BRADBURY: PPDC public health work group? Going once.

(Whereupon, there was no verbal response.)

MR. BRADBURY: Anything for Kelly on the human studies rule?

(Whereupon, there was no verbal response.)

MR. BRADBURY: Any follow-up questions for Wayne? Ray and then Darren.

MR. McALLISTER: On the PSEP funding situation, I have sat through about three hours of explanations on

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how money gets from EPA to USDA to the people who actually do this work. I still don't understand it. I would just ask that you straighten that out. It makes no sense whatsoever. I have been led to understand that the very convoluted nature of getting money from here to there is the reason no money is being put in at the front end. It just doesn't make any sense.

MR. BRADBURY: Thanks for the opening. Let me provide a little clarification as to what's in play. Actually, there's a time earlier in time, which isn't on Wayne's chart, where something that just happened this last year played out.

Part of it is just the way the cash flow is moving from EPA moving money to USDA and then USDA distributing the money to the states, and just sort of tracking the cash flow. Every once in a while, there's sort of a bottleneck of the funds. So, part of why we didn't fund this year is to let some of the funds move through the system.

The other point is that the agency has no intention of not maintaining a reasonable level of funding with the discretionary funds that we have, which

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is what would go to USDA and get to the states. Exactly how much that will be, we'll have to see how congress finally does the budgets and things like that.

But getting to Ray's point, we're taking a look at some other vehicles or approaches by which to get the money to the states and working with USDA. Maybe there's a way that EPA can just try to directly set up the extra vehicles to get to the appropriate parts of the state to get the funds there. That may help reduce some of the transaction costs in moving the funds around.

So, a little bit of what you're seeing in this window right now is part of a cash flow or the equilibration step, which actually happened a couple years after I got here. So, it might have been 2003/2004 where we did one of these resets just to get the cash flow straight. This cycle, taking a look at maybe there's a way that EPA can just directly get the funds to the states. That's what we're looking at right now.

I'm not going to go through the convoluted stuff, but more about where we're trying to head.

MR. BUHLER: Thanks for that explanation. It saves me from having to explain something I don't

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understand. But yes, the federal passthrough is one of those complexities that has created problems over the years. There is actually a paper written on it, if you're interested. I could talk to you more about that later, Ray.

MR. BRADBURY: Darren.

MR. COX: One of the points we brought up on the pollinator protection is education, education, education. Here we're looking at this form and kind of going budget cuts. I can tell you just as a suggestion, beekeepers in my state -- I'm just going to shoot from the hip and throw you a number -- we're going to pay $50 every year to be registered beekeepers in our state.

Then, the chemical applicators, they'll come by every three years and we'll pay a $30 charge every three years to be able to conduct business. So, there's two years where they get a gap. I can see this program as being self-funded by the applicators for a minimal charge to pay for updating their materials and for education.

MR. BUHLER: You bring a good point. Actually, there are programs, like my own, that do receive funds. That's the only way I can retain or remain in existence.

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That will vacillate, and some states just can't do that. Some of those monies will go to the respected states department of agriculture or environmental management. Others can go to general funds. So, they meander through different rivers and not always go to the education arm.

So, there are states that can function well in that way, and there are others, through problems that I don't quite understand, that just are not allowed to do that. But, even at that, there are administrative hurdles to get through. Even in terms of funding, we have an administration that requires us to receive some federal monies before we can be recognized as an identifiable program at the university level.

So, in that case, by not having a flow of federal funds, some administrations would just assume think that the program may not even exist in their state.

MR. BRADBURY: Jim.

JIM: Just to clarify a point, not all training of professional applicators goes through the program. Most of the states that have agricultural chemical and fertilizer associations do a lot of in-house training. Actually, if you look at the real statistics, and I think

it's important, are usually other types of applicators, independents, PCOs, a lot of other educational projects.

So, I don't want to leave you with the feeling that applicators are getting federal funding for all of their training. That is actually not correct, particularly in recertification. Your point is well taken; they should be paying. In most cases, they actually are. This is really supplemental.

UNIDENTIFIED MALE: It's true. The extension service provides training. Typically, that's done with no fees. But we can't train every applicator in every state. So, we're thankful for people like ARA and others that can do that.

The money, again, is an issue. It relates mostly to the ability to deliver programs and provide monies that are used for developing materials. So, if we have a downturn, or perhaps the governor would prefer to take those funds away from us, then we have no monies for that year to actually develop materials. Some of that is being worked through now.

I do want to recognize Kevin Keeney (phonetic) in the audience. Kevin is the branch chief for worker

protection as well as pesticide container and containment here on the 11st floor for the building. Kevin has really been very helpful in supporting all of the work that educators are trying to do. There's a lot of work in developing training materials on a national level that then can be adopted and used within the states. So, that kind of effort is really appreciated.

MR. BRADBURY: Gabriele.

MS. LUDWIG: Just to sort of add to this, since I was at the meeting of the IPM specialists last week, I think the other merit to having some federal funding in the game is there is a sense of independence. I think that's very important in these kinds of things. So, I just put that out there. That's not always, in my mind, the best way to go, to go to private funding for certain issues. I think this is one where it's useful to have some federal funding in it.

MR. BRADBURY: Okay. I think we'll call it an evening. Nobody signed up for public comment. Unless there's any last tidbits, insight, tomorrow morning we'll meet at 9:00.

Steve Owens, if all his travel and flight

connections work, should be here and spend some time with us. Then, at 9:30 we'll do a session on endangered species, in particular, the process improvement work group activities in terms of how to feed information into the system. We'll spend a fair amount of time on that. Then, we'll spend some time charting out what our goals are for the next meeting.

So, thanks a lot. It was a very good day. I appreciate the very focused comments. It was very efficient and effective. So, thanks, all, and have a good evening.

(Whereupon, the meeting was adjourned.)

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CERTIFICATE OF TRANSCRIPTIONIST

I, Marilynn H. McNulty, do hereby certify that the foregoing transcription was reduced to typewriting via audiotapes provided to me; that I am neither counsel for, related to, nor employed by any of the parties to the action in which these proceedings were transcribed; that I am not a relative or employee of any attorney or counsel employed by the parties hereto, nor financially or otherwise interested in the outcome of the action.

MARILYNN H. McNULTY,
Transcriptionist

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In the Matter of:

Environmental Protection Agency

October 13, 2011
Pesticide Program Dialogue Committee Meeting
Day 2

Condensed Transcript with Word Index

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UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY

PESTICIDE PROGRAM DIALOGUE
COMMITTEE MEETING

October 12-13, 2011

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, all. Again, I want to thank everyone for all your input in yesterday's meeting, the various topics we went through. I think we covered a lot of ground. It was a very effective conversation.

I appreciate again the work that goes on in between the meetings with the work groups getting a lot done and being able to bring to the full committee status of efforts, recommendations for the next step. I appreciate the time you all are spending in preparing for those conversations. So, we got a lot done, on time, and I appreciate that.

So, today, we've got a half-day agenda. We'll start with Steve Owens and spend some time going over his perspectives on the program. We'll have a big chunk of time to go over the Endangered Species Act and ideas on implementation and effectiveness of that. Then, we'll spend a little time planning for our next meeting.

So, without further ado, I'll turn it over to Steve.

MR. OWENS: Thanks, Steve. I apologize for not being here yesterday. I was out of the office. I didn't get in until the afternoon. Rather than coming over and disrupting the proceedings at that point, we decided I would come today.

This will be an easy morning discussing something that's light-hearted like the Endangered Species Act. So, there won't be much going on anyway, comparable to yesterday, I guess, where you covered a lot of the simple things like spray drift, and EDSP, and pollinator protection, and all that.

Actually, it's always fun to be here with you guys. This is one of the things I find -- unfortunately, I can never stay here long enough, but it's one of the things I find most fascinating about the job I'm in, the opportunity to interact with all of you to kind of get advice from you on some very challenging and sometimes longstanding issues that this office is dealing with, not only looking at the range of perspectives on this, but the diversity of efforts that are involved in it and the contributions that all of you make to the process that we have here where we have to not only evaluate things from

a policy and technical perspective, but from real world impacts on the ground approach as well.

Like I've said, just about every time I've been here, it doesn't do us any good to come up with a policy or a decision or anything like that if it actually isn't going to work when it's being implemented out in the field. So, that's one of the very valuable things that this group does for us.

I'm going to talk about a few things. But before I do that, I want to also just introduce someone who is new with us, not so much new to the office, but new to this group, and that is Louise Wie (phonetic). You can raise your hand. There you go.

Louise is the new Jim Jones. We're not (inaudible) Jim Jones now since Louise has been with OCSPP since July. She came in in the middle part of July to take over for Jim, actually, to really take over for Bill Diamond, who had taken over for Jim. Bill had agreed to serve as the acting deputy of OCSPP for just a couple three months while we went through the time-consuming process that we have to go through in the federal government for filling these kinds of positions.

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We were very fortunate that Louise was interested in this job. I've known Louise a long time going back to before I joined EPA, back when I was with the State of Arizona in other lives. She's held a variety of positions, none of which I will try to go into -- I might ask her to say just a couple things very quickly, actually before I even start talking -- throughout the agency, so she has a very broad and comprehensive perspective, not only on what this office does, having seen it from the outside looking in in different capacities, but also how it interacts with other offices within EPA.

That's going to be of immense value to us as we move forward not only on all the things we talked about yesterday and today, but other challenges that we'll face of sort of making all the disparate pieces of EPA work together a little bit better, especially in this arena.

So, I've often introduced Louise as Jim Jones with better hair. Someone said the other day, no, you mean Jim Jones with hair, which I can say since Jim isn't here. But actually, Louise, I don't know if you want to just say a couple things, and then I'll take it over.

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MS. WIE: I'll just say I'm really happy to be here. As Steve pointed out, I've been at the agency for a while. I've circled through a lot of offices from OGC to OSWER, to water, to the policy office. So, I've gotten an inkling of all the statutes. I actually came from -- starting with pesticides. So, I feel like I've circled back.

I'm really happy to be here. I see some familiar faces, so it's nice to see you. I look forward to getting to know you better and also to hearing your perspectives. So, thanks for having me.

MR. OWENS: Thanks, Louise. We debated whether we'd do a go around and have people introduce themselves for Louise's benefit. I decided not to do that in the interest of time because I know some of you guys will need to be getting out late in the morning to catch planes and things like that. I don't want to delay the morning proceedings too much by being here.

I know you went over an awful lot of stuff yesterday. Steve Bradbury was giving me the rundown on the great discussions that you had. What I would like to add to that is how important that process is as we

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actually try to move to conclusion of some of those things.

Almost everything that was on the agenda yesterday, with the exception of, for example, the school IPM initiative that we've engaged in, and then maybe one or two other small pieces, but just about everything else that was on the agenda yesterday are things that were not only underway when I came to EPA back in the summer of 2009, but had been underway for a long time at EPA.

I know there are very difficult, very challenging, and very complicated issues that have to be wrestled with as we are, and have been, moving forward with those issues. But we're getting to the point with some of those things, as I'm sure was discussed yesterday, where, as I used to say when I was growing up, we have to fish and cut bait. I think we'd much prefer to fish on things than cut bait on things that we've worked on a long time.

So, it's going to be very important to make sure that we have not only the benefit of your advice but your active involvement as we try to put things together. I won't go into any individual things, we talked about

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them yesterday, but, over the next few months, as we try to reach a point where we can say, okay, we've really worked this issue as much as we can. We've tweaked it here and there.

We need to move forward with some of those things, through whatever formal process it will be, because so much of what we've been doing has been not necessarily informal but hasn't gone into official notice and comment and things like that. So, I'm hopeful that at some point in the not too distant future some of those things will be starting to come to a resolution. Again, that's why this group is very important.

But there are other thing that are out there as well that we really need to start thinking about as we go forward. I've only been in this administration a couple of years now, I guess two years and three months now, but who's counting. When you start actually hitting the end of a third year of administration, people start thinking about okay, what do we really think we want to do in the next year, what can we wrap up, what can we really get done.

I think we're going to be looking to you in

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many respects as part of that discussion as well. A lot of the things that are close enough (audio problems) move forward and one of the things that's going to take a little bit longer time to resolve. That will help us better allocate resources, help us better figure out where we need to spend our time, where we need to ask you to spend your time.

Everything is important. We need to continue to work on as much of that as we possibly can. It's just that when we're getting close to the finish line on some of these things, do you sprint or do you keep going or what do you do? So, that's where we're going to have to put our heads together and figure that out.

But there are some other things that we've really been working hard on, which I want to talk about just for a few minutes, since you're going to be spending some time on them this morning, which is the Endangered Species Act issue. I know you touched on it a little bit yesterday.

Today, I guess, is the bigger, broader picture. We appreciate Jim Lecky being with us today. Jim, I think we're going to refer all questions to you on that.

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But I do want to say, actually, Jim has been a very active participant in this for a long time. I've really appreciated getting to know him and all the folks over at NOAA, as well as the folks at Fish and Wildlife Service as well.

We've been engaged in an invigorating process over the last couple of years where we've really, I think, make a fair amount of progress in addressing some very complicated issues on the Endangered Species Act and how it affects not only what we do in the Office of Pesticide Programs with pesticide reauthorizations and approvals and all that kind of thing, but the work that gets done in both Commerce and Interior as they have to do the job that they're charged with doing under the Endangered Species Act.

It may not feel like it to folks on the outside, but I don't think anybody on the inside would disagree that we have come a long way on both sides. We very much appreciate the level of cooperation from NFMS and from Fish and Wildlife Service, also the involvement of the Department of Agriculture, and other folks from the government side.

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There are many of you around this table who have been involved in the discussions we've had on how to address not only the process issues but the science issues and then some of the more challenging implementation issues out there as well. That effort is going to be underway for a while going forward. I don't think anybody has any expectations that there's a simple and easy solution to this, and that this is going to get fixed anytime soon.

But I can say I think, accurately and with all sincerity, that everybody is absolutely committed to figuring out how to fix it and how to make it work for everybody involved, both from the registrant's perspective, from the grower's perspective, from the NGO community's perspective, from everyday people's perspective, as well as from the perspective of the folks in government who are actually responsible for implementing the requirements that we're faced with.

