Transcript of Meeting of

Pesticide Program Dialogue Committee

Georgetown University Conference Center

3800 Reservoir Road, N.W.

The Leavey Center, Main Floor, Salon H

Washington, D.C.

October 20-21, 2005

Day 1

ATTENDANCE LIST

Jim Jones	Director, Office of Pesticide Programs, OPPTS, Chairperson
Margie Fehrenbach	Designated Federal Officer, OPP
Lori A. Berger	Ph.D., Director of Technical Affairs, California Minor Crops Council
Robert Rosenberg	Director, Government Affairs, National Pest Management Association, Inc.
Bill Tracy	National Cotton Council of America
Rebeckah Freedman Adcock	Director, Congressional Relations, American Farm Bureau Federation
Dr. Steve Balling	Director, Agricultural Services Del Monte Foods

Carolyn Brickey	Executive Director, Protected Harvest
Erik Olsen	Senior Attorney, Natural Resources Defense Council

ATTENDANCE LIST (cont'd)

Michael Fry	Director of Pesticides and Birds Program, American Bird Conservancy
Amy Liebman	Environmental Health Consultant, Migrant Clinician Network
Troy Seidle	Director, Science Policy, People for the Ethical Treatment of Animals
N. Beth Carroll, Ph.D.	Senior Stewardship Manager, Syngenta Crop Protection
Allen James	President, Responsible Industry for a Sound Environment

Stephen Kellner	Senior Vice President and General Counsel, Consumer Specialty Products Association
Dr. Hasmukh Shah (Day 2 only)	Managing Director, American Chemistry Council
Julie Spagnoli	Executive Director, Regulatory Affairs, Clorox Services Company
Jay Vroom	President & CEO, CropLife America

ATTENDANCE LIST (cont'd)

Gary Libman	Vice President, Regulatory Affairs and Quality Assurance, Emerald BioAgriculture Corporation
Alan Lockwood, M.D.	Chair, Environment Committee, Physicians for Social Responsibility
Dr. James Roberts	Associate Director of

	Pediatrics, Medical University of South Carolina
Dr. Nancy Lewis	Associate Professor, Department of Nutrition and Health Science, University of Nebraska
Mary Ellen Setting	Assistant Secretary, Office of Plant Industries & Pest Management, Maryland Department of Agriculture
Dr. Jose Amador	Director, Agricultural Research & Extension Center, Texas A&M
Amy Brown	Coordinator, Pesticide Safety Education Program, UM

ATTENDANCE LIST (cont'd)

Larry Elworth	Executive Director, Center for Agricultural Partnerships
Dr. Robert Holm	Executive Director, IR-4 Project

Patrick Quinn	Principal, The Accord Group
John D. Schell, Ph.D.	Vice President/Toxicologist, BBL Sciences
Dr. Terry Troxell	Director, Office of Plant and Dairy Foods, CFSAN, FDA
Allen Jennings	Director, Office of Pest Management, USDA
Dr. Melody Kawamoto	National Institute for Occupational Safety and Health, Centers for Disease Control & Prevention
Jennifer Sass	(Portion of Day 1)
John Kepner	Beyond Pesticides
Frank Gasparini	(Day 2)
Maureen Serafine	New York
Nancy Golden	
Craig Thomson	EPA, Region VII

P R O C E E D I N G S

DAY ONE - OCTOBER 20, 2005

Brief Opening Remarks were made by Jim Jones followed by a presentation on Registration Review. The transcript begins during the presentation by Susan Lewis and Jay Ellenberger.

MS. LEWIS: -- we can get valuable input during that comment period. We hope to have a final rule issued next summer, Summer of 2006, and then we'll begin implementation in the Fall of 2006.

Next. I also wanted to post our website. After the rule was issued, we developed a relatively extensive home page website for registration review and I'll leave you with the web address. There's a fair amount of information and there are links to the schedule and the rule -- proposed rule itself.

Thank you. Any questions?

MR. JONES: Before going into the registration and reregistration, I think it will be useful to have a little bit of discussion here. I do want to thank all of you who have participated on this workgroup. One of the things I failed to mention in my opening remarks is we've tried, in the last year, to have more workgroups and then giving us more focused time and attention in between the meetings. One of the frustrations I've had is that some of the issues we deal with are so complicated, you really can't give informed advice in a 30-minute or a 50-minute session twice a year, and so, we've been relying more on workgroups. This workgroup's been incredibly effective, I believe, in both spending the time, the energy and the effort to give informed advice and has given us very good advice and that advice has, frankly, underlined the proposed rule, and will continue to, I expect, help us make choices about how we implement.

But I'd like to open it up on this topic before

we move on to the registration and reregistration presentations.

Julie?

MS. SPAGNOLI: Just one question, you know, with the scheduling, and I know we had a lot of discussion and debate, but if they're going to do it by classes, are you still -- there's still going to be individual decision documents issued. Are those -- so, they're not going to all -- you're not going to wait to issue all the decision documents for the whole class at one time or, I guess, just looking at that scheduling, that was a question that it kind of raised for me. If you're going to do it by classes, then does a decision for the entire class get made all at once or for each individual chemical? Because we were going to be looking at all the individual end use products as well.

MS. LEWIS: I think the initial concept is the decision ultimately will have to be on an individual

active ingredient basis, as we're doing it today. There may be times when there is no issue and you may be able to make independent decisions because there may be a two or three-year window if the class is large enough. There may be other times, depending on whatever the technical issue is, that, to resolve it, it all gets done at one time. So, I think it's really going to depend on the class.

MS. SPAGNOLI: If an issue for a class is an environment effect, then a product that only has indoor uses --

MS. LEWIS: Yeah.

MS. SPAGNOLI: -- may be not -- it may just fall out right away?

MS. LEWIS: Yes.

MR. JONES: Okay, thanks, Susan and Jay.

Okay, Debbie Edwards, the Director of the Special Review and Reregistration Division is going to

give us a tolerance reassessment and reregistration update now.

MS. EDWARDS: Thank you. This presentation is, obviously, in your packet and it's got a lot of numbers and chemical names and so forth, so I'll be going through it relatively quickly. But it's for your reference.

First slide there, just to start out, what I want to do today is tell you what we accomplished in FY 2005, which ended on September 30th, and what we intend to do during FY 2006. In FY 2005, you can see here the program -- this is for the entire program, not just the Special Review and Reregistration Division, but it's Office of Pesticide Programs, so this includes biochemical, biological pesticides and antimicrobials. We did 41 decisions, of which 28 were reregistration eligibility decisions and 13 were tolerance reassessment eligibility decisions.

We reassessed a total of 722 tolerances, of

which 167 were inert ingredients and 555 were active ingredients.

There are a couple slides here just showing the REDs that were completed. Like I said, there were 28 of them. You can see on this slide one that probably would draw your attention. 2,4-D is obviously a very big chemical to have completed this year.

Next slide. These are the rest of the REDs that we completed this past year, and there you will see that all of the EBDCs have been completed. So, that was a pretty big accomplishment as well.

Next slide. This is the list of the 13, I believe -- I think that's right -- TREDs, tolerance reassessment eligibility decisions. Probably the biggest ticket item there is Cyhexatin. That's an Organo-10 that's now been closed out and essentially all the tolerances, except for one import, has been revoked.

Next slide. This is the slide that we show you

each time. The pie chart on the left shows you that we have completed 271 of the REDs. We have 110 REDs yet to go, but that includes -- that's not just for FY '06, that does include the '07 and '08 REDs that we will need to do for non-food uses, as well as the IREDs that will convert to REDs once we complete our cumulative assessments.

The bar graph there, you can see how we're moving along in our progress. The Government Performance and Results Act goal this year was 7,838 tolerances and we completed 7,817. So, we were very close on that goal. In terms of the overall goal, which is 9,721 tolerances, we're currently at 7,817.

Next slide. This just shows -- this is just a bar chart showing what we have done by year since 1996. You can see that 2002 was a very big year at 2,600 and some tolerances reassessed that year. That was the second and third goal. The last bar on the right is actually what we need to do this year. So, this year, we

need to reassess 1,904 tolerances. That's actually the 2006 goal, and you see it's not as big as what we had to do back in 2002.

The next slide just shows the progression over the years. This is the same information presented a variety of ways, but it shows us moving toward that goal of 9,721 tolerances reassessed.

Next slide. This, again, we give you each time. It's our progress toward completion of tolerance reassessments for the organophosphate pesticides, the carbamates, organochlorines, carcinogens and high hazard inerts. You can see there that in FY 2006, we still need to complete 544 organophosphates, 228 carbamates. These include, though, tolerances that were nearly reassessed when we did the IREDs. So, once we're done with the cumulatives, those will be done.

And then carcinogens, 478 with other being 654. So, that's kind of the breakdown for this year of what we

need to get reassessed.

Moving into, again, the goals for FY 2006 or actually the plan for 2006. As I said, we have 1,904 to be reassessed. This is the breakdown of what those tolerances are. 286 of those are inert ingredients, 52 are antimicrobial active ingredients, 5 are biopesticide active ingredients, 38 will actually -- we've already determined are simply revocations, and the remaining 1,523 are conventional active ingredient pesticides. But, again, if you look down there at the bottom, 528 of those -- of that 1,523 are associated with complete IREDs.

Okay, next slide. The bottom part of this slide we pretty much already covered, but there at the top it says overview of our plan for this year. We will be doing 66 decision, 49 REDs and 17 TREDs.

Next slide. These are some highlights. I'm not going to give you every single chemical that we're going

to be doing next year of those 66, but these are some highlights that you might be interested in of the FY '06 plan. You can see there we're doing organic arsenicals, copper compounds, ethylene oxide, methyl bromide, permethrin, pyrethrins, piperonyl butoxide and MGK-264, pentachloronitrobenzene, and the triazoles, triadimefon, triadimenol and propiconazole. But this is actually bigger than that because it will include the free triazole assessment, which encompasses a number of other chemicals that have been registered since 1984. So, that's a very big and important assessment. We expect that public comment period to open early in the calendar year, probably late January, mid to late January.

Next slide. We have four remaining cumulatives to complete this year. They are the organophosphates, the N-Methyl carbamates, the chloroacetanilides and the triazines. You can see here -- oh, go back -- the remaining organophosphates we have to do are DDVP,

dimethoate and malathion. The N-Methyl carbamates, obviously, are aldicarb, carbofuran, formetanate HCl.

Next slide. The remaining chloroacetanilide is acetochlor. The triazines are simazine and propazine.

For antimicrobial decisions that are -- I would highlight here, these are the three wood preservatives, CCA, coal tar/creosote, pentachlorophenol. They will also be doing, by the way, all the quaternary ammonium compounds and chlorine dioxide, which are also pretty high profile antimicrobial chemicals.

Next slide. What we're going to do very shortly is put up new schedules and the new schedule that we keep up there for the revolving -- it's a revolving six-month schedule around public comment periods opening. So, that should come up in the next few weeks. So, be looking for that. Thank you.

MR. JONES: Any questions for Debbie? Carolyn?

MS. BRICKEY: There's a lot of big ticket

chemicals on that list. Are you going to be giving us, in the future, more of a qualitative review of what you're doing with all these chemicals? I mean, pick out some that you think are important, because it all just sort of spins in your head when you look at this.

MS. EDWARDS: Jim?

MR. JONES: We have not used in at least six years the PPDC as the forum to get into chemical-specific or cumulative-related issues associated with tolerance reassessment. That had fallen under the purview of the CARAT now. It's certainly something that we can have some discussion around, the extent to which there may be the desire for using -- the committee, itself, doesn't seem like the logical place. Perhaps a subcommittee to look at a few. I'm certainly open to what your needs are around that.

We have -- the process that we, of course, have been using is the CARAT-informed process, which is the

six-phase public participation process. Many of the chemicals that I think are making your head spin have a six-step process where there are two specific opportunities for public participation. But I'd be open to getting some feedback from this group as to is there anything above and beyond that that you, this committee, would like to have, and then, of course, I've got to think about it and talk to my management about the intersection between this committee and the CARAT around an issue that has historically been the purview of the CARAT.

MS. BRICKEY: Right. Well, it's not so much that I think there aren't adequate opportunities for public comment on each one. It's just that there's so -- there's implications for so many of these as a group and I just would like to get a better handle on understanding that, I guess.

MR. JONES: Okay, okay. We'll do some thinking

around that and perhaps we can get some further insights into how we might do that.

Larry?

MR. ELWORTH: Well, you raised the issue that it's not something we need to discuss in this meeting, but when was the last CARAT meeting? It was like --

MS. EDWARDS: Probably two years ago.

MR. ELWORTH: Was it two years ago? Several years ago. It's fine with me if this is addressed in CARAT. If it's not going to be -- if we're not actually going to have a CARAT meeting, if there's a way to come back to your management and say, there's significant interest in stakeholders, this is an existing forum, we've avoided doing this up to this point because there's another advisory committee established.

MR. JONES: Right.

MR. ELWORTH: But I think that kind of discussion is real helpful, and if it doesn't swamp the

entire agenda for this meeting, that would be really good to do.

MR. JONES: Well, help me with the "it" there. For example, the chemicals in '06, probably of the ones we listed there -- help me out, Debbie, I'm going to guess -- half of them already are -- the risk assessments are in the public domain. Maybe even more.

MS. EDWARDS: Yeah.

MR. JONES: So, I need a little help with the "it" about what exactly -- because, you know, having us give you sort of the functional equivalent of technical briefings for some subset, I'm not sure that's it. So, think about that. I definitely want to understand what would make it useful for all of you. I'm very open to the idea. I just want to make sure we do something that's useful.

MR. ELWORTH: Right, right, that's a good point. I think from the point of view of this committee -- and

it kind of goes back to what Carolyn was saying -- what would be interesting to me, and I won't speak for everybody else, is for you to, perhaps, go through an example that illustrates some of the issues you're running into in evaluating these chemicals. And I don't know which one it should be, but that's very instructive. We have -- it's the kind of thing we went into in detail in CARAT that I don't think we need to do in terms of process here.

But having an opportunity to look at the kind of issues you folks are running into, whether it's about the bromide or the pyrethrins or some of the -- or the triazoles, whichever it is, that would be very interesting to us because it illustrates some of the policies that you're dealing with. That's where it would be interesting to me.

MR. JONES: Okay.

MR. ELWORTH: But that would be germane to this

committee.

MR. JONES: Okay, Jay?

MR. VROOM: I guess I would agree with Carolyn's observation that looking at this can make your head spin, but I would say that from an entirely different perspective, in sort of a wow, what great progress. You know, not that you're necessarily just going to be able to fall down and cross the finish line and meet the deadlines for August 3, 2006, but I think you've got tremendous momentum. And absent, you know, great advice from the CARAT for the last two years, apparently you've been able to work without the interference of too much advice. But I think it represents a lot of good progress.

Jim, I'm curious. I remember one of the things that was a concern about sort of the distance between whenever and 2003 August -- 2006, August 3 deadline was the potential for relocating the offices physically of

OPP. Where are you at on that or is that something you want to defer to Marty to tell us about?

MR. JONES: We fought mightily to not move before August 3rd and we did not succeed in that respect. We did succeed, however, in ensuring that the move will occur in one fine week in May, as opposed to over a five-month period, which was the original schedule.

UNIDENTIFIED FEMALE: (Inaudible) PPDC meeting.

MR. JONES: Okay. Well, maybe that's what it will have to be because we don't want to be back moving our -- so, for a week in May, right, Marty? May?

MS. MONELL: The first week of May.

MR. JONES: We will be moving about -- a little less than three-quarters of a mile down by the old Crystal Station I. It looks like it's going to be a beautiful building.

UNIDENTIFIED MALE: Don't get FEMA to help.

UNIDENTIFIED MALE: I've got a couple extra

trailers for you.

(Laughter.)

UNIDENTIFIED FEMALE: I was just curious to a comment you made. You said the CARAT six-step process. Whatever happened to the abbreviated process that was presented to us?

MR. JONES: We actually put out a Federal Register notice that described not only the six-phase public participation process, but when and under what situations we would use an abbreviated one, which would include a four-phase process or even for some low-risk compounds, a one-phase process. All of the chemicals that Debbie walked through on her website -- on our website, it tells you which of these phases, whether we're going with the low-risk one or the four-phase, which is a one public participation, or the six-phase, and it has the intended schedule for all of them. So, it is being used for chemicals that we think warrant it.

But that being said, if we're in a four-phase process, and during the public participation process we realize, oh, stakeholders think there's a really big issue here, we'll amend it to a six-phase.

Allen? I'm sorry, is that Jose? I'm sorry.

DR. AMADOR: Jim, sometimes people ask me about the PPDC and, you know, what goes on in the Office of Pesticide Programs, and you can relate to some of this reassessment, like we had 10,000 -- almost 10,000 reassessments, you know, since 1996. Do we have a sense of how many products were voluntarily withdrew or withdrawn from companies not wanting to go through the process? You know, it seems to me that would be something that people might want to know, how many companies --

MR. JONES: Let me ask Debbie, but --

DR. AMADOR: -- voluntarily withdrew not having a product?

MR. JONES: I'm not sure that we have that off the top of our heads. One of the things, as a general comment I'll make, is there is so much done associated with all of these chemicals. We have always struggled with how to efficiently communicate it, and that is as it relates to the kind of risk mitigation all of them get, from changes in PPE to changes in REIs to use deletions, the range of it, it's just so vast. It's been very hard for us, affecting so many chemicals, to succinctly communicate that. But I'm going to let Debbie give a sense as to how many products have been voluntarily removed.

MS. EDWARDS: Not actual products, but back on the pie chart, it does show that 231 cases were canceled. So, that's a fairly significant percentage. People that dropped out, I think, pretty early on.

MR. JONES: Yeah, those are the ones who tended to drop out early on because they didn't want to support

the chemical with the data generation. One --

DR. AMADOR: Is that just the chemical or the use of the chemicals (inaudible)?

MR. JONES: That's a chemical. That's a whole chemical, which is a very crude --

MS. EDWARDS: That represents about 400 active ingredients.

DR. AMADOR: Four hundred active ingredients.

MR. JONES: Gary?

MR. LIBMAN: This question, I guess, is for Debbie. You say that you have 286 inerts left. I'm curious about inerts. We didn't talk much about the inerts. I assume that list is also on the website. How would this change the so-called -- the old lists that we had, List 3 and List 4A and B and so on on the inerts?

MR. JONES: Debbie's conferring with some of the originators of that list, who happen to be at her left right now.

(Laughter.)

MS. EDWARDS: I don't know that that list -- is that list on the Internet, Lois?

MS. ROSSI: I'm not sure if it's on right now.

MR. LIBMAN: So, where did the 280 --

MS. EDWARDS: There shouldn't be any more list one inerts, I wouldn't think after --

MS. ROSSI: No.

MS. EDWARDS: I'm not sure that there are now.

UNIDENTIFIED MALE: No, those should have been those high -- those five high risk (inaudible).

MR. LIBMAN: Well, it's the List 3 ones I'm concerned about.

MS. EDWARDS: Ideally, they all end up down in List 4.

MR. LIBMAN: Well, there still are some on List 3 and those are the ones that have not been evaluated yet.

MS. EDWARDS: Right.

MR. LIBMAN: So, how are we moving towards getting those to List 4 or off the list?

UNIDENTIFIED FEMALE: Each reassessment decision concludes with what list it should go on. If you look at some of the reassessment decisions that we've done, it will say, and this was formerly on or this was on List 4, it stays on List 4 or this was formerly on whatever list and that's the new classification.

MR. LIBMAN: I was under the impression that the lists -- the so-called four lists would actually go away at the end of 2006. Is that not true? Those lists will still be there?

UNIDENTIFIED FEMALE: I don't think so.

MR. JONES: The inerts subject to tolerance reassessment are only those with a tolerance. The Lists 1 through 4 includes all inerts, which would include those without a tolerance. Once we have finished our

inerts -- total inerts review, you'll either be on List 1 or List 4. This will deal with it for those that have food uses. The food use inerts, you'll either end up as -- on List 4, meaning we've made the safety finding, or we'll designate you as a List 1 inert and you'll have to do a lot of data or some other kind of regulatory action.

But then there are a meaningful number of non-food use inert ingredients that will not have been addressed through the tolerance reassessment process.

Anyone -- Julie, you've asked your -- okay.

MS. SPAGNOLI: This is kind of further on Larry's point about, I guess, what it might be, and I think, you know, the CARAT and the TRAC really address a lot of the big policy issues. I mean, that was really what they were set up to do. But I think as these -- especially some of these bigger chemicals have come through, you know, additional issues have been raised or policy issues, and a lot of times it comes through that

public comment period that a particular issue is raised about some water issue or something in particular. So, that may be -- you know, if it doesn't go to the CARAT or the TRAC.

But some of these issues that maybe have been raised later as some of these chemicals have gone through and through the public comment period, that may be something that might be valuable to bring back to this committee, some of those smaller policy issues that have been raised.

MR. JONES: I understand. My experience in this program is that you -- stakeholders representing all parts of the stakeholder community are quite facile at figuring out what it is about our assessments and our regulatory -- but our assessments they have an issue with, and they're not shy about doing that. And so, one of the things that we rely on is as our assessments roll out the door, which I mean over half of the ones that are

going to be decided next year -- and it may be as high as 75 percent -- the assessments are out there. What happens then is people who have a stake in them look at them, and then as they identify issues, generic or specific, they raise them.

Partly, I think we're just implicitly relying on that process to help us define issues that may require or may benefit from deliberations from a larger body. If there are some other aspects of that work that you'd like to engage in dialogue around, it would be useful for us to put our heads together and figure out what they may be.

Bob?

BOB: Jim, I just wanted to comment from a specialty crop perspective. I think we feel that there have been a lot of inputs to the agency. I know we participated through the EBDC Task Force, the Triazole Task Force, and I think there are a lot of listening

posts out there and I perceive that the agency has been working with at least these bigger task forces in getting input and particularly on specialty crops, which are always concerned that we may lose products. I think we're very positive that we've been listened to and our concerns have been addressed.

MR. JONES: Okay. Well, over the course of -- Larry?

MR. ELWORTH: I guess it's not so much that I have an issue with anything you're doing on this, but I think there's something that you need greater oversight for. I guess, in a sense, what I wanted to suggest is that the level of policy discussion in CARAT was very useful, and if we're not going to do that, it would be nice to fill that in either through a CARAT meeting or through this. That's all I'm saying. It's not a --

MR. JONES: Just an observation, and perhaps my analysis is wrong on this, but my observation of the

CARAT process, which I think gave the agency excellent advice, most importantly around the public participation process. I thought that was a very valuable activity.

My observation about when CARAT meetings would be held would be when the stakeholder said, we need a meeting and we need to talk about this, and the agencies would get together and go, okay, that seems like a logical thing. I'm hearing all of this vibrating around this issue. We need to get together with everybody and figure it out. I think that one of the reasons we've gone for two years, I'm not speaking for the Administrator or the Deputy Administrator, just as an observer and a participant of the process, is that that's not occurred where people are saying, here's my issue, I need to have a forum to talk about it. If that were to happen -- now, being the good bureaucrat, I'd like to suss it out, figure it out, and go to my management and go, this is what people really want to talk about, as

opposed to having you all run to the Deputy Administrator.

But if we could do that, I would be happy to facilitate that kind of dialogue either at this meeting or at a CARAT meeting. Yes?

UNIDENTIFIED MALE: On behalf of USDA, I mean, I'd like to echo the same thing. If there are specific items that you feel are worthy of tabling right now, I certainly would like to hear it and be happy to pass it up in order to do that. But, personally, I mean, if it's a matter of, well, we'd like to just put together a meeting, I don't know what to put on the agenda. So, I mean, if there's specific policy areas or, you know, even some general areas that you can flush out for me, I'd be happy to listen.

MR. JONES: Let me just ask all of us, us at the government and you and the committee members, to think about over the next day-and-a-half, a little bit more --

in a little bit more flushed out way, what is it that would be useful for you and if you think it's useful for you, we're going to find it useful for us. I will tell you that.

