Transcript of

United States Environmental Protection Agency

Office of Pesticide Programs

Pesticide Program Dialogue Committee Meeting

May 11-12, 2005



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**PROCEEDINGS**

**Day One**

**May 11, 2005**

JIM JONES: Good morning everyone. Welcome to the National Press Club. I'm very excited about being here. Not just because it's the National Press Club but because I'm with all of you as well. This is the Pesticide Program Dialogue Committee and the first order of business other than introducing myself, Jim Jones, Director of the Office of Pesticide Programs is to introduce my boss, Susan Hazen, who for the last two years has been in the very challenging role of being the Acting Assistant Administrator for the Office of Prevention Pesticides and Toxic Substances, OPPTS, and we're fortunate to have Susan here this morning to give us some opening remarks.

SUSAN HAZEN: Thanks Jim. Thanks very much. First of all I want to welcome you all here to Washington. Some of you are clearly all that familiar with Washington. Others are not. I'd like to thank Margie. Where is Margie? Margie Fehrenbach for finding this incredibly nice venue. This is a very hard place to

get, so, I don't know how, I don't want to know how. But thank you. It will make for a very nice meeting. You might see some interesting people in the hallways as the day goes on.

As I say, thank you very much for taking time out of your schedules to not only come to this meeting, but to be active members of this committee. I've worked with this committee in various ways over the course of the past five years, when I was directly in the Pesticides Program, and I have always found it to be one of the most active and effective committees that we have in the Pesticides Program, which is not to say that our other committees aren't good. I don't want that word to go out of here. But I've always seen this committee as sort of the roll-up-your-sleeves, let's tackle the real issues. Let's not talk sort of philosophically or you know in the abstract. But I've always seen this committee as a group of folks who tackle the real world sort of day-to-day problems. And in doing that, I have just seen tremendous progress in moving us forward on some very controversial and critical issues. So the good news is that I think you have helped EPA and helped the

Pesticides Program in particular, really advance on a lot of issues. That being said, we have in front of us not only another challenging year where we're trying to complete projects and programs for the first time, but I think what we're now beginning to see is programs that we put in place years ago. We all together put in place programs that we thought were the most effective programs we could and we're now seeing evaluations of those programs. And so they're coming back to us and now we're getting to see what in actuality they have accomplished, where there may be shortcomings, where there may be room for improvement, where there may be room for reduction in some kinds of efforts as well. And so what we have in front of us I think for this meeting and over the course of the, quite frankly, next few years, is completing a number of things such as FQPA, continuing to focus on PRIA, taking on new issues, the all-time favorite of spray drift has to be addressed one way or the other. But also on the agenda are things coming back to us. Worker protection, certification, training. Programs that have been in place for a while that we need to take another look at in terms of how they've been implemented.

So just let me share with you my thoughts on at least for the Pesticides Program over this coming, the rest of this year and through 2006, which is kind of the time frame I keep looking at, 2006. It's just that number, that year, that just keeps popping up in my head. Clearly we've got FQPA deadline to meet, August 2006, for the food use tolerances, 2008 for the non-food tolerances. That is an incredibly important deadline for EPA. We have taken it very, very seriously from the day the statute was passed and we have worked diligently with your help and others to continue to move along in a stepwise manner in order to reach that deadline. I know that there has been concern expressed by some that we are letting the deadline drive us. I think it's fair to say that we take the deadline very seriously but we will within that deadline assure that we continue to adhere to the processes, the procedures that we've put in place, so that we do take the appropriate time to hear from stakeholders to be able to address their concerns and continue to move forward. It's not a one or the other. It very definitely can be a combination of the two and that is certainly how we would like to see it move

forward. PRIA is moving from my perspective very, very well. And clearly many, if not all of you, have been very instrumental in helping the agency not only get that program in place but to move it along effectively. I know there will be some discussions about that but from at least from the agency's perspective we think the collaboration and the partnership of making it work effectively is working very well. I've talked to some folks, I've talked to Jay and some others about some new ideas in terms of putting forward the incredible stewardship and voluntary efforts in the pesticide industry in order to assure that the public has access to safe and effective pesticides. I've often wondered why there's not more public recognition of the extreme efforts that companies and users and processors go through to assure that their products are in fact used safely, that there is education. But I think it's time that we sort of get that word out and one of the things that at some point in time I'm hoping we can bring to this committee is a proposal on how to advance a fairly aggressive voluntary stewardship program for the industry. And so we'll keep you tuned in as that moves

along.

ESA, major challenges for us as you know. Still in litigation on many fronts. But I believe the agency is making an incredible good-faith effort to live up to not only the letter but the spirit of the law. We are taking it very very seriously, putting a tremendous amount of effort into it. And we will continue to do that because it is important. As I say I think one of the agenda items probably right after this is to talk a little bit about worker protection and certification of training. I'm going to try and stay for some of that discussion because I'm very interested in hearing your perspectives on that.

And then we've got a whole bunch of new stuff coming along and it's not clear where it fits into the pesticide world but we need to figure that out. The whole emerging science of nanotechnology and is there some fit here with the Pesticides Program and if so, how does it fit in? My office as Jim said also has the Toxic Substances Program and there's a clear fit there. Nanotechnology falls subject to the premanufacture notice requirements of TOSCA, as well as some others. So in a

way it's helpful that we've got both programs under the same office. And so we'll be looking at that and obviously working with you all to see where that fits in. There's a public meeting that the agency is hosting on nanotechnology. I didn't bring the date with me but I think it's some time in the end of June, and I can send that date over in case anybody here is interested.

So with that being said, I don't want to use up valuable discussion time and your time but it is a pleasure to be here with you. This as I said is one of the groups that I think really has been most effective and I look forward to working with all of you and hearing from you. So thank you.

MR. JONES: Thanks Susie. Why don't we go around the room now and have everyone introduce themselves and what organization they represent and then I'll make some additional remarks before we get started. If I could ask that you -- if you're sitting in for someone as an alternate if you could let us know who it is, who the PPDC member is that you're sitting in for. But why don't we get started. And one additional thing, for my government colleagues who are at this end of the

table, obviously the screen is behind us. Most of the materials are in our books and so you can actually just look at hard copy or if you choose so we could sit over there so that those of you on the PPDC who want several of us to move over there it's really just to see the screen. But I thought it would be best if the government officials be the ones with the screen to their back as opposed to the people who are giving us advice. So with that why don't we get started. Berlson, do you want to start and go around?

BERLESON SMITH: Berleson Smith, U.S. Department of Agriculture.

AL JENNINGS, Department of Agriculture.

TERRY TROXELL, Food and Drug Administration.

JAMES ROBERTS, Medical University of South Carolina.

BETH CARROLL, Syngenta Crop Protection.

AMY LIEBMAN, Migrant Clinicians Network.

DAN BOTTS, Florida Fruit and Vegetable Association.

AMY BROWN, University of Maryland and American Association of Pesticide Safety Educators.

ALAN LOCKWOOD, Physicians for Social Responsibility. And my day job is Professor of Neurology at the University of Buffalo.

JOHN VICKERY: Good morning. I'm John Vickery. Palmer Land Trust, Colorado Springs.

KEVIN KEANEY: EPA.

JAY VROOM: CropLife America.

LORI MCKINNON: Yerok Tribe and Tribal Pesticide Program Council.

ERIK NICHOLSON: United Farmworkers of America.

FRANK S. BRADY: I'm sitting in for Allen James of RISE Responsible Industry for a Sound Environment.

STEVE BALLING: Del Monte.

NANCY LEWIS: University of Nebraska, Nutrition.

GARY LIBMAN: Emerald BioAgriculture.

CAROLINE KENNEDY: Defenders of Wildlife.

STEVE KELLNER: Consumer Specialty Products Association.

LORI BERGER: California Minor Crops Council.

SHELLEY DAVIS: Farmworkers Justice Fund. And I'm sitting in for David Fisher of the American Bird

Conservancy.

LEO ALDERMAN: With EPA Region VII in Kansas City.

DENNIS HOWARD: Florida Department of Agriculture Consumer Services.

JOHN SCHELL: BBL Sciences.

TROY SEIDLE: People for the Ethical Treatment of Animals.

MARY ELLEN SETTING: Maryland Department of Agriculture.

BOB ROSENBERG: National Pest Management Association.

JULIE SPAGNOLI: Bayer Healthcare, Animal Health Division.

SUE CRESCENZI: Steptoe & Johnson. Sitting in for Has Shah, Manager, Biocides Panel American Chemistry Council.

DIANE SHUTE: I'm sitting in for Warren Stickle of the Chemical Producers and Distributors Association.

MELODY KAWAMOTO: National Institute for Occupational Safety and Health.

NANCY GOLDEN: U.S. Fish and Wildlife Service,

sitting in for Greg Nassen.

MARTY MONELL: EPA.

ANNE LINDSAY: EPA.

MR. JONES: All right. Thanks very much. The agenda for this morning I hope reflects the earlier commitments that I had made to this committee that we would try to do a number of things at these meetings. We would try every time to give you some general updates about some of the pressing matters before the Pesticides Program and I think that that's scattered throughout the agenda here. We would follow up on some key activities that this committee has given the agency advice on in the past. And I think our agenda also has a number of those, whether it be the registration review subcommittee that has been working for over a year now or the consumer labeling activities. But there are a number of items on the agenda where we're basically following up on some activities or some advice that the committee has already provided to the agency. And then each time we would try to identify a couple of areas where we were going to be perhaps briefing you on in an update sort of way but also asking for some further participation from the committee

and I think we have a few of those here today. Spray drift, which we'll get to later on, I believe this afternoon or tomorrow morning. And results, which we're going to spend some time on this afternoon. So a combination of -- you know we don't want to be just giving you sort of talking heads although we have a little more than we have historically, at least the last two years, as it relates to us giving you updates. But there's a lot of meaty things going on that we thought we needed to spend some time on. Keep ourselves collectively accountable by following up on activities that you've already engaged on and then identifying a few things that we're proposing that the committee work with us in a follow-up sort of manner. And I think that the agenda that we've got here today reflects that balance. You've got the agenda before you. I don't think it's necessary for me to walk through the entire thing. So with that being said, I think we may be a little bit ahead of schedule. Let's get started on the first topic of the day. I've got to make sure Bill Diamond is here. Is Bill here? Okay. Kevin Keaney is going to lead our discussion around worker safety activities. Kevin.

MR. KEANEY: Bill sends his regrets. He was looking forward to sharing with you the results of these studies we've done and the findings in the reports. But he's been sick the last few days and so in the interest of public health he won't be sharing with you. (Laughter.) The reports are in your pack. The first one I'll be dealing with is the Strategic Program Assessment of the Pesticide Safety Education Program and the transmittal memo there as well from Bill Diamond to Jim Jones and to Ralph Otto at USDA, the Extension Service coordinator, the Extension Service leader there, the Deputy Administrator, and the rationale for the particular study. The presentations, both presentations on the two reports are to set the context for your readings of the reports and we'll close each presentation with a challenge for engagement on the ongoing activities we're going to conduct as a result of these two exercises. And they cover the programs and the regulations that deal with pesticide worker safety, so it's dealing with the full span of pesticide worker safety covered by the certification regulation and the agriculture worker protection regulation, the state lead

agencies that we deal with, and the Extension Service that we use primarily for the safety training for competency of pesticide applicators. So in this particular report of the Pesticide Safety Education Program, the rationale and goal of the revue was that the PSAP, the Pesticide Safety Education Program, is one of the lead providers of training to ensure competency of applicators, certified applicators. It's an old program, it's an old regulation. And matters of just good government affect their program management and require periodic assessments. We have had an assessment group that we formed a few years ago to deal with the national program but it wasn't specifically focused on the Extension Service aspect of it or the Pesticide Safety Education Program aspect of it. So increased client demands highlighted some operational issues, some funding concerns over the last couple of years have heightened those concerns for operational issues and growing demands and needs for accountability generally in government programs provided good drivers to conduct this review. The scope of the review was intended to determine how well critical needs were being met by the Pesticide

Safety Education Program to serve the applicator community and the clientele of the applicators are trained to be competent. So the goal in the review process was to bring together practitioner perspectives, to bring together expert practitioners drawn from the clients of the program and participants in the program, and deal with a range of critical issues and concerns that we had and structure the discussions by the framing of questions and responses from the expert panel, practitioners who were brought together. So we were dealing with those that are -- were aware of the program and we gave a number of information pieces to those folks we brought together so that we would be assured we're all working from a common information base. And then we wanted to deal with questions that would guide us in the future direction and management of the program. And how to deal with operational issues and funding issues that are destined to continue in the program. So, the who of the review was the client and the practitioner representatives we brought together. We distributed the information to them. We held two discussion meetings. In those discussion meetings we identified areas to focus

on. Those were goals, activities, measures, operations, and future directions. We developed mission and critical questions, statements to give to the assessment group. And we collected their perspectives on the critical questions and this is the results, the publishing of the results of those activities and the perspectives. The review panel, the review group -- as you can see it's widely represented. Many of the group are players in this advisory committee or attend it -- are regular attenders of the committee. As you can see by the array it is those that are in the network of certified applicator activities and training activities or are clients of those activities. So those were the folks we brought together, as well as folks from my staff that are behind me here to conduct this exercise. We framed out critical questions in these areas as I mentioned, discussing the nature of the mission. Is there a clear understanding throughout the network of the nature of the mission? Is it understood by all the critical stakeholders? Are we all in agreement on the scope and the appropriateness of the mission? Is it consistent with statute and regulation? Is it consistent with

program needs if not consistent with statute and regulation? As far as the program activities, are the current activities appropriate? Do you need more? Are there gaps in audience? Gaps in the training or the priorities? Who are the training providers in the various states? And who should be the program partners? If we have a fixed set we're working with now need that be expanded to involve more in the support of the training exercise to ensure competency? In the area of program accountability are there clear measures of program success? There are things that we can use to justify our existence in the national program and at the state level. Are they appropriate measures? Are they measures that are outcome measures rather than output measures? Are they manageable given the resources that we have to sustain the program? As far as program operations, are they efficiently and effectively conducted? How can we improve management, mainly of funds or coordination between state agencies to leverage resources or consolidate activities so that there's not duplicative expense of resources? As far as future directions, after the discussions -- after the

discussions of these other points there were discussions of are we moving in the right direction in the development of the program in the guidance begin given by USDA and by EPA? And what should be the focus of the program to face short-term needs and pressures but to move toward a sustainable long-term program. And then the general discussion of how we can better work together as agencies, as state participants, and as stakeholders in this whole process.

Now the review findings as a result of the discussions -- they were broad and intense as some of the folks sitting around the table here that were at the discussions I'm sure would support. There were intense discussions and they did highlight both the strengths of the existing program but some of the deficiencies of the existing program. And they were individual perspectives we were looking for. And they're included in the report specifically. There were suggestions for improvements and perspectives on the current activities and suggestions for follow-up activities. We didn't intend the report to be a consensus report. We weren't looking for consensus necessarily but the various perspectives

and when you look at the membership of that review group it's quite wide and varied and the perspectives would be important because they are the clients or the participants in the program. So although we weren't looking for consensus, there were emerging commonalities that come out of the various perspectives and we intend to use those as our guide in future activities. So we did move to address emerging and current training needs, changing needs, implement program efficiencies to maximize resources, establish accountability measures, and improve funding mechanisms. So there are commonalities around these particular themes. And we, as I said, would pursue these in follow-up activities. In the area of operational efficiencies there is a need to improve funding mechanisms. I think there was general agreement that level of funding in any national program is always a challenge to find it adequate, but you certainly want to have it adequately dealt with as far as distribution and use of the funds. So we are going to examine the current funding distribution process and try to work with the partners that we have in the program to improve accountability for the funding.

I think there was general agreement or there was a theme running through the perspectives that we could see as agreeing on the need to set training priorities, determine who has the responsibility for providing the training to various audiences and I think as Bob Rosenberg mentioned at one of the sessions that our current perspective on restricted use as being the driver for certifying applicators from the federal perspective is perhaps the tail of the dog, the tail wagging the dog, if we're focusing all of our energies on that small segment of pesticides to be used and concentrating on the developing of competency only there then that's not what states are doing. That's probably -- as we discovered is quite likely what many -- is not what many of the pesticide education coordinators are doing as well. So establishing priorities and getting a better focus on national needs, establishing strategies to meet national needs and to leverage resources by fostering or mediating regional coordination of activities to avoid duplication and wasteful, waste of resources is important and we're going to pursue that.

As far as essential program improvements,

expanding on the discussion on the type of remark that Bob would make, there was a theme running through the perspectives that endorsed an expansion of the scope of the program to cover -- to think in terms of nationally and federally and at the state of a broader umbrella of competency to be brought to the applicator community, to ensure public safety and to increase competence in the safe use of pesticides. So we would pursue that.

We also, as all of us in government programs and those receiving or distributing federal monies, need to establish fairly rigorous accountability measures to defend our existence in tighter budgetary times, so we would pursue that and ensure that the accountability measures are reasonable and capable of being implemented and not overly burdensome.

So that's the context of the report that you'll be reading. Our challenge to you is to engage with us on our next steps. We intend to move forward and develop, as you'll see in the report, we have the framework for a work plan to begin to look at regulations, regulation change in this area. It's a 30-year -- it's the regulation that formed the program. It hasn't been

changed since it created the program more than 30 years ago. So we are thinking of creating changes in that regulation in the sense of tiering of the regulation changes in the applicator certification regulation to try to get a reasonable spread of assurance that the applicator community is competent, not simply the certified applicator is restricted use as being competent to safely apply pesticide. We in the past have worked through an interagency agreement with the Department of Agriculture to distribute federal funds to the state Extension Services to help fund their programs, to train for applicator competency. That interagency agreement expires in 2006 and we were going to use that particular juncture to -- or move toward that juncture with discussions with USDA and our state partners to consider alternate funding mechanisms or alternate means to distribute monies that we have. Now, as I said, the challenge to PPDC is how do you want to engage with us in these various activities? Assuming you will be engaging with us in these various activities. We're inviting you to engage with us. I think our preference would be to begin these activities and brief you as we get into the

follow-up activities to the report and as you've read the report and at your next session perhaps get the briefings of where we are, we'll have framed out activities to the point where you can see particular points of engagement you might be willing to work with us on individually or as a group.

MR. JONES: Okay. What I think we'll do is take some -- get some feedback at this point on the PCEP piece before moving on to the next piece which Kevin will also do. I probably should have said at the outset that this activity and exercise in our report back is a follow-up to discussions we had starting about a year ago at this committee associated with -- at the time the initial issue was PSEP funding and one of the follow-up items to that discussion a year ago was we said we would do this review that you were just presented with. So right now why don't we hear back from you as to any feedback you may have specifically on what Kevin has just provided but frankly more importantly about the questions that Kevin asked at the end of his presentation about what role the PPDC wants to have in the follow-up activities. Eric, start with you?

MR. NICHOLSON: Kevin, are there currently any objective measures EPA uses to evaluate the effectiveness of the education program? Because it seems to me that at least from worker perspective one of the - or the purpose of the training is to ensure compliance with the label, you know avoid misuse, reduce exposure, and it seems like there are some objective measures out there and I didn't see in the report or your presentation any reference to objective --

MR. KEANEY: Some aspects of that will be in the next report on the comprehensive worker safety program which involved the ag worker protection regulation and the certification regulation as well. This was dealing with the Pesticide Safety Education Program and its ability to efficiently and effectively serve the program. But that is a valid question. What measures are there in the existing structure to determine a successful program? I think Amy would be best to address the measures that USDA asks of the Extension Service coordinators.

MR. JONES: Eric, that's a very good question and perhaps the next presentation may elucidate it and

I'll certainly let Amy if she wants to further elucidate the point as well. This afternoon we're going to be presenting to you sort of measures and results that we have begun to collect and quantify in the Pesticides Program broadly and one of the things we're going to be asking this committee is your advice on -- well, one, do you have information that will help us better measure the results of our program that you can share with us or point us to. And some just general advice about areas that we need to do a better job of measuring. So your point is one that we're very much interested in hearing back from you, as we have found it very hard to develop measures for our programs. Amy?

MS. BROWN: Actually there is a template that the Pesticide Safety Education Program coordinators are required to report back through to USDA to our national program leader. It has a number of components that we're required to report on. Of course when it started it was mostly things like number of people trained, number of people trained for certification and for recertification, number of materials developed. But we've gone more to a system of asking states to provide information on

behavioral changes that have occurred so you actually get some impacts and some outcomes of what benefit has the training done. And most states are -- I just reviewed that myself. Most states are reporting behavioral changes. The hard thing in trying to see a broad scope is that states have very very different programs and are able to monitor different things in different ways so the results on behavioral changes are not always directly comparable between states but you can get a feeling for this. It is public information. I don't have the web site with me, but I can certainly get that to the committee. It's public information. It's all there and one of the things that actually AAPSE has suggested is having a summary of that. We don't really understand if it hasn't been provided to EPA why it hasn't been provided to EPA. And a summary would certainly be helpful. And that surely could be accomplished either by the national program leader or AAPSE is willing to step in and do that.

MR. JONES: That's very helpful Amy, thanks.

MR. KEANEY: I believe part of your question was we're getting at the notion of incidents and

enforceable activities and in the next presentation we'll have some discussion of the recommendations there to get better use of field data relative to both areas of enforcement and poisonings as measures.

MR. JONES: Jay?

JAY VROOM: I want to express appreciation for this follow-up and all the work that Kevin has described that's been done since as you indicated, Jim, this became a relatively hot issue at a PPDC meeting about a year ago. And it seems to me that the answer to all the questions in Kevin's last slide ought to be yes. I'm not sure necessarily how PPDC work group on PSEP would fit with the group that you've already had together or you know would it expand that group or whatever. I would hate to see, you know, you have to deal with two separate groups so maybe the existing group supplemented by others from PPDC could enlarge that or somehow complement it, but I'd hate to duplicate that. One question that I don't sense necessarily was addressed in what Kevin described was the sort of crisis point that some of us felt we were at a year ago, which was that this program was on life support, particularly around some states

being underperforming and I know it's probably not politically correct to name names around states and problems but I don't know if any of us know enough to be able to address that. But it would be interesting to know how we're sort of getting tactically forward day by day and ensuring that applicators are getting the proper training so that they can continue to be licensed under the current regime.

MR. KEANEY: Well, we have the commitment of the same level of money that we had last year and anticipate the same level of money next year, so they were sustaining themselves on the million two then they will be continuing for the next couple of years to do that. There were some programs we know that shifted focus and the state agricultural departments have accommodated and so I don't think -- and Amy can direct me, but I don't think there is the general crisis nationally that we thought existed. There is the crisis of adequacy of funding obviously and we are through the certification and training assessment group, which I'll discuss in the next report, we are pursuing a training exercise at our national meeting and in other meetings

that would bring to the state coordinators a way to approach funding, a way to approach an analysis of their own program so that they in effect approach it as a business and establish a business plan, working off the LOGIC model that will allow them to justify their existence and justify appeals for more funding to support their existence. So it's an exercise we're going to aggressively support to try to change the way the state coordinators think of their programs and think more of a service that is a valuable service and a valuable service that should be dealt with with resources not necessarily from single sources.

MR. JONES: Amy, why don't you respond to that and then we'll go to Steve.

MS. BROWN: I do have to respond to the issue of whether it's in crisis. Yes, I guess once you've cut so much that you've lost staff you can continue programs and that's what has happened. So in that sense we're no longer in crisis because there aren't the people to cut. They've been cut. I don't know of any state that's simply said we will not do any more training. The states have managed to keep doing training but for instance if

you look at California's program, which was very large and addressed a number of initiatives that were excellent and not directly tied to just the letter of the law, they were very broad, that program is done. It is now done under an IPM staff. It's a very small effort. Michigan has lost people. In my state I've been largely reassigned to teaching duties on campus. So we're doing things still but I would say the quality and scope is very much in crisis and has gone down and we're looking at again, as we look at the other issues that we're going to be talking about at PPDC over the next two days, endangered species, water quality, and particularly GHS, this is a huge effort that will have to be done and we don't have the staff with the background to do it anymore. So it's not out of crisis.

MR. JONES: As I've said at this meeting a number of times and will continue to say it, that the questions of funding, if I could get a consensus around this room about what EPA should reduce its funding for to further fund this program, that would get serious consideration by myself. I'm not sure we can do that but if people wanted to engage in that dialogue again, I also

think it would be appropriate to have a broader dialogue about what is the appropriate fund -- who are the appropriate funders of training in pesticide safety? At this meeting, because this is the Pesticides Program, we only talk about Pesticides Program funding. I think that that issue though of who the appropriate funders are is a much broader issue than that and I'd like to talk about it. In a broad sense who should be broadly, and I mean broadly, I mean every group around this room and potentially some who are not, has potential funders and not just the Office of Pesticides Program. So again we can, if folks want to continue that dialogue, those would be sort of the parameters that would be useful for the Environmental Protection Agency to have the discussion on. But thanks Amy for that. Steve?

MR. KELLnER: Well, first of all, I want to say that DelMonte is not considering being one of the funders of the program. (Laughter.) We are very supportive. But in light of this issue of real limited funding, I was curious Kevin about the comment in the areas for follow-up action where you say require training certification for a broader of applicators. That's provocative. What

are you talking about? Or what did the review talk about there?

MR. KEANEY: Well, we were talking about the fact that much training now is focusing on more than just restricted-use pesticides. And the notion as we were saying is they're restricted to just focus on the certification of competency of applicators of restricted use is probably inadequate. And that there are applications of pesticides in sensitive areas that you would like to assume had competent applicators working the application. So that was the discussion spun from that point.

MR. KELLER: So you need more funding to do that most likely.

MR. KEANEY: You would need more funding or you'd need a different approach to address the funding. It's not simply from here but from a variety of sources. And you'd need to have a clear focus on purpose at the state level and you'd need to get folks out of the mindset that everything has to be state-specific, that every state has to have their individual set of manuals developed and incur the cost of developing them for each

state as opposed to taking a New England approach to developing manuals for New England or some agronomically logical segment of the country to save resources. You have to begin to leverage resources in those ways so that if your expense is face-to-face training then perhaps you should address the efficacy of that as a way to conduct training as opposed to other methods. So there are a number of ways you can approach spreading the money further and getting more effect and acknowledging the fact that there are needs for training for competency in other than just restricted-use pesticides.

MR. KELLER: Well, then, in follow-up, and this is probably for Amy, what about Spanish language programs? What's the extent of that in PSEP?

MS. BROWN: Well, first I support what Kevin said and also what Jim said about the scope and the need for funding and I do want to make the point that the EPA funding that supports PSEP is just to support a small piece of the program in each state on which the state's much broader program is built. And we do use funds from many other sources to build and keep our programs ongoing. But I would welcome that discussion. As far as

Spanish materials, a lot of states do training and have a need for training in other languages including Spanish. That would be the largest, but there are many many languages. EPA has supported translating some materials into other languages. We do have needs there but, again, there are -- there's an issue of how much to train in a language if you want to require your applicators to be able to read the label in English and be able to apply along those lines. But we also have -- well, the consumer labeling initiative is going to talk about this for consumers, but we have the same thing with occupational users of pesticides who may be applying under somebody else's supervision who either don't speak English as a first language or who do speak English but can't read English. So you have a lot of needs for non-English-literate people, both in materials that they can read but far more in materials that can be gotten across in some other way, in both Spanish and English.

MR. JONES: Shelly.

MS. DAVIS: My comments actually follow up on Steve's in this category of the broader range of folks who need training and possibly this is being covered in

your next report. I just want to make a few quick remarks on that. That from our experience the workers who are pesticide handlers operate under the direct supervision of certified applicators are not being adequately trained in any respect and the issue that Amy just raised about language is certainly part of the mix but in general their level of training is vastly inadequate. And so I would just like to make a plea first of all that when you do reconsider or you convene a broader group on figuring out how to do this training better that you include representatives from the worker community of this category of folks who are pesticide handlers, representatives of those folks. And that you really seriously take into account that a system predicated on English-only labels is just designed to be unsafe and it's wholly unrealistic. And it's just another way of saying we don't really care if these people know what's on the label or not. So I just want to say that first include workers and to be realistic.

MR. JONES: Kevin, for the benefit of the broader group, could you sort of describe how the regulations are constructed as it related to who is

required to be trained for each restricted-use pesticides and then who actually can apply them and under what conditions.

MR. KEANEY: Okay. The two regulations we're talking about cover the span of those that can work with and around pesticides in agriculture and in the certification regulations those that apply restricted-use pesticides. The agricultural protection regulation deals with field workers and pesticide handlers and others and their specific training requirements, safety training requirements, for pesticide workers and pesticide handlers. The certification regulation is designed to establish standards of competency for the applicators of restricted-use products and they are trained to pass a competency exam, a core competency exam in safety, and then category exams in specific areas of application like agricultural plant, agricultural animal, structural, and so forth, public health use. And they can apply restricted-use products or supervise the application of restricted-use products. And under the regulations supervision is a very broad, has a very broad read and so we have a million or so in the country holding

certification to apply restricted-use products and you can pick your multiple of how many are actually applying because of that under the supervision provision. So that's -- and Shelly is correct. In the training of handlers and the training of workers under the agricultural worker protection regulation it's simply -- it's an obligation the agriculture employer has to either do the training or ensure that the training occurs and it's simply -- there isn't a gauge of competency in that regulation. It's simply sitting through the training and not being asleep or dying during the training, then you've been trained and there's a presumption of competency, which we're all uncomfortable with, I think we're all uncomfortable with, as far as the handler segment, well, the workers as well, but there is no gauge of competency under the worker protection regulation as opposed to the certified applicator regulation where you are training to competency of competency standards and you have some gauge of that competency generally and specifically through either core exam and the category exams.

MR. JONES: Thanks. Okay. A couple more.

Bob? And then Jennifer.

MR. ROSENBERG: I just want to say a couple of things. First of all, thank Kevin for the generous characterization of the committee members as a panel of experts. Secondly, to thank Kevin, Bill, the other OPP staff, and the USDA staff for what was at times a very honest and candid discussion and I'm sure it was uncomfortable and difficult to be a part of that for some of them. Thirdly, though, and I think this is the important point, some of us, I mean I think a lot of us, believe that certification training really is the cornerstone of an effective pesticide regulatory program and both in terms of what the statute requires and in terms of what the agency has done has not always received as much attention as we think it deserves. And this effort to sort of elevate the visibility of certification and training is a huge step forward and would love to see it be an ongoing process and part of these PPDC discussions. And I'll just add one thing to what Kevin said, and this kind of goes to that core question. FIFRA says you know the person who supervises the application of a restricted-use pesticide must be certified period.

In my world, the world of commercial applicators, that's probably less than one-tenth of 1 percent of the pesticide application that's done. The states, every one of them, require the commercial applicators of general-use products to have some people certified and virtually every state in addition to that requires that the persons operating under the direct supervision of a certified applicator, either general- or restricted-use products also has to be certified or trained and there are probably 100 of those people for every one person who falls into that very narrow federal statutory definition. So anything we can do to kind of refocus the program towards the training of that much broader universe of people I think is a very important part of this discussion. Thanks.

MR. JONES: Thanks Bob. Jennifer?

JENNIFER SASS: Thanks. Well, actually some of my questions have been held because the discussion has been quite helpful but I guess my questions are going to be because I'm really naive in this area. I often feel at these meetings like PPDC is a real inside ballgame and at least me I'm not following all the little ball

subgames along the way. I'm often quite confused. So I'm going to ask some really basic questions. This program is hosted by EPA, is that right? It's coordinated by EPA?

KEVIN KEANEY: The Pesticide Safety Education Program is the state Extension Services and our money passes through the Department of Agriculture out to the state Cooperative Extension Services.

JENNIFER SASS: Okay. That's two questions so that's great. That was my next question. What is the funding for the program? And you already mentioned earlier that the funding that you get is only partial and that it's coordinated with a lot of other state programs and that other funding comes in from there which was helpful, too, but what is --

KEVIN KEANEY: Over the 30 years of the program it's varied obviously. A lot of front loading of the program to start it and it reached a relatively stable state at around two million for a number of years.

JENNIFER SASS: And that's from the Department of Ag?

KEVIN KEANEY: No. From EPA.

JENNIFER SASS: Okay.

KEVIN KEANEY: And was recently reduced to a million two from a million 880, which was the amount for about five or six years.

JENNIFER SASS: So 1.2 million.

KEVIN KEANEY: And it goes out to 50-some entities at the state level.

JENNIFER SASS: Okay.

KEVIN KEANEY: Yeah. More than 50.

JENNIFER SASS: Okay. And then I have another concern I guess. And I know it's, because of overheads, it's a short presentation, so in your overhead three you say that the purpose that your participation, and then you have a list of your review expert practitioner groups, your participation are your clients and practitioner representatives, so they appear to me to be federal, maybe state-level government, and the different applicator groups and CropLife America is here, and some different users, manufacturers, and applicators of chemicals, I don't see involved here some of the other people that are represented around the table here that represent more of the worker communities. And I assume

-- I know that they are applicators, we know that. So that's a concern to me. But when you -- in the same slide three you have who, how, and what, and your what is that you're going to collect practitioner perspectives on critical questions and publicize the results, but in your presentation I didn't see any of those perspectives.

KEVIN KEANEY: They're in the report.

JENNIFER SASS: In the report? Where is the report?

KEVIN KEANEY: In your package.

JENNIFER SASS: Somewhere in this package that we were given this morning? So did anybody have time to review this or are we just all hearing this cold or is it just me?

KEVIN KEANEY: You're probably all hearing it cold and that's why the last few slides were to suggest means of engagement in future activity. That's to set the context for your reading of the report.

JENNIFER SASS: Okay. Then I'm going to continue to ask a few questions then, and you can help me. So all the perspectives are in the report, not in your presentation?

KEVIN KEANEY: That's right.

JENNIFER SASS: Okay. And then on slide five you have your critical question areas that you identified but on slide seven you have your areas for follow-up action and I can't find much overlap between your follow-up action and your critical question areas unless it's just the way the language is used.

KEVIN KEANEY: If you look through the perspectives those critical question areas were to structure everyone's perspective in a fashion that we could and if they existed to see commonalities emerge when they gave their response to those particular questions in the critical question areas. After they did that the commonalities that came out are the things that we're following up on.

JENNIFER SASS: Okay, so, I mean, okay. One of the things that I saw was program accountability and program, you know, measurements and accountability and whether it's working or not. So I'm not sure I see that clearly coming out in the follow-up actions.

KEVIN KEANEY: We're going to establish accountability measures. Under the central program

improvements. In the areas of follow-up those particular things are the expansions of the commonalities that came out of the perspectives. When you read the report and you read the perspectives provided by the review team, the review group, you'll see that we have taken and we do specifically take out of the perspectives what we assume to be the commonalities that we can then frame out in an action plan to follow up. That's how they're being characterized.

JENNIFER SASS: Okay. And then the next steps would be to actually do some of those things.

KEVIN KEANEY: Yes.

JENNIFER SASS: Is that right?

KEVIN KEANEY: Yes.

JENNIFER SASS: Okay. And how long has this been going on to get to this point? Has this been since in the last year? Has this been a one-year process?

JENNIFER SASS: And it's been two meetings, is that right?

KEVIN KEANEY: We had two meetings, some conference calls, a lot of e-mails, a lot of material sent to the groups before they convened.

JENNIFER SASS: Okay. And -- okay. And now is that budget spent in the last year to get to this point?

KEVIN KEANEY: The budget is -- no, no, the budget issue is a question of what money goes from us through USDA out to the Amy Browns in the country that coordinate the trainings at the state level.

JENNIFER SASS: Okay. Okay.

KEVIN KEANEY: The budget issue, the budget figure has nothing to do with this report.

JENNIFER SASS: With this process. Okay. Thank you.

MR. JONES: Very good. Oh, Lori, do you want to take the last?

MS. BERGER: Just a quick comment. Coming from California, a specialty crop state that has a lot of people moving in and we have a lot of worker issues as well as urban issues, we really do support PPDC looking at creative ways for funding a program. I hope that a work group can either be continued or established to look at this situation because it's obvious that there are a number of stakeholders. The programs, as Amy has said, had been getting weaker in the states yet the pressures

to be accountable at a number of stakeholder levels are increasing. So we really do need to figure out ways to fund this from a multiplicity of sources and it seems like this would be a great place to really start to examine that realistically.

MR. JONES: Thanks. Okay before we move on to the next topic, which certainly has a relation to this one, the -- what we will do in our follow-up activities, which we have identified here a number of follow-up activities and they're more clearly articulated in the report itself as it relates to this exercise. I think that the point that Shelly made that it be useful and Jennifer reiterated it to have some worker perspective on the group is an important one and the we'll work with you and others to get that perspective added to the list of individuals who have been working with us and we will continue to work in that format, whether we call it a PPDC work group or just an activity that we're going to report back to the PPDC is a distinction I'm not quite ready to cut on. But we're going to continue down in the follow-up mode in a similar manner that we did to get to where we are, which is to have a broad -- actually we're

going to broaden the stakeholder group work with us on implementation of the next steps. And we'll have those perspectives brought back here periodically to inform all of you as to how we're doing on the follow-up items that we've identified here. All right? Okay. Kevin, this next piece is yours as well.

MR. KEANEY: This is the second report in your pack and the transmittal or contact setting memo or note to colleagues from Jim. And it's a broader assessment. PSEP, Pesticide Safety Education Program, is a part of this, a subpart of this obviously. But it's a broader assessment of the worker protection program assessment activities that we conducted over a few years in the form of workshops around the country and work groups growing out of those workshops. The work that's been ongoing with the forum that we set up called the Certification and Training Assessment Group, that's a forum group composed of state regulators and state training folks from the PSEP network and federal USDA folks. And the suggested improvements that have come out of these two major exercises and the strategic plan that we have to address the findings that came out of this exercise. So

the assessment, the background setting for this after the worker protection regulation went into effect in '92 and then went into full effect in '96, after it had been in effect for a number of years there was a GAO report on its adequacy of implementation and enforcement. There was some focus from another advisory group, the children's health protection advisory committee was focusing on this regulation as a means to protect the children of migrant workers, farmer advocacy groups, farmworker justice, enforcement of the regulation and we as well felt it was timely after a certain point after the regulation went into effect to look at it and gauge how well it was being implemented and enforced. And how consistently it was being -- those things were happening across the country. So, we needed to establish a gauge of the effectiveness of this implementation and focus on efficiencies in areas that might need improvement in the program. Now, this is two-part because we do have an agricultural worker protection regulation driving some segment of protection for ag labor. You do have the certification regulation driving the establishment of competency for applicators. So under the worker

protection assessment activity that we undertook in 2001, 2000 I think it was, in late 2000 we began holding meetings and over the next few years we had national workshops around the country and then had work groups growing out of them. So we had public meetings and work groups that focused on particular issues coming out of the workshops, though the public meetings and the attendees were just the wide range of attendees that you would assume would have interest in the work that we were doing. So there were state officials and tribal partners, state partners and tribal partners, other federal agency representatives, farmworkers, farmworker advocacy group representatives, Cooperative Extension, commodity interest growers, and others. So there was a wide variety of folks that attended the public meetings and then those that expressed interest we tried to mimic that wide variety in the work groups that we developed out of those public meetings. We had work groups focusing on developing more of an ability to do hazard communication with audiences of workers that present any number of challenges we've heard about today as far as the literacy and their mobility. We formed work groups

to establish a curricula for a train-the-trainer network that we could market nationally to establish consistency in the type of training that went on to train field workers. We established a work group on general training issues and how to develop better training material and better modes of conveying safety principles through training. So we had a number of work groups that then spun out activities and products over the next few years and actually the train-the-trainer pilots we were conducting in a variety of states just finished last summer. So we have the results of that type of activity in this report as well as the activity that's been conducted in the certification and training program assessment group. We formed this group because, as was alluded to, the certification activity hasn't had a bright light focused on it for some time and we wanted to provide a forum of the participants in the program, the state regulators and the state trainers, to work with us and with the Department of Agriculture on issues that we felt needed to be addressed in the program. So we formed the certification and training assessment group and the results of their activity is contained in this report.

The assessment report tries to capture the breadth of the discussions in the areas that were being addressed by these two streams of activities. And this report is an attempt to try to convey what we found and then what we are doing or have done with the findings or what we plan to do with the findings. So in effect it's outlining our future direction, our future actions and directions in the whole spectrum of activities that you could characterize as pesticide worker safety programs. So under the -- the part of the report that deals with the worker protection assessment, we grouped the findings under these particular areas. And again it was holding a meeting, holding a collection of workshops, and then because of the levels of discussion that you have after the workshop you begin to see themes evolving and focus areas that people are concerned about. And so the particular findings we -- the grouping of the findings were the way they evolved out of the work, the public workshops. And there was a focus and needs expressed in the area of program outreach and communication, the worker training, the way that the labels are constructed and the way that the protection is attained through label

regulations, the need for incident monitoring and increased awareness in the health care community, the need for better hazard communication provisions in the regulation or in the training materials. There are a variety of general program issues. And then there was the overarching concerns for compliance and enforcement.

In the area of the certification and training assessment group, which is again focusing on the array of activities that PSEP functions in, the groupings of concern are under these headings: providing quality training programs, improving applicator competency, ensuring adequate and equitable resources, and improving operations and efficiency. And the CTAG group has a web site and you can see the evolution of issues on that web site, the variety of issue papers that have been framed out there and a variety of plans for future actions that exist on that web site. Do you recognize anyone on that slide do you? (Laughter.)