What has been going on, which I know you'll talk about today, is there have been some pretty significant agreements reached with regard to, for example, the upcoming National Academy of Science's

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study. I know we've talked about that before in previous meetings. I just want to say to folks, do not underestimate the significance of that effort. I say this to compliment the folks at NMFS and the Fish and Wildlife Service.

They work very closely with us and also USDA who has been very active in helping not only to define the issues that the National Academy of Sciences will look at but also helping to work on some of the technical presentation aspects that will go before the NAS when they commence their work, I guess next week or two weeks, whenever it is.

It's taken a while to kind of get that effort going from the time we reached initial agreement to do that and began to scope out the questions to the NAS and then to start working with the NAS as they pick the people who are going to be on their panel. I think they've got a very good panel that they've proposed, at least so far.

That's going to take a while for them to get that done. I think we're looking at probably 18 months or so. But that group is intended to address the science

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issues underlying the way that we look at Endangered Species Act issues, how the services address the science issues when they're developing biological opinions, and what kind of inputs we have into that process at EPA.

We've had lots of discussions between our agencies about how -- I've said this before to you all -- how what we do here at EPA can be adjusted so that it's more in sync with what the services do over there and how they can adjust what they do and the information they need so that it's more in sync with what we do.

Part of the process we hope that will come out of the NAS review is that we'll get a better perspective, certainly an independent scientific expert perspective on what are the real nitty gritty scientific issues that we need to wrestle with going forward, how do we address the questions that are out there, are we doing it right, are we doing it wrong, are we completely missing the boat or are we right on target.

The issue for us at EPA is kind of a two-part question. One is, what is it that we have to do under FIFRA and FQPA and the other governing authorities we have when we're reviewing registration applications and

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registration reviews and those kinds of things, compared to what is it we can do and what kind of information can we provide to the services as they move forward, recognizing the issues that some things may present to registrants and others. We'll have to have those kind of discussions until we get further into the process with the NAS and we see what the NAS comes out with.

I don't know that we'll ever actually be in that perfect world that they once tried to achieve with the counterpart regs where we do something and then it's deemed a nirvana. But what we're hopeful for is that we'll be able to keep moving our process a little bit in this direction and the services will be able to have enough information up front early enough in the process.

That's something that they have to figure out as well for themselves, what do they need, when do they need it, and how they can use it. So, when we get to the end game on this, we're not that far apart and we're not having the situation that we've been in for the last number of years where there's just a lot of back and forth, which doesn't serve any of the agencies any good. It certainly doesn't serve the public at large good.

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We're going to have to do all of that, I should say, up front. I think there's a genuine commitment to do that, certainly on the part of leadership of the agency. The staff has been working very closely together, Jim and Brady.

We put Brady back here on the low section of the room. They sit back there and they go like this when I'm talking. Are they doing that now? Usually, Brady says, what, I wasn't listening, whenever I talk.

But anyway, they've been working hard for a long time, long before I got here. But they've been working even harder since I got here to try to get these things figured out. What I was going to say also, we're also operating in the context of litigation. So, we are going to try to have as open and frank and comprehensive discussions with all of you and others as we possibly can going forward.

There will occasionally be a situation where because a particular issue happens to be in the middle of litigation or pending in front of a court, we may be a bit circumscribed in terms of what we're able to say or do or something like that. So, I'll ask you to bear with

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us on that.

Some of these things may get some resolution or some clarification of some of the more contentious issues based on how some of the court decisions come out, or it may just be that the court decisions make them even more confused and complicated. We don't know. But we're going to continue to work on this as much as we can. We're optimistic that this is going to get worked out.

We know there's an awful lot of attention on this, not only from all of you in this room but from people outside who are affected by the decisions we make. There's also a lot of interest on the part of members of congress that we've been working very closely with to try to help them work through these issues as well. So, we again appreciate your involvement in that.

I know I unfortunately won't be around for the discussion this morning, but I anticipate it will be a fairly lively one. I would hope that as you get into it, that you not only make Brady earn a living, but you come at him hard with lots of tough questions and things like that. Brady is doing the presentation, isn't he?

MR. BRADBURY: And Keigwin backing him up.

MR. OWENS: Keigwin is back there as the relief pitcher. This is the opportunity, as you guys know, for those kinds of questions. Not to make him squirm, although that's always fun to see, but the more challenging the conversation, I think the better off we are because it helps us figure out where the opportunities for agreement actually are.

I know that sounds a little bit weird to say, but rather than glossing over the key points of contention, I always think it's better to get them out on the table to figure out what is the real nub of an issue, what is the real problem, how can we actually figure it out. Sometimes we can't, but most times we can.

So, it's really just a continuation of a longer discussion. But we're going to keep coming back to you with these issues as this process unfolds. My view is that over the next period of time as we go through the NAS process, as we move forward with some of the other issues out there, this is going to be one of the more significant things that we will have done and that certainly all of you will have done in terms of helping us figure out how to address this issue and resolve it.

So, I appreciate your willingness to be part of that discussion. I appreciate the time you're going to give to it this morning. Again, any hardships you can create for Don Brady this morning will be greatly appreciated.

With that, I'll turn it back to Steve. Thank you, guys.

MR. BRADBURY: Well, maybe we should get right into it and see how Don holds up.

MR. OWENS: I know you guys were supposed to get on to the agenda right now, at 9:30. I've got a few minutes before I have to leave. I don't know if anybody has anything easy to ask me before I leave. I do want to listen to at least the beginning of it. I knew Cindy would have questions.

MS. SMITH: Steve, yesterday, one of the updates we got was from Allison on NPDES. I know that it's not directly in the shop of OPP; it's in the shop of Water. But one of the things that I think was alarming to a number of people to hear was that there still isn't a final permit that can be out there due to consultation, which we've just been talking about, whether it be with

NMFS, which it sounds like they're closer, and Fish and Wildlife Service, which it sounded like maybe they're not even close.

So, there still, I think, remains a question about why wouldn't the agency seek an extension to get that resolved so that people have an understanding of when that permit is actually issued, what the requirements are going to be with respect to things that may have changed as a result of the consultation.

I don't know if you want to share anything about that. Allison wasn't able to share all of it, but I'm imagining you're having a conversation about that internally.

MR. OWENS: Let me avoid answering your question this way. I think that's exactly right. There are a lot of things that are in the works (inaudible) as you noted, officially in our office. There's Office of Water and also Office of General Counsel and others who are looking at all those issues. I think we're close to getting the consultation issues resolved.

I think the most important thing to keep in mind about the consultation -- and Jim will probably

speak to this a little later, if he's inclined to -- it's a limited subset of areas that will be affected by what comes out of the consultation process. Certainly, some areas will be affected.

But, for the overwhelming majority of the people who are covered by the permit, who are in activities that are covered by the permit, they're not going to be affected by what goes on in the consultation process. So, I can't tell you exactly what's going to happen when.

I can tell you at the moment there is a commitment by or a determination by the agency to just get it done. Part of it is that level of uncertainty that's out there of what's this going to look like. It's a fear of the unknown which I think causes more issues than what might actually wind up being in the (inaudible) when it's done.

We do have a court deadline right now at the end of this month. Certainly, that's the path we're on right now. That's about all that I can really say because, as I said, I'm not the decider on that one. There are others who are making those decisions.

UNIDENTIFIED FEMALE: You alluded to the fact that you had additional conversations, services, but you also mentioned congressional involvement in the classroom. Can you expound on that? What type? And I have a second question.

MR. OWENS: There's no mystery on that. There's just been a lot of congressional interest. There's been hearings. Dr. Bradbury has testified. So, there have been hearings on it. There have been a lot of briefings on the Hill with the staff. A lot of that has mostly been just informational, trying to figure out -- sometimes with the pesticide general permit, but mostly on the bigger picture, the Endangered Species Act consultation process, kind of what's going on not only with the litigation but as we work towards the National Academy of Sciences review.

There's some interest in having us look, for example, at the economic issues associated with it, which we think are a good idea. We just have to figure out the right way to do that. So, we're trying to work between the agencies but also with members of congress and others on making sure that not only are they kept fully informed

of the process as it moves forward and as we work as partner agencies here to develop a process that works, but that we address any questions or issues that they have along the way that they may be hearing, for example, from their constituents, things that come up, that kind of thing.

So, there's nothing terribly new or unique. It's just that we're trying to be even more proactive than we have in the past in making sure that people are kept informed of what's going on.

UNIDENTIFIED FEMALE: The second question is just real practical. This NES panel coming up, will the charge questions for that be made public? At what point would they be?

MR. BRADBURY: The broad charge areas are already public. When the administrator on behalf of USDA and Commerce and Interior wrote the letters to the NAS, it lays out the topical areas that we want to look at. It ranges from how to define best available information, how do you evaluate the information that goes into geospacial information, mixtures effects of sublethal and cumulative modeling, advice on how to use models, and

then how to talk about, analyze, interpret uncertainty in the overall decision-making process.

Those are broad areas and that letter lays out some of the specifics. As you go into the actual meeting the panel and services, USDA and EPA can clarify or drill in a bit deeper. Everything will be public. If you go to our web page, you can see the letter and it lays out the broad topical areas.

UNIDENTIFIED MALE: Any meetings coming up?

MR. BRADBURY: The first meeting is November 3rd and 4th in Washington. These guys will correct everything I say that's wrong, but there's, I think, three public meetings of Washington, out in the Pacific Northwest.

So, there's opportunity for public comment and for the public to put things into the record for the panel. The first two-day meeting is November 3rd and 4th. I don't know if NRC has scheduled the meetings out west yet or not.

Scott and then Joe.

MR. OWENS: And then I'll wrap it up.

MR. SCHERTZ: Obviously, the OMPDS issue has

been very complicated for the agency. But also, it certainly is relevant that it's going to be complicated for the decision makers to comply. As we understood Allison's comments yesterday of this gap between compliance and the NOI requirement in January, that is a very problematic area for the decision makers.

We do have a request that that be formalized of exactly how that takes place. We really think this is very difficult to be in compliance of something like that when you just see the final provision literally days before compliant with it.

MR. OWENS: Okay. I'm not quite sure what she said yesterday, but I think the bottom line is that the agency is going to work with really the states who have to implement some of this at the state level. Also, where the federal permits will fly, we're going to be as reasonable as we can to make sure that everybody understands what requirements there are. It's a new thing. We get that. It's been part of the conversation for quite a while.

I think people are going to be bending over backwards to make sure the information is out there once

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the permit goes into effect to try to do the kinds of outreach efforts that need to be done and to be paying attention, again listening to what's actually happening out there on the ground and trying to accommodate those interests as best we can.

MR. BRADBURY: Joe.

MR. CONLON: I'm well aware of the constraints under which the agency is working in this regard. I do applaud the efforts that are trying to be made to make this as amenable as possible to all. However, the end users, like I am, are a little bit less sanguine about this whole process. We think that an extension should be asked for. I understand that it's probably not going to happen, but we think an extension should be asked for.

I think in our role as an advisory committee, this committee -- I would like to see the agency afford us an opportunity to vote as to whether we want to give the advice to the EPA to request this and formalize it as something on the record, that this committee either wants you to extend it or doesn't. Then, you can take it from there. But I think at some time and at some point, the advice that this committee gives needs to go on record.

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So, I was wondering whether you'd entertain a motion for a vote on this by the committee to ask for an extension.

MR. BRADBURY: The committee works by whether or not we can reach consensus or not on a position. Sometimes the committee reaches consensus and sometimes it doesn't. But we don't vote on motions. I'll just leave it at that.

Having said that, you have lots of venues to get the word into the agency. Certainly, the minutes here will reflect varying opinions about where we are in the process and the next steps in the process. Certainly, we're not shifting it to Office of Waters. Office of Water has the point on this that, by all means, people should be communicating with the Office of Water on your views. This isn't to shirk our responsibility, but just to get the information to the right place.

Certainly, our minutes can reflect the fact that there's varying opinions on the process and the status and the time line. Obviously, Allison heard it and you can share that with Allison, the diversity of opinions and thoughts on the topic.

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MR. OWENS: The only thing I would add is, looking around the room, that certainly not all of you, but from a number of you, we, meaning EPA, the letters to the administrator or to the water program, and sometimes to our office, those opinions have been expressed. So, we do have a record of that in the agency as well.

So, I absolutely understand your point, Joe, but I think that the agency has heard that. We got that. We've got, actually, correspondence from a number of you. Some of you have actually been in meetings with us and with Water, as elsewhere. So, we appreciate that.

Thank you, guys. I didn't want to delay you too much, but I did want to at least give you guys a chance to talk about that a little bit. We will keep you advised as things are developing on all this.

MR. BRADBURY: Thanks, Steve.

Why don't we move on to the main part of the morning which will be an update on our efforts with the Endangered Species Act. In particular, this will be a report out from the PRIA Process Improvement Work Group, which was focusing specifically on ESA and processes that can be used to try to make the (inaudible)

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determinations, the consultations more effective, how to get the right kind of information in at the right time. You'll hear some presentations that will let us explore some options on how we might take a look at the registration review and perhaps adjust that approach.

I think Don and Rick are also going to give you a little bit more update on the NAS process and some of the other things that are going on, as well as some of the process options that are being explored. So, Don is going first.

MR. BRADY: Today I go first. Yesterday Rick went first. So, we have a nice block of time set aside this morning to talk about some of the work that we've been doing in regards to endangered species. I'll give a short update on NES. Most of what I was going to say has already been covered, so I'll add one or two small details.

Then we'll have a presentation. Rick will take us through some work that we've done internally in the agency that looks at where the appropriate place in our registration review process might be to initiate the consultation discussions with the services.

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Then, following that, we'll have presentations from Tilghman Hall and Mike Willett. They will be relating some work that has been done through the PRIA process improvement group as to their ideas that relate to sort of the timing of where consultations might occur that would help us fulfill both our ESA obligation, but also would allow us to meet our schedules under registration review.

So, we have a couple presentations and then in your agenda, there are printed five questions which we'll use to guide the discussion with the PPDC members as we move through this session and get some views by using those questions to elicit those conversations.