All right, why don't we -- Lori?

DR. BERGER: Just one quick question, especially in regard to what you mentioned there, Burleson, and CARAT. It was my understanding, and I'd have to go back and look at the minutes or record, that there were some items that the group is going to be following up on, a to-do list or comment on or there were some specific things that the group did want to reconvene on and discuss. So, that's my recollection, and from a stakeholder's standpoint that represents several specialty crops, we really find that that's an excellent forum and we'd like to see it continued. So, any recollection of that? I know that there were a lot of transition issues and cooperative extension concerns and

that type of thing.

UNIDENTIFIED MALE: I think that there are -- you're correct. There were specifically related to some of the utilization of farm bill type programs for some interaction with specialty crops, but some of the other pesticide uses. I will be candid with you right now. That's an area that is still -- we're still working on and don't feel that I have something to report back to you at this point. I'll try to see if we can find a little bit more. But that is a work in progress.

MR. JONES: Okay, thanks very much. I appreciate all that.

Lois Rossi, the Director of the Registration Division, is going to give us an update on our registration activities broadly in OPP. Thanks.

MS. ROSSI: With the conclusion of the Fiscal Year 2005, we completed our first full year in implementing the Pesticide Registration Improvement Act,

better known as PRIA. It was certainly a year of developing comprehensive work plans, process improvements, and efficiency measures.

Next slide. What you have presented there, during the Fiscal Year, we approved 24 new active ingredients. As you can see there, we had 12 biopesticides which are listed for your information there.

Next slide. We had two antimicrobials and, next slide, and we had 10 conventional pesticides, two of which were for import tolerances only. So, that was our new chemical activity list. On that list, you can also see that there were two reduced risk pesticides, both of which were NAFTA joint reviews, and I am pleased to report that these two active ingredients were approved within 14 months and 16 months of the day they came in the door, which certainly validates the efficiencies that you experience when you do a joint review.

Next slide. New uses. 164 new uses associated with 702 crops associated with 32 previously registered active ingredients or conventional active ingredients were approved in the Registration Division. Twenty-seven of those were reduced risk new uses, 45 were OP alternative new uses. And then we also had eight new uses in the antimicrobial area.

Next slide. This slide presents our Section 18 activity for this year, and a lot of which was associated with approving exemptions in anticipation of soybean rest. But that gives you a look at the number we received and approved and the crises that were declared, which I understand is a lower number than usual, and with still our average turn-around time of around 42 days.

Next slide. This slide presents a description of all the PRIA actions that we've encountered this year, except for, obviously, the first one which is Fast-Track amendments, which were not approved -- which were not

covered under PRIA, and you can see there's a fairly large number of those that we still have. I know there was a lot of talk throughout the year in various discussion groups about focusing our attention on PRIA paid actions and not focusing any resources or attention on Fast-Track amendments. But, as you can see, there's a fairly large number across all the divisions, and in the conventional area, we were able to eliminate our backlog with Fast-Track amendments this year, and we intend to almost treat them like PRIA in trying to meet the 90-day. I know antimicrobials has been doing that for a long time, and the Registration Division, that's our goal this year. And you can see the numbers for other PRIA actions, non-Fast Track amendments, Fast Track new products, non-Fast Track new products. Quite a lot of work and accomplishments this year.

Next slide. With regard to the inerts, we are pleased to have a new branch in the Registration

Division, the Inerts Ingredients Assessment Branch. The Branch Chief is Pauline Wagner, formerly of the Health Effects Division. And we have nine people working, including Pauline, working in that branch right now. It was set up to handle the approvals of food use petitions, new clearances of inerts, as well as the reassessment that Debbie was mentioning in her overview.

This year, we were able to complete 17 new food use approvals. Last year, I think we did 16. So, we did one more than we did last year. We currently have 32 pending, including those we received in this fiscal year. I think for those of you who are concerned about the inerts and the approval of new food use inerts, it represents a backlog from the beginning of PRIA of probably about 12 pending old ones that have been pending since 2004 or prior to March of 2004. We intend to eliminate that next year by trying to complete 22 to 25 new approvals.

And our reassessment program, I think, Debbie, our numbers differ by one, but we'll -- I think there might have been one of those ones that was signed very late on September 30th. We have 168 completed this year and we've got 285 remaining to be reassessed to meet the August 3rd deadline of next year.

Next slide. This just gives you some statistics on what the workload has been like since the enactment of PRIA. We've had 2,850 total submissions, of which we've completed a little more than half. Over 99 percent have been completed by the PRIA goal. We did issue 18 "not grant" decisions, which is less than 1 percent of the total submissions and we had 144 actions, which is approximately 5 percent of the total submissions that we had to renegotiate the due date.

And the next two slides just give you a little more breakdown of where those "not grant" decisions, as well as the -- next slide -- the negotiated due dates

data.

UNIDENTIFIED MALE: Could you tell us what AD, BPPD and RD mean?

MS. ROSSI: Oh, sure. Antimicrobials Division is AD, Biological and Pollution Prevention Division is BPPD, and RD is Registration Division. Those are the three regulatory divisions in the Office of Pesticide Programs.

Okay, just a look ahead of what's on our plate. As I said, we have comprehensive work plans now which basically are work plans that list all the work. For conventional pesticides pending in the Registration Division, we have 21 new active ingredients on our work plan. They roughly break down into 13 active ingredients that will have domestic registration and eight active ingredients requesting import tolerance only. It may appear to be a very high proportion of import tolerance only actions, but many of those were pending many years

and they never were on the work plan in previous years and now they came in and paid the PRIA fee and consequently are on the work plan. Many of those are on schedule to be completed within Fiscal Year 2006.

There's 22 biopesticide new active ingredients pending and 10 antimicrobial new active ingredients. And, again, the goal, obviously, is to meet the PRIA deadline, and in most cases, we beat the PRIA deadline.

Next slide. I'll just call to your attention the website for the conventional pesticides. We do have the new chemical work plan posted and it gives the information on the PRIA due date, as well as the anticipated quarter that the agency intends to make the decision on the pesticide. We shortly will have -- in the month of November, we'll shortly have a very comprehensive work plan of the new uses for conventional pesticides, as well as the inerts. The new use work plan, just to give you an idea of the size of it, when

you put it in tables on this size paper, it's over 40 pages, and so, consequently, it takes a lot of review before we put this up on the web. That's what we're going through the final stages of now.

So, that, in a very brief overview, is the status of what the Registration Divisions have been up to this last fiscal year. Thanks.

MR. JONES: Questions? Steve?

STEVE: Lois, what is the PRIA deadline? What's the time frame?

MS. ROSSI: Well, it depends what kind of an action it is, like, for example, a new chemical that comes in the door today would have a 24-month time frame.

STEVE: Um-hum.

MS. ROSSI: If it was reduced risk, it has a 21-month time frame. If it's a me-too product, it has a 90-day time frame. It depends on the category. There are 90 categories, and those are on the web. They're all

associated with a different time frame. There is a different time frame and there is a different fee associated with all those 90 categories.

STEVE: So, presumably, there has been an improvement, it sounds like there has. So, what percentage more? How many more new registrations are you running through this system now?

MS. ROSSI: Well, for new active ingredients, I think we're pretty much at the same -- this year, we were at the same capacity that we were at in previous years, between the 10 and 12 or 10 and 14 range. But I think you're going to see that the workload then starts dictating the outputs, and so, like, if you have -- like right now we have 21 actions pending. I think all but about seven of those will come out in the next year. So, we'll have that.

As far as new uses go, this year we had -- generally we have sort of in the range, typically, of 200

to 230. This year, we had 164 for conventional pesticides. And -- but it was over a large number of active ingredients. In other words, you didn't get a lot of new uses for one active ingredient.

Next year, what's on the plan of all the work that we're trying to accomplish in 2006, I think the new uses come out to be 268. So, I don't think we've had enough experience to start seeing how the outputs are going to be directly related to the inputs yet, but that's what you're going to start seeing.

STEVE: I'm trying to get a sense of what the end of the pipeline's going to start looking like in the next several years.

MS. ROSSI: Right. And you'll be able to tell that --

STEVE: When do you expect to see a whole lot more available --

MS. ROSSI: And it will depend. Like, for

example, this year the conventional -- RD, Registration Division, only received one new non-food use chemical application and one import tolerance. That's all the new stuff we received in the whole fiscal year.

STEVE: Wow.

MS. ROSSI: I already know in 2006 we're expecting to get at least four new active ingredients within the first six months. So, it really is going to depend on what comes in the door.

STEVE: And so, from a workload perspective, do you have to go to outside consultants to do a lot of this? Can you handle it all internally?

MS. ROSSI: Well, we do have contracts -- we have contracts in our Health Effects Division and in our Environmental Fate and Effects Division. So, we have contracts for the review of the -- for the initial review of the data.

STEVE: So, they can expand and contract --

MS. ROSSI: Right. And for new chemicals, pretty much the new data comes in -- the application comes in the door and the data is shipped to the contractors for those various disciplines.

MR. JONES: But I think, Steve, the biggest change is the predictability completely turns around, whereas you submitted five years ago and --

STEVE: It's still there.

MR. JONES: Well, that -- that was the case five years ago, and what was going to come out and when it was going to come out was difficult for anyone to have predicted. Now, you submit and 99 percent of the time, 99 percent plus, you'll get a decision from the agency in the time frame that's set in the statute.

STEVE: That's fine.

MR. JONES: I think that's the real change in the system, which we've been hearing for years and years and years was the most important part if you're trying to

run a company, is the predictability of the timing of your decision.

Larry?

MR. ELWORTH: A couple of things that I actually would modify based on Lois' comments. I'd be interested in -- not necessarily today -- in looking at the -- what the revenue stream is from PRIA.

MS. ROSSI: What?

MR. JONES: I'm sorry, Larry, the what history?

MR. ELWORTH: The revenue stream.

MR. JONES: Revenue stream, okay.

MR. ELWORTH: I don't need to see that now, but it would be interesting to see that. Based on what you just said and what Lois said, actually looking it over -- looking at it over more than a one-year period would probably be more instructive than looking at it in an individual year.

MR. JONES: Right.

MR. ELWORTH: But I'd, also, at some point, again, and maybe not right now, be interested in some feedback from registrants about how PRIA's worked for them, both registrants that are taking advantage of PRIA opportunities and registrants who aren't. I just want to flag that.

MR. JONES: Okay.

MR. ELWORTH: Because I think it would be a real interesting discussion.

MR. JONES: Okay. Sure, we can do that in a subcommittee. I can tell you in FY '05, we collected $10 million in PRIA.

MR. ELWORTH: Yeah.

UNIDENTIFIED MALE: Was that on target or was that (inaudible)?

MR. JONES: You know, when we were giving technical advice on the bill when it was being developed, we thought we'd collect around $15 million. But what

isn't so important is what you think you're going to collect because you collect what's submitted. So, you're always in balance. So, it really doesn't matter so much how much you collect, it's how much -- that you collect enough to do the work that you get, which it's designed to give you that equilibrium.

UNIDENTIFIED MALE: Yeah. One suggestion and one question. I think it might be useful to go back and I think you've got the data to take a look at average time frames for completion of various actions pre-PRIA and what you're doing now, because I think it's -- when you talk about performance measures and efficiency, I think that's a great way to quantify some of the improvement that we're seeing. And I think it is -- I mean, it's an exceptional, you know, first year. I think you guys all ought to be proud of it.

Lois, I've got a question for you, though. What keeps you up at night? What do you worry about most when

you look ahead about ensuring compliance with these time frames and what categories do you worry about the most?

MS. ROSSI: What categories -- I didn't hear the last part.

UNIDENTIFIED MALE: What actions? I'm thinking particularly about the short-term actions, and as you look ahead and you see obstacles to full compliance or, you know, time -- timeliness, uncertainty concerns, what are you seeing or are you not worried at all?

MS. ROSSI: Well, yeah, first of all, nothing related to PRIA keeps me up at night.

(Laughter.)

MS. ROSSI: Well, I think the single-most important factor for successfully meeting deadlines, internally and externally, externally is the quality of the package. The renegotiated dates, the "not grants" are all related to quality of package, data and that it was -- that should have come in with the package and

didn't, or data wasn't up to speed. So, I think from an external point of view, that's probably the single factor that assures success.

Internally, I think it's just -- I think having a work plan and having the work laid out for down to the reviewer level, so that if you're a reviewer in the registration division, for example, you can print out your workload for the week, for the month, for the year, for the next quarter. You can print that out. The Branch Chief can do the same, the Product Manager can do the same, across all different categories, new chemicals, new uses, all the PRIA codes, the me-toos, the non-Fast Tracks, all the different ones, including product re-registration and Fast Track amendments.

So, they can see their workload and I think it's just -- it's really truly managing the workload rather than having this vision of this over-burdened -- this huge burden of stuff that you don't even know sometimes

where it is. I think that's been the challenge for the managers in the Registration Division. I think that's where we've really concentrated our efforts this year. So, I mean, I think that's the challenge, to just stay on top of and manage the workload.

MR. JONES: Bob?

BOB: Yes. I just wanted to thank Lois and the Registration Team and Tina and the HED Team on behalf of IR-4 and specialty crop growers for the spectacular job this year. We count on a calendar year rather than a fiscal year and we have 655 clearances that have been granted so far. Our long-term goal is 500 to 600 a year and we expect to have over 800 by the end of the year. So, it's been a great partnership. We just had another technical working group meeting this week with the agency. I can say our relationship with the EPA couldn't be better. We have very open cooperation. We're working on some new initiatives like international harmonization

through crop grouping, which Lois has taken the lead in, so we're thankful.

I also wanted to thank industry because part of -- you know, we submit a petition, but also with PRIA, it requires the notice of filing, the labels and so on. In the past, those could come in independently, and now, we're charged with putting that all in together as an initial submission package. Crop Protection Industry has been very cooperative in working with us to put all that information together in initial submissions. So, again, thanks to the agency for a fine job.

MR. JONES: Thanks, Bob. Allen? I'm sorry, Gary?

MR. LIBMAN: Hi. My questions are regarding the negotiated due dates. Someone more skeptical than myself would say, are these negotiations because the --

(End of Tape 1, Side A)

MR. LIBMAN: -- due dates.

MS. ROSSI: The usual reason is is that, at least in RD, that the -- there's some piece of data that needs to be either clarified or redone or some data that's just not acceptable at the point after it's been reviewed. That is, by far, the most reason.

I think in -- and I think it's probably more of a piece of data in RD whereas in maybe, for example, the Biological and Pollution Prevention Division, it's the whole package of completeness of the package. So, that's what -- that's really what most of these have been related. And just to -- just to let you all know what the process is for a negotiated due date, it's not an easy thing to do internally. It -- what has to happen is -- in other words, a reviewer just can't go out on their own and renegotiate a due date. It has to be brought up to the division level, and then actually Jim or Marty actually sign a form in which it's articulated, the whole history of this application and why, at this point in

time, do we feel we need to renegotiate the due date. And it's approved at the Office Director level.

MR. LIBMAN: But are they renegotiated back to zero again or is it just like a month or --

MS. ROSSI: No, no, no, no, not at all, not at all. They're -- the rule of thumb we use in RD is if it takes six weeks, for example, for the registrant to get that piece of data in, we extend it for six weeks and then we allow ourselves whatever time we think it would take to review that piece of data. So, let's say it takes four weeks, we would ask for a 10-week renegotiated date. And we actually speak to the registrant about that before we even do the proposal that then goes up the management chain. So, it's not just like, okay, this is PRIA action that has a one-year PRIA time frame, renegotiated date, we tack on another year. It's very specific to what needs to be completed and the time frame it will take to review that piece of information.

UNIDENTIFIED FEMALE: Just to further clarify what Lois raised, we do have management controls over the renegotiation of due dates and we have a regular process for that. It's also less than 5 percent of the total number, which you -- if you noticed, one of Lois' slides, there's a huge number of actions that were submitted over this past year and less than 5 percent had to have negotiated due dates.

The statute also puts the restriction on us that we have to have this agreed upon in writing. So, this isn't something that the agency can arbitrarily impose upon the registrant. We have to actually negotiate it, and what we do is rely upon email in this day and age, and we have copies of those email exchanges, along with the form that Lois was describing. So, it's a pretty thorough examination and a rigorous review of any requests to renegotiate a due date.

MR. JONES: Okay, Allen, Jose, Jay and Julie.

Let's try to wrap this up.

ALLEN: Thank you, Lois. On your third slide, if we could go back to -- I just have an easy question that would clarify something for me. The one that is titled '05 Registration Activity New Uses. That's not it. Back up one. It must be the other one.

MR. JONES: Allen, could you speak into the mic a little more clearly so we can get the --

ALLEN: Go back the other way. One more. It's near the front, the third one. We don't need the slide necessarily.

(Laughter.)

ALLEN: The line indicates that you approved 164 new uses associated with 702 crops. I work in the non-ag area, so I'm a little confused. I thought every crop that you had a use on counted as a use. What's the difference between the new use and associated with multiple crops?

MS. ROSSI: It's the crop grouping. For example -- and, Bob, you probably can give a detailed example of a crop grouping, but like, for example, there's a crop grouping called the bulb vegetables, and that would include like onions, garlic. shallots.

ALLEN: But you lump those all into that use?

MR. JONES: That's one new use.

MS. ROSSI: Yes. Yeah, that's one new use.

MR. JONES: So, sort of give some representation of how much work you have to do. One use could have 15 crops.

MS. ROSSI: Right.

ALLEN: But the companies submit data, I suppose, for each crop?

MS. ROSSI: They submit it for the crop grouping and there's representative crops that you have to submit the data on to get that crop grouping.

ALLEN: Got it, thank you.

MR. JONES: Thanks. Jose?

DR. AMADOR: I wish you had left the previous slide on, that's the one that I needed, but we don't need it either. I notice on the section --

MR. JONES: Can you speak into the mic? You need to really speak into the mic, folks. It's hard to hear.

DR. AMADOR: I notice that you have on the Section 18, you know, it's an outstanding record there, no request denied, zero. But there were 66 that were withdrawn. Were they withdrawn because they were going to be denied anyway or by an objection that was raised by your group? That one there, that's, you know --

MS. ROSSI: In some cases, that's true. That's definitely true in some cases. In other cases, they were withdrawn because we were able to register a new use. So, there is a variety of reasons. But the reason you gave definitely is in there.

DR. AMADOR: And does the state still play a very important role when submitting a Section 18 petition to EPA?

MS. ROSSI: The state submits the application, yeah.

DR. AMADOR: Yeah, I know. But still how well they do the package and the whole thing has a lot to do with whether it's going to be approved or not.

MS. ROSSI: Definitely, especially in justifying the emergency.

DR. AMADOR: I think this is outstanding then, because Section 18, particularly in our area, we get new pests or diseases or something loses the (inaudible) and we need a Section 18 and I think this is an outstanding record. Congratulations.

MR. JONES: Thank you. Jay?

MR. VROOM: A factor that's going to cut across all three of these areas is the impact of the -- whatever

the new part 158 requirements will end up being, and I wondered if each of the three groups could comment on what they would anticipate that might mean given what we think we know about where Part 158 will resolve. Most particularly, I think from our perspective, opposite the registration review process, looking more prospectively -- I don't know if Susan can come back up or Jay can speak to that. But in particular, we feel, you know, as we've expressed previously, that we really prefer, from the agricultural registrant perspective, a more solid commitment to a chronological approach because we think we've been through enough of the kind of so-called high risk or worst first process steps with FQPA tolerance reassessment and reregistration that we ought to get back to a more orderly kind of chronological predictable kind of process for that.

And as an example, we think it would be not logical to force the OPs and the carbamates through a

registration review process right away. But, once again, I think Park 158 is a factor that -- I know we're going to talk about that on the afternoon agenda with Bill, but in the context of these three presentations, I'd be curious to know what sort of your gut sense is.

MR. JONES: Well, for -- and Lois and I have spent some time talking about this. For registration of conventional pesticides, the chemicals that are submitted and have been submitted for the last three years or so are already in compliance with the proposed 158. That's what companies are submitting right now. So, to me, that's no impact.

We were going to follow 158 for conventionals with a proposal for the microbials, which should be -- you'll hear about later this afternoon, and then a little further down the line will be one for antimicrobials, which is -- I just can't really speak to in so much detail because it's not developed enough to really -- to

speak to it. So, I don't think that it would be much impact in the finalization of 158 on our registration program, our reregistration program. I think it will provide greater clarity to registration review.

And the issue of the scheduling, again, we're trying to balance kind of a -- in registration review, a -- our preference going in was chronological. It's the only way you -- we felt we could manage it in an effective manner. As we got more into it, we began to realize that you can have even more efficiencies when you group things, because when you use the same kind of science, you use the same kind of economics, you use the same kind of biological information. So, we're trying to balance the let's try to move this through chronologically with the need to be more efficient in how we do things by grouping. I expect that that workgroup is going to continue to talk about that issue in the months to come.

Julie?

MS. SPAGNOLI: I guess somebody had asked sort of what the registrant's perspective was about PRIA, and I think from a business planning perspective, predictability is just -- you can't -- I mean, that is so valuable because when you're trying to, you know, plan for a business, an introduction of a product, obviously, having some idea of predictability is just invaluable.

I think, also, just to speak to what Lois said about, you know, for the reviewers, too, to have a work plan, to know what they're -- you know, kind of what the order of their work is, I think that has got to increase efficiency, because I -- you know, speaking as someone who was in -- did registration work for a number of years, it used to be kind of the squeaky wheel tactic. You know, you were at that product manager constantly, especially if you were getting pressured from the business and --

UNIDENTIFIED MALE: You have a friend who was.

MS. SPAGNOLI: What?

UNIDENTIFIED MALE: You have a friend who was.

MS. SPAGNOLI: Yeah. No, I mean, you know, I just -- I believe that this -- having that predictability takes that aspect -- you know, where you don't have to -- you can know when you can, you know, expect to hear something, so you're not, gee, I got to call the product manager every day to keep bugging him because, you know, if I don't do it, my competitor is. So, I just think it's got to have increased the efficiency within the reviews, too.

MR. JONES: Okay, Michael and Larry and then we're going to wrap this session up. Michael?

MICHAEL: You said for the carbamates that have already started the process that all of the 158 requirements have been complied with. (Inaudible) days of FIFRA and never had an avian reproductive study done.

Is that going to be required for (inaudible)?

MR. JONES: I think I said conventional pesticides. I was talking about --

MICHAEL: (Inaudible) carbamates, isn't it?

MR. JONES: I was talking about new submissions to the agency. If you're submitting to the EPA in the last three years a new chemical, I said those chemicals already have the data that's in the proposed rule for 158. Sorry.

Larry?

MICHAEL: But you didn't answer my question. Will it be required for reregistration (inaudible) avian reproduction studies?

MR. JONES: I -- Debbie, do you know if there's an avian reproduction study required for -- or in-house for --

MS. EDWARDS: I don't believe there's one in-house. I think we will be requiring one.

MR. JONES: The decisions on Aldicarb have not been made, but will be in the spring of this year -- next year.

Okay, Larry?

MR. ELWORTH: Just a quick question, and this may be a typo. What's the difference between the number of requests received and 340 and 66 and even 27 doesn't add up to 517.

MS. ROSSI: They can't add up because they're over the course of different years.

MR. ELWORTH: Okay. I just wondered if there was like another mystery category.

MS. ROSSI: No, no.

UNIDENTIFIED MALE: Ignored category.

MR. ELWORTH: Right.

UNIDENTIFIED MALE: Maybe it will go away.

(Laughter.)

MR. JONES: All right. Well, thank you for

that. I think I may have misjudged how much interest there was in talking about some of these issues from past meetings where there wasn't as much interest. But I, frankly, appreciate the engagement on these issues amongst all of you.

Before we move on to the next session, I think there are four people who came in since we originally did introductions. Michael, I believe you -- if you could introduce yourself and who you're representing to the rest of the group.

MR. FRY: Sure. I'm Michael Fry. I represent American Bird Conservancy. I'm their Director of Pesticides and Bird Program.