Now, this construct is something that I surfaced last year with you, some variation of this in discussing PRIA money and the expense of PRIA money to support or enhance pesticide worker safety activities and

it is a construct. It's a good construct to keep in mind when we're talking about our strategic plan for activities and that we want to have adequate training, training materials, adequate expression on labels on how to protect yourself or apply pesticides in a safe and effective way, and we do that as a means to express our regulatory decisions and our risk management decisions designed to protect workers who could be exposed to pesticides. If they are exposed to pesticides we want adequate field data coming back to us in the form of good measures, good accountability measure if you want to use the term, for pesticide incidents and enforcement incidents, coming back into the program, EPA program, in an analysis that could affect the future way you do risk management activities, risk mitigation activities, the way you do frame out regulations, the way you do change your training, change your labeling, change your training materials to better protect workers. That's an ongoing cycle there. And periodically we will report out to the public the findings of this activity, these two reports being in that public communication box. Some of the PRIA money is going to be supporting developing better field

monitoring data, field data that would give us better pesticide poisoning incident data, better collection and integration of enforcement incident data, so they could better affect the way we do business within the program. Now, there are some strategic benefits other than just the immediate findings that came out of the assessment and we found these equally valuable in that they did -- the exercise we conducted and we are ongoing in is creating better transparency as to how we do business, how we intend to do business, how we think business should be done by our partnering with state agencies and individuals. It's certainly increased the awareness of the problems and issues in worker protection at the agricultural worker level or establishing competency at the applicator level. It's built for better program coordination because it has provided these ongoing forums for discussion so we are in better program coordination with our regional and state partners and our grantee partners through, by extension, to extension. And it does create a visible and I think a very robust worker safety network that can effect change. And we have identified areas for program improvement or change. Now,

we have as a result of the assessment and as a result of the certification and training assessment group activity improved program coordination and guidance. There were a number of changes with -- this is sort of EPA talking to itself or talking to its state partners, but we did after the assessments, both assessments, begin to change fairly dramatically the guidance given to our regions that they in turn would give to their states to be in compliance with the conditions of our grants that we give them to help implement their programs. We've obviously improved communication and outreach as a result of this. We've established as I said fairly robust communication networks and listservs through our network partners and have tried to better coordinate our activities with the external and internal stakeholders. We developed, as I said, as a result of one of the work group activities a set of train-the-trainer materials that we'll be marketing nationally to try to establish a training standard that we can assume would exist if everyone is working from our train-the-trainer curricula, training of workers and training of handlers. We are, we did have a work group dealing with hazard communication program

development and we've got contract efforts afoot there to pursue some of the suggestions that Shelly and others on the work group suggested to us to better communicate hazards to workers in a simple fashion given the challenges that the worker community presents as far as literacy and language.

And we've in the applicator arena developed a national core exam and a manual for applicator certification and basic core safety principles and we did that with -- it's a valid exam and then it is an exam testing for what you want it to test for. And we did that in conjunction with Canada, so it's the same type of exam used in both countries. And we're pursuing that process of developing valid exams with Canada in the area of aerial application. We are developing a core package for fumigation and rights of way. And by doing so we would hope to relieve some of the resource burden on the states because they won't have to develop these competency exams and they can be used nationally or internationally for that matter. And they are valid exams. They are developed by a very rigorous process that ensures that you are going to test for the

competency that you want to test for.

So our priority here is in this arena we have committed to -- we hold in the even -- in the odd years we hold a national conference in the area of certification, bringing together the Extension network folks and the state lead agency regulatory folks and the federal agencies involved in the whole area of certification to focus on issues there. We have committed to bring together in the even years for national workshop those that are focusing more broadly on the whole area of worker protection as in field worker and handler. So we are planning for the spring of '06 the first, the second actually, of these workshops. We are considering potential rule revisions in both of the rules I've been talking about, both the regulations I've been talking about, the agricultural worker protection standard and the certification for pesticide handlers regulation. And we are through PRIA money and other activities trying to improve the data, the field data, collection and use by more aggressively addressing pesticide incident database development and projects focusing on that and refining enforcement databases so

that they can be seen as accountability measures, outcomes of these particular programs. We are about the business, EPA is about the business of protecting human health and the environment and a very basic measure of that is you aren't creating an environmental insult and you aren't poisoning people, or you aren't having rashes of enforcement incidents that might be related to label, might be related to inadequate training, might be related to a number of things that we can address to correct. So with those our priority areas we're going to focus on and as far as next steps we're again going to continue on this and begin to work in the priority areas, plan the 2006 worker safety workshop, and you know, it never hurts to belabor a point, but how would PPDC like to be involved in this as well?

MR. JONES: All right. Dennis.

MR. HOWARD: Kevin, you mentioned the set-aside money from PRIA being used for improving accountability measures or --

MR. KEANEY: For a number of things. Yes.

MR. HOWARD: Right. Could you compare the funds for that type of task versus the funds that states

receive from OPP for enforcement actions for WPS?

MR. KEANEY: PRIA money is a minimum of 750,000 and a maximum of a million a year. And it's less than the money to states.

MR. HOWARD: Do you know offhand what the states receive for WPS?

MARTY MONELL: Overall it's 11.8.

MR. KEANEY: Yeah. 11.8, that covers a variety of things. I think it breaks down to three or four. It's not -- well, I was going to say it's not adequate. Nothing is ever adequate but -- the PRIA money is intended to enhance existing activities so we're looking at things we're already engaged in that perhaps needed bolstering or needed expanding. We are in an agreement with NIOSH to be involved in a project called Sensor, which is an instant monitoring system. We had put PRIA money, some PRIA money, towards that to expand the states involved in that system. We're going to use PRIA money to get more aggressively involved in the Poison Control Center data and data analysis. We're using PRIA money for some of the HAZCOM development.

MR. HOWARD: And I think those are all very

merited types of endeavors. The problem that we have in many states is, just as you alluded to, lack of resources to be able to fully implement enforcement programs for WPS and that sort of thing and I was curious in the assessment your -- in the previous discussion we talked about funding problems and challenges and there's a mention in here about funding again concerns for the certification and training but from the enforcement side I didn't notice anything, at least in this presentation. Did that come up at all?

MR. KEANEY: It did in the workshops and you'll find some alluding to various aspects of it in the findings. And obviously we've seen the APGO surveys and essentially APGO making the case that there's a need for more to

ANNE LINDSAY: Kevin, can I just add something? I know Dennis you know this, but maybe not everybody around the table. Kevin gave you a picture of the money that OPP is able to pass on to the states to help carry out the development of the field programs like worker protection but our office of enforcement is actually the office that provides the money that goes to states for

direct enforcement activities. And then it's actually in the neighborhood of 18 to 19 million, if I'm remembering correctly, across the 50 states and plus territories and that is then actually managed through our regional offices. So when you divide -- even when you divide that enhanced sum of money Dennis' point is correct that it's not very much on a per-state basis. But one of the other things that we've actually been able to do this year is to engage APGO in the agency's senior management planning process so that there will be some direct representation at that level.

MR. JONES: Shelley.

MS. DAVIS: Thanks a lot. First of all I would like to commend EPA and Kevin especially and his team for the WPS reassessment process. The holding of regional meetings around the country involved a lot of folks and you know a lot of farmworker representatives were able to participate so we really appreciate that. And I attended many of them so I know you did get an earful. I'd like to make two comments. First, the point you made about the worker protection standard as a regulatory process, and I know that you highlighted some of the materials you

developed like the train-the-trainer manual, etc., and that's really good, but at the risk of asking you to tell us the last page of a mystery story could you maybe highlight what your thinking is in terms of some recommendations for changes in the worker protection regulation? And also what kind of time line we're looking at for a proposed regulation change? If you can respond now and then I'll ask my second question.

MR. KEANEY: We have the -- next month we're putting both regulations into the queue, the agency queue, which will put us on a schedule for development. And when we get to that point I can give you more specifics but we're trying to put it on a fairly fast track for both regulations. Well, actually there are three regulations. There are the certification regulations, the ag worker protection regulation, and the labeling regulations that would have to change to accommodate the changes in the other two. So we'd be working with changes in three regulations.

MS. DAVIS: Well, has your thinking crystallized as to any of your recommended changes?

MR. KEANEY: Some of them, yes. There are

some. We are obviously going to be piloting various aspects of hazard communication and incorporate whatever comes out of the pilots into the worker training requirements. There have been a number of studies and state concerns for the sequence, the cycle for the training, the every five years for workers. That was suggested in a number of arenas that that should be shortened. There was concern for more variety in training materials so that it does sustain immediacy and, you know, appeal. And we try to aggressively address that. There's concern --

MR. JONES: If I can, Kevin. One of the things that we've tried to do in the last few years is before we get in my words too far out in any policy regulatory development, get feedback. I think that everyone benefits when you can get early input into what you're doing so I'm trying to keep us from getting too far out, in your words, things crystallizing too much, that people think we have already made up our minds. So one of the follow-ups to this activity is likely to be for us to engage with stakeholders to get together before we get so far out that we're dealing with rear action guards and

trying to defend positions that really were only just thinking, our early thinking. So --

MR. KEANEY: I would look at the report and the way things are arrayed there it's -- the findings from the particular sessions, the assessment activities, then the status if we've done it, if it's ongoing or to be done or we're considering it as important to look to, because any number of them have to be characterized as we can only deal with these through regulatory change. And the response in the response column is we'll be considering them. These are potential areas for regulatory change. So in a way it gives you a very broad blueprint of where we may be going. Obviously not all of those things would end up in regulatory change, but they're the things that we've heard around the country that the only way to address would be through regulatory change. And that would be the challenge for engagement of PPDC to work with us when we've framed out a bit more. We are putting together what's called a regulatory blueprint, which is essentially a rationale for the need for regulatory change and in that we would be broadly describing needs. When they get a bit more specifically

described, then I think it would be appropriate to have the engagement of a group like this or any number of groups like this to help us shape the changes in those two major pesticide worker safety regulations.

MR. JONES: But the report itself actually on page 13 identifies the kinds of things that are under consideration.

MS. DAVIS: Do I still have the floor? On that point I just want to say that, you know, to the extent that you would develop a work group around that so that you ensure that the stakeholders most interested in this set of regulations, you know, participates, that would really be helpful.

My second question really revolves around the incident and enforcement reporting system. Jim, and you know it's not a secret, you know, we've had some conversations about this. We want to have more. But now that PRIA is about a year old, we're looking here, too, to go beyond nice conversation stage and moving into the action stage. So I was wondering do you have a time line on your development of, you know, a coordinated effort to collect data on incidents and enforcement actions and

when we might see the first report?

MR. KEANEY: Yeah, we were planning the first report at the end of this year and that's described in the process where the PRIA money has gone to this point and the intent of the -- what we expect as a result of the process we put in place and the, you know, expense of monies. So, the first report is not going to give you an index of incidents or anything of that sort but it would be describing what we are building that we would hope would generate the outcome measures through incidents and enforcement databases.

MS. DAVIS: So when will you have your first report with actual incidents?

MR. KEANEY: A week -- a year from the first report, which is at the end of this year. So next year.

MR. JONES: Eric. I realize you've lost your card there but --

MR. NICHOLSON: Well, first I just want to echo Shelly's comments. Kevin, thank you for doing this. It's been as we know, many years in the making and it's nice to have it out. I realize you just gave us a brief overview. I had a couple of specific questions. Shelly

already touched on one. I think that enforcement database is key. In our last PPDC meeting we talked about, I know you guys aren't calling it multiple REIs, to us it's multiple REIs. I don't know how you can make that decision without looking at how REIs are currently being enforced and if the existing stuff is adequate, which speaks to the urgent need to having that database. I know some states are doing it. Oregon has stepped forward and I think every year does a pretty good comprehensive overview of their WPS inspections. But I just wanted to be explicit on a couple of questions, Kevin. So now do states have specific guidelines as to what constitutes a WPS inspection?

MR. KEANEY: Yes.

MR. NICHOLSON: Okay. The next issue, I know the GAO report and others were very critical of the agency for overlooking the issue of children and how the WPS did not adequately protect children. What steps is this report recommending to protect children?

MR. KEANEY: The -- as you know, the regulation is silent on children. It just speaks about workers. And there's a presumption that they're legal-age workers.

So that defines the age presumption in the regulation. And the way we programmatically would address it would be more aggressive training and focusing training that would be given to the workers that would engage them in protecting themselves, obviously, but certainly the protection of their children if their children are being brought to the field. And working with the states to obviously try to ensure that that isn't the case.

MR. NICHOLSON: How about younger legal-age workers? I mean teenagers. Does GAO -- the report made some specific recommendations about REIs and other steps.

MR. KEANEY: They spoke about REIs and labeling specific to sensitive populations, yes.

MR. NICHOLSON: So is that echoed in the report?

MR. KEANEY: It's a finding and it's something that internally we'd obviously be considering but it's not anything -- there's nothing in the report that says yes, we're doing this, that, and the other relative to that issue.

MR. NICHOLSON: Okay. And then the last thing, I would welcome -- I just quickly paged through the

report, kind of a more specific report back. I know a lot of the issues are labeled considering. May we get a time line as to when a decision would be made one way or another, you know, given how long it's taken us to get to this point, I'd just welcome knowing are we talking another five years before we get a decision one way or another, or what's the time line on these specific issues that have been described as considering?

MR. KEANEY: Okay.

MR. NICHOLSON: Thank you.

MR. JONES: Amy? And then John.

AMY LIEBMAN: I, too, want to thank the EPA and Kevin. I just have a couple of questions regarding the role of the health care provider. And I know that you have sort of divided it into, you know, the worker protection and your health care provider initiative. I was just glancing through your report and I'm encouraged to see the establishment of a national pesticide incident monitoring and reporting program. But I know that you mentioned you're funding Sensor and some other things. Can you elaborate a little bit more on where this is going in terms of it becoming national?

MR. KEANEY: Well, we're, as you mentioned, we have out of our group we have a three-pronged focus in that there's a regulation dealing with the agricultural workers, there's a regulation dealing with applicators, and a special initiative dealing with raising the awareness of health care providers about the implications of working with and around pesticides. And we currently have, well, we've recently closed out a request for proposals to continue cooperative agreements with folks to continue the health care initiative. And that would -- the request was characterized in a way that would continue the type of activity we've been doing, which is essentially more top-down, a top-down approach, trying to effect the way health care providers are trained, the way they're recertified, the way their training resources are given to them and so forth. Another aspect of that in this grant request was to have activities at the field level, not unlike the work that your association does. That would give us that field data that we could then feed back into the program so that we would have the Sensor project, which is a 12-state network that we want to increase to have it focus on high-ag, high-labor

states. It doesn't make sense to fund necessarily every state, but make sure you get something representative for high-ag and high-labor and you could get then an indicator, a measure, an index, of concern. Use the Poison Control data, use a variety of data sources to probably move toward an index of concern rather than just an array of various numbers from various databases. But try to bolster that through the grants we have in the health care provider network. We'll be addressing -- we'll be redoing the recognition and management of pesticide poisoning manual and making that more robust than it is now. So I can --

AMY LIEBMAN: I just want to continue to encourage you that I think the health care provider with a more simple reporting system that's national can be a critical player in your collection of the data that you want to and so I just encourage you to sort of look at these various segments, that there's a lot of overlap and that for the incident reporting and data collection part with a good system in place I think the health care provider can be an even stronger player in getting you some of that data.

MR. KEANEY: Yes, we certainly think so. Yes.

MR. JONES: Thanks Amy. John.

JOHN SCHELL: I was just wondering, we've heard a lot about dwindling dollars and this is a pretty comprehensive program. Have any of your work groups looked specifically at ways of cutting costs? I see a lot in your presentation about coordination and dissemination of information and just looking at -- perhaps looking at innovative ways to reduce duplication of efforts among states and expediting the dissemination of these costs?

MR. KEANEY: Yeah. We are trying to -- we're encouraging that certainly and we're trying to facilitate that. We've put some seed money to North Carolina to establish the first pesticide safety education center that could do training of inspectors and training of county agents. We've recently put money to Penn State to establish a Northeast pesticide safety education center and we're encouraging -- we're still waiting for some gelling up in the West and North Central to get that type of thing going so that you don't have every state incurring the costs of training those types of folks.

You can have it centralized and they can conduct a train-the-trainer sessions. Those folks go back and pass along the information and the resources that they've gotten there. Another area of obvious savings is the training manuals. As it is now, every state has its own set of training manuals to train applicators in structural or health or public health or ag plant, ag animal, type of category exams. Some categories it doesn't make any difference where you are in the country. If you're an aerial applicator or a fumigator or a rights-of-way guy, you know, a manual is a manual is a manual no matter where you are. Why does a state have to particularize it? They could have a module that would be state-specific for peculiarities in regulations but the basic substance should be the same. And we can facilitate that type of saving. They're working with the state Extension Service and the state regulators we can divide the country up in some fashion that makes agronomic sense so that, as I said, pest pressures in New England are probably all the same in all the New England states so why shouldn't they have a set of manuals that is developed once, not by state by state. So those are the

obvious areas of savings. And then the ways of administrating -- the ways of delivering training, the ways of administering tests can be done in a variety of ways that could generate savings as well. But it would, you know, it requires people to be willing to think about change and there's nothing like less money to force you think about change to stay in business.

JOHN SCHELL: The thing that made me think about it was when you were talking about like the New England region. Have you tried to exploit web access to some of these things?

MR. KEANEY: Yeah. We are. I have a number of Extension folks who are very aggressive in that area, distance education and training and web training, web-based training.

MR. JONES: Thanks very much. We're going to wrap up this session. Similar to the follow-up on the PSEP discussion, we will be pulling together a group of diverse broad stakeholders to focus on the recommendations that are articulated both in the briefing and more clearly in the report itself. And we will periodically come back to this group to get reports as to

how that follow-up is going. Thanks very much. Take 15 minutes. I think we're off to a good start. Got some good advice in this first session. We'll be back at 11:00.

A piece of advice we got, again, I think it was probably a year ago at this meeting, under the Pesticide Registration Improvement Act, the agency is strongly encouraged under the law to pursue process improvements in its registration program. And we came to this committee and asked how you wanted to give us advice as it related to process improvements in our registration program. And the -- if it wasn't unanimous it was close to unanimous. Advice that we got was get together with those who are submitters, we call them registrants. And because they're going to understand the process better than anybody else on this committee with the exception of the agency. And identify process improvements but bring them back here to this committee and let us know the kinds of improvements that you are all thinking of so that the broad stakeholders have an opportunity to give the agency advice about these process improvements. And so we have run with that advice and we have a group that

largely is consisted of registrants but a number of you who are not registrants have chosen of your own desire to participate in our process improvements work groups, including I believe we've had some public interest group participation in our process improvement work group and some other non-registrants. So what we're going to be doing here for a half-hour or so is telling the committee here are the process improvements that are under consideration or have already begun and get some advice about them from you. So with that I'm going to turn it over to Marty Monell.

MS. MONELL: Okay. Well, Jim basically said my opening remarks so we'll flip to the first slide which is the actual statutory provision laid out in PRIA. And you can read it for yourselves. This is basically our mandate to look for opportunities to improve our processes throughout the program with the ultimate goal of facilitating our registration decision-making activities with the goal of reducing those time frames especially with regard to reduced-risk pesticides. What we've done to date, we have -- you heard at the PPDC meeting last fall, you heard some of our initial efforts

and I'm just going to briefly run through them for those of you who have not, were not at that meeting, or to refresh your memory. We went to USDA's the Food and Drug Administration, which has had a fee-for-service program for a number of years. We took a lot of their successes back to our program and implemented them. We went up to Canada and spoke with folks from the Pest Management Regulatory Agency, which has a similar but little bit different, fee-for-service program and learned a lot from them, particularly around their information management activities and their electronic submission capabilities. We're still engaged in extensive discussions with them about trying to implement something similarly within our program. Our OPEN, which is our data management IT system, we provided some enhancements to that so that it would facilitate our in-processing of applications. We've sped up the 865 data review process. I believe the original performance standard under the contract was 21 days. We were lucky if we got it in 30. We're now down to 10 days. We invested a little bit to get a significant improvement in that process. And then we implemented new application screening procedures where we

have a team of experts from each of the registering divisions go down to the in-processing unit and review on a daily basis every application that we receive and make some preliminary cuts as to which category the action belongs in, as to whether or not the application is complete. We have the ability to send you electronic invoices in conjunction with the application. We do completeness checks where we check to make sure all the forms and the labels are there and that the labels if submitted are appropriate. We've improved coordination with IR-4 and then we do a whole lot of scoping activities before we even start the reviews to basically determine what type of review is needed, what the level or depth of review is needed for any particular application.

That's basically where we were as of last fall. Now, what we're doing and we're continuing to refine those improvements. Now, what we're doing is -- you're going to hear a presentation of efforts since last fall that have culminated in some success stories and you're going to hear from Greg Watson from Syngenta, who is a representative of one of the trade associations,

CropLife, and he's going to give you an additional update on the FACA work group activities. I should also mention that at the back of this whole presentation there is a list of all of the work group members so if you had any questions that you wanted to ask them you'd feel free to shoot them an e-mail or call them. And also if you have a particular idea or interest in a subject matter you can contact one of these work group members and we'll be sure that it gets discussed at our next meeting. Greg?

MR. WATSON: Thank you Marty. First I think since this is the first official meeting that Elizabeth has been working with the FACA, I'd just like to formally welcome her to this process, and it's again very good to see again the commitment that EPA has given to this process. And I think that is important to mention as well. It's very evident that the work that EPA has been doing here has been very critical to the progress that's been made. Also I think both Marty and Jim mentioned the constituency of the FACA. It does represent the construct of PPDC fairly well, so I think that's important to mention. There are activities just to set sort of a commercial for something that will come later.

One of the issues that has been identified from across divisions is again the completeness or the quality of the submission applications and the work that's been done, the antimicrobial division, is meant to aid the smaller firms that may not be part of a national organization, so they have frankly a step-by-step guide about how such a submission be put together. The only other comment before we begin is again, it's important to mention that FACA is trying to address all the registering divisions, antimicrobials, NBPPD, as well as RD. And the balance between the topics that are being addressed is important. So, again, just a quick recap, what industry brought initially to the table was 14 problem statements or issues where we felt like process improvements could be made. Those were combined with around three to five that came to EPA trying to look again for common ground and places where we can make some progress. And one of the first early areas that were identified was in the area of labeling. And again that was important going across all the divisions. One of the first aspects of that that was brought to attention was -- or a recommendation is that the current label review manual needed to be updated and

that this is an important operational guide, not just for registrants but for EPA in terms of what is appropriate language to be placed on labels, the components the labels should have, and that also it again internally for those folks with reviewing labels. I think again as we said certainly in the FACA, and I'd like to repeat it in the forum, is that the interest in the label review manual shows that the document is a very important one and that again merits keeping it up to date with decisions and policies as they are created or evolved. There also was a suggestion coming out of our discussion around there is that there used to be something in the agency called the labeling unit and that provided some guidance on labeling and that was the initial idea brought forward, or a comment brought forward again. Another component was to try to provide some guidance to EPA on use patterns that, because of they're unique nature, where additional labeling guidance might be needed. And for example, with NBPPD use is of their products within areas of turf and greenhouse use were two areas that some additional labeling guidance would be needed or suggested. I just want to mention that also

there was a PR notice, it's PR notice 2005-1 that actually goes very directionally towards this issue and provides very good standard language for who could or should be applying adult mosquito products. So, again, I think that was a good first step in terms of the kinds of things that the FACA is talking about. So just a brief recap. You know the labeling effort, and something Elizabeth will talk about again, the creation of a labeling group within EPA. It's in its early stages. It's certainly a welcome step. I think that the guidance, also, we talk within the FACA about public participation, and again that Lois will speak a bit about that, later again, that's been another area we've tried to provide some guidance. And I think because we've now gotten to the point that there's some implementation actions within the labeling statement, that the group now needs to step back and look at are there other areas that we need to turn our attention to, other problem statements, other topics. And one question that, for example, at APCO meetings and other places they've talked about electronic labeling. And certainly from EPA's point of view from the reviews versus being able to

produce final labeling in e-form, that perhaps FACA has a role to play in there.

One other issue that is important, we've begun to discuss or think about as next steps is that having gone through in my career several mergers and changes and one of my favorite quotes that's come out of that is -- Change is the illusion of progress -- and I think what we want to make sure is that yes, we're seeing an awful lot of activities and changes and processes being implemented. We need to be careful to make sure that those changes are indeed process improvements. So I think that's another thing that we've tried to provide feedback. So, thank you for the time.

MS. MONELL: Thank you Greg. Next we're going to hear from Elizabeth Leovey on the implementation of our internal label committee, but first I want to introduce Elizabeth. Elizabeth Leovey recently joined the Immediate Office staff as a senior advisor for PRIA implementation. You'll recall Rick Kegwin held that post for about a year when PRIA was first passed and Rick has moved on to become the Acting Division Director of BEAD. So Elizabeth comes to us from lengthy service in OPP and

has, while she's primarily worked in the science division, she's a scientist by training, she has extensive knowledge about our regulatory program and has been a great choice to join us in the implementation of PRIA. Elizabeth?

MS. LEOVEY: Is this on? Thank you. And thank you Marty for the kind words. I'm going to spend a couple of minutes talking about the OPP label committee. Greg talked about the fact that the FACA committee identified labeling as a major issue. OPP for many years has had a number of groups dealing with labeling, that's label team, label clearinghouse, claims board, and so forth. The program has decided to consolidate all of these activities into an OPP label committee. The primary purpose of this committee will be to address cross-cutting label policy issues and these are issues that cross the various different regulatory divisions. In addition, this group will maintain the label review manual, which Greg talked about. Also, to gather comments, ideas, and so forth to improve labeling, the group will manage a web site and also an e-mail box devoted to labeling issues. Next slide please. Now, the

group is composed of representatives from AD, BPPD, RD, and SRD. They tend to be branch chiefs and senior advisors, so we're looking at a group that has had many years of experience in the Office of Pesticide Programs. The committee has support from FEAD, the Office of General Council, and the Office of Enforcement and Compliance Assurance. Now, this group reports to an oversight committee composed of the directors of AD, BPPD, RD, SRD, and FEAD. (Laughter.)

MR. JONES: You may want to tell them.

MS. LEOVEY: What?

MR. JONES: Spell out those divisions for them.

MS. LEOVEY: Okay. Back to the last slide. Here we go. AD, Antimicrobial Division. BPPD, Biopesticides and Pollution Prevention Division. RD, Registration Division. SRD, Special Review and Re-registration Division. FEAD, we've got the Field and External Affairs Division. Okay? You can tell I've been in the Office of Pesticide Programs for 26 years. All right. Now, the committee has only been in existence for about a month and during this time they've developed a six-month work plan. Their major focus during the first

six months will be to develop and communicate the existence of an e-mail box, form a subgroup for the label review manual. Now, the label review manual is currently on the Web and whenever there are revisions to this manual they will be placed directly on the Web. Since there are many many groups within OPP that we're dealing with labeling issues, another thing that the group will do in the first six months will be to develop and implement a process for resolving issues. They've looked at the issues that the FACA work group has forwarded to them and they've started to prioritize those. These will be additionally prioritized by the oversight committee composed of some OPP division directors and as a result of the existence of the e-mail box and also web site they will continue to identify additional issues and work to resolve these.

MS. MONELL: Okay, thank you Elizabeth. Moving right along, one of the overarching areas that we wanted to focus on when we first started these efforts was on communication. We wanted to figure out how we could develop better processes for communicating the work that we do. So one of the divisions really took a proactive

role in developing something and that was the Registration Division. And we'll now hear from Lois Rossi on where they're at.

MS. ROSSI: Thanks Marty. With regard to making the registration process a little bit more transparent, we discussed with the process improvement group some ideas and what we arrived at as a path forward would be that once a pesticide -- a new active ingredient is registered the supporting documentation, the risk assessments, would be available in a docket as well as posted on the Internet. And potentially this would be expanded to active ingredients once a new use is added also. But right now we're trying to accomplish it for the new AIs that we registered this year with the hope that once the machine gets up and running we could expand that to some previous years. So we'll begin with the two new AIs, the two new conventional AIs, that we registered so far this year and we are in the process of getting the risk assessments cleared and also the DERs assembled and with the notion that the DERs would be all together in an electronic format for registrants and states as well as other regulatory bodies around the world, that they could

easily use these DERs once they're cleared and once the risk assessments are cleared with NECBI and we would begin the posting. So I hope that this process will take place over the next month or so with maybe a posting by late June, early July. Thanks.

MS. MONELL: Okay. One of the other issues that came to our attention early on was that in trying to refine our processes with the idea of meeting time frames, reducing time periods, for action on an application, that we really needed to address the quality of the submissions that we're getting. So your next speaker is Michael Hardy from our Antimicrobial Division, who is the ombudsman for that division. He's going to talk a little bit about what AD has done with regard to addressing the quality of submissions.

MR. HARDY: Thank you Marty. Next slide. We had a few meetings actually with the subgroup from the streamlining committee that actually talked about what we could do to enhance the PRIA process within AD. So we're going to go over the purpose of the meetings, the industry perspective on the AD PRIA actions. One of the things we did was a give-and-take. We asked what they

thought the PRIA process entailed for us and we gave them our perspective of what PRIA meant in terms of the incoming submissions. And then we'll talk about the registration model and next steps.

Okay. AD has met with industry representatives to improve the overall PRIA process. At the beginning of these discussions we realized that AD had previous experience dealing with statutory deadlines under the Food Quality Protection Act. We were the only division within OPP that had the judicial review provision included in our time frames. So, for example, if we missed a 90-day action, then we could be sued. So we were under the gun since '96 on doing most of our regulatory actions. Previous slide, go back. Go ahead one now. There. Okay. Most of the streamlining activities from FQPA were still being utilized within AD for PRIA. We were mandated under the Food Quality Protection Act in order to seek streamlining options. We worked with ISSA, CSPA, and ACC, and a lot of other groups in terms of trying to figure out how we could make our process more streamlined and so those processes were still in place and still could be utilized under PRIA.

And lastly, both AD and industry sought methods to ensure that good submissions came through the first time. By good submissions we realized that the more we had to do work on a submission in order to "fix it" the more time it took away from other submissions that were coming through and so we realized that we need to figure out a way to make that happen, make them good the first time.

Next slide. Now, this comes from Ron Derbyshire. He couldn't be with us today but he was the industry rep that we had been working with specifically on some of these issues. And one of the things he said was that industry had a few examples of problems involving AD and PRIA. Some of these may have been miscodings or differences in times, but most of these issues were company-specific. They were not across the board. So we were able to address those one at a time. Industry wanted to assist AD with educating small businesses in terms of PRIA. As we said, when we looked at the good submission scenario, we realized that some of the companies just weren't aware of what they needed to do in order to get it through the first time. Next slide. Now, AD's perspective on industry and PRIA

actions. AD met with industry -- I'm sorry. Applications were not being identified as PRIA. One of the things that we had asked initially a year ago was that when you submit an application identify it as PRIA so we'd know the time frames and know to put in a certain queue. Well, with FQPA some of the actions were being coded as FQPA when they should have been PRIA and vice versa, so we had to actually sit down and work with our expert group and make sure that they not only check for that code, but make sure the code was correct because in many instances companies were putting the wrong code on. Later submission continued to be rejected due to format issues. They weren't formatted per 865 and so they were being rejected routinely, which slowed down the process. Too much time was being spent on fixing the submissions. That goes back to 865. You forgot to sign the study director page. Little things that just take time to get them fixed. And overall, one-third of the applications were being deemed deficient. Either no offer to pay statement, there was an incomplete data matrix, the wrong master record identification or study numbers, and not all the acute studies were being addressed. Next slide

please. So we sat down with industry work group and we decided the best way to do this was to give a real-life example of what a small business or any registrant should do when submitting an application. The very first application we thought we'd pick were the ones we get the majority of, which were the ME2 actions, those comprising the 90- and 120-day response times. So the registration model would range from ME2 to a new active ingredient at some point down the road. These models would represent an electronic example of what the package should look like. It would encompass a submission checklist and then later on it would actually be virtual application on our web site that you could click and see how it's supposed to be formatted, see where the trouble spots are, make sure there's a highlighted section of sign here, check here, the things to watch for. Next slide. This is the submission checklist so far for our fast-track items. I believe they're in your handout so I'm not going to go through each one of them. But for the most part we weren't getting these. There would be elements of these applications that were missing, which would cause a problem in the review time frame. And the next slide

actually continues some of this submission checklist for a standard fast-track 90-day action within the Antimicrobials Division. And the last slide please. The next steps we want to do is we are willing to work together on furthering the rest of the registration models. Right now industry has it in their lap and they're going to actually go back and populate it to make it more virtual so to speak. We will do the review of that. And AD and industry will present additional registration guidance at the workshop we have. We tend to have an antimicrobial workshop every 12 to 18 months or so. One is scheduled for November of this year and at that workshop we want to have more models to actually roll out and we also would like to have a generic template of what the data requirements you can expect when filing for some of the typical antimicrobial applications, so whether it's a wood preservative, ? paint, swimming pool product, hospital-grade disinfectant, or food contact sanitizer, we thought not just having a model up there but also what you can expect in terms of data generation in order to get this through. And we've also asked them to provide us with the costs of

doing this for registration purposes. Thank you.

MS. MONELL: Let me just say that the experience that AD enjoyed was broadly experienced across of the registering divisions and so we're going to do some more work within RD and BPPD to make sure that we enable the smaller companies, the smaller registrants that may not be part of associations, we're going to make sure that we focus some attention on providing them with some assistance on submitting the applications because it's not to anyone's best interests to have to spend a lot of time working on these applications and attendant data needs, so we will be working more broadly on that. Any questions for any of the presenters?

UNIDENTIFIED MALE: A general comment, and then a question about the labeling thing. The comment is that as you indicated, Marty, the other divisions had done that, too, and the Biopesticide Industry Alliance has been working really for the last couple of years, but certainly the last year, very closely with Jen Anderson's group and BPPD and I think rather successfully to work out a lot of the PRIA questions and the checklists and so on and I think we've come a long way as well. So that's

a very positive thing. My question is on the labeling team committee, I think that's great. I think that that's been set up and it's certainly something that's needed. On the e-mail system that you have set up, who is manning this system and if there's a specific question regarding whether it's RD, AD, or BPPD, or whatever, will it go to those correct division?

MS. MONELL: Elizabeth, do you want to --

MS. LEOVEY: The e-mail box hasn't been set up and the questions that you ask are very very good ones and will be considered by the committee in putting together a process for responding to the inquiries.

UNIDENTIFIED MALE: From a BPPD perspective I think it's very important to -- that we can get the e-mails directed to the right division certainly.

MS. LEOVEY: There is a member of BPPD on the committee and that's Jim Downing and I think if you dealt with Jim over the years you'd find out that he is an expert in dealing with labeling issues. And I would anticipate that he's probably going to be answering many of your questions.

UNIDENTIFIED MALE: Great. Thank you.

MR. JONES: Steve.

UNIDENTIFIED MALE: On the label review manual, I think it would help -- there's still confusion about the manual and what it is. Is it regulations? Is it advisories, etc.? So I think when you do that over there should be some kind of explanation up front as to exactly what it is. It's great in that it's a collection of all of the labeling issues, all of the labeling mandates, and then there's some other things that even conflict with the regulations, so as long as you're going to do that I think it would be a great help to go ahead and put up front a little explanation.

ANNE LINDSAY: Thank you Steve. Marty, could I just -- a good suggestion for the next edition of the label review manual but for everybody's benefit, the label review manual is not a regulation. It was actually originally developed as an internal tool for product managers. We have a lot of our labeling requirements in, if they're actual requirements, in our labeling regulations. We have other labeling guidance in PR notices, like the one that Greg referred to earlier. There's other labeling, I'm not sure what I want to call

it -- the various internal memos, documents over time. There are also simply practices that people have developed with regard to labeling. The label review manual was meant to try to pull all of that together in one place in an organized fashion so that if you were a product manager in one of our registering divisions and you were reviewing a label and you wanted to refresh your memory as to what the toxicity categories were, and actually I bet there are not a lot of questions about that, but if you did, and what were the corresponding precautionary label statements that went with the toxicity categories, it would be in the label review manual. However, the label review manual is not a place to develop new labeling policy, new guidance. So if this process that Elizabeth has described brings up a new issue that's not already dealt with in existing regulation, PR notice, or anywhere else, then we will have to look at a process for not only sorting out what should be on the label but actually getting it out there. So it might be something like the mosquitocide PR notice, that could be one avenue. If we felt it needed to be a literal requirement you might have to actually look at

rule making. So I'm sure we can clarify in the next edition of the label review manual what its function is, but I wanted to make sure everybody knew it wasn't a place to develop new solutions, but rather an easy reference tool for solutions that we think have already been developed and are in place.

MR. JONES: Thanks. Mary Ellen and then Julie and then Shelley.

MS. SETTING: I, too, am encouraged by the regrouping for the label committee and glad that OE will be a part of that because as a state regulatory agency enforcement issues for label directions are often a problem. I was wondering if there was a way to also loop in the SLITS group, the state labeling issues tracking system into this where the states do an e-mail system and ask for clarification. For others that don't know about SLITS. Where we write in for clarification to registration division on label language and oftentimes that's a way to pick out a few label statements that need to be worked on for future products.

ELIZABETH LEOVEY: The committee has looked at the SLIT system and is looking to incorporate those

comments.

MS. SETTING: Good. Thank you.

MR. JONES: Thanks. Julia. Sorry, just a follow-up to that. That was actually when the next FACA meeting were going to try to coordinate with a ciphering meeting, so there could be some crossover gain and highlights. So that was one of the suggestions we're trying to take in terms of meeting planning.

JULIE SPAGNOLI: A couple of questions with regard to the committee that, you know, I think I was part of that group when we had the discussion about the previous labeling team and how that was set up. And, you know, that was a group that that was their primary job function and so I see -- you know, this committee is going to be representatives from the division who this will be part of their responsibilities. Is it going to be rotating? Are you going to rotate people on and off of this committee or are they going to be -- is that going to become a permanent part of their job function? And, you know, how much time is going to be dedicated to this because, you know, one of the other recommendations that came from the process improvement group with regard

to labeling is this idea like we did with termiticides or mosquito labeling. You know, looking at labeling guidance for particular use patterns and is that going to be a responsibility of this group as well? And are we -- is it going to be able to be done in the context of committee that meets on occasion?

ELIZABETH LEOVEY: Besides the committee we're going to actually form a subgroup and initially the thought was to have them deal primarily with the label review manual but that subgroup will actually be staff very similar to the previous label team. And they'll be developing the issues and so forth since the committee is currently -- well, the individuals on the committee have been permanently assigned to the committee and they are Don Stubbs, Dennis Edwards, Jim Downey, and Ken Garvey. They are senior staff so they will be overseeing the subgroup who will be dealing with the label review manual and it will probably be within that subgroup that most of the issues are embedded and developed.

MR. JONES: As we go, Julie, we'll see whether or not the infrastructure that we create is able to sustain the kind of progress that I think we're looking

for, as well as the submitters are looking for, and if it doesn't we'll need to revisit that. Okay, Shelly, and then I think Dennis.

MS. DAVIS: Not being familiar with the group or the process and all that this may not exactly fit but I just, you know, want to raise it again if it is appropriately within the venue of this labeling committee that you take a serious look at the issue of producing Spanish-language labels. Most of the registrants are companies that sell their products in Mexico and Latin America so the notion of devolving a Spanish-language label would be within their capability and it would far advance the process we were talking about earlier of ensuring that handlers could actually read the labels.

ELIZABETH LEOVEY: Well, that's a good point.

MR. HOWARD: Lois, if I heard you correctly, you're planning on putting out the DERs and risk assessments for new active ingredients right after you complete the registration action. Is that correct?

LOIS ROSSI: Yeah, at least the risk assessments. We're not sure if we're going to put DERs on the Web but they would be available in an easy format.

MR. HOWARD: I'd just like to say on behalf of Florida and probably a number of other states, that will be a very big help to us in processing state registrations. It'll simplify things for the registrants and for us, so that's a good direction to move. Now, if you could also put out information on environmental risk assessments before the registration then we'd really be happy. Thanks.

MR. JONES: All right. Well, thanks. Before we wrap this session up I want to say that the -- I recognize that this discussion can seem very much like, as Jennifer said earlier, inside baseball. I think it's very important that as we work through process improvements that we do it in a very transparent manner. It might be inside baseball but I think anybody around the table can see a foul ball when they see one and that is the point of this. If you see a foul ball you say I think that was a foul ball. That's out of bounds. And that's the objective here. So I appreciate your patience with hearing out some things that may seem like they're very much about what EPA does specific to people who submit applications to us, but I do think it's important

that when we talk about process improvements we do it in a transparent manner. So we're going to continue to use this setting to bring back our process improvements so that you all can give us advice, are we sort of on the right things or do you think we need to give some further thought to any of these, so I appreciate that very much. Okay. Thanks Marty. Thanks to the team. The next session is going to be giving some of the program updates that we always use this meeting for, talking about our -- the two core programs in particular, registration, tolerance reassessment, re-registration. We have a specific topic as well on fumigants that we know that there's a high degree of interest in. So this goes very much into the category of updates starting with Debbie Edwards, who's the Director of the Special Review and Re-registration Division.