So, the only thing that I really would add to the discussion on NAS is just to recap that the first meeting is set for November 3rd and 4th. It's here in Washington. There are additional meetings being discussed. As of yet, they aren't scheduled by the National Academy folks.

The extent of the conversation we've had with them is they indicated that they're thinking of having two additional meetings and probably on the west coast.

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One of them probably in the Pacific Northwest. They haven't said anything further to us about that. So, that's the thing that we can all watch web pages. As soon as we know, we certainly will provide that information to our avenues of communication, our regular communication avenues with you.

Then, the other thing is that in addition to the broad charge letter that both Steves talked about, there will be some more information provided by the agency that's in process now. There's two blocks of information, if you want to think of it that way.

One is background materials, which constitute reading for the panel members. Each agency is preparing that material now to transmit to the National Academy. Then, there will be some more detailed explanation of the questions or the issues that we would like advice from the National Academy on. The agencies are working on those issues.

Now, we're loosely calling them charge questions just because that's the term we're used to using. The target date to have all of that material to the academy is Friday, October 21st. Once that gets to

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the Academy, it will all be posted on their web site and made available to the public. So, it's an entirely transparent and clear process for everybody involved. So, that's really the only thing I would add in addition.

At the meeting, the first meeting, there will be time for public presentations. The format will be the agencies will have presentations to make to the panel. The panel itself will invite some presentations from other organizations. Then there will be public time for anybody who wants to speak to the panels, to address the panels. So, it will be an intensive two days or day and a half on endangered species from all sides of the issue, so to speak.

As was said earlier, I think those of us in the agencies are really looking forward to the advice that the panel ultimately provides to us and hope that it forms a very solid basis for us all to sort of move forward and find our middle, so to speak, as Steve Owens was saying. So, I think that's really it on the NAS panel.

So, the first thing we wanted to talk about was to have Rick share some work that his group has done on

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the registration review process and how ESA would conceivably fit in or some options that were prepared. Then we'll have a presentation which addresses similar issues from Tilghman Hall and Mike Willett that is based on, as we said, the PRIA process improvement work.

MR. KEIGWIN: Thanks, Don. These next four slides are not in your packages. We apologize for that, but they may look familiar to many of you because they were some slides that we used at the April PPDC meeting where we began to get some advice from you all and one of the reasons why we went to the PRIA Process Improvement Work Group on trying to flush out some ideas on how to create some efficiencies in the registration review process for us, for stakeholders, for the services, as we move forward in trying to complete the program.

So, let me just sort of refresh everybody's memory, because I think the next couple sets of slides really set up Tilghman's and Mike's presentations really well.

The slide that's up here now represents what the current registration review process is from docket opening through preliminary risk assessment, final risk

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assessment, proposed risk management decision, and final decision with opportunities for public comment at various stages throughout. As originally envisioned, we would consult, where necessary, with the services at the preliminary risk assessment stage. We've done a couple of pilots of this approach, and those chemicals are still in consultation.

At the last PPDC meeting, we brought to you two options for consideration and feedback. The first option was to move the point in the registration review process in which we would potentially consult. That would be moving it from the preliminary risk assessment stage to the proposed decision stage.

Among the reasons why we discussed why that might be a better way to pursue things was that we would be getting closer to what the actual end game final federal agency action would be. The decision would be based upon a more refined risk assessment. There was the potential to include mitigation at that stage. So, that's potentially what would be the subject of a -- any consultation would be on a much narrower scope and would be more reflective of what the final registration review

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decision might be.

We also talked about another option where we would wait until we had issued, really, an interim final decision where we had already gotten to the decision phase but for having completed consultation. Some of the discussions that we had in April highlighted that many of the pros of this approach would be the same as were in the previous option, but there was some discussion about whether or not an interim registration review decision could somehow be interpreted to be a final agency action made in the absence of consultation. There was some degree of hesitancy about that approach.

The third option is an option that actually came about in the course of our discussions in April in this meeting. That was to do a bit of a bifurcated approach to the consultation process where at the point that we would put the preliminary risk assessment out for public comment, we would seek informal consultation with the services to get more refined information about species habitat, species biology, species behavior.

Incorporate that information along with public comment that we had received in developing our final risk

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assessment and proposed decision and then, if appropriate, based upon all that information, as well as any mitigation that might have come forward during the previous public comment period, make a determination to consult formally at that point on the near final registration decision.

Again, we've taken all three of these options to the PRIA Process Improvement Work Group. There has been some interest in this last option because again, it's based upon additional information that helps refine the assessment, has many of the same advantages for both the agency and the services. We had some success with this approach.

We actually employed this to a degree with a consultation last year with the Fish and Wildlife Service. This particular use pattern did not have issues that necessitated consultation with NOAA. But we didn't know how sustainable this was to effectively potentially be in a situation of doing two consultations for every registration review chemical every year, particularly given current resource pictures across the federal government.

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So, with those three options in hand, we've had two meetings now with the PRIA Process Improvement Work Group. We met with them first over the summer in July to get their feedback on these options. We then had a meeting in September in which CropLife America made a presentation to our committee that we thought would be really useful for you all to hear because there were some really good suggestions that came forward there. So, Tilghman is going to give that presentation next.

Also, it was announced at the spring PPDC meeting, the Minor Crop Farmer Alliance held a meeting in Denver that was really focused on how growers might be able to get more involved in the registration review process as it affected endangered species determinations. So, Mike Willett is going to give us a brief presentation on that.

Then we'll circle back to some charge questions that are, as Don said, listed in the agenda for today's meeting. So, with that, I'll ask Tilghman to come forward. If somebody could help put Tilghman's presentation up.

TILGHMAN HALL: Thank you for the opportunity

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to present this. It's some of our thoughts on registration review in general and how it impacts ESA, and then some additional thoughts specifically on consultation.

For the sake of time, I can give kind of an intro of the slides, which is really -- the whole goal here, I think, is we have a commonality across all of us. We all want a predictable process. We all want to understand that process. We want to make sure there's opportunity for people to give input into that process.

At the end, we want a comprehensive risk assessment that we can all interpret and understand. We want well-documented risk management decisions, how was a risk or no-risk conclusion reached. We want all the stakeholders to know when they can participate and how to participate. We want, basically, a balanced implementation. We want to protect species but we also want to protect agriculture, so minimizing that impact on ag.

This slide is kind of the basic five phases of registration review as it's currently defined. So, you have the docket opening, your final work plan, your

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preliminary risk assessment, your final risk assessment with proposed decision, and then your final decision. As noted already, there's public input at various points along here.

What we're going to do is just give some brief comments on each one of these phases and how we might think things can be improved a little bit. So, in the first docket opening, registration review up to now didn't have really the smart meeting opportunities where the registrants were really going in earlier, much earlier than when that first docket opens, to explain these patterns.

So, we think it could be a lot more efficient to go ahead and reinstate those kinds of meetings to get that kind of information out so that the first docket opening isn't focused on did it get the use patterns right; it's focused on some of the other main issues that might be coming up in the risk assessment.

We need a clearer mechanism for stakeholders to supply information, not just the registrants but others, the states, USDA. It's very confusing to know when to provide the information given the time line of

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registration review. It could take three to five years for it to be complete. So, when should you give that information? That needs to be specified a lot more clearly in that first docket opening as well as throughout the whole process.

At this point, you can interact. You can identify what you anticipate the interaction with the service being. Is it going to be an informal consultation, a formal consultation, some sort of memorandum of understanding of how you might work together. Start giving some indications of how you might move forward in that type of interaction.

Then we identified that perhaps after the first docket opening, if the registrants have a lot of additional information that they're planning on providing, they could possibly request a second meeting just to make sure everyone understands all the information that might be coming in between that period and when the final work plan is coming out.

So, when we're talking about the final work plan, again, the focus here is more about the restatement of the data needs and all the information you want.

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Currently, registration review has a one- or two-page document in there that says please provide us all of this great information. It is a very good list of information that they want from the states, from USDA, from the registrants, from anybody who has that information.

Again, when do you give it? If you have a DCI and EPA is not going to start that risk assessment for three years, then really you want that information close to the end of the DCI and not at the beginning where it might become quickly outdated. So, that needs to be more clearly stated in the final work plan of when you anticipate needing all that type of information.

Again, included in that could also be a statement of any sort of endangered species data requirement that might be necessary. That should just be made clear in the final work plan as well.

This one really talks about the preliminary risk assessment, but there's a line in front of the preliminary risk assessment to the final risk assessment. It's kind of blurry a little bit. Essentially, as you're working through the preliminary risk assessment, it's at that point where you need to increase the communication

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with the states and other stakeholders on how you want to use that local information that you can gather. So, there needs to be some outreach to them to make sure you really are getting that information in.

As the risk assessment becomes clearer as you're working through it, it starts becoming more obvious what are the drivers of the risk assessment. If there's a risk occurring, is it primarily from spray drift, is it primarily from runoff? What are the drivers behind the potential risks that may or may not be occurring? That's where you can start the dialogue with appropriate stakeholders on those drivers of the risk assessment.

If spray drift is a major issue, then let's start talking with the novel groups, the aerial applicators, the people who know more about that type of information. If it's runoff, then maybe USDS or USDA or other experts can help feed information into the process that might help refine that risk assessment and making sure we all understand where things currently stand in the current science.

Again, the line between the preliminary risk

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assessment and the final risk assessment, continue that dialogue as you go along. You'll have to document that dialogue. We understand that. You'll have to include it in there that we talked to this group and these were some of the recommendations that can be documented.

Then, what's important is after you have the preliminary risk assessment, you're going to the final risk assessment. Risk management decisions are becoming clearer. Those risk management decisions have to be well documented. How did you reach the no-risk conclusions? If you reached a risk conclusion, what was that risk and how did you get there?

That's not necessarily always done on the current registration review in terms of ecological effects type of thing. Risk management decisions aren't not necessarily as transparent as they possibly could be. So, this is a really critical step in order to understand how to move forward, and especially to understand if you're going into consultation. How did we reach our conclusions? So, it's important that this risk documentation phase does occur very strongly.

This is our version of what EPA proposed on the

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different options of consultation. I don't think I need to spend any time on it, but essentially (inaudible) preliminary risk assessment, the final risk assessment, or a combination of informal versus formal at the preliminary or final decision. So, these are all viable options.

What we're going to do now is just give you some general recommendations about consultation and what our thoughts are around that. So, wherever consultation occurs, informal, formal, preliminary, whatever, the role of the applicant has to be identified whenever it's occurring. I think everyone understands very well these days about the role of the applicant being identified as part of ESA.

It's a very important step. It's a very important step in terms of the registrant because that gives them an understanding of the process that's going to be used, the timing, and how that's going to be done. So, it should be an easy one to just make sure the letters go out about who are the applicants in this consultation.

So, one of the comments made earlier is that

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you can use informal consultation as a way to gather information. I guess we kind of disagree with that a little bit. What we believe is that EPA and the services definitely should interact throughout this whole process. But you don't necessarily have to initiate consultation to do that. If you need information, there should be a mechanism to gather that information without initiating consultation that has all the time lines and everything associated with it.

So, our recommendation is that you just continue the interactions through the process as needed. If you're going through an informal one, that's certainly an option, but you don't have to initiate an informal consultation, or shouldn't have to, in order to get that information.

We certainly acknowledge that the services are the experts on species location information, on other species biological information that might be needed to help with that risk assessment. One mechanism to do this is just coming up with some sort of MOU, memorandum of understanding, about how you want this process to work. There's an understanding that there might be some

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outreach needed for EPA to do this risk assessment. Hopefully, those databases are kind of generated by the services and this isn't a huge workload.

There are options for consultations for sure. We've already outlined a couple of them. The counterpart regulation were not completely overturned in the court of law. The alternative consultation process that was outlined in the counterparts still exist.

The alternative consultation essentially says let's kind of do this risk assessment together, so you're kind of initiating it early. You're working together through the risk assessment. So, by the end, you essentially have reached an agreement on the effects determination, as well as consultations. That is an option that could be used. We certainly would encourage trying it.

There's also section 402.46 in the counterparts that survived. That actually allows EPA to go and do an effects determination. They could actually make a jeopardy, incidental take statement, RPA and RPM judgments as well. So, they could actually take these assessments, if you'll let me call it that, much further

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than they currently are.

Of course, all of that would be subject to the services review as outlined in the counterparts. But it might be one way to streamline some of the processing if we can get to the point where EPA can make decisions such as that. The services are reviewing them and agreeing or disagreeing with them.

Again, we think you use these consultations as needed for regulatory decisions. Don't use consultations as a way to interact with two agencies. Use them to make the regulatory decisions and get to a decision so that you can do it in a more timely fashion.

So, our ultimate consultation goal, and this may take a little time to get there, is that if consultation is required and you're thinking about kind of the normal one, where it's formal consultation after EPA completes their effects determination, it should be conducted on as complete an effects determination or biological assessment, whichever term you want to use, as possible.

It should only be for that part of the decision that really needs the consultations. We have a

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significant resource limitation going on between the agencies. So, we do need to think about how best to use those resources. So, our recommendation is to only do it for the decisions that need consultations.

The reason we want it to be on the more complete effect determination is if you do it too early, you remove the stakeholder input. That is a very critical point for us. We do have additional data that can be provided that might change a preliminary risk assessment to a final risk assessment. Risk assessments can change. If they change, you would have to reinitiate consultation again based on a new risk assessment.

So, we want the consultation to consider all the stakeholder input. We want it to be the most informed and refined risk assessment. We want full documentation of any risk management decisions. Again, that helps to clarify what is the need of consultation and maybe perhaps what is not.

That would allow a clear identification of what species are at risk, essentially have a no effect or maybe a not likely to adverse effect decision or a species that might be at risk and need informal

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consultations such as may effect or likely to adverse effect decision. We think this is one way to really get a best use of the services resources as well as EPA resources.

We acknowledge, though, things aren't perfect right now between the services, so alternative options may be needed during the next couple of years as the NAS panel continues. We need to think a little bit more about that because there is an underlying assumption that they kind of agree with the risk assessments coming out with EPA. So, we need some of the science questions being answered. As Steve Owen said, you shouldn't underestimate the NAS panel and the influence it will have on how these risk assessments are done.