MR. JONES: And I think Steve Kellner and Bob Rosenberg and Erik may also have joined us, and anyone else who I just haven't -- Steve? Where is Steve? Oh, there you are. They're all next to each other, too.

MR. KELLNER: We represent the --

UNIDENTIFIED FEMALE: Wait for a minute.

MR. KELLNER: -- (inaudible) portion of the industry and -- thanks -- I guess we're involved in a lot of different things, regulatory things, in particular, and we're headquartered here in D.C.

MR. ROSENBERG: I'm Bob Rosenberg. I appreciate you drawing attention to my tardiness.

(Laughter.)

MR. ROSENBERG: I'm the Senior Vice President for the National Pest Management Association which is a reference to my age, not my responsibilities.

MR. JONES: Erik? Someone pass Erik a mic.

MR. OLSEN: I'm Erik Olsen with Natural Resources Defense Council.

MR. JONES: Okay. We're running a little behind schedule, which makes me very anxious, but I'm going to try to just chill out and I'm certainly not going to shortchange this next session, which I think is something

that many, not all of you, are very interested in, and that is the proposed rule and a few other issues associated with human studies. Anne Lindsay is going to moderate this session.

MS. LINDSAY: Okay. A lot of you know that in my job I do a fair amount of travel, including international travel, so I always have the experience when I'm on the plane of looking at the landing card, and it seems to be a universal requirement, both in the U.S., but all the other countries I go to, that you have to identify your occupation. This always provokes some kind of identity crisis for me. I don't know whether it's just because I'm now very tired having traveled long miles and I'm befuddled, but I think what should I call myself?

Government official, federal official, nameless, faceless bureaucrat? Sometimes that probably would be the right choice. But I always end up choosing civil

servant. I do that not because I always feel that I live up to that job description, but because I think that is the best job description for anyone who is public service. We are here to be your servants, the servants of the citizens and public in our country. I go off on this little tangent as the introduction to this discussion because I know that the topic of human studies is one that's fraught with all kinds of controversies, with very strong feelings, very decided views. It's one of those topics where I actually think it can be hard, even within yourself at times, to find agreement.

I know, just speaking for myself, I'll look at a particular issue associated with this topic and find myself of many minds and find that I actually need to consult and talk with a lot of other very thoughtful people, many of whom have very different views than I do, in order for me to come to a resting place on an issue that I'm comfortable with, that I feel good about, that I

feel responsible. It's not very often, certainly in my work experience, that you get to directly confront and try to grapple with ethical issues.

I will not describe that as a fun experience because it's actually a very hard experience. You have to actually ask yourself what your values are. You have to ask yourselves, I think, a series of hard questions about the values that are held by the society within which you live, and sometimes some of those values may not be ones that you personally share or that you share easily, but you also have to understand them so that you can respect them and do them honor.

So, this is a topic where, since I've been engaged in this, I've been very proud to think not only of myself as a civil servant, but what I really want you to know are I believe that those people at EPA who have been shouldering the largest part of the burden on our human studies work over the past -- now it's many years

actually -- I was going to say few, but it's actually many years, are some of the people that I most respect in our organization and that have consistently taught me what it actually means to be a civil servant. So, I can assure you that in your interactions with this -- on this topic, you are dealing with sort of the very best and the finest of this country's civil service, and that's the resource that our agency's bringing to bear to handle the issue and a sign of the seriousness with which we treat it and the import.

The session itself, as opposed to the topic, is organized along some very simple lines. Bill Jordan and John Carly, who are two of those finest civil servants that I was talking about, are going to do a short recap of the rule that we proposed about a month ago. And although I know many of you have probably actually read the rule, are reading the rule, are studying the rule because you want to give us comment, we thought it would

be good just to give you this sort of summary. So, if you already know it, bear with us. If you don't know it, it will actually maybe help your study of the proposal, and then we would save as much time as possible, having gone through that recap for all of you who care to either ask questions that would help clarify portions of the rule and help inform your comments on the rule, or if you just have observations and perspectives that you want to share with us and with each other at this point in time, opportunity to do that.

I do want to do the specific caution that Jim gave generically earlier. Comments that you make here are important to us and will, I think, really enrich our understanding of your perspectives and your concerns. But they don't substitute for the official comment in the notice and comment process. So, don't neglect to do that if this is a topic that you want to weigh in on.

Another caution, which, again, I'm assuming is

probably not necessary, but you all know that in our Appropriations Act this year, there were certain prohibitions that were put into place in terms of what EPA can consider acceptable to rely on with regard to human studies that involve intentional dosing toxicity types of issues. Those are things that because we are under that prohibition until the rule -- the proposed rule becomes a final rule, we can't talk about specifically today. The focus is on the rule itself, the proposal, not on the specific chemicals. I doubt that you would want to bring any of that up, but if you were thinking about it, it would be helpful if you didn't because you'll find us saying we're sorry, we can't actually respond to something.

And with that, I would really like to turn it over to Bill and John to do the recap.

MR. JORDAN: Thank you very much, Anne, for the useful introduction. We are going to go through a

presentation that we have used in various places. Jim Jones, Anne Lindsay, John Carly and I have participated in meetings with particular stakeholder groups and conference calls and the like, and so, if you've been in any one of those previous sessions, we hope this material will sound familiar and that -- but I, nonetheless, want to say that it's become clear, as John and I have gone forward in conversations with people, that there are still aspects of the proposed rule that we -- that folks don't understand completely. I put that at our feet as the responsibility for not having made it as clear as we should, and so, I hope you'll listen carefully and try to follow through and follow our presentation.

I'll say that if you do start talking about one of those human studies that we're not permitted to accept, consider or rely on. We had thought about doing one of the see-no, hear-no, say-no -- speak-no evil kind of things with Anne and John and me, but we'll have some

sort of signal to let you know that's out of bounds.

I want to give credit to John Carly and Keith Matthews who, along with me, were the three principal drafters of the rule. For whatever flaws, I think I take responsibility. But they've done -- Keith and John, in particular, have done a good job in making it more intelligible. And, today, we're going to go through and talk about the rule. It was published on September 12th in the Federal Register. It contains some of the strongest protections for human subjects ever proposed by the Federal Government, including a categorical ban, without exception, on any new testing of pesticides, which involves intentional dosing of pregnant women or children.

The public comment period is open, as required by the Appropriations Act, for 90 days, and it ends on December 12th. You can find the Federal Register notice announcing the rule, together with background materials

on EPA's website at the location listed on our slide.

I think it's important in this conversation for everybody to be on the same page with respect to the terms that we're using. So, we're going to start with an explanation of key terms and then summarize the context of the proposal, laying out some elements relating to the background of pesticide regulation and human studies, and then I'll summarize the key provisions of the proposed rule and talk about the agency's plans for the next several months. That should take maybe 15, 20 minutes, and then we'll open it up for questions and discussion.

The first term to talk about is human research. Research is defined in the Common Rule or regulation that already exists as a systematic investigation intended to develop new, generalizable knowledge. It involves intervention or interaction with living human beings and/or with identifiable information about them. These definitions are very broad and embrace many different

kinds of studies. To make sure that we understand and appreciate the breadth of these definitions, I'm going to illustrate that by describing some of the many kinds of human research that we received with regard to pesticides.

Many human studies involved collecting data on people who, in the course of their daily activities, are exposed to pesticides. For example, somebody who's mixing, loading or applying a pesticide. These studies do not involve intentional exposure. Other examples of human studies which don't involve intentional exposure include epidemiological studies, analyses of accidents or incidents and monitoring or observational studies.

Now, there are other types of studies that do involve intentional exposure, that is to say, exposure to the subjects which they would not otherwise have been exposed had they not been participating in this study. There are many kinds of intentional dosing studies. For

example, studies to test the effectiveness of a mosquito repellant. In this study, a human volunteer will apply the repellant to his or her forearm and then insert the arm into a chamber filled with hungry mosquitos, and then we monitor to see whether or not the mosquitos like and bite.

Another example is a dermal absorption study. In this kind of study, a small amount of the chemical is placed on the skin of a volunteer. The researchers then determine how much of the chemical is absorbed through the skin and how quickly by measuring levels of the chemical in blood, urine, or other excreta. This kind of information can be very important in assessing a pesticide's risk in occupational settings.

As a final example, there are the intentional dosing studies to identify or measure toxic effects, which have been the subject of most of the public controversy. In these studies, volunteers typically

receive small, but increasing doses of a chemical to ascertain the dose which causes a threshold adverse reaction. The great majority of human studies on pesticides received by OPP come from observational studies. That is ones which don't involve intentional dosing.

And by the way, we use the term "intentional dosing" or "intentional exposure" interchangeably. They involve collecting information on people who, as research subjects, are simply engaging in their normal daily activities.

The next term I want to talk about is the Common Rule. The Common Rule was promulgated in 1991 and it defines the ethical and procedural standards applying to all human research conducted or supported by the 17 participating federal departments or agencies that also adopted it at the same time as EPA. In very broad summary, the Common Rule requires that proposed research

be reviewed and approved by an independent oversight group, known as an Institutional Review Board. In the human studies area, that's reduced to an acronym, IRB.

It also requires that participants be selected fairly and that they give their fully informed and fully voluntary written consent to participate in the research. EPA was an original signer of the Common Rule and our version of the Common Rule or our codification of the Common Rule appears in Title 40 of the Code of Federal Regulations Part 26.

Finally, I want to define the terms first party, second party and third party research. Human research conducted by a federal Common Rule agency is referred to as first party research. Research conducted by others with support from a federal Common Rule agency is referred to as second party research. This would include academic researchers who are working on grants, for example, from EPA. Research conducted by others with no

support from any federal Common Rule agency is referred to as third party research.

EPA's Common Rule, as it now exists, applies to all of EPA's first and second party research. It does not, however, cover third party research. This proposal that we have put out would extend EPA's Common Rule to certain regulated third party research as well.

Okay, you all have, I'm sure, a better appreciation, the vast majority of people, about the complexity of assessing the risks of pesticides. You understand, I hope, that we look at animal toxicity studies to develop an assessment of the pesticide's potential toxic effects, at fate and exposure studies to estimate how and at what levels people may be exposed. Sometimes, however, we have other information, including data from human research, to help us in assessing the potential human risk from pesticide use.

We think that the record shows that human

research can help inform regulatory decisions and we know that the use of human research has also raised profound ethical and scientific issues. We have struggled for a number of years to find the most appropriate approach to regulating intentional dosing pesticide studies. Although it started earlier in 2001, we asked the National Academy of Sciences for advice on whether and under what conditions such studies should be allowed and considered by EPA. The current proposal that we put forward relies very heavily on the NAS's advice.

Our goal in developing the proposed regulation has been to protect the welfare of human research participants in two ways, by setting rigorous standards to guide how new human research is performed and by defining criteria by which EPA will judge the acceptability of research once such research has been completed. All people who participate as human subjects in research must be treated ethically and must be fully

informed of the potential risks that their participation would raise. Every effort must be made to minimize their risks from participation in research, and we strongly discourage and hope to do everything we can to prevent the conduct of research that do not meet rigorous ethical and scientific standards.

As you'll hear in these next set of slides, the principal focus of our proposed new regulation is intentional dosing human studies for pesticides conducted by private researchers without Federal Government support; in other words, by third parties.

So, let's turn now to the rule. This regulation will establish stringent enforceable standards for the ethical conduct of research involving intentional dosing of humans with pesticides. Our proposal is based on and generally consistent with the recommendations of the 2004 report from the National Academy of Sciences, which they developed after a distinguished panel spent over a year

studying this controversial subject. In some respects, our proposed rule goes farther. It contains even more protective provisions than the NAS recommended and goes beyond the specific requirements of the FY 2006 Appropriation Act.

The provisions of the proposal affect a variety of players and activities, and it's important to keep in mind and be clear about these distinctions. For purposes of the discussion, it can be divided into the following categories. There are requirements applying to third party investigators regarding the conduct of new human studies. There are requirements applying to first and second party investigators, EPA and EPA's grantees regarding the conduct of new human studies. And finally, there are requirements applying to EPA in our role as regulators regarding how we will review completed human studies.

In one of the most important provisions, the

proposed rule would prohibit any new third party intentional dosing studies with children or pregnant women intended to submission to EPA under the pesticide laws. This prohibition is consistent with the requirements of the Appropriations Act, that the rule not permit the use of pregnant women, infants or children as subjects, but it is broader in that it would apply to all intentional dosing studies, not just toxicity studies, which is how we understand the Appropriation Act to require us to act.

We think these special populations deserve additional protection and we can see now justifiable reason for testing pesticides on either of these groups. These prohibitions against conducting new intentional dosing studies with pregnant women or kids do not allow any exceptions, either for EPA or regulated third parties. We want to send the message to everyone clearly that certain kinds of human research can never be

acceptable and should not be conducted.

In addition, these same prohibitions also apply to EPA. The proposed rules would prohibit EPA or our grantees, first and second parties, from either conducting or supporting any intentional dosing studies with pregnant women or children. Now, here it differs from what I just was talking about for third party because it applies not just with respect to a pesticide, but with respect to any other environmental substance. This prohibition is also consistent with, but broader than the requirements of the Appropriations Act and it would apply to all intentional dosing studies, not just toxicity studies, and it applies to all substances, not only pesticides throughout EPA.

The next prohibition that I want to talk about is one that prohibits -- not only prohibits the conduct of the new intentional dosing studies, but it also forbids EPA from relying, in its pesticide decision-

making, on the results from these studies, whether they're new studies or old studies. There is one very narrowly crafted exception that I'll be talking about in a few minutes.

In addition to these basic prohibitions, EPA's new regulations would extend the requirements of EPA's Common Rule to all third parties who conduct intentional dosing studies intended for submission to EPA under the pesticide laws. Now, remember that the Common Rule defines the ethical standards that apply to human research conducted or supported by EPA and other federal departments and agencies, and remember, too, that because there are no exceptions to the prohibitions that I've been discussing, this extension of the Common Rule would apply only to third party intentional dosing studies with adult subjects, not including pregnant women.

Extending the Common Rule will help ensure that people who volunteer for third party intentional dosing

studies are treated ethically, that potential risks are fully disclosed to them and that every effort is made to minimize the risks that they bear on behalf of society.

Third party intentional dosing studies, human research with pesticides, is not now required to undergo any kind of external review, although I will point out that many studies do undergo at least some external review. We think the absence of such a requirement is not wise. And so, the NAS recommended that each proposed new study should be carefully examined on a case-by-case basis before it is conducted to evaluate the soundness of the study design, the potential risk to subjects and the potential benefits to be gained from the study.

Consistent with that recommendation and with the related requirement of the Appropriations Act, EPA is proposing to establish a Human Studies Review Board. Now, we're going to create a new acronym, HSRB. The HSRB will review study protocols before the research is

conducted and also review the reports of research after it is completed.

We received a lot of questions about how the HSRB would operate. The rule provides that no EPA employees would serve on the HSRB and that the members would have to meet the conflict of interest requirements for special government employees. That means that they could not work for or have a financial interest in any stakeholder such as an environmental advocacy group or a pesticide company if that stakeholder had an interest in the issues that they were addressing.

Every new intentional dosing study for a pesticide would undergo ethical review by a local institutional review board, IRB, and then also be reviewed by EPA staff and then the HSRB. The recommendations of all three groups, the IRB, the EPA staff, the HSRB concerning both science and ethical issues, would be provided to the investigators before a

study begins. Under the Common Rule, the IRB is required to monitor the research while it is in progress and both EPA staff and the HSRB will review the report of the research when it is completed.

We've gotten a lot of questions about other aspects of the operating details, the frequency of the meetings, the opportunities for public participation, the organizational location of the HSRB, and those details are still under discussion within the agency and remain to be decided.

The proposal breaks new ground in putting forward, for the first time by any federal agency, ethical standards for the agency's decision to accept or reject completed human research. There are three elements in this part of the proposal. First, for studies initiated after the proposed rule is turned into a final rule and becomes effective, those studies would be accepted only if information is available to the

agency to demonstrate that the research complies with the Common Rule. So, scientifically valid and -- scientifically valid and relevant research conducted before the final rule becomes effective would generally be accepted if there's no clear evidence that they were fundamentally unethical or significantly deficient with respect to the standards prevailing when those studies were conducted. Both criteria track very closely with the advice of the National Academy

The proposed rule allows an exception to these criteria under very restrictive conditions. Under the proposed exception, EPA could consider and rely on a scientifically sound and relevant study which does not meet the ethical standards only if to do so would be crucial to the protection of public health; that is to say, it would lead to a more protective regulatory position on EPA's part. And then we would do so only after seeking public comment and consulting with the HSRB

about our determination.

I want to underscore that this exception applies only to EPA's consideration of completed research and it does not provide an exception to the prohibitions against conducting new intentional dosing studies with pregnant women or children. If such studies were conducted, they would be subject to the administrative actions detailed in the rule for non-compliance, except that we might consider it if it led us to put a more restrictive program in place for that particular pesticide.

UNIDENTIFIED FEMALE: Bill, could you repeat that, please?

MR. JORDAN: Okay. I want to point out that the exception that we're talking about here applies only to EPA's consideration of completed research. It does not provide an exception to the prohibition against conducting new intentional dosing studies with pregnant women or children. If such a study were conducted, it

would violate our regulations and would be subject to the administrative actions detailed in the regulation and we would not consider it unless we concluded that the consideration of that study and reliance on it was necessary to support a more protective public health outcome in terms of, for example, reducing the amount of pesticide that would be allowed into the environment.

On August 2nd, the President signed our FY 2006 Appropriations Act. That law includes a provision specific to human studies with pesticides. The provision prohibits EPA from using any of its resources to accept, consider or rely on third party intentional dosing human toxicity studies for pesticides or to conduct any intentional dosing human toxicity studies for pesticides until the agency publishes a final rule or issues a final rule setting specific standards in this area. We've taken pains, we think, to ensure that the proposed rule is consistent with that legislation.

As required by the Appropriations Act, we've allowed for a 90-day public comment period on the proposal. That ends December 12th. The Appropriations Act also requires that a final rule be issued within 180 days of enactment or by the end of January, January 29th. We expect to meet that target.

Rather than waiting for the beginning of the new fiscal year last October, we began discontinuing our reliance on third party intentional dosing human toxicity studies in our decision-making under FIFRA and FFDCA. We have developed guidance that we've given our staff to make sure that they understand the scope of the prohibitions in the Appropriations Act and that is being implemented as well.

So, I want to review the six elements of the rulemaking that are sort of the key highlights, although there are certainly a lot of other details in it. EPA's proposal prohibits third parties from conducting

intentional dosing human studies for pesticides with children or pregnant women. It prohibits EPA from conducting intentional dosing human studies for any substance, pesticide or something else, with children or pregnant women. It prohibits EPA from relying in its pesticide decision-making on intentional dosing studies with children or pregnant women, subject to the exception that I just described.

EPA's proposal also extends the ethical standards of the Common Rule to all third party intentional dosing human studies for pesticides intended for submission to EPA. It established a Human Studies Review Board to conduct a rigorous review of all intentional dosing studies for pesticides, both before they are conducted and after they are complete, and it's consistent with the principles of the Nuremberg Code and the 2004 NAS report.

So, at this point, I'll turn it back to Anne to

moderate the discussion.

MS. LINDSAY: So, you've had a recap and a recap of the recap at the end. Now's the time to open the floor to questions, observations, comments.

Carolyn, you're up.

MS. BRICKEY: I just want to highlight two aspects of this rule that I want to comment on. First of all, and this may be a silly question, but I don't think it is, what are kids? What age?

MR. JORDAN: The proposed rule defines a child as any person who is younger than 18 years old.

MS. BRICKEY: So, college students would presumably fit the bill for giving informed consent?

MR. JORDAN: If the college student is 18 or older, then they would be treated as an adult.

MS. BRICKEY: I have some of those and --

MR. JORDAN: So do I.

MS. BRICKEY: -- I shudder to think about their

ability to evaluate the risks of being exposed to a pesticide, much less the other risks they're exposed to.

UNIDENTIFIED MALE: I shudder to think about the stuff they're testing already.

(Laughter.)

MS. BRICKEY: So -- I can't regulate that, Larry.

(Laughter.)

MS. BRICKEY: So, my question to you is, how much thought have you gone into or how much can you talk about the aspects of written -- full informed written consent and how that will be evaluated? What requirements will be in place to make sure that that happens?

MR. JORDAN: The proposed rule, by extending the provisions of the Common Rule to third party research, captures a long history of thinking about informed consent. Informed consent is required by the Common

Rule. The IRB looks at the materials developed by the investigator to make sure that once consent is given, it is informed. The IRB is responsible for examining the design of the research and comparing that with the informed consent materials to make certain that they are, in fact, appropriate in terms of conveying content in a way that people can understand and appropriate in terms of conveying all of the kinds of content that the volunteers who participate in the research should receive.

In addition to that, the materials developed for informed consent will go to EPA staff who will do the same kind of review, and finally, will go through a review by a Human Studies Review Board. So, with those three layers of review, we're hoping that -- and from very different perspectives, the perspective of the local IRB, as well as EPA, who deals with pesticides and has a full understanding of -- as best a -- as good an

understanding of the potential risks involved as possible, as well as the expertise brought by the HSRB members, we hope that we've got a good shot at getting it right.

MS. BRICKEY: Will the designers of the studies be required to submit anything other than just the form that they're going to use to get people to sign? Will there be other materials involved? What other evidence would be required?

UNIDENTIFIED MALE: In the proposed rule, somebody proposing to conduct a new study would submit the complete protocol. All of the informed consent materials, both the information materials and the consent materials, which are often done in different documents, recruiting materials, advertising materials. The Common Rule, itself, has one section which --

(End of Tape 1, Side B)

UNIDENTIFIED MALE: -- certain of those specific

questions, such as exactly how has the risk been minimized. IRBs are charged by the Common Rule with finding that risks to subjects have been minimized. We want an explicit discussion of risk minimization and so forth. There's several other of the specific points. In short, we expect to ask for a considerable amount of information, certainly far more than a form, and we also expect to require submission of evidence after the study is completed that these design aspects were properly carried out. Bill didn't mention it, but the staff and the HSRB will be looking on the backside of the process to make sure that what we reviewed and approved on the front side is what actually happened and that the design was properly carried out.

MS. BRICKEY: Second thing, quickly, because this is important.

MS. LINDSAY: Okay, because now we've got lots of -- you opened it up very well because now we've got

lots of cards.

MS. BRICKEY: So I get my say since I opened it up.

(Laughter.)

MS. LINDSAY: That's good, but just remember your neighbors.

MS. BRICKEY: In regard to your nearly drafted exception, it appears to me that what you've done is create a rebuttable presumption, but it goes the wrong way. The people who have to show that these things weren't done would be people that weren't involved in the studies, and I don't see how that's ever going to happen. The people who are bringing the study forward to get the study accepted would not have to show anything. I mean, do you see what I mean?

UNIDENTIFIED MALE: I understand exactly --

MS. BRICKEY: The burden of proof is reversed.

UNIDENTIFIED MALE: -- what you mean, but I

don't --

MS. BRICKEY: Thank you. You don't agree? Why not?

UNIDENTIFIED MALE: With respect to new studies --

MS. BRICKEY: No, we're talking about your exception here for old studies.

UNIDENTIFIED MALE: All right, okay. Now we've just shifted gears substantially because the earlier discussion had to do with new studies, the proposal of new studies and the review of the materials.

MS. BRICKEY: Right.

UNIDENTIFIED MALE: Now, if we're talking about acceptance of old studies, it's a completely different focus. The starting point is the realization that when a study has been completed, there's not a whole lot we can do one way or another to affect the conduct of the study. It's been conducted. So, we have to decide what to do

with it.

Yes, there is a different burden of proof between the two standards. This was discussed at considerable length by the Academy in their report. It's important, also, to recognize that there's a wide range of old data. There is data germane to pesticide risk assessment that goes back to the twenties that's on some of the World War I war gases that is relevant to some fumigants, for example. And this is the -- in many cases, this is the only or the best available data about the relevant assessment of the toxicity of those materials. And those assessments are important today, but it is irrational to expect people in the twenties to have followed standards that were developed generations later. It's also unreasonable to expect to be able to track down those investigators.