MS. EDWARDS: Thank you. What I want to do is just update you on where we are in fiscal year '05 for re-registration and tolerance reassessment, what we intend to do in FY '06, or at least the first 10 months of the year due to the August 3, 2006, deadline there. I'll give you some summary slides of about where we are,

both for re-registration and tolerance reassessment, and give you a little preview of '07 and '08. So, for '05 this is what we still intend to get done. Thirty-six re-registration eligibility decisions, 24 of which of are actual REDs, re-registration eligibility documents, and 12 are the tolerance reassessment decisions. Next slide. These are the actions we have completed thus far this year. You can see there are three REDs completed, four TREDs, 100 tolerance reassessments and I believe that number is actually a little bit low now. I think there are a few more, but -- next slide. These are the REDs that are still pending for the fiscal year '05. There are 22 of them so you can expect to see decisions on those by September 30 of this year. I draw your attention to some in particular. 24D obviously is a very big chemical and you see all of the ethylenebisdithiocarbamates there, in addition to PC&B. Next slide. These are the pending TREDs for the remainder of fiscal year '05. Again, all of this is in your booklet so hopefully you can take it with you and study it. Next slide. This is the 2006 plan. We're looking at 71 decisions to be done in the 10 months

there. There are 47 REDs, seven IREDs, you know what an IRED is, that's a RED for a chemical that is part of a cumulative assessment, and then 17 tolerance reassessment decisions. I'll go quickly through -- I've actually listed out all the chemicals involved. So these are starting with some of the REDs I draw your attention there to adback and the quat compounds. Very important probably for antimicrobial registrants and users. Chloropicrin, a very high-profile fumigant. Coal tar and creosote and the coppers are there in that listing. Next slide shows -- again, you can see this is the second slide of FY '06 RED. You'll see ethylene oxide there amongst them as a chemical that I'd like for many people to pay attention to as we roll that one out. Next slide you'll see two more fumigants there at the top. Methyl bromide, meta sodium. See over there to the right pentachlorophenol, permethrin, propoconazole, pyrethrins. High-profile chemicals among others. Next slide, and this is the last set for REDs scheduled for FY '06. Moving on to the IREDs. You can see these are all very important chemicals. You're looking at the last three in methyl carbamates. That's aldecarb, carbafuran, and

formetenate HCl. You're looking at the last three organophosphate IREDs, DDBP, dimethylane, and Malathion, and the last triazine RED, or IRED, which is Simazine. Next slide for TREDs that year, FY '06. These are some of the TREDs. We have acetachlor scheduled that year. That is, too, as well part of a cumulative assessment for the chloracid annelids. You'll see oxytetracycline there. And propazine, which is also among the triazine cumulative assessment. Next slide. This is the end of the TREDs scheduled for FY '06 and you'll see there streptomycin and other antibiotic chemicals. Next slide. These are the cumulatives we still have to actually close the door on in FY '06 and so you can see them listed there. We're looking at four cumulative assessments and we have actually done -- once we're done with those we'll be able to count as completely assessed the 548 tolerances that we've already reassessed through IRED assessments. Next slide. So to give you a summary of where we are with both re-registration and tolerance reassessment. Out of 612 cases we've completed 478 for REDs, that's 78 percent. You can see the statistics there. 231 of those, or almost 40 percent, were due to

voluntary cancellations. We have 22 percent remaining to go. And of those 23 actually do have their IREDs completed. Next slide. This gives you an overall status of both the REDs and the tolerance reassessment and you can see that to date we are at 7,194 tolerances reassessed out of 9,721 totally to be looked at. Next slide. We always give you this chart which shows you where we are with respect to a number of categories of tolerances that were to be reassessed. So you'll see the organophosphates, carbamates, organochlorines we're at 100 percent, carcinogens, high hazard inerts we're at 100 percent, and then other. To give you a total again of 74 percent of the tolerances have now been reassessed. Final slide. This is a little bit of a preview of what we're rolling out for FY 2007 and 2008. Once a RED is signed there's a great deal of implementation to be done to actually bring a real-world outcome from our decisions. That involves a lot of work on DCI compliance and review of data, response to comments and addenda if need be from the responding of comments and review of those comments. Completing our 6F notices and cancellation orders, tolerance revocations and revisions

as needed. Obviously memorandum of agreement implementation. And certainly product re-registration, the label amendments to actually make the decisions real. We also have scheduled in 2007-2008 36 REDs to be done. These have no food uses associated with them. And finally we will be beginning our registration review program in 2007 and probably towards the end of 2006. Thank you.

MR. JONES: We're going to take questions before we move on to the next. Does anyone have any questions or observations for Debbie? All right. Very straightforward. All right. John Lahey, who works in Special Review and Re-registration Division is going to give an update on the fumigants, which you can see from Debbie's presentation many of the fumigants are scheduled for assessment and regulatory decision making about a year from now. John?

MR. LAHEY: Okay. We're looking for slides that have soil fumigant clusters, the first slide. There we go. I'm John Lahey. I'm in the Special Review and Re-registration Division. I'll give a brief update on the soil fumigants including our goals and our schedule.

Next slide. These are the six chemicals that are in the group. They all have the common denominator of use as soil fumigants. Of them the first four are currently in review for re-registration. 1,3-d or Chelone has already completed re-registration and the last, iodomethane, is not yet registered. As a new chemical iodomethane is on a slightly different track. Next slide. We have three main goals for the project. First we want to make sure that all the soil fumigants which we recognize are very important to agriculture are safe and available. The second is to keep the playing field level by looking at all the chemicals in the group at the same time, which is why we're including 1,3-d and iodomethane. And the third goal is to make good risk management decisions for all of them by considering the risks and the benefits of each in light of the others. In other words we hope to maximize safety and minimize impacts on agriculture. In addition to the usual risk assessment challenges this group poses some particularly interesting ones, principally predicating off-site exposure to bystanders using both monitoring data as well as models, dealing with variability in terms of geography, weather, regional

differences, use practices and equipment, and different toxic effects associated with each chemical. And the big challenge will be translating the risk assessments and the benefit assessments into risk management decisions that are practical and effective. In terms of process, we're using our six-phase public participation process, which includes an error correction step and two public comment periods before making our risk management decisions, which we expect to happen early next year. Next. Now I'll give a little bit more detail on the schedule, milestones we've reached, and what's coming up. Last November we completed an initial error correction phase on the draft risk assessments. Next slide. Then from November to January we considered the comments from the registrants and also incorporated into the assessment use of a distributional exposure model for predicting safe distances from fields. This was based on comments provided by SAP last fall on three of the models that have been developed for that. In February and March we had a second error review on the preliminary assessment so that the registrants could see how we handled the exposure modeling and checked that for errors. These

comments came in in March and that closed phase one of the process. Next slide. We're currently in phase 2. We're considering the phase one comments and revising the preliminary risk assessments and preparing them for public comment. We plan to open phase 3, the first public comment period, in July. We're also planning to hold a day-long technical briefing on the risk assessments when we open phase three so that we can walk through the risk assessments, explain how we've handled the data, and begin discussion of the risk assessments with the public. The phase three comment period will close in September. In phase four we'll consider the public comments and make any necessary revisions to the risk assessments. At this point we'll also complete a preliminary benefits analysis and develop preliminary risk management options. Next slide. We expect to open the second 60-day comment period, phase five, in November. At that point we'll be looking for public feedback on the revised risk assessments, the benefits assessment, and the preliminary risk management options. We also plan to hold stakeholder meetings in some of the major use areas to get direct input from stakeholders on

the assessments, the use and benefits information, and on our risk management options. And the last phase will begin early next year. We'll consider the public comments we get in phase five and develop our risk management decisions. And our goal is to have decisions for each of the re-registration chemicals early next year. That's it. Questions?

MR. JONES: All right. And lastly this morning, Lois Rossi is -- you've already met the Director of the Registration Division, is going to present for all three of our registering divisions, progress on both registration in the current fiscal year as well as general PRIA implementation. Lois?

MS. ROSSI: Thanks Jim. We're just a little over the first two quarters. With regard to our program goals for this year, for new active ingredients our goal is 26 new active ingredients and the breakdown you can see in your slide is 12 conventional chemical pesticides, 12 biopesticides, two antimicrobials. So far to date we have made decisions on two conventional pesticides, tetraconazole and spiromesifen, and those obviously will be the two active ingredients that we try our opening up

the process on. And then listed on the next slide are the six biopesticides that were registered. Okay. With regard to new uses, another big part of our work plan, we have approved so far 55 new uses and maybe that's even a couple of new uses higher than when the slides were prepared, associated with 280 crops and we have four new uses for previously registered antimicrobial active ingredients and three for the biopesticides. We're very pleased with the 55, 57 probably by now, number at this stage of the year because traditionally all our new uses have come out at the end of the fiscal year so it's a kind of a process improvement of ours to try and spread the decisions across fiscal year. Next slide. Our section 18 activity. Now, please first of all don't try to add these numbers up. They are based on what is happening in the first two quarters of the year so for the first two quarters of this fiscal year, which is since October 1, we've received 266 section 18 requests. We have currently 230 pending and we've approved so far 119. We've denied none. And in 12 cases crisis use was declared. Now, our average turnaround time, not including the soybean rust, which we'll go into in a

minute, which has been a big workload for our section 18 program this year, is 23 days. The soybean rust has added because some of these are new active ingredients and some are difficult active ingredients to deal with. But that's where we are with the 18 program and we're in the midst of a heavy season right now. Next slide. Okay, this is a little bit of detail on the soybean rust fungicides, which have been new this year to us. We've invested extensively in helping to prepare the soybean industry with products to control the soybean rust. The disease was confirmed in the continental United States in November. So far we have 19 in-use products that carry the soybean rust claim. There are section 18s as well as some under section three, and we've approved section 18s across 32 states. Actually this slide I like the later slides better so why don't we go and continue and come back to that. There are more detailed slides on that. I'd like to talk a little bit about the inerts part of our program, which typically isn't always necessarily included in the status of what we're doing in registration. But this is another area that we've invested heavily on to get it on track to meet not only

the reassessment goals but to diminish the backlog of new petitions that we've had pending. And I'm very pleased with the group. They are officially actually a branch as of a few days ago. We do have a new inerts branch and I'm very please with the progress they've been able to make. With regard to the new petitions, we have 22 decisions scheduled for this year. As of today we've published three final rules. We have six very close to completion in final review. And by the end of this fiscal year we will have reduced our backlog, which we considered a backlog anything that was pending when PRIA was effective as of last March. We'll have reduced it from 45 to 25 and we believe that at this rate we can clear out the new petition inert backlog by the end of next fiscal year. So I'm very pleased with that effort. At the same time this group is doing the reassessment and as of October 1 they had 453 to go. So far to date we've done 58 with 392 remaining and we are on a schedule to complete those actually by March of next year, so we're giving ourselves a little breathing room in case we have some difficult decisions to make before the actual August deadline. Okay. Under PRIA, we're now a little over a

year into PRIA and presented here are some statistics on submissions and completions. We've had a total of 2,170 submissions under PRIA with 892 completions. And percentage-wise greater than 99 percent have been completed by the PRIA goal. We have had 15 not grant decisions, which is less than 1 percent of the total submissions and 68 actions where we had to renegotiate the due dates. And this is across all the registering divisions. On the next slide it breaks down the not grants into the different divisions. AD has had 0, BPPD 12, and RD has issued three not grant decisions. And then on the next slide it breaks it into the negotiated due dates and you can see AD, BPPD, and RD with 18, 28, and 26, respectively. With regard to what else is pending -- well, actually what's pending. I'll go through some of the major breakdowns of the pending actions. With the new active ingredients, RD has 28 conventional new actives on our work plan. Seventeen of these are requesting domestic registration. We have 11 that are requesting import tolerance only. Some of these import tolerance only have been in-house for quite a long time, never making it on the work plan. PRIA fee was

paid and so they're on the work plan. Twenty-eight biopesticide new active ingredients, 12 antimicrobial new active ingredients. And most of the active ingredients are scheduled for completion well in advance of their PRIA deadlines. With regard to some of the other actions, the fast tracks, the non-fast tracks, we'll talk about the fast tracks first. These are actions that have a PRIA time frame of 90 days and you can see in your charts the totals and right now there are 56 of these pending within the divisions. And you can see the amount received, the amount completed. And also with the bar charts you can also compare the receipts as well as the completed. You can kind of get a visual idea of our ability to keep up with receipts and completions. And this again is only for these first -- well, no, actually it's for the last two quarters of 2004 and the first two quarters of 2005. And the same thing is presented for non-fast tracks. You can get an idea of the volume, the completion, the negotiation, and what's pending on our plate. And the next slide shows non-fast track amendments. Actually I guess you don't have color but the bars go according to the -- the first bar is the

third quarter 2004 and so on. And the last inventory bar is actually what's pending this quarter 2005. And I think that's where we are right now. I think that's the last slide. Thank you.

MR. JONES: Any questions? Yes?

UNIDENTIFIED MALE: You mentioned that soybean rust has been a heavy burden for the agency's emergency response team. And from a state perspective we really appreciate all the work up-front that the agency did to help to process these. As you go through kind of lessons learned with soybean rust is the agency looking at considering a different mechanism or fine-tuning the mechanism for processing these pest emergencies that are national in scale for the future? Is that something that you will be looking at?

MS. ROSSI: We've actually had a lot of thought around that but I don't think we're at a point where we have what I would call a plan. But we have had some discussions with our colleagues in USDA on how to address that. But I don't think we've really come to any conclusion at this point.

UNIDENTIFIED MALE: I was curious to know how

the registration activity overall compares to, say, the last couple of years and what the impact is compared to what the expectation was on PRIA revenue for registration activity.

MS. ROSSI: I'll answer part of this and then -- as far as new uses and new chemicals I think the activity for new chemicals is probably the same, new AIs. It's probably going along at the same pace, largely though because of what we have on our plate and how much work we had accomplished on some of them prior to PRIA. New uses I think, well, the fact that we have 55 already -- last year at this time we weren't anywhere near 55. I think so new uses I think you're really starting to see much more work evenly coming out through the course of the year as well as all of them scheduled. We do have a work plan. I didn't mention the work plan but we're very close to being able to issue the new chemical and new use work plan. And in that work plan you'll see every new use we have pending as well as the new chemicals. But the new chemicals is a much easier and more confined universe to deal with. You're dealing with 28 objects as opposed to in the hundreds of objects. So I think that's

where you'll see a big difference. On the other -- well, the other big difference I think is with the non-fast tracks. I don't really have the experience but my previous people who have had this job have said that we really haven't worked on non-fast tracks. And now we have to because of PRIA. And you can see the number of completions of non-fast tracks. So I think those three areas -- those are the biggest areas where I think you can see the difference.

MR. JONES: We've -- I think that Lois is right. We've not yet begun to do comparisons of PRIA years and pre-PRIA years, but we will be doing that shortly. We don't yet have a full PRIA year. October 1 will be the first full PRIA year that we have. But certainly non-fast track amendments, which we gave very low priority to, now are -- they get the clock that comes with it statutorily. And my expectation is that it's going to be about predictability is what's most going to be improved across all of these categories. But we'll see. We'll be running those numbers when we get enough experience to do some comparative work around that. Allen?

UNIDENTIFIED MALE: Does the agency envision any tightening up on the use of methyl bromide. That's a compound we're supposed to be eliminating according to the Montreal Protocol, but I think one of the recent meetings we heard that something like still two-thirds of the amount that originally was used is being approved for use.

MR. JONES: Well, there are a couple of things going on Allen. What you heard from us today was the Pesticides Program's plan for the re-registration activities associated with methyl bromide, which should come to conclusion around a year from now. We'll be looking at methyl bromide in the context of the FIFRA and FFDCA standards and so that process, which will involve two opportunities for public comment, will inform that regulatory decision making. Our sister office, the Office of Air and Radiation, manages the implementation of the Montreal Protocol, which has a phase-out associated with methyl bromide and also has associated with it a critical use exemption process. The Air Program manages the implementation of the Montreal Protocol. The program provides a fair amount of

technical support and the U.S. Department of Agriculture does as well. So our activities associated with methyl bromide are going to be associated with making the necessary safety findings under FIFRA and FFDCA and it's premature to say what the outcome of that regulatory review is going to be. This time next year, though, I think we'll have a much clearer sense because we'll be much farther along in our public participation process. All right? We're going to break for lunch. And I would like to see if we can get back here at, let's say, 1:20. So we're not going to have an hour and 15 minutes but an hour and 12 minutes. (Laughter.) 1:20.

All right, let's get started.

MS. MONELL: Well, hopefully now that you're all refreshed, you'll be ready to tackle the tough issues around the budget. No, really, seriously, I'm just going to give you an overview of where we are at. As those of you who follow these matters may be aware, we now have an operating plan in OPP and OPPTS across the agency. And the first slide basically give you a snapshot of the 2004 enacted, which is the equivalent of an operating plan, which is $131.1 million and then for

2005 we have $126.1 million and then the last column you'll see is the 2006 president's budget, which contemplates $139.8 million for OPP. These numbers, by the way, do include regional amounts. The next slide is the FTE, or full-time equivalents. That's sort of a code for the way we manage our employees and the number of employees that we're allowed by statute to have at any given time. For OPP in 2004 we were authorized to have 904. Again, this does include regional numbers. There are about 93 total regional FTE in all of these numbers. The 2005 operating plan you'll see a reduction and this reduction is part of an overall agency-wide effort to reduce FTE by 300 across the agency over a 2-year period of time. So OPP's share and those of the regional share is reflected in that reduced amount. 2006 again, you'll see a reduction. Again, it is due to that reduction across the agency. That is our proportionate share as well as the regional share. This slide gives you a snapshot of how we dealt with the $5 million differential, if you will, between the '04 operating plan and the '05 operating plan. For 2004, the amount of money that we had available, this is non-payroll, to

spend on contracts and grants to support our core activity, was $26.9 million. In the appropriation for 2005 the Congress and President authorized a cost-of-living increase for our employees. That's a good thing. Unfortunately they didn't give us the additional appropriations to fund that so right away we had to cover that COLA, as it's called, with $1.4 million out of the contract and grant reserve because that was the only accounts, if you will, that we have to take money from for this purpose. And then because of the $5 million reduction in the appropriation for 2005 we had to take that away and we end up with $20.5 million available for our contracts, grants, and interagency agreements. This is across the board. This is activity that supports our core programs of registration and re-registration as well as our field programs. How did we do it you might ask? We took -- generally we took a reduction in all of the these areas. We took a very hard look at what was arguably discretionary because it was not totally necessary to accomplish our core program and made some reductions there. But everything got a certain amount reduced. We reduced our IT, information technology, and

information management investments. We have some much needed work to do in this area around document management and if we ever want to go to electronic submissions, there are some investments that we need to make resource-wise to get there. We've had to scale those back significantly because we just don't have the discretionary money to invest heavily in them. We're taking incremental steps to get us ready for it in terms of doing some design and other kinds of activities in preparation for a significant IT/IM investment but we had to scale it back for this year. And then lastly, we had to scale back our field program funding. The key objective was to keep essential services going. I mean, there are things like our support of SPIREG and APCO meetings and TPPC. We didn't touch that. But other areas where there were some extramural grant monies available we scaled back those kinds of activities. You'll see tribal is one area that we had to cut back. And these are just examples, this is not the whole range of field program activity that was subject to cuts. International activities we cut back and then the PESP program that is run out of BPPD. Next slide. You may or

may not know that PRIA requires that there is a minimum appropriation in order for us to be able to collect the fees and thereby for the registrant community to get their time frames. And the specific language is up there but essentially we can not go below 3 percent of our 2002 enacted level. That magic number is $122 million. You see for '05 we are perilously close to that amount. As a matter of fact this amount in '05 is what we had in '02. But we still, nevertheless, we have what we need to have and we're able to continue with the PRIA program implementation. And then the next slide shows another part of the President's budget for 2006 and this concerns fees, which you've probably read something about. One is -- one of the provisions provides for the assessment of pesticide registration fees and although the '04 omnibus bill, which actually was the vehicle by which PRIA was passed, prohibits collection of this fee through September of 2010. The '06 budget proposes the permanent reinstatement of this fee. The fees will be deposited into a new account and then EPA would have access to it through further appropriation. So it's not going into the general treasury, which would make it impossible for

us to get at, but it would go into another fund and then we would have to through an appropriation get it. It is -- the proposal -- I believe the original rule was developed in the late '80s and the anticipated revenues were $26 million. None of that has been updated so we don't know exactly at this point what in fact would be generated but it would be more than the $26 million. And it would be on top of the PRIA fees. And the other fee that is proposed to be imposed is the tolerance fee for which there has been attempts at rule making. And, again, the Omnibus Appropriation Act of 2004, by which we got PRIA, also prohibits the collection of this fee through 2008. This fee rule was to be issued this year and work has been done on it. You'll see there's a bullet there that the draft rule was due to OMB on April 14. And then the monies collected was anticipated to be $20 million and they would be transferred to the EPM account. That's our main appropriation account in EPA. Through, again, we'd have to have another appropriation. And then lastly, there's this premanufacturer notice, PMN fee, which is basically a fee for toxics. The intent here is to increase the ceiling for the collection of

these fees. So there's $50 million in fees proposed in the President's budget. Next slide. And then we have the current fees. And you all know the enhanced registration service fees. These are what are authorized under PRIA. And to date we've collected $6.5 million. That's just for this fiscal year. In actuality since the beginning of PRIA, since March 23, 2004, we've collected $21.2 million. This fee funds both the tolerance petitions and other registrations. The collections depend upon the number of applications. There's no ceiling. It contains this minimum appropriation provision, which I referenced earlier. It is deposited into a separate account to which we have immediate access, direct access. And the -- because of the way PRIA was passed we have to have an authorization through our appropriation every year to collect it. And then we have maintenance fees. Maintenance fees are -- right now we are authorized to collect $27 million under PRIA. If you'll recall one of the primary interests of the public interest community was to make sure that OPP would have sufficient resources to complete its tolerance reassessment work, all of the non-food use REDs, and so

forth, and so PRIA provides for five years of funding at various levels. It was $26 million for 2004, $27 million for 2005 and 2006. That gets us to the statutory deadline. Then 2007 it's $21 million and $15 million for 2008. And that's the date by which we are to have completed all of the non-food use REDs. The funds for the maintenance fees fund both the tolerance reassessments and our re-registration program. It's deposited into yet another fund, the FIFRA revolving fund. We don't have to depend upon using them by way of a separate appropriation or a mention of it in our yearly appropriation. PRIA takes -- has set the ceilings, we send the bills out now in December. We know what we can expect to collect. We collected over $27 million actually thus far this year. But some of it will be rebated for various reasons. And maintenance fees as I said before are authorized through 2008. And that's basically it. Questions?

UNIDENTIFIED FEMALE: So Marty, the President's budget for 2006 is about nine million more than the 2005?

MS. MONELL: Yeah, this is what the President is asking for. What the President asked for in 2005,

just for a frame of reference, was $141.9 million.

UNIDENTIFIED FEMALE: Well, I'm just wondering though, compared back to 2004 I think Kevin said before that for the Pesticide Safety Education Program you've been funding it at $1.2 million in 2004 and 2005, which is a 35 percent cut from the historical level. Is that -- then my question is why in the 2006 budget are we still only anticipating 1.2 million for that? Could that not be raised back up to the historical levels there? I realize it may get cut but --

MS. MONELL: Well, for the 2005 there was report language that instructed the program to fund it at the 2004 level. So I think that the presumption is that there may be like language in 2006.

UNIDENTIFIED FEMALE: And where did that instruction come from?

MS. MONELL: The report language in the budget.

UNIDENTIFIED MALE: Congress.

MS. MONELL: Congress tells us in some instances how to spend our money.

UNIDENTIFIED FEMALE: Okay.

MR. JONES: The '06 budget you really do need

to wait to see what Congress does. What we know right now is what the President is requesting. Which also has some -- it makes it hard to understand what we're ultimately going to get because in the President's budget there are these fees assumed will be collected, which are currently -- we're prohibited from collecting. So if Congress, for example, authorized -- didn't rescind the prohibition you wouldn't collect those fees and you would subtract that from the 136. So until we have a clearer sense as to what the appropriators are going to do I think it's very hard to really figure out what you're going to do with that money because that number right there could swing anywhere from 20 to 30 percent either way depending on what the Congress does.

MS. MONELL: Jim, I can't see everybody that --

MR. JONES: Oh, sorry. Sue.

UNIDENTIFIED FEMALE: I'm always a little dense on this so if you can -- so just to follow up now on what Jim was saying. This projected 139 million for the 2006, does that include the assumption of this 46 million here?

MS. MONELL: The 139.8 is the President's budget.

UNIDENTIFIED FEMALE: Right.

MS. MONELL: And it -- the agency's budget authority is reduced by the $50 million proposed in fees. So, yes, arguably the $50 million will have an impact on this 139.8 million but what it did, the way it was put into the budget was it reduces the overall EPA budget authority.

UNIDENTIFIED FEMALE: The overall agency, not OPP?

MS. MONELL: Correct.

UNIDENTIFIED FEMALE: So OPP -- in order for OPP in 2006 to be able to collect PRIA fees by staying at the 122 baseline, money would have to come out of other EPA programs in order -- okay.

MS. MONELL: Or Congress would have to restore the budget authority.

UNIDENTIFIED FEMALE: Okay.

MS. MONELL: Increase the budget authority.

UNIDENTIFIED FEMALE: Okay. I will just make a comment that I make all the time. If we kept our books the way the U.S. government does we'd all be in jail.

(Laughter.)

MR. JONES: We just swear to uphold the law.

(Laughter.)

UNIDENTIFIED FEMALE: Not a comment on you all. Just the system in general.

MR. JONES: Pat.

UNIDENTIFIED MALE: What I'm wondering about the PRIA fees. It looks like you're collecting about 20 million a year over a 12-month period. Is that --

MS. MONELL: No.

UNIDENTIFIED MALE: No? What do you anticipate?

MS. MONELL: We, for fiscal year '04 we collected 14 million some odd. And that in large part was due to the fact that there were a lot of mandatory payments and voluntary payments that were collected during that first year as a result of specific language in the bill. The first true picture of what we're going to collect will be this fiscal year that ends September 30, where we've billed for 8.1 million thus far. You know, if we get 12 to 15 that would be wonderful.

UNIDENTIFIED MALE: Oh really.

MS. MONELL: Yes.

UNIDENTIFIED MALE: And remind me, how does that compare with projections when you were thinking about the law.

MS. MONELL: It's less. We were thinking 15 to 20 million.

UNIDENTIFIED MALE: And any sort of analysis of why that's the case?

MS. MONELL: We haven't yet done that but we are in the process of doing it. Elizabeth has got a little group that's working on it. I think the waivers have come in a little bit heavier than we anticipated when we were doing the projections. I don't believe we really thought about how to project the amount due to waivers.

UNIDENTIFIED MALE: Thank you.

MR. JONES: Gary?

UNIDENTIFIED MALE: My question is on my favorite subject which the maintenance fees, which we kept thinking was going to go down every year but they seem to keep going up. Any thought if they're going to be going up in 2006? It sounds like you're going to need an additional million dollars for 2006. I think you said

that. And there's probably some product attrition, maybe there isn't but --

MS. MONELL: It's already set. For 2006 the number is $27 million, so come next December we'll just send the bills out by the same formula that will be driven by your -- the report that you submitted I think in March.

UNIDENTIFIED MALE: Right. But in '07 it's statutorily required to go down?

MS. MONELL: Go down. Right. It starts going down in '07 and then the authority ends in '08.

UNIDENTIFIED MALE: But the number this year, we can probably expect the number -- it's probably -- it's like $4100 a product and then there's a cap with the larger companies having the benefit. Is that anticipated to be higher? Or you just don't know right now?

MS. MONELL: It probably will be a little bit lower. I would -- because we -- you know when we try to figure out the charging mechanism it's based upon our experience and our best estimate and so we were a little bit over this year. As I say we collected 29 and I don't know, 29.5, something like that. So next year it'll

probably -- we'll have to shoot to make it a little bit lower so your bill, the product price, will go down a little bit. How significantly I couldn't speculate.

UNIDENTIFIED MALE: Okay. Thank you.

MR. JONES: Ray?

UNIDENTIFIED MALE: This week the Senate made the final vote on the supplemental appropriations bill which carried language to prohibit publication of the tolerance fee rule. I'm assuming that language survived intact. Do you know what period of time that prohibition specifically covers?

MS. MONELL: It would -- if it's associated with the supplemental, the supplemental is related back to the '05 appropriations so it would be for fiscal year '05.

UNIDENTIFIED MALE: Okay. The trade presses reported some details from the appropriations bills for fiscal year 2006 reported out of I think the House committee with numbers that are quite a bit different from the President's budget here. And they were very confusing. Do you understand them?

MS. MONELL: Honestly, I spent all day

yesterday trying to figure out what numbers they were using. One of the problems is we have three different appropriations and we have these two funds. And then we have the regional budget piece, if you will, and then the headquarters budget piece. And depending on how you ask the question you get different numbers. And it's very difficult. I think in your particular case the offset was we didn't include homeland security and the science and technology numbers in the presentation that you were given by our senior budget officer.

UNIDENTIFIED MALE: Okay.

MR. JONES: Rebeckah?

UNIDENTIFIED FEMALE: I don't know if it will be possible to get, as far as the President's budget proposal, how you guys would plan on ideally in a perfect world, you know, if things go great, spending the discretionary funds and sort of that allotment of where what goes -- you know, in your perfect world according the proposed President's budget. Because that's often where a lot of the issues that we all have concerns about fall, you know, is within the allotments there. And that's not always how OMB compels you to issue the

numbers and that would be helpful to get that either for the group or I know it would helpful for our purposes. And I know that that might be what you're stuck with but, you know. Just to get a sense.

MR. JONES: I think that's the last comment I think for this session. One of the things that I've struggled with is how to get meaningful advice on an area that I would like advice on, which is how we spend our resources. From a group as diverse as this that's one of the issues, but that's frankly the strength of it. The second issue that complicates it is that when we get our actual allocation, which really does not happen until after the appropriation, is very unpredictable. And so it could be, you know, ideally it's by September 30 of this year but that rarely happens. It could be on October 20, it could be on January 20, it could be on April 20. And so how you sort of line up a meeting when you don't know when the appropriation is going to happen so I could actually ask you all before I have to made decisions, that complicates it. And the third thing that I think complicates it is that it is so fundamentally complicated that it takes more than an hour to get

everybody up to speed so that they can meaningfully give advice. But I have not given up trying to figure out how to maximize the potential for getting some advice around the budget, as it impacts basically everything that we do. All of these conversations that we've had over the last year at least on PSEP are directly related to that as are so many of the other things that we talk about. So we'll continue to give consideration for how we can try to frame the issues associated with our resources so that we can get some meaningful input from this committee, with knowledge that there are these elements that make it complicated. The timing in particular and then it's just very hard to get your arms around it in just 30 minutes. So we'll keep thinking about how to do that but I very much would like to have the benefit of this group before we actually have to finalize decisions. The next course of decisions we have to make will be fore FY '06. So, we'll take that under advisement and try to think of something. Anything else on this topic before we move on? Thanks Marty.

Today, although it may not have been exactly how you would do it if you were trying to achieve what I

was but I think it was close enough, that the morning we spent talking about what I -- like, it's the core work, it's the outputs. It's the things that we do day in and day out that basically together complete our program, more or less. I mean there are some things that were not on there, whether it was worker safety, registration, re-registration, tolerance reassessment. Those are the core activities that we do day in and day out. The budget sort of underlies all that and had I been doing this a little bit more creatively I'd have had that one first. Because you have the budget underlying all of that. Those are the resources you've got. And then there are the activities that you do with that budget because they're statutorily required or because you have statutory authority and they help you achieve your mission. At the end of the day, though, what you're looking for are results. And that's what we're going to be talking about now. The -- as I think I've said to this group before, we have been in the last couple of years, although the statutes that have required this have been in place for some time, it's just been in the last few years where both Congress and the administration have

been very aggressive about saying to all federal agencies you need to be able to demonstrate the results of your work. And of course the first time we started talking about our results we did what we've come to do best over the last 30 years in our program, and I don't think by any means we're unique in the government, we started counting out our outputs associated with our activities. And smart people that they are, and I'm not being facetious, in the administration on the Hill are saying Those aren't results. Results are for EPA protecting human health and the environment. Those are the results we're giving you this money for, not how many registrations you did and not how many re-registrations you did, not how many workers you trained, how you protected human health and the environment. Now, come back in two weeks and tell us how you did that. That was kind of the not-so-smart part I thought. But underlying all of this and this is the layperson's explanation of what GPRA is, the Government Performance and Results Act, or you may have even heard the acronym PART, which is administration created an exercise, the Program Assessment Rating Tool. These are efforts to get the

Executive Branch to talk about its work in the context of results. And so we finally kind of got the message a little over a year ago, you know, we've got to start looking at our program and not just talking about outputs, but what are the results that we're getting from them. And it has been quite difficult. We've become quite adept, as I said, at counting outputs. It's a whole different game trying to measure results. Now, of course we like to say to the people who we're reporting these things, well, if you give us a bunch of resources we could measure a bunch of results. But they're saying, You figure out a way to measure the results of your program and that's the line that everybody is getting so we're not in any way being treated differently. So what we're going to do this afternoon is to walk you through what we have done as our first effort to try to get our arms around the results of our work. We do not feel that we have got the definitive either group of results nor do we necessarily feel like we have measured them perfectly. What we have is a first effort in a number of different parts of our program to measure the results of our work. And we're going to close this session with asking you a

number of questions about, you know, are we trying to measure the right things? Are we measuring the right things correctly? Are there other things conversely that we should be measuring? And then of course the standard, How would you like to participate in this? We actually have in our mind a vision of how we'd like you to participate in this. But think a little bit about those as we go through this. Kathleen Knox, who I think many of you know, has been leading this exercise in the Office of Pesticide Programs. A few months ago Kathleen took an assignment within our organization that has made leading this exercise, which is a full-time job, pretty challenging. And so Sherry Sterling, who is sitting to Kathleen's left, who I think some of you probably know, if not many of you. She's been in the Office of Pesticide Programs in her career a couple of times. She's rejoined us to take the baton from Kathleen to focus on results. But Kathleen will be giving the presentation. Kathleen?

MS. KNOX: I just want to give you an overview of what OPP has been working on in terms of measuring OPP results. And if you could, I think generally we're doing

this, but hold all your questions until the end and let me get through it all. We really need to start with what's in the EPA strategic plan. We're basically -- where does OPP fit in? OPP fits into goal four, which relates to healthy communities and ecosystems. You can read the definition. But more specifically on the next slide, OPP's work fits into subobjective 4.1.1 and 4.1.2. Now, the difficulty of this is that EPA's strategic plan has to cover the whole agency so it may seem somewhat reduced in scope but what really are sort of interpreted as our goals are here as subobjectives. And those basically relate to two parts of our program. The first, the language says reduce exposure to toxic pesticides but it's really about protecting human health communities and ecosystems from pesticide use. And then the second one actually captures the other part of our program, which is protecting human health communities and ecosystems from pests and disease by ensuring the availability of pesticides. Of course that include public health and antimicrobials. But again, there's the meeting the health and safety standards as well in that component. In terms of these subobjectives, what this language

really means, it really breaks down into two pieces. 4.1.1 talks about ensuring safety of existing pesticides that are already in the marketplace. 4.1.2 talks about ensuring safety and availability of new pesticides or bringing new pesticides onto the market for use in controlling disease and pests. The strategic plan, and this is just -- was put into place a couple of years ago, it covers years 2003 to 2008. But just in case you missed it, there was a public comment process for that strategic plan that exists but it's going to be updated starting probably within the next six months. We're not sure. But there will be work groups starting to update the EPA's strategic plan and there will be opportunity for interaction and for public comment on that new strategic plan. So keep your ears tuned or your eyes peeled to the web site for when that starts. In terms of what we at OPP do to meet our strategic goals, I just listed an overview of activities in some major areas. And for the existing pesticides in the marketplace, that include re-registration and tolerance reassessment, and again subcomponents of that are risk assessment and risk management. It also includes communication, and that's

providing information, doing education, outreach. And then we have a field infrastructure for safe use. That includes worker protection training, certification and training. And it includes our stewardship efforts. Again, not big in terms of our budget but part of the way we try and get the message out. On the new pesticide side, I don't want to jump to registration, again, that includes registration, new actives, new uses, new products. And again risk assessment and risk management. It also includes section 18, emergency exemptions, section 24C, local needs, etc. Our hope is that overall the results of the activities for the existing pesticides on the marketplace and bringing new pesticides to the marketplace, because of our regulatory action along with communication and outreach, training, and stewardship, will actually help to move the pesticide marketplace in a safer direction.

So how do we know if we're getting results? I don't really want to give a lesson in results measurement but we first need to talk about what is a good measure. So there's just one little slide here that deals with what is a good measure. Very simply, a good measure is

meaningful, and that means it's relevant and that means it's directionally correct, and it means it passes the laugh test. It needs to be cost effective. We're not going to get a lot of funding for major data collections. And it needs to be sustainable. That means that it's doable, that we can use it over time, that we can find an efficient way to run the numbers, do the analysis on a regular basis over time so we can see if there are any differences. Ideally, I mean, the best measure that we could hope for would be of high value and low burden. There are a couple of ways to start with this. You can start with this. You can start with what would an ideal measure be and that's sort of brainstorming in the best of all possible worlds, what would be have? We can also then take that -- you'd have to take that the next step, which is to say what data can we use to show that? But the other thing you can do is look at existing data sources and try and figure out what we can do with existing data to try and use them either as a measure or as an indicator. Jim's already mentioned output measures. I'm going to start at that. Measures exist at several levels, the most basic of which really is an

output measure. It's accounting. It's counting complete actions. We're very very good at this. We've done this for years. You had a little report earlier on this very thing, the report on re-registration, registration of how many actions we've completed this year. The OPP annual report also summarizes actions across the whole program every year. I'm not going to read them all but you can see the examples of them. The next level is intermediate measures. These are in between output and outcome. They're not something you do on a temporary basis. The intermediate measure might actually be a component of an outcome but isn't really an outcome on its own. The examples here that I'll mention are pesticide residues. Residue is not risk. It may well certainly meet the legal limits. In terms of the residue data we can determine that or not. But what a residue on food tells us is that there's some potential for exposure. Again, that's one part of a risk equation. Now, obviously the other part is the toxicity and so before you get risk you've got to have exposure and the toxicity. Percent of acre treatments using reduced-risk pesticides is another measure that we've looked at. Part of that is we've had

a reduced-risk expedited review and registration process for many years and the reason that we make these judgments is we think it's in the public interest to get things that truly are safer alternatives to the market more quickly. So what we need to do with this is look and see if these reduced-risk pesticide that actually get section three registrations are being used. Is anybody buying them? Are the estimates that we made in making the public policy judgment to expedite really true? Are they really replacing a riskier alternative?

The last item on that intermediate. Many people look at pesticide use data as something that we might use to measure our results. But pesticide use data alone does not really measure our results. We clearly license things so that they can be used to control pests and disease. But in order to use use data, and we do need use data, we need to go further than that. We need to use it as part of a formula or a model. The hardest thing Jim has already talked about, are outcome measures. What are our actions really resulting in in the long run? Are we really meeting our goals? The examples that I've mentioned here, poisonings, trends over time, and number

of systemic poisoning incidents associated with pesticide use. One mention and we're not going to get into great detail, but this is -- the data that we use for this is only poisoning cases with follow-up and know medical outcomes. So we're not taking every call to a Poison Control Center or National Pesticide Information Center. We can do other things with phone calls but when I mention poisonings as an outcome it's actually cases that have had follow-up.

The second thing on this list is wildlife mortality. We have used this over time. We have used this to track the number of wildlife mortality incidents reported. We've had some difficulty the last few years with this. It's a reporting issue. With decreases in state budgets there's been a real decline in the reporting of these data. So our data set becomes very unstable and if you can't really do, again, meaningful trends over time if you know that your reporting has declined to the point where it's not consistent with what you had before. The percentage of priority threatened and endangered species. Again, we're reexamining how to do this. How do we measure this? We're changing a

little bit of our process in terms of how we handle it so we're reexamining this.

The last category is economic. Again, because of 4.1.2 that talks about our licensing function, that really gets at the benefits of getting products out on the market to control pests and disease. So we're starting to look at economic, the economic aspects of outcomes, losses avoided, and I'll talk a little bit more about this later. But it's a different kind of look at outcomes than you might see elsewhere in the program. This is just a list of some examples that I'm going to talk about. These are examples of existing data. The reason that we're going to show them to you is to talk about how to use data or different ways to look at results. And when you look at these you've got to remember again that a good measure is meaningful, cost effective, and sustainable over time.

The first two examples are examples of pesticide poisoning data. Again, it's using the same data base. Next slide. This is actually data from the toxic exposure system of the American Association of Poison Control Centers. We've done statistical analysis.

Again, reminder, only cases with follow-up and known outcomes. We have done statistical analysis of this data set to look for confounding factors and to look at the stability of the data over time in terms of being able to do trends. And if you'll look at it, the -- in this particular case we've separated OPs from the other insecticides and the top three lines are other insecticides, disinfectants, and OPs. Again, it's a matter of looking over time and seeing whether you can see anything significant. This looks like we've got a pretty good story to tell here. The next slide is actually another way of looking at the poisoning data. And what we did is we took the numbers for one particular OP unidentified here. And we look at the number of poisonings over the same time periods. And that's the green line on this chart. The red line, and I need to tell you that it says proportion of all poisonings on the side and at the bottom in the legend, it should be percent of all poisonings, so that on the side the .25 means it's .25 percent of all poisonings for this particular OP. The reason that we graph the two together is to see -- you could say if we've got one particular

pesticide and poisonings are declining, what does that tell you about the rest of them? Perhaps the alternative that's being used, maybe the use has gone down, the alternatives are maybe spiking poisonings up in the other directions. So, if you track the number against the percent of all the poisonings you can tell whether the trends are going in the same direction.