So, that leads to one of the questions that I think are on your sheet about interim decisions. An interim decision could be -- you have interim decisions hanging out there, but the question is, can you have interim decisions based on some uses or species that aren't at risk and some species that (audio trouble) make that kind of interim decision. That's a slightly different question than I think has been asked before.

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Our thoughts are that that's definitely worth pursuing, that you have perhaps an interim decision that leads down that path where there are no effects decisions reached by EPA on certain uses or species. Let's move those through the registration review process, and maybe others need to go into the consultation.

That said, there are a lot of nuances to that statement I just made when you do that. The first thing is semantics. What do you mean by interim? How do you define that? How do you move that forward? There's issues with ESA. The definition of the action would have to be defined. That would have to be very clarified.

Ultimately, you would need a very clear document of the process that would outline how this could or could not work. I guess our recommendation would be to require more thought and evaluation on whether or not it could work. But it's probably worth pursuing at this point in time and thinking more about it.

So, in general, some of our process improvements that we think would really help registration review but also help with the ESA part of registration review, early registrant interaction to help work through

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use patterns and things like that and help influence perhaps a better problem formulation coming out. You would have increased communication with stakeholders occurring even more, but you would have document anything that influenced risk assessment and what came out.

Concurrent with that is a better understanding of the data needs and the timing of the commission of those so that the states, or USDA, or the registrants, or other people know when to provide the information to be more influential in terms of its use in the risk assessment.

EPA and the services should definitely be interacting early and often. You could come up with an MOU to help define how you want that interaction to occur, or some other mechanism. Consultation, essentially, the registrant would be clearly identified as the applicant.

Use the counterpart regulations that survived. They do provide some good mechanisms just to make things more efficient. The more formal consultation process should be a more complete effects determination. Then there's the discussion on final versus interim decisions.

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It certainly needs further evaluation, certainly input from this group on what they think about it.

Some of the potential benefits, again you'll have better understanding of those use patterns, if you can get that information done quickly. Increase understanding of the data and information used in submission opportunities so that you are getting information you really want.

You need to better figure out how to integrate that local information and any best available data that's coming in, the full consideration of all the mitigation options and the documentation about what you did there. So, again, ultimately leading to that clearly defined and fully informed risk assessment and all the assumptions behind that risk assessment so people understand how you reach decisions. And lastly, more efficient and targeted interactions with the services.

Our conclusions, much of what I just said, are restated here. A more open and transparent registration review process will benefit all. It will also help with the ESA consultations. You need that mechanism for the registrant and stakeholders to provide that information.

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You need that early and often interaction with the services. You need that final decision to be understood by all and lead you down where needed. The consultation and needs clearly defines the path of the consultation.

Better utilization of the counterparts, again, our ultimate goal here -- and it might take a little while to get there -- is that consultation is completed. Make sure you've considered all of the stakeholder input and look at it at the more complete effects determination phase, and only for those decisions that might need the consultation. That's it.

MR. BRADY: Thanks. We have a few minutes for questions if anybody has any.

Mark.

MARK: I have several actually. Richard, you introduced this and you thought it was appropriate for us to watch it. These recommendations, I want to get your opinion. Is there any unnecessary time difference or delay in implementing these recommendations as opposed to what you're currently doing?

MR. KEIGWIN: I think there are pieces of them that -- I mean, we haven't fully considered everything

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that Tilghman presented to you all. I think Don and I got this presentation about three weeks ago. So, we're still in the process of entertaining it. But we thought it would be helpful as we were considering these ideas that came forward to get some input from you all and what you all thought.

Many of them are probably implementable. Some of them, I think, are probably in some ways intertwined with the NAS review. So, how quickly we could move forward on aspects of what you just heard is unclear, pending the outcome of advice that we would get from the NAS.

MARK: My concern is that the folks who do this, you and the agency that do this, you look at it and say if it's an improvement, then we need to understand that you think it's an improvement. But if it's not, then I want to get your opinion on it, too. This is pretty cumbersome stuff for those of us that don't do it all the time. So, as you look at this more, maybe we can get an opinion from you on that.

MR. KEIGWIN: Sure.

MARK: Which is a tough thing to do, put you on

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the spot like that.

I do have one more question, and I can come back to others if we have time. But it says on page 3, slide 2, relevant stakeholders may include registrant, USDA growers, crop experts, nozzle manufacturers, aerial applicators, state and local programs, including services, et cetera. Are environmental activists considered relevant at this point or not, I mean, if they're experts?

MR. KEIGWIN: So, EPA would consider all stakeholders to be relevant to this process.

MARK: Okay. I just wanted to make sure that they were still included on that because they're not in there.

MR. KEIGWIN: Remember, this was CropLife's presentation.

MARK: I understand that.

TILGHMAN HALL: We would agree.

MARK: NGOs aren't listed on this.

TILGHMAN HALL: No, they're not listed on there.

MR. KEIGWIN: On earlier slides I think they're

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listed.

TILGHMAN HALL: Don't mean to exclude anyone who wants to provide information. Let me just say that. If they have information that should be provided it and it's relevant, it should be used.

MR. BRADY: I think what we should do is limit these questions to clarifying questions on the presentation. Then we can have the discussion after we see Mike's presentation.

MARK: That was a clarifying question.

MR. BRADY: Right, I appreciate that.

Dr. Keifer.

DR. KEIFER: Mine follows up on that question to some degree because one of the -- I'm just wondering about services when it comes to the species homo sapien/sapien laboralis, the worker. Who is representing that particular species in this process? Where are they? Are they coming in as a service like OSHA, or is it EPA that represents the protection of workers in this process? Do they interact in this process at all? I'm just wondering.

MR. KEIGWIN: As part of registration review

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overall, there are -- that slide I put up early on that overlays the entire registration review process, each of those public comment areas there's an opportunity for any stakeholder to participate in that effort. But, generally speaking, it's EPA that's making the worker safety determinations.

There's not a requirement under OSHA or any other law to consult with OSHA or NIOSH. But, on occasion, where there's a unique methodology or a unique issue, it may. We're trying to focus this discussion, though, just specifically on Endangered Species Act issues.

DR. KEIFER: I would argue they may be endangered species.

MR. BRADBURY: Just to clarify, Matt, the reg review process is reevaluating everything about the registration. We're looking at if it's a food use pesticide, we're looking at FQPA issues and dietary exposures, aggregates. If it's a cumulative, we're looking at that. We're looking at occupational risks. We're looking at residential uses.

We're looking at ecological risks, and we're

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looking at endangered species. And if everything works right, we're folding in endocrine disruptor screening programs as well. So, it's looking at everything associated with the registration.

What we're doing here is just trying to get the conversation going on how do we try to optimize the efficiency and the effectiveness of getting the endangered species part of this overall registration review process (inaudible).

So, why don't we just get clarifying questions on this presentation. Then we'll get to Mike. Then, our charge questions, if you will, kind of get at the meat of what we want to do.

UNIDENTIFIED FEMALE: I just have a quick question, and it's clarifying. Has this approach come out of the PRIA Process Improvement Work Group or are they still vetting it and discussing it, too?

MR. KEIGWIN: This was the presentation that CropLife made to the PRIA Process Improvement Work Group. But we haven't received yet a recommendation out of the PRIA Process Improvement Work Group.

MR. BRADY: I think we'll go to Mike. Thank

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you, Tilghman. We appreciate it.

DR. WILLETT: Thanks, Don. First of all, Minor Crop Farmer Alliance was asked to make this presentation. This presentation is a subset of a presentation that Dan Botts made to the American Chemical Society summarizing the outcome of the Minor Crop Farmer Alliance ESA meeting that was held in Denver in May.

Dan's presentation was quite a bit longer. I've cut it fairly short. One of the reasons why I did that was obviously for the interest of time. I knew that the charge questions were going to be there that were going to cover some of these issues. Also, you have the entire text of the summary of the meeting that was distributed this morning, thanks to Margie's efforts. In fact, most of everything that's happened here over the past two days are due to Margie's efforts. So, we appreciate that.

Just a little bit of an introduction. Minor Crop Farmer Alliance is an organization of about 30 specialty crop producer organizations. We've been around since about 1989 working on pesticide policy issues. As the issue of endangered species started intersecting

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pesticide policy, Minor Crop Farmer Alliance decided it was an important thing to get involved and to try to give those grower organizations, who are relatively small organizations with all the employees having other day jobs, a voice in the process in some way. We think that the endangered species process needs improvement. I think everybody agrees that it needs improvement. It needs to be as open and transparent and science-based as possible.

So, we put together this meeting. The planning committee consisted of growers, EPA, National Marine Fishery Service, US Fish and Wildlife, USDA, and registrants. You're going to see the word growers in this presentation.

Really, this is the grower perspective, because this is one of those unique situations where because of the consultation process, the people that are actually applying the pesticides are not part of the formal legal process. They're not involved. Their information is not considered as part of this consultation. So, it's a challenge, because obviously, those folks that are applying pesticides know how they're used. So, how can

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that information be placed in the process? You'll see that that was the subject of significant discussion.

So, the goals of the workshop were to try to provide grower representatives an understanding. We had 75 people participate in the meeting in Denver. We invited you all. Some of you came. We would have liked to have seen more. But it was a good group, a really cross section of registrants, user groups. Folks from EPA, National Marine Fishery Service, Fish and Wildlife all were there.

We wanted to identify, where we could, grower level data that would enhance the risk identification and risk mitigation decision process that's going on, working with EPA and, where we could, work with the Services, and to initiate or at least start the discussions on mechanisms to provide the kind of data that we thought we could provide and was important in the process of making these risk management decisions on endangered species.

Well, the first question is, is there actually grower level data that would inform the process. If there is, what information is the most desirable? Most of these organizations that make up the Minor Crop Farmer

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Alliance are relatively small organizations. They might have one or two staff members. How do you collect that data if it's not already being collected somewhere? It's a real huge challenge for these kinds of organizations. Yet, in the case of the west coast, it's those users that are most impacted by the Endangered Species Act. So, it's a significant issue for them.

Once you have data, how is it entered into the process? Right now, if there isn't sort of a full engagement of all the agencies making this decision, we don't have access to the existing consultation process to plug data back in that's is grower level data. Hopefully, that's one of the things we'll work on.

Then, of course, at the end, everybody that uses the data has got to agree that it's complete and accurate. So, how is that decision made about whether accuracy and completeness is there? Then, of course, where does it get plugged in?

So, what we wanted to determine is how important grower information can be collected and used on the regulatory process, provide an overview of how EPA, National Marine Fishery Service, Fish and Wildlife, and

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USDA can use grower data developed in the process, and determine the best places in the biological review process where that data can be plugged in.

In that handout, I didn't put it up because it was about three pages, there is a matrix that is really a lot like the matrix that Rick showed. It's an slightly expanded version. We actually produced this matrix in a meeting with 75 people. So, I'm totally impressed with the fact that we actually captured everything that's in that matrix in a group that size.

But it's an example of where we think that this information could be plugged into the system. It doesn't vary a whole lot from what Rick had pointed out and the talk that the folks from EPA gave at our April meeting. It doesn't vary a lot from the kind of approach that Tilghman suggested as well.

We think it benefits from both formal and informal discussions between growers, EAP, National Marine Fishery Service, and Fish and Wildlife. We really have appreciated that Cheryl's group and the folks at USDA have been really willing to step up and try to find ways to plug existing data and to maybe tweak the way

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that the existing USDA data is presented to be able to help inform that process even more than they are now. I know they're working really hard right now to try and do that with some pesticide use data, as a matter of fact.

This is the last slide, just sort of a summary. One of the things that we wanted to do -- and I want to say that Dan Botts really did all this work. I am absolutely amazed all the time about how much Dan gets done. He wrote -- and we helped him edit -- the workshop summary that you have in your packs. You have a summary of what was discussed at the meeting. We want to continue this dialogue wherever we can and make it part of this entire process. I think that it's a way of providing what we view as valid information into the system only used on alcolide d-beds (phonetic) and then only on the borders of alcolide d-beds.

Well, first of all, the question in most people's mind is, what is an alcolide d-bed. It's a lot smaller than you think, or maybe not. I don't know. Maybe you know. But, at any rate, the discussion is if you know that that's a use and if you knew that was a driver, how can you help inform the process by providing

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information about how many alcolide d-beds there are somewhere and how big an alcolide d-bed normally is, and that kind of thing.

I think the other question came up when the issue of tank mixes came up. We provided input back, in my particular case, on a specific crop situation. We say, well, these tank mixes are never used. It turned out that the label was a label that was not ever being sold. So, those are the challenges that we face.

We'd like to understand how important those things are and how we can help sort out what the important types of information are that the Services need to have as they begin to do these biological opinions so we can find ways to point them in the right direction to collect that information, given the constraints that they have. So, we intend to continue this dialogue with National Marine Fishery Service because, obviously, they've been the most receptive to being able to have those discussions with us. We appreciate that.

Then, finally, we want to continue to review and participate in data collection, review and analysis as these processes go forward, and engage in the

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discussions that are going to appear here and will continue to occur all way through the entire National Academy of Science process, which I think is going to have to be completed before we sort out how all of these things are going to go forward.

Thanks for the opportunity to be here and make the short presentation. I suppose, Don, if there's -- what do we call these? Clarifying questions.

MR. BRADY: Clarifying questions.

DR. WILLETT: I'll be glad to answer one.

MR. BRADY: Dave, do you have one?

DAVE: So, I'm wondering what you're envisioning. It seems like it's a big country and there's different minor crops all over the place. Are you thinking that whatever groups might be affected by a particular opinion are going to interact directly?

I'm wondering how much effort do you envision the growers going through to give the level of detail in how these things are used to the Services staff people that need to know this?

DR. WILLETT: Well, Dave, you're absolutely right. It's a huge challenge because minor crops are

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produced all over this country. But I think that the one good thing is that the Minor Crop Farmer Alliance does represent a lot of those organizations that have folks that are involved in this pesticide decision making process, whether you're a tart cherry grower from Michigan or an asparagus grower from the State of Washington. I think that we would be able to use the vehicle of the Minor Crop Farmer Alliance to inform people about the process.