So, we have to -- we tried to find a way to accommodate the very, very wide range. In the case of

more recent studies, our conduct has been when there wasn't enough information to support a finding, we asked for more good data and we've gotten it. But, you know, we have the authority to do that. We can ask for information.

MS. LINDSAY: Okay, Carolyn --

MS. BRICKEY: Okay --

MS. LINDSAY: -- I would like to let some other people -- I'll come back to you. Would that be all right?

MS. BRICKEY: Very well.

MS. LINDSAY: I'm also worried -- I see some cards going down, and so, I'm --

MS. BRICKEY: They'll keep going down as long as I talk probably.

MS. LINDSAY: Well, if you don't mind, I'd actually like to let a few other people ask their questions and then I'll come back to you. I'm going to

try to do it in the order that I think they appeared. If I don't get it quite right, forgive me. But I think, Erik, you would be next, then Amy Liebman, Jay Vroom, Bob Rosenberg, Alan Lockwood and John Schell. So, Erik -- and remember which order I just said -- oh, and I skipped Melody. So, it will be Jay Vroom -- I don't know, you're going to come after John Schell, Melody, if that's okay. Erik?

MR. OLSEN: Yeah, I guess I wanted to first acknowledge that I think EPA has sort of jumped into an anaconda pit on this issue. I mean, it's not an easy issue, and recognizing that, there are going to be a lot of difficult questions here. I wanted to just explore a couple of questions. One is the rule appears to be limited to studies that were intended to be submitted to the agency. If I, for example, did a test on children or pregnant women in Europe and submitted it to a foreign regulator or submitted it to California DPR and that

foreign regulator or California DPR submitted it to EPA for consideration under harmonization or some other reason, would that be prohibited? Would that be covered by this?

I guess what I'm going to is it seems to us, at least, that the requirement that a study be intended to be submitted to EPA -- and that's just one example, there are plenty of others -- is problematic, and perhaps creates a hurdle for the agency that you don't need to create for yourselves. That the agency has plenary authority under FIFRA and other laws to regulate any use of a pesticide, including in research, and it would seem to us, at least, that that requirement of intent is difficult to impossible to determine in some cases and unnecessary. So, I guess that's sort of a two-part question on the intent issue, and I wanted to come back to another question if I can.

UNIDENTIFIED MALE: I'll take the first shot,

and Jim and Anne, feel free to add. Requirements as it relates to new research apply to third party intentional dosing studies for pesticides. That's the phrase that we've been using and I've been using in the presentation here. It's actually spelled out in some detail in the Section 26-101(J), and there it says that research conducted by any person who conducted such research, intended to submit the results to EPA are actually the people who are covered.

I think it is that particular provision that Erik is zeroing in on and saying, does it have to be limited only to people who intended to submit the data to EPA or can it be -- why didn't EPA propose something that's broader than that? And the answer is that we understand our authority under FIFRA to be limited to the regulation of certain people who are engaged in the business of selling and distributing pesticides in the United States, or developing data, and we think that we

can regulate their development of data in connection with that, and so, our authority defines the limits where we can regulate the behavior of companies, individuals engaged in research.

MS. LINDSAY: Jim?

MR. JONES: A little bit further on that. We've had a number of discussions with some people who have raised this issue. As Bill said, our understanding, our belief about our statutory reach here is what drove us to that conclusion. We've done a couple of things in the rule to help make it clear that it's presumptive if you're a pesticide manufacturer, no matter what you say, we're going to infer your intent is to submit to the Environmental Protection Agency. But we are open to and have committed to actually having some dialogue around does the statute constrain us in this way because that -- we are not intending to create any kind of a loophole around this. We're just trying to put our -- put a reg

out that is compliant with what we understand to be our statutory reach.

MS. LINDSAY: There's actually something else that I want to add, but I want to check with Bill to make sure, though, that I'm also right as I'm doing it. So, Bill, you can say, no, you're wrong, Anne, if I'm wrong. But I also believe another piece of the proposal, Erik, is if there were a study conducted that was not intended to be submitted but nevertheless came to us for whatever reason, we would be looking at that and considering it using the same ethical standards that we would for something that was clearly intended for submission to EPA, so that if it comes to us, it gets judged -- if this is newly conducted after the rule becomes final, we are using what are the current standards, and this final rule would, for us, be the current standards.

Am I right, Bill?

MR. JORDAN: Right. The provisions that I

talked about regarding the conduct of new research is just that. It is the conduct of new research by investigators who are third parties. Anne's talking about the behavior of EPA in our capacity in the review of data and there is no limitation whatsoever about the applicability of the ethical standards. Those ethical standards apply whether the study was generated with the intent to support a registration or whether it was done by an academic researcher in Japan and simply came to our attention, and there was no reason -- no earthly reason to think that that researcher had an intent to submit it to EPA. We would still apply the same set of ethical standards in judging whether or not it was acceptable.

MR. OLSEN: I think I understand what you're saying, but what the rule says is there needs to be substantial compliance with the standards and the requirements of the rule. And that sort of brings me to my second question. The preamble talks about substantial

compliance being sort of -- that if there's a trivial administrative oversight, that that's not a problem. But the rule, itself, doesn't speak to that, and I'm wondering if the agency is considering being clearer about what substantial compliance really means. That it really means pretty much compliance with all the requirements except if you initialed on the wrong page or signed in the wrong place or something like that. Is that what you're thinking?

MR. JORDAN: The proposal contains a discussion of that particular phrase and refers to minor administrative non-compliance. It cites a report by the Food and Drug Administration. We've had conversations with people who serve on IRBs and they say that almost no study that comes through their review process meets every single aspect of the Common Rule, that some problem is identified for virtually every study. So, what we are trying to get at is the notion that we want to make sure

that the people who are participating in the research are treated ethically so that there will be substantive compliance.

We've asked for public comment on it and we did that because we recognize that the terms or the phrase "substantial compliance" was not very exact. We hope the public comments will give us a way to do something that's a little more precise.

MR. OLSEN: Your public health exception specifically allows consideration of studies on children if there is a -- you described it as a narrow exception. Would increasing crop yield be a public health exception?

MR. JORDAN: That certainly was not what we had in mind when we wrote it.

MR. OLSEN: My last issue is on past studies. I think it was John who mentioned some of the old phosgene experiments, for example, from years ago or maybe some other studies. My question is, what would you look to

for evaluating what the past standards were? Would you be looking to the Nuremberg Code and Helsinki Declaration and Common Rule or what are you evaluating in that circumstance?

UNIDENTIFIED MALE: As the standard is stated in proposed Section 602, we would be looking at standards prevailing at the time the studies were conducted. None of the standards that you just mentioned were developed. The earliest was 1947. These war gas studies were done in the twenties, some were done in the thirties.

MR. OLSEN: I'm only referring to, say, John, past the 1940s.

UNIDENTIFIED MALE: We would, as the criterion says, look to see what standards were prevailing at the time of the study. Between 1947 and 1964, Nuremberg was pretty much the only thing out there. 1964 was the first edition of the Declaration of Helsinki. There were significant revisions to the Declaration of Helsinki in

1975 and in 1983 and in 2000. The HHS Rules came out in 1971 as guidelines; in '74 as rules and so on. I mean, there's a whole history of a gradual accretion and refinement and maturation of prevailing standards.

MR. OLSEN: So, that's what you're talking about? You're talking about --

UNIDENTIFIED MALE: That's what I'm talking about.

MR. OLSEN: -- the gradual accretion of the Helsinki Amendments that came in over time and the Common Rule, once that was accepted, the HHS Rules that came in and so on.

UNIDENTIFIED MALE: Also, I want to make it clear that we're also talking about, in addition to the Declaration of Helsinki, we're talking about other international standards, the SIAM (phonetic) Standard, the National Standards in the U.K. or various other places where studies have been conducted.

MR. OLSEN: Thank you.

UNIDENTIFIED MALE: Prevailing studies when the standards were done is what we're talking about.

MS. LINDSAY: Okay, Amy, thank you for your patience.

MS. LIEBMAN: Thank you. You spend a lot of time talking about pregnant women and children and Carolyn brought up, you know, college students in terms of, you know, a population that she was concerned about. But there's a lot more vulnerable populations out there than children and pregnant women. There's a lot of low literate, non-English-speaking poor people who might be very interested in getting some money, and I'm just curious about what kinds of protections that we're looking at and how we deal with other vulnerable populations.

UNIDENTIFIED MALE: The core Common Rule, Subpart A, directs IRBs to take particular care to ensure

that a proposed study provides adequately for the protection of people in vulnerable populations. It lists, among others, pregnant women and kids, but it also mentions prisoners, it mentions people with reduced mental capacity. I think it may be broader than prisons, it may be institutionalized people. I've forgotten exactly. But certainly there are a lot -- and it specifically mentions people in reduced economic circumstances.

There's a large body of literature and interpretation in the guidance to IRBs that HHS has put out about how to interpret the level of payment, for example, whether that becomes an undue influence in encouraging people to agree to participate in studies which they might not otherwise participate in.

The Common Rule approach starts from the premise that the subject populations are all potentially vulnerable, and it's the responsibility of the

investigators to design something that incorporates risk minimization, fair selection and those sorts of things, and it's the further responsibility of the IRB to confirm that those things have been done. And in the case of the subparts applying to pregnant women and kids or the HHS subpart for prisoners, that there's additional specific guidance there that says IRBs are supposed to also think about this and this and this and this and this specific point. That's kind of the general approach.

MS. LIEBMAN: You guys just take an extra step and you specifically mention women -- or pregnant women and children in your proposed rule, correct, even though there's all these other populations out there -- but you don't mention them in your rule.

UNIDENTIFIED MALE: Well, we do. We mention one other one, which is prisoners, and we said that because the provisions are unsettled, generally, in the rest of the Common Rule community, we're going to defer decision

on that.

UNIDENTIFIED MALE: But we're prohibiting testing on those two sub-populations, we're not prohibiting testing of people of reduced economic means or people who don't speak English. John then talked about the things that you need to do to ensure that they can be properly informed and consent in a way that's properly informed.

UNIDENTIFIED MALE: I just want to say something that I hope most of you appreciate, but it bears repeating and it bears pointing to, and that is that there is an enormous body of work already in existence in the area of human research ethics. It is not EPA's place to step forward and unilaterally change that. We work within a long history of development of understandings about what it means to treat research participants ethically.

So, when it comes to questions of vulnerable

populations, there are, in fact, as John mentioned, specific provisions in the Common Rule which we are extending to third party research. There are specific understandings about what people ought to do, what investigators ought to do when dealing with members of those populations, which we are adopting and embracing by virtue of having extended the Common Rule there, and which we will try to bring to bear through our role in EPA and through the Human Studies Review Board, who will all be people familiar with that long history.

So, rather than try to commit that material to regulation, we are trying to align ourselves with that existing body of understanding and ethical practice.

MS. LINDSAY: I want to underscore Bill's last point here. I know for me one of the -- it's a learning lesson that I've not completed yet. The phrase "Common Rule" stands for an extraordinary amount of work in this arena. And so, when we say the word it's very short, but

it's referring to a very large body of information and every opportunity I have to interact with someone who either has been involved in the design and conduct of a study involving people or who have been on an IRB, my eyes are opened as to what goes on when the process works right. I know there are times when the process probably doesn't work right.

But for those of you who may be like me with a lesser experience of the Common Rule, it may sound like there are lots of issues that are not being thought of. But I actually think the Common Rule covers a very large gamut of issues that aren't individually articulated.

Let me move on. I think, Jay, you got the honors next, and I know there are two new cards that are up. So, you'll come after Melody.

MR. VROOM: Thank you, Anne. I wanted to commend the presentations that all of you have made, beginning with your remarks about the grasp of ethics and

I'd argue that even before this issue started to take shape in the FQPA process, now quite a few years ago, that there's been an overlay of ethical considerations that civil servants in the agency and elsewhere in the Federal Government that have something to do with pesticide regulation and pesticide registrants and the user community have always applied. It is a cumulative process and we're adding a lot to the body of knowledge and I think, you know, the points that Bill made about getting a common understanding about key terminology is really important so that we're all, more and more, speaking the same language represents a lot of very important cumulative steps around getting final resolution to a place that we've needed to be collectively for a long time.

Specific to the concept of things that are already on the books, not only at EPA but also in other agencies, the NAS report did refer to the existence of

the Office of Human Research Protections at FDA and I wonder if Dr. Troxell could comment on this. Was there a consideration, though, Bill and John, to -- actually in the new EPA rule, contracting by way of a memorandum of agreement, this responsibility to this group that already has momentum and experience and operational processes in place at FDA? And if that was considered and rejected for certain reasons, is it possible to take some of the operational processes that the Office of Human Research Protections at FDA had in place that would -- so you don't have to reinvent those wheels and, in particular, since the vast majority of the studies that pesticide registrants would do going forward, as they have in the past, will be done by contract research firms that are also doing pharmaceutical tests submitted to FDA? It seems like there would be a lot of sense around having the same kind of process design within whatever EPA is doing in the Office of Human Studies and Review Board

that FDA applies.

MR. JORDAN: The Office of Human Research Protections is located in the Secretary's Office at the Department of Health and Human Services, and it's responsible for overseeing all of the issues relating to ethical treatment of participants in human research across HHS, including FDA and NIH and NI -- CEC and on and on. But they also serve as a place where, across the government, they are the leaders and we have turned to them repeatedly and worked with them in the development of this proposal and expect to continue to work with them as we move forward in the final rule and as we try to implement it.

I think your question focused primarily on could we somehow hand off to OHRP or somebody at HHS the review functions related to Human Studies Review Board? That's one of the details regarding the functioning of the Human Studies Review Board that we're still discussing. I

don't think that we have either decided that's a good idea or a bad idea. But it's -- it's a possibility that we're -- we would look at.

MR. CARLY: Let me just add that an awful lot of what OHRP does is compile and disseminate the guidance material for IRBs and that kind of stuff. They are the clearinghouse for this huge body of information and law that's secreted over the years that Anne and Bill were talking about. That is not a function that overlaps with what we've been talking about in this rule.

Among the things that OHRP also does not do is they do not make study-specific acceptability judgments in behalf of any of the HHS agencies, including FDA. So, that kind of decision remains a responsibility internal to all the participating agencies and we would have to do that ourselves.

MS. LINDSAY: Okay, thanks, John. Bob, I think you're up next if I'm remembering correct.

MR. ROSENBERG: Yeah. And you know what, my educational experience is in political science, which is, of course, not really science at all. So, I have like a -- I mean, a dumb question but one that would help me kind of understand the issue better. Why is this data valuable? Does anyone understand the relative -- or can they explain the relative value of human versus non-human data? I mean, is it more reliable, more valuable? I mean, what's -- you know, how do you even think of it?

MR. JORDAN: Okay.

UNIDENTIFIED MALE: There's not a clamor of people trying to reach the microphone.

(Laughter.)

MR. JORDAN: I'll take a shot at it. The National Academy of Sciences report discusses why human data might -- I underline the word "might" -- provide information that's not available from research with animal models or other kinds of research. And it has to

do with a couple of different things.

One is that sometimes humans and animals do not respond in the same way to exposure to a substance. And when there is a difference, that difference may matter in terms of what kind of regulatory decision is made. There are some notable examples where humans are more sensitive to the toxic effects of substances than animals are. So, that could lead to a more stringent regulatory position with regard to what's acceptable.

Secondly, there are kinds of effects that animal models simply aren't capable of picking up, even though the animal might be experiencing those effects. A headache, for example, is hard to diagnose in a laboratory animal, and there are other kinds of things that somebody who knows more about animal testing could probably list off a dozen or so types of effects. So, those are a couple of reasons.

I think, to be fair, there are folks who want to

do testing with humans in order to demonstrate that humans are less sensitive than animals, and therefore, exposure to the material at a given level would be safer than you would think otherwise from an animal study.

MS. LINDSAY: Okay. Alan, thank you for patiently waiting.

DR. LOCKWOOD: Thank you. I think if I were to extend the metaphor that Erik Olsen made, I wouldn't have said jumping into a pit of anacondas. I think maybe cobras or some other highly poisonous snake might be a more appropriate analogy.

First a comment and then two specific questions. I think that if the proposed rule actually did what was indicated in the presentation, there would not have been the intense scrutiny and exceptions taken to the proposed rule by people in the media, letters to the editor and various conversations. I think it's fair to say that -- and I think that this was one of the things that you said

was sort of off-limits for specific questions, but the number of exceptions that would appear to allow inclusion of pregnant women and children into various testing regimens.

The two specific questions that I would have, one centers on the prevailing standard, noting that Nuremberg came in the forties and the other standards that were mentioned came thereafter. But the Hippocratic Oath and the first Do No Harm principle of the Hippocratic Oath is substantially older than any of those. Is that one of the standards that will be taken into account by the agency?

And then a more specific question about the provision in the proposed rule that would allow the administrator to waive all or parts of the rule, if you could comment on that. Thank you.

MS. LINDSAY: Can I just say one thing before we actually let the experts answer your questions? First of

all, I may have been confusing you. The only things we don't want to talk about are the specific chemical studies that might fall within the prohibition defined in the Appropriations Act. So, anything about the rule, itself, is a legitimate field for discussion at this session. So, you don't need to feel like you can't talk about some of those other parts.

The other thing I wanted to say, I actually -- my family, many members -- I'm the outlier. Many members of my family are physicians, and so, I actually am very pleased to hear you refer to the Hippocratic Oath. It is actually what I say to myself when I'm engaged in these discussions and looking at the issues, whether they might be around individual chemicals or the rule itself. I think it perfectly and very succinctly captures what we all need to keep in mind when we're trying to sort our way through or step through the cobra pit, if that's how you'd like to characterize it.

So, Bill?

MR. JORDAN: Why don't you do it? I'll let John Carly answer the question about the Hippocratic Oath. Dr. Lockwood's question about authority to waive requirements is one where perhaps the regulation is not as clear as it should be, but I will take a second or two and explain what I think he is referring to.

In the proposed rule in Section 26-401(A)(2), it says that the administrator may waive applicability of some or all of the requirements of these regulations for research of this type, which refers back to research conducted or supported by EPA outside the United States. It contains an erroneous cross reference. The appropriate cross reference should be to part of the Common Rule which says 26-101(H) and -- okay. So, now that I've done all of the kind of legalistic connect the dots part, let me tell you what that's all about.

The Common Rule, which has been in place for

nearly 15 years, says, in effect, sometimes research by the government will be conducted outside of the United States, and when that happens, it will need to comply with the ethical standards of the country in which that research is taking place. And in recognition of the fact that other countries have different schemes that may not align completely with the scheme that is set up by the United States in the Common Rule, it is permissible for the head of the agency to allow a waiver of the Common Rule so long as the provisions of the host country for the research are -- provide at least as much protection, are at least as protective. So, that's the reference back to 26-101(H).

And 401(A)(2) says you can do that for studies involving children as well. Now, that has nothing to do -- nothing to do with the prohibition against doing intentional dosing studies with children. It does not authorize any exception to that prohibition.

The last thing to say is that the language that we have here is verbatim the language that appears in the Health and Human Services regulation providing additional protection of children for subjects in research and it has been in force for over 20 years. And I have not heard that that provision -- I've asked folks. I've asked whether that provision has led to some sort of creation for loopholes for HHS to somehow vitiate the protections for children and I've heard no one say that they've ever heard the slightest suggestion that that would be abused in that manner, and we certainly don't intend it that way.

Now, the -- one more thing. Dr. Lockwood referred to reports in the press that dispute the assertions made in our presentation today. I won't go into the details other than to say I do not agree that EPA has put forward a proposal that contains the kinds of loopholes that have been reported in the press, and I

find those mischaracterizations very troubling and ones that, frankly, have gotten in the way of the quality of the debate about things that I think are important to talk about, and I'd be happy to continue that conversation with anyone at another time.

MR. CARLY: Thank you, Bill. Tough act to follow. With respect to the Hippocratic Oath and the more general question of what sorts of standards might be deemed to have been prevailing at sometime before the Nuremberg Code was developed. The criterion in which the reference to prevailing standards occurs begins by saying that -- by referring to the possibility that something might be fundamentally unethical. And then there's a parenthetical defining what that might mean. For example, intended to inflict harm. That's the flip side of the Hippocratic Principle of doing no harm.

If there's any evidence that a study was intended to harm the participants, that would tip it into

the fundamentally unethical bucket, which is one -- that's the first of the pair of criteria there that says if it's fundamentally unethical or significantly deficient with respect to prevailing standards. So, in my sense, the Hippocratic Oath is embedded in that first part, the fundamentally unethical. So, it would -- it doesn't quite enter the prevailing standard argument, but it is problematic to figure out what standards people thought they were complying with.

There are some documents from the early 20th Century, in fact, from the late 19th Century, addressing research ethics. They are few and far between, and the extent to which they prevailed is a matter for academic argument. It's tough to deal with those really old studies. But we also have to first find them to be scientifically meritorious in today's terms and directly relevant to the issues that we're addressing. So, the issue doesn't arise very often.

MS. LINDSAY: Okay. Just a matter of timing and sequence. I'm remembering my original -- and by my count, there's five new cards up after my original sequence. It's quarter of 12:00 and you've all been extraordinarily patient sitting here all morning long. I'd like to finish it out by noontime if we can, but I also don't want to cut anybody short who needs to raise an issue or question. I'm mindful of the promise I made Carolyn Brickey, that she gets the closure comment. So, just to reassure folks that I'm noticing the cards, but I'm also trying to keep an eye on the time because I don't know that you can all sit here a whole lot longer without being given an opportunity for a break.

So, with that, John, I think you are next in my order.

MR. SCHELL: Thanks, Anne. This is just real quick and Jay brought it up previously. The FDA has a lot of history with dealing with working with humans in

clinical trials. Bill, you made a statement earlier that with this rule, you're sort of blazing new ground. Are these provisions substantively different than what the FDA uses in its Phase II clinical trials? And if so, why?

MR. JORDAN: The vast majority of the proposed regulation is taken from existing regulations that have been promulgated by either HHS or the Food and Drug Administration. The new material, the place where we are blazing new ground is the last subpart, which contains the ethical standards for judging whether or not to rely on the results of human research in our decision-making at EPA. And we have worked with FDA as well, I should add, not only OHRP.

MR. SCHELL: And one more quick question and it has to do with -- and Erik talked about this earlier, too -- the submission of data that's collected elsewhere. There's likely to be a real swell of information being

generated by the Reach program over in the EU. Are you familiar with how close their standards are to the Common Rule? We're doing a pharmaco-kinetic study and we're being held to some very high standards, just how applicable would those data be if we wanted to submit them over here?

MR. CARLY: There have been several studies done that took the contemporary versions of the Declaration of Helsinki and the Common Rule and the SIAM's guidance and various other standards and kind of stacked them up in a table and concluded that in -- if you look at what they try to do in substance, they're very close. They differ in procedural detail and in the level of detail. The Declaration of Helsinki, for example, is more on the side of a declaration of principles than it is an operational guidebook, whereas the SIAM's guidance goes into a whole lot of procedural detail.

So, if you look at these documents and try to

find differences, there are lots of small points of incongruency. If you look at these documents and compare them in terms of the substance of what they're trying to do, they rest on the same fundamental principles. They may take a somewhat different approach, but they're basically trying to do the same thing.

As a matter of practice, EPA and other agencies have, in the past, generally concluded that a study that meets a contemporary ethical standard in the EU is -- you know, it's not an automatic thing, it's not a free pass. But the presumption is that something that his highly ethical in Western Europe is going to be considered highly ethical in the U.S. I mean, there's a lot of interchange and sharing of data. It's not going to be a problem.

MR. SCHELL: So, the term -- when you say complies with the CR, you'll know it when you see it, you can't --

MR. CARLY: Yeah. But remember that the Common Rule incorporates this 101(H) Section that says here's what you do with data that's actually run in other countries. So, the provision for assessing the comparability of international standards to the Common Rule is built into the Common Rule itself. You don't need to do a separate thing that allows for that crosswalk.