The next data is National Health and Nutrition Examination Survey data. It's biomonitoring data. We know that interpretation of the results of these data is controversial, but in this case the one thing that we do know is it shows that individuals have been exposed to something. This is one single OP metabolite, again unidentified. So it's something that for the moment we're just keeping track of it. We're going to look at these data and see what it tells us over time.

The next data set is the Pesticide Data Program. I think you're probably familiar with it. It's U.S. Department of Agriculture Pesticide Data Program analyzes pesticide residues on foods. In particular we've focused on kids' foods and we've focused on the riskier pesticides. Again, the residues are not risks.

OPP has over the last year done a very thorough statistical examination of these data to try and look at what factors are important in terms that we need to keep in mind in terms of developing indicators. They've looked at seasonality, geographic distribution, domestic versus import. You can look at tolerance exceedances versus residues within the range of the tolerance. What we're trying to do with this data set, again, is work towards a summary measure that's meaningful. We know it's good data. We know that it doesn't get to an absolute outcome, but, again, it's that potential for risk which is one component of the outcome measure that we might want to develop. In terms of these kinds of data, levels of detections is always a question. We think that we've got statistical techniques like maximum likelihood estimation to try and be able to use that. Again, this is still a work in progress. We've gotten pretty far on it. And what this particular slide shows you, it's one particular OP on one treated domestic commodity. And those little bars on the points are the 95 percent confidence intervals. And as you look over time, if those little bars don't overlap it means it's

statistically significantly different over time. So this is one way to look at it. One crop, one pesticide. The next slide actually is a way of looking at overall number of pesticide detects in food. That top line is that there were zero residues detected. Again, we're looking for a better way to summarize the data. It might be number of residues detected but we are aware that many of the residues are within the legal limits. So work in progress. Something that we can use in terms of moving in the right direction for our measures.

The next slide is a little bit more interesting. 682 data. 682 data is required to be reported under FIFRA. It's reports from registrants of adverse effects and incidents. It's intended for screening purposes. That's what we've used it for. We're aware that in terms of actually using it as a measurement tool we've got to be pretty careful in terms of what it is and how we validate it or not in fact. What we decided to do, though, was we made a regulatory decision for risk mitigation some years ago affecting two pesticides. What we decided was to take a look at the 682 incidents reported for these two pesticides. In each

case all uses were not removed so we still had uses on the market. So that light blue bar is the number of incidents reported in the year before we made the regulatory decision. The dark blue bar is not the following year because we didn't do a recall of these pesticides. They were still on the market. We assume there's a time for the products to clear the market. It's generally called channels of trade. So we skipped two years of data and then we looked at the third year, the complete third year following the regulatory decision, figuring by then all the product for those uses would be off the shelves, out of the market. And so we just looked at the totals to see whether there was a decline. Now, we would expect to still have incidents reported because there are still uses on the market but because a lot of uses had been removed we were hoping to validate the results of our decision. That we were really mitigating some risks. So we took a look at the data and it looks like it shows us that we probably made a good decision. Again, we have to be careful with 682 data. But there are times when I think we can use it, particularly in case of a significant change over time.

So we're just exploring existing data sets and ways to look at what we've done.

Next slide. As I mentioned before, we started to look at the economic side of things, at the benefits side of things. Our economist recently did a pilot study of economic benefits. We started with section 18s, again because section 18s have a very definite benefit economically based component to them. Rather than starting with the data that's submitted in the section 18 request where there's an estimate of an economic loss to be avoided, we actually used the data that was sent in by the states after the section 18 had been utilized as it were. This study included really five case studies of 16 crops. They tried to get field and specialty crops and some geographic distribution as well. So what they did is basically look at the section 18s at the end. The data's in the next slide. This is really done to try and see what it would bring to bear, what it would cost to do it sort of. We're in the process of developing some methodology. Can we do these kinds of analyses routinely on a broader scale and cost effectively? The data in the table, and you can see it was California strawberries for

white fly, Montana barley aphids, Minnesota sugar beets, water hemp, Kansas sorghum, and Florida tomato nutsedge. Over the years, through 2003 or 2001, 2002, the average yield losses that they calculated show that there were local impacts to growers. In terms of focusing on the results the section 18 program is very much focused on alleviating losses to local growers, so part of it is could we do this on a broader scale? What would it cost us to do it? I think the regs require that states send in the data after the fact. If we had some way of routinely capturing that could we start to do some more analysis on a regular basis? Again, we'll need to – it needs to be a cost-effective and sustainable process for us as well. So there's more work needed. We also need to start looking at benefits of section three registrations, not only in terms of economics but in terms of health benefits for public health, pesticides, for antimicrobial pesticides. So there's really a lot more to be done. I just covered a few examples. These are some of the examples of the better data that we actually have. But there are several high-priority areas that really need measures development. Obviously human

health, we've made some progress in terms of the food safety issues with data that exist. We need to work on the worker area. Ecological areas, there has been work done in the ecological areas but there's more that needs to be done. Surface and groundwater. And again as I mentioned, the benefits area.

Next steps. New work group. Jim introduced Sherry. There are new work groups that will include regional, state, and tribal participation. We're going to continue to work on available data to refine the indicators that we've currently developed. We certainly need to work with other EPA programs and other federal agencies and departments, those organizations that actually collect the data that we need or with whom we share some part of our goals. And we need to work with stakeholders. That's partly why we've brought this here today. So basically what we're asking today, we've got three areas that we want advice for. One is advice about our existing measures that we mentioned today and do these measures actually show OPP results. What is your advice about further measures that we should develop? And then how can PPDC contribute to the work in these

areas? OPP looks forward with folks today and in the future on this.

MR. JONES: Great. Thanks Kathleen. We have a meaningful chunk of time by design for this part of the session. Why don't I propose that the first group of questions be if you have any clarifying questions about what Kathleen presented. We'll do that for, you know, until people don't have any more questions. And then figuring we have about 15 minutes for each of these by the way. Then we'll do about 15 or 20 minutes on the first question. We'll entertain -- we'll get some advice on the measures presented today. Stick to that so that we're all sort of talking about the same thing for a little while. Then we'll move on to what is your advice about measures OPP should develop. Do that for 15 or 20 minutes. And then the last group of -- the last feedback part will be about how OPP can contribute to work in these areas. Now, that being said, my experience is large groups have a hard time following directions but -- (Laughter.) We're going to try it anyway. So, again, the first part of this is getting -- if you have clarifying questions about the presentation. So right now we'll

entertain some clarifying questions and then we'll move into the advice part of this. Okay? Jim.

UNIDENTIFIED MALE: I have a question on your slide number 15 where you talk about estimated poisonings for one organophosphate. And actually a couple of the other slides as well on the poisonings. Are those primarily as acute poisonings or do you also look at chronic poisonings over a period of time?

MS. KNOX: David? Excuse me. This is David Miller. David -- I believe it's acute because it's things that got called into the Poison Control Center and then are followed up, so --

MR. JONES: Jen?

UNIDENTIFIED FEMALE: That was one of my questions but I had a follow-up on it. Is it only Poison Control Center data that you're taking or do you use other data sets to, like I know that NIOSH also collects this data. Are there other things or just Poison Control? For the human exposures, human poisoning incidents.

MS. KNOX: I think that the Sensor data gets reported into the TESS system so that would include those

poisonings.

UNIDENTIFIED FEMALE: It would? Okay. And they're all medically confirmed, is that right? I assume? When that data is given to you or maybe you sift through it beforehand. Those are doctor-confirmed poisoning events?

MS. KNOX: I don't know that they're doctor confirmed but they are confirmed and the outcome is determined. So I mean there is definitely an investigation of them. I don't --

UNIDENTIFIED FEMALE: Okay. And do you get that data -- I doubt but I'm wondering if you get that associated with a particular chemical exposure or not usually?

MS. KNOX: We buy the data set from the Poison Control Center. It is pesticide specific.

UNIDENTIFIED FEMALE: Okay. As much as possible. And then for the wildlife incident data, who's collecting that?

MS. KNOX: Those data over time were reported by the states. By state organizations. Again, it's something that we could use over time as long as the data

base was stable and fairly consistent. But the reporting has declined significantly so --

UNIDENTIFIED FEMALE: Okay. Would that be -- okay. Even Fish and Wildlife doesn't have something that could help you or no? I don't know, I'm just wondering. So it's state by state. Okay, that's it. Thanks. That was a great presentation. I really enjoyed that.

MS. KNOX: Thank you.

UNIDENTIFIED FEMALE: I'm excited by these points. I know it's not a follow-up, but --

MR. JONES: Okay Amy.

MS. LIEBMAN: I just had a question on the pesticide poisonings, on 14 and 15. And one of my questions is, I guess I'm confused, is if you are trying to do efforts to increase reporting. Some of your efforts involve increase reporting of pesticide incidents so what are the trends that you're looking for because if you see an increase perhaps that's because you are successful and better reporting. Do you understand what I'm saying? If your trend is that you're looking for the poisonings to go down, you know, that might be a good thing that poisonings have down but on the other hand it

might show that the reporting efforts are not as strong as they should be. So I'm just curious as to what are the trends that you're looking for in your outcome measures?

MS. KNOX: One of the reasons that I mentioned that we do the statistical analysis of this whole data base is to try and look at those possibilities over time and see what might have changed and use other ways of looking at the data to see whether there can be confounding or whether it's biased in one direction or the other. So we have done those statistics, so we think that these data are as good as they can be to look at over time. There is a statistical report that's been done that looks at those things. I wasn't going to get into that level of detail today. But in terms of follow-up, I mean, whatever follow-up the group has in terms of measures development certainly that's the time to get into more of those levels of detail. But we're aware of that and we've done those kinds of analyses on the data.

MR. JONES: Rebeckah?

UNIDENTIFIED FEMALE: I guess this is a separate but related line of questioning. One of the

lists of OPP activities in addition to re-registration and infrastructure and safe use is the building and the communication and the outreach, and I was just wondering where in here, I mean I know we had the discussion earlier this morning on PSEP, but in the greater perspective of education and outreach for use, which theoretically would lend itself to impacting poisonings and residues and some of the other things that are reported, where is build in EPA's effectiveness and productivity as far as educating and outreach? In genera, not just on one particular program. Is that built anywhere in here and if so is it possible for clarification to build that in in the future?

MR. JONES: We are trying to convince OMB, which wants to sort of separate everything out, and say show me the results of each individual component. That actually it's a totality. You don't necessarily get an outcome just because you registered the new product or just because you restricted an old product to meet the safety standards and just because you had an enforcement program, just because you educated. You got it because you did all of the above. There's this push and pull

between saying, no no we want to be able to parse each one of them out and we're saying, well, you know we're having a hard enough time just identifying the change in the system. To attribute it to one of the above we think is trying to parse it to the data doesn't support that. So we see that you get the results as a result of a comprehensive program because if you leave out one part of the program, like if you don't have any enforcement at all then chances are even if you restrict something you may not get the result -- or just because you registered something if you didn't educate people how to use it you may not get the result.

UNIDENTIFIED FEMALE: Those things aren't built in. You haven't measure that --

UNIDENTIFIED FEMALE: We haven't. In general, you know folks used focus groups and those kinds of techniques to measure success of communications efforts and I think in some cases over time we've done some of that but in terms of an ongoing thing, we really haven't. Like Jim said it's really a comprehensive thing. We think that all of those things contribute to our success in terms of moving in a positive direction.

MR. JONES: And that being said, if there is data, like one of the things we're going to look at is the data that Amy referred to this morning that does allow you to do that in a narrow, then we need to get that onto the table. And there are times when you can actually say this happened directly because of that result, but often it's basically because you have a comprehensive program as opposed to just one part of your program. Beth?

UNIDENTIFIED FEMALE: Having just helped a part of USDA go through the program assessment rating tool, has OPP been through that?

UNIDENTIFIED FEMALE: Oh yes. Oh, more than once.

MR. JONES: A couple of our programs.

UNIDENTIFIED FEMALE: And can any of that be helpful?

(Laughter.)

MR. JONES: This has been fed into that.

UNIDENTIFIED FEMALE: This was fed into that?

MR. JONES: Parts of it, not all of it because some of it is newer than our part review.

UNIDENTIFIED FEMALE: So this is the part analysis then, really, there's not pieces of it that can come back into this. This is just a portion. (Inaudible.) Got it. I was just curious because that thing looked like a bear.

MR. JONES: Some of what we presented today wasn't because -- when we did the part analysis a year ago we didn't have the measure yet.

UNIDENTIFIED FEMALE: Mm-hmm. And then the second question is in order to go to your next portion of this discussion. When you ask -- you're asking for advice from PPDC, are you asking for advice on the last two slots, the next steps? Or have you already figured out what you're going to do with HHS?

MR. JONES: Well, that'll come a little later. I want to just get clarifying questions off the table and then we'll sort of move to the first question.

MS. KNOX: I'll answer this as a clarifying question.

MR. JONES: Okay.

UNIDENTIFIED FEMALE: Yes, this is just for clarification. Sorry.

MS. KNOX: We do have folks who are aware of and involved in the things that are going on at HHS. Any studies, any whatever. You know, it's obviously not our full-time job but we're aware and we've got partnerships there. We track things. And if a study gets to the point where it's going to be analyzed, you know -- we just -- we try to stay on top of that. We need to work a little more closely with some of the folks who do the bigger picture data collection and see whether we can get more of our needs met. We already do this with USDA on several things, certainly pesticide data.

UNIDENTIFIED FEMALE: So in the three areas for advice you're not necessarily looking for advice on how to better --

MS. KNOX: I think if we got that advice it would be welcome. But we are -- it's not that we're isolated. We're currently working where we know things are going on.

MR. JONES: Thanks. John?

UNIDENTIFIED MALE: Yes, this is about slide 20, and then just referring back to your introduction, the topic about what EPA's charges here and that was

health and environmental effects. And I'm wondering is this one really part of your charge? I mean is this one that you really need to do? That's the economic benefits part under section 18.

MR. JONES: Yeah, we believe it, very much so.

UNIDENTIFIED FEMALE: I think anybody who's planting soybeans believes it is.

UNIDENTIFIED MALE: Yes, but that seems more what USDA (inaudible).

UNIDENTIFIED MALE: I have a question on slide number 18, the pesticide detects in food. I know you expressed some caveats about whether counting the number of residues in a sample is appropriate but does the PDP data count as separate residues a pesticide and its metabolite and could that account for some of the multiple detects? You may not have an answer for it right now.

UNIDENTIFIED MALE: To answer part of it, which is for some of the pesticides we also measure the major metabolites and those are reported separately. And I don't know what EPA used of the data.

UNIDENTIFIED MALE: So if you had the

metabolite plus the parent compound that might count for two residues.

UNIDENTIFIED MALE: I don't know how EPA counted them. I know we have collected such data.

UNIDENTIFIED MALE: It's something to consider when you report data in this format, that it doesn't necessarily represent application of multiple pesticides if there are metabolites in that count. And then another question on slide 19, where you're reporting 682 incidents in a year period before an action was taken and in a year period after the action, did I understand that there is a one-year period in between those two, which is not reported?

UNIDENTIFIED FEMALE: It's actually a two-year period.

UNIDENTIFIED MALE: Two-year period in between.

UNIDENTIFIED FEMALE: Yeah. We assumed two years so there's a two-year gap between those two bars.

UNIDENTIFIED FEMALE: Do you have an answer to the first one? Dave?

UNIDENTIFIED MALE: Traditionally PDP has reported parent plus metabolite as two. We began

conversations with them a year ago or so about that and they've changed now, this most recent one. The data you see up there is according to their usual convention which was they would count as two. We're in the process of actually changing that.

MR. JONES: Thanks. Lori.

UNIDENTIFIED FEMALE: I had a question on slide 12, percentage of priority threatened and endangered species that are highly vulnerable to pesticides which are protected from jeopardy by pesticide use. Just a clarification. Is that saying you're looking for the percentage of threatened and endangered species that are protected by pesticide use?

MS. KNOX: No, that's not what it means. The wording.

UNIDENTIFIED FEMALE: But Jim's feeling very vindicated because when we showed him the slide that's how he read it, too, and we said no, no, no.

(Laughter.)

UNIDENTIFIED FEMALE: We're trying to say pesticides that might jeopardize an endangered species and then the percentage because we've done some action

but they're no longer jeopardized.

UNIDENTIFIED MALE: I like the first interpretation.

(Laughter.)

UNIDENTIFIED FEMALE: Well, you know, actually both of those would be useful measures, but our intent and we'll work on the wording of this was not as Jim and Lori thought. But the other way around.

UNIDENTIFIED MALE: My question is -- I wasn't sure which of four categories to put it in but since it's probably a clarification question, I'll put it in the first category. I'm trying to clarify the entire concept. You want to monitor benefits in a sort of almost in a negative way of saying no this or no that. And one of the problems of a regulatory body which has enforcement pieces of it is that you might actually have a conflict sometimes. Especially if you have goals that you're measuring these negatives things. No recalls. You know, whether it's a quality assurance department of a large corporation or whether it's the FDA or the EPA or the USDA, if you're measuring about things that don't occur, there may be a tendency to, I won't say minimize

but maybe I would say minimize, but not ignore but certainly minimize, bad news if you will. So sometimes having that type of a goal if you're actually setting it as a goal could be a negative effect, too. And I think you need to be very careful about that.

MR. JONES: That's a good point. The example that we put forward was in that context frankly because it was the easiest one for us to measure, loss avoided associated with the program that requires the applicant to tell you what their projected loss avoided would be. But we're not limiting ourselves to that. I think it's just more challenging sometimes to measure just general societal economic benefits. But those are some of the things that we want to figure out how we can do. Steve.

UNIDENTIFIED MALE: Slide 10. For slide 10 should we also -- are the ADC also considering amendments as another bullet in ME2 registrations or how the agency is meeting the PRIA time lines? I mean that's -- it seems to me if you're doing those things and meeting the time lines, etc., that that would be used as an output measure.

MS. KNOX: Right. These are just examples. It

wasn't meant to be an exhaustive list of things that we report on or count.

UNIDENTIFIED MALE: Okay.

MR. JONES: Yes. Dennis?

UNIDENTIFIED MALE: I just wanted clarification on slide four. For 4.1.2, ensuring safety and availability of new pesticides. Does that really mean just new pesticides or are you also consider re-registration actions on existing pesticides? Where the products are made still available basically through those activities?

MS. KNOX: Re-registration falls under 4.1.1. 4.1.2 means either new pesticides, new actives, new uses, new products. So re-registration does fall under 4.1.1.

UNIDENTIFIED MALE: The 4.1.1 seems to deal strictly with safety whereas 4.1.2 deals with both safety and availability.

MS. KNOX: Again, that's what's in the current EPA strategic plan. Those things will be revisited as the work groups get together, so keep your eyes peeled and participate next time around. That's the way it got divided. That's the way we divided up the body of our

work. Again, we didn't have the opportunity to split it into very many categories.

MR. JONES: The strategic plan is at the agency level. We certainly participated in it. But once the administrator signed off on it, that's it for, until he or she decides to change it. The plan is to change it, to modify it, to make any appropriate changes coming up in the next two years. And again that will be first an internal process and then a process that considers stakeholders and so that will be something Dennis, to keep an eye on when that process becomes public. But we'll give that some consideration as part of our internal comments on the plan as well.

UNIDENTIFIED MALE: Not to belabor it, but if you look at slide three, and there's probably much more to this than meets the eye, it doesn't -- in reading 4.1.2 there it doesn't really seem to limit it to new pesticides, just pesticides meeting the latest safety standards, which should be new and old if they're going through re-registration.

MR. JONES: All right. That was very good. Caroline?

UNIDENTIFIED FEMALE: On slide number nine where you talk about cost effectiveness. Historically the things that you looked at have been relatively easy to measure but some of things that you're talking about looking at in the future may have a more significant cost associated with them. So do you have a figure in mind in terms of how much you're going to spend in determining these measures? Because I think it's going to be a lot more expensive than it has in the past.

MR. JONES: Yes, it's been pretty clear from both the agency level and the administration level that resources above and beyond our base programs are not going to be available to do that. So we need to figure out how to do those things within our existing resource base. To date, we've done it with using existing FTE. So, we're going to need to figure out what we can afford above and beyond existing data sets that we just get more serious about putting some expert manpower, person power, onto it. So right now the plan would be to do it as inexpensively as possible and see how far that gets us and then see if whether or not we're able to demonstrate results that are considered adequate for the

administration and Congress. If they are, I'm not sure I'm going to then ask for money to demonstrate further results. If they're not, I think I'll make a pitch for, you know I think I could use some resources to actually show to you we're demonstrating results in this particular area. Okay. That's it for the clarifying questions. That was good. Now for the advice part. And again I'd like to, so that we can all be talking about the same things for a chunk of time, start with the first question that's on -- and actually can we put up the last slide so folks can always keep looking at it. So let's spend 15 or so, maybe 20 minutes on advice you have to the agency about the measures presented today and that corollary question that goes with that is do these measures show OPP results. But you know focusing on the first part. What is your advice about the measures presented today? Amy.

UNIDENTIFIED FEMALE: Okay, first I want to compliment you for taking this on, because it's really challenging to develop -- to think about what makes good data for impact. I do have some comments. First, on the poisoning data and using the poisoning data. First,

there are a whole lot of inputs into that that really muddy the picture for what you're collecting. One is as Amy Liebman said, you may be looking at better reporting, but also there's this effort that EPA is participating in to train health care providers to recognize pesticide incidents better. So if physicians and other health care providers are recognizing it better presumably they may be reporting it as well. So that feeds into the reporting as well. And it actually might be a better measure of the fact that physicians are now recognizing it. Then of course you're only looking at the acute data and not the potential chronic or other long-term effects, but also some other things that go into there. I guess if you're looking at just the impact of whether regulating pesticides has resulted in a decrease in poisoning incidents that's possibly what you're getting out there. So, like taking pesticides off the market, has that been effective? As one pesticide has been taken off the market there are fewer poisoning cases with it. But if you're also looking for training impacts, which we get pressured to use pesticide incident data, poisoning incident data, for our stuff and I have a lot of problems

with doing that because then you have to start looking at who actually got trained versus who didn't get trained and did they do it right versus did they not do it right. But my biggest problem with using pesticide data is that you're muddying it up by having people who are better trained to look for pesticide poisoning. So I'd be really careful with that. Also, on the business about using residue data as a measure or the number of pesticides found as residues in foods, well, presumably residues can exist in foods without causing an adverse effect on health or environment. So wouldn't what you really want to be looking at would be violative residues rather than just all residues? Because otherwise you're implying that there is some health impact from just having a residue in your food. And that sort of to me is what the whole tolerance things is all about.

MS. KNOX: That's why I mentioned that it's not a risk measure. It's an intermediate measure, it's one component of a risk.

UNIDENTIFIED FEMALE: But if you reduce it to just the violative measures that clearly would be a measure of --

MS. KNOX: No, that's a violation of the law. It still doesn't mean it's a risk.

UNIDENTIFIED FEMALE: That's true.

MS. KNOX: Amy, again, we need to do some more talking within the program about where we end up with the summary measure for the residue data. We've done thorough analysis and we know now what the data set looks like. We need to make some of those decisions about how we want to track things. So it's just there are various ways you can look at it. We've imported things in, we can take imports out. Part of it is what question are we trying to answer in terms of is it the overall food supply, is it the impact that we have on domestic growers, whether it be training, outreach, education, or regulatory. There are a lot of different questions.

UNIDENTIFIED FEMALE: I recognize that. But I do think it's important to be careful to not give the impression that if EPA says that you can't have residues in food that are not going to be an adverse health effect then why would you be reporting reductions of residues as a necessarily good thing or a bad thing? You are by implication giving it some weight there, so I'm not sure

I would use that.

MS. KNOX: Okay, thank you.

MR. JONES: Ray, you're next.

UNIDENTIFIED FEMALE: Can I just jump in before you do that? Because I just wanted to add to this discussion on residues. The other thing that you need to keep in mind, too, is that we continue to drive down the limit of detection and so when you look at something like this that has detects it doesn't give any kind of context as to what the actual limit is. And I think that's really important. Thanks.

UNIDENTIFIED MALE: Well, I had one comment that expands on this issue also. A large share of what EPA does is to determine levels of risk and set allowable limits on those levels of risk. And if you're measuring components of risk with the idea of driving those relentlessly toward zero, I think that's counterproductive. You should be setting allowable limits of risk and making sure that product use stays within them as opposed to a relentless pursuit of zero. That's some of what's measured here by simply counting or measuring residues that are within the legal limits. I

applaud your efforts to bring benefits of pesticide use into the measures of the efficacy and effectiveness of pesticide regulatory programs and I think that should be expanded. It's -- a licensing statute or it's a licensing program and FIFRA has its elements in it addressing benefits and so they should be a measure a part of the efficacy or effectiveness of the program. In terms of both advice on what you've got here and advice on what else you should be measuring, there's a lot to think about. We can offer you some advice today but I also think we need to take more time to respond in a more measured manner.

MR. JONES: I appreciate that. We're actually going to propose some more intensive outside of this room kind of working group to do just that, Ray, but we'll get a little more into that later on this afternoon. John.

UNIDENTIFIED MALE: I'd like to comment on what Amy was talking about. In putting some -- as you mentioned Kathleen, risk is a calculation of exposure times toxicity. And we do have some, albeit some crude, benchmarks that you could use for presentation of some of this information. As Bev pointed out with our analytical

techniques continually improving, it's also important for you all to show that you're accomplishing something and when you look at this graph it's just a dichotomy. It's yes or no. And it looks like things really aren't changing all that much. You look at the zero and it's going up a little bit. But if you express that as residues that exceed some tolerance level, you would express that much differently. In the last few years we may see none of them that have three or four residues that exceed a tolerance level and you would actually show an accomplishment as pesticides are being effectively used out in the field, that we're decreasing exposure and then decreasing risk. You could even take that onto some of the NHAINES data that you have. We have BIs for some of these, not all of them, but for some of these pesticides where they have biological indicators that are demonstrated to be safe and you could express it that way as well. And I just think as we increase our effectiveness in the use of pesticides that it's an important message to translate. And again as Amy said, just because you have a residue doesn't mean that there's an inherent risk.

MR. JONES: Thanks. Okay, Jennifer and then Julie.

UNIDENTIFIED FEMALE: You can go around the table, that's okay.

MR. JONES: Okay. Julie?

UNIDENTIFIED FEMALE: You know we've had a lot of discussion on labeling and labeling is always a continual topic. And I guess, you know, a suggestion is for something that we need to measure perhaps is the effectiveness of labels and label changes. When we, you know, and we'll have some discussion about this tomorrow with registration review of the time it takes and the costs involved with making label changes. And I think if we could have some way of measuring -- you know, are we accomplishing through this label change what we intended to accomplish? And it's going to -- I think what you'd be measuring might vary on based on what the label changes is, but I think it would be good to have some way of saying are we accomplishing through these label changes what we intended to accomplish. And I think especially as we're working now in this area of consumer labeling and we're kind of re-engaging in the consumer

labeling area, you know, working with the marketers of these consumer products, let's you know, can we find out some way of determining whether these changes are having their desired effects. And then the other kind of like -- and I'm also glad to see benefits in there. And I think an area of benefits, you know at least from our area, that you may also want to consider you know when you're looking at economic and public health but also animal health and welfare. Because a significant use of, especially in the consumer market of pesticide products, is on animals and what that contribution is to the health and welfare of animals. And I'd suggest maybe working with the American Veterinary Medical Association and to you know maybe kind of determine what some of those benefits are.

MR. JONES: At least for the next remaining, the next three, stick right now for the -- what's your advice about the measures presented today and then we'll get to what additional measures you want to offer. Yes?

UNIDENTIFIED FEMALE: You've already touched on this briefly, talking about wildlife mortality but I just wanted to reiterate the problems with using mortality as

an indicator. I know there's been a decrease in reporting in the past couple of years, especially since New York and California have decreased their budgets for that kind of data analysis. But I think even when that data was coming in, I think that's really an inherently biased data set. Most wildlife mortality is believed to go unreported and it's biased towards large conspicuous species that people collect, people report, people send in for analysis. It's largely driven by how much money is available to analyze that data. I know there are large scores of endangered species that have died for years that we don't even have money to analyze to see what the cause of that death was. So even the most important species that we're looking at for the Fish and Wildlife Service, if they're not getting analyzed -- I don't -- it leads to scores of other species that are out there that aren't being found, aren't being analyzed. And I don't know that there is an unbiased set of data that exists for wildlife mortality at the present and I don't know quite how to incorporate that. And I think it lends itself to a larger problems. We just don't have a uniform system of monitoring wildlife exposure or effects

in general, especially for terrestrial data. So I don't know what the answer is but I'm certainly willing to work with you on it.

MR. JONES: Good. Terry.

DR. TROXELL: Well, of course I agree with the folks around the table that are basically talking about the right measure and I think what EPA is interested in is if we had a measure of real risk but there's not good way to really quantitative actual risk. These days we tend to use reference doses and that sort of thing, which is more of a negligible risk standard and real quantitative risk. So in lieu of that one uses surrogates and looking at various exposures. Biomarkers are probably a good approach and CNC has a whole range of those. If you decide that you want to use some kind of level of detection of pesticide **(End of audio.)** - diets for range of age-sex groups and that could give you an idea if, you know, at least the kind of the typical person that doesn't give you the extremes, but usually you can estimate those by a factor of two to three or so high or lower then those exposures. But that would be another measure. Because all -- what you really can do

these days is look at a number of measures to see what your progress is towards whatever goal.

UNIDENTIFIED FEMALE: Jennifer.

UNIDENTIFIED FEMALE: On the same topic, I would agree with Dr. Troxell and those comments. And I guess those are the part of the comments that I wanted to make which is I think it's good, it's important to understand the confounders and the weaknesses and the biases in the data, but I would still maintain that you should collect all the data and I would hope that we could see all the data the way you've presented it here. So for example I think it's understood, and at least I would continue to argue, that the reference dose or the tolerance is not a safe level or a bright line for the whole population. And so I wouldn't want to see data that was limited to only legal violations because then I would argue what else is there under the legal violations that we don't know about. So at least from my perspective I would always want to see all the data and understand the confounders and understand the weaknesses and understand the limitations as I know that you do. And maybe to have those explicitly listed the way we want

to see in published data and things like that. And I would say that about sort of the whole discussion and all the discussions that have come up. The mortality data I would say the same thing. I think it's important to understand the weaknesses and the limitations, especially because it helps all of us to make a case for the need for funding to collect appropriate and adequate data and I would help make that case. Nonetheless I'd want to see the mortality data even if it's just for the big beautiful furry species or whatever it is they're collecting it on. And I know the weaknesses of mortality data versus more subtler sensitive end points, but I would still want to see it all. So I would like to support the way you've done it here and to -- but to include I guess an appropriate discussion of confounders, what they might be and how we could adjust for them. And I would like to support any further data collection that you'd like to do.

UNIDENTIFIED FEMALE: That's really the gist of my comment and it applies to both what you've presented today and what measures we might suggest for further development is that you do need a clarification statement

on all your measures. You want to explain your methods and you want to provide context. And for the templates that the Pesticide Safety Education Programs report on, you know, it's always tempting to all of us to just report the numbers or report the final result of whatever we're collecting, but in our template we're given space to explain the method that we used to develop that particular impact data. And I think that you would probably want to do that, too, so that people can take issue with it if they need to. But they can also see the limiting factors of it and you would also want, as Jennifer said to put the same kinds of qualifiers on it that you put in data that are going to be published somewhere. So it's really reliable.

MR. JONES: Thanks.

UNIDENTIFIED FEMALE: I do agree with that but in terms of -- and if we had a perfect measure, that certainly would be the case. But sometimes we may only be able to come up with an indicator and you can think of it in terms of a weathervane. It doesn't tell you very much. It tells you what direction it's going in. It doesn't tell you how fast the wind is. It doesn't tell

you all the other weather things. But sometimes that might be all you've got or it might be all you need to rely on and you need to figure out whether that's useful or not. That's one of the reasons when I said that a good measure is meaningful that to me it has to pass the laugh test. It doesn't have to be the level of statistical validity that you might want to use in risk assessment but it needs to be useful and sensible enough that you know that if you look at it over time you're aware of these other possibilities. And again if we can track several of these at the same time and they're all going in the same direction that might tell that we're going in the right direction. Again, it's not about -- it's hard to measure increments but to the extent that we can we certainly always look at our data like that. That's why it's been hard to work in an organization with a lot of scientists to talk about measures because they want the level of validity and the level of data and they want to be able to prove things and it's like, well, no, sometimes we need to step back a little and say, you know, how do we do that. Obviously.

UNIDENTIFIED FEMALE: I'm actually supporting

you.

UNIDENTIFIED FEMALE: I know you are.

UNIDENTIFIED FEMALE: Your ability to do this and that's why I'm doing it as a scientist.

UNIDENTIFIED FEMALE: Right. Right.

UNIDENTIFIED FEMALE: That we do that all the time. We use the best measures that we have but we explain how and why.

UNIDENTIFIED FEMALE: Right.

MR. JONES: Ray.

UNIDENTIFIED MALE: I'm probably restating some of the things that others have said but I think that the closer that you tie these individual measures and whatever else we come up with to specific or general regulatory actions that it's that much better indicator of your success. You've done a couple of these approach that very carefully. The measure of the incidents under 682 is one of the most closely tied to specific regulatory actions. If you can look at pesticide poisonings and perhaps do additional analysis on individual events to see which were tied to problems with interpretation of the label, etc., that maybe that's not

measuring what you have done but it points to what you should be doing. But, you know, you'd hate to spend a whole lot of money and effort measuring something for which you can't make even a remote tie to specific actions you can control in your regulatory program.

MR. JONES: Nancy.

UNIDENTIFIED FEMALE: My comment deals with the whole area of health benefits and whether or not it might be possible -- and this might be just too far out, too hard to do, to show relationship of specific foods to health improvement and the role of pesticides in making that food and increased consumption of that food available. For example, in the nutrition literature you might see something on blueberries and some of the components of blueberries that have contributed to reduction of heart disease and then the role of the pesticides in making that food available and increased consumption.

MR. JONES: Thanks. That's a good segue to the next part of this discussion, which is what advice do you have about what measures that weren't presented here today that you believe we should be spending time,

energy, and effort in developing.

UNIDENTIFIED MALE: Thank you. First I should say I really enjoyed the presentation. I think it's very helpful. But in reading through the slides it does seem like we're looking at the question of results in a bit of a bubble. And typically I equate results with benefits and the other side of the equation is cost. And in looking at slide nine in particular where you are considering cost effectiveness, efficiency, and sustainability, the other side that I'd suggest having a closer look at is how efficient, how cost effective, and how sustainable is the program that actually yields the benefits at the end of the day. And in particular I'd suggest looking at the costs of part 158, both the current approach, which I can tell you the baseline now is millions of dollars to register a pesticide, and approximately 12,000 animals. And at the same time we have no ? testing strategy that suggests that you can get the same benefits at a markedly reduced cost. And then we have the part 158 rule that's been proposed, which would actually elevate the bar, elevate the costs. And I think it would be relatively easy to have a look at some

of those economic indices to actually factor that in so we have a more balanced assessment of costs and benefits. Because I think if the efficiency of the overall program could be improved you'd have a much stronger case for the benefits and the results that you're presenting.

MR. JONES: Thanks. Jim.

UNIDENTIFIED MALE: I have two suggestions. One, Amy reminded me about the health care providers initiative. In the past pesticide poisoning has been low on the list of interest of physicians for continuing medical education and we did recently put in that process a few years ago. And made the point that, you know, identifying pesticide poisoning often falls on the health care provider and so you might look at what has changed in both activities in continuing medical education and in provider knowledge since the last few years when the health care provider initiative started. But the other kind of goes back to the point about the acute pesticide poisoning. I would also suggest that you look as best as possible at chronic exposure and chronic poisoning. Admittedly that's a lot more difficult to look at. But I think that it's an important area to look at in terms of

things such as birth defects or neurodevelopmental disabilities, especially in children. There's a few studies with adults and neurologic deficits. There's one study that's just now coming out that looks at farmworker children and neurocognitive effects. And I think that trying to do some more work on chronic exposure would be important.

MR. JONES: Allen.

UNIDENTIFIED MALE: I would just like to second what was just said a few moments ago. I think it's really important for the agency to reach out to other agencies and try to make correlations between detected residue levels and various measures of outcome intellect. How many of these kids go on to develop disorders on the pervasive development disorder spectrum? Autism? Asperger's type kids? And eventually really expand that into some kind of a program that would enable the agency working in collaboration with others to determine whether the high-level exposures are the people who bear a higher burden of the neurodegenerative disorders in later life. These are long-term projects but I think they ought to -- I mean, they've got to start sometime if they're ever

going to occur. And also to work with other agencies to expand the lower-age measurement levels of the NHAINES study, which really now start at about six. We don't know very much about exposure levels to kids who are younger than that age.

MR. JONES: Thanks. Eric.

UNIDENTIFIED MALE: This kind of plays off the discussion this morning. But I think it's just critical that we close the circle and look at to what degree are what your office doing is complied with out in the field, because if growers can't make heads or tails out of labels, applicators can't make heads or tails out of labels, you guys might be pumping out a lot of labels and think you're doing a great job, but in the field it's meaningless or it's counterproductive. So I think I understand enforcement somewhere else, but I think that is an objective measurement that you have access to that gauges the degree to which you are being successful in your work. So I think compliance is important and I think the other very important thing to avoid is the presumption of no data-no problem. I was reminded of this by the section 18 reference. We have a section 18

chemical in Oregon. I think it was approved 16 consecutive years. In Europe it had been shown to contaminate groundwater. No one was looking in the groundwater to see if it was contaminating groundwater. Required protective gear for re-entry. No one was out there enforcing to see if the protective gear was actually used. So I think it's important so this does not have the appearance of spin. If an economic benefit is going to be articulated that there's also some discussion of what are those presumptions or the missing data that may override or undermine those claims as you're looking to make -- especially on the economic side of the picture.

MR. JONES: Gary.

UNIDENTIFIED MALE: An extension of what I was talking about earlier, by the way I don't think economics should be a factor in your measurement because that's not one of your -- the goals of the EPA itself and so I mean, well, maybe it is to a small degree but not -- I mean, it's not the emphasis. What I would suggest is that the agency does some benchmarking with their comparable agencies, maybe globally, maybe even the republic of

California, maybe the FDA, USDA, and so on, and get some ideas about how they're looking at the same types of questions, how they can measure themselves from a nonspecific standpoint of, you know, how many registrations we've given this year type of thing. I think a benchmark might be very useful to find out what they're doing and, you know, just do something comparable.

MR. JONES: Lori?

UNIDENTIFIED FEMALE: My comments are very similar. I think it would be a -- first of all, I enjoyed your report very much and I think that there's a lot of useful information and it's a great point to start and continue the discussion on the benefits of all the regulations and where we've come. I'm all for accountability. One of the things I think might be interesting, just like Gary just mentioned, is trying to evaluate the synergies and also areas of antagonism with other states. I think that there might be some really useful information there on how efficiencies could be increased both at the federal and state levels.

MR. JONES: Steve.

UNIDENTIFIED MALE: Well, I'm going to be disagreeable. First of all, I'd really struggle with the concept of chronic as much as I would love to see the ability of EPA to measure impacts on chronic health effects. I think the white noise would be so huge in a short time period. You're trying to measure the impact of EPA's decisions on chronic health effects? I don't see -- maybe, clearly you guys know more than I do about how you might do that, but it seems like trying to tease out the small issue -- health effect that EPA might have over a period of five years or something out of all the other impacts that occur in any human development seems very difficult. Secondly, I guess I disagree with Gary on the economic issue. I think there is a very important economic issue associated with EPA's role and that is to register pesticides that are of value. And we can register a lot of compounds that have absolutely no value to the American public and check off on the list that we have lots of registrations. It's an issue we've had discussion with IR4 about for years, that just ticking off a list of pesticides does not mean it's effective and that you are using the public's money in a wise manner.

And I think that's an important issue for EPA, is to be sure that the kinds of registrations that are being -- the new registrations, the new uses, and even re-registrations, even though that isn't necessarily part of the law, is of real value to all users. Thanks.

MR. JONES: Okay. Thanks very much. I appreciate all that feedback. For the last part of this session, which is -- **(END OF TAPE).** As Kathleen mentioned earlier in her presentation, the agency is -- the Pesticides Program is actually working with our colleagues and PPDC and the regional offices put together a work group that is focused on the body of work that you have before you. We are going to feed the feedback that you've given us today into that. We would like, however, I'd like to put on the table, the idea that we have going on in a parallel way, not necessarily part of the EPA work group but in parallel with it where there's information going back and forth between the work groups, a PPDC work group that is working on the issues that we discussed here today, further giving us insights into -- along the lines that you just did here but with a little more time for you to digest what we've done, perhaps

bring forward information you think might inform any of these results or other results, help to see if we can come to some consensus on some of the issues like were being discussed here today. Is there value to it? I'm going to refer to it as intermediate results or are they generally not that useful? Is there consensus around here is the next area that the agency needs to focus on, here are the next two or three areas that the agency needs to focus on. So I would like to see a subgroup of this PPDC that represents the breadth of the stakeholders that we have around the table, working in parallel to the EPA work group around results that this work is -- it's become pretty clear to me in the last year of critical importance to our ability to succeed in the context that we're operating in right now, with both the Congressional oversight as it relates to results and the administration's insistence the programs demonstrate results or perhaps they won't be programs anymore, to be blunt. We need to take this and we need to do this and we need to do this in a serious way, but I think it's best informed when it isn't just a group of people in Washington, and I use that term broadly, meaning all of

the EPA, but people who have a breadth of experience that we may not have access to and that is why we have this group, frankly. So I would very much like to ask if the PPDC would like to accommodate that and if enough of you are interested in it we will have a work group that is basically working on results and indicators. So if you can give me some -- you don't need to sign up right now, but if you can give me some reaction to that I'd appreciate that. Beth?