But I think that the only way that any grower organization is going to have input into the process is not going to be through a process that solely relies on us feeding large volumes of paper to National Marine Fishery Service and expecting them to be able to process all that information for every active ingredient on every crop.

I think it's going to have to be a process that works through the existing re-registration processes at EPA that are fully transparent and vetted by all stakeholders that are in the process, and are also going to be informed about those processes through the existing registration review process.

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MR. BRADY: Gabriele.

MS. LUDWIG: Dave, I just wanted to respond to that. In terms of the process for the Food Quality Protection Act, when that got enacted, and then the risk assessments were made public, that was the first time grower groups had an opportunity to be part of the process. It made a big difference.

What I would say is that we have experience. If there is the opportunity to provide data on how we really use the product, grower groups will work to get it together. The issue here is that there is no place for us to get it into the process from a services perspective, plus a really lack of transparency of exactly how services get to the decisions that they make.

So, it's very hard to figure out what data is most relevant because we can't understand how they came to the decisions they came to. So, that's really where the rub is right now, based on my experience. I had the opportunity to attend that meeting. It was very helpful.

I reiterate what Michael said, that Dan Botts is just amazing that he pulled it off. And that he got all these people in the room together was also just a

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minor miracle.

But I'm just saying that we have experience from FQPA process, even for smaller crops, of getting data in, finding ways to get that data together when it's really needed. The issue here is figuring out which data makes the most sense and how to get it in.

UNIDENTIFIED MALE: I just wanted to say I wasn't casting down on the value of it. It just seems like an enormously big project. Each active ingredient and each minor crop opens up a whole new set of interaction. I'm not quite sure how to get a grip on this. I kind of doubt that your constituents would have the capacity to interact each time -- and also the Services -- to interact each time.

So, I'm wondering if you have an idea of how to maybe get both sides' level of understanding of each other's issues to a level where you don't have to do it every single time.

UNIDENTIFIED MALE: Well, Dave, one of the things about the folks that I work for is they say, geez, we'll let Mike do that. One of the good things, Dave, is that the Northwest (inaudible) Council and organizations

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like the Northwest (inaudible) Council, the organization that Gabriele works for, the individual producers don't have to make those responses back, which is helpful.

Now, obviously, there aren't all organizations that produce minor crops that have staff people. So, that is a challenge. So, it isn't going to have to be the individual growers that make these responses. It's going to be a summary of how growers use a particular product based on information that we have.

In many cases, Dave, it's not just numbers that we're collecting just based on communication with our members. It's information that's being collected by the National Ag Statistic Service, because we're a pretty strong supporter of that pesticide use collection or chemical use survey that they do. Most of the minor crops that have significant acreage in each state, the data is being collected on those commodities.

We often work closely with, for example, NAS to fine tune their data collection. For example, if they're missing something, we'll try to go back with them and say, well, it looks like part of your questionnaire is not quite picking up all the uses. If you adjusted it,

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did it this way, you'd actually get more of the uses.

So, we do that. You're right. I represent about 1800 apple growers, for example. I couldn't collect that information on my own. So, we have to rely on other sources. You're right also on the second point -- and I'm not going to speak for Jim Lecky, but I think it would be very difficult if all of a sudden all these minor crop groups started feeding his folks information, because they don't have a very large staff, but just to even process the papers.

So, it has to be a partnership arrangement within the existing risk assessment process that's going on within the EPA, which has shown an ability to handle that kind of information and input.

UNIDENTIFIED FEMALE: I'm all in favor of more data. That's good. I mean, it seems like one of the things that would be useful to know is what level of awareness do growers have of endangered species in their areas? Is that some information that you might consider collecting? Is there an education task in here as well?

UNIDENTIFIED MALE: Well, of course, in the case of these initial issues that are occurring on the

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west coast and the northwest, we're dealing with endangered species of salmon or some -- there's a really high understanding of salmon as an endangered species in the northwest.

It's just part of the culture, frankly, and you know that, not only in relation to pesticides but in relation to most other issues that impact people's lives on a daily basis in the northwest. You live near rivers. There's dams on rivers. All those issues. So, I think people understand the issue of endangered species.

I think that the challenge is trying to sort out and sort of parse out what the contribution of risk is by all the factors that are in there. I think that as we work with growers, what we try to do is not, at least personally, try not to say that the sky is going to fall on you tomorrow if something goes wrong, but here are the issues that we need to address.

I think that we need to be extremely honest with people, but I also believe that if decisions are made that can have an impact on their ability to continue farming in certain places, and they're doing things that aren't really representing risk to endangered species or

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their habitat, then we need to make sure that we're able to provide that information back.

MR. BRADBURY: Scott, and then we'll get to the broader questions.

MR. SCHERTZ: To give it a little bit of other insight to Dave's question, I think generally the growers and the grower groups are very motivated. Usually, they have a very limited tool box. These are very important tools for the specialty crops. In this case, I would say there's probably a pretty high level of interest, just because there are very limited choices, even though like IR4, et cetera, works on providing those. But it's a continuing challenge.

MR. BRADY: Okay, thanks very much. So, our challenge now is to walk through these charge questions and elicit some help from the committee as we explore these issues further. So, I'll just start with the first one, which is, at what stage in the registration review process should stakeholders provide information to EPA? What types of information should be provided at each stage? I won't read A through E. I think folks can read that.

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I see Jenn Sass's card up.

DR. SASS: Thank you for the presentations, too. I thought they were helpful. I thought the CropLife one had some good ideas in it. So, I just wanted to add a few ideas to it. Number one, obviously the stakeholders came up with the clarifying questions, but I had that written down. I wanted to point out that including all stakeholders is important. You guys already know, everybody knows, that sometimes the issues related to worker health are the opposite of issues related to endangered species protection.

I remember a particular pesticide where the worker protection folks wanted it in granular form to protect the workers and the animal folks wanted it in liquid form so the animals wouldn't eat it in granular form. So, that was a learning moment for me, but it also made me realize that you can't actually solve the problem in isolation. So, just make sure that worker protection folks as well as the environmental and public health people are there at all stages.

The other thing I felt was interesting, the data, relevant data, and data at relevant junctures is

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really important. So, I really support that. But I want to make sure that that data is also publicly available, because, right now, a lot of isn't until we get DERs, especially with the DCIs, the data call-ins, which are identified at stage -- early in CropLife's presentation, slides 1 through 5.

EPA does the data call-ins. Well, the public can see what EPA is requesting. You can see what the list of called-in data is, but we can't actually tell when or if EPA has received the data it's called in and we can't see the data it has received. We can't tell where it hasn't received data and we can't see what EPA thought of that data, some kind of assessments or a DER or whatever.

So, that's something that should be public. Maybe the chemical search engine system that was presented yesterday at lunch is a good way to compile that. That was an exciting presentation, by the way, just so you know. That was good lunch entertainment. I was excited.

Then, the last thing is it also reminded me in CropLife's presentation about having more meetings with

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registrants and with stakeholders along the way that I wonder if there wouldn't be a way EPA is supposed to log the meetings so that we can tell when these meetings are taking place and what the subject is. Thanks.

MR. BRADBURY: Cindy.

MS. SMITH: I guess I'd like to ask a question before I make a suggestion here. You guys have a process already. You have experience through a lot of the work that we did in FQPA. When you open a docket, do you get very many comments?

UNIDENTIFIED MALE: It varies. I think it depends upon how high profile the chemical is. For the vast majority chemicals, no. Typically, the registrant will respond with some clarification errors that they find in the problem formulation. Some of the task forces will respond and say, I just want to remind you that the registrant is or is not a member of X task force, so some of the data compensation type things. On occasion, we'll get things like this use isn't that important to us. So, we'll get some early mitigation. But generally, it's not a high volume of comments.

MS. SMITH: I asked the question because I

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think this point about efficiency, efficiency for you guys, efficiency for registrants, efficiency for grower groups of trying to know the Services, when to put in and use -- anybody who wants to put in information -- it seems like there's a balancing act between -- people want to comment when they know there's an issue. That's generally how it comes in.

So, if you open up a docket for chemical A and everything looks great and there's not going to be any problems, you're probably not going to get a lot of interaction. So, I think it sets the stage where you say we've got a concern here that we think we need to refine or we might have to mitigate or whatever it might be. I'm not close enough to know when the exact right time for that is.

It seems like you guys are struggling through that in the interactions that you have with the Services as well. You might come to a conclusion that you don't have an issue, only to find out that you do have an issue. So, it seems like it's a challenge to decide when that actually is.

But I guess what I would support in that first

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question is that refinement of what the actual uses are up front is really critical. That piece of information -- and that would come from growers, it would come from NGOs, it would come from registrants, whoever has a concern. I think getting that refinement done up front seems to be a huge efficiency savings for everybody to have an understanding of what are we actually going to do a problem formulation around.

MR. BRADBURY: I'll just talk for one response to Cindy's point. So, my philosophy has been at the beginning that it's better to get the information at the end. It's better to refine at the front end than at the back end because that's resource intensive. Most of these registration review decisions aren't starting de novo. They're not new active ingredients for which we know nothing. They're coming out of REDS (phonetic).

Some of these REDS, like with organophosphates, had just gotten done. So, looking at the RED and the risk assessments, if you see risk quotients or risk estimates, the ecological attributes that are exceeding our levels of concern, even under FIFRA, they're probably going to be either to direct or indirect the fact

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something we need to think about from an endangered species perspective. So, I don't think it's too hard to see, for all of us, going into a specific case where there may be some problems, some issues to resolve.

Not surprisingly, most times, not always, those risk quotients are driven by the estimates of exposure, as Cindy was getting at. So, I think it would behoove us all, everybody, all sectors, to take a look at how realistic some of those input assumptions are at the problem formulation stage -- either get information that says nobody is using that much, it just doesn't happen -- let's get information on that and how does that sort of factor into the science. Then, maybe we can talk to the registrants, and growers, and others, that it's time to change the labels now.

We don't have to wait five years to change the labels. Or, nobody even uses that. Or, that example that somebody had that yes, it's a registered use but it's never been put in the marketplace. Or, let's just get it out of the freezer and throw it away.

So, I think it's very important, and I don't think it's necessarily a mystery to figure out where the

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challenges are going to be and try to get resolution up front. Or, it may be because we're missing some ecotoxicology data so in the RED we had to make a very concerted assumption due to certain information we didn't have. That could feed into the DCI point.

Is there information in the literature already that could cover it or -- all that kind of stuff. I don't think it's as mysterious as it may seem. I think it's pretty straightforward, actually.

UNIDENTIFIED MALE: It's been my understanding in many of the biops, or at least some of the biops produced to date by the Services, that it's common for them to assume a worse case exposure scenario based on the labels of the pesticides. All products registered on a particular crop are used together on the same crop and used at maximum use rates, maximum number of applications, et cetera.

At what stage can the Services exercise some flexibility in addressing the real-world situation? I've asked that from the perspective of the label itself, the instructions for use of that product on a particular crop are for controlling the pests at a worse case infestation

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that is likely to occur.

That worse case doesn't come along very often. So, the actual uses of that product are likely to be much less than the potential that's expressed on the label. This is where stakeholder input is essential to determine how often is it really used, how often is it really needed, even for frequently used products. So, what is the likely exposure scenario resulting from typical year-to-year use?

We need to know if, when, and how the Services are going to put that information into its evaluation and biop. We can't often or can't always modify a label to bring that use rate down, or the frequency of use, because you have to be prepared for that maybe once in a few years, maybe once in several years, high infestation of a crop or the disease.

UNIDENTIFIED MALE: So, that actually is one of the biggest criticisms of the biological opinions that National Marine Fisheries Service has produced. It's relevant to exposure and what assumptions we make about exposure. So, we have heard that argument.

We are working closely with Department of Ag

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and state pesticide regulation agencies to look at how do we come up with better tools for estimating the actual use and exposure. Our challenge is that we're consulting on the federal action. The federal action is those labels. So, yeah, that scenario that you laid out is what's authorized.

So, we have to render an opinion on that. I don't think we go so far as to assume the worse case everywhere all the time, but it is evident that by looking at the labels and assuming that crop patterns change over time, that pest load pressures change over time, the challenge to predict how a particular label requirement is going to be used for the duration of the registration.

So, we're not only looking at what the cropping patterns have been for the last several years or the last decade, but what might they be in the next 15 years while this label is still active. I understand there's even issues with how long they stay in place. But we are looking at what's the affect of the registration decision.

So, it's a challenge for us to refine how do we

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come up with a realistic, legally defensible, prediction of how a particular registration is going to be manifested on the ground during the duration of its registration into the future. What will those effects of that be on the endangered species that will encounter that?

MR. BRADBURY: Dave.

MR. TAMAYO: Well, first I wanted to speak to just that last point. I don't quite get why -- it seems like you can account for a worse case and maybe have a separate set of mitigation measures that might apply if there's a worse case type of application that's necessary and would still allow for that.

But you could have some sort of mitigation to go along with that. I think that might be necessary because if you kill something, it's gone for quite a while. It doesn't matter if you have that impact just once every 10 years. That's going to be a lasting impact.

But, the other thing is on the other side, it's like I don't think it makes sense to have the worse case type of mitigation measures applied to the average case.

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I think that really is a very good point.

Now, what I really wanted to talk about, though, is I actually have a lot of -- I support what Michael was saying, that the need to have that type of information, relevant information, given to the Services and to EPA -- we've run into that, and the same sort of thing that we run into with urban uses all the time. It's very important.

We tried to work very closely with structural pest control business in trying to make sure that we understand how those uses are. When we were working with pyrethroids in an urban area, we had sort of like a little mini conference at DPR early on in the process so that we all kind of understood what are the needs, what are the pest management needs, what are our concerns?

So, the DPR staff and everybody else kind of came to a common understanding. It seems like there's a need for a general sort of almost like a conference that would involve staff who are writing these opinions, EPA staff who are managing these actions, and then the registrants and the growers that are involved with this.