MS. LINDSAY: Okay, Melody, you end sequence number one.

DR. KAWAMOTO: Okay, thanks. I'm asking about the HSRB members would be free of any conflicts of interest. I realize that conflicts of interest has a pretty specific definition, so I'd like you to clarify it and to give examples of who would be eligible, because you did mention two groups that wouldn't be eligible. And then after that, the second question is, what would be the scope of their authority? Would they have the

final say, especially with regard to exceptions?

MR. JORDAN: The Human Studies Review Board members would advise EPA. They would not make the decisions. EPA, under the statutory authorities that we administer, is the final place where decisions are made. With regard to the conflict of interest, there is a federal law that prescribes conflict of interest requirements for special government employees. If you're familiar at all with the FIFRA Scientific Advisory Panel operations, that would be the simplest way to illustrate how this set of requirements would apply because that's what they follow in selecting members to perform peer review of scientific research and guidelines and risk assessments that we've developed here at EPA. Generally, we tend to get people who are in government or academia as members of the Scientific Advisory Panel, and I would expect those two places to be sources that we would turn to again.

DR. KAWAMOTO: Okay. I was also wondering if, since some of this isn't scientific, other types of experts would be involved? For example, maybe religious or ethical, people who are dealing with it in academia or in the public.

MR. JORDAN: Right. The National Academy of Sciences' recommendation regarding the Human Studies Review Board identified three disciplines that they thought should be represented as part of the Human Studies Review Board, expertise in research ethics being one of them, biostatistics being a second and --

UNIDENTIFIED MALE: Human toxicology.

MR. JORDAN: -- human toxicology. We would expect those disciplines to be among the ones, although not necessarily the only ones. The question of whether to bring in people who are sort of representative of community values, for example, from a religious group or some other patient representative group, for example, the

patient advocacy group, is something that's a detail we haven't discussed. But, you know, I think it has a lot of merit.

MS. LINDSAY: Okay, my second sequence, which I think is roughly in the correct order that the cards came up, would start with John Kepner down at the end of the table, Amy Brown, Steve Kellner, Michael Fry, Dr. Roberts, and if no new cards come up after Dr. Roberts, we would end with Carolyn.

MR. KEPNER: Yeah, just two parts. One's just a clarification from the answer from Amy Liebman's question. Would there be -- you mentioned that, you know, for ensuring that folks that are low income, low mental capacity, you know, prisoners, et cetera, that they would -- you know, they have to be properly informed. But is there any protocol to avoid or prohibit like a study that would be just made up of folks from those communities or is it just that they have to be

properly informed?

MR. CARLY: I think this -- first off, this certainly isn't covered by the proposed rule specifically. Secondly, part of this -- one of the two parallel towers of this edifice of accumulated information and the history of oversight of ethics is the whole business of informed consent. There's an immense amount of information. There's guidance all over the OHRP website to IRBs, about how to deal with informed consent in special circumstances, including some of the ones that you alluded to, but a much longer list of cases that have turned up where there were kind of special concerns or issues. People started thinking about it and oh, goodness, and a case like that, how do you really make sense out of the principle of respect for persons and autonomous consent?

Rather than address the specifics, I'd encourage you to look at that body of stuff that applies to any

Common Rule work, and it's available routinely to all IRBs. And by the way, OHRP requires training of IRBs in these and related matters in order to maintain their registration and certification as approved IRBs.

MR. KEPNER: Okay. And just one --

MR. JORDAN: Before you ask your next question, I want to disagree slightly with John in that I think the regulation that we proposed does address the question in that it extends the Common Rule to third party research, and the Common Rule specifically provides, in 26-111, Paragraph A(3), that selection of subjects is equitable. And then there's a discussion of what equitable means, and it would, in my view, under this language, not be equitable to target a population that was low income or exclusively mentally limited in terms of their ability to understand something.

MR. KEPNER: Okay, thanks. The other thing is, you mentioned that folks would have to submit

recruiting --

(End of Tape 2, Side A)

MR. KEPNER: -- ag study or something like that. So, are they required to say it's a pesticide dosing study or could they just say you're going to -- you know, they'll do this chemical, here's the scientific name, you know, that's about it?

MR. CARLY: It has long been -- I'm not sure if it's quite correct to say required. It has long been common practice in a great many areas for IRBs to review recruiting materials, and in a lot of cases, particularly in university settings, these IRBs are -- they have books of policy guidance and things, and they probably specify, in at least some cases, what those things are. But there's no regulation that says here's what you're permitted to do or what size type you're permitted to use in recruiting.

I've got to say, as far as I can tell, there are

a fair number of cases where recruiting materials are not addressed by the IRB, they're not submitted to the IRBs. That would change under this rule for the covered studies where we would specify that that stuff and the IRB's comments on it would have to be submitted to us. Then the after the fact stuff, we would expect to see the actual recruiting posters that were used, make sure they reflected any comments that came from the HSRB or the IRB or whatever.

MS. LINDSAY: Okay, Amy? Amy Brown?

MS. BROWN: Well, I'm not sure I want to open my mouth anymore because I am one of those who actually does do observational studies with my students, not intentional dosing studies, but have done a number of them over the years. I've been thinking about the IRBs that I work with and they all, very rigorously, review my protocol and my informational materials, my -- what I'm going to say to the people, all of the recruiting

materials. But I don't believe I've ever been asked if all of my subjects can read and understand the language that the materials are printed in.

Now, because I've known my subjects and I know that they can do that, that's never been an issue, except in one case when I had a subject who spoke primarily Spanish and I just opted him out of the study. But I suppose it would be better -- it would be easy if you're running, say, a farmworker study. The IRB is going to think about it and say, gee, we need to make sure that they can read and understand the materials. But they don't typically ask me if my people in a campground or my pesticide applicators all are literate and all actually read English.

So, I wonder if there can -- there are certainly -- for my IRB, there are definite pieces of information that I must provide and certain wordings and certain things -- a whole huge list of things they require. I

wonder if it could be a question that could be part of the Human Subjects Review Board. You know, I'll take it back to my IRB and suggest that they do this routinely, but ask if people who speak other languages can actually understand these materials, that you have to somehow certify that.

MR. CARLY: It's already part of the Common Rule, that IRBs are supposed to satisfy themselves that the informed consent material is likely to be understood. It has to be written in -- I've forgotten the precise language -- understandable language. And there's a whole body of literature about whether that means a sixth grade level or an eighth grade level or, you know, a graduate level. And in criticisms of things, some people say, oh, this is too sketchy, it's not complete, and then they look at another one and they say, oh, this is too complete and confusing, it's not brief enough. There's somewhere in there that the IRB picks on any given study.

But they're supposed to be thinking about that. It would not be new.

MS. BROWN: Absolutely. They think about the level of the language.

MR. CARLY: Yeah.

MS. BROWN: And the technical level of the language. They don't want hype.

MR. CARLY: There's also --

MS. BROWN: Whether they've -- they've never asked me if my people can (inaudible).

MR. CARLY: There's a lot of recent (inaudible) coming out of OHRP and elsewhere that asks investigators to explore ways to confirm understanding. I was reading a couple of articles just recently about ways to do that, different ways of getting people like to say back in their own words what you've just told them kind of thing.

MS. BROWN: There are good ways. I'm just suggesting that since EPA is going to establish an HRSB

-- HSRB?

MS. LINDSAY: Yes, HSRB.

MS. BROWN: That that be really specifically included -- for any study.

MS. LINDSAY: And, you know, Amy, I was going to say, I think you're offering some good practical experience and insight where there are opportunities for improvement. When the HSRB gets up and running, we actually expect that one of the things that will happen is that there's this kind of practical experience that will get more broadly --

MR. CARLY: Best practices guidance.

MS. LINDSAY: -- disseminated. So, it's a good -- I really like your suggestion.

Steve?

MR. KELLNER: A real quick one. With respect to the HSRE, is there a turn-around time by which the review must be given back to the agency?

MR. JORDAN: The proposed regulation does not have a turn-around time. We did ask for public comment on it, recognizing, as somebody said earlier today, that predictability is an important benefit for people who are dealing with the agency.

MR. KELLNER: Thank you.

MS. LINDSAY: Okay. Michael, you're next.

MR. FRY: Thank you very much for your explanation this morning. I think the final rule is going to reflect a lot of the questions here. But you did bring up just the appearance to me of a possible loophole when you were giving your definitions of first, second and third parties and then, in your description of the prohibitions on intentional dosing studies with third parties. When you mentioned that the prohibition applies to regulated third parties and that not all third parties are going to be regulated in this, what classes of third parties are not going to be regulated and how does this

regulation or non-regulation of third parties apply to your acceptance of data from, say, oversees?

MR. JORDAN: Okay. This is -- your question is a replay of the question that Erik Olsen asked and it's been one of the challenges for us to try to communicate clearly about. The prohibition applies to persons who are conducting new studies that they intend to submit to EPA under FIFRA, the pesticide law or the Food, Drug and Cosmetic Act, the provisions that relate to tolerance setting. The reason that we voted that way is because we think that's the extent of our legal authority. We're happy to have people send us comments saying, no, you may actually have a broader legal authority. But we can't prohibit things. We can't reach out and effect people who are beyond our legal authority.

So, that's -- to the extent you call that a loophole, it's not a loophole of our choosing. We believe it's a loophole of Congress' choosing.

Now, that has to do with what investigators are allowed to do with regard to research, according to EPA. We're telling the investigators, don't do this kind of study. Wholly apart from that is what we are telling ourselves we will do when we get the results of completed studies. There is no limitation whatsoever. We apply these ethical standards to all studies that we will be reviewing. That standard is the Common Rule for studies initiated after the effective date of the rule. Does that answer your question?

MR. FRY: Yeah.

MS. LINDSAY: Okay, Dr. Roberts?

DR. ROBERTS: I think I'd like to preface by saying, as a pediatrician, I certainly agree with not intentionally dosing children. But my question deals really with the fact that, in some situations, we have more of an absence of data on children's exposures. And so, my question would be if there's -- in the event of

data -- lack of data on children, but there was a study done on adults, how would EPA then determine exposure limits in children? Would it be the same exposure levels as an adults or would there be some type of additional protective factor since children are physiologically different?

MR. JORDAN: The short answer is that in preparing a risk assessment for the effects of a pesticide on human health, we have a very large database, primarily from animal toxicology studies, that informs our understanding of the potential risks to humans. That database includes testing of animals at different life stages so that we can evaluate whether or not there are differences in susceptibility between the young and the old, or mature adult animals. We also take into account whatever information we might have from accidents and incident reports, but that, I would say, is a less significant factor in understanding and appreciating the

differences and hazards for adults and children. That deals with the hazards side of the risk assessment.

The other piece of the risk assessment has to do with exposure, and there, we have a huge amount of information about sources of exposure that children could have, and the databases that we use captures the differences in exposure attributable to the fact that children have a different surface area to body weight ratio, have a different food consumption to body weight ratio, have different activity patterns that cause them to be in places where pesticides might be used more often or with greater frequency. They engage in behaviors like sucking their fingers that would -- you don't see me doing except toward the end of the day.

(Laughter.)

MS. LINDSAY: Okay. And I guess, Larry, you just couldn't resist the opportunity.

MR. ELWORTH: A quick procedural question. When

comments are made in the PPDC, in order for you to be able to consider them in the rulemaking, they still need to be made in formal comment, is that correct?

MS. LINDSAY: Yes, they need to be submitted to the docket.

MR. ELWORTH: Okay, good, good. Because there were a couple comments made. I'm glad you're considering this rulemaking because I want to make sure people --

MS. LINDSAY: I mean, I -- just to say, obviously, for me, everything that people have said, I hope to incorporate in my thinking and to use as wisely as I'm capable of. But the specific consideration, you have to have it in the docket.

So, Larry's going to put his card down now that he's asked his procedural question. Carolyn, did you have something you wanted to close this out with?

MS. BRICKEY: Yeah, I have a couple of things. First of all, with regard to the exceptions for old

studies, what I was trying to point out is that given the fact that we had a moratorium on the use of old studies for several years, it would be logical and reasonable to have a presumption that those studies would not be used. Yet, the language incorporated in the rule reverses the presumption and there's no one out there who's going to step forward with clear evidence that these studies were fundamentally unethical because there's, in most cases, not enough information to do that. You might look at the surface value or the facts about the study and conclude they were unethical, but they probably wouldn't be fundamentally unethical. I think that probably falls under the shock the court kind of standard.

As to significant deficiencies, a number of these studies were conducted at a time when there was very little substantive rule requirements out there. So, the ones I know about, I can't think of any of them that are going to be rejected under this standard, and that is

a concern that I have.

Secondly, as to the comment that Bill made about the fact that vulnerable populations can be taken into account, I thought that was incredibly important, and I would urge you to incorporate that into the rule, because I think the more those fundamental significant points can be incorporated, the better the standard is going to be and the better the rule is going to be. I realize you can't incorporate everything and I realize that this new board you're creating will probably have a lot of those issues to be addressed at that level. But I believe this is fundamentally important and ought to be part of the rule.

With all due respect to the folks who are experts on the history of these rules, they may have a long and glorious history, but we have some equally bad history in the way human testing has been conducted in the past. So, we have to look at that very carefully and

make sure that what we're doing on the ground is done right.

MS. LINDSAY: Okay, thank you. I think that was a worthy close-out statement and I appreciate you doing that for us.

I want to take just one more minute because I know you're anxious, and I think Jim needs to talk just a little bit about a revised schedule for the rest of the day, but speaking, first of all, just on behalf of myself, I do really want to thank each and every one of you for the questions, the observations, the suggestions that you've made. I know that it will have a very significant impact on my participation in the agency process to develop a final rule. I'm very impressed with the seriousness with which all of you take the topic. It makes me feel good about being a civil servant.

I hope we have been able to do the same sort of service for you in our presentations and our answers as I

think you've done for us. With that, let me turn it over to Jim.

MR. JONES: Thanks, Anne. Thanks, John. Thanks, Bill. I would just like to add I'm not someone who's afraid or shies away from controversy. It's something I do in my job every day. I would like to say that I think that was the most useful dialogue I've seen around this controversial topic in the six years or so that I've been a participant in such a conversation. I want to thank you all for that.

We've had to make some adjustments to the schedule. As I say to my team in both old and new chemicals, it's important to be on time, it's more important to get it right. So, we extended both of the topics this morning because I think it was important to hear what you all had to say and advice to us. So, we did make that adjustment.

What we're going to do is take lunch right now.

If folks could be back at 1:10, and we have shortened the -- to the strategic plan update to just 15 minutes. So, when we get back, Marty Monell is going to give us a 15-minute update on where the agency is on that. And then I understand we may be able to pick up a little time in one of the topics in the afternoon. If not, we will just go over a little bit to make sure we have enough opportunity for all of you to give us some more good advice.

So, I will see you all back here in one hour. Thanks very much.

(Whereupon, a luncheon recess was taken.)

AFTERNOON SESSION

MR. JONES: As I mentioned before, we broke for lunch. We've had to make a couple of adjustments to the agenda. I do very much appreciate the robustness of the dialogue this morning, actually in both of the sessions. We very appreciate it. We really don't mind so much having to maneuver the agenda around to accommodate that.

So, what we're going to do this afternoon is

we're going to start with an abbreviated version of the preview of the EPA strategic plan, which Marty's going to do right now. And then we'll move into the pesticide performance measures discussion. Let me just preface Marty's presentation, the agency's strategic plan is what Marty's going to be talking about, and the agency does create -- it's a revision to an existing strategic plan that's been in place for a number of years. We're getting into the public participation process in the not too distant future, and it just is important for -- what may appear to many to be a bureaucratic exercise, though, for people to be heard.

So, one of our messages around this is simply that it's something worth paying attention to. It isn't just a bureaucratic exercise. It actually is used by the agency in evaluating performance. There is a trickle down effect that's very meaningful to us in the pesticide program and for all the other programs at EPA. So,

realizing that not everybody is here yet, but time's short. We need to get started.

Marty?

MS. MONELL: Okay. As Jim said, this session is going to focus on EPA's strategic plan revisions, which we have just begun to become engaged upon. I thought I would start by laying out what the National Pesticide Program's goal is. This is not a specific goal within the EPA strategic plan. This is our programmatic goal. It's to protect public health and the environment by ensuring pesticides and alternatives are safe and available for a healthy America. Pretty good to capture all of the various kinds of issues and concerns that we have in our program.

GPRA, the Government Performance and Results Act, basically mandated that agencies update their strategic plans every three years. EPA's last revision was in 2003. We are now starting in 2006 on our next

endeavor. Although it's a five-year plan, we do have to revise it and look at it, at least, every three years for possible revisions.

It's very, very fast-paced. By the way, this presentation will be available on our website, so although I'm going to rapidly go through it, if you want to focus in on any particular items, it will be available on the PPDC website.

The important changes of this process and across EPA is the focus on stakeholder involvement. I think the agency learned from its experience in 2003 that it engaged in a limited amount of stakeholder involvement, really reaching out to every possible concerned party to provide us feedback and input into the strategic planning process. We here in the Pesticide Program, I think in particular, we're a little short-changed because our stakeholders in the states and regions aren't necessarily those which were engaged by the rest of the agency in

terms of getting feedback from states and other stakeholders.

There have been goal teams formed and they are led by two co-national program managers, Susie Hazen, our Acting AA, is one of them, and Al McFarland from ORD, the Office of Research and Development, is the other co-lead -- excuse me, it's Jim McFarland, I'm confusing names. Then we have several other offices that are involved, including a regional office as a co-lead, Region VII, who's represented at the PPDC today, is one of the co-leads for this goal.

What you see on your screen now are the five goals for EPA basically laid out by media. Although our goal, Goal 4, has a lot of cross-cutting issues and cross-media involvement. So, for instance, we have the Brownfields Program from OSWER (phonetic) in Goal 4 and the rest of OSWER is in Goal 3. We have a tiny little piece of water activity in Goal 4, as well as OECA and

international activity. So, we're sort of the potpourri of the goals, if you will.

These are the milestones. Again, they'll be on the website if you want to see it, but if you do take a look at it, it is a very aggressive schedule for arriving at these changes and agreeing upon them.

For OPP, we're going to take one objective and we want to focus it on protecting human health in the environment by ensuring that pesticides and alternatives are safe and available for a healthy America. And then we have two sub-objectives under that. One is focused on pre-market or sort of the gateway activities of registration, and then one focused on registered pesticides already in use, and we have several strategic targets under that.

This desire of ours to restructure our piece of the strategic plan really is part of a larger effort to make an alignment -- a better alignment from the agency's

strategic plan to our piece of the agency's strategic plan to our annual planning processes and right down to, as Lois was talking about this morning, to the divisional work plans and the individual employee's work plans. So, we want them all to eventually line up so that they are in accordance with one another.

Along with that, of course, we're attempting to get our budget structure lined up in this format, also, so that we have a -- we have a couple of budget program areas, if you will, that match up with the gateway, the entry to the marketplace types of activities, and then dealing with existing chemicals in another arena.

The field programs, for those of you that don't know, are right now separated out as a separate program, if you will, within OPP's budget, and we really think that this has done a disservice to the entire program. Field programs don't exist in and of themselves. They basically support -- for the most part, they support the

existing old chemicals program, but in many ways, they also support the registration, the gateway activities that we're engaged in.

So, we felt that it was more appropriate to incorporate the field program activities, as appropriate, into the gateway and then the stewardship components under this restructured architecture. We would also, as you see there, we would incorporate all these examples of particular programs within the field programs into those two areas.

This is Goal 4 as it currently is written. My understanding is that the goal teams want to keep the current five-goal structure, so that this Goal 4 will, in fact, stay the same. That's fine. It's general enough that it will -- that it certainly covers all of our activities and it also recognizes the fact that we are unique -- this goal is unique because of all of the cross-media and cross-agency approaches to the work that

we must do.

This breaks it down a little bit more. Now, we're getting down to the objective level. This is the current architecture. We are basically combined with the regulation of toxic chemicals. So, you've got TOSCO and FIFRA combined under this one objective by addressing both chemical organism and pesticide risk. What we propose to do is to pull out the pesticide piece, to have a single objective of, again, protecting the public health in the environment by ensuring pesticides and alternatives are safe and available for a healthy America by being the effective gateway to the market and an effective steward for those already on the market.

We think this really is appropriate to capture what we do that is somewhat different from what the Toxics Program does.

Under that objective, that proposed objective of addressing our Pesticide Program distinctly, we will have

two sub-objectives. The first sub-objective currently talks about through 2008 -- again, this was a five-year plan -- we would be protecting human health and the environment from pesticide use by reducing exposure to the pesticides posing the greatest risk. Now, we're considering the sub-objective to read that -- to acknowledge that we're dealing with registered pesticides already in use and then talk about ensuring their safety and including in that sound science/risk assessment, acknowledging that very significant part of our work in this area, and then also the risk management issues and the field infrastructure that affords the safe use, the international activities of harmonization and so forth and all of the communications and outreach that we're engaged in in the region states and with the tribes.

Under those current sub-objectives, there are -- they call them strategic targets right now where we've labeled it areas emphasized, because I didn't want to

list out all of the strategic targets because, quite frankly, they're not as meaningful as we thought they might be back in 2003. So, basically, we recognized the reregistration, protection of endangered species and threatened species, reassessment of tolerances, reduction in the decision times, reduction of mortality to wildlife, and then address tribal pesticide exposure.

What most of these targets consist of are (inaudible), are outputs, they're the number of decisions you make, they're the number of endangered species that are threatened on -- one of the services lists that we have not endangered them any more than they already were, those kind of targets. That, while meaningful, really didn't do justice to the way our program runs.

So, what we're doing now and what you're going to hear in the next presentation is we've zeroed in on three areas for which we're developing measures and for which the measures will include indicators of whether or

not we're meeting our measures and to arrive at the desired result, which is an outcome, as human health performance, ecological effects performance and then, of course, benefits, the benefits of use and registration of pesticides.

The second sub-objective that I referred to is, again, currently talks basically about ensuring the availability of pesticides, including public health pesticides and antimicrobial products that meet the latest safety standards, sort of a general registration type of sub-objective. What we want to do is, and are proposing, is to change that a bit, change the emphasis a bit to include the sound science risk assessment and risk management activities that are included in the registration activities, which is all part of the pre-market registration work that we do in OPP.

Again, under the registration component, if you will, the current targets include promoting the use of

reduced risk pesticides. That's basically how many acres are being treated with reduced risk pesticides. Well, again, that tends to be output-oriented. It's numbers without telling what the outcome of doing that might be. So, we're doing a lot of work towards addressing outcomes again rather than outputs. Then registration numbers, reduction in registration decision times, number of tolerances again, and then maintaining timeliness of Section 18 decisions, again numbers, numbers of days it takes us to do the Section 18s. Not that that is not important to measure, but what you also need to be covering or caring about is the outcome of reducing those Section 18 times.

So, again, these are the three areas that you're going to be hearing about shortly that we are proposing to focus upon for the strategic targets as indicators of the measures that we're in the process of developing.

Now, the next steps is we have a Coordinating

Committee and we have a Senior Management Steering Committee and we have involved the states and the tribes in the measures development process. As far as the strategic plan is concerned, I'll just back up a little bit and say that while you're being given this very brief, fast, quick overview, there will be opportunities coming up over the winter for public comment, for further discussion of where we're going with the agency's strategic plan, and certainly, we encourage you to become engaged at the appropriate time if you have a strong feeling about where we're headed with the new architecture that we're developing for OPP.

That was really fast, I know, sorry about that. But any questions?

UNIDENTIFIED FEMALE: Are we going to get copies of your --

MS. MONELL: Yeah. I mentioned earlier I'm going to put it up on the PPDC website.

Yes?

UNIDENTIFIED MALE: Marty, I may not have seen it because Rosenberg's head was in the way most of the time, but what did --

UNIDENTIFIED MALE: Is there a reflection?