UNIDENTIFIED FEMALE: Yes.

(Laughter.)

MR. JONES: Steve.

UNIDENTIFIED MALE: (Inaudible.) I think it's a great idea and one of the things that I'd like to see is I remember I took enough statistics to just get in trouble but I remember one of the things you're not supposed to do is take a database and search for a hypothesis and vice versa, have hypotheses and search for the database that'll fit it. It would be nice to actually establish precisely what the measures are going to be and then go forward and measure those so that we really are truly measuring what we think is an impact

versus trying to randomly fit stuff together. And I realize that's the inexpensive thing, portion that you had to do, but maybe we can sort of combine the two.

MR. JONES: Jennifer.

UNIDENTIFIED FEMALE: Yes. And I'll sign up. And you often start out by actually picking a database and looking and seeing what kind of hypothesis pops up and I think this fits that as a crude first pass to help us all to see what's there, what the landscape is, and what kinds of tools we might get out of it to refine this job that I think it pays taking on. I'm supporting it.

MR. JONES: Thanks. John.

UNIDENTIFIED MALE: This is really a question to see how much we can help from some of our other experiences. Do you all tap into some of the other federal agencies like the NTP and the FDA. Are they part of your working group or is this just strictly within the pesticide group?

MR. JONES: Right now it's EPA, the two, at least two, the two agencies that are soon going to be asked to join are sitting up here with me. Actually that's two agencies, USDA. FDA certainly got data that

is of interest to us as does NAIHS and other parts of HHS but -- and then we'll be talking to them about whether or not they can afford to participate, but we're certainly interested in exploring data that they've got available. So yeah, they will be very much party to the work that we do. Oh, Julie, sorry.

UNIDENTIFIED FEMALE: Yes, I also agree and maybe even looking at your existing work groups and having those groups look for what they can measure within the work they're doing and, you know, to start, you know, as we're doing these work groups and what's that work group out set to accomplish and what then are some measurable results from that work group. And I think in particular process improvements, but -- and the consumer labeling as I already mentioned. As we're putting together recommendations from these work groups we should also be thinking about, well, how are we going to measure what we've done?

MR. JONES: Thanks. Carolyn.

UNIDENTIFIED FEMALE: I just wanted to make a request that maybe we have two work groups, one that would focus on subobjective 4.1.1 and the other focus on

4.1.2, since there seems to be people with different expertise in each of these areas. They might work more effectively if they were separated.

MR. JONES: We'll take that under advisement. Thanks. Frank.

UNIDENTIFIED MALE: I just want to express strong support for the work group to address the results and measures.

MR. JONES: Thank you. We've never had such diverse support for anything.

(Laughter.)

MR. JONES: Rebecca? Not to set you up for --

(Laughter.)

UNIDENTIFIED FEMALE: I guess in the notion of establishing work group, you know, just toss the idea out and what would be the receptiveness, hating to come back to the almighty dollar, but the reality is much of this is working towards supplying folks like OMB with what they need in order to justify what you need to continue on down the road of getting the resources and I guess I would be remiss if we didn't all note that a lot of this information is going to be used for those sorts of

purposes. So it's a good exercise for a whole host of reasons. And I guess along that vein, having been a part of the PSEP evaluation or sort of internal look at itself and what it means and how you value the results of a program like that, appreciating the pressure that is put on you, not always fitting within the OMB traditional boxes of how you measure results and how you show things of value that don't fit nicely on charts. Would it be a value for the work groups to consider some sort of capacity of corresponding or in some way supporting you as an office in showing that -- or helping them to understand that that's not -- that not everything necessarily that you do is going to fit within the context of what OMB and other budget-minded people are used to quantifying and justifying. And you know, I'm not sure exactly you know the mechanism to do that properly and appropriately without getting you guys into trouble, but, you know, I think it's a message that they need to be hearing, not just from the Office of Pesticide Programs but from a lot of places that are feeling similar pressures of losing resources to do very important things that just don't fit neatly in the

traditional packages that OMB likes to see them in.

MR. JONES: Right. Well, what I can say, and it's fair for someone in my position to say, I can't totally comment on everything you've asked, but what I think is true and will get a hearing is if we're working with our stakeholders meaningfully on results and being able to find some areas where we can demonstrate them, whatever they are, that that will carry a lot of weight. I think that will be a way of being effective. Now, there certainly are other ways of being effective that I'm not going to comment on but -- you probably know what they are. Amy.

UNIDENTIFIED FEMALE: Just to say that I certainly support this effort, too, and since PSEPs already have to do this and we have some subinitiatives we're willing to give you 8 to 13 percent of the credit for the amount that you support the program.

(Laughter.)

MR. JONES: Hey, just bring your data, is all we really want. Dennis.

UNIDENTIFIED MALE: Yeah, I just had a question about timing for the work groups to get the kind of

information input to the agency that they need. What sort of time lines are you looking at for having measures in place and then going back to OMB with them? Can you talk about that a little bit?

MR. JONES: The next report that we're going to be doing, I think it's a year -- go ahead.

UNIDENTIFIED FEMALE: It isn't scheduled yet. It could be as soon as next year and I think when we were doing our sort of tentative planning focused more at that point around our agency regional state work group activities, we were looking to have things in fairly good shape by the start of the new year if I recollect Sherry? Is that -- not that it would necessarily be all perfect but that we would have a good set of indicators that we could actually show some measurement with, not just a conceptual idea but here's the idea and here's actually what we've measured and here's what it's showing at this time. So I would presume if we set up the kind of mirror groups inside the PPDC that's the general time frame that both of the groups would be asked to do initial work.

MR. JONES: Thanks. All right, well, that seems pretty much a consensus. We will endeavor quickly

to get back out to you using the various means we have to electronically communicate, to find out who wants to participate in this work group and Sherry Sterling, who's sitting next to Kathleen, as I mentioned will be the EPA point of contact. All right. Thanks very much. That was helpful. Okay. The next session is -- this is another part of our agenda where we're basically going to hear about a follow-up activity that we have talked about before. And Len Sauers is going to lead this session. Len?

MR. SAUERS: Thank you. And also joining me is Dr. Rodger Curren. He's President of the Institute for In Vitro Sciences. He'll be speaking after me. I just wanted to spend a moment talking about why this particular piece of work is important to the cleaning products industry. About 20 years ago research began in earnest on animal alternatives to find replacements for the use of animals in a lot of safety testing. The work predominantly focused on skin and eye irritation testing replacing animals for those end points and focused predominantly on the cosmetics and cleaning products industries. And although that research has been very

very productive, about five years ago we had gotten to the point where we had viable non-animal testing methods for skin and eye irritation and these methods were employed broadly by industry at that time to evaluate skin and eye irritation of cleaning product formulations. So as of today, those animal tests are no longer used to evaluate these particular end points. For the cleaning product sector today, though, the only place where we need to use animals to evaluate the skin and eye irritation testing of our formulations is for the registration of antimicrobial products under FIFRA. It is the only place we still need to do this testing. And it represents a small part of our business. I'm with the Procter & Gamble Company and we're fortunate enough to have a 50 percent share of the cleaning products business in the U.S., and only about 5 percent of our products are actually registered cleaning products, registered pesticides. So the vast majority of the products that are out in the marketplace today have had their skin and eye irritation evaluated through the use of non-animal methods and have had labeling determined through the use of non-animal methods. So we wanted to embark on this

program here to take this one last piece, where we still needed to do animal testing and bring that now to the point where animals were no longer needed. And that's why it was important for this program to get started and why we initiated it. I'd like to turn things over now to Pat Quinn, who's going to give a quick synopsis of the sequence of events that began 18 months ago up to today and then turn it over to Dr. Rodger Curren, as I said, he's President of the Institute for In Vitro Sciences, and he's been the technical leader of the program and he'll explain to everyone where we are today in the process.

MR. QUINN: Thanks Len. I just -- for those people who may not have been through the discussions that this committee has had on this I just wanted to review the bidding very quickly. As Len said, this discussion started about 18 months ago here at the PPDC. This is a PPDC project. It is something where there was a fairly broad expression of interest by members but something where Jim I think also decided that it needed to be taken outside of the committee itself and put into a project that clearly was going to require technical review of the

adequacy of the methods and this is important for a narrow regulatory purpose. Much of the work that ICVAM has done, the interagency committee that validates the test methods, is a very broad validation across many product sectors. What's different about this project is that we're trying to establish the adequacy of these limited number of methods for EPA to do its business, to make labeling decisions, one through four category labeling decisions, based upon the use of alternative tests for these two particular end points. It's a novel idea. It's a new model for ICVAM. Bill Stokes, who is the head of ICVAM, and Jim have corresponded back and forth. Jim set forth some goals in a letter to him where we'd like to see these methods reviewed by the end of this year and assuming that they are valid, then proceed toward development of an interim policy where the agency could decide whether or not it wanted to implement the methods as alternatives to the animal test methods that exist. And I'd just like to say there are a number of people here at EPA who deserve some thanks for their leadership on this, Jim among them, I think Debbie Edwards, who very early had a lot to contribute to this

project, and more recently Tina Levine, who's also been a great partner as we've worked through these issues with people at NICEDEM. And with that I'll turn it over to Rodger.

DR. CURREN: Thanks Pat. Can we go back to the first slide? Much of what I'll say here is an iteration of what Len and Pat have said. But essentially what we want to do in a diagrammatic fashion that I put up here is take antimicrobial cleaning products and some examples of things that you're quite familiar with, put them through some type of non-animal hazard evaluation, and determine ways that we can make a good estimate of what the hazard is. A lot of it perhaps through formulation analysis, and then additionally with in vitro test information. And then use that information to give it an EPA, classic EPA labeling category. Example, caution toxic category three eye irritant. What Len said, and what I think is very important and is important to us as we do the technical portion of this activity, is that many of the products that up until now have been required by EPA by the Pesticides Program to have the animal testing are very similar if not virtually identical to

products that are on the market today and that the companies themselves have made the safety decisions on using non-animal test methods. And you can see some of these products up here exist without an antimicrobial label as well as with it. Next slide please. The general approach, we tried to be almost a bit into overkill here, because we know that the review of these methods is not going to be done just by the pesticides group within EPA but by a broader scientific community. And so we wanted to make sure scientifically we're on the right path so we've taken the approach of dividing these cleaning formulations into smaller categories where each category is defined by the type of eye irritation that might be caused by this product or by the mechanism of action of this material in the eye. We then wanted to gather both the non-animal and the existing animal data where it occurred, we aren't conducting any new animal tests for these studies, to have these contributed to us by manufacturers in the area, look to see if we have enough data from that set of information to make -- to be convincing and make decisions. If not suggest that there was potentially in vitro information that was needed on

some of the materials, do that testing and then take all the data that's in this data base and combine it into some type of intelligent testing program, and then determine how predictive that testing program would be. Next slide. Probably ending up with some type of tiered approach that would start with knowing the formulation, the materials in the formulation, knowing the pH and so forth, and moving down through this essentially similar to globally harmonized systems that exist today. Next slide. The time frame has shifted a lot since we started the program. One of the major reasons has been that we were able to obtain much more information and data from manufacturers than we ever thought was possible. So things have moved out a bit. This is the time frame that we're looking at now, such as at the point we are now is looking for the final data gap identification, deciding what testing needs to be initiated, going through the testing, doing the data analysis, and then hopefully having a complete submission document for, as Pat said, ICVAM, mid-September, mid-October range. So fairly tight time schedule. Next slide. The progress, the actual progress we've had, we've made the decisions on the

categories on the types of eye irritation that we expect. We've had agreement on the confidentiality from the companies, which is that none of the data in the submissions could be linked back directly to an individual company. So it will all be looked at as a mass. And we determined and had agreed from the company as to what the level of formulation description would be. In other words, in broad percentage range for the different components of the materials. What is very encouraging is that we've had seven companies now who have been willing to submit data to the project, Clorox, Colgate-Palmolive, Dial, Eco Labs, Johnson, Diversy, P&G, and SC Johnson. This has been very very helpful. And right now we have about 330 existing animal studies, 280 that probably have all the individual animal data that we need, about 500 in vitro studies. Of these, you know, some of the animal studies are on one set of compounds, some of the in vitro on another, but we have at least 160 paired where an animal study and an in vitro study were done on the same materials. And there may be one more slide I think. All right. If that's it, that's fine. Anyway, that's -- as I say the most encouraging thing is

that companies are willing to put some of this data out here that they've collected all the years in a good common cause that's going to be very helpful to everyone and I commend them for it. Thank you.

MR. QUINN: I guess I just wanted to emphasize that this was not intended to be exclusive to antimicrobial products or antimicrobial cleaning products. It simply was a model and a group of products where there appear to be a particularly robust set of data where you could go ahead and establish some progress early on. And certainly we hope it's going to be a model for an expanded examination. I guess the other thing, just to note that on process what Rodger will be doing actually with his colleagues is preparing what ICVAM calls a background review document. It's the technical document that will go to their expert panel that will review the data and make some judgments about it, perhaps late fall, perhaps early next year.

MR. JONES: Great. And we basically wanted to stay true to the principles of this committee in that work that we ask some group to -- some subgroup of us to proceed, that we come back and explain, you know, here's

where we are, here's what we're doing, here's what's going on for this committee. I think this particular project, because the ICVAM process, this Interagency Committee on the Validation of Alternative Methods, is a public process, I think we're also achieving a level of transparency above and beyond what the PPDC offers in that the evaluation of what we're going to see out of this effort is going to go through a very public process. But we wanted to give you all an update. If anyone had any questions or observations? Jennifer.

UNIDENTIFIED FEMALE: I have a quick question.

MR. JONES: Sure.

UNIDENTIFIED FEMALE: I don't understand what the test is. What are you doing? What are you sending to ICVAM? What is the test? What is your solution?

DR. CURREN: There are -- because we have a diverse group of companies there's more than one test that had been used by the companies to make their safety decisions. The vast majority of the data right now are coming in utilizing three methodologies. One is what is called an ex vivo model. It's using an excised cornea from cattle that are normally used.

UNIDENTIFIED FEMALE: We saw that presentation, right?

DR. CURREN: Yes.

UNIDENTIFIED FEMALE: That was impressive.

DR. CURREN: And then there's another model which uses a reconstructed human, using human cells, essentially a reconstruction of the outer layer of the cornea.

UNIDENTIFIED FEMALE: Like the epi-skin, epiderm type thing?

DR. CURREN: Exactly.

UNIDENTIFIED FEMALE: Yeah, I think we saw that too.

DR. CURREN: That's right. And the third is using an instrumental technique that measures very small changes in the cell's metabolism after a toxic treatment. And that's used for mild compounds.

UNIDENTIFIED FEMALE: I remember that. That was the corrosion test.

DR. CURREN: Mm-hmm.

UNIDENTIFIED FEMALE: I remember that. So what you've done then is you've collected data on the

different companies that have used those three different tests for their products and you've basically collected all that data and then used it to compare -- what have you done?

DR. CURREN: Well, you're speaking in the past tense here a bit and it really should be in the present tense.

UNIDENTIFIED FEMALE: Then let me ask what you're going to send to ICVAM.

DR. CURREN: We will send to ICVAM a description of how the final in vitro methodology that we've chosen, which is as I said again, some part of the decision made on the basis of what constitutes the formulation of that product, what we know about it, with the results of the in vitro tests, and combining that information will come up with a prediction of what the EPA labeling category will be. We'll have evidence that this is a correct approach because we have this historic information of animal tests that were already done on the same products. We know what the EPA labeling is on that, we know what it is on similar products, so we know what the -- also the error associated with that, which is very

important in this type of study, especially since the EPA utilizes the results. A single rabbit's information can drive the labeling, so it's not the average but it can be -- so you have to know what the range of that error can be and then the combination of the data graphically even will --

UNIDENTIFIED MALE: And just to add to that, we stopped using the animal studies five years ago and for us to be able to move away from those studies five years ago prior to that we had run paired studies of the in vivo study and then the non-animal alternative. And once we got to the point where we had collected enough data to show that the non-animal model was indeed predictive we made the switch. And a lot of companies did that back then. So in essence we're just taking all those databases which allowed us internally to move to the non-animal methods, collecting them all from the various companies, putting it all together, and now giving it to ICVAM, expecting them to come to the same conclusion we came to five years ago that you don't need to do these animal tests anymore.

UNIDENTIFIED FEMALE: Okay. So let me just

clarify. There is no fourth test then. I have this vague sense that you had the three and then you were putting them all together to come up with the perfect one or something. There is no --

DR. CULLEN: Well, I focused on eye irritation. Here there's also a section on skin irritation. If we were doing that there's going to be clinical trials or in-use trials that would -- information from those that would factor into it.

MR. QUINN: And we want to keep it simple so these three tests appear to be able to cover all the needs that everybody has, so we'll keep it limited to that.

UNIDENTIFIED FEMALE: Great. Thank you.

MR. JONES: Beth.

UNIDENTIFIED FEMALE: I just would like to ask if you guys could make these overlays available, these slides available? Because some of -- I know that some of my colleagues in the EU will be very interested in them because they work on that. And then secondly, I was just remembering a past presentation. I think it was the same one that Jennifer was talking about where there was a

gentleman, ORD maybe, that discussed computational toxicology and have you guys been following any parallel with them and what's going on there?

DR. CURREN: We all have. I think for right now those kinds of methods are not at a point where they can be a full replacement. They're certainly helpful. Personally I see that as the next iteration five or 10 years out where we move away from these cell culture based methods and then everything is going to be done on the computer. And you won't need toxicologists then.

(Laughter.)

MR. QUINN: And these slides are available here so I'm assuming they can make them.

MR. JONES: Julie.

UNIDENTIFIED FEMALE: Well, I think this is a good way, you know, where you're looking at what the existing data tells you and using all that existing data to be able to make sound decisions and recommendations. And we did a similar thing then also with the granular pesticides where we collected all of the existing acute toxicology data and realizing that based on the toxicology data on the active ingredient and knowledge of

the formulation you could make very -- you know, that we saw the same results over and over and over again. And I think it was Tina Levine at that point said why do we keep looking at the toxicology of fertilizer, because that's really what we were looking at. And I think wherever we can see opportunities for, you know, using existing toxicology data if it's the data on the active ingredient for a given type of formulation, you know, low level, ready-to-use, you know, liquid. If they're the same types of formulations and we're seeing the same results over and over and over again I think you can probably, you know, start to say we can -- I guess it's a predictive kind of way. Based on the data we know and the large amount that we already have we can make a recommendation or we can make a labeling decision without doing another full six-pack.

MR. JONES: Thanks Julie. Jose, did you have a question?

UNIDENTIFIED MALE: Yeah, I'd just like to know how the parameters are set for all these tests. I mean when you're doing irritability tests when do you know when you got below a certain level is okay, above a

certain level is not. Who sets the parameter? What is less than desired or above what is desired? How is that thing done?

DR. CURREN: Well, if you're talking about the existing methodology right now and we're talking about a rabbit eye test that is often used. And there are grading scales for the rabbit eye test based on primarily within the EPA based on whether that rabbit eye if it's injured if it recovers within 21 days or not. And that's sort of one of the major cutoff points. And then there are four other categories. There are lower cutoff points of seven days or 14 days, changing. But it essentially looks at things like cloudiness of the cornea, redness of the conjunctiva around the eye, and grades these at certain levels. And then essentially the bottom line is has this reversed in 21 days or not. If it hasn't reversed in 21 days then it gets the highest category labeling. And then the in vitro correlate will say, you know, what are those scores in vitro that we find historically end up with the same product having the rabbit not reverse in that 21-day period or 14 or whatever.

MR. JONES: All right. Thank you. We're going to take a break now until 4:00 and then we will finish up for this afternoon. Thanks.

MR. JONES: Well, let me just apologize in advance. I need to step out a minute to take a call from my boss. There's only one or two people I'd do that for but the boss is one of them. Anne Lindsay is on the agenda right now to actually give a number of updates and so I'm going to turn it over to Anne and I will be rejoining you in hopefully about 10 minutes.

MS. LINDSAY: Okay, this is what you call good planning. You put me on the agenda at just the time that Jim's boss calls. I've got a series of three updates that you can see on the agenda. And then Lin Moos is actually -- it's not what I really think of as an update. It's more like a prequel or something like that. It's an early alert advance notice of tomorrow afternoon. So I'll start with Part 158 and just so I'm not speaking bureaucratic babble, that refers to a section of the Code of Federal Regulations where we have a regulation that articulates basic data requirements for getting your product registered. And it's been in place since 1984.

Prior to that time we had no articulated data requirements and it was all a case-by-case kind of decision making process between the applicant to EPA and the EPA. And it was sort of the system I think we'd actually inherited from USDA and FDA. So 158 was a landmark regulation in 1984 and it is sort of kind of part of the fundamental base of our program at this point because you can't make sound scientific decisions if you don't have sound data and information to inform your risk evaluations and then your risk management decisions. We have actually proposed a revision to Part 158. We issued it at the beginning of March, March 11 to be exact. And what it actually does for those of you who may not have looked at it, it specifies what data is required to register a product and when it is required. Like if you don't have a food use pesticide there's certain data requirements you don't need to do. But if you do have a food use pesticide you've got other sets of data. The proposal is actually largely an update to reflect practice as it's developed between 1984 when the current rule was issued and now. So over time as we've made case-by-case decisions on pesticides our practice in

terms of what we required for data expanded beyond what's in the current 158. This proposed revision largely just codifies that. There are some areas in which there is a change but by and large the bulk of it is just putting down in writing what we believe we are currently doing today. The other area that it focuses on is trying to clarify categories of use. Your data requirements are often impacted by categories of use, my example of food or non-food. And we felt that the original Part 158 was ambiguous in a number of ways with regard to those categories of use and that if we could clarify them based on our experience in using Part 158 it would be a more useful tool for registrants and others who actually care about what our data requirements are. So there are changes in that regard. And we think that by putting out a rule that largely codifies our current process and practice that registrants for example will be able to do better business planning when they're actually developing a new product, a new active ingredient. We think that we will do a better job in terms of increased consistency across our individual actions. One of the downsides of case-by-case is that it can allow for sort of an

inconsistency to creep into what you're doing, although it also gives you flexibility, which is a good thing. How you actually have to conduct the studies is not part of the rule making, so that these are not test guidelines and there's a whole separate process for test guidelines that are essentially protocols about how to conduct the studies. And for almost everything that's in Part 158 test guidelines are in place. In some cases there are some of them that are being updated through kind of a standard scientific updating process that both goes on within the agency as well as outside the agency, and in fact through the international community through the Organization for Economic Cooperation and Development.

Last week we held a workshop on May 3 and 4, focused on the proposed Part 158 and it was not to take comment at the workshop per se, but simply have our agency scientists who were involved in putting it together walk people through what was in there so that people who do want to comment on the rule hopefully will be able to do that from the basis of understanding what's in there and just be better informed in terms of making their comments. I think from experience with other rule

making part of the time you discover that although you thought it was really clear when you wrote it, and you put it out for comment, in fact it wasn't all that clear and you get a set of comments that are reflecting confusion that then need to be sorted through. It's kind of like the example from earlier today when Lori MacKinnon was asking what we meant by our endangered species indicator. So we're hoping that that workshop, because we thought it was pretty well attended, will serve a good purpose. The comment period, or at least I would say the initial comment period, ends June 9, about a month from now. Just in the last week we've gotten two requests for an extension of 90 days and the agency is currently considering what it will do with that extension request.

A few other things I should probably mention in relation to Part 158. We held an SAP meeting last week also as I recollect around one of the specific proposals for change in Part 158 and that's the deletion of the chronic dog study. We've gone back and done an analysis of what we learned from a whole set of chronic dog studies that we received over time and what it would be

like basically if we hadn't received them, how much that really would have impacted the decision and a similar analysis actually has been done in Europe, I think led by a German team. And so we took our work, the work from the German exercise, to the SAP last week. Thought it was a good meeting. I was not there, some of you may have been there but I'm hearing verbally is they were very interested, thought it was good that we'd actually done this retrospective look across the data set to see what you can learn from it. But I gather that they also wanted us to do more analysis, think a bit more about his, and also to make sure that as we were considering the deletion of this dog study requirement that we were vetting it globally. And that we not simply approach it as a purely U.S. domestic kind of issue. So we'll see what their actual written report says but we thought it was actually a good meeting.

The other piece that I wanted to talk about is there is a variety of other work that EPA is involved in but many people outside of EPA are involved in to take what I would call a more fundamental rethink of the approach to data requirements. And actually in last

session there was some allusion to some of that work. The work that's been done through ILSY. NAS is actually doing work. There is a whole array of scientists doing work in the arena of comp tox. And we think that this is very important, very exciting work. From our perspective this is work though that's still largely in the developmental stage, in various stages of development. I mean, some of it I think is really a 10-year out, some of it may be five years out. We're going to be doing a lot in terms of putting together a strategy for advancing that work. We would like to see it when it is really ready to be put into the regulatory framework and used to make day-to-day decisions. We'd like to see it get to that place as promptly as is possible but that's not what this particular proposal for 158 is really about. And in fact what we think is that by doing this sort of housekeeping function in updating 158 and bringing it to reflect the current state of affairs, as we're ready over time to phase in this more radical rethinking of how you approach testing requirements so that you get testing I think that will actually deliver more information than current studies do, that will probably in many cases

serve to actually reduce the need for animal testing, will reduce costs, and I think in some cases will speed up time to testing, which means faster decisions. Having an updated 158 as the place to work from is something that we're going to need just as a matter of good housekeeping. So that was really all I had to say about 158. But do get your comments in. We need the comments.

Mosquito labeling is the next update. And I should probably start here with actually a thank you to a number of organizations. First and foremost of course to the Pesticides Program Dialogue Committee. We managed to issue our PR notice on upgrading the labeling for mosquito adulticides this spring at the beginning of March. In fact, there was a reference to it earlier as an example of good improved labeling. And I think that it would not have been as good a PR notice if we hadn't actually come to the PPDC at least twice as I recollect to get your advice and input as to how to handle some of the tough issues. And also some other folks that we probably ought to be talking to as we were putting it together. We basically think that we're going to as a result once the labeling goes into effect, mosquito

control for adults will actually be more effective than it is currently because there's clearer, more appropriate labeling. We think because of that public health will be better protected and we also think that the environment will be better protected because you're less likely to introduce more pesticide into the environment than you need to in order to achieve effective control. So it should be a win-win. There are a lot of different recommendations. Some of them go to training, to clearly distinguishing directions for mosquito control from farming operations. Some of the existing labels are kind of garbled on that front. It provides a model environmental hazard statement. It encourages consultation with state lead agencies and tribes for pesticides so that if there are local requirements vector control officials will know what they are. And then there are a series of technical changes around droplet size and treatment intervals. And one of the early feedback we've heard from, sort of what I call the registrant community who manufactures these kinds of products as well as the vector control community. There is a little bit of confusion around the droplet size and

the retreatment intervals. And so just our broad advice at this point, and we will be talking to registrants of these products directly over the succeeding months, but the broad advice and if you can carry this back out into your community we actually think it would be very good if the principle registrants were to get together with vector control officials and actually talk through some of the issues around droplet size and retreatment intervals because we think this is practical information that derives from what registrants and the vector control community know about efficacy. And that's what we want to see reflected on the label. But I hope -- actually by the time we have a next PPDC, which would be in the fall, that we can report to you that at least the primary registrants have actually got approved new labels and by the next active use season the new labeling will be going into effect for as many of the products as possible. So thank you.

The last thing I want to talk about is drift, although I'm not sure when I say I want to talk about that's actually what I mean. I have to talk about it. And in a way I want to talk about it. It's a topic that

I think that those of you who have been with the PPDC for a long time and have been engaged in pesticide issues from whatever your particular vantage point is have spent probably considerable time and energy on it one way or another over the years. Drift is definitely a fact of life. If you're going to use a pesticide, there will be drift. It does contribute to nontarget exposure so there's no getting around that. I think over the years our capacity to estimate both exposure from drift and therefore risks from drift has grown substantially. We certainly have a lot of modeling tools that we never had before and those modeling tools are sort of under continuous improvement. So from that perspective things have really advanced. EPA's goals in dealing with drift I think have always been first and foremost to mitigate any unacceptable risk that result from drift. Kind of bottom line for us. At the same time what we would like to be able to do with the labels in this arena is to provide the folks who are really going to use the product with practical instructions, instructions that can be understood and can be followed and sort of the assurance that if they follow those instructions that they'll be

doing their job right and they're not going to be at risk for an enforcement action, for example. So long as they follow that label. And we do want to make sure that the label allows our state and our tribal partners to take effective and timely enforcement action when it really needs to be done. And so those are kind of the three principle criteria that we've always tried to use to guide our actions. You all will remember that we have a long difficult public dialogue about how to improve the standard labeling. We were actually hoping to have a PR notice that in some ways would be similar to the PR notice that we did put out on mosquitocide labeling that would serve as model language that would across many products serve to standardize things. And that was the process that I think at the time, well, I don't just think I know, at the time didn't really meet with the kind of success and sufficient agreement amongst all of the stakeholders to really allow us to move forward with that PR notice. So we've not done that. And in terms of making our individual decisions on pesticide products we've been very much following a case-by-case process starting back with the science. What do the best most

refined models show us? Where is it that we really need to do risk mitigation? What is practical in terms of doing it? And trying on a case-by-case basis to follow those three criteria. And working very much with registrants and anybody in the stakeholder community who has a stake around a particular pesticide. And I actually think that's served to make decisions go forward on an individual case-by-case basis and it's not been a bad thing to do. In addition to that we've actually been working with our Office of Research and Development and the part of our Office of Research and Development that actually has been a contributor to the creation of programs like the Energy Star Program, and looking at would it be possible to actually take a particular drift reduction technology, measure the amount of reduction that's achieved with sufficient reliability, to be able to then go back and look at the label of the products and say, Oh we can change some of the risk mitigation measures, we could reduce the buffer zone, we could alter some other aspect of the drift labeling if the user uses this specific type of drift reduction technology. We know in Europe, for instance, there's extensive use of

drift reduction technology that's not use here in the U.S. and it does achieve substantial reduction, anywhere I think from 50 to 85 percent drift reduction. So we're looking at that. We're in the very early stages. Our Office of Research and Development actually runs sort of a competitive grants program that we're going to be applying to to see if we can get funding to actually test this concept and come up with -- it won't be called the Energy Star Program, but it'll be the -- maybe you'd like to suggest a name for it. The Drift Reduction Technology is what we're calling it now. So I actually think that that's an exciting development that we I hope will win the grant and will be able to move forward on it.

The last thing though that I wanted to mention is that for a variety of reasons drift is sort of a policy issue, has been in the forefront of both work within OPPTS as well as our Office of Water, particularly associated of course with issues around the MPDES permit program and how that applies to drift. One of the questions that our senior management has asked us is whether we should consider starting again some sort of public dialogue around drift and the drift labeling and

all of the issues that actually we were engaged in in the past. And so what I'd like you to do is, not right now because this is just an update session and we don't really have time to have a discussion, but perhaps over the evening amongst yourselves think about at this point in time would you see value in EPA starting another public dialogue around drift and drift labeling for pesticides. And if so, what venues do you think would be appropriate? Do you think this committee or a subcommittee of this committee could be an appropriate venue? Do you think there is some other venue that would be better? How might we frame that discussion so that it hopefully would have a more constructive outcome than our last effort? It's very clear that there are really different perspectives on it. There are a lot of different issues at work that are not just related to drift but related to many other concerns that -- I think legitimate concerns that people have. So I will leave you with that. But I think tomorrow when we come to the end of the PPDC in that sort of half hour about future topics things that you believe the PPDC might be able to give us good advice on and that you're willing to get

engaged in, you might think about sort of what your advice would be on drift and whether to move forward and try to start a new public dialogue. So let me turn this over to Lin Moos.

MS. MOOS: Hi. I'm just going to briefly go through the agenda for tomorrow's meeting on the consumer label improvement work group. And actually I was surprised to find out it's on the back of your agenda so you probably already know what's there. What we're going to do is convene after the full PPDC meeting. I'll be in here at the end of the meeting and it'll be up to the folks on the work group as to whether they want to go two hours or if they want to go take off and get some lunch and come back. And I'll leave it to the folks in the room to identify how they want to work this. I don't know if people have flight issues or not, but we're looking at probably about two hours. We're going to go through the charge to the work group, what the mission statement is, what we're expecting as a product from the work group. Paula Boday is going to give a brief discussion on what's actually required on the label so that folks have a firm understanding of that as we go

into this. And then when I sent out the table with language that had been identified as problematic and suggested alternatives I got a great deal of e-mails from other people, from everyone, suggesting changes to the changes. I'll come in with the three sets of suggested changes. I could have had a table that would have wrapped around this room, moving commas, and changing one word here and one word there. But the two issues that seemed to -- the broad issues that seemed to be raised most frequently was the literacy level issue and so Amy Browne is going to lead a discussion on that with the group. And the second issue that was the issue that was most frequently raised was the alternative language that went from "do not" to "avoid or minimize" and there's very strongly held beliefs on both sides of that equation. And so Mary Ellen Setting is going to lead a discussion on that issue as well. And then we can talk about whether there are other broad issues that people want to discuss, either tomorrow if we have time or in a different forum. And then we're going to spend some time just talking about what's the process we want to use to go through and complete the project. The mission

statement had four outputs. I don't know that a room full of 15 people working on 20 sets of label language are going to be real productive to moving the commas and changing the words. Does a small group want to do it? Do folks think we should have criteria around which language we decide to do? Just an open discussion there and the process. Maybe there was something that was done in the CLI that was particularly useful in terms of breaking up different things. So that's basically the discussion for tomorrow. I will have folks from the registrations division and SRD here that do work with labels so that if anyone has any specific questions they'll be here as a resource for us. And the other thing we'll just have to sort out tomorrow and think about it today is whether to start at 1:00 or whether we want to delay and start a little bit later. So that's tomorrow afternoon. Thank you.

MR. JONES: Thanks Anne. Thanks Lin. Well, are there any questions for -- yes, Dan.

UNIDENTIFIED MALE: Thank you. Just a quick question for Anne on the Part 158 workshop that was held last week. Were the materials that were used in that

workshop available on the Web somewhere, the presentation from the staff on how to interpret that or read them and if so how would we find them?

MS. LINDAY: You know you just asked me a question I don't know the answer to, but I'll find out. Because I'm sure that if they had additional materials --

UNIDENTIFIED MALE: We promised to put them up on the Web and actually they're not there yet.

MS. LINDSAY: Okay. Thanks Gene.

UNIDENTIFIED MALE: Okay, if you could just let us know where they are when they come up because there are some of us who would like to have been here that didn't get a chance to attend.

MS. LINDSAY: Sure. Sure.

MR. JONES: Any other questions for Lin or Anne? Jose?

DR. AMADOR: I know this is going to be raised tomorrow but I'm going to be leaving just about the time you start talking. I would like to see something done on drift and maybe get a -- I mentioned that a couple of times before. It is an issue out there, there's no question about it.

MR. JONES: All right. Thanks.

UNIDENTIFIED FEMALE: Just a clarification. I'm not in the mosquito adulticide part of the business anymore but one of our affiliated business is a primary registrant there, and so I just -- was I correct that they understand what this issue is? The confusion over the -- and you know, is it -- I guess I'm just looking for before I report back to them and say recommend to them that they try to work with the -- I'm just trying to make sure I'm a little clear on where they're at.

MS. LINDSAY: Maybe I should talk to you off-line.

UNIDENTIFIED FEMALE: We can do that.

UNIDENTIFIED MALE: With respect to Part 158, in our request for an extension of the deadline we raised the possibility of an open stakeholder dialogue on that that's kind of more extended than just the public comments period. It's probably premature to discuss that now but I just wanted to raise the possibility so that the rest of the group is aware of it.

MR. JONES: Thanks. Anyone else? Okay. Well, I understand that we don't have any public commenters who

would like to either ask a question or make remarks so that being said -- oh, we do. Okay. If you would just introduce yourself and let us know who you're affiliated with.

MS. HOOVER: Sorry was I supposed to put my name down?

MR. JONES: Yes, but I didn't announce that.

MS. HOOVER: My name is Shawny Hoover. I'm with Beyond Pesticides. I did have a quick comment actually. In the background section of the pesticide registration notice, 2005-1, March 9, EPA stated that the proposed changes to the adulticides were presented to the PPDC and that there was essentially general agreement among the PPDC. However, you know, PPDC agreed essentially that the initial set of recommendations were generally appropriate is what was stated. And I believe this information is being presented much further, obviously, than this forum. Now, clearly, although not all of the objections that were later made to the proposal through the public comment process were made in this forum. Some of them were made. And there is record of that. And therefore we don't feel that it's accurate to say that

there was or that there is general agreement in the PPDC when public interest groups have raised serious concerns that are still not being addressed. So I'd just like to -- it's very important. I would also, you know, like to make it very clear to the agency that most public interest groups, and you know which you probably already know through the public comment process, but I still feel it's very important that we speak it verbally, that many public interest groups and several industries including those that are not otherwise represented here such as fishing associations, the honey bee industry, and others, object very strongly to the agency's proposed changes of the labels for adulticides. Several of them. These changes would essentially allow environmental mitigation measures that are listed on the label to be overridden when the, as we consider it, vague, widely subjective, and undefined notion of a public health threat is declared. And in the language that's used by the agency, it can actually be declared by a vector control agency. The addition of vector control agency, you know, declared by state, tribal, or local health agency or vector control agency. Now, the addition of vector control

agency to those that can declare a public health threat is extremely troubling. We believe it is vital that the public health departments be integral to any decision to use adulticides within any locality period. Lastly and separately I would just like to stress the fact that in the face of uncertainty of the effects of these proposed label changes on the environment and potentially on human health clearly, the agency should be indeed erring on the side of caution. It's not like you haven't heard that before exactly but we have done a lot of work in this area since 1999 as you know. And as a group with thousands of members and partners in small and large localities all across the United States, every mosquito season we get hundreds of calls from people reporting some harrowing practices of mosquito control including the sole reliance on adulticides without any conduction of monitoring, surveillance, or larval control. This is a major problem. In addition to that there is really no viable evidence that exists right now to show that the use of adulticides.

**(End of tape.)**

**PROCEEDINGS**

**Day Two**

**May 12, 2005**

MR. JONES: I hope everyone had a good evening last night. It was a beautiful night in Washington. Had a good day yesterday I thought and a little later on at the end of this session I'll summarize some of the follow-up that I've identified from our meeting yesterday and I'll add onto it whatever we decide to do following this morning's session. We're going to get started this morning with one of the follow-up activities. This is something that we began working with in the PPDC about a year-and-a-half ago and it has to do with getting stakeholder input into the design of the Registration Review Program, which I think has been a very effective model with how we in the Pesticides Program can operate, where when we're about to embark on a new program or some new policy development we early on get input from a broad, diverse group of stakeholders before we actually put forward a proposal. And then we're going to do some – we have a couple more updates, which I think will be of great interest to many if not most of you or all of you.

And our last major session this morning will be associated with endangered species, which I think most of you realize is one of the more challenging issues that we have in the Office of Pesticide Programs right now. So with that, why don't we get started and Jay Ellenberger and Susan Lewis who have been leading OPP's efforts around registration review program development are going to introduce the next session. Thanks.

MR. ELLENBERGER: Thanks Jim. Well, as many of you know, especially those of you who have been to the previous PPDC meetings in the last couple of years we've been giving presentations on our development of registration review. It will be the new way of doing business so to speak for how the agency reviews and reassesses all the pesticides in the future. Some of you and others have played a very important role in providing the agency with input and advice and suggestions on how we construct this new program as we are developing a proposed rule as required by FIFRA. I think in your packet that Margie mailed to you is an updated fact sheet on this topic and I hope it was helpful to those of you who are new to this issue. But as Jim said, Susan Lewis

and I have been the co-leads for this work group to develop not only the proposed rule but just trying to think with this external work group how to design this new process, that's got to be much more efficient given the goals in FIFRA for reviewing all of the active ingredients and all the products, all the registrations on a 15-year cycle. So it's quite a heavy workload, quite an ambitious goal for us. So in the past few PPDC meetings like this one, various work group members have presented summaries of issues that they've discussed with us, key issues that Susan and I and others in OPP have brought forward. Key issues that are important to us to help design, to think through the design of the new registration review program. So work group members have given a summary of not only the issues but some of their thoughts and recommendations to us, how we want to think about designing this program. But before we get into some presentations by a couple of the work group members, namely Julie Spagnoli and Sue Crescenzi, I just want to bring you up to date with where we are on drafting the proposed rule. OPP drafted the rule at the end of February and as required by FIFRA sent it on to USDA and

OMB for their 90-day review. Next week we will close on that 90-day review. But we've been talking with OMB to make sure they understand it and answer questions that they have and actually hope to wrap that up actually this morning. There's a companion meeting going on as I speak with some of the OMB reviewers. And if we are successful at that then we will move into the next phase which will be publishing the proposed rule in the Federal Register notice next month or in July for a 90-day comment period, to make sure that everybody -- as many people as possible, know about the opportunity to comment on the proposed rule. We will also put a link to it on our Web site. Right now we've got a Web site on registration review, keeping it updated with the issues that the PPDC work group has been working on. We'll expand that and as I said put a link to the Federal Register notice of the proposed rule, put on some summary documents and so forth. And also provide instructions for those who wish to comment how to comment. We are going to have an e-docket system so everything will be electronic. Not to say that we also won't take written paper comments but we will encourage the use of the electronics as much as

possible. We will also have -- plan to have some public workshops, one here in Washington and another one in another major city in the Midwest or west, we haven't picked that location yet. We want to -- during that comment period we want to have a couple of these workshops to sort of go through it and explain what is in the proposed rule, how we arrived at the proposals, and so on and so forth. And then also do a fair amount of internal in-reach to make sure that all the people in the Pesticides Program understand it, sort of what the schedule is, the implications, so on and so forth, and make sure our regions understand it and other key federal and state agencies that have a need to know and an interest in actively working with us in the future on our decision making for registration review. So after the 90-day comment period is over, this slide says 60, I think we're moving towards the 90 though, we'll then review the public comments in the fall and make changes to the proposal as we think is appropriate and then go through another round of internal agency review and back to OMB for their hopefully the final review. The goal is to publish the final rule early next summer as soon as we

can, so summer of 2006, and actually start implementing it in the fall of 2006. So it seems like a long time from now to then but it's really quite an ambitious schedule for us to do what we've got to do. But I think that the time that we've spent up front with this, the PPDC work group, and bringing the issues to you all and getting your comments I think is going to be well worth it. I think it's a good investment up front. I think the comment period will be smoother and our development of the proposal and the final will be much smoother than what we've done in the past with various rules. So the bottom line is we will be ramping -- as we ramp down for the current re-registration program, tolerance reassessment over the next couple of years and finish up product re-registration we'll be ramping up into the new registration review program. So let me now move into -- and turn this over to Julie Spagnoli of Bayer, who's going to share with us the PPDC work group's thoughts regarding the role of product label review and label revisions and the new registration review program and then following Julie, Sue Crescenzi of Steptoe & Johnson will give an overview of recommendations of the work

group on what they would like to see in our decision documents for registration review, the content and format. So with that, Julie.