That could be a place where you really get into

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this is how this works. This is the type of concerns that we have. So, raise the general level of knowledge, not even necessarily about a specific action, but getting the people who are actually doing the work. Get it into their head.

One thing that's been really frustrating is to have part of EPA kind of understand what our concerns are and then start dealing with it. Oh, okay, looks like they've got it now. And then you find out there's another group, another little silo, and it's a whole new set of understanding.

I'd be amazed if that doesn't occur in this type of situation where maybe upper level understanding of the need for that, but the staff people who are supposed to apply that in their direct management maybe don't get the need to have an understanding of how these things are actually used out in the environment and what sorts of mitigation measure makes sense and could achieve both the environmental protection and the affect of pest management.

So, having that sort of general discussion raised to everybody's level and then to sort of repeat

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that on a more specific -- when there's a specific decision about specific chemicals that affect specific crops, have that same sort of discussion repeated. You'd have to sort of have very knowledgeable people on both ends, especially since there might be quite a few minor crops that have to have their input at that point.

But I think the general tone of this, I support the notion of having very early conversation because it just doesn't make sense to be developing opinions under a misunderstanding of how things are used out there. It just seems like a mess to do it that way. Thanks.

MR. BRADBURY: Caroline.

MS. COX: I wanted to follow up with what Jim said about making it possible for public interest groups and the general public to have input into this ESA process, and access to information that isn't currently publicly available makes that possible.

Just one specific example. I know that in several of the biops that NOAA Fisheries has done, the issue of the inert ingredients in the products has been a significant concern. It's really hard for either public interest groups or the general public to provide any kind

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of useful information or feedback when that information is not publicly available. So, I just would like you to consider mechanisms by which you could help with that.

MR. BRADBURY: Susan and then Cheryl.

SUSAN: In response to your question, I think earlier is better. I think it's as whoever gave the CropLife presentation said, it seems that there should be involvement of the Services early on, too, so that you know what information they need.

I think a lot of the problem has arisen in you guys thinking you have enough information to do it and they say we need more information. So, having them involved early in that information gathering process seems kind of critical.

I guess a clarification here. By risk assessment, preliminary risk assessment, do you mean effects determination?

UNIDENTIFIED MALE: So, how we've been trying to do this is as part of our FIFRA preliminary risk assessment, we're also doing our ESA effects determination.

SUSAN: So, it's a piece of the risk

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assessment?

UNIDENTIFIED MALE: Right.

SUSAN: Then, the other thing I'd like to say in terms of worse case is the Services did a really new approach to looking at shallow water habitats that EPA doesn't do. This is perhaps a worse case scenario, but it's a very realistic one. It probably happens more often than just the every few years when there's a major pest infestation. So, I think it's pretty important to look at realistic situations that are likely to occur on a fairly regular basis.

MR. BRADBURY: Cheryl.

CHERYL: So, there's a lot of things that impact worse case, rates, numbers of applications. Those are going to be really explicit on the label, and there's not much arguing that those are worse case. But there are also a couple of gray zones that can occur on labels, and not all labels are equal.

One place that gets really gray is how quickly do you go back in and retreat? So, retreatment intervals not explicit on the label can be a real big difference in the way that you interpret worse case. Okay, we're going

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to go back in one day. A typical grower would say, no, I'm not going to go apply a single day afterwards. But you're looking for that really worse case on the label.

So, one of the places where I would suggest that this typical information could be better used, even in the worse case assessment, would be what is your real retreatment intervals? Retreatment reentry for worker exposure? PHI for dietary? That's probably not part of this ESA. But those gray zones, even in the interpretation of worse case, would really benefit from user community information.

UNIDENTIFIED MALE: And that's actually one of the areas that we're already now starting to work on. As we prepare for the release of a preliminary work plan, in house we're going through and some of the older labels just say reapply as needed. So, what does that mean?

So, we're starting to independently ask it directly during the public comment process. We're going back to the registrants and saying what's really meant there and is there an opportunity for some better depiction of how the registrant wants that product to be used so there's better clarification on the label.

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MR. BRADBURY: Ken and then Jennifer.
MR. NYE: I want to encourage the agency and any others that are looking for this kind of data to try to seek out and find the actual use data. The worse case scenario or the label is not normally what's used. It could be, but growers and users are driven to try to use as little as they can. These materials are expensive. There's time involved. There's consequences and so on. There's worker safety issues and so on.
I'm really pleased that the Minor Crop Farmer Alliance has recognized this issue and has put some significant resources into it. They have some special considerations, given the size of the crops and so on and their lack of having full-time people to do some of these things, in all of these little specialty areas.
We certainly have specialty crops growing all over the country. Some of them I really don't have full-time expertise, but they'll try as much as they can, given the opportunity from the agency, to provide that information. They'll try to do it as well as they can.
I really appreciate the USDA data collection process. That should be used, I think, by the agency as

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much as possible. It isn't perfect. We don't cover everything there every year, but at least it gives us some guidance. We need to continue to seek out that actual use data.
MR. BRADBURY: Jennifer.
DR. SASS: My comment is kind of the same. I had put my card up earlier but put it down. Dave covered a lot of my points. I just want to point out that it would help -- if that were made public, then other people like me could also help to talk about things. I mean, if we're talking about worse case or whatever, at least we know what we're talking about. At least we would have a sense, if we had the real data, to understand realistic situations. So, that would help all of us if that could be public and shared.
MR. BRADBURY: So, I'm looking at the clock and I think we have some play. Some of the conversation that you all had has gotten us some aspects of number one. Some we can sort of imagine, different kinds of information at different kinds of places. Some of you talked about mechanisms for transparency in your comments. That's been helpful. Different venues or

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processes by which the information can flow.
So, I think it would be helpful if we could spend a little time on question 3, which was, how might the agency make an interim reg review decision for uses that do not raise ESA concerns and how would you, perhaps, bifurcate or chunk up a reg review case by ESA versus non-ESA? Maybe let's get some initial thoughts on that from you all.
UNIDENTIFIED MALE: So, the idea that the conceptual thinking is that there may be uses that don't raise an endangered species concern. Perhaps the registration review process for those should go forward on a different time frame, which would allow them to go through the registration review process while the uses that do raise ESA concerns would be handled on a slightly different time table because of the need to complete the consultation. So, that's one sort of formulation to that idea.
The other idea that has arisen in various conversations we've had internally is we were calling it an interim decision. That was just the term we applied to it. It has no particular meaning. But the idea

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behind that would be that the agency would complete its work and go ahead and make registration review decisions while the consultation process is occurring. We would say, this is the registration decision for now. We've initiated consultation. Then, when that consultation completes, we would come back and make any adjustments to the registration that might be necessary.
So, that's a fairly new idea in terms of things that we've heard discussed. So, we just were interested in getting some thoughts from the committee on that idea. There are other variants of that idea that people can obviously think of. So, I think that captures it.
UNIDENTIFIED MALE: I appreciate that, especially in at least two instances where it seems like the agency would likely have to respond fairly quickly. One is invasive species. Obviously, in the others, resistence and resistence management, in those two instances, there may need to be some sort of consultation such that a use could be adapted, especially in the crop area where those two instances are, as we speak, impacting clear across the country.
UNIDENTIFIED FEMALE: So, those of us who have

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been around too long remember IREDS and TREDS and REDS and all of those things that we had back in FQPA. So, I guess my initial reaction was just do it. You allow the uses for which -- I assume what's implied in here is that you have a use pattern that results in no effect. So, you don't need to consult until you're ready to just clear it. With the rest of the stuff that you're ready to clear on your own, you clear. I guess these other uses, then, have to be held up.

I mean, the converse of that is that you hold the whole thing up, which then just seems to create a work backlog for you guys and takes away uses that may or may not be necessary to take away in the case of no effect or absolutely not necessary to take away. So, I would think you would go forward and release them.

MR. BRADBURY: Or you may have identified some risk mitigation for other reasons.

Susan.

SUSAN: A couple of things, a clarification. Typically, a label has many uses. So, what would happen if you identified one use, corn, where it wasn't a problem. But if you think about applications in almonds,

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it would be different. I guess I don't understand how registrants would deal with that where they have a label with multiple uses. That's question one.

UNIDENTIFIED MALE: So, I think this has been part of the confusion about what registration review is. It's not that the registration goes for 15 years and expires and then needs to be relicensed. In fact, what it is is registration review is a cyclical period of time over which we do a periodic reevaluation. But the registrations don't expire.

So, under this model, we would sort of create a clearinghouse, if you will, to say these uses for this chemical, we've done what we need to do from an ESA standpoint. We've reached a no effect. We've incorporated mitigation and we're done.

There may be some other uses that still trigger the need for consultation, but maybe it's because of worker risk or maybe it's because of dietary risk, we've put some interim mitigation in place. But we sort of have them in the other quadrant, if you will, while we're pursuing consultation.

So, it's a way to move forward on decision

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making as opposed to putting everything in a band while we try to figure out all of the endangered species problems. But there's a tracking issue that becomes involved, but it doesn't affect the label.

SUSAN: So, similarly, then, it seems that the flip side of this should also be true. If you find a particularly problematic use, there should be actions made immediately to solve the problem, rather than waiting for the consultation.

UNIDENTIFIED MALE: Right. So, like we do with worker risk or like we do with dietary risk, if we found a major issue that we felt warranted swifter action, we would take that authority now. We would take that action now.

MR. BRADBURY: Gabriele.

MS. LUDWIG: I was just going to say I forgot the right terms, IREDS and so forth, that Cindy was mentioning. So, what I don't understand is I don't know how it works with the legal world of ESA. But since you've done it before, it doesn't seems like it's that foreign a concept.

MR. BRADBURY: Yes, in some ways. In some ways

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you probably need to talk to the attorneys, though, in terms of some core cases in terms of when is the FIFRA action done. Is it done when the ESA part is done or is it done when the FIFRA part is done, but you're starting the ESA part? So, that's another dimension to this conversation. But keeping the legal stuff aside, that's where you're getting your initial thoughts on the non-legal practicality, or lack thereof.

Jim, I don't want to put you on the spot, but we've worked together for a long time.

JIM: Well, actually, I was trying to think my way through some of these things.

MR. BRADBURY: One thought that might be helpful to share is from your perspective, when to get information and sort of how you all have to manage your resources, just some thoughts you have about timing of information and iterative steps. How does that sort of factor in?

JIM: I'll just reiterate Dr. Willett's comment that probably we aren't going to get there until we get the NAS stuff done. I think we do have issues on disagreement among the agencies with the risk assessment

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methodology and how certain things are assigned. So, assuming that --

And I don't think NAS is going to give us the magic bullet either, but I'm hopeful they will give us enough information that we can have a dialogue that will allow us to close the gap and we can come up with a risk assessment methodology that we can both agree is sufficiently robust to both FIFRA requirements and ESA requirements.

If we can get there, then I think sort of the process that Rick laid out in his slide where there is providing technical assistance rather than informal consultation so we don't trigger any requirements, but I think there's an opportunity up front at the preliminary risk assessment stage to provide relevant information about endangered species to the extent there's information from toxicity studies relevant to a species that's not captured by the overarching process that that should be provided, information about presence, absence, distribution, seasonality. All of that could go in there.

It makes sense to me that the other information

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that folks have talked about, can we come up with a realistic assessment of what is likely to happen on the ground over the course of 15 years and what's a reasonable case which can be used for your risk assessment to cover those species.

Come up with your final registration decision that includes where appropriate mitigation measures to reduce impacts and consult on that. If we could get to that part, then I think the counterpart regs that still remain in effect actually would be useful.

It would be taking advantage of the resources at EPA to put together comprehensive documents that the Services could review. Then, the Services would be able to use our limited resources in that sort of effective review stage rather than having to build up a competing army, if you will. I'm not in favor of doing that. I think we really do need to figure our way forward here. But the service is truly in a consultation mode where we agree on the process.

So, I guess that's the long way around saying I think there are some data needs out there that we haven't even quite figured out how to ask for the data.

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Hopefully, we are working on that, coming to an understanding on ways to do that. We ought to get that all in to the process up front. I agree with your statement, that getting it in earlier is better than trying to squeeze it in later.

UNIDENTIFIED FEMALE: I have a very different question. We've heard about the Denver conference. We've heard about the NES activities. I also know that there was an American Council Society Symposium on ESA recently and there was EPA engagement. I'd really like to hear what EPA's reactions were to some of that conversation.

UNIDENTIFIED MALE: There was a session at American Chemical Society in Denver. I can't remember the exact date, some time in the summer. There was a day-and-a-half session which the Services and EPA participated in two ways.

The first was, the Services provided between them a very nice description of the process and the ESA requirements and how they viewed those as applying to the FIFRA registration process. Then, we provided some context from the EPA perspective on how we thought those

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things -- our process worked with their process.

There were a number of presentations that focused on the scientific issues, how to determine aquatic exposure, how do you use models to do so, how do you look at the fate of chemicals, and your approach to do that. Most of those were provided by folks from the registrant community or consultants who were making presentations based on work that they had done.

I personally -- I don't want to talk for ACS; I'll just talk for me personally -- I thought it was a very useful session. The reason I thought that was because it had broader representation than is typical. It wasn't just the government agencies talking to each other.

It wasn't one agency of the government talking to just registrants or to the NGO community. There were folks that were present at the meeting and who presented to or from, as I said, the federal agencies, registrants, state agency representatives, and from the NGO community, the environmental group community.

So, that was the first time I'd seen that broad a net cast around this issue. Some of the folks thought

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that this is the beginning of engagement at the science level, sort of at the technical level, where everybody was in the same room and all listening to each other for the first time.

So, I'll leave it at that. I don't know, Jim, if you heard any feedback, but you had folks there. There will be more formal ACS summaries and whatever coming out. I don't want to speak for them, but that information will become very widely available.

MR. BRADBURY: Cindy.

MS. SMITH: I have two thoughts. So, the question I asked about how many comments you got to the docket I asked as my gut was the sense of the answer that you gave, but I wasn't sure because I only see the stuff that I look at that's mine.

But I asked it because I think that probably the reason that you don't get a lot of comments to that is to your point, Steve, is people haven't gone through that refinement process yet and they're not there. So, these last three questions are similar in what you're asking for.