(Laughter.)

UNIDENTIFIED MALE: Yeah, keep Bob away from the projector, please.

(Laughter.)

UNIDENTIFIED MALE: Pesticide effectiveness. I mean, you can register lots of pesticides. Is that one of the outcomes is does this stuff actually work?

MR. JONES: Well, it's implicitly caught in the benefits, what benefits does it provide? If it doesn't -- if it's not effective, chances are it's not providing many benefits to society or to the user.

UNIDENTIFIED MALE: The benefits you were speaking of were mostly health benefits, weren't they?

MS MONELL: No.

MR. JONES: No, we're thinking of them very broadly.

UNIDENTIFIED MALE: Okay.

MS. MONELL: Actually, the benefits were separated out from health and ecological and the benefits we were contemplating were more of the economic side.

UNIDENTIFIED MALE: Okay. That was the Rosenberg's head portion.

(Laughter.)

MR. JONES: Jennifer?

MS. SASS: Yeah, thank you. I, obviously, came in late -- a couple of us have. But I'm concerned about some of the wording in the objectives because it's very important -- obviously, you understand how important it is, to get the objectives right because that's how you're going to measure the success of your program. So, I'm curious about how you're going to use sound science to

measure the objective of ensuring safe pesticides. There's other things that I just think need a little qualification or detail or thought out. If that's your objective statement, I'm concerned. You can't make pesticides safe. You can use them safely, you can use them safer. You can encourage a safer development, but you can't make something that kills pests safe, and if that's an objective, I'm concerned about the measuring standards. It's important.

MR. JONES: Sure.

MS. MONELL: Um-hum, um-hum.

MR. JONES: I mean, one of the things, I think, we've got to figure out is independent of the agency's participation, getting individuals and groups like you to participate with comments like that, do we want to have some other forum to get your feedback that we can make sure it gets fed into? Because I'm a little bit nervous, based on past practice, that people aren't necessarily

going to avail themselves of the agency's strategic plan public participation process, whereas I do know you will be coming to these meetings and if we did have some kind of focused time, whether it was in a conference call or something, that we probably would get some meaningful feedback. So, I think that's one of the things we've got to struggle with.

MS. MONELL: Well, what the --

MR. JONES: So we can get very specific comments like that, Jennifer, in our --

MS. SASS: Well, one of the reasons why it struck me specifically is because I'm on this NIPTAC (phonetic) interim ad hoc working group on nano materials, which means we exist for a very short time in cyberspace. But one of the things is that the -- it's a multi-stakeholder group. We work really well together and I'm impressed, but one of the things I've learned is that the industry people on the group are not willing or

not particularly amenable to having an objective statement that says our objective is to develop nano materials safely. They've expressed concern that that's a standard that's too difficult to meet.

So, I'm curious about how you guys are going to meet that.

MS. MONELL: I would just note one of the slides that I rapidly proceeded through has the time table and the agency's document is going to be put out for public comment in April, and so, we may be able to pull our piece together and present it at the next PPDC meeting for full discussion before it's too far in cement.

MR. JONES: Or maybe even before then in kind of a conference call. Because I'm not sure, Jennifer, if that's actually going to be the objective statement.

MS. SASS: This is like a draft early thing?

MR. JONES: Um-hum.

MS. MONELL: Oh, yes.

MS. SASS: I was just thinking about it then.

MR. JONES: No, you raise a good point.

MS. SASS: A number of the objective statements go toward facilitating pesticides into the marketplaces. That seems, to me, to be an objective you can obviously achieve. The objectives on the protection side seem to be more difficult to achieve, let's say. And what concerns me overall is that only the objectives that involve facilitating market availability are going to be achievable.

MR. JONES: Okay.

MS. MONELL: Well, we will certainly work on figuring out an appropriate forum to incorporate those kinds of comments. That was very helpful, thank you.

UNIDENTIFIED MALE: I don't want to get into it and I --

MR. JONES: Yeah. (Inaudible).

UNIDENTIFIED MALE: I don't want to get into a

debate over that issue right here. We'll comment on it later. But actually the Food Quality Protection Act does provide that if the EPA requires the testing and the testing has been reviewed by EPA that it is a finding of safety of our products. It is different from the past laws. The Amendments of 1996, in fact, do provide a finding of safety for our products. So, it's not just any more safe use, applicator protection and the others. The products, themselves, after going through the comprehensive review of the Environmental Protection Agency today, under FQPA, when the agency makes its finding, it is making a finding of safety.

MR. JONES: Right. I think what I'm hearing from Jennifer -- and it's one of the -- it's a good segue to this next topic, it's -- as you've heard our vision involves ensuring safe pesticides and available pesticides. How do you measure? How do you measure safe? And if you don't lay out the correct objective for

measuring it, then your ability to evaluate it becomes -- that's largely what this next group, which is going to be talking about indicators and results, is what they're struggling with. How do you create appropriate measures? But I agree with your statement that that is the standard that we're trying to meet and that's the standard that we have in our vision statement, where we want to be.

UNIDENTIFIED MALE: The slide you just showed us gave us a time line for commenting and development, but it indicates a public comment period in the April or so time frame next year.

MS. MONELL: Well, that's for the entire agency strategic plan, correct?

UNIDENTIFIED MALE: Are you planning on a public comment process before we get to that stage for -- specifically for the OPP?

MR. JONES: Well, that's what I'm thinking of. It will sort of somewhat be dependent on when we schedule

this next meeting. We may have to do something in advance of that so that we can accommodate that. But I really -- I think that if we're going to get meaningful feedback out of the stakeholder community, if we don't host some kind of forum, I'm just not sure we're going to get -- the agency is going to get the kind of feedback that it's looking for.

Okay, more to come on that. It's a good segue to the next topic, which is pesticide performance measures, which we, after our last PPDC meeting, began a workgroup which I understand a number of you have participated on. I can't emphasize enough just how important it is for EPA and the Pesticides Program to get this issue right. The increased attention by Congress and by the Office of Management and Budget on federal programs being able to demonstrate results is not seeming to lessen. I think it's just going to continue on.

I, frankly, think it's an appropriate attention,

that we ought to be demonstrating results. I think that we have demonstrated, in this program, high capacity for measuring output, and for many years, that is what the system expected and just when we think we get our arms around outputs, they say, well, that's not good enough, I want outcomes. But actually outcomes is why we're here in the first place. We're here to protect public health, to protect the environment, to ensure that pest control techniques and technologies are available. Now, the people who we report to are saying, well, you need to be able to measure that and it can't just be number of Section 18s, it can't just be number of reregistrations and registrations and tolerance reassessments. You got to get to the outcome. So, we have engaged, in the Pesticides Program, with our colleagues in the regions and with the states, and now, more recently, with our stakeholder community, as captured by the PPDC, in attempting to develop outcome measures, and it is very

difficult.

For those of you who haven't participated in this exercise with us in any of the sub-workgroups, you'll probably come out of this session today understanding just how difficult that can be. So, with that, I'm going to turn it over to Sherry Sterling, who joined the Pesticides Program a number of months ago, expressly with the responsibility of leading our efforts in this effort. Sherry?

MS. STERLING: Good afternoon. I am here on behalf of the workgroup that this group commissioned at the last PPDC meeting. They've asked me to go over and get -- have an overview of this, and also David Widowski (phonetic), who's the Chief of our Economic Analysis Branch will also, at the workgroup's request, will be going through an example of the other benefits.

So, with that, what we're going to talk about today, just very briefly we're going to go through some

information that the workgroup felt is important for you to understand so that you understand how the PPDC's advice will be used. The PPDC workgroup members will talk about their goals for that workgroup. We will give you the overview of the other benefits piece. David will do that. And then, finally, we'll end with some next steps that the workgroup has talked about.

The first thing I want to kind of walk through, and Marty mentioned this just briefly, but I want to go into a little bit more detail about this. The workgroup found it very helpful to understand this in a little bit of depth, so please bear with me with the bureaucracy and the red tape for just a moment.

We have a three-level process here, a three-tiered process. At the bottom, we have the task groups. Those task groups are looking at and trying to develop the measures that Jim was just speaking of, we're trying to develop those measures in very specific task areas,

and they're down at the bottom. ESA being endangered species; of course, water quality; worker safety includes the CNT elements as well as worker protection; food safety, actually this kind of got merged into just a basic human health as we worked through the issues; and also, the last one there, the code -- I'll break the code for you, Strategic Ag Initiative and Pesticide Environmental Stewardship Program is the last grouping and those are voluntary programs.

So, task groups are working on those. The staff are developing output measures and then outcome measures, actually looking towards the things that we do, how do they really matter out in the world. That information is going to the middle tier, which is the Coordinating Committee. David and I are on that Coordinating Committee. I'm the Chair of that with a regional person, and our focus is to come up with mission areas, three mission areas, and we'll go into this -- I'll go through

this one more time, but the three mission areas are protect human health, protect the environment and these other benefits from pesticide use. We're doing those overarching, big picture, mission area measures and we're also taking the task -- the very individualized task measures and we're forming a quilt, if you will, that will show the picture of what the agency -- what OPP is doing and how what we do matters in the world.

These measures aren't just measures to tell a story. That would be great. We do have some -- we've identified some measures that will tell a story. We call those indicators, environmental indicators or health indicators, but indicators. What we're trying to do with this is focus more on management, what can we effect, how effective are we in our program? So, that's why we're calling them performance measures. Make that distinction. They need to work together to tell the full story, but we're focused, in this group, on performance

measures.

What we do, the Coordinating Committee, is they'll send it to our executive level that Marty is the Chair with a Region VII Division Director and numerous Division Directors in the program, so that's our executive level. We'll look at the recommendations, at this quilt that the Coordinating Committee has developed, and they will eventually make recommendations to Jim. That will then go up our chain of command to the system administrator and to the Office of Chief Financial Officer and all that kind of good stuff before it makes its way finally to OMB.

We'll hope that it goes -- we just do a one-shot deal and it goes straight through, it's very linear, boom, boom, boom. But, in fact, we expect that at all stages, there will be lots of -- there will be iterative loops in there, people will come back and ask us, can you develop this better, what does this mean? So, we expect

that this will be iterative.

We're really pressing to keep things moving in this, as far as we have control of it, up to the point where we -- it goes out of OPP, we don't have as much control over it. So, the -- when we talk through the time frame, it gets a little bit sketchy once it goes out beyond OPP.

On the next slide, I just wanted to emphasize again the mission areas. These are the big -- these are really the three areas that we're working on based on our program goal. So, protect human health, protect the environment, and this last category is a little bit hard to understand, so let me spend a moment on that. By other benefits, we put other in there because we think protecting human health and protecting the environment are, indeed, benefits from the program. These are the additional benefits, and this is something that's important to understand.

When David gives his example of benefits, you'll be thinking, but what about the human health elements? Those benefits are captured in another mission area. So, this will be just those in-between sorts of things and the -- and more -- and some of the economic benefits. So, I want you to keep that in mind as we go through this with -- as David goes through that.

So, we go to the task areas. These relate in most of our part to the field programs that we have now. But they really support the program as a whole. So, I would say that as we're looking at this -- at the three mission areas, the first two, water quality and endangered species, while they will have some impact on protecting human health and the other benefits, those primarily are focused on protect the environment mission area.

The last two, worker safety and this food safety/aggregate risk, while they will have -- those,

too, can have impacts on other benefits and protecting the environment; in fact, those two really are strongly in support of the human health area. So, that -- when we come together and pull everything together, that's pretty much how things will sort out, working together.

So, we go to the schedule, just -- we are -- and we really have a need to be moving forward. So, our goal is to have measures that the Steering Committee has reviewed during November and we turn over to the Office Director to -- for his final recommendations/decision process.

Does that mean that you have lost your chance? Absolutely not, because what's very important is the very last bullet on this page and that is that we are going to continue -- the year of -- throughout 2006 -- I have 2005 there -- but 2006, if we do it this way, is the year of tweaking. We'll be tweaking our performance measures throughout this time. We have some other -- we really

do, though, have to kick that off, though, in 2006, in January, we need to begin implementation of those measures that are ready and not all the measures that you'll see today will be ready in January 2006. I apologize for the errors on here -- on the date there. I was brain dead last night when I did this.

Anyway, there -- those that are ready to go, we want to implement them. Those that aren't quite ready to go, we want to keep working on them because sometimes it takes more than just a couple of months to develop a measure and, you know, all the supporting information and the baseline information that you need.

What the group will be getting, I do --

(End of Tape 2, Side B)

MS. STERLING: -- so that it's not completely -- it's still draft. So, it's not completely finished up. We're doing that because we would value having input

early on and you'll see today by the example that we think that we can be partners in this. So, with that, Steve, or workgroup members, if there's anything else you want to add?

STEVE: Yeah, I'll add a few things. The first thing I'll add is, never be late for a meeting. You got to sign things. Although, actually, this time, I was an hour-and-a-half late, I missed half the meeting yesterday. So, I thought, hey, I'm going to be able to avoid it.

UNIDENTIFIED FEMALE: You thought you were safe.

STEVE: Yeah, I thought I was safe. I don't know anything, right? But, of course, Larry volunteered and then conveniently had to be gone this afternoon. So, I will stand in.

One thing I ought to do quickly is go through the members, Sherry, does that make sense, so you have a clue who's on this committee, which will give you a sense

of why Sherry probably felt brain dead last night. I'm on the committee. Dan Botts, I think, is on the committee. I think he was on one phone call, but I don't remember him actually saying anything. Carolyn Brickey is sort of a virtual member, in absentia. Amy Brown, Larry Elworth, Caroline Kennedy, Jimmy Roberts, Bob Rosenberg, John Schell, Julie Spagnoli, Michael Fry, Jim Burdette from North Carolina. What's Jim's background? I'm not sure what his role is.

MS. STERLING: Jim is a state representative.

STEVE: Okay. Izzy Sidiqi (phonetic) representing Ray McAllister, representing Jay Vroom, who sometimes represents himself.

(Laughter.)

STEVE: And Nancy Golden. Did I miss anybody?

MS. STERLING: Is Tom Byden --

STEVE: Oh, Tom Byden, that's right.

MS. STERLING: And Caroline Kennedy.

STEVE: I said her.

MS. STERLING: I'm sorry.

STEVE: So, you can imagine that it's a rather difficult group to work with and Sherry certainly has her challenges.

We believe our primary objective is to review and comment on the process for developing the performance measures and the substance of the performance measures as well. This is a really big, big elephant to get your arms around. We've all been touching various parts of it, and so, we're not quite sure how we're going to proceed, particularly --

UNIDENTIFIED FEMALE: The back part of the elephant?

STEVE: Yeah, that would be Larry. The time frame is very tight and I -- you know, obviously, they're going to be presenting to the Steering Committee next month. So, we're trying to get rolling fairly quickly to

get into substance, which David will give you some sense of in the upcoming discussion. Our point of contact then is that Coordinating Committee, as Sherry said, but we do think that we're going to have to probably, at various points, reach down to the workgroups, the individual workgroups, to get more detail, to get better understanding on specific issues.

We're looking at a number of things. The validity of the measure, does it make sense? The meaningfulness of the measure, are you actually going to accomplish anything with this? The value of the measure to EPA, to OMB, to stakeholders, to whomever; the sufficiency of the data; and any additional measures that may be necessary. Sort of to discuss the issue of sufficiency of data, one of the things that I think we are very concerned about is the issue of cost, that there is a direct correlation between the value of the data, the accuracy of the data, the depth of the data and the

cost of getting that data. Relatively little of the data that EPA needs on outcomes is readily available.

So, those are the kinds of things that we really need to think through and whether it makes a lot of sense -- now, it's not our choice, it's OMB's choice in many cases, but whether it makes a lot of sense to be spending tremendous amounts of dollars on seeking out data measurements that take away from the job at hand. That was a little editorial, though. I'm not sure the rest of the group agrees with that.

I mentioned that we feel our role is to look at substance, but in that process, we will also be looking at the process part. You know, as we go through, we think we might have some thoughts about process. An additional point is that we very much appreciate the issues that Jim and his staff face in this whole process. It is a bit overwhelming, but there is a lot of great information out there. If we can get OMB to understand

sort of the dynamics of what we're trying to accomplish, I think it will go a long way. But we'll have to see how that process continues.

I think that's it. Are there any questions? Beth?

DR. CARROLL: Yeah, Tom and I passed in the air, so I haven't had an opportunity to talk to him. But who makes up the task groups? Is that EPA individuals?

MS. STERLING: Yes, it's EPA staff, plus each of the task groups has a state representative, at least one state representative on that group, and also a tribal representative. So, it's pretty much just folks within our internal circle, if you will.

STEVE: Yes. Julie?

MS. SPAGNOLI: I think another point that was brought up in the discussion, too, is to make sure that we're looking broadly at the whole program, at all of OPP, that we don't focus purely on measures that are

measuring conventional chemicals for crop uses. Because it seemed that when we got into the discussions, that there was sort of a very focused and that we want to make sure we're looking at measures in other areas to kind of cover the program as well.

STEVE: Would that be antimicrobials as well?

MS. SPAGNOLI: Antimicrobials.

STEVE: Okay, changing focus.

(Laughter.)

STEVE: Bob?

BOB: And other non-ag uses.

(Laughter.)

STEVE: See Sherry's challenge.

BOB: Exactly. And I think, Steve, you sort of covered it. One of the things that struck me was we looked at a bunch of possible measures that David presented to us, and some of them lent themselves to some fairly easy measurement and some of them didn't, and the

concern I have is that if you only measure those outcomes for which there is readily available data and ignore the ones for which there isn't data, then you get a very distorted picture and it's, I mean, I think, worth asking whether or not there are funds available or ways available to collect the data for which those easily, you know, or readily available data sets are not currently available, or else maybe the whole exercise is somewhat distorted.

MR. JONES: One of the things that I keep reinforcing with our team is that it isn't necessary that for every measure you can actually measure it. You may -- there may be -- the best ways to evaluate the program may be in areas where you can't right now measure it. But maybe in five years or in ten years you can. But that being said, it's also important to have a number of measures that can be evaluated. We can't just sort of wrestle -- well, here's the 10 measures that would

optimally evaluate our program, none of which can be -- we have data to evaluate us against. At the same time, I really don't want to just have, as you were describing, well, here are 10 things we can do that we know we can do, but they give you an incomplete picture of the effectiveness or lack thereof of this program.

So, I'm comfortable with having a mix of the two, and that being said, even the ones that we're not -- you can't measure, we're not necessarily going to be asking for funds to be able to measure them, the theory being that if you have out there in the public domain, here's how we'd like to evaluate this program. Over time, people who are into measurement begin to measure those things.

STEVE: Jennifer?

MS. SASS: I don't know, but are we going to discuss some examples of the measurements at this point?

STEVE: Yes.

MS. SASS: Okay.

STEVE: Okay. David, good lead-in.

MR. WIDOWSKI: Thank you and thank you very much for those introductory comments from the working group. Although, Steve, you said that your group can be difficult to work with, and I'm not going to comment on that, I will say that I am very appreciative of the insights, the comments and sometimes the appropriate criticisms that were raised yesterday on the presentation that we made to the group. So, I think however you're working together, you represent a wide range of expertise and it's been very helpful so far, and I'm sure as we present other measures on human health and the environment, that same expertise will prove very valuable.

As Sherry said, I'm going to talk today about eight specific measures that we'll give you a chance to kick around and chew on. I'm going to point back to the

objective that Marty mentioned or pointed out in the strategic plan with respect to our mandate, to ensure that pesticides and the alternatives are safe and available for a health America. I'm going to focus -- and this area of measures focuses on availability and we've decided to take a fairly economic approach to the benefits or the importance of availability of pesticides.

So, in order to take this -- what is a pretty broad portion of our mission landscape, the other benefits, and connect that to a set of performance measures, as task group, as part of our process, identified six goals that would allow us then to translate our strategic mission statement into a set of potential measures that have some concrete validity and the other aspects of performance measures, as Steve mentioned.

I'd like just to run through them very quickly. We identified improving and maintaining user

profitability as an important goal. The second was maintaining or improving trade opportunities. The third is lowering expenditures of remediating -- for remediating pesticides in the environment. The fourth is enhancing and/or stabilizing the food supply. The fifth is protecting property and the last one is protecting public health. And the challenge for the group then is to translate these goals into performance measures, that as Sherry said, reflect not -- aren't just an indicator of the environment, but reflect what we can do and things that we can change as a regulatory or as a government program and satisfy the importance of being measurable, being replicable and are based on data that we can collect periodically that allow us to assess our progress or our performance over time.

So, that said, I'm going to jump into these eight measures and these eight measures are on three different slides, and each one of those slides represent

a different tier of the data availability, the cost question, how much data are out there right now that we could measure, what are going to be harder for us to get and what kind of measures really would depend on a new set of data collection, either by the government or by the public in order to support our evaluation of our performance.

So, the first measures are kind of in the low-hanging fruit category, and these are two measures that are both associated with improving or maintaining user profitability. The first one is a measure that's proposed to cover a portion of our registration program. It doesn't cover the entire registration program, and one of the reasons we focused on the Section 18 program is that it is something that we evaluate on an annual basis in the Biological and Economic Analysis Division where I'm the Chief of the Economic Analysis Branch. On an annual basis, we evaluate a number of Section 18s with

respect to the potential economic loss that's avoided through the potential granting of a Section 18.

So, one of the attractions of this measure and each one of these measures, I've listed some attractions or some pros and some challenges or limitations. One of the advantages of this is that we have a well-developed methodology for measuring loss. We do it on a regular basis and a Section 18 program does require that states submit data that allow us to make this evaluation whenever a Section 18 is submitted to the agency. So, we have data that will allow us to make that measure, and generally, people find the measure to be the avoided loss or the value of the avoided loss as a concrete and understandable measure.

One of the challenges or limitations of this kind of measure is that it doesn't fully measure the benefits of registration. So, that raises the question, how much of our program and how much of the benefits of

availability are we actually describing with this kind of a measure? And that's one of the things that we would need to consider as we contemplate moving forward with potentially adopting this measure.

One of the other factors, just in kind of a process or internal issue is that the Biological and Economic Analysis Division sees a portion of the Section 18s that are submitted annually. So, we would need to do some additional work to develop mechanisms and models for estimating the overall value of the avoided crop loss from all the Section 18s that are submitted to the agency.

The second measure is what was described as the benefits of our generic registration or me-too program. This is intended to measure the benefits to pesticide users of having generic pesticide products available for use and the potential savings and expenditures that would result from the registration of me-toos or generic

products.

The advantage -- and what we did is we focused actually, and that's one of the points that Julie raised, is we had originally focused on looking at agricultural uses, and one of the reasons is listed in the first advantage or the first pro, and that's that we have data readily available for expenditures on different kinds of products among agricultural uses. We don't have at our disposal a huge amount of data for the antimicrobial uses, but that's obviously something that's a point of discussion that we can talk more about.

The other thing is that the advantage of this measure, it's really intuitive. It's how much does a user spend on pesticides or pesticide products? The limitation -- one of the limitations of this measure is that pesticide expenditures tend to be a fairly small proportion of agricultural product expenditures, and it does, again, focus on a limited aspect of our program.

The question that we'd have to evaluate is to what degree this captures an important part of our program in deciding whether or not we want to move forward with that measure?

So, those are the first two measures for which we've got data kind of at hand that we could easily access.

As we move into the next tier, I call this a group of measures that potentially require substantial data collection. These are -- they're a set of three -- these address two of our goals. One is maintaining or improving trade opportunities and the last two have to do with lowering expenditures for remediating pesticides in the environment.

The first measure, looking at measures for the trade opportunities that arise from our regulatory program kind of covers two different parts of that landscape. One has to do with phyto-sanitary assurance

and minimizing the adulterated commodity that could potentially be rejected for export across state or international boundaries, and the other area has to do with the value of our harmonization system for tolerances that allow us to export commodities internationally.

One is we might be measuring our work with registering or maintaining availability of pesticides that limit or prevent adulteration of commodities and, therefore, could be facilitated in international trade in the various commodities and the important economic value of that trade. And the other one is kind of the flip side of that, it's listed as a harmonization.