MS. SPAGNOLI: Okay, I'm going to speak to -- you know, we've talked a lot about the active ingredient review but we also know that registration review will also include the review of end-use products containing a given active ingredient. May I have the first slide? Looking at some of the previous work group recommendations, this was the recommendations made by the work group to the committee last year, that following a decision on an AI and its uses, what uses are acceptable that will followed by a review of individual products containing that active ingredient. Product labels will have to comply with the decisions made for that active ingredient and its particular uses and with all current label policies. As we had talked of a number of times, we see registration review as this safety net, a way of making sure that all products comply with all current policies, so not only any new decisions that may have been made for that active ingredient but all other label policies that may have come into play during that 15-year

period. Also, products with multiple active ingredients may be reviewed and require updating more than once in a 15-year period depending on the schedules for the various active ingredients that it contains. The communication of the decisions with regard to an active ingredient will be communicated by a letter or some kind of communication to registrants. Data call-ins may be issued when necessary, but there will also be a public communication effort of the decisions made for an active ingredient and there could be agreements between registrants and EPA to set various conditions. But key in this with regard to the end-use products is that a failure to amend labels could lead to cancellation of those individual products. Looking at ways that we can communicate or the process for amending each individual product label we looked at -- there are a couple of options that could be considered. One would be a process similar to the current re-registration process which when decisions on required label changes for a product containing a given active ingredient and uses are communicated to the registrants via some type of decision document with the requirement to submit revised labels for review within a

given time frame. Currently in re-registration that time frame is eight months after issuance of the reg. Then the registrants submit those revised labels for review and then the agency reviews the labels for compliance with the required changes and either approves, approves conditionally, or requires resubmission with additional changes. The downside to this type of process is that the registrant may have overlooked other label requirements unrelated to the registration review process. If there were PR notices or other policy changes that weren't necessarily noted in the registration review decision, that could lead to additional rounds of submission and review and delay implementation of the new labeling. If there are products with multiple active ingredients this could pose complication of registration review time frames where various active ingredients are similar. A registrant may submit labels for one active ingredient and then, you know, a couple of months later have to submit another round of labels and they could all be in review simultaneously without being really consolidated. An alternative process that we could consider is that, you

know, the decisions and label changes for a required product containing a given AI and uses are communicated to registrants, but then instead of the registrant submitting a revised label the agency reviews current labels and notifies registrants of all labeling changes required, both to comply with the registration review decisions and all other labeling policies. And priority could be given to product labels with uses of concern. Then registrants submit final labeling and release products for shipment with revised labeling by a given date, likely 18 months. Registrants can contest the required change by submitting a rationale and if accepted receive a stamp accepted label. Compiling the current labels could pose a difficulty. Products, again products with multiple active ingredients can pose a complication if AI time frames are similar. And if large numbers of labels have changes that are disputed this could also delay the implementation of revised labels. But again, you know, looking at for the most part this may be a way of addressing labels with uses of concern first and getting those changes into, you know, made more quickly. There has been some discussion with regard to the timing

of getting label changes made. Currently the regulation at 40 CRF Part 152.130, states that normally if the product labeling is amended at the initiative of the registrant by submission of an application for amended registration the registrant may distribute herself under the previously approved labeling for a period of 18 months after approval of the revision unless an order subsequently issued by the agency under FIFRA section six or 13 provides otherwise. However, if paragraph D of this section applies to the registrants' products, the time frames established by the agency in accordance with that paragraph should take precedence. And what paragraph D states is that a product's labeling -- if a product's labeling is required to be revised as a result of the issuance of a registration standard, label improvement program notice, or notice concluding a special review process, then the agency can specify in the notice the time period that previously approved labels may be used. In all cases, supplemental or sticker label may be used as an interim compliance measure for a reasonable period of time. The agency may establish dates as follows governing when label changes

must appear. There could be a date after which all products are distributed or sold by the registrant must bear revised labeling and the agency may also establish a date which no product may be sold or distributed by any person unless it bears revised labeling. One thing to note that this regulation was promulgated May 4, 1988, and therefore does not address implications of re-registration, tolerance reassessment, or registration review specifically. But, however, time frames can be specified for revisions that are due to cancellation of uses subject to FIFRA section 6. So currently the regulations don't specifically address either re-registration or registration review as far as time frames but obviously there's -- you can look at sort of the intent there is that there could be interim measures. There could be supplemental labeling or stickering that time frames can be specified based on the seriousness of the labeling changes and I think, you know, we would see that same type of application here for registration review. One of the things to consider when we're looking at the time required for implementing label revisions is existing product inventories, production schedules, lead

times for the production of new packaging and printing of new labeling, the complexity of packaging and labeling. Some packaging, you know, if it's a cardboard box it might not be that complex, but you know, some of the newer packaging on products is much more complex and may have more longer time frames associated with getting it produced. Also the number of product SKUs, the actual, you know, one registration may actually have six or seven SKUs which means you've got six or seven sets of packaging even for one registration. Also there's the issue of just disposing of obsolete labeling and packaging. If you have lithograph cans, if you have to dispose of a lot of them there's significant costs and issues associated with disposing of obsolete packaging. And just costs in general, for making labeling changes can be significant. Time frames that are shorter than 18 months can be problematic for a number of reasons. One is that production is often not a continuous process. In some cases products are only produced once a year. They may do one production run for an entire season. And so, you know, it's not going to be possible necessarily to make label changes, you know, within a season. It is

often most efficient to consolidate multiple changes at one time,, once a year is typical. Generally if labels -- there may be graphics changes or other changes and registrants will typically consolidate all their changes into one printing change once a year. Low sales volume products may have very slow-moving inventories. You know, you just have a lot of existing inventory of product with the old labeling and it may just not move that quickly and be able to be changed that quickly. In some cases state approvals may be required for labeling changes. In particular, I think California and New York will often review revised labels. Lead times for packaging may not be flexible. It may not be possible to get new packaging in a shorter time frame and even if it might be possible to shorten these lead times it may increase costs significantly. It really ranged -- I kind of surveyed some registrants on these label changes and it really depends on the kind of packaging, but it can vary from twice as much to five or 10 times as much, you know, just to expedite the packaging. Also formatting, editing, and review label changes takes significant time. A compressed time line can increase potential for errors.

Most registrants have some process by which, you know, the proposed label or revised label is reviewed by usually the regulatory department to make sure that there are no errors or that all the changes have been made. If we try to compress this process too much and not carefully review these revised labels it significantly increases the potential for errors. Also, supplemental distributor products increases the number of entities involved. Again, for a given registration there could be, you know, a dozen supplemental distributors, so again all of those labels also have to be changed and those changes communicated. So we're looking at ways of addressing mitigation of risk through label changes. We believe that unless an imminent hazard exists as opposed to a concern measures to recall, repackage, or relabel products are probably not warranted because to actually recall packaging or to take product and re-package it or re-label it is a pretty significant undertaking. It probably is not warranted unless there's a real concern. It may not be possible to have revised labels for products released for shipment into channels of trade sooner than 18 months for some of the reasons that we

said. And that quicker time lines can incur significant costs. So again looking at some measures that if risk mitigation is deemed necessary, again, looking at some interim measures that could be considered in addition to, you know, having labels actually changed, is that in particular for like agricultural or vector control products for public health programs when possible that, you know, if it creates no conflict with the current printed labeling, distribution of supplemental labeling is a valid option. And for consumer products, you know, where it might not be as easy to -- you can't really as easily issue supplemental labeling. The recommended use changes or any concerns could be communicated through other means, either the media or the Internet. So that, you know, looking at this, you know, we had -- the group had quite a bit of discussion over the time frames and, you know, I guess from the registrants' viewpoint, you know, we tried to implement changes in a reasonable fashion, but that there are a lot of considerations and not only just costs but again just wanting to make sure that all the label changes are done and done correctly. So we believe that, you know, the current 18-month time

frame is probably -- is going to be most adequate in most cases.

MR. ELLENBERGER: Thank you Julie. Sue?

MR. JONES: Jay, do we want to open this up for discussion before moving on to the second piece just so --

MR. ELLENBERGER: Okay. Questions or comments?

MR. JONES: I have a question. Julie, how would you characterize the breadth of the consensus around this presentation. I know we were doing this as part of the work group, the PPDC work group for registration review. Does it go beyond sort of the registrant perspective? Is it a registrant user public interest group? How broad would you say is the consensus around what you put forward?

MS. SPAGNOLI: I was asked to essentially present this issue, especially on the timing of making label changes from the registrant's perspective. And I don't necessarily know that there was a consensus of an agreement on it but more so from the registrant's perspective, you know, what are the considerations for how quickly we can make label changes. So it's more to

communicate, you know, why can't we make a label change in six weeks? You know, why would that be problematic, so just trying to communicate what the considerations need to be. And what some alternatives are.

MR. JONES: All right. Thanks. Mary Ellen?

MS. SETTING: I would just like to voice concern about the recommendation for getting the changes on consumer labels out by a different media other than the label itself. We have a hard enough time communicating what we want done when the words are on the container and I'm just concerned about additional confusion if we try to portray additional information or changes to the use of a product other than that being associated with the product itself.

MR. JONES: I guess sort of the question for this group as it relates to this issue is what should we ask the registration review work group do as a next step as it relates to this perspective? Meaning sort of vetting those kinds of issues to see if there are areas where there are agreement and then identify areas where there aren't agreement. As I said before it's always easier when the agency understands where there is

agreement so we can quickly move forward on those and then focus our energies on areas where there isn't an agreement. And I think that is what the registration review work group has had a lot of success in, is focusing in where there can be -- where consensus exists so that we can then spend our time and energy figuring out where there doesn't so we can make choices in an informed way. I don't know if Jay or Susan have any thoughts on this.

MR. ELLENBERGER: I guess our thoughts are when we met on this issue -- when the work group met on this issue back in April, and the one that Sue's going to talk about, it was problem identified that, you know, I think OPP always deal with and many of you know that even in the current re-registration program of how do you set up a process of getting the label changes done as efficiently as possible, both from the agency's standpoint, the registrant's standpoint, and the public's standpoint. How do you communicate the kinds of changes, to whether they're just sort of error corrections if you will, all the way to significant -- what we think of as a fairly significant risk mitigation issue that we think

needs to be put on a label. How do you do that quickly and efficiently knowing that not only do we have the requirements to go through OPP but then there's the state registration that Julie mentioned. So the work group talked about a number of this issues and options. Frankly it was a relatively small turn-out for the work group and, you know, there wasn't the -- I don't think it got really to the consensus standpoint as much as here are all the kinds of issues that the agency has got consider in making label changes, companies consider, states have to consider, and so on and so forth. We didn't come up with here is a single way of doing it.

UNIDENTIFIED FEMALE: One thing we did talk about though is registration review will be quite different than our current reevaluation process. Now, before we can approve the labels we have to review acute tox and product chemistry, which sometimes requires more than one cycle. That can add to the time that a changed label gets to the marketplace. And registration review we believe that won't be the case, that it will typically just be the label changes. So then we were trying to look at the path that we could have to get those to the

market in a reasonable time frame. We did share the presentation with all the work group members but, you know, it was very short turn-around, probably they just had a couple of days to look at. So it would be tough to say there was a consensus. People did have a chance to look but we probably need more time to fully vet the issues.

MR. JONES: Sue?

UNIDENTIFIED FEMALE: The last meeting in April as Jay mentioned was probably the most poorly attended by the actual work group members of any meeting that we've held. And so it would be impossible to say that these necessarily that the discussions represented any kind of reaching of consensus because there just weren't -- what, four out the whole work group participated. I was the only person participating in person and I think there were three on the phone for part of the time and then one for the remainder. So as you can see I think it's fair to say that, you know, we didn't have adequate representation. I think that perhaps the thing to do is send out these two documents again after this meeting and specifically request that all of the work group members

review and respond, you know, to the extent that you need some idea of where the consensus lies.

MR. JONES: The good news is that this is an issue that we are going to have some time before we have to grapple with it. So there certainly is some time for this to get vetted before we're dealing with the reality associated with it. But that's some good advice. Beth.

UNIDENTIFIED FEMALE: I'm just curious. There are two options that were presented for the individual product label reviews. Is this something that we're going to be asked to comment on? Or is this something you're going to try and see what -- try a few examples and see what works best? And then my second question is it seems like both of the cons contain the multiple active ingredient issue and has any additional thought been given to what better way we might have to address that problem?

MR. JONES: My hope is that after further discussion and vetting around issues of how you implement on a label, the registration review decisions, that the agency will understand where there is agreement around that, about how we should do it and where there isn't.

And so that by the time we get to doing it, not only do you all know what we're going to do, we know what parts of it you don't necessarily agree with. So I think that the issue that's been identified is one that we have a little bit of time we're actually going to be doing it and I'd like to have some sense as to 1) people understand what our plan is going to be, and 2) we understand what they like and don't like about the plan, so that we're making informed programmatic choices.

UNIDENTIFIED FEMALE: I actually would suggest that if you send this out you might send it out to the entire PPDC for comment instead of just the work group. Because, you know, I wasn't aware of the work group timing or any of that and I think we at Syngenta would certainly like to comment on the plans.

UNIDENTIFIED MALE: I appreciate the work that's been done on this. It gets to the point of one of the issues that is a user community we face on almost a daily basis is how you implement either PR notices or labeling changes and one of our pet peeves is the inconsistency and time frame in those decisions translating to label language at the field level. And I

just -- one of the questions I've got right now because you've had a process where you've negotiated agreements and required label changes and what's the process now in the agency to check to be sure that there's consistency in labeling as products come forward either to the normal review renewal process or when a label change -- new labels are submitted by the registrants. How does that process work right now? And how big of a change is it going to be when you get to this level if you're talking about a more rapid turn-around time than what you've historically done, at least from my perception in the past and looking at when these labels actually hit the street with some of these required changes on them.

MR. JONES: Susan, do you want to take a stab at describing the current product re-registration process, making the distinction between the standard process and the process that can exist if there's a special concern, where we may preempt it and make it quicker.

MS. LEWIS: Under the standard process for existing program, our decision documents actually have a label table in them that outline all the new changes that

are required for mitigation or just for updating the label. Those labels come in nine months after issuance of the red and then we review the acute tox product chemistry to see if there are any additional changes that are necessary. Then we actually have a group of individuals within special review and re-registration that look to make sure that the mitigation has taken place on the label and done a review. And then they pass that on to the product manager, who has a final review of that particular label. That can take some time under the current process. I don't have a time frame for average but it's probably a year-and-a-half plus, if not longer. However, if we have identified risk of immediate concern, whether it's dropping food crops that are necessary, adding protective clothing, we have worked out agreements on particular chemicals and there may be three or four in any given year where we need immediate label changes, immediate may be with 30 or 60 days. And we work out existing stocks and stickering provisions. But those typically are for some very significant risk issues.

UNIDENTIFIED MALE: I guess my question is either of these processes to me look like if you're going

to group these and bring them in as a group of all of the products that have that active ingredient in it and look at it at one time. Right now it's separate, as I understand it, separate labels that come in and they're not necessarily grouped when they come in. It depends on when whoever is responsible for that registration sends a label in for you to review and this is just personal experience in looking at some of these labels when they come out, we'll read a decision document that says these are the changes that have to be made and sometimes 18 months, even under the current time schedule, to try to get some of these in, you start getting labels out at the field level and they're extremely inconsistent in the requirements that are there, either how they're worded or how the actual management issue comes in. And it becomes a real interesting dynamic in the marketplace because that becomes a marketing tool between the individual products a lot of times and I'm not sure that the goal of mitigation that was intended to be reached by the label changes in the decision process happens. And somehow this has got to be streamlined to the point where you're either looking at all of them at the same time as a group

with side-by-side comparison to be sure you're not giving competitive advantage in the marketplace because of how some of these things may or may not be caught in the process. And I don't know how difficult that will be. I think it's going to require resource issues no matter how you do it because I think just from my understanding of how the process works, it's not quite that intensive right now and I just think this is something as we move forward we need to set a goal that we don't get in a position where you're creating those kinds of situations. Especially where you're mitigating risks.

MR. JONES: There are a combination of factors. One of them I think has to do with the management and we have done some work in the last year or so to really beef up the management focus on product re-registration. But a part of it that isn't going to go away I don't expect is that there -- what the agency is left with if a manufacturer does not submit according to the time frame is to cancel the product. That is the only available tool to us. You can call them and ask them but you're then otherwise left with, well, you missed that deadline, we'll have to cancel your product. So far we've chosen

not to do that. So I think that there's some work on our part in terms of making sure that we're investing what we need to make sure it's moving through as smoothly as possible. But then I think there's another part is the compliance with the requirement, what's left to the agency is simply a pretty heavy hammer.

UNIDENTIFIED MALE: It's a pretty big stick.

MR. JONES: It's a pretty big stick, which so far we've not seen appropriate to use for that. But hearing from the field about the realities of this is very helpful in the moment when it's happening. We had a very similar dynamic would occur with states for years and it actually came up yesterday in the talk about this system we came up with referred to as the state label improvement system or SLITS, where states would observe this kind of phenomenon in the field. We didn't have a real good mechanism for hearing back when they saw this happening. And so we came up with a process whereby they could let us know in a basic e-mail message that then went to the right PM in the organization that brought the issue to resolution, hopefully in a timely manner. And we may want to think about how we can hear from others in

the field who are observing label discrepancies so that we can in real-time get on top of them.

UNIDENTIFIED FEMALE: Well, first actually I wanted to thank you Julie for doing the work to actually lay out from an industry perspective some of the issues and problems that are involved in actually changing labels, that it's actually a fairly complicated labor-intensive process. But I also -- it feels to me with registration review that there is an opportunity, if we collectively choose to take it, to look at the business of designing labeling, revising it, getting it into place, in a very different way than we've done in the past. I think historically it to a large extent has been as one-by-one. We do it one-by-one. We're not thinking about it as a whole system from start to finish and also a whole system where we want to have a continuous updating feature, which is what is implied by registration review. So I think the PPDC work group on registration review has really done an excellent job helping the agency think through how to redesign what I'd call the front end of the process, where we're looking at the active ingredients and I think we've, you know, we

believe we're going to have a good proposal for folks to comment on about how you look at the front end process with the chemicals in a tailored way. And that will take into account really what's changed over time and therefore needs to be reconsidered and doesn't bother with the things that don't need to be re-looked at. But I'm not sure that the work group has actually looked at the labeling part of it with the same kind of fresh look and whether there is in fact an opportunity to look at it as a whole system in which the registrant obviously has a very big role to play in all kinds of necessities that need to be met. But the states do, the user community does, and we do. So and it may be that the work group has not felt like that was really part of its mandate but I guess I'm wondering, and maybe this is something for the whole PPDC to think about, whether that should be a part of the mandate to go back and spend a bit more I would call it creative time looking at it as a whole system and identifying, well, if we wanted to make this system work in certain ways, if wanted greater consistency, if we wanted an easier ability when it was important to make changes sooner rather than later, what

would have to change in order to make that work. Because I believe you can design systems to do whatever you want but you do have to be looking at it from a sort of systems point of view and you have know what your goals are. So I think there's an opportunity there.

MR. JONES: That's a good point. Melody?

UNIDENTIFIED FEMALE: (Inaudible) had discussed this issue of unless an imminent hazard exists as opposed to a concern whether you discuss the parameters and criteria of what is imminent hazard and who makes the decision? What kinds of criteria or guidelines should be used? And what would trigger the process because it seems to me that this issue is I think at heart of why we want to do label changes. You know, what should trigger label changes? So it seems to me that it would be important to at least consider and have some debate about the pros and cons or what are the parameters that should be in the consideration for what is an imminent hazard.

UNIDENTIFIED FEMALE: A lot of that discussion that we've had and we kind of keep coming back around to the fact that registration review just like re-registration is not the only mechanism for the agency to

address a concern should a concern arise with a product. I think our feeling was that -- if some particular hazard has been identified because of incidents or other concerns that they don't necessarily have to use registration review as the mechanism for addressing a particular concern. So in fact we would be hopeful that you don't -- if there is a real concern that it doesn't, you know, wait 10 years if the product's not up for review for another 10 years in order to address it. So I think our feeling was that we're probably not going to have a great number of cases in registration review where in the course of a routine 15-year review is the first time that a particular risk is identified. Most products have either undergone tolerance reassessment or other reviews in the meantime so we really don't necessarily see that that should be a routine occurrence in registration review, that there's -- what we really do see it as is that it's a mechanism for making sure that labeling does comply with all current policies and all current standards for all the uses that are on the label. And that, you know, unless in the rare case that there is a really -- and I don't know what the criteria are to

determine if it's an imminent hazard. I guess that would be subject to the agency's discretion as to decide what would be considered a hazard. That most of the time label changes can be made as efficiently as possible but what we're saying is efficiently as possible for some products is not going to be immediate. In getting feedback from this, I mean, I didn't get a lot of feedback from the work group but I did get, you know, I had solicited comments from a great number sent out through the trade associations, from registrants and got pretty good feedback from registrants as to what some of the problems were. It was from my own company I found out some of our products that we have a single production run once a year. And there is an issue right there depending on when the change comes into play in that production cycle it will affect how soon the label changes can be made.

One of the other things that I got feedback from a lot of registrants on was this, you know, alternative process and registrants in general seem to favor this idea of the agency reviewing the label and then telling them, notifying them of what changes that

need to be made. Because now when the decision is made the registrant revises the label, submits it for review, we can't make those changes until we get the label back and so it's sort of this time period that, well, I may have just finished a production run of packaging and now I get it back. Well, I'm not going to be able now to make that change again until next cycle of production, whereas when if you get a notice of okay make these changes and within 18 months before you release product packaging, now you're not, you know, kind of waiting to see back to see, well, am I going to get it approved, here's the changes I have to make and you can put those more into the time frame of okay I've got these changes and I need to also change it from blue to red or something and you can plan a lot more efficiently. So the feedback we got back from registrants seemed to favor this idea of, you know, instead of okay we'll propose the changes, wait for them to be reviewed, but we can't make any changes until we get it back, that if we're told what changes to make and then go forward with making them it seems to be a much more efficient process. To address Mary Ellen's concern with consumer products, I think we

weren't looking at this as a substitution to making the label changes it's just maybe an addition, an interim measure. Okay, these changes are going to be made to labels but maybe communicating it ahead of time. It's just sort of an idea thrown out as okay what are some things we could possibly do as interim measures.

MR. JONES: Dennis.

UNIDENTIFIED MALE: I just wanted to speak to Anne's point about taking the opportunity to look at this in a systematic way and a new way of looking at the process. As most of you know the states do their own label reviews when the products come in for registration at the state level and we kind of serve in the states as a backstop for both the registrants and EPA for policies that may have not been applied to the label properly. I'm just wondering if there would be an opportunity to think about having the states participate in some form of a review process when the registrant is being told by EPA or the registrant is telling EPA these are the changes that we want to make, if you opened that process to the states at that point to look at the label language, especially the significant new label language, not

necessarily the routine material, that may help us in the states to get labels that are better labels coming down into the marketplace. It may help EPA to catch things that they may have missed otherwise and it may help the registrants in the same way. So maybe somewhere in this process if there could be a -- not even limiting it to the states, but some review process from the outside that would allow for input on these label statements as they're being negotiated or discussed.

MR. JONES: Let me wrap this up because we're going to have to shut this down. I always say we're 15 years into re-registration. Anne always corrects me and says, No Jim we're really 30 years into it. But we are way into re-registration. I don't think that many of us are perfectly happy with how product review has occurred associated with that, many of the issues that Dan identified and then other ones. I know it's hard to focus on something that you're not going to be dealing with for two or maybe three years, which would be product review associated with registration review. But this is the time to design something that will take care of the kinds of issues people have struggled with associated

with re-registration. Again, it's hard to focus on something you may not be dealing with for a little bit of time, but now is the time to do it. So I would like to ask the chairs of this work group to reconvene the team, see if you can get a little bit more and broader participation to focus on many of the issues we heard here this morning and others that will come up when you get more people engaged in it. Again, the beauty is that we don't have to have it solved by September or October. The hard part is because the problem is not facing us right now it's hard to get people to focus. So let's see if we can get a little focus before we find ourselves so far down in registration review that there is similar dissatisfaction with the product review part of that.

I'm going to move on to the next session as we are -- not to the next session, to Sue's presentation now because we're short of time.

UNIDENTIFIED FEMALE: May I comment on this?

MR. JONES: If you could fold it into the --

UNIDENTIFIED FEMALE: It won't look like it's folded in but I can comment after it if you like.

MR. JONES: Okay. One minute. Go ahead.

UNIDENTIFIED FEMALE: Okay. First of all I wanted to support Dan's comments actually, that anything that will sort of consolidate, standardize, and make it easier to comply with certainly needs to be done. That's certainly something that we should all be thinking about and the agency should be thinking about. I also wanted to raise concern about the imminent hazard, the change in language from the concern to imminent hazard in order to recall, repackage, or re-label. But since raising concern at the PPDC meeting may not be heard I'd like to raise an imminent hazard. So I'm raising an imminent hazard about this language so that I don't want to be in a situation like what Shawney Hoover pointed out yesterday where later we find out that the language is that the PPDC had general agreement and acceptance with this. So I wanted to go on record that I raised an imminent hazard to this.

MR. JONES: Thank you. All right.

MS. CRESCENZI: I'll try to make this quick since we're running behind. I think it is probably less controversial. Next slide. I'm just going to very briefly talk about the basic elements of a re-

registration -- cross that out, it's a registration review decision document. Other elements in addition, the level of detail, format, and references, whether or not a fact sheet summary is appropriate and then the standard that the group talked about and does the proposed format, does it actually provide the flexibility we need to address all of the audiences and the complete range of regulatory decisions. Next slide. The basic elements, and this reflects a consensus of the folks who attended the last meeting so that was mostly registrant representatives and EPA, but I think that we did discuss this enough that we thought this made a lot of sense. Again, it does need further stakeholder input. Always of course a description of the uses is essential. And highlighting any additions or changes to any of the previous assessments that have been made. A summary of any new data that had been received and were reviewed for the registration review or that had been to support new uses. Description, of course, of any risk or concern and any mitigation. And then the actual final decision. Along with those basic elements would be links to previous regulatory decision documents and I think that

this obviously would refer to previous re-registration decisions. I think this also would dovetail very well with what Lois Rossi discussed yesterday and that was putting up, establishing dockets for the registration decisions. And this is something the group has talked about a lot, that we need electronic files that are accessible to all the stakeholder and that is going to make everybody's job easier and the whole process more transparent. And then data summaries, risks, concerns, mitigation, on which previous regulatory decisions are based, are to be referenced. They're not to be re-summarized or incorporated into the new registration review document. And we think that's very important. This needs to be efficient and can't be a make-work exercise. Other elements. Decision documents should address the impact of any applicable change in scientific or regulatory approaches to risk assessment. Since the previous regulatory decisions show if there was in fact revision to a risk assessment for existing uses, that should be highlighted. On the other hand if there is no impact for many of the changes on the existing uses, that should be mentioned. I mean the document should not be

silent. It should at least state that it has been reviewed in light of any of these new regulatory or policy approaches and that there was no impact. And then of course the data call-in, if any. And the explanation here, and this is something we've talked about before, to the extent that a registration review decision is made but data are still being called in, there needs to be some explanation on the basis for the decision in the absence of the data that are being called in and those are typically to confirm decisions that being made. As appropriate, the document should discuss ongoing activities of interest that are expected to occur within the near future, I mean to the extent that the near future is predictable. For example, we did talk about, well, should this registration review decision wait because there's a pending application for a new use. And I think our take on it was no it really shouldn't. The fact that a new use has been applied for and is being considered should be mentioned but then again anticipating that when the new use is actually -- there is a decision on it, that that decision document will then be made a part of the electronic record. Again, to

the extent that there might be an anticipated issue and some data call-in for a class of chemicals in which this particular chemical fits, we had said again that registration review should not be the be-all and where-all to the extent that there is going to be a data call-in for a particular class of chemicals because of a particular issue, that the registration review decision for a chemical that's already come up should not have to wait for that particular data call-in and then all of the final reviews and regulatory decisions based on that data call-in for the whole class. And likewise that the data call-in should not wait for those chemicals that are further years out. You know, if there is an issue for a particular class of chemicals that should be addressed outside of the registration review process in terms of scheduling. But again because all of these documents or decisions would ultimately be made a part of the electronic record that really shouldn't be a problem.

The other thing we talked about is that tolerances don't need to be addressed because there's no requirement in registration review for tolerance reassessment, unless of course dietary risks have been

reassessed and they require a revision of the tolerance or cancellation of the tolerance. Next slide. We did discuss the fact that these documents have to address the needs of different audiences. And those needs could range from just a kind of 30,000-foot regulatory overview to the real nitty-gritty of risk assessments, data analyses, mitigation issues. And again, electronic documentation permits flexibility. Next slide. Because what we can do in the electronic version of the document is establish live links to not only historic but also the supporting documentation and so this could include, for example, risk management memoranda, the data evaluation reports, and any other specialized data. Next slide. One of the things, though, that we did talk about to the extent that the electronic document has live links. The document also needs to have complete references so that somebody using a hard-copy version would have a reference that would enable that user to be able to locate the document other than electronically. So that was something we did talk about and thought that we had to have some form of reference that could serve for the hard copies as well.

We also talked some about whether or not it would be useful to have a fact sheet summary that was really geared more to the casual reader that, you know, four or five pages at most. And I think that would be kind of a parallel to the registration fact sheets we have, that the agency currently has. We need a framework that permits adequate flexibility for a range of decisions, remembering that we're talking about and what we've talked about from the beginning, is the fact that you could have an easy off, basically, you know, nothing's changed or there are no new uses, there are no different risk assessment decisions through the whole way to we have significant risks of concern, we're going to cancel uses, and so what we were trying to determine was whether or not the elements that we described that were listed on the first slide provide the necessary flexibility. And that's again for the audiences as well as for the range of activities that will be involved in registration review. And this is just a recap of those basic elements. Again, do they permit the kind of flexibility that we think will be needed, as well as, I might add, efficiency. Because we really wanted to avoid

any kind of make-work.

MR. JONES: You know, partly given the time constraint, and partly because of what I heard from both Sue and Jay and Susan that there was relatively small participation at this group. I think that probably this is another piece of work that the work group at large needs some time to digest, reconvene to give people who did participate some feedback on it. I think I'll ask that that definitely happen. But I'll open for questions now. Jennifer.

UNIDENTIFIED FEMALE: Yes, thank you. I want to suggest two things and maybe this is the place to discuss it, it seems, in this presentation. The first is I want to support something that was presented here but also brought up yesterday, which is the need to have the data evaluation reports made public or publically accessible in a timely manner, obviously with no CBI. But that would just be so normal. And, you know, they're pretty easy to read. They're summaries, they're not lengthy or technical. And they don't have CBI in them, so -- and they're available by Freedom of Information Act so I don't understand why they can't just be available.

And the second thing is with the data call-in, the DCI, I think there is a real need to set up some kind of a DCI management system or tracking system, an easy database, that -- (END OF TAPE) -- then or not, whether it's been review by the agency or not and then what the review was. Like maybe it's a DER, maybe it's something that just says acceptable nonstudy guideline, or not acceptable and wasn't used. But some way of tracking that because actually right now I've personally found it impossible and yet in the end decisions are made and we can't figure out if the data call-ins have actually been met or not. So maybe this is the place to talk about it and if it is, that's where I'd like to put my suggestion. I'd like to put it as an imminent hazard because I actually think it's more than a concern. I think it's really important for people to be able to track that. Thank you.

MR. JONES: Julie.

MS. SPAGNOLI: Just to address your issue about this, you know, the small turnout we had at the last meeting, which was really the purpose of that meeting was to I guess discuss what we were going to present to the committee. You know, a lot of the issues, these have

been discussed and vetted through the work group over a number of the meetings so I don't -- these particular issues -- this really wasn't the only time some of these things were discussed. In fact, you know, we've had a number of discussions about label reviews and what registration review would comprise and so I'd say, you know, Sue and I were kind of charged with putting together what we were going to present but basing it on a lot of the discussion that's gone on for the past couple of years. And, you know, I don't want to have to say it, but just for the record, in the discussion that we had about making the immediacy of label changes and the term, using the term imminent hazard, Erik Olson was on that call and did not raise any concerns about that term at that point. Also, the presentation that I prepared was circulated to the work group and I received comments back from two work group members, neither of which commented on that. So there was a chance to -- you know, if that language was problematic it was presented to the work group and it was just the terminology that was used in the course of the discussion that we had and that's – it wasn't anything defined legally or any criteria set. It

was just in the course of the discussion. So just for to clarify that.

UNIDENTIFIED FEMALE: I don't actually think it's something that the EPA should respond to. How are they going to define it was asked before. The EPA didn't respond to that. I mean, you know, 15 minutes ago. But also I do know that Erik was concerned because I know that it's in our comments that we put in, so I know it was raised as a concern. I don't know if it was raised on that call. I wasn't there.

MR. JONES: We should -- what I'm looking for is, out of work groups, is a sense of where there is agreement and where there isn't. So that the agency has before it a sense of where does consensus exist and where it doesn't. And where consensus exists it's pretty simple for me to make a decision. It's likely to go with the consensus unless it's illegal. Where it doesn't exist is very helpful for me to know where people are, where different groups are, where the consensus doesn't exist. And so what I'm asking for -- and I know this is a little bit different way of operating, although I think fundamentally this is how government always operates, is

that the work groups attempt to figure that out. I fully recognize how difficult it can be to give the amount of time to the exercises we're asking you to participate in. And that's why I can understand that at any given meeting, at any given time we're unable to get the kind of participation that we really need to ascertain whether there's consensus or not. Again, the beauty of working on an issue that is a year-and-a-half or two years before it's reality, is you do have a little time to figure that out. So I'm just going to ask again that for both of these exercises we -- both of the discussions we had here this morning, that we spend a little bit more time trying to figure those two thing out. Where is the consensus around this and where doesn't it exist and what are the various perspectives around that. I can imagine that there actually may well be a fair amount of consensus on the latter discussion but less so on the former. Well, that's, you know, it is what it is. I just want to have an understanding of what it is. So let's see if we can spend a little more time on both of these and so at the next meeting a little more clarity around where that consensus exists and where it doesn't. And maybe we can

think about presenting it in that way and that those who have participated in it are going to say, well, yeah, that characterizes our position. Maybe that person can present that position. Sue?

MS. CRESCENZI: Yeah, I would just make an appeal for everybody who has a work group member to please make every effort to get, you know, your organization represented at the meetings because the attendance rate has fallen off significantly over the past year-and-a-half and, again, I don't think we can succeed as a consensus, you know, to make consensus recommendations without that complete participation. So I would just make that as an appeal.

MR. JONES: Jennifer.

UNIDENTIFIED FEMALE: Just quickly. One thing that would help me a little is if in the different presentations throughout the day I guess, throughout the meeting, if the different working group members were listed so that when we are talking about consensus or perspective then we have a sense of what that is. Because I can't keep track.

MR. JONES: Sure. I'm going to ask the work

group also engage in two other issues. One, is that we have -- the general consensus as I understand it is that yes we should be doing this in a time-oriented way, that the oldest and analyzed chemical chronological ought to be looked at first. And that generally should be the principle that we operate on. And we've done some work to basically identify what that 15-year schedule would look like. And when you look at it you go, oh, well, there's certainly some inefficiencies built into that because you have things that are in the same class spread over the whole 15 years. And so we've taken an initial stab at seeing other ways to stay true to the principle of chronological but make some smart choices about grouping. And I would like for the work group to spend some time on that to see if we can get a consensus that in cases where we're not just going to be chronological because it seems like a smarter thing not to be -- you know, always for being smarter even if it marginally is off what you said your idea was going to be as long as you stick to the principle, and get some advice back on that. So if the work group could also spend some time on that.

The second one is that as a program manager I'm struggling with something I've understood to be a consensus of this group. I'm not sure whether it is or not. And that has to do with registration review being independent of when a DCI is issued. As a program manager I have one group of resources, my old chemical resources, to deal with old chemical issues. And so the idea that you issue a DCI, do the registration review, and then the DCI submits -- results and data submitted two or three years later. I'm sort of stuck with what do I as a program manager do. What resources do I bring to bear to review the DCI, the data that comes in, to do any reg management that may be the result of that? And I'm having a hard time with that conceptually. So I'm going to ask that the group take another look at that issue and we'll sort of try to bring some of that programmatic perspective to -- the answer that I actually need is, what do I do with that? What resources do I bring to bear? What process do I use to deal with that? So that's something that we very much I think need to have sorted out before we're in implementation as I think that might be one of the first big issues we're confronted

with.

So those are the two issues that I'd like the group also to spend some time struggling with us. All right. Very good.

UNIDENTIFIED FEMALE: Do you want to know what you do with the information received on data call-ins?

MR. JONES: No Jennifer. I know what to do with it. (Laughter.) My problem is if the registration review program isn't the program that deals with it, what does the group think will be that program? That's the question. I have registration review, I have registration.

UNIDENTIFIED FEMALE: You mean that when the data call-ins come in they just come in for the chemical and nobody -- and it's not really clear who is in charge of doing that?

MR. JONES: No. This is a program management issue. I have a couple of programs. I have registration. I'll have registration review. If my registration review program isn't the program reviewing it, what is that the people in the stakeholder community think is going to? Now, as a program manager, if we're

going to follow what I've heard is the recommendation, what I will have to do is take resources away from registration review to review the data when it comes in. And so you'll end up with sort of two things moving simultaneously, which will frankly have very different schedules. So it's a basic program management issue. It's not are we going to do it, it's how are we going to do it.

UNIDENTIFIED FEMALE: How are we going to do it as in how are we going to resource it?

MR. JONES: How are we going to resource it, how are we going to sequence it, how are we going to schedule it. The resource base is sort of how do you sequence things so that you're doing things in the most efficient manner possible. We'll sort of bring kind of some examples that will show you what will happen in terms of how we have to manage it if we follow the recommendation. Which, hopefully, that will sort of elucidate to the group. Well, it will either help you understand why I struggle with it or you'll be able to tell me why I shouldn't be worried about it. It'll be one or the other. But we're clearly going to review the

data. The matter is how do you do it in a way that best avails the resources the agency has so that we're not running two or three programs simultaneously. That's the issue.

UNIDENTIFIED FEMALE: I want to try something Jennifer. One of the things that I do when I'm not doing EPA work is I like to cook. But I only have me, I don't have prep chefs in the house. So, if I have a lot of time one of the things I'll do is I'll get all the things chopped, washed, arranged in order, sequenced, so that when I actually start cooking it's all ready to go. And that has some great benefits in that what I produce actually is probably a good product. On the other hand, when I went home last night and I had no time after work, I tried to do everything all at once. So I get something started while I'm cutting something else up and when I'm really good and I'm on my toes it still comes out okay. But that can also lead to a situation where I burn something, something is not quite as well presented as I would like because I'm trying to do it all at once. And to me that's kind of the issue with the DCI. If you have a lot of prep chefs at EPA to do the slicing and dicing

and cutting and arranging, you can think about how to do your DCI one way and then fit it back into the menu you're constructing. But if you're not set up to do it that way and you have to sort of do it as you go it leads to other management challenges. It's the same set of people doing the work and looking at the chemical. But it's how do you organize not just the time of one individual but the time of many individuals across the organization so it actually produces a product that is well cooked.