So, I think to be really specific, I think that

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there should be a meeting very early on with the registrants -- we don't want to call it a smart meeting or whatever -- where we fully refine what are the assumptions about is this label still sold, is this use still active, can you address the number of applications, the intervals between applications, try to get all that stuff cleaned up up front fast.

Some of these things, even though they've been through a lot of reviews, some of these types of issues haven't completely been addressed. So, I think there will be some natural refinement and new information shared with the agency at that stage.

Then, I think that what goes to the Services has to be that refined amount. At least I've heard in some of the discussions when we talked about some of the biological opinions is they looked at labels and model labels that we knew were no longer active, you guys pretty much knew were no longer active, but somehow it didn't all get communicated exactly right. So, I think that really that refinement up front is really important to do.

Then, all of that can be shared publicly. I

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mean, for everybody who is concerned about what happens, then that gets shared. So, here's now what is left for what people are going to do and when the labels are going to change, if they're going to change, and the whole nine yards. I think that, to me, seems fairly easy to do and would save a lot of people a lot of headaches up front.

The 15-year thing that you just mentioned, Jim, creates some confusion for people, I think, because I don't know if that's because you think the agency is only going to look at it every 15 years, so a registration decision isn't going to be revisited again for 15 years. So, you want to look 15 years out.

But the reality is that, at least my experience, is that that has never played out that way. I mean, we did a RED in '98. We did another one in 2001. We did another one in 2006. I'm doing another one right now in 2010 on one compound. So, it never goes 15 years.

I mean, prior to FPQA, I think that could have been the case. That was one of the elements that came in there. But that simply is not the reality today for how these decisions happen. If there's a risk that comes up or there's a new use that somebody wants to add, it gets

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a full review by the agency again. So, it's not often that you go by more than two or three years without something getting looked at.

UNIDENTIFIED MALE: So, what Rick said was the registration never expires. That tells me we've got to look forever into the future, not just 15 years. So, that's sort of the opposite end of what you just laid out. I think we are looking for what is a reasonable time frame because the further out into the future you model things, the less reliable your results are. We're trying to come up with a reasonable framework for how long are we going to look at this.

Certainly, there are triggers for reinitiating consultation, a new use comes up, a new piece of information either about use or about risk or about exposure. All those things can be triggers for consultation.

But I think, for at least the initial instance where it's the first time we're looking at one of these things under the Endangered Species Act, we need a time frame to kind of bound our analysis. The re-registration review cycle seems to be a good thing to pick.

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MR. BRADBURY: So, we're going to start wrapping it up. We don't have any public comment. That's why I let this play out a little bit and keep you all on your schedules and our agenda.

So, a couple of perspectives and then a proposal for the process improvement work group to wrestle with. Folks that aren't on those groups from our group can play in this one.

So, one backdrop. The National Academy of Science process obviously very important because it will help establish a variety of approaches for doing the science and we do want to get to the day where we've all agreed upon that science of how to move from the FIFRA risk assessment, the non-listed species risk assessment, into the listed species risk assessment, that process is agreed upon, the information needs and how that information is going to get used.

So, if we do have to go into consultation, that can be very efficient because the Services are just adding their areas of expertise onto what needs to happen to ensure those in jeopardy if there's a possibility that would be the case, then not redoing everything we've done

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because we've done it in a manner that we've all agreed is the way it needs to play out. USDA is involved in feeding critical information into that process as well as all of you in your various roles and responsibilities.

Having said that, I don't think we need to wait 18 months for that report to come out to start approaching some of the challenges we know that exist, regardless. So, for example, better understanding of how a product is used and what the distribution of those uses could be. All the other permutations we talked about is clearly information that's going to be useful.

NAS may give us some advice on how to interpret uncertainty around that information or how to make projections over different time frames or how to make projections over different landscape scenarios. But clearly, having that information is going to be a critical component to the evolution of the risk assessment technique.

So, I think there's work we can be doing on process and kinds of information that we're going to be using that can happen right now. Frankly, if there's some things we can do over the next six months or so,

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some of that insight could be shared with the NRC panel as they go through their series of meetings.

We may be able to get some feedback from them, even though they're talking, kind of brainstorming, at meetings, the public, or us, the Services through work we've all been doing. We can share with them some ideas we're exploring in terms of how information could come in which could inform their recommendations back in terms of how that information can be analyzed and incorporated in the risk assessment.

So, I really think that where it would be helpful in the initial stage to get feedback to us, and you all part of that, is that the early stage, the beginning, the beginning of the process. The Minor Crop Farmer Alliance report talks about some process ideas to help that along. You've seen it in some of the Power Points here and some of the other background information that people have shared.

There's been some ideas about before you start, so zero at the beginning date. How do you start before zero to start getting information that becomes part of the preliminary work plan? Then it gets more refined and

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you finally have your final work plan.

I think before the preliminary work plan goes out for comment and while the PWP is out for comment and moving towards final work plan is a time zone, a time frame that we need to concentrate on. Having said that, we have the experience where we know there are chemicals that have just gone, as Cindy implied, pretty much just finished their re-registration. We already know there's certain risk profiles, some ecological perspectives, that need attention. So, there isn't a mystery there. But we're still not seeing a lot of information coming to the dockets, which is sort of a disconnect.

So, what I'd like to see, if you all are in agreement conceptually, is that we work with Rick and Don and really try to dig into the details. If you were going to have a smart meeting, or whatever we call it now, what would it be? When would it have to happen before the docket would open? What would be some of the logistics of actually doing that?

That means logistics of probably looking at the calendar and figuring out the timing. But how would you get that information out to the public so if some people

couldn't make it to the meeting, how are they going to know what's going on so they can see in some ah-ha ideas as the team and EPA finally has to buckle down and get that PWP written, as well as what could be happening during the comment period during the PWP to again make sure more ah-ha moments can go on out there, because people may not have caught up to the other steps. They can be part of that process virtually, if not in the room.

So, it would be a group that gets together and really gets specific. Is it 45 days before the PWP opens? Is it two months before? Is it three months before? How do you structure those meetings? How do you identify what the information is? What's the roles and responsibility of the registrant?

What's the role and responsibilities of the NGOs, of the grower groups, of the states, and the Services, for that matter, in terms of looking at that RED and thinking about that RED? What's clearly going to be the issue that is going to be driving this ecological risk assessment?

I'm convinced that even if we don't know

exactly all the recommendations the NAS is going to provide, making sure we've got access to the best available information and understand the distribution of that information, it's going to be critical to going forward. Right now I think we're mostly struggling with lack of appropriate information and it's carrying too far through the risk assessment process into the consultation process.

We're not going to blame Jim or the Fish and Wildlife Service if we're giving them use as needed on the label. That's pretty darn hard for us. It's hard for everybody. It's hard for all of you. There's just no reason to have that.

I agree with Ray's point. It doesn't mean that the label -- the label may need to capture those extreme pest scenarios that could happen. You have to make sure you can legally use the product when that situation occurs. But how do we get information that helps articulate how likely is it that that scenario is going to happen? So, we've got the information to take a look at what are the likelihoods of different scenarios planning out that are going to help inform the risk

assessment.

I've kind of talked too long, but I think you get the idea. Where in the process before our typical process can we get people around the table in reality or virtually and make sure it's all public and transparent so everybody can see it until we get the more refined information we need to start the risk assessment. There's a lot of logistics and there's a lot of process stuff to figure out to make it efficient. I'm pretty convinced right now we have an inefficient process.

With that sort of rough cut, I'll make these guys write that up so it makes sense. Then we can share with you to see if -- does something in that domain seem useful to you all? I think it's useful to us.

UNIDENTIFIED MALE: I've got a real quick question. Are you sure that Don Brady is up to this task?

MR. BRADBURY: I've got my doubts. I just wonder if there's something in that realm, which I realized I talked a bit too much, but something in that universe that seemed reasonable? Then, Don and Rick and others can try to fine tune it, maybe reaching out to

some of you, get it back out to everybody to make sure that seems like a reasonable activity, charge. Then we can formalize it through the PPDC and start working it.

Cindy.

MS. SMITH: Yeah. I mean, I think that seems very reasonable. I think it's what we should do. The logistics piece of it, I understand, is the hard part of it. If you have the initial meeting with the registrant early on, a month before the docket, two months before the docket -- I'm not sure that that matters too much -- where you address these kinds of general issues that we talked about, number of applications, intervals, uses that you're no longer selling or haven't been selling for years, or whatever, the easy stuff, it seems like I don't know that anybody else would care to come to that meeting. I know people would care to comment about other parts and they want an opportunity to comment on that.

But it would seem like if you've got the registrant in there and did the easy high level cleanup stuff, and then you have a public schedule so that if chemicals A, B, and C are critical to apples, they know chemicals A, B, and C are going to do their refinement

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and use of data on this schedule, then they could provide their input.

If those are the chemicals that some of the NGOs are most interested in putting some input on, they would know. So, everybody would know then when you're going to have your discussion about those or when the time line is to get input in about those, or however you format what you're going to be able to do with it. I think that in itself would help.

But I think part of the problem today is that the docket opens for hexydiasox (phonetic) and you have to read through everything in there and try to figure out is there a worker issue, is there a dietary issue, is there an ESA issue, are the data requirements going to trigger an issue once those -- I mean, it's just too much overwhelming right now, I think, to go at it that way.

So, I think if there was a way to capture where you think there -- if you know up front you're going to have a concern about an ESA issue, because you can look at the data that you have available to you today, say up front we think we're going to have to address some endangered species things here, or whatever, and people

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are then more ready to comment, I think.

UNIDENTIFIED FEMALE: We did an open process before we did our surface water regulations in California. That's exactly what we did. We got the stakeholders together. We talked to them individually and then we talked to them as a group. The registrants were also talked to individually and then as a group with the NGOs. It really worked out.

So, I think -- well, for us, it's just California so it's easy to travel. But the federal would be a little bit harder on logistics. But I think the communication piece really is the one that (inaudible) even with the registrants, NGOs, and even with the state water board.

We talked to the state water board in the surface water issues. We talked to the regional boards in the surface water issues, stormwater agencies. The PCOCs, we used the urban pest control products that we put in and are now proposing for surface water regulation. So, it works out really well.

UNIDENTIFIED MALE: I hope this doesn't complicate this discussion. I think it's a great idea to

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do the smart type meeting up front. I would just hope that if possible, and this may help you out a little bit, is to include what's in the pipeline for that particular active ingredient in these discussions.

MR. BRADBURY: The uses may be in the pipeline.

UNIDENTIFIED MALE: Not new uses in the pipeline but what is going on -- yeah, new uses for that particular active ingredient.

MR. BRADBURY: We do try to roll that into the registration with the dockets, but we'll make sure we keep focused on that.

UNIDENTIFIED MALE: I think obviously for a lot of grower groups where you're always sort of parsing what issue you have to work on, sometimes it's pesticide policy, sometimes it's a whole other realm of things, making sure that -- and I agree with Cindy absolutely.

But trying to find some way to highlight the importance of that first round and being able to really highlight the questions that are important to have information on, that would be really helpful because that would allow you to really look at -- because we don't always feel the need to comment on every single active

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ingredient.

So, it would give us a chance to sort of go through that start finding some way to put the neon light on the issues so that those folks that are interested, no matter who it is, can comment, would be aware that here's the moment. Then, of course, once you start doing that, I think it's going to become a little bit easier for people to know how to plug into the system once they get started.

UNIDENTIFIED MALE: I wonder if some of these discussions could be amenable to having sort of a webinar sort of format so that people who are widely distributed around the country don't feel the need to -- I mean, it's really like a three-day process to come here and participate in something that might last a few hours. So, that might make -- then also, it makes it --

There's an inherent transparency to having webinars because then, even if you don't feel the need to go and comment, you can participate and see what's being said. There's really a pretty clear record. Some of the people who would maybe prepare presentations for it, that information would be readily available already and sort

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of help people to focus what their issues are.

Then, really, I think it's also an opportunity for people who are not really sure, well, maybe this is going to affect me. It's not worth me traveling to Washington because I don't really know. But then they start thinking, oh, well, that really is something that I ought to comment on either during this meeting or figure out a way to follow up on it.

So, I think that would be very helpful for some of these. It may not always be appropriate, but I think that could be a really useful tool, if you can fix some of the communication issues.

MR. BRADBURY: Twenty-first century EPA technology.

Cheryl.

CHERYL: So, you really actually already have a mechanism to do some of what you're being asked, if that's what the scoping document is supposed to do, identify those initial issues. I have seen them be better prepared as you've gone through this process a few times. But I think you're hearing a call for those scoping documents to have one more level of detail and

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identification of issues.

Then, I understand that it's very problematic. How do you start before you start? When do you make things public and when do you figure it out? It's kind of chicken before the egg almost. So, I just think you have a call for making those scoping documents as clear as possible. That's what you're hearing.

The other thing is I still think that the biggest thing, and I'm just reiterating, it's very clear that getting clarification on uses. Uses that might be up on a master label and not turned on yet could be a really good thing to clarify up front, too. Just all of that use information, since it drives everything, that's an easy place to not put the chicken before the egg. That's your low hanging fruit.

MR. BRADBURY: So, this is very helpful because you all were reflecting on everything from logistics of how to have conversations before the PWP opens to make sure everybody is engaged, as well as some of the specific topics that should be addressed, as well as what -- even though the goal was to have a very efficient and already cut to the chase PWP, it's not happening, in part

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maybe because there's so much stuff to read through that it's hard to distill out what's needed. So, all this I think reinforces some of the topics a group could be working on in terms of getting more specific about how to make the process more efficient and effective for everybody.

So, the way I'd like to close this session out is charge Rick and Don, working through the PRIA Process Improvement Work Group, which is under FACA, to fine tune sort of what the charge would be for a small work group to tackle some of these issues about how to adjust the reg review process to take on the things we've talked about. See who all wants to do it. Work on that so that we certainly, at least by the next time we meet, get a report out on here's a proposal of how to do it.