The advantage of this is, obviously, that trade is a very important economic activity. One of the challenges, with looking at this measure, is the sometime difficulty in linking our program activities to international trade and to what degree the volume of trade is related to pesticide registration or the

registration activities and to what degree the volume of trade is subject to other economic factors. And so, that presents a methodological and data challenge for us in potentially contemplating implementing this measure, and collecting those data could be tough as well. So, those are a couple of challenges of that potentially important measure.

The next two measures, as I said, have to do with our goal of expenditures for remediating pesticides in the environment. The first one is a description of solid waste remediation. In this case, we're thinking primarily about pesticide containers and the programs that we have, they're voluntary programs that exist for recycling pesticide containers and the grant program that we provide for clean sweep activities for eliminating pesticides and pesticide containers in local programs.

One of the pros of this measure or advantages is that there are some data out there that track the amount

of solid waste that's collected through these voluntary programs, and it's -- and the -- and I list it as an advantage, but it's actually something that you could look at both ways. It's an important -- some folks will say it's an important part of our waste stream monitoring and some folks would say, when you look at the total volume of solid waste in the United States, pesticide containers represent a pretty small proportion of that. And so, the questions that are -- that's a point of discussion and debate as we consider or contemplate going forward with this particular performance measure.

One of the limitations on this measure is the expense for collecting data and how those expenses are borne that would allow us to continually collect information on pesticide container recycling. Particularly for some of our clean sweep activities, there's been one or two studies on looking at the volume of waste that was collected, but those were pretty

intensive and expensive studies, and it comes back to that question that Steve raised, how much are you willing -- do you want to spend on performance measures and what is it telling you?

As I said, both a pro and a con would be, depending on where you sit, is the importance of pesticide containers in solid waste and to what degree it represents an important proportion of solid waste.

The third measure in this tier of requiring substantial data collection is also associated with remediating pesticides in the environment and that focuses on the -- I wrote down cost changes, but the working group has very kindly suggested that we have cost because we're talking about economics and in a fairly narrow sense, in this particular set of measures, we're going to substitute expenditures. So, I'm going to rename this expenditure Changes for Remediating Pesticides in Drinking Water.

The advantage of this potential measure -- and in this case, we would be looking at or possibly looking at what it costs community water systems to implement or develop mechanisms and tools for removing and/or remediating pesticides in drinking water and how those potential expenditures change over time, both for capital expenditure and ongoing variable costs.

The advantage of this measure is that it addresses an important part of our program which is drinking water. The challenge for this is that collecting systematic data from a large number of community water systems can be a challenge in and of itself, but then that raises one of the questions that we -- the working group raised yesterday, which was how do you know when you're looking at expenditure for a particular remediation system in a particular system is designed to be used when the water is turbid, when there are suspended particulate matters, and this same kind of

system may be also useful for removing a pesticide? How do you portion those expenditures to that portion which is attributable to pesticides? So, there's potentially some methodological and data collection issues associated with that measure.

Now, that's the second tier of measures, as I mentioned. Then we go into -- we occasionally call these the pie-in-the-sky measures, but I think I'll be a little more concrete and those are the ones that maybe require new methods and new data and could be potentially costly. Yesterday, in our discussion, we had some very good -- oh, I should say I appreciate the insights that the working group members provided in trying to help us conceptualize what kind of data really are necessary where we may not have data readily available, but it's important to measure a particular aspect of our program. So, this gets into that area where -- and I should say across all these, we appreciate and we value the input of

the PPDC and this is an area where we can really use some of your expertise in helping guide us how we might move forward with these measures.

The first measure has to do with maintaining -- our goal of enhancing or stabilizing the food supply and that's the characteristic of resistance management, because the pests do -- or the spectrum and the distribution of pests do change over time, resistance management is an important part of our program, both in the kind of products that are available through the registration and the reregistration activities.

The obvious advantage of this is it's important for our program, but one of the big challenges, how do you define or measure resistance? One can look at it as defining a specific set of pests on a pest/use/site combination and then trying to track the biology of that particular pest over time. But that becomes a very expensive proposition. One can also look at kind of the

macro level, how many different products or how often do you have to change products for managing a particular pest? But that has its own limitations, too, and interpretation.

So, we see some big challenges in implementing this measure. At the same time, we recognize that it's potentially capturing important benefit from one of our key mission areas. The second measure on this list is -- has to do with our goal of protecting property and this is one that's described as expenditures on structural best control and damage. I had initially been thinking about this in terms of termite control, but I was reminded yesterday that toxic mold remediation is also an important part of our structural pest control and structural damage environment that we have to be concerned about.

The advantage of this measure is it's another important economic activity, an important part of our

mission area. The challenge associated with this measure is where do you get data on this measure? There's a couple of ways that we -- and Bob mentioned a couple yesterday, that there were a couple of ways to look at this. One, you could look at the value of the wood that's been destroyed on an annual basis and looking at the kind of expenditure on replacing that. You can also look at the changing expenditures associated with your structural protection activities. In both of those cases we were challenged, in our task group, in trying to identify sources of these data that meet the requirements for developing an appropriate, valid, replicable performance measure. But it's an area where we would welcome input from the PPDC.

And then the last measure is associated with our goal of protecting public health. This is probably one of our most challenging measures that we thought was important to include in our set of potential measures,

but we really kind of hit a wall in what kind of sources we would have for collecting data to help us evaluate this particular measure.

The advantage of this measure, obviously, is that protecting public health is an important part of our mission. The challenge is, how do you define the pesticide contribution for disease and disease transmission across vectors, across human beings and different kinds of environments, and how do you portion that to the things that we can do, getting back to what Sherry mentioned, as a performance measure. And then how would you go collect data on a systematic basis that would allow us to have kind of a level or a baseline from year to year or whatever period you're measuring across, whether it's year to year or every three years, every four years, or every decade?

So, in a quick nutshell, those are the kind of measures that we've developed for contemplation and

consideration. These are the ones that we presented yesterday to the working group and now I guess I will open up to the entire committee to start kicking around and providing some insights into helping us understand our measures. Thank you.

UNIDENTIFIED MALE: Well, if I can add, one of the frustrating parts of this, as you can probably tell from looking at what David presented, is we're sort of back to an elephant analogy. We're ignoring the elephant in the room, which is the giant bulk of registrations of compounds that actually mitigate pests. So, we're looking at Section 18s and we're looking at me-toos and, you know, all the little extra stuff because those things have measures.

But the real effect of benefits is actually having effective compounds available in a safe manner, you know, to be managed in a safe manner. That's what EPA does at least from a benefit standpoint. So, that's

a little frustrating.

I think it's particularly important the fact that, legislatively, EPA is required to get rid of the bad actors. That's what FQPA was all about. And so, what they're doing is replacing the bad actors with newer, better compounds in -- of course, with their industry partners.

But it -- this is a real value that I -- you know, I'm not quite sure how to get a handle on the fact that we actually have good replacement compounds available to us that are safer and better and that sort of thing. So, that's a frustration that I think when we look for readily available measures, we don't get the real effect of what EPA does.

MR. WIDOWSKI: I'm just going to go right around the horn here. So, Julie?

MS. SPAGNOLI: You know, again, looking at it from a public health standpoint, I think we don't need to

try to limit the program's contribution and just would say how much do we reduce illness? I think when you're looking at -- I mean, getting away a little bit from vector borne illnesses into emerging pathogens. I don't think anyone would deny there's a benefit -- whether you even have to measure that benefit if you have something to kill the, you know, avian flu virus.

So, I think -- but how do we -- the performance measures, how do we get to that product? How do we assure that that's -- we have a safe and effective product for that use? So, I think there may be a different way at looking at what is the program's performance measure and getting from Point A to Point B instead of saying what's the benefit once we get to the Point B, because the benefit, once we get to Point B, is fairly evident. So, I think it may be just another way of looking at what performance are we trying to measure?

MR. WIDOWSKI: Carolyn.

MS. BRICKEY: Yeah, it strikes me from what Steve was saying and what I was thinking already is that we are kind of nibbling around the edges a little bit and maybe we're looking at it backwards, I'm not sure. But it sort of seems to me like we need a Jimmy Stewart model, you know. Remember that movie where he imagined the world if he weren't there. I think probably just about every agency in government has that same issue. You know, what would the world be like if you didn't exist?

So, I'm not a modeler, I don't know how to do that. But, you know, it seems to me that's what you really need. You need to make some reasonable description of what would happen if you didn't have a program that did what you do. I mean, there's no more -- in just looking at these individual measures, you know, for example, cost related to remediating pesticides in water. Well, you're remediating pesticides in food to

the same extent or more. So, you know, nothing strikes me particularly singular about these individual items. They're not invalid, but they're not singular. There's others that are just as important and you could spend a lot of time spinning your wheels coming up with 14 more of those, but I'm not sure you'd be any closer to figuring out how to collect data to show what they are.

So, Jimmy Stewart.

(Laughter.)

UNIDENTIFIED MALE: I just heard a bell, another angel got its wings.

UNIDENTIFIED MALE: That would certainly be a full employment act for all the economists that I (inaudible).

UNIDENTIFIED MALE: Just one thing for the working group, even the virtual working group member here to my left, to keep in mind is that not all pesticides, obviously, mitigate pests. You know, we have -- there's

a large group of pesticides which are plant growth regulators, for example, and actually they're easier to measure because you can measure yield increases or quality -- quality is hard sometimes, but you can certainly measure yield increases and get a better understanding. So, I'd like to remind everyone to put that into the equation, too. That it's not just killing things.

MR. WIDOWSKI: Beth?

DR. CARROLL: Well, I kind of -- I agree with Carolyn. It does look like it's nibbling around the edges. But the other thing that strikes me about it -- and I'll pass all this along to Tom who is serving on your committee. It strikes me that a lot of these overlap and I think getting at the overlap is going to be a little bit difficult. For example, if you're looking at incidence and cost of vector borne illnesses, are you going to look at that from the standpoint of water

quality as well? You know, there's just a lot of things that look like they do overlap.

I'll just mention, too, as far as trade opportunities, industry has data, you know, on what goes where. I mean, we kind of know where -- if we have a product that goes on an orange, for example, we kind of know where that orange is going if it's in a certain state. We kind of know what's coming in from other countries. So, there is data out there that could be helpful to you. If you ask us for it, I'm sure we'd be able to figure out some way to make it available to you.

Then I would also suggest from the trade opportunities portion and also resistance management, the scientific societies have some of that information and I think we may want to take a step back and see if Leonard Geonesi (phonetic) couldn't participate in some of these activities because he has an awful lot of this data already collected.

MR. WIDOWSKI: Thanks. Allen?

ALLEN: I think one outcome measure that the agency could consider would be a measurement of concentration of pesticide residues or metabolites of pesticides such as is being done in the National Exposure report. So, partnering with the Centers for Disease Control and expressing support for that program and expansion of it, I think you can consider if a concentration of a residue goes down in the average American, that that would be likely to be a health benefit. I think --

UNIDENTIFIED MALE: Allen, if I could just quickly comment on that over here?

ALLEN: Sure.

UNIDENTIFIED MALE: That's actually sort of the next thing we're going to look at. This other benefits part was really like --

UNIDENTIFIED FEMALE: Besides human health and

the environment. What (inaudible).

UNIDENTIFIED MALE: Right. What do pesticides do? Well, they kill insects and grow plants. There's a whole section -- the much larger section is the human health benefits portion that presumably we're going to go over next. That's the next burden.

UNIDENTIFIED FEMALE: So, basically, this benefit --

UNIDENTIFIED FEMALE: Other benefits is other things besides protect human health and protect the environment.

UNIDENTIFIED MALE: Right. This is --

UNIDENTIFIED FEMALE: This is other benefits.

UNIDENTIFIED MALE: There are three goals or three issues.

UNIDENTIFIED FEMALE: Right, protecting human health, protecting the environment.

UNIDENTIFIED MALE: This is the easy one.

(Laughter.)

UNIDENTIFIED MALE: Can I just add a little bit to that? That was one of the things I was going to say because we talked a lot about nibbling around the edges and overlapping, and we felt the same way yesterday. So, when we decided we were going to do human health next, one of the issues behind that is that when you look at the last one, vector born illness, well, that also relates. So, we were trying to make the point that when we do the human health, we really need to try to wrap all these things together.

UNIDENTIFIED MALE: Just one final quick point on that. There's also a need for support for the National Children's Study, which is envisioned as being a longitudinal study starting with preconception or conception to age 21 or so. That's a program that's struggling to get off the ground and could possibly be integrated into the agency's mission as well.

MR. JONES: Thanks. And when we do get to the workgroup on the human health side, you'll see that both of those are being explored by the task group. Thanks.

Jennifer? All right, thanks.

MS. SASS: Well, the advantage of going last is I have a lot less to say.

UNIDENTIFIED MALE: You're not last.

(Laughter.)

MS. SASS: Oh, right, we're going around again. So, it's possible that what I'm going to say is in the next section, in which case, I'd like to say that I think there might be some tactical communication problem with your designations of your titles. That actually -- my concern goes back to my statement about setting your goals very carefully, because these goals were defined by you as meeting the benefits of pesticides on -- and human health issues. But I don't see these as the human health issues, I see them as important and I think they've been

identified well, but I see them as covering the -- you know, the pesticides are good for your part of the equation and that's important and that's legitimate.

But there's another part and I want to second what Steve said because it was exactly what I wanted to say, which is and there's a whole initiative by EPA to encourage reduced risk alternatives and there's no way of asking -- the questions here are all, you know, how -- what would life look like with or without Chemical A on tomatoes or something or whatever? I want to ask the question, what would life look like -- what's the cost and benefit of Chemical A and how could you get the same benefit to your tomato, but get an increased benefit to your health or water or avian species if you move from Chemical A to Chemical A minus one? That question isn't in here. Does that make sense?

UNIDENTIFIED MALE: That's right. Again, today we're just looking at the benefits piece of it. We're

not going to be doing anything --

MS. SASS: Well, that would be a really important benefit. We might have a communication --

UNIDENTIFIED MALE: (Inaudible).

UNIDENTIFIED MALE: We would --

UNIDENTIFIED MALE: Because there's also protect the environment as the third mission.

UNIDENTIFIED MALE: We would capture that, Jennifer, in the environment or the human health side, and in theory, you would have good outcome measures for all three and then every five years when you looked at how you were doing, you would always show, if you were doing your job right, that benefits stayed high and got higher, human health got better, the environment got better.

MS. SASS: Right.

UNIDENTIFIED MALE: If you saw benefits going up but the environment going down, you'd go, whoa, whoa,

whoa, we can't be doing this right if that's what we're doing, or in converse, you saw human health increasing or -- human health decreasing, there was more sickness associated with this, you'd stand back and you'd go, we're obviously not implementing this program very well. So, we do syntactically. It is a syntactic --

MS. SASS: So, what are you calling this section that we've just seen?

UNIDENTIFIED MALE: The benefits.

UNIDENTIFIED MALE: Other benefits.

UNIDENTIFIED FEMALE: Other benefits.

MS. SASS: These eight points are called other benefits?

MS. STERLING: Other benefits because if you'll remember, I said, we see that protect human health and protect the environment are benefits, too. We have benefits wrapped into those. These are the benefits other than those that are direct to -- directly related

to those other two areas.

MS. SASS: Okay, I think these are important, but one-sided then. I think it needs to capture the other side. So, I'll wait for the whole discussion, but I also think when presenting this to people, we need to be very careful about how we all -- we all conceive benefits differently.

UNIDENTIFIED MALE: Sure, absolutely.

MS. SASS: And I think we just need clear communication and titles.

UNIDENTIFIED FEMALE: These are the benefits.

UNIDENTIFIED MALE: I was worried yesterday in the presentation that the costs -- the environmental costs, the human health costs are all in different sections than the benefits. And to derive a real meaningful cost benefit analysis, you have to address them together. So, you know, the cost of protecting a crop, you have to factor in spray drift, the effects on

asthma of children. You have to look at run-off, water quality, the expense of the municipalities in having to monitor their water and getting rid of pesticides in their water. All of these things are in the environmental section and I'm sure there are going to be some benefits in the environmental section, as well as costs. But I think you really have to address the costs along with the benefits in each of these performance measures.

UNIDENTIFIED FEMALE: I second that. It's difficult to think about it in this way.

UNIDENTIFIED MALE: Well, can I respond to that? I had sort of the same question, but maybe from a different angle, and that is, if we were all still using DDT because it's a wonderful life and EPA isn't here, the costs would be tremendous.

UNIDENTIFIED FEMALE: What do you call the costs?

UNIDENTIFIED MALE: The health and environmental costs. But it would be a great product, the benefits -- you know, the resistance problems might be a bit of a problem, but, you know, it was a good product.

(Laughter.)

UNIDENTIFIED MALE: But the point is, what we do is we remove those from the system and we try to maintain the benefits approximately the same and then we keep ratcheting up the health and environmental values, and that's what Jim was trying to get to. So, we can't say that every compound is perfectly clean. We don't have that compound yet that has absolutely no environmental or health effects. Hopefully, we will someday. But what we do is keep mitigating those effects.

UNIDENTIFIED MALE: Just a few points. It's a wonderful life because EPA is here.

(Laughter.)

UNIDENTIFIED MALE: I want to make that point.

I can't imagine it not being here. It's a wonderful life because we're here. But the -- analytically, every individual action has every one of these elements and they're all integrated. Every individual action that we take, of the 2,000 we took last year, has some element of economic benefits, human health and environmental. What we're trying to get at is how you look at the entire program, not any specific action, but the entire program, what are the results as it relates to the environment, what are the results as it relates to human health? Are they getting better or are they getting worse? And what are the results to aggregate societal benefits other than human health and the environment?

So, I can understand how you can, on an individual basis, look at them all together, and that's actually the appropriate way to do it and the statute makes you do it that way. But when you're looking at the program in an aggregate, I think it actually makes a

great deal of analytical sense to look at them separately. Is the environment getting better over time, is it getting worse? Is human health getting better over time, is it getting worse? Are societal benefits getting higher over time or are they getting lower? So, I think that that -- I hear what you're saying, but I think the analytical framework that we are bringing to that separation makes sense in an aggregate.

UNIDENTIFIED FEMALE: And to think, you know, something like resistance management, why that has to be part of the -- you know, we struggled with it trying to figure out a way to measure it. But you can have -- you know, if you find this chemical -- Chemical A is the safest chemical of all and we don't really need anything else from a safety standpoint, let's only use Chemical A and really soon Chemical A doesn't work any more. So, I think that's why -- you know, you're saying, we really need, not only for food issues, but even for public

health and for other, you know, that resistance management needs to be something we somehow have to get our hands around as a way to measure, because if we don't factor that into the whole picture, we're going to end up, in the long run, not being as successful.

UNIDENTIFIED MALE: Ray?

RAY: Well, most of the points I've thought of have been covered. Understanding what other means and the fact that these -- the two preceding mission areas are going to be discussed subsequent to this meeting is helpful. It's important to -- that the users of pesticides go through this kind of cost benefit analysis every time they purchase a product and decide to use it. And they get very quantitative in their measurements and maybe we can learn something from the way they make their decisions in analyzing these costs and benefits. We also need to keep in mind the non-essential clause in tempering our discussion of when a benefit means you do

use a product or are unable to use a product.

UNIDENTIFIED MALE: Bob?

BOB: Yeah, I was going to give Ray a plug here and then he didn't take advantage of it, but I know that somebody mentioned Leonard Geonesi and I know Croplife Foundation just came out with a report on fungicides and the benefits, and I think that's a pretty important database.

I wanted to mention about the Section 18 economic loss avoidance because IR-4 is like any other government program, we're always looking for measurement performance standards, and we always do and have done like the agency, the number of clearances and registrations. But what we started to do, in cooperation with the agency, is looking at the Section 18 economic loss avoidance data of petitions or Section 18s that were supported by IR-4 data, and we've got a database now from 1998 through 2004 and we're going to continue it. It

basically shows a $10 billion economic loss avoidance. We have this database by state crop and active ingredient and so on. So -- and certainly, Jim, you know, that's available.

So, I would say, you know, that's one measure, but then we keep -- one of the other things we keep asking is, well, what is the adoption rate? I think California captures most of any state, you know, the products that are being used. Unfortunately, other states don't capture that. They're also economic data services that you have to buy the data and I think the agency has some access to that information.

I wanted to comment one thing on the trade harmonization, as an opportunity, I would tend to argue that that could be a barrier. In the NAFTA context, it may be true, but a lot of the commodity groups we're working with are saying that because IR-4 and the EPA have been so up front in the global market of registering

a lot of new products, these products are not registered in other countries and there are no MRLs or tolerances in those countries. So, we're running into a number of issues where growers that grow products here and export to countries where MRLs are not established cannot use these products if they're going to export their crops. So, I'd be very -- there's a downside to this international harmonization and I would say it's very serious right now.

UNIDENTIFIED MALE: Bob, I would just possibly tweak your last statement. There's a downside to registering so many things so quickly. The upside would be international harmonization, so that everybody else is moving so fast.

UNIDENTIFIED MALE: That's right. It's certainly not a downside.

UNIDENTIFIED MALE: Okay.

UNIDENTIFIED MALE: We're just so good at doing

this.

UNIDENTIFIED MALE: Bob Rosenberg and Gary?

MR. ROSENBERG: Well, I mean, just a few quick comments. I'm not even sure what the point of them is, but one of them is I'm just like --

UNIDENTIFIED FEMALE: He's going to say it anyway.

MR. ROSENBERG: You knew I would. It's just the difficulty of measuring the OPP contribution to a particular outcome seems to me like something that's very difficult to do. If, for instance, you just took a very simple measure, for instance the outcome was a reduction in the incidence of West Nile Virus, the question then would be if we could count that, and I think we can count that, then is how much of that reduction in the incidence of West Nile Virus was attributable to the availability of effective pesticides? And if you could measure that, then how much of the fact that effective pesticides were

available is attributable to OPP actions? I mean, I just don't even know where you begin to think about some of these things. I'm only saying that just to highlight the complexity of thinking through some of these issues.

The second point I wanted to make, and one that I'm sure some people will disagree with, was in addition to the eight that were up there and one that -- if there was a fourth category of like beyond pie in the sky, just like not even worth talking about, but there's kind of a quality of life issue of the six-and-a-half billion dollars of structural -- commercial structural pest control done. Almost none of it is done -- I shouldn't say almost none of it. A --

(End of Tape 3, Side A)

MR. ROSENBERG: I think it's one that actually drives most consumers in their pest management, lawn care and other practices, and it's probably a fairly important factor.

UNIDENTIFIED MALE: Okay.

UNIDENTIFIED MALE: Okay.

UNIDENTIFIED MALE: Well, I appreciate all of the -- I'm sure you guys are ready to -- oh, sorry, Terry.

DR. TROXELL: Well, I just want to echo what Carolyn said and indicate that the FDA, I'm sure USDA, also, has great difficultly with developing appropriate performance measures for part. Exactly what you're saying, Bob, is we do things at one stage and the measure is -- you know, if we put out a guidance, well, how do we relate that to fewer people getting sick, whether it be EPA or FDA? So, there's many steps in the process.

I really do think what Carolyn says is critical. I mean, how do you model if there were no EPA? You can model for a corporation. If they come out with a new product, they can measure how many units they sell, you know, how many -- people are walking around with iPods

and smiling or whatever. But you cannot -- but what it seems we're being asked to do so often is how -- how can we enhance rather than -- so, what's the incremental change rather than what is the total impact, and it's very, very difficult to get a handle on quantitative, to get a handle on the results.

Just to point out that this is, I think, pretty generally a problem in government agencies, at least, that are involved in public health and so on.

UNIDENTIFIED MALE: Okay, Sherry?

MS. STERLING: Just that the workgroup asked me to tell you something that you've already heard, that the next thing that they will tackle is the human health mission areas, and included in that will include the safe -- the worker safety, as well as the food aggregate risk piece. Once we've gone through that, we'll then tackle the environment mission area with the water quality areas, as well as the endangered species. And I'm sure

that after that, we'll want to take a -- they'll want to take a step back and look at everything together and --

UNIDENTIFIED MALE: After that, we'll retire.