MR. JONES: We'll tee the issue up at the work group session so that people have a clear sense of what it is that we're struggling with around this concept. Okay. We're going to change the schedule a little bit of our next session. Cliff Gabriel, who is the new Director of the Office of Science Coordination and Policy, which is a science coordination shop within OPPTS, which manages the endocrine disruptor screening program at EPA. Cliff needs to go first because he's got a conflict that he's got to --

MR. GABRIEL: I guess this is the hot seat. I appreciate the opportunity to make a few remarks to you

about this important program. I think it's an understatement at best to say that this has been a very difficult program to not only conceptualize but then, you know, follow through with the implementation. And I think, you know, back when this was envisioned back in 1996, science has evolved and we're certainly in a much better place now to work on getting this up and running. What I would like to do is -- I'm not sure where everyone is as far as their knowledge about this program, is give you just a little bit of history and then a very quick update as to where we are. And then spend some time answering your questions.

Basically, this program was established back in 1996 with the Food Quality Protection Act. This is in section 408P. And what this did was essentially require that the agency provide for the testing of all pesticides. And this would include active ingredients as well as inerts for estrogenic effects that may have an effect in humans. It also required that we use validated test systems or other scientifically relevant information. The legislation also gave us discretion in terms of bringing in other endocrine effects, so just not

restricted to human health or estrogens. In addition, the Safe Water Drinking Act was modified that same year and also gave the agency discretionary authority to screen contaminants in drinking water that might have substantial numbers of individuals exposed to it. The agency realized right away that this was an extremely daunting task and formulated the advisory committee, the endocrine disruptor screening and testing advisory committee that was chartered in 1996, broad stakeholder representation. And this group came out in 1998 with recommendations to the agency for how this program should be structured. They recommended that the program focus on three endocrine systems: estrogen, androgen, and thyroid effects. That the program include human and ecological effects and also to the extent possible that we cast a very broad net in terms of chemicals covered while the FQPA amendments addressed specifically pesticides. Again it gave us some flexibility. And if you look at the recommendations they included up, to I think it was like 87,000 chemicals, which is certainly an awful big apple to take a bite out of. They also recommended a two-tiered approach, again because of this

large number of chemicals. But basically a tier one screen which would include in vivo and in vitro screens and this would basically be to determine whether or not it was possible for these chemicals to have -- to affect the endocrine system. And then the tier two screens, the tier two tests, which would essentially provide the hazard data, dose response data, this sort of thing. These recommendations were reviewed by the DSAP and the SAD and they were broadly endorsed. They had some, you know, commentary about them in terms of how we should go about implementing them but in large part they endorsed the recommendations that were given to us by the ETSAC. In keeping with the commission of transparency and input into this program EPA just rechartered the advisory committee, the endocrine disruptor methods validation advisory committee, and this is a bit smaller. The committee is only about 20 folks and it had its first public meeting just last month. Next please. The program divided into three mean activities. By far and away most of our focus has been on the assay validation process. There's also the priority setting and then making sure that we have the necessary regulatory

mechanisms in place to require the various testing procedures. So let's take a quick look at where we are with the various assays. That's interesting. I have dots on mine. I'm not sure what the scissors and the crayons actually mean. (Laughter.) Computers are very good. Okay. As I mentioned in the beginning of my remarks there is a requirement in the statute that we do work with validated test methods and, you know, this has presented some interesting challenges for the agency. There are clear -- with discussions going on both domestically and internationally about how to validate these various activities, working with ICVAM and with DOECD, and looking at method development, prevalidation studies, and then also in our lab validation studies to make sure that the techniques are actually transferable between laboratories. Here's a list of the various in vitro screens that we're working on. You can see that we're making I think very good progress on, you know, across the board. There's one point of interest here. It's with the steroidogenesis rat slice testes assay. Last -- at the advisory committee meeting last month, it actually recommended that we stop work on this assay

because they thought it wasn't going to be successful in the long run. So our -- there are few work products that are still ongoing there but for the most part our emphasis will be placed on the H295R assay, which is adrenal cortical tumor cell line that still has all of the steroidogenesis enzymes near the pathway still intact. So that will be where a good deal of our emphasis will be on pursuing that test as an alternative to the rat slice testes assay. Here you have the in vivo tier one screens. You can see here with the Hershberger, the uterotrophic, the male and female assays, there is a potential for quite a bit of redundancy in what we're doing and that's largely a reflection of the fact that I'm not sure how all of these are going to turn out in terms of validation. My sense is that, you know, once these play out through the various validation processes that there will be some sorting out in terms of looking at some of the costs and end points and making sure that we have a screen that provides for all of the end points of interest without excessive amounts of redundancy. With the frog metamorphosis assay there you're looking at thyroid effects. And the fish screen, you're looking at

both estrogen and androgen effects. So we do have a set of tier one screens that do cover the full range of estrogens and androgens and thyroid effects. Next please. The tier two assays are a little bit further out. They're not quite as developed. Probably two that are the furthest along would be the two gen assay and also the mice and two gen assay, the invertebrate assay. And as you can see many of these are being worked through the OECD validation process. Next.

Okay, the next issue that I'm sure you're interested in is the chemical selection and priority setting process. To date our focus has been on selecting what would be the first 50 to 100 chemicals that would be run through the tier one screening process. This was a recommendation really coming out of the SAB/SAP review that, given the large universe of chemicals before you have flipped a switch and start testing all of these, make sure you have a system that works well. And they recommended focusing our initial activities on a discrete list of 50 to 100 chemicals. In December of '02 the agency published a Federal Register notice that proposed our approach for selecting those chemicals was largely an

approach based on exposure. And for actives looking at residue information from food to drinking water, residential use, occupational contact. And for the inerts using the fact that it's a high-production volume chemical, then also monitoring data on different residues and drinking water and indoor air. I think this is pretty much on track as far as being final at this point. Probably early summer we'll be seeing the final approach notice coming out for selecting the first 50 to 100 chemicals. Next. This is the last slide. This is a time line. You know, all of this is subject to change. But it's our hope that we'll have a sufficiently robust tier one battery ready for testing starting in 2007. In order to do that we've got to make sure that we have all the validations squared away, but also the proper regulatory framework in place to do the testing orders. And I know one of the concerns the stakeholder community has is to make sure that there's adequate time for comment on the list and that has been built into the time line. And also I know there's concern that once the tier one screen data come in that we have appropriate validated tier two tests for any chemicals that might be

-- you know, come up as positive in the tier one screen. And right now, as I mentioned earlier, the manilian two gen and the mycid should be ready in a way that would allow chemicals to flow into the tier one test from the tier one screen. At this point I think testing in the tier two process is going to be pretty case-by-case. You know, looking at existing data sets, what's out there, where these chemicals are in the various review programs that exist over in the Pesticides Program office. What types of assays are currently validated? Issues of exposure. Do you expect this pesticide to be primarily human exposure in water, this sort of thing. I think when we look at the total situation as a case-by-case analysis we'll be able to hopefully fine-tune the tier two testing requirements for a given chemical. So with that, I'll be happy to try to answer your questions. Thank you.

UNIDENTIFIED MALE: Clifford, is there a mechanism in this process to include a new tier one screening study like some of the genomics work that's being done?

MR. GABRIEL: Yeah, I mean, I guess I see none

of this as being set in stone. I think science is going to evolve. New assays are going to be developed. The agency is spending an awful lot of time, for example, looking at alternative methods, whether they're in vitro methods or even looking at QSARs and computox type of approaches. So I think as new methods are developed, or new methods are contemplated, developed, through the validation process, we should be able to find ways to integrate those into a screening battery. So I think it would be a mistake just to draw the line and say, you know, this is perfect here and we can't mess with it.

UNIDENTIFIED MALE: In the process right now what is the way that you do that?

MR. GABRIEL: That's a good question. And I think the way to do that would be through the advisory committee process. Again, it's late in the game for this first cut at the tier one screening battery. But again I think all good ideas are welcome and, you know, it's a matter of resources, timing, all of these sorts of things that you can imagine.

MR. JONES: John, we are actively involved with our Office of Research and Development on this very

issue. Nancy?

UNIDENTIFIED FEMALE: I have a couple of questions. The first one I keep reading in the newspaper that the endocrine disruptors in the water supply anyway seem to be coming primarily from hormone supplements, so I'm wondering how much of this endocrine disruptor issue is a pesticide issue, or is it something else?

MR. GABRIEL: Well, I mean, you're right. There is a lot of concern about the contaminants, you know, birth control pills down the toilet and this sort of thing and what effects those types of contaminants might be having. 408P specifically targets pesticides, so that's where our focus has been. And as I said earlier, we do have discretionary authority to look at water contaminants as well and, you know, I'm sure the agency will be addressing those issues after the program gets up and running.

UNIDENTIFIED FEMALE: And my other question is coming more from my food background, food nutrition. In foods, there are estrogen-like compounds like some of the phytoestrogens. What about your tier one screening tests, have you looked at -- there might be normal

constituents in foods.

MR. GABRIEL: Diets are a huge issue for the folks developing these assays, making sure that we have a handle on the effects of phytoestrogens, say, from a soy-based diet, this sort of thing because they can have a potential effect on what we're seeing in terms of measurable end points. So there's quite a bit of attention placed on standardizing diets if necessary. You know, some of the assays are robust enough where that's probably not a concern. Some may be more of a concern so there is a pretty high awareness of making sure that to the extent possible those types of issues are controlled for.

UNIDENTIFIED FEMALE: I was thinking more about normal consumption in humans.

MR. GABRIEL: Right.

UNIDENTIFIED FEMALE: And do we know much about what is the normal consumption of phytoestrogens or other estrogen-like compounds in foods. I know that's not your issue.

MR. GABRIEL: Yes, that's not part of the screening program but clearly those types of issues are

going to have to be factored into the overall risk assessment process.

MR. JONES: Lori, Jay, and then Troy.

UNIDENTIFIED FEMALE: Well, I think that this is a really great setting. I think a lot of people have been asking for this. My concern is that in terms of exposure in populations that you're looking at, they don't often reflect more rural populations or exposure scenarios. And they definitely take into account a lot of tribal exposures or concerns. And our consumptive patterns for dietary are often quite different than the normal consumptive patterns. And if you look at the fish consumption levels that have come out, you know, they're many times very very high compared to what the normal fish consumption patterns are for the rest of the population. So I guess I would just say that when looking at endocrine disruption I don't know if you're looking at sensitive populations or subpopulations like a tribal scenario.

MR. GABRIEL: At this point we're not. We're looking at overall exposure to the general population for the first 50 to 100 chemicals. But the agency is going

to be, you know, reassessing its approach to priority setting after we get that experience under our belts. So those types of issues may be factored in.

UNIDENTIFIED FEMALE: And I think the tribes have been working with the agency in trying to find out how tribal scenarios can be fit into risk assessment processes or even risk management decisions. I know we just had a big meeting on it a couple of months ago. And so this seems like a really relevant place to insert that or to start thinking about it.

MR. JONES: Thanks. Jay.

UNIDENTIFIED MALE: Cliff, I was curious to know what you think or what the agency generally thinks is the regulatory authority under FQPA and the Safe Drinking Water Act with regard to wildlife effects and the provisions in those two laws for endocrine effects.

MR. GABRIEL: Well, certainly, you know, we feel that the 408P provides the agency with authority to look at endocrine effects sort of as -- you know, generally. Again, the focus was on pesticides in humans, but it also gave the agency broader discretion so we think that there is authority there.

MR. JONES: Chuck.

UNIDENTIFIED MALE: Thanks. As you said 408P has focused on human effects and pesticides in particular and looking at the way the tier one and tier two batteries have been structured, there's only one tier two test that's focused on ostensibly human health effects, which is the rat two gen and that already exists in Part 158 for all food use pesticides. So my question would be from an implementation standpoint what's the value added by running a pesticide that already has 30 to 50 separate studies from Part 158 through this? What are we going to learn that we don't already know?

MR. GABRIEL: Well, I believe (inaudible) recommended and we would agree that we look at multiple taxa, because there is information to be gleaned by looking at endocrine effects across rats, birds, fish, etc. You know, the degree to which the rat is the best predictor for human effects I think is still an issue that we're looking at. So the extent to which you have data across multiple taxa that helps inform or your overall risk assessment at the end.

MR. JONES: All right, well, this is an area

that I expect that in the coming months and years that this committee will probably get more involved in as this goes more from the design stage to the implementation stage, but I thought it would be useful and actually you've been asking for some time now for some update on where we were on our endocrine disruptor screening development program development. So thanks very much for joining us Cliff. Okay. The next two updates, three updates, Bill Jordan is going to give us an update on where we are as relates to human studies. Bill.

MR. JORDAN: Thanks Jim. I'll forgo the detailed discussion of the content of the Federal Register notice that appears in the materials that were handed out to you. But that Federal Register notice that was published on February 8 is -- of this year, is the main development that has happened in the area of human studies since this work group, since this advisory committee last met. The Federal Register notice did two things. One is that it announced a plan for moving ahead on the recommendations made by the National Academy of Sciences the year before in its report on intentional human dosing studies for EPA regulatory purposes. And

we've identified a number of things in that plan, including rule making that we will do to strengthen the protections for human subjects who participate in studies that could be used by the agency.

The second thing that the notice does is to describe what EPA will do in the meantime, until we have completed the rule-making process. It's not clear how long the rule-making process will take but we are obliged by a decision that came out of the U.S. Court of Appeals for the District of Columbia in the CropLife America case to consider human studies on a case-by-case basis, taking into account statutory standards, the common rule in high ethical standards. And we are in fact doing that. We are looking at individual chemicals and the human studies that are available for that in making sense of the database on a case-by-case basis. And we're also looking at not only at the science but also at the ethical attributes of these studies in order to decide whether to use them and if so how to use them. The Federal Register notice had a public comment period. The comment period closed on Monday and the latest information that I have as of Tuesday night is that we had approximately 130

comments. Of those comments, about 100 are letter-writing campaigns, postcard campaigns from various points of view and tend to say the same thing and not to be particularly detailed in terms of comments. So that means that there are really about 30 sets of comments that come from a fairly wide range of stakeholders, including a number of folks who are participants on the PPDC. We will be looking at those and moving ahead to implement the plan after we've thought about what to do with the suggestions that are contained in the comments. I will say that at this point we have the sense and the highest priority for rule making and it is something that we're going to work very hard to press ahead on and our hope is to have a proposed rule on the street by late summer. That's the report on the human studies front and Jim do you want questions now?

MR. JONES: Questions, yes. Alan.

DR. LOCKWOOD: Thanks very much. While there are many things that are good features in the document that was posted in the Federal Register there are a number of things that we find troubling. One of which is the criteria that will be used to determine whether

existing studies are acceptable. And it says here, and this is a quote from the Federal Register, "EPA will continue to generally accept scientifically valid studies unless there is clear evidence that the conduct of these studies was fundamentally unethical, e.g., the studies were intended to seriously harm participants or failed to obtain an informed consent." This is not high ethical standard and is not consistent with the content of the documents that guide human research ethics, such as the Belmont Report, Nuremberg Code, the Declaration of Helsinki, and I certainly hope even though this wording came from the National Academy of Sciences that this is something that will be revised substantially and conform with the high ethical standard that we hope for from the agency. The other point is how disputed or sticky-wicket-type studies will be resolved and the document says that they will be referred to a human subjects review official. Our concern is that this individual, and it's our understanding that this is a political appointee, will be making these decisions rather than referring them as we would hope to the yet-to-be-constituted bioethics advisory committee. There was a

notice posted in the Federal Register over two years ago about the formation of this committee, which to our knowledge has not yet moved forward. We would greatly prefer to see these kinds of issues discussed in a public manner where various stakeholders can participate in the process rather than have this function performed by a single individual, particularly at a time when research that we and others, including the Union of Concerned Scientists, show that there's an increasing distrust for decisions that are made in this manner, that will all too often rely on political expediency rather than best science and evidence-based decision making. Thank you.

MR. JORDAN: A couple of quick comments and clarifications. Dr. Lockwood did indeed read some of the text of the Federal Register notice that described our case-by-case approach. There's additional text that I think may be useful to point to. In addition to using fundamentally unethical tests, the Federal Register notice indicates that we will also look to see whether the conduct of the test was significantly deficient relative to the ethical standards prevailing at the time the study was conducted. So if in fact a study was

conducted after the Declaration of Helsinki was issued, after the Belmont Report, after Common Rule, those existing ethical standards become another benchmark that is used in our consideration of evaluating the ethics of the study. The second thing, Dr. Lockwood referred to the human subjects research review official. That is a position within the EPA that is currently held by Dr. Peter Prouse, who is a member of the career civil service. He's a senior executive service member. And I would expect that that position would continue to be filled if Dr. Prouse no longer does it by someone who is in the senior executive service. It's a position that we thought particularly appropriate because that individual is responsible in addition for overseeing EPA's compliance with Common Rule and so that person has an enormous experience with a range of different kinds of studies and works regularly and closely with the Common Rule, which is accepted as the normative ethical standards for conducting human research in the U.S. The third thing is that Dr. Lockwood referred to the advisability of having outside peer review, particularly through the science advisory board ethics subcommittee.

He noted that the ethics subcommittee has not, to his knowledge, been convened and that is still the state of affairs. But I do want to say that the human subjects research review official has the discretion and it is noted in the Federal Register to go outside the agency to draw upon expertise of bioethicists. It may be on a more ad hoc basis rather than through the standing subcommittee that was contemplated. But we've by no means ruled out the idea of using external peer review to help us deal with some of the sticky-wicket issues as you suggest.

MR. JONES: Let me say that for any assessments that are done that where there is consideration given to human studies in our old chemicals program, where they're most likely to be, the public participation process that we have committed to in our old chemicals program will be followed and so there will be opportunity for public review and comment of the agency's assessments before any final decisions are made. Jay?

UNIDENTIFIED MALE: Just to follow on the point that Alan raised about the, you know, the acceptability of data that has been submitted, being if you will I

guess sort of the harbinger of format for kind of ethical approach going forward is certainly appropriate. However we also know that there's quite a wide range of existing and previously submitted human clinical trials to EPA in support of pesticide reviews, some of which are quite old and may indeed predate some of those international organization treaties and standards. And some of which were done under the guise of being conducted by laboratories that were doing pharmaceutical trials so may represent some technical missteps with regard to the informed consent forms and so on. And I would just suggest that there's also an ethical consideration around having sound scientific information that exists that may not be exactly to the letter of the standard of ethical review that these studies would be held to, being prospectively proposed to be done going forward, and that we ought not to ignore sound scientific data that is close to the ethical standard and the exact letter of where the policy might be going forward.

MR. JONES: Pat.

UNIDENTIFIED MALE: We talked about this before and my question is if you could just briefly explain how

under the interim policy the agency will treat the submission of human clinical patch studies for irritation or sensitization.

MR. JORDAN: The interim approach says that we'll generally accept scientifically valid studies unless there's clear evidence that they were fundamentally unethical or they were significantly deficient relative to the ethical standards prevailing at the time the study was conducted. Using that standard we would look on a case-by-case basis at the particular study, asking ourselves questions about the science and questions about the ethics. With regard to the science, the question are, Is this study relevant? Is this study scientifically sound? Does it help us make a better decision using all of the information that's available on that chemical? With regard to the ethics, taking that approach we will ask ourselves, well, does this study look to us like it's fundamentally unethical? Was it designed to hurt people? Were people coerced or otherwise tricked into participating? Those are the kinds of things that the National Academy referred to in its explanation of what it means to be fundamentally

unethical. And then we turn our attention to, well, what were the standards at the time this study was conducted? What were the expectations in the scientific community about how to do a study ethically? And frankly, those standards have changed over the years. The earliest sort of pronouncements on that were the Nuremberg Code. They've since been embellished and elaborated on in the Declaration of Helsinki, which has gone through multiple iterations. The Belmont Report, which is a very important seminal piece of work in the United States, led to the development of the Common Rule. The Common Rule in turn over the years has gone through interpretation, although it's not been rewritten. People's understanding about how the Common Rule applies has evolved. Basic to all of those principles, though, are sort of three fundamental ideas. One is respect for the people who participate. That means that they get to make their decisions about whether to participate and they should do so on an informed basis. The notion of beneficence, that these studies ought to be conducted in a way that does more good than harm. And so that means doing things to minimize the potential for harm to the participants and

making sure that there is something valuable that comes out of it that justifies doing the experiments. And then equitable selection of participants, that you do not try to -- that you try to design the study in such a way that you get people into the study without focusing on a particular group that may be particularly disadvantaged economically or in terms of their understanding or in terms of their ability to make a responsible decision to participate. Those broad principles informed by what the understanding of them was at the time the study was conducted would guide our ethical judgments.

UNIDENTIFIED MALE: Right. And respecting all that, I guess what I want to suggest is that the agency has routinely in the past accepted those kinds of studies and drawn a distinction between those and intentional third-party dosing. And I think the NAS pretty clearly drew that distinction as well. My concern going forward just for the program from a workload standpoint is that you're going to be in this rule-making process for a very extended period of time in all likelihood. And I think maybe putting off a decision of being able to separate out that group of studies for something other than a

case-by-case review, where John Carly is looking at each and every study that comes through the door, might be desirable. I think you can safely do it given the advice you've gotten from NAS and the agency's past practices.

MR. JONES: Amy.

MS. LIEBMAN: I just want to say that Migrant Clinicians Network echoes the concerns raised by Physicians for Social Responsibility and I do also -- it doesn't seem very clear to me based on some of the comments that you mentioned that you would take into consideration, you know, informed consent. But I do have a concern in terms of low income and people of color, particularly migrant farmworkers that may be involved in studies and what does informed consent involve and what does coercion involve. You know, and I think we can for the CHEER study a little bit in terms of low-income participants and where do you draw the line with coercion or incentives? So I just wanted to make sure that we remain conscious and aware of studies particularly with low-income populations.

MR. JONES: All right. Oh, Troy.

MR. SEIDLE: I just wanted to echo the comments

that Pat raised, particularly in view of the presentation yesterday on the antimicrobials. Some of these products are antibacterial hand soaps that are designed to be put on human skin. And as this project moves forward if a human clinical patch test becomes part of the non-animal testing strategy, there does need to be an expedited fast track for the agency to deal with these studies. So I'd just like to reinforce that point.

MR. JONES: Okay. I'm sure we will have more opportunity whether at this meeting or another forum we provide to engage in this critical issue. Okay. Mary Francis is going to give us an update on the GHS, another issue we've talked about here before.

MS. LOWE: Okay. Thank you very much. And you'll be relieved to know that we're not going to go through all the slides that you have in your handout. A lot of those are just background. Just to quickly recap. What is the GHS? It's a common and coherent approach to defining and classifying hazards and communicating information on labels and safety data sheets. It is not a system that deals with risk assessment or risk management. There are other efforts to try to harmonize

in those areas. It is based on the major existing systems that are used in transport, in the workplace, in pesticides, and in consumer products. And those major systems are the U.S. system, the EU system, the Canadian system, and the international transport system. And it was developed by consensus of government and stakeholder representatives. The goals are to promote safer transport, handling, and use of chemicals worldwide; to facilitate international trade by promoting greater consistency in regulatory requirements; to reduce the need for testing; and to assist countries, particularly developing countries, in developing strategies for the sound management of chemicals. And we're already on number 6. Implementation, why should OPP care? The implications for OPP programs are that implementation of the GHS would affect virtually all pesticide labels and obviously then every pesticide user and handler would need to understand the new labels and we do have to look at our other regulations and policies related to classification categories to see whether or not we want to continue that linkage or whether they should be decoupled. Expected benefits to the U.S. stakeholders

fall into two main categories. The first category results from greater consistency in the information that is provided to people who are exposed to chemicals. The GHS should increase health and environmental protection by making the labels consistent to users of chemicals, workers, the public. Whenever they see a signal word, a pictogram, or a hazard statement it will mean the same thing in all settings and across sectors in the U.S. and internationally. The second major category of benefits to U.S. stakeholders are those that result from greater consistency in regulatory requirements that our industry must meet here and abroad. It reduces market barriers because you won't need to learn and comply with multiple hazard classification communication systems. At least there will be consistency in that area of regulation. And perhaps the biggest single advantage is that companies would only have to classify once for all the authorities that are implementing the GHS. But obviously given the implications key to all this will be strategies to minimize the cost of label changes and ensure smooth transition. So since we last talked about the GHS in this group we have released a white paper outlining our

initial thinking on how to apply the GHS to pesticide labels. The basic guiding principles that we had in that paper were 1) we would cover all pesticides alike. Technically we didn't need to cover microbials because they're not chemicals but we really did want to treat all the FIFRA-defined pesticides alike. 2) That we would adopt the GHS for the hazard classes that we now label. And 3) in general we wanted to limit the changes we would make in our program to those that are really necessary for GHS consistency. So the key issues in that white paper were the scope of application, actual mechanics, how would labels be submitted and reviewed. We put out two options. One was a separate dedicated approval process and the other was our preferred option, what we call the routine business model, when people are making other changes in their labels they would also make the GHS changes so that it would not be an added burden and significant burden. We also raised the issue of whether or not there were work sharing possibilities with states or with Canada and possible pilot project timing issues and inviting comment on effective outreach and education strategies. The comment period is now closed. Not

counting requests for extensions of the comment period, this is basically who we heard from. One federal agency, three state and local governments, seven trade associations, six individual registrants, two professional associations, one consumer group, and one individual expert, and then a letter on behalf of a coalition of I think it was about four animal rights animal welfare groups. And the major issues that commenters raised were 1) cost benefit considerations. There were a number of technical, what I would call interpretation questions and issues that perhaps could be handled by clarification. For example, concerns about possibly inadvertently creating incentives for additional testing. We got some good discussion of the pros and cons of the implementation options we put out there. We had a number of comments that stressed the education and training aspects, scope of coverage issues, and issues relating to interagency and international coordination. So our next steps will be to work with stakeholders to address the concerns that were raised in the comments and continue to raise awareness about the GHS in the stakeholder community. We are initiating planning for an

all-stakeholder meeting. We've had some conversations with some of the major industry trade associations but we're going to want participation and involvement from all stakeholders so we'll be asking you all to alert the people you represent and hopefully you'll be able to participate in this meeting or some representatives of your groups will participate. We are continuing at the interagency coordinating process and coordination within our NAFTA group. I think it was just last week -- was it only last week, the NAFTA executive board met and there was a discussion of the GHS and the readout I have from that is that there really was a great deal of stress and commitment on the need to try to have harmonized approaches in implementing the GHS. And then finally at some point in the near future there are some things that were adopted into the GHS over the last two years that we need to consider in terms of whether or not we would pick them up for pesticides. One major example is the category of aspiration hazards. And then finally we want to work at the global level to try to minimize further changes so that the GHS does not become a moving target. And this has been really quick but you have our contact

information -- **(END OF TAPE)**

-- subject to the GHS labeling rules and I think in particular products that are classified as pesticides in the United States are classified as drugs or animal in particular, products that are classified as animal drugs everywhere else. Our approach outlined in the white paper in to -- whatever we do we would apply it to all pesticides as defined in FIFRA. Now, in terms of other categories of chemicals, the GHS is not limited to pesticides, so it does apply -- it is intended to apply across the board to all chemicals, not just pesticide chemicals. I could get into a great deal of detail but pharmaceuticals would be covered in the workplace and in transport but not at the end use patient level and so on. It tracks the U.S. system.

MR. JONES: Jose?

DR. AMADOR: I have a comment and a question. The little musical thing right at the beginning, there is only one song you have in there?

MS. LOWE: No, no, I was limited by the clip art.

DR. AMADOR: So that's just to show harmony I

guess, huh? The question, would you tell me what we're doing with the NAFTA group? Are these coordination with groups in the countries that are included in NAFTA or this is groups of American companies that are dealing overseas?

MS. LOWE: The NAFTA group I referred to was the NAFTA technical working group on pesticides, which is the U.S., Canada, and Mexico government representatives, although there's also a great deal of stakeholder involvement. They have published a five-year strategy which includes coordinating approaches to GHS. And there's a great deal about that group on our Web site.

MR. JONES: Amy. And then Alan.

UNIDENTIFIED FEMALE: I just have a question. I asked this a couple of meeting ago and it's still a concern for me. What are the implications of -- and this is on a slide that you didn't include but it's in our handout, on slide 12, of the OPP deciding not to be in harmony with our European colleagues and others on the carcinogenicity and the reproductive toxicity in terms of the labeling?

MS. LOWE: Well, we have not -- actually we're

a little bit out front on this. We have not heard from anyone else what they intend to do on those end points in any kind of official category. But we were following our guiding principle of not changing more than we needed to change in order to be considered to be consistent with the GHS. In other words, not picking up new hazard classes to start labeling.

UNIDENTIFIED FEMALE: So it's not that you disagree with it, it's just that you didn't want to add these to our current labeling?

MS. LOWE: The U.S. government joined in the classification criteria and so on and we expect, for example, the OSHA group to pick up those end points because they do now cover them. But, so it's not a matter of we think that the GHS is wrong on those points, it's just a matter of the building blocks we pick up are those that compare to what we now label.

UNIDENTIFIED FEMALE: I guess I just don't -- I don't understand like what one would get on a European product. Like if they were to purchase a pesticide for instance in Europe versus here. Are they going to be different labels?

MS. LOWE: Well, there are going to be some differences in terms of language, directions for use, and so on, but in terms of the hazard communications elements the Europeans have not announced what they plan to do for pesticides.

UNIDENTIFIED FEMALE: Okay.

MS. LOWE: So I can't say.

MR. JONES: Alan.

UNIDENTIFIED MALE: I had essentially the same question but I would also refer to the previous slide where you didn't show that has to do with germ cell mutagenicity. I can understand that the registrants are not anxious to have this information appear on the label but in terms of public right to know I think this is information that should be there.

UNIDENTIFIED FEMALE: Well, I think the registrants are beginning to be concerned with needing a magnifying glass to read the labels. But one question I had because you do have the comments on cost benefit considerations, has a cost benefit analysis been performed on what this would cost the industry because I know for Syngenta just a merger and a name change cost

$2.5 million to redo all our labels. And so I wonder if you intend to do any kind of cost benefit analysis and let us know what the cost to the industry is going to be. Another question is my understanding of this GHS is that it was originally intended to be directed toward transport of larger volumes of chemicals. So I don't really understand why the agency is driven to put this on the end use label. And to go along with that, if it applies to all chemicals is FDA going to put it on end use labels and if not, then what is the big difference here between the two agencies? I see interagency coordination but that doesn't seem to be coordination to me. And then just a final question is, can you tell me when this stakeholder meeting -- when you're planning to have it.

MS. LOWE: Okay. I think I got your questions. In terms of a cost-benefit analysis, that we would have to do that as part of any rule making and we will also need input from industry on that. Obviously the costs will depend a great deal on what implementation options are used. If we were to go with the routine business model that we were suggesting this would happen at a time

when companies were already designing, redesigning their labels and therefore the incremental costs would be expected to be small. So we are going to be doing that as part of any rule making and we will be looking for information from the companies on that. In terms of the target for GHS, there already is an international transport system so the purpose of the GHS was to go beyond the them. It was never intended to be limited to transport. And in fact transport does not cover a lot of the hazard classes that came up earlier. So for example we don't expect them to pick up cancer and reproductive effects either. We expect that they will pick up physical hazards and the most severe classes of acute toxicity and corrosion. Finally, in terms of FDA regulated products, the GHS tracks the current U.S. regulatory system. And there is actual language in there that explains this. It doesn't say it tracks the U.S. system but in terms of patient labeling, just like pesticide residues in food or food additives in food, those are not intended to be within the scope of the GHS. But those same chemicals would be covered in transport and in the workplace. And then finally in terms of

scheduling the meeting, we hope in the next couple of months but we don't have a date.

UNIDENTIFIED FEMALE: Well, I guess to come back to FDA-approved products, I mean I will go back to the question Nancy asked earlier. If there's estrogen coming from birth control pills that's going into the water that's affecting fish, then the dead tree and dead fish should be on that label.

MS. LOWE: Well, that's something that you could ask FDA to do if you think it is a good idea. They could go beyond that but in general it was considered that there is a trained professional intermediary. It's an individualized patient treatment decision and therefore the intention was that GHS would not get into the -- necessarily get into the drug labeling. It would get into -- it is intended to cover other consumer chemicals, those that are regulated by the Consumer Product Safety Commission.

MR. JONES: Jay, Alan, Jennifer.

UNIDENTIFIED MALE: So this certainly tracks with the whole notion of, you know, things that can be done more alike than less alike around the world are good

for industry, are good for users, and improve the environment, health and safety. I guess we see this as a threat, though, to those initiatives around pesticide regulatory harmonization by way of deflecting resources away from the more important work of harmonizing regulatory requirements, testing protocols and labels. And it's going to be a long time before we see significant amounts of pesticides that are co-labeled in two or more countries. Hence, the harmonization on this end of hazard warnings seems to be a consumption of resources, particularly at the agency level that is getting ahead of the more important work that you've been doing in pesticide harmonization for a long time. So that's our caution and concern, and of course to registrants as Beth indicated, the potential for cost and confusion around label changes driven by this by itself seems to be also a potential loss of important resource focus. And lastly, and I suspect Amy will talk about this, you know, there's a huge investment in training that beyond just the grower community and pesticide registrants from the public sector that need to be taken into account in terms of that cost-benefit consideration.

MR. JONES: Thanks. Amy.

UNIDENTIFIED FEMALE: Yeah. If we're going to talk about the costs of this I really think EPA needs to seriously consider the cost of not just changing the labels but the education process that has to take place. We have federal requirements for certification and training of restricted-use pesticide applicators so we need to get all of our training materials and all of our testing materials updated to include this. But it goes far beyond that. Kevin mentioned all of the different manuals that we have for training. We also have leaflets. We have tapes. We have all kinds of media that we use to accomplish training, not only for restricted-use applicators but also for general-use applicators, for handlers and workers under the WPS, for train-the-trainer type stuff, for the trainers themselves, for both WPS and certification trainers. We have registered employees or registered technicians in many states and we have materials for them. And then we have consumers. And all of those would have to have not only the materials changed, and by the way Kevin talked about the training manuals, for instance, and whether we

share them. Most states do in fact share training materials. We have a lot that we produce ourselves but we also have a lot of materials that we share. Right now one of those shared materials that we're looking forward to is the national core manual for certification and it's going to be some time in another year or so when we'll get that and then very soon thereafter somebody is going to have to develop a new one. So it's just a matter of a huge number of training materials that have to be re-prepared and completely redone. It's very hard for me and the other trainers in the states to see how you can -- in many cases we can add a supplemental section or an extra section to a manual or extra sections to literature that we give out. But a lot of our training materials for this, because it is so global in the sense of applying to so many groups, we are going to want to have materials that are not just readable materials. So you can't go back and make a readable handout supplement to the tapes and the other audiovisual materials that you have. Because that's why we made them audiovisual is because those audiences don't necessarily read, can't read. So you have to have all of this training effort

prepared well ahead of time. And I think the cost is just going to be huge. And somebody really needs to consider if you're going to go ahead with this, how you're going -- I mean, how you're really going to fund this.

MR. JONES: Thanks. Jennifer.

UNIDENTIFIED FEMALE: My comment is going to be so simple after that one. And it won't cost anything. I just wondered if your last slide, or second to last slide, 21, you mention that you were coordinating with NAFTA and OECD pesticide groups, but you mentioned when you were talking also that in addition you've got a great deal of interaction with stakeholders. So it sort of goes back to the question, I always feel like I'm a little bit left out of the circle, so my question to you is what's your coordination method with the stakeholders and what stakeholders are they?

MS. LOWE: Well, we have tried to enlist as many as possible. During the negotiating process before each major international negotiation we had an interagency public meeting that was announced in the Federal Register. I maintain an electronic stakeholder

list that is not just pesticides but it's across the board. And so if you would like to be added to that list it's focused on the international updates, we'd certainly be glad to add you. We add anyone who wants to be added. In terms of outreach to stakeholders, since the system has been adopted it's just been a matter of participating in as many public fora as we can get invited to and don't involve travel. And we -- including this meeting two or three times. And like I say we hope to have an all-stakeholder public meeting in the not-too-distant future.

UNIDENTIFIED FEMALE: So who have your stakeholders been?

MS. LOWE: Well, I would say everyone who commented. We were talking about the pesticide industry, the pesticide educators, professional associations, some consumer groups that have involved themselves. They have not been as deeply involved as other stakeholders throughout the negotiating process. Let's see, states, you know, anyone who commented I guess and anyone who would like to be involved would be considered a stakeholder. Anyone who reads a pesticide label would be considered a stakeholder.

UNIDENTIFIED FEMALE: Right. But I was just wondering what interaction with -- what stakeholders you've had interactions with. That was my question. This is good.

MS. LOWE: I can send you our list.

UNIDENTIFIED FEMALE: Okay. Thanks.

MR. JONES: As Mary Francis mentioned, the white paper, which we talked about in this meeting a year ago saying it was going to come out soon, was issued for public comments so that anybody, whether they were reaching out to us or we were reaching out to them, had access to commenting on the white paper. Julie.

UNIDENTIFIED FEMALE: This is just a little extension to what Amy has said, but I think there's also, you know, just the pest control industry because each individual company does training and all of their training costs will also need to be considered in this. And I guess I just have a little bit of a hard time understanding how this routine -- and I read it and I think, you know, we maybe reflect it in some of the comments, that the routine business model and, you know, that labels will be changed as they come in for other

changes but, you know, especially if you're having to revise all of the training methods how can you train if they're maybe over the span of 15 years because of registration review, that you may have all different sorts of labels out there then, with different labeling in different categories. I just have a little bit of a hard time understanding how that would work.

MR. JONES: I need to stop this part of the dialogue because we're running out of time. But this is meant as an update. We gave an update. We've given a lot of forum, we're going to give some more, about how to engage in those kinds of issues. The white paper was about that. The next stakeholder meeting is going to be about that. Obviously we've got a lot of good feedback in this session associated with issues that people have from all parties and we'll continue to provide opportunities for people to engage in substantive feedback to the agency. Beth is there anything that you felt you need to bring up before we --

UNIDENTIFIED FEMALE: We didn't get to -- do you know when the date is? For this stakeholder meeting.

MS. LOWE: No. Like I say we hope in the next

couple of months but we haven't set a date.

UNIDENTIFIED FEMALE: Okay.

MR. JONES: Okay. Thank you. That was very helpful. The last part we were going to do in this session -- in the interest of time we have passed out a paper. It's a very process-oriented discussion so we're going to skip it for here. It's the statistical approach to setting MRLs, which is simply a way to standardize MRL setting as opposed to it being reviewer by reviewer using statistical methodologies. I'll be happy to hear from anyone who wants to spend some time looking at that. So why don't we take a break right now and come back at 20 of 12:00. I'm going to pass out something that Amy gave me associated with resources and PSEP.

UNIDENTIFIED FEMALE: Okay, to reward those of you who came back, we're going to actually get started. And in the interest, frankly, of maybe picking up the pace a little bit and not totally recouping all of the time, the endangered species panel would like to do their presentation from start to finish and then we'll have a comment/discussion session which will probably be, just given where we are in the day, a little bit abbreviated

anyway. So don't be surprised if your panelists answer with short answers and proposed side discussions outside the meeting or other mechanisms to explore more fully. So with that, I'm going to turn things over to Steve Bradbury, Arty Williams, and Nancy Golden.

MR. BRADBURY: Well, what we're going to talk about today is a handful of issues to give you an update on where we are in the office and with our partners in putting together the next steps in integrating the endangered species analyses and decision making in the overall pesticide regulatory decision making. So what we are going to do is touch upon some organizational alignments in the office. We're also going to be providing an update on some of the process steps we're taking to put things into motion, highlight some of the specific FY 05, calendar year '05 activities we're doing with the services in terms of specific compounds. Arty will be providing an update on litigation that we're in. And also Arty will be giving a highlight on some of the risk mitigation field implementation steps that have been ongoing since the last time we were visiting with you. And some updates from the services with regard to Canada

species that were announced this past week. I think you've all got handouts, right, that go with the Power Point? When we go to the next one, it deals with the OPP realignment. You may see it on the screen but hopefully can see it at your table. One of the decisions we had made at the end of last calendar year as we looked at the evolution of the whole process in terms of evolution of the regulatory decision making, risk assessment, risk management, with how the endangered species implementation within the program office was evolving. And it made sense to not only look at that functional evolution but also take a look at structural evolution to try to optimize efficiencies and effectiveness in the way we go about doing our business and become, as best we can, more proactive in the way we're integrating endangered species affects determinations within the overall decision-making process. So in that context of integrating functional and structural evolution we felt it made sense to realign our folks in FEAD, the Field and External Affairs Division, and the Environmental Fate and Effects Division. In that context, we took a look at the 13 folks that are in the endangered species team in FEAD

and made a decision that we'd move a large number, most of the folks, into the Environmental Fate and Effects Division and integrate those skills and capabilities and strong solid folks in with the other members of the Environmental Fate and Effects Division, again in the context of trying to create some efficiencies in throughput capability. So there were 11 folks that moved from the endangered species team in FEAD into the Environmental Fate and Effects Division. Eight of those folks with their background in wildlife biology, aquatic biology, toxicology are integrated within the five risk assessment branches within the division and therefore bring their skills and expertise in wildlife biology, population biology, in with the mix of Fate and Effects folks that are already in our risk assessment teams. Another three folks are joining our information and support branch, which is a branch that's sort of our hub for ecotoxicology information that feeds into the risk assessment team. It's also our hub for GIS support for the division. And it's also the hub that will help integrate all that information and provide some of the outputs of the overall decision making, for example,

county bulletins as those come on line. So there's three folks with that kind of expertise in information management and the preparation and integration of information are joining that branch. So that's a real quick update in terms of how we're doing the structural evolution along with our functional evolution. The idea that we're evolving as we move forward and we want to try to optimize our efficiencies and effectiveness in moving forward. Okay, we'll go to the next slide. Good. One of the -- as part of the functional evolution increasing efficiency, there's a number of things that have been going on since the last time we visited with you. One has to do with the document that you got in your folder, and I'll talk about that in a second. I just wanted to touch on two other related aspects of putting the program forward and advancing forward. As part of the counterpart regulations there was embedded in that process an alternative consultation agreement. We sort of laid out some of the steps that we're going to go through with the services in putting everything into motion. One aspect of that was the need to form an interagency coordination, communication, and

implementation panel. And that has been formed or getting the last signatures from the last part of our collective organizations to formalize that. And it's a committee that's made up of senior managers and senior staff members across NOAA, National Fisheries Service, across the U.S. Fish and Wildlife Service, appropriate suborganizations as well as the divisions in the Pesticides Program. And in fact that group has been meeting since roughly the time that the counterpart regulations were finalized. We're meeting on a monthly basis to go over a variety of issues that range from how we take a look at current processes, how we can take a look at implementing the processes that we're talking about, how we can advance the science or advance some of the aspects of implementing these processes, and how we can reach consensus when there are some tough issues that we have to work out. So it's a group that's helping to work across our organizations and then help the various risk assessment teams and regulatory decision-making teams as we put the program into motion. One aspect of the charges to that group was to help facilitate and implement a training program for the EPA senior staff.