I will put a little asterisk there. If the group is making good progress and we're watching the NAS schedule playing out and if we think there's some insights that can be useful for the NAS, we'll figure out some way to convene all of you so that -- put a proposal out maybe before six months from now so the timing is useful to the NAS review. Make sure you all are okay

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with it. We wouldn't do anything without talking to the full committee.

But I do think this could be complementary to some of the work the NAS will be doing. So, we won't rush it, but we'll keep track of what's going on so we don't lose an opportunity if it materializes. So, these two will get some ideas out to you all quickly so that you can see if you'd be interested in participating.

We all will be looking to make sure we get a good cross section of all the stakeholders that are involved in this to be part of that process, because that's what we all talked about. Everybody has got a game. Everybody has done the game. So, we need everybody in the game; otherwise, what we create won't serve everybody that needs to be involved.

So, Cindy, did you have one last --

MS. SMITH: Yes. It's sometimes difficult to get information to an NAS panel once they've started working, unless they ask for it. So, it's really important at these public meetings if you've got something to give them before they start their work, before they start deliberating, that they can go back and

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refer to, it's really helpful. That's really the way to get it to them. Otherwise, you're going to fight it all the time. It's not iterative.

It made me wonder whether or not the PRIA Process Improvement Work Group, if they came up with something that they could provide at that public meeting, based on the charge to the panel, that that then implies we'll still be working here in the background and would welcome the NAS coming out to them to ask for information at a future date. Otherwise, it's very hard to get anything to them. The mechanism isn't there for them to accept stuff in the middle of their work.

So, those public meetings, the couple that they have scheduled to allow you to make comments and provide materials, that's the way to get it in at the beginning.

MR. BRADBURY: Right, total agreement. So, we'll work through those issues.

Why don't we take a break until 5 to 12:00. I don't think it will take us more than 10 or 15 minutes just to go over agenda topics for the next meeting and still get done at 12:15. I imagine folks need to stretch a little bit. So, we'll meet in 10 minutes.

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UNIDENTIFIED FEMALE: Steve, is there any reason why we don't just finish up?

MR. BRADBURY: I need a little time just to collect my thoughts, if that's okay.

(Whereupon, a brief recess was taken.)

MR. BRADBURY: Thanks, everybody. We'll make sure we get done at 12:15. I appreciate all your help in keeping on schedule.

Let's first talk a little bit about the agenda for next time and kind of get some initial thoughts on that. Then I'll turn it over to Margie who can give us some ideas on dates so you can start thinking about that. Then we'll probably go around real quick if somebody has got some closing comments. Then we'll call it a meeting.

So, my first ideas on the agenda for next time I think are pretty self evident based on the work the work groups have been doing. We gave all of them various charges to report back out. So, I would think this time a significant portion of our day and a half would be hearing back from the work groups on recommendations.

I don't think I'll go through everything I've

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got written down, but the pollinator group had a number of tasks to take on from labels and surveying labels to what's the status of education, to what's the status of BMTs. We've got them all written down and they're in the transcript. So, we can tune that in our EPA folks that are helping those groups. We'll reach out to them and start to get that cranking.

On the IPM, we had the school IPM starting to at least get those metric options ready to roll as the strategic plan comes along, we can see how to integrate different metric options with the strategic planning and, frankly, helping us make sure we get access to the work of that group. It could influence the strategic planning exercise that EPA will be doing. As that gets along, the PPDC will be among many groups to take a look at that plan as it goes.

We also talked in the IPM about looking at a cropping practice, a public health scenario, and a hospital or residential community scenario to take a look at how would you go about evaluating the effectiveness of an IPM program. Again, not to do it but to look through some case study options and report back out on some

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options, and then go to the next step.

The 21st century group will be reporting out on next steps from the exposure biomarker work shop. We also identified maybe some low hanging fruit that can be tackled real quickly in terms of clarifying what may already be in the registration packages through analytical methods or other information that could be part of the stepping stone to where we need to go.

Then, we just finished with the ESA effort. Don and Rick will work through the PRIA improvement group and get my babbling words into a tight handful of sentences to describe the outcome of that exercise and what we're looking for. But the bottom line is how to make that step at the beginning of reg review as efficient as possible to get us the best information we can possibly get at that time to focus our resources on what we need to focus on collectively in moving forward with the endangered species effort.

We'll get that description out and look for people to participate in that. We really need to get a good cross section of all the stakeholders for it to work. There's going to be some options there in terms of

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who meets when, what, how do you get the information out, that kind of thing.

So, I think that probably makes sense, right? Keep mostly focusing on work groups working in between meetings, reporting out, getting them advice, and putting them back to work. We'll definitely feed in some update sections, some verbal, some written. As in the past, give Steve, Margie, any requests you have for update information.

What would be helpful, while we've got a few minutes, did you find this session to be a reasonable balance between verbal updates as well as some written materials you got in your packet? We didn't really talk about it, but we put them in your folder. Does it look and feel about right?

UNIDENTIFIED FEMALE: Well, I have a three-part response to that. I have first of all an acknowledgment and a thank you, an observation, and a question. So, my acknowledgment is yes, this is very helpful. It is really good to be engaged in this kind of community and listen to all of the different opinions. The updates are very, very helpful. The work groups are very good.

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But my observation is that there are some things that are kind of perhaps being left out, because we're either getting really, really deep into an issue on a work group or we're getting a little teeny snapshot of what EPA is already doing.

Is there some middle ground? So, that's my question. Joe wanted to take a vote and you said, well, we don't vote. But are there things that don't deserve a full work group drill but deserve more than an update so that this group can really advise and weigh in on the update rather than just kind of hear them as snapshots?

UNIDENTIFIED FEMALE: So, I would agree with your comment, Steve, that I think the work group process has worked for those issues. I mean, I'm not on the 21st century tox so those guys have to weigh in on that one. But on the two that I was most engaged in, IPM and the bee pollinator one by accident -- I just happened to be free to show up -- that format I think works really well.

I think you guys had the time about right to let people present from the work group and then get discussions from the full committee so we got the balance right. I would say in the update, I like the format of

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having an update. But I like what you did this time. I don't know if you did it intentionally or if you just got lucky that there was some time afterwards. But if there is like 10 or 15 minutes afterwards so that people could comment on some of the updates, I think that's productive.

I think some issues are bigger issues than others and would be easier to say -- so, part of what we got in this meeting was that spray drift likely will be finalized. Inerts disclosure likely will be somewhat finalized.

There was an update in our packet on worker stuff. There was some stuff with workers that -- so, maybe in the area of those three, which are big deals to everybody, we add just a little more time next time. You give an update and there's just a little more time for comments after those. But I think in general, the way it's working is good.

UNIDENTIFIED FEMALE: I agree with everything they said. Also, I think we brought it up before, but it would be great if at some point at each one of these meetings, you sort of gave a low down on what you thought

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was coming down the pike for EPA.

As an advisory group, we're not going to think of it ahead of time. But if you know that there's something that's kind of rumbling, well, it looks like we're going to be facing working on this, or whatever, as sort of a heads up. So, when it does start coming, we have the ability to help advise on it.

MR. BRADBURY: Caroline, Susan, and Beth.

MS. COX: I have a few suggestions for updates that I'd love to see on the agenda for the next meeting. One, as always, is the inert disclosure rule making. Also, I would love to have an update on veterinary incident reporting portals, or whatever it was called, and what kind of reports are going to be coming into that.

Sort of in that same vein, I would love to have an update on also human incident reporting, both the poison control centers and pick -- something that happened a couple of years ago, I think, but not recently, is when you all kind of explained the OPP budget to us, and sources of funding, and how they're being spent. I would love to have an update on that.

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MR. BRADBURY: Me, too. I was joking a little bit because congress continues to work. There will be aspects of PRIA-3. As the budget plays out, we can fold that in. Right now, it's kind of uncertain.

Susan.

SUSAN: I'd like to thank all the EPA staff. I really feel like this meeting we ended up with lots of action items. We're moving in a direction, so that's good.

Let's see, I agree with what you said in terms of having a little bit more time to talk about things. But you're fairly new to the committee, right? We've been back and forth on this. We've had short times, long times, intermediate times. We're now in the long time phase, so we'll swing back. But it would be worthwhile having a little bit more time for questions on the kind of confusing or more complicated things.

I would like to see an update next time on kind of where -- it'll be six months out and we will have been through part of a fumigation season. I would like to see where we are on the fumigant mitigation measures, implementations, and kind of how is that working, an

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update.

MR. BRADBURY: Beth.

MS. LAW: I agree that this has been a very good meeting. I do like the balance that was struck between the presentations and the actual updates and the written updates. I agree that I think maybe a little more opportunities for just to have a little more discussion about the updates would be great.

At the next meeting, I think in addition to Susan's comment about where you see or the things you see coming up in 2012, I'd also like to have an idea of anticipated rule makings for 2012, if you have an idea of what might be coming down the pike.

In particular, I'd love an update on the status of 25B rule making. Thanks.

MR. BRADBURY: Valentin.

MR. SANCHEZ: I understand that farm worker justice and (inaudible) petition back in 2009 to require registrants to provide labels in both Spanish and English. So, it would be nice to get an update on that.

MR. BRADBURY: Thanks.

UNIDENTIFIED MALE: Just to add one thing.

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Process-wise, I believe we're supposed to be an advisory body to you folks. I get the impression that we're providing a lot of individual insights and opinions. There was some talk about consensus versus voting. When issues are brought up, I think the question needs to be asked, what is the consensus of the body to the EAP. For example, I don't know what the consensus is of this group requesting an extension for the NPDES.

So, if there are issues that are brought up, I think we should have the body provide a consensus to you of what the body believes to be occurring for next steps or future steps.

MR. BRADBURY: Thanks, and that's what we do. To the best of my ability, get input from folks in terms of next steps and action items that we're taking on. I expect people to raise their hands and say, no, we shouldn't do that and then engage everybody to talk about the merits of going forward on an activity or not. Continue to do that.

It is an advisory committee, so we don't hold votes. We do try to sort out if we have consensus on an issue or we don't have consensus on an issue. Frankly,

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if we don't get consensus on an issue, that's still helpful for us because we can understand what the diversity of opinions are.

Using the spray drift example, that work group did a lot of work and they did great work. They couldn't quite reach consensus on every piece of that challenge, but they did on a lot. It helped clarify what the tough issues were. So, it was very valuable even though we didn't reach consensus. So, we'll continue to do that.

The NPDES permit one is just a -- we're not a FACA that reports on the Clean Water Act, so it's just a little cumbersome. But many of you have all been involved in a lot of the public processes going on around that, getting your views into the agency. So, that one is just a little odd in terms of jurisdictions on the statutes.

Cindy.

MS. SMITH: I would just say in response to that, I think one way we might be able to show that is there was a lot of consensus in some of these work group meetings, not on every single point. But I think on some points we had consensus. So, maybe when we present,

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maybe one of the things is to say, here's the areas where we had consensus and here's the areas where we had some differing opinions. But here they are. So, that might be a way to help get at that issue.

Then, the other thing has nothing to do with this. I just wanted to remind everybody about the donation cup. You know, all the water and food we get, EPA can't pay for that. So, they pay for it largely through out donations. So, don't forget about the donation cup.

MR. BRADBURY: Thanks, Cindy. Your point is well taken, Mark and Cindy. Sometimes we're sort of used to the process over the years. I think the clarification that Cindy is making is good.

Jennifer.

DR. SASS: Two things. One is regarding the consensus issue. I mean, the thing is we mostly don't have consensus. It would be painful if we had to come to consensus on these issues. It's more important that we're able to give EPA our feedback based on our stakeholder sort of positions.

I do like Cindy's idea of having some -- I

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mean, if we have some sort of way of representing ourselves without having to individually speak, that would save a lot of time in the meeting, if we could just go, like, I, or something, and that would be it.

As for the thanking EPA for the munchies, it's really great. But I will raise again that I don't think we should be buying bottled water. Check with your water office and see what they think about bottled water.

UNIDENTIFIED FEMALE: Back to the consensus thing, many of these issues have a lot of complexity. In terms of having an informed opinion on every single issue and enough so that you could vote on it intelligently, I think it's going to be difficult. So, I would really like to avoid kind of knee-jerk voting. I think that voting is not a good idea.

MR. BRADBURY: Okay.

UNIDENTIFIED MALE: I don't believe in voting either, okay. So, let's get that clear. I also agree when we have 35 or 40 people here with diverse opinions and diverse experience, there's going to be differences. But when there are areas where we do have consensus, that should be clearly identified. If we don't have a

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consensus, that's fine, too.

But I think there are points in time where we say, this is the way we all agree we should go, or the majority of us should go. Majority is not (inaudible) when you use consensus, but that's where I'm coming from.

MR. BRADBURY: Thanks. I'm going to turn it over to Margie and run through some options for the next meeting, the spring meeting.

MS. FEHRENBACH: We're looking at dates in sort of late April/early May. I'll send an e-mail to everybody offering April 18th-19th, 25th-26th, or May 2nd-3rd. If you're aware of any major meetings that would conflict --

MR. BRADBURY: While we've got everybody together, I'd like to thank Margie for all her work in getting this meeting up and running and another great success. I don't think we'd have a chance to get any of these meetings without Margie, so I can't thank her enough.

I think she talked about it last time, but the work it takes when FACAs have to get reauthorized and the process Margie had to go through with, she calls them --

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I should be careful what she calls them -- but the bureaucracy to ensure that this FACA could continue and the documentation and then the work to get all of you on the panel, it's an incredible amount of work. So, I want to thank Margie for that as well as this specific meeting. So, thanks, Margie.

MS. FEHRENBACH: One other thing I forgot to mention, the charter and the membership are on different tracks. So, there will be a Federal Register notice soon to show that the charter to this group is being renewed starting like October 31st for two more years. It's just the charter.

The membership process for the next round will actually have to start, I think, in a few months. They like you to have six to eight months for the process. It's a little out there but it's over the next year.

MR. BRADBURY: So, with that insight into the bureaucracy, let me thank you again and have a good trip back. Looking forward to seeing you in about six months. Take care.

(Whereupon, the meeting was concluded.)

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MARILYNN H. McNULTY,
Transcriptionist

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