As part of the ACA there was the need to ensure that the EPA folks were certified in their ability to as a group make a not likely to adversely affect decision as the science and the risk assessment, risk management process came to a conclusion. And so over the course of the last several months, I think we've had three session now with about 30 to 40 branch chiefs and senior scientists in the Pesticides Program across all the divisions, both risk management divisions and risk assessment divisions, that had been taking the training so that they have gone through the steps that are described in the ACA to ensure that decisions that we do make are consistent with the overview document and all the various procedures that we put in place. A good example of all three organizations working very effectively together in creating a training program where there are risk assessment staff and risk managers from the Pesticides Program working with senior staff in National Fisheries and National Fish and Wildlife Service to ensure that the training, while getting across what we needed to know about the Endangered Species Act of course, was also integrated with the processes going on in FIFRA and the risk

assessment, risk management process. Again do it right and understand how we connect these things to do it efficiently and effectively. So in addition to the continued process development to increase effectiveness and efficiency we also, inside the agency and then sharing with our colleagues in services, spent some time taking a look at how say re-registration works through its 604 phase, how the registration process plays out, taking a look at that. Taking a look at the overview document which is our shorthand version for a technical support document that went along with the counterpart regs that describe the risk assessment process for pesticides and how that's functionally equivalent to the same kind of processes Fish and Wildlife Service and National Fisheries Service would go through if they were doing an effects determination. We otherwise need to sort of sit back and connect the dots between the risk assessment processes and the overview document, the phases we go through in the registration and re-registration process to help for internal guidance among our staff to better understand how all these pieces come together. And the goal being to ensure that we focus our

resources efficiently and effectively, zeroing in on the questions we need to answer, document, and when we can move on to different phases in the process. So, the step document has sort of the attributes that are on that screen and this. Switching over the second page you have on this general topic. I won't go into great detail. You've got the document with you. You can read it and I'm sure as Anne was implying in other sessions, updates, or other fora we could talk about it in more detail. But the basic four steps are designed to figure out where to focus your resources and when you can determine you've made a sufficient decision and can stop going down a certain path. The first step just has to do with the basic baseline risk assessment, just determining whether or not you have risk projections that are exceeding the thresholds that are described in the overview document. And if in fact from indirect effect or a critical habitat effect and direct effects you're not exceeding key thresholds in fact you've got a no-effect and that process or that specific use for that specific product is done. Step two, if you had some exceedances of those thresholds then gets into the process of taking a look at

the overlap of the pesticide use with where the species are located and the critical habitat is located to again determine where you can do refinements or where you may be able to make some decisions. Steps three and four then get into higher spatial and temporal resolution of a risk assessment to really start to zero in on more species place, time specific analyses to reach credible and defensible and opening transparent no-effect, likely adversely effect, or necessarily likely to adversely effect decisions and create the kind of information that then helps the services and us go through the next stages of the process. Throughout the whole step process we talk about focusing resources, asking questions, keeping in touch with the services. In some cases we may have certain situations where it would be more resource smart for all the agencies to be working together early in the process to optimize getting key information early on because it doesn't take rocket science to see where a risk assessment may be heading. There may be other cases where we can quickly confirm, we're probably okay don't need the services right now but we'll keep them apprised of where we are just in case we hit a bump in the road so

their resource planning can be anticipatory in some of the things that they're going to be dealing with. So in a snapshot, the steps document is designed to connect the dots between the overview document and the various registration and re-registration processes we have. How do we optimize efficiencies? The document will also acknowledge the fact that it's very difficult to have a process and have it immediately turn on a dime and implement everything that's described in the overview document. Some chemicals are well along in re-registration and to go back and update all those techniques and still make our re-registration deadlines becomes sort of a challenge in physics and time-space continuum and we just can't really do that. So we acknowledge that but we acknowledge the need to be transparent and document what we have and haven't done in terms of the overview document and the effects determination so that we're prepared to move forward in other steps in the life of that product to come back and take care of those things. And that sort of philosophy is consistent with what Bill Diamond already was describing at some previous PPDC meetings in terms of

registration and re-registration and registration review being techniques that we will be forwarding these approaches as we move forward.

The last comments that I'll have before turning it over to Arty is also a topic that's identified in the step document and relates to some of the efforts that we're doing as we move forward with the services in terms of making sure that we all understand what the overview document says, the risk assessment techniques, describing that document in the context of real chemicals and real risk assessments on real time lines. And so what we've been doing is looking at opportunities where we can still meet our deadlines but at the same time use that as an educational process for all the parties that are concerned. And we had workshops, I think we had a workshop last fall talking about metolochlor in the context of the Washington toxics case and how as part of that continuing consultation we're using that chemical as a way to again make sure we understand exactly how the overview document works. But using those learning tools, learning opportunities in the context of meeting deadlines that have to be met. In the same context taking a look at

some compounds that are in the re-registration pipeline, if you will, on the overhead identifying some compounds that we are going to -- we've already done the communications with the services indicating we'd like to go into informal consultation on these compounds. And the reason for doing that is to again increase efficiency and effectiveness, to start working as a team earlier in the process rather than late in the process. At the same time use it as an opportunity to again make sure we're working out all the kinks in the overview document, the risk assessment process, and the risk management decision-making process. The unnamed new chemical isn't a secret that we're trying to keep from you. It's just that we haven't picked the new chemical yet to use as part of this both let's get things done on time and make sure that we've got ongoing education working effectively. So that's -- we just haven't picked that compound yet. And with that I'll turn it over to Arty and go from there.

MS. WILLIAMS: Thank you. I'm going to touch on just the status of litigation that we're facing regarding endangered species and the risk mitigation and field implementation aspects of our endangered species program.

We've talked to you about both of these in the past so these are truly updates. I just wanted to let everybody know the status of the major lawsuits we're facing. First in the Washington toxics case, if you all will recall, that case is currently on appeal to the 9th Circuit and that's a case that focused on approximately 54 active ingredients relative to 26, I'm going to call them subspecies, but environmentally significant units of Pacific salmon and steelhead. It is currently on appeal to the 9th Circuit and we're awaiting a decision on that. Kind of as a follow-on to that case, the plaintiffs in that case filed some papers with the court moving the court to require us to go back and reassess all of those 54 pesticides in a way that was completely consistent with the overview document that Steve mentioned. If you remember the timing of all of this, I think all but about two of those assessments were actually completed before the overview document was finalized and endorsed. So they are not 100 percent consistent with that overview document. The court looked at that motion and looked at our arguments regarding that motion and ruled in the federal government's favor. So rather than going back and

starting these all again we're going to continue on the path we had taken, which was to continue consultation with the service, with National Marine Fishery Service, on the subset of those 54 that we found either may affect, not likely to adversely affect, or may affect likely to adversely affect. So we are continuing with those consultations. In the case that we colloquially call CATs, that's a case that was filed by the Californians for Alternatives to Toxics, and I only wish all groups had such nice names that we could acronize. I like saying that one. In the CATs case we had entered into a consent decree with them to review the effects of 18 pesticides on 33 plant species in California and a subset of those same salmon and steelhead that I mentioned in the Washington Toxics case. The subset were those populations or ESUs or subspecies that were in California and southern Oregon. That schedule has come and gone. We completed those assessments. Subsequent to the final deadline for those CATs has written us a letter questioning some of the methods that we used in terms of whether they were compliant with the consent decree. So we're currently looking at that and we're in discussions with them to see

if we can resolve the issues that they've raised.

The next case, the Barton Springs salamander case, which was actually a case not brought by the Barton Springs salamander, (Laughter) although that would be unique I suppose. It's actually a case that was brought by the Save Our Springs Association, Alliance, SOSA, and it focuses on six active ingredients and the potential effects of those six active ingredients on one species and that's the Barton Springs salamander, which resides in Barton Springs, Austin City, Texas. There is a briefing schedule for that case. That schedule has currently been stayed while we're engaged with those people to see if there's any potential for settling that case.

The next case is the red-legged frog case, which again was actually a case brought by the Centers for Biological Diversity, focusing on a variety of pesticides' potential effect to the California red-legged frog. The motions in that case have been filed, our cross motions have been filed, and a hearing on the merits I believe is scheduled for next month. So there should be some action on that within the next month or two.

The atrazine case is a case brought by NRDC and

focuses on the potential effects of one pesticide on 23 aquatic species in a variety of locations across the U.S. There was a motion on the part of NRDC to go through a process called discovery and a magistrate judge concurred in that and ordered discovery. The federal government at this point has objected to that and has asked the court to review that decision. And we're waiting for that decision.

And then kind of, finally, last but certainly not least, on the list is a case that has been filed that actually is not a case directly against EPA, I'm so glad to say. But I'm sorry to say against our colleagues at the services and I'm going to let Nancy tell you what the status of that is.

MS. GOLDEN: Okay. This is a case filed against both the U.S. Fish and Wildlife Service and the National Marines Fishery Service, filed jointly by eight different groups, the Washington Toxics Coalition, Northwest Coalition of Alternatives to Pesticides, Defenders of Wildlife, NRDC, Center for Biological Diversity, Pacific Coast Federation of Fishermans Associations, Institute for Fisheries Resources, and Helping Our Peninsulas

Environments. We need an acronym for that. Basically this action challenges the counterpart regulations as a violation of section seven of the Endangered Species Act, that's the section that deals with consultation issues. Also challenges the services for failure to prepare an environmental impact statement. And we're really just in the beginnings of this case. We have -- both services have prepared an administrative record and submitted that to the plaintiffs and right now we're engaged in discussions with the plaintiffs regarding that administrative record.

MS. WILLIAMS: That's it on litigation I hope. In terms of risk mitigation and ESPP, that stands for Endangered Species Protection Program, not a good acronym to try and say, field implementation. What I wanted to do today was update you on where we are with issuing a notice that kind of is the last piece of this puzzle, which is we've been through the process, the risk assessment process. We've potentially identified areas where pesticides may be causing a problem for a species and we need to put something in place in the field. How do we do that? That's what this notice is about. We've discussed

with this group pieces of this notice in the past and we are anticipating a June publication date for this. It's not a regulation, it's a notice of how we intend to implement risk mitigation measures for endangered species. The notice will provide some context as background for the entire program, so when you see it you'll see some information in there about how the counterpart regs and the overview document and the ACA and this piece all kind of hang together to make a complete program. But that is provided for context purposes. It's not going to be every single aspect of each of those pieces of the puzzle. Probably the two major aspects of the notice and two that I want to just mention a little more specifically in a second, are the way that we're going to be telling pesticide users that something needs to be done and what the opportunities for public participation are potentially going to look like. And we have specifically talked about both of those issues with this committee so I'm not going to go into a lot of detail right now except to tell you that given the input from not only this committee but the public comment that we took in December of '02 on this program, one of the major aspects of this is how do you

actually get information to the users. We are continuing to go down the path of using a generic statement on pesticide labels that refers the pesticide user to an endangered species protection bulletin that in a very geographically specific manner will outline where pesticide use needs to be changed and what specifically that change needs to be. Probably the new part of this is that our major distribution method is likely to be through the Web as opposed to printed paper copies. We looked at a variety of ways to get this information into users hands and just think this is probably the most efficient and effective manner. We also will have a kind of a backup system in the event that people who need one of these documents don't have access to the Web, where they can make a phone call and have one sent to them for their particular area of the country. We're hoping to work with a variety of people to help in this distribution even though it is electronic. And some examples would be to work with the Extension Service to get them accustomed to helping people with that, to start discussions with trade associations so that perhaps when a user goes and purchases a pesticide a dealer can assist them in showing

them what information they're supposed to be following. And then also other federal partners that are out in the field to help us with that.

The second thing I wanted to touch on was public participation. We had a whole session with this group about public participation some time back on this program. When you see this notice, hopefully in June, you will see that we still are making a commitment to have a great degree of public participation. We're still going to be saying what we said to you last time, which was where the endangered species process lines up well with the registration, re-registration, registration review processes, these standard public participation approaches for those ongoing processes will be used as well to get input on endangered species assessments and determinations. However, we also noted last time that there are situations where those are not going to line up well and we're going to need some other participation avenues for people when that doesn't occur. You will not see what those avenues are spelled out in this notice that's coming out in June. You will still see a commitment to them. The reason they're not spelled out is

because we've struggled with what the best approach is and we think the way to figure out what the best approach is is to actually start doing some of these and kind of test running them. So we're going to be developing those aspects of public participation as we go and publishing them on the Web, much like we did years ago for re-registration, with the ability then to upgrade those and modify them and augment them as we go along and learn more.

And then I guess finally on our agenda of things to update you on is also a services issue that we wanted to provide them an opportunity to tell you about.

MS. GOLDEN: We just wanted to mention briefly to make you aware of a notice that a came out on the Federal Register yesterday, which is our yearly update of candidate species. A candidate species is a species in which the service has sufficient information on biological status and threats to propose listing but is precluded from taking action by other higher listing priorities. So they're not listed species, they're not proposed species. They're candidate species and these are species that can come off the candidate list before they become listed or

can be reviewed to become proposed species. For your information, prior to this listing we had 283 candidate species. Two were removed from this listing because of successful conservation measures that have been invoked, and five were added. There's a whole list, if you go to the Fish and Wildlife Service Web site we have a press release on this where you can get more information about the specific species, or of course go to the Federal Register notice. This notice also includes 21 species that have been proposed for listing into the endangered and threatened list of plants and animals. And in point of fact, basically candidate species, they're not species that we would formally consult on. They're just things that we want to stay aware of if we had specific information that there was a threat to that species, then we would consider that. We wouldn't do a formal consultation until the species was actually proposed for listing. So if you want more information please look into that.

MS. WILLIAMS: Okay. Before we actually move into the comment period, we have a public comment period after we finish the endangered species discussion. I

think right now there are three people signed up but if anybody in the audience wants to add their name to the list now would be a good time to actually do that so we have a full list of who wants to make comment during that period. The other thing as you're thinking about what questions you might to want to ask the endangered species panel, I wanted to mention that David Miller, who's a branch chief in our Health Effects Division, is the technical contact person for the statistical MRL project that we didn't talk about. And so we'll make his contact information available after the meeting so that when you take a look at the technical document if you've got questions and you want to discuss it more you'll know how to get hold of David for those discussions. So now I think we're ready for comments and questions on the endangered species panel presentation. Dennis.

UNIDENTIFIED MALE: Just a quick question on implementation and workshops for the future. Do you all have plans for public participation in a workshop that will go over the concepts that you've talked about today and with more detail as you get into implementation?

MS. WILLIAMS: Yeah. Thanks Dennis. We

actually have -- I wouldn't say it's planned, we have the funding set aside to do such a workshop. I think we originally had intended to hold three such workshops, kind of one on the East Coast, one mid-country, and one West Coast. Because of budget constraints I think we're only going to be able to hold two. One probably will be in the D.C. area and one somewhere outside the D.C. area. The purpose of it will be precisely what you're talking about, to kind of go over implementation, how it's going to function, to start getting people on board with that, not only the state agencies who are going to be instrumental in enforcing any limitations that are put in place under this program but also the growers and other pesticide users so they can understand how they're supposed to comply with it, and of course anybody else who's interested. It's not going to be immediately after this is published because as I mentioned we've actually not organized those yet. But I'll close my response by saying we think that will be okay because while the notice will become effective 60 days after it's published and actual limitation on a pesticide will not be required until the label statement references the bulletins in the

appropriate manner and the bulletins are up on the Web site. So while it's effective there will be nothing to be effective immediately.

UNIDENTIFIED MALE: Steve mentioned the training of EPA staff on risk assessment for endangered species. Is there any way that interested stakeholders could audit those training sessions so, you know, for instance registrants could sort of also gain from that learning?

MR. BRADBURY: It would seem that some of the -- good question. It would seem that it would be a pretty reasonable thing to think through in terms of both the PowerPoints and the training materials, because frankly it's taking a look at section seven and the steps that go through an NOAEL, not likely, and cross-walking that to some of the basic pesticide risk assessment techniques. I think it's something we should probably talk about and see if there's a way that we could try to help share some of that.

MS. WILLIAMS: Actually in the interagency coordinating committee we talked about that. I hadn't actually thought so much in the context of registrants but certainly for our regional staff and our state partners.

So I think that's a good add-on idea. We may be asking, though, for some assistance from trade associations in actually executing it. Carolyn, I think you're next.

UNIDENTIFIED FEMALE: Could you just elaborate where you are on the rodenticides and the carbafuran assessment? I know that you said that you had met with the services on these but then what happens next?

MR. BRADBURY: We just within the last -- let's see with rodenticides I think it was in the last few weeks, that we sent a formal letter that goes over to the services to ask to go into informal consultation. And that's in the context that we've done the risk assessment to a point where we know there appear to be some issues with nontarget organisms in terms of potential risk and therefore we think it's reasonable to start earlier rather than later to explore whether or not those risks as they currently look like could in turn create risk to listed species. Part of the process also then sort of accelerates the exploration of all sorts of issues, like the habitat requirements of listed species that may be associated with these uses to again help us zero in and focus as to whether or not we have an issue and if we do

have an issue whether or not it would appropriate to go into formal consultation. So that letter went over a couple of weeks ago and we're just in the early discussions about how to plan our first meeting to start to get everybody together and get the teams together. And the aldecarb and carbafuran letters are just going over shortly. They went? Okay. We've been having sort of discussions. It's not like a surprise to the services that the letters are coming over. So we've already been starting sort of informal planning for the informal consultation.

MS. WILLIAMS: Okay. Nancy?

UNIDENTIFIED FEMALE: Just in listening this morning to the -- and seeing the list of the litigation made me wonder about cost-benefit and overall, and maybe this is totally an unfair question you don't need to answer, but do you see these cases as moving things forward more quickly or has this helped all these cases or in a sense has it drawn your attention away from your normal processes and you haven't been able to move forward as quickly as you might have otherwise? Just a thought.

MS. WILLIAMS: Just very quickly. The agency

always takes really seriously litigation and court decisions that basically tell us we need to be taking on an issue in a way that we've not been doing it. So in that sense, obviously the litigation and the court decisions provide an incentive to get us focused where perhaps we weren't giving the right kind of attention to do it. On the other hand, people often talk about death by duck bites and where we definitely would prefer to have a systematic program of endangered species implementation, which is why actually a large part of this morning's presentation was about the internal operational things. We want it to become a routine way of business because it's a better way we believe to protect species more rapidly, more effectively, and with a more effective use of resources and consequent benefits to users and others than if we were to try to run the whole program in response to litigation. Well, it looks like we're done and I'll turn it back to you.

MR. JONES: All right. Thank you very much. I appreciate it. At this point in our agenda is, we have some time for public comment. Right now I've got three individual who signed up for public comment. The first is

Jennifer Shaw. Jennifer?

MS. SHAW: Thanks. Hello. My name is Jennifer Shaw. I'm with Syngenta Crop Protection. I'd like to thank EPA for the opportunity to comment today at this PPDC. And specifically I'd like to comment on behalf of the pesticide registrant community to provide our perspective on endangered species data requirements. As background, registrants must provide to EPA information on the proximity of federally listed species to pesticide use sites. And this is part of the registration and re-registration process. This information provided by registrants will be used by EPA with other information for preparing endangered species effects determinations. Given this, registrants are seeking clarity as to how to satisfy these endangered species data requirements. And it's our intent to satisfy these in a way that's meaningful to EPA and their endangered species protection program. There are two categories of data that are pertinent to satisfying these data requirements that I'd like to explain. First, general data that are information, databases, are tools that are applicable to many different pesticides, not pesticide-specific, but can

be applied to a pesticide-specific evaluation. For example, information on the location of species, information on the location of crops, are tools that can systematically manage this information. In contrast, pesticide-specific data help characterize different aspects of that pesticide. For example, maximum use rates, typical use patterns, what sort of taxa are potentially at risk from that particular pesticide. Together these data can be used by the registrants to satisfy their data requirement on proximity of pesticide use sites to listed species. EPA has provided an excellent overview of the data methods used in endangered species assessments. We've seen this in the overview document that was referenced today as well as in public workshops that EPA has held. And today we've learned more about the internal process that EPA intends to follow in preparing these assessments. However, bringing this back to registrant-specific tasks, we seek guidance on how to combine these general data sets with pesticide-specific information in a way that will provide information on the proximity of federally listed species to pesticide use sites. In other words, to satisfy our data requirement.

It's important to know also that EPA has clearly articulated the trigger for requesting endangered species data and this really goes a long way to providing transparency not just to registrants but to other stakeholders. This trigger provides the basis for EPA to ensure that data requirements can be consistently required as an important aspect of implementing the new counterpart regulations. In response registrants must provide both general data and pesticide-specific data in order to satisfy their data requirement by citing to existing data or developing their own data. Quality standards are critical to all FIFRA data generation and therefore should be emphasized as well for endangered species data requirements. Specifically, standardized data inputs, for example, ag census data for crop rotations. Second, standardized ways of comparing the data. For example, comparing use sites with species locations and reporting that information. And pointing out measures to check on the reliability of sources of data and quality criteria for ultimately determining the acceptability of input data and consistent retrieval and application of general data to pesticide-specific evaluations. Further, integrity is

key and this should be proven through a thorough underlying documentation and transparencies are clearly defining the data deliverable and EPA's process for completing the assessments and decision making. Also demonstrated utility of data and adequately informing regulatory decision making. And finally quality criteria for determining the acceptability of an overall registrant data submission and ultimately developing those data evaluation records. In summary, registrants need clarity from EPA on how to satisfy pesticide -- **(END OF TAPE)**

-- data together with pesticide-specific information to evaluate proximity, guidance that includes information on the quality criteria that will be used for determining acceptability and also transparency in the process by which EPA will rely on this data. EPA should consistently impose data requirements from these triggers and in response affected registrants should provide both general data and pesticide-specific data in order to satisfy the data requirements and do this by developing their own data or citing to existing data. In closing, a registrant is committed to seeing the successful implementation of EPA's endangered species program and

your input is going to be very helpful as we move forward in satisfying our endangered species data requirements in a way that's meaningful to EPA's initiative. Thank you.

MR. JONES: Thank you. Jim Kunstman has also got a public comment. Jim, if you would introduce yourself and your affiliation.

MR. KUNSTMAN: I got a little nervous when I saw a slide show up. I don't have any slides. But I just had one comment. My name is Jim Kunstman, Director of Registration for PBI Gordon. I wanted to highlight one of the things that Julie brought up earlier in the discussion about labels and you've heard a lot of information this morning about the various things that are going to affect labels over the next couple of years. And I wanted to emphasize the importance of timing on the requirement of these label changes. As PBI Gordon, and we're not alone in this, if you go to the store and look at products that you buy for consumer use, a lot of them have multiple active ingredients and so the concern that we have as a registrant of products that contain multiple active ingredients goes to the timing of when those required changes are. We have over a hundred product with multiple

active ingredients, some with three or four active ingredients in them, and so when you consider the changes that are going to be coming along because of registration review, re-registration, if there are some things that come up because of the consumer label initiative, we've heard of global harmonization, we have a lot of things coming up in the next couple of years that are going to require us and encourage us to make changes to those labels. And if we can put some real thought into making sure that the timing is appropriate so that we don't have to come in three to four times with each of our labels to, you know, make the required changes to them, and also for the EPA's resource requirements in reviewing those labels, I think some time well spent up front will be well used. Thanks.

MR. JONES: Thank you. And our final public commenter is Jean Rimers. Jean? Interesting. Somebody signed you up. (Laughter.) Okay. Sorry about that. Okay. I'm going to spend a few minutes first walking through some of the follow-up items that we've already decided to do following some of the advice we got over the last day-and-a-half. Now, this does not -- isn't a

comprehensive listing of how we're going to deal with all of advice we got over the last day-and-a-half. Some of it is going to require me and my team to get back together again and talk about some things before we decide what to do with some of the advice that you've offered over the last day-and-a-half. There are a handful of things, though, that we've already -- I've already made a decision as to what our next steps are going to be. So I think it's useful for me to share back with you what specifically we're going to do before you head out of town. And then we'll spend some time -- I'm actually going to do that first because that may inform a little bit the next discussion which is about potential topics for the next meeting. I'm going to do it in sort of the order in which we ran the meeting.

As it relates to the first thing we talked about yesterday morning, the PSEP, the strategic program review, OPP is going to continue to work with the existing work group on implementing the recommendations from the program review. We are going to supplement to that existing work group at the recommendations of some members of this committee, some individuals from the farmwork community,

and we'll talk to some of the farmworker representatives who are on this committee and elsewhere as to who could join us in that effort. So we'll follow up basically on adding farmworker representation to that work group and then that work group will continue to work with us on implementing the recommendations for the strategic program review. The comprehensive pesticide worker safety program assessment, again, our plan is to follow up on the recommendations of that assessment and to keep the PPDC apprised of our efforts in that respect. We are also going to either at the next meeting or potentially the meeting after that, but most likely the next meeting, we're going to give the PPDC an update on our efforts as it relates to the PRIA resources that were made available specifically for the worker protection program. Again, this is going to be an update as it relates to how we have invested those resources. The results work. As we said yesterday, we've got an internal work group focusing on indicators and results. There seem to be very meaningful consensus around having a PPDC work group that would work in parallel to the agency effort. They'd basically be informing each other back and forth, given the direction

that I've given the agency work group I have a feeling that at the beginning at least they're going to be moving ahead quite rapidly and the PPDC work group is going to be giving advice back to that. But hopefully at some point the PPDC work group picks up and maybe even becomes a driver in that. But I see them working in parallel to each other so that one is informing the other and we will keep that on the agenda at our subsequent meetings hearing back from the PPDC work group.

We will -- EPA, the Pesticides Program, using our electronic means, will solicit membership in the next week or so from all of the members here. It's very important in this and every other work group that we have that either we expressly acknowledge as we have in the process improvements work group that it is not necessarily going to be a diverse group of stakeholders. That's not going to be the case here. We very much need for there to be representation across the spectrum of our membership on the results effort. One of the things to note, and we've utilized this before, for PPDC work groups, for any FACA work group, you don't have to be a FACA member to be on the work group. So what we'll do is first canvass all of

you about your desire to participate. If we find that we've got some gaps, we don't have any individuals representing any particular part of the constituency here, we'll ask some of you if you have some recommendations of people who may not be on the PPDC who could participate. We have used that mechanism a number of times in our work groups and it can be very effective.

One of the commitments that I made, and it was based on some comments of a member of the committee, that we will continue to think about how we can get in the Pesticides Program, PPDC input into budget decisions the program is going to have to make in FY '06 and I yesterday articulated how -- why that's hard for us to do. But we're going to continue to work on seeing if we can come up with some proposal for engaging this committee as we go into the '06 budget process. Spray drift. In a couple of minutes I'm going to ask you give us some advice along the lines Anne asked yesterday. What would be a good forum for the agency to engage the public broadly, stakeholders broadly, in spray drift policy development.

And the last issue which I'm going to let you know sort of how we have taken the advice we've gotten

over the last day-and-a-half is as it relates to registration review, that the work group get back together, the PPDC work group get back together again and basically looking at four issues. Two of them that were discussed today, to further vet them, and report back to the committee about where consensus can be identified and where it can't. And what are the issues around the areas where it can't be identified. Again, that's associated with the two issues discussed where we had presentations today, documentation of registration review decisions and how we implement the product part of a registration review. And then there were two additional issues which I put on the table and asked the work group to get back on. One had to do with the schedule. What -- when would it be logical for the agency to not follow a chronological schedule without any deviation at all. And the second had to do with what I've understood to be an area where there seems to be consensus in the work group and I'm going to ask that the issue be revisited and vetted a little bit more and it has to do with how the agency deals with data coming from a DCI that's identified in registration review if the registration review decision isn't dependent on

that data having been submitted. And we're going to do some work to try to show for you why this creates a bit of a challenge for us and see if that issue can be revisited. So there are four issues that that work group is going to re-engage in. And again, this is true for all PPDC work group. It's very important to try to identify where consensus is achieved and where it hasn't been achieved and then talk about the things that have prevented it from being achieved, what the issues are associated with that. So that's some of the follow-up items coming out of the last day-and-a-half based on some of the advice that you all have given the agency. That's not totally inclusive. There are some other things that we're going to have to go back and talk about a little bit before we decide how to respond to that advice.

Talk about the next meeting and one of the struggles that I think all of us have as we get together is that for the agency -- these meetings are about the agency getting advice from a broad group of stakeholders. And it's important for us to keep that in mind all the time. That we do spend some time at this meetings just sharing information, because I think it's important for us

to be sharing information periodically. There's a lot going on in this organization as you can see, and I think it's useful, worthwhile, and cost effective to share information periodically. Not periodically, we share information all the time. But using part of this meeting to share information. However, the point of this meeting is not for us to educate the PPDC. The point of this meeting is to get advice from the PPDC. Getting advice is -- getting good advice is a function of how well informed the membership was. I recognize how hard it can be to be well informed on any of this issues. It is no small act on your part to be informed on any of them, let alone many or all of them. But to get good advice, to give good advice, involves an investment of being informed on the issues. And I think that we can do more to help you get better informed. You can do more to get yourself better informed. And if we're both investing in that we can get better advice. One of the ways we've tried to deal with that is by having work going on in between these meetings in the form of these work groups. Again, I realize that that is a barrier for many of you because of resource constraints associated with that. But I think that it is

worthwhile to try to have some meaningful part of these meetings be getting work group reports back where there has been some vetting of an issue in between the meeting. I just really -- I think it's very hard on these issues to get yourself up to speed based on some piece of paper we may have given you a week or two weeks before, reading it on the airplane, and then coming to the meeting. Again, I recognize how hard it can be to invest in the way one would need to in some of these work groups. So there's a little bit of a bias in the next meeting, in the topics that I want to discuss at the next meeting. I think that this bias has been consistent for the two years that I've been in this role, towards hearing back from work groups of ours about issues that they've been vetting. And I realize that that bias exists and I'd like to sort of get some feedback from you because I'm sure many of you can't participate in one, two, three, or all of these activities. But so the next meeting candidate list that I have right now, and we have some time today to get some feedback on this but we also can use the standard electronic means that we do where you can be sending messages to Margie and actually Margie will ask you over

the course of the next four month, do you have any other ideas about what we can talk about? But results and indicators is something that I'd be hard pressed to be talked out of having on the next meeting agenda. There are some -- the PRIA worker protection resource. How we are planning on -- how we are spending the resources that came to us from PRIA as it relates to worker protection is one topic. Spray drift, and the first thing I'll ask is sort of your advice about how you think the agency should engage stakeholders on spray drift policy development. It may well be useful, it depends on what happens, I think this afternoon and subsequently the work group that's meeting on consumer labeling. That is a potential agenda item at our next meeting. And hopefully there will be some meaningful progress over the course of the summer and early fall as it relates to the four topics discussed a minute ago by myself around registration review. So those are some areas where I think that we would benefit from advice of the PPDC at our next meeting, which by the way, we've tentatively targeted about October for that. So with that, why don't I start by getting some sense of members as to your advice as it relates to spray drift

policy development and what would be an effective means to engage stakeholders? Would a PPDC subgroup or some other forum be an appropriate way to get stakeholder engagement as we go into spray drift development? Or would you rather we just shut ourselves in a room, come up with something, and float it out in a PR notice? (Laughter.) All right. Final PR notice. That would be against our policy on policies though. So start with spray drift and any other ideas you may have about topics for our next meeting. Julie.

UNIDENTIFIED FEMALE: I want to go back on the two issues, the two additional issues, the scheduling and the DCI. Those issues really have been discussed by the work group but in a different context than the things that we were discussing today, and which may be why it didn't all kind of mesh together. But we really had talked about the scheduling in the context of public participation and there was quite a -- you know, we did vet that one quite a bit. And --

MR. JONES: On those two issues, Julie, and I recognize there is a consensus around them and what we're -- as we've done more thinking some things have come up

that we want to bring back and say, Could you help us think about these things? So I recognize that there's been a lot of very good work there. The nice thing about starting early on something is things come -- you think of things as you mull them over. And we've identified a couple of areas in those two topics that we want to bring back to the group and say, What do you think about this?

UNIDENTIFIED FEMALE: Right. Because we did, you know, do quite a bit of discussion on the data call-ins with regard to the decision, final decision. So I just, you know, those really aren't new.

MR. JONES: Yep. I'm aware of that. Thank you. Mary Ellen?

UNIDENTIFIED FEMALE: On stakeholder engagement in regards to drift, I can't help keep going back to the model we put together for the mosquito labeling. The model that we -- that model process that we went through for the mosquito labeling, we convened a meeting of stakeholders, brought together the issues, and then worked through, it took us a year or two to come up with recommendations and then brought them here to the PPDC and other venues. I'd like to suggest that we do that again,

bring stakeholders that would be members of the PPDC I'm sure representational.

MR. JONES: Or otherwise.

UNIDENTIFIED FEMALE: And come up with some specifics again with how to deal with some of the drift labeling issues and then bring them here when we've got something in front of us.

MR. JONES: So in that experience we -- there were members of the PPDC who participated in that but it wasn't limited to it. So it was more of a public meeting where people who had a stake came and brought their perspective. It then got worked more aggressively by state and federal folks and then brought to the PPDC.

UNIDENTIFIED FEMALE: Right. Right. And of course since the state lead agencies are the ones doing the actual enforcement and getting the complaints on drift issues we would want to be a large part of that course.

MR. JONES: Steve.

UNIDENTIFIED MALE: Well, I know we've said this before and I don't want to be terribly repetitive, but it does actually help to get the material early. I think this time we only got a couple of pieces from the entire

agenda early. So if you come in really cold to a lot of this information and I think a number of us felt a little lost, we weren't in the ballgame entirely, and so I think it help to do that. And I also understand how I'm always the 11th hour hero on all things I do so, which is why I'm reading it on the airplane. I can understand why many of those bits of information of late. The second thing relative to spray drift, maybe I missed this but isn't there a -- there was a spray drift task force that's been working for forever?

MR. JONES: Not on the policy issues associated with spray drift, on the technical. They're sort of a science technical group as opposed to a policy group.

UNIDENTIFIED MALE: Diane was talking about some technical issues yesterday.

MR. JONES: Well, there are technical issues, but basically what we're struggling with are the policy issues.

UNIDENTIFIED MALE: Okay. I just thought there might be some value in having a report from them on some of their issues, but if it's purely technical then -- well, they still may have some opinions on policy as well.

MR. JONES: Sure. Jay?

UNIDENTIFIED MALE: Still on spray drift, I think number one that it is appropriate to form a work group from this body and/or others to join. I'm of the opinion that it needs to be re-branded because I think the topic really, for policy purposes that you're trying to tackle, is somewhat broader than just pesticide products that happen to come in liquid form and go through a nozzle. So it is a little broader from a policy context and the technical stuff that, you know, the spray drift task force and registrants and others have developed scientifically over the years certainly is an important underpinning to all of that. But that science will continue to evolve as industry and the user community go forward as it has significantly in the last 10 years, but what you're looking for I think, Jim, is establishment of policy that kind of allows you to then make case-by-case decisions around, you know, what is acceptable risk. And that's where I think this is really broader than, you know, liquid formulations of pesticides that are sprayed.

MR. JONES: Right.

UNIDENTIFIED MALE: And so I think it needs to

be reformed a little bit in that way and I think you need probably some representation from OGC and people from the stakeholder community that can bring some legal expertise to bear because it really is, in my view, translating the risk standards from the relevant statutes that govern what you do in regulating pesticides into regulatory policy or practice. So that would be my view.

Another subject that I think is worthy of a work group is section 158, despite the fact that, you know, there's some comment period going on. Our sense is, at least from CropLife and our members, that there is a lot more need for some dialogue with a broad cross-section of stakeholders and EPA on a lot of the major pieces that are now proposed on 158 that I think we would benefit from a FACA-enabled kind of forum of one sort or another. So whether that's appropriate for a PPDC work group or some of the venue we would recommend that.

MR. JONES: Okay. Amy.

UNIDENTIFIED FEMALE: I think Jay just summarized some of the answers to my question but it's still not 100 percent clear to me exactly what do you need in terms of stakeholder input on the spray drift issue?

MR. JONES: It is as Jay characterized it. It is how do we take the science as we understand as it relates to a chemical's ability to move off of its target and translate that into implementation which would be largely through labels. And what is the policy -- what are the policies that are going to govern that process so that when we're making individual label decisions we're able to use that science and that policy to lead to appropriate labels issues.

UNIDENTIFIED FEMALE: In that case, I do think a work group would be a good idea. I'd like to participate on that.

MR. JONES: All right. Thanks. Jennifer.

UNIDENTIFIED FEMALE: As to spray drift I had a different suggestion.

MR. JONES: Mm-hmm.

UNIDENTIFIED FEMALE: I wondered if we couldn't talk about -- this came up yesterday earlier and we couldn't talk about the methyl bromide issues and especially I would really appreciate learning because I've tried to do this research on my own, what are the alternatives that are being proposed? What -- where are

they going to be able to replace methyl bromide? The ones where there are no alternatives being proposed or people say there can't be, what are those uses? And some of the alternatives, what's the toxicity data on them if we know? Because I -- it's an arduous task that I know we're all trying to understand and I think that at least falls within EPA's purview if I'm correct.

MR. JONES: Yes, it does. The -- Lori?

UNIDENTIFIED FEMALE: Just another topic that might fold into one of the other work groups, Jim, would be the pesticide safety education issue and ideas to fund that from a multiplicity of organizations.

MR. JONES: Okay. Anybody else? Amy.

UNIDENTIFIED FEMALE: Just to prepare for a discussion on that, Lori, I wanted to bring everybody's attention to the handout that Jim passed out from AAPSE that does explain where current funding comes from, how it's used, and the multiplicity of sources that we already do use. So it would be helpful if people would read through that before any further discussion of it.

MR. JONES: Thanks. Alan.

UNIDENTIFIED MALE: Just to second what Jennifer

has said, also and add to that how the agency can help the United States move into conformity with the Montreal Protocol by the methyl bromide elimination or reduction.

MR. JONES: Let me comment on the methyl bromide. The activities that are governed by the Montreal Protocol and the Clean Air Act are not the purview of Pesticides Program, that is the air programs. The activities governed by re-registration, tolerance reassessment associated with methyl bromide or any of other pesticide are. Our approach as an office over the last 10 years as it relates to the PPDC has been not to use the PPDC per se around chemical risk assessment, risk management. We have created a process that was informed by a different FACA, to have a process that allows for what I think Jennifer, you, and Alan have just described which is the release of our risk assessments in a multi-phase process as well as proposed risk benefit and risk management sort of the at the later ends of it as it relates to methyl bromide and the other soil-applied fumigants. We have decided not only just to do a release of the risk assessment but also to do a technical briefing, which for those of you who followed some of the

earlier tolerance reassessment chemicals that had a high level of public interest. Technical briefing is basically a several-hour briefing done by the technical staff at EPA and the Pesticides Program to walk stakeholders through our assessments, because we recognize that not only are they complicated but it's also challenging for people to sort of slog through very long and technical documents. We provide a forum for us to walk them through it and then ask questions. So we are planning on having a fair amount of public engagement associated with methyl bromide and the other soil-applied fumigants and it'll probably be more than just an hour -- well, it won't be at the PPDC. It's going to be at -- during the public participation process identified in our OP pilot that was expanded to all old chemicals. But there will definitely be a technical briefing associated with methyl bromide and the soil-applied fumigants. And when we have that schedule nailed down we'll make sure through the PPDC listserv we're getting that information out to all of you.

UNIDENTIFIED FEMALE: Any idea when that might be?

MR. JONES: Tentatively in July. But we're,

again, we're still trying to nail that down. All right. Well, I have -- I think the agency's gotten a fair amount of very useful feedback and advice. And as I said earlier that is the point of having these meetings. Hopefully I've given you a flavor for what we're going to do with some of the advice you've provided. We'll mull over some of the other things that we heard over the last day-and-a-half. I really do appreciate not only your attendance in these meetings and your engagement in these meetings but also all of the energy and the effort that each of you bring to attempting to understand these issues, engage in these issues, and give the agency the advice that you do. It isn't easy I know for any of you to invest the amount of time that's necessary for you to be meaningful participants in this exercise and we really do appreciate all of the time and energy that you put to it. So for those of you who have travels to get back to where you're coming from, safe travels. And for those of you who are local, safe travels to you as well. And I'm sure I'll be seeing all if not most of you before our next meeting in October. Thank you.

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