(Laughter.)

MS. STERLING: Not before I do.

MR. JONES: I want to thank, in particular, the members of this committee for working on this issue. Even though some judgments have to be made in the January time frame, I can assure you they will be interim in their very nature because I'm quite certain that we will not have nailed it and that it's going to take some time to nail it, and I expect that we're going to work at this both in EPA and with this committee until we get it to the point where we can stand back and go, you know what, I think that those are meaningful and appropriate measures for this program. So, thanks very much for what you have done and we look forward to future advice from all of you in the not too distant future.

Now, Bill Diamond is going to give us just a few updates here on some of the other rulemakings that we have going on. We heard this morning about the registration review rulemaking. Bill, the Director of Field and External Affairs Division, is going to just give us quick updates on three of the rulemakings that we have in the active stage in our program right now.

MR. DIAMOND: Good afternoon. This is one of those sessions where we're going to be able to make up a little time on the agenda, not only because I talk quickly, but because this session, by design, is supposed to be an update on the status of activities as opposed to issue engagement like the previous two.

What we're going to try and walk through fairly quickly is just to give you a quick sense of where we are on a couple of the rulemakings that are pending that will be out in the not too distant future, we hope, a sense of how this rulemaking fits into our broader activities

overall programmatically and then just give you a quick heads-up for some of the ones that are a little bit further down the rulemaking pipe and that you ought to be paying attention to in the not too distant future again.

In terms of the role of rulemaking overall, just to set a little context, we think it's just another one of the components we've talked about that carries out the overall mission that you've heard a number of times, and the intent of what we try to do with the rulemaking is to make sure that it advances that mission in terms of the contribution it can make, but also in a high quality fashion under the time desired.

The role of rulemaking overall is fairly clear to most people, but just to reiterate a couple of things we see as the most valuable contributions, is that it's -- you don't need rules to do everything in the program, but for a couple of things, it's essential and for this it makes a valuable contribution here, and I

think that's reflected in the rules that we're focusing on right now from a number of perspectives here.

Here's some of the benefits that we try to achieve overall in terms of the rulemaking part of our program, the real regulation rules as opposed to our registration rulemaking activities here. Clearly, it's essential for establishing some of the base requirements and things like worker protection and other areas to achieve the overall objective of public health and environmental protection, but also, additionally, it gives some secondary benefits that are reflected in a couple of rules as well, clarity of understanding of what the rules are, transparency in terms of what's applicable to everyone, consistency of application. It's in the rules, people understand it better, people can utilize it better, and there's less redundancy on case-by-case determinations there.

Overall, in terms of just the structure, when

we're trying to make some changes in the program and how we do overall, the rulemaking process is very valuable, we think, to try and achieve that objective.

When we move to our rules, there's a big demand for a number of different rules, some small, some large. These are the types of areas we try and group them into in terms of helping us to organize our efforts, but also in terms of trying to decide priorities when we have to choose between them with a limited number of resources.

Clearly, the health and environmental improvements are at the top of our list. Some of those rules that fall into those bins would be the container integrity rules, containment rules, certainly the worker protection rules, applicator certification rules in terms of their competence and their safety, protect themselves. A second large category would be program modification. Registration review that was talked about this morning falls into that bin.

Sound science through sound data to help us make the decisions. The complete suite of the 158 rules that we're working on would advance those objectives. And then, finally, efficiency process improvements, some things like the Section 18 emergency exemption process would fall into those things. These aren't the only ones we're working on in those areas, but these are some of the key ones that would advance on all four fronts how we do our business.

In terms of just a quick update on a couple of the rules that are the most pressing ones here, these are updates, we're not going to get into the issues. These three sets of rules are all post public comment period. We're going to talk to process and timing and what the issues are in terms of how do we get it out as opposed to the content issues here.

Section 18, emergency exemption process is intended to streamline that process, make it more

understandable to people and try and move things more quickly through that process. It was proposed about a year ago. We got a relatively finite number of comments on that, some fairly detailed, but a fairly small number. We've basically got the final rule drafted in response to those comments and it's going through the final inter-agency review process internally and then, obviously, through OMB and coordinating with our other partners who have a review role in that rulemaking process.

As people are aware, while this is going on, we've got a pilot program that continues until the final rule. That basically is test driving and taking advantage of some of those improvements while the rule's under development. Promulgation of the final rule looks like it's going to be probably early in 2006 as we wrap up that process. We think it's on the right track. We don't see any major barriers holding that up yet.

And then we're already planning the

implementation of the roll-out workshops to educate people in terms of what will be different, how do you do things, and for the people that haven't been involved and knowledgeable on the pilot, what it means for the changes in this rule here.

The container and containment rule, we've got an effort underway to try and upgrade or improve the requirements for the specific structural integrity of containers, so we can minimize the exposure during handling, facilitate container disposal and recycling, cleaning them up and making sure that they're the right and proper and safe level, and then through the containment aspects, try and prevent exposure through spills and releases is the underlying attempt at that.

This rule has been under development for a number of years now. We've had several rounds of public comment period. The most recent one was in June of 2004. We had a significantly larger set of comments on this

than we did for the last Section 18 we were just describing. We're in the process of revising that comment -- that final rule package now and then we'll move into final agency review. We're right on that cusp now in terms of trying to get it into that process of closure internally through the external review.

Right now, it looks like we're on the same track for early 2006 for the final promulgation of that rule and we'll also be getting the rule out in terms of how do we implement that through whatever changes are necessary at the state level, education and training and other activities.

As an aside here, I'll just mention that in terms of this package, one of the issues that has come up recently is the agency's endorsement and support for recycling as part of this, separate from rulemaking. The agency's been strongly supportive of recycling activities now. Recently, we've been actively involved with a

number of the other partners in terms of developing a voluntary standard for recycling of pesticide containers, and just recently, the Assistant Administrator has committed us to try to explore regulatory options to enhance the container recycling that's already out there on a voluntary basis. We expect that that's going to be an increasing activity for us in the coming months. It won't be something that will be contained in terms of the final container rule, it's on a different time frame. We do feel a certain sense of urgency to try and make sure that that happens and we'll be working with some of our partners to try and develop that.

The last big rule that I'll be talking about in terms of specifics here is the conventional pesticides data requirements rule, Part 158, big 158. That's to update the requirements, basically, to reflect current practice overall. And the benefits of this is primarily some of the objectives we talked about earlier; clarify,

transparency, consistency, but also to give us an updated foundation in the rulemaking for the next generation of data requirements that we'll be looking at.

This rule was proposed in March 2005. It was based upon a lot of the case-by-case lessons and practices that have gone on over the last decade. So, there's a lot of involvement on this, contains a lot of specific issues that went to the Science Advisory Panel throughout, again, the last decade, and it's kind of capturing it all. It also is a means to clarify and reorganize the rule structure itself so it's more user-friendly and understandable.

We proposed a 90-day comment period. We had requests for an extension of that comment period, so we went to a full six-month comment period to enable people to get their thoughts together and give us informed comments. That comment period closed in September. We had over 150 different comments, again, some fairly

extensive, some more focused, some technical, some programmatic. We're in the process now of reviewing that -- those comments, trying to break them out in terms of different activity areas and then we'll move, obviously, to finalization and modification of that package as appropriate.

Right now, that package is targeted for final issuance in early 2007. That time frame is going to be flexible in terms of the extent of the difficulty of dealing with some of those issues. It could advance a little bit, it could slide a little bit as we get our hands on it in terms of the work that's involved to look at, modify and debate some of those issues that the comments will raise.

The last area that I'll look at here is just some of the other upcoming rules that are in the pipeline. We've got one in terms of data requirements for plant incorporated pesticides. Again, the entire

suite of 158 that's in the early planning stages, this is kind of an early warning. The next one we have is the 158L&M rules. That's data requirements for biochemical and microbial pesticides. It fits into the same structure of the large 158. These are sequenced so that they can be all -- we've got the structure in place when these things are ready. It also is reflective of the amount of work and where we are in the developmental process.

That proposed rule is now currently undergoing inter-agency review and we plan to issue that early in 2006 as a proposal.

One of the things that was referred earlier, I think, in one of the sessions is the crop grouping expansion. We see this as more of a technical fix. We're planning to expand the crop grouping for tolerance setting. We're working closely with the IR-4 people who have done some of the scientific legwork of what's the

documentation and what's appropriate. Benefits there, obviously, are some less testing, some increased speed. This is a scoping type of thing determined in part in terms of the contents and the timing in terms of when that documentation is ready.

One of the things that's not mentioned up here, I'll just say in passing, is the 158W data requirement rule that has the same scope for the antimicrobials, the data requirements, what testing requirements are there. That's in the queue. It's a little bit further behind the 158L&M. We expect to have that one moving along in the next calendar year as well.

That's the quick tour of what it is in terms of timing and what's in the pipeline. Any questions, I'll be glad to address them.

MR. JONES: Carolyn?

MS. BRICKEY: Well, I just -- it just strikes me that there's an awful lot of good verbiage about the

whole rationale for your rulemaking program that might be applicable to the performance measures group.

MR. DIAMOND: Well, we've obviously been involved, in terms of working with them and in terms of the performance group people. In terms of rulemaking itself, it's just one of the contributions under that large protective umbrella. We're looking for measures internally in terms of how effective we are, what would be a good kind of programmatic measure. Timing would certainly be one. You can't get the benefits of these rules if they're not on the streets. We've done a good effort over the last couple of years to try and accelerate those types of things.

The contribution in terms of the quality of those rules is a little bit harder to get our hands on, and since it contributes -- ultimately, if we have better data -- to better human health and environmental protection. Breaking that out in terms of a separate

measure is kind of difficult, but it's something that we're at least exploring.

MR. JONES: (Inaudible).

UNIDENTIFIED MALE: First of all, I wanted to commend you. This was an excellent presentation. And, also, commend your group because you got -- a lot of people who are not heavily involved in this thing may not know this, but there is a lot of discussions internally and externally. You had part of our industry come in and talk to you about this 158L&M and we do appreciate that. I think our points are in there, too, as you'll see.

MR. DIAMOND: Yeah, we appreciate that in terms of -- particularly in the early planning stages. The earlier that we can engage people and get their input, as opposed to just waiting until the public comment period, the quicker it is for all of us, the better for us, so we make a large effort. And that's not just my group, but all of the client organizations, the other divisions play

a large role in that, and I think that's contributing to our means to accelerate some of these processes.

MR. JONES: Beth?

DR. CARROLL: I'm just curious and maybe I missed this along the way, but why would you not be able to go ahead and put recycling into the container and containment rule? It seems like a perfect place for it. And we spend a lot of money, our company does, at least, and we'd kind of like to see a level playing field.

MR. DIAMOND: We explored that extensively in terms of trying to determine if that was a vehicle and there's a couple of reasons for that. One is that, just legally, there was no mention in terms of a recycling proposal or a recycling aspect in the proposal. So, we would need a re-proposal, we would need a re-notification process, et al.

The second part of that is we've done none of the -- we've had some discussions in terms of what that

recycling type of approach would be, but there's a range in terms of scope and coverage that is not defined here. We also haven't done any of the economic analysis that would have to be done to support those things. Once you get that, which goes to the substance and contents of what the rule would be, even if it's kind of a narrow and defined thing, you've got to run through the whole gauntlet, again, of not just the public comment period, but the internal review process.

The container rule, which I say has been under development, is kind of at the eleventh-and-a-half hour out there now. We don't think it's appropriate to lose the benefits of having that one out there by holding it up for a year, a year-and-a-half, if that was the case, for this narrow one that can proceed on a separate trail, and the decision we've got is to explore those. We haven't got a decision yet that the agency will go ahead on that. Senior management and others still have to be

engaged on that decision.

MR. JONES: Bob, then Jose.

BOB: Yeah, Bill, I just wanted to personally thank you and your division for working with IR-4 and the crop grouping expansion and also the Registration Division and Health and Effects Division. I don't know whether people really -- I know Lois mentioned it this morning -- really realize the importance of crop groupings. There are currently 508 crops that you can register on in the U.S. right now, and if we had to do residue studies on each individual crop, we would get nowhere. So, by having the current 19-crop groupings and representative crops, we can get a lot of mileage out of doing GLP residue studies.

We're proposing to probably double or triple that number. It's amazing about the number of crops that are being grown in the United States now with our diverse ethnic populations. I think people will be surprised to

know how many there are that currently there are no pest control tools for.

The other benefit of this, and I think we're just seeing it more recently, is in the international arena. This may be a mechanism by which we can work with the Europeans and the Asians in harmonizing MRLs, because some countries have crop groupings but without representative crops and others are looking to adopt a uniform system. I think we have an opportunity to provide a global leadership role with this project. I want to thank the agency for taking this as a strategic initiative.

MR. JONES: Thanks, Bob. Jose and then Troy?

DR. AMADOR: Bill, it looks like you're going to have that workshop on Section 18 early in 2006. Is that more or less the target date?

MR. DIAMOND: Yeah. Well, we hope -- what we're hoping to do is once we roll these rules out is that not

too far after that, we move into the implementation mode. The first thing is communication and training. So, we haven't got a date set yet. Once we get closer to a firm thing that we know when it's going to pop out of the final process, then we'll get to scheduling, but we expect that to be not too far after when it's actually published, which would be at least in the first half of calendar 2006 is our hope.

DR. AMADOR: What audience are you going to target for that workshop?

MR. DIAMOND: Well, we'd have to look at that, too. Part of it is the interest of that, but the Section 18s could have a wide variety. I think part of it -- the thing that we would be talking to is state counterparts and also the people who have been engaged in the pilot to inform us where it would be -- where the training and the outreach would be most valuable.

DR. AMADOR: It would be nice if you let some of

the universities know, as well, because these states are the ones that submit the 18, but a lot of the data that the states need is collected by the universities in experimentation like mine. So, it would be nice to know ahead of time when it's going to happen. I'm pretty sure there would be a lot of people in my group that would like to know about it.

MR. DIAMOND: Right.

MR. JONES: Troy?

MR. SEIDLE: Thanks. I appreciate the heads-up about the plant incorporated protectants rulemaking. Can you give a little more background on the time frame? Which division, is it BPPD or OSCP that's --

MR. DIAMOND: It's BPPD -- I've got too many Ps in there probably. Yeah, it's Janet Anderson's division that we're working closely with. As you probably know, a lot of these rulemakings require a lot of legwork up front. Her division on the L&M and on this one is being

very aggressive in doing that so we can get to that point. I'd say we're just now starting to tier it up, which is the internal agency process to identify that it's going to be there, have the other parts of the agency, have the workgroup. That's usually at least a year in advance. The reason we're doing that now is so there's no surprises and the process can start becoming aware while we're still preparing the substance.

So, it's a little ways off. I'm sure Janet would be glad to talk to you in terms of more details of the direction we're headed on that.

MR. JONES: All right, well, very good. We're 30 seconds ahead of schedule.

(Laughter.)

MR. JONES: So, we now get a 15-minute and 30-second break. See you all back at 3:15.

(Whereupon, a brief recess was taken.)

MR. JONES: We need to get started here. We've

squandered our 30 seconds of being ahead of schedule.

UNIDENTIFIED FEMALE: Shhh. Shhh.

MR. JONES: Thank you. Okay. The next session, which will be led by Drs. Bradbury and Levine, the Directors of the Health Effects Division and the Environmental Fate and Effects Division in OPP, not in that order, is to be a little bit of a tickler for all of you about where we see the future of toxicity testing for pesticides, and frankly, for other chemicals, how we see it evolving in the coming years, and I think in terms of five to 15 years.

Not necessarily is this session designed to engender a lot of dialogue around it, but as much to sort of begin to inform you about the long-term strategy that we're engaging in as are several others within the Environmental Protection Agency and outside the EPA as it relates to toxicity testing. So, with that, I'll turn it over to Steve Bradbury and Tina Levine.

DR. LEVINE: Thank you, Jim. What we're going to do here is give you a bit of an update on where our thinking is about the future of toxicity testing. A few years ago when we were in the midst of TQM and the government, we used to talk about continuous improvement, and that's where this sort of fits in. Even as we are codifying changes into Part 158, we're thinking about where are we going from here and what are the next improvements that we need to make to the testing scheme?

We face challenges at EPA, as the regulated community does, too, as well as the regulated community and regulating authorities abroad, but given that we have finite resources and time to generate and to evaluate data, how are we going to cope with this? When confronted with large numbers of chemicals to assess, which ones do we look at first? When confronted with a wide range of possible toxicity endpoints, which outcomes are more likely?

We like to sort of visualize this, as do many people, I think, as a funnel with filters selectively screening out to be able to hone in on the most important endpoints of concern. We're going to talk about a couple of areas, both in terms of more efficient use of animal testing, as well as using non-animal methods to screen this afternoon.

There are a number of current projects going on to consider the best way to do toxicity testing in the future. There's a project that NAS/NRC is working on. We have a couple of programs at EPA, computational tox programs, as does the FDA. There are a number of projects with ILSI/HESI and the OECD has also been considering these challenges.

Among the principles and goals we have for the next generation of toxicity testing, we want to have a sufficient and credible amount of data for assessing and managing our decisions. We don't want an overwhelming

amount of data, but we want to have enough and of good quality. We want to be able to reduce cost and time to develop data, as well as reducing the cost and time for us to review the data. We want to reduce the use of animals. We want to take advantage of advances in science and technology, but we want to have peer-reviewed credible sound science decisions.

We want our data requirements to be clear to the interested stakeholders and consistent in the way we apply them, and we want our -- the process that we use to transition to these new paradigms to be transparent.

With that, I would like to turn the discussion over to Vicki DeLarco (phonetic), who is a Senior Scientist in the Health Effects Division, who has been very involved with the ILSI/HESI project on tier testing -- whole animal tier testing.

DR. DeLARCO: Yeah, I'm going to tell you a little bit about this project. But let me tell you who

is HESI, the Health Environmental Science Institute. It's a global organization under ILSI that supports scientific projects that address important issues in the area of health and environmental risk assessment by bringing together scientists from academic, government and industry to work together to seek balanced approaches to addressing these problems.

Designing an improved toxicity scheme to provide a better basis for human health risk assessment is a high priority topic among a number of organizations. Therefore, there's multi-sector interests in this area. So, towards that end, HESI pulled together a group of scientists from all over the world, about 50 or so scientists that represented nine different countries from Academic and government, in addition to EPA. It also involved some of our international regulatory authorities, in addition to the industry.

In the first meeting that they had, they wanted

to reach consensus on a scientifically credible and viable approach for evaluating the safety of pesticides more efficiently, with fewer animal, with fewer artifacts, and more accurately. So, when we first got together in 2001, there was unanimous agreement that we wanted a science-based approach. We wanted a more hypothesis-driven paradigm and that we should take a tier testing scheme and that this scheme needed to provide assurance that pesticide -- that the pesticide can be used without damaging human health, and that it starts with existing knowledge, what you understand about the toxicological properties of that class or that class of chemicals, and also, the use patterns.

To develop this new paradigm, they broke out the group into three task forces. There was a group that looked at how to improve the metabolic information that we get, how to improve the systemic tox and how to improve the life stage information. Two of our senior

laboratory investigators were the co-chairs on two of these task groups. Dr. Hugh Barton from our National Human Effects Research Laboratory at RTP chaired the -- what we call the ADME, absorption, distribution, metabolism and elimination task group, and Dr. Ralph Cooper co-chaired the life stage group.

The charge to each of these task groups was to, as you designed this tiered approach, to introduce greater flexibility, so it could accommodate the existing science, and also keep up with new science that might emerge and to emphasize the three Rs, reducing and refining animal usage and to ensure that it included evaluation, at least in the base set of studies that they start with, for all relevant toxicity parameters.

We wanted a more integrative approach where you just don't do the systemic tox test and then you do the life stage test and do the metabolism test, but these different tests would interact and inform each other.

And then incorporate and improve understanding of exposure. In other words, how would this be used? Were we concerned with intermittent, episodic situations and therefore we wanted to focus on getting better hazard data, short-term hazard data, what were the routes that people would be exposed by?

If you look at the papers, these papers are now available on the HESI website. We asked them, even though they're not in publication right now, to make them available, so people can start reading them, because we do think that this is an important milestone. When you think about it, you bring 50 scientists together from all over the world to reach consensus, that, in itself, is a milestone, and we think this proposal has some merit. But it's just rolling out. It's undergone journal review. It will show up in critical reviews in toxicology. It will probably be published, if not the end of this year, the very beginning of next year.

But we need to -- we want to engage an extensive dialogue not only with the scientific community, but our stakeholder groups.

Although there are a lot of improvements in this proposal, there still needs to be some foundation building, in our opinion, and -- for example, the proposal drops the mouse cancer bioassay. For years, we have been asking for two species, and this will be an issue that will not only need more discussion and documentation, we realize there will be different views on it. Another area is that because it is science-based and you start with this base set, what are the triggers that may take you to an upper level of testing, in other words, a toxicity that you might see that you want to chase down, not that you want to chase down, that you need to chase down and characterize further. Although there's some discussion about those triggers, there will be a need for more dialogue and discussion thinking

around them.

The scheme is based on exposure considerations, depending on a margin of exposure, you may not need to go to more upper tiers of testing. But what is that margin of exposure? We have considered exposure in other situations, like for our biopesticides and our antimicrobials, that we haven't done in this situation. So, more dialogue is needed there.

The other thing is -- for example, the one generation enhanced study that they've proposed to look at life stage effects has a lot of things built into it. It will be important to do a prospective analysis to take this new approach and get some laboratories, government laboratories, maybe in collaboration with the industry laboratories, and run some new chemicals through it to see if it's going to do what we think it's going to do. As we engage in further dialogue with the scientific community and with our stakeholder community, other

issues might arise, technical issues, maybe policy issues. So, again, this is just beginning to roll out.

Now, in any new proposal that you look at, it's important to document that. We've started the scientific documentation process. In other words, if you design something new, you want to go back to look at what have you been doing for the last 30 years and what have you learned from that. And so, we have this large database and we've been examining it to look to see what studies or measures have been very valuable in the risk assessment process and what measures have contributed very little.

One analysis that we did recently that we released publicly is looking at the dog studies; in other words, what benefit is there to do a one-year dog study beyond the 90-day dog study? From our look at the database, it appeared that there was very little information that we were getting from that one-year

study. So, we took that to the SAP to get their opinion on it and to review that and they were generally supportive, but they had several major recommendations. Our original analysis was based on about 77 pesticides, and they wanted us to go back and look at more pesticides, particularly those where the dog was not necessarily the sensitive species to set the RFD. And they wanted a larger analysis to ensure that we had more classes of pesticides represented. So, we've already begun work on that based on those recommendations.

The other thing that's important is sort of international harmonization and they felt that we needed to engage with our international colleagues on this issue. In Germany, they have done similar work in looking at the database on dog studies, and we are in communication with them now seeing how we can bring our two analyses together and continue that international work.

There's other analyses of our database that we have ongoing and we're looking at our rodent cancer bioassays. Right now, there's four studies that are done and -- to see if somehow we can reduce that protocol and not lose information. We're also looking at our two generation reproductive studies and seeing how often do we detect effects in the second generation that you wouldn't pick up in the first generation or get a lower (inaudible) in the second generation. And then the last thing that -- one of the other things that we're looking at is rat developmental neurotoxicity study. As some of you might know, we put out retrospective analysis of that study a couple of years ago, but last year, we received a number of new rat DNTs, and so, we've been evaluating and looking at them. So, that analysis is ongoing.

Another important step as you move towards the next generation of toxicology data requirements is to work in several venues to gain international

harmonization, and that's really critical. It's unlikely that the regulated community are going to want to meet different data requirements. So, we have a commitment to international harmonization and we began that dialogue with -- earlier this year at an OECD meeting and we'll continue that dialogue.

The other thing is this is new and it hasn't been widely available. So, an education process is going to be very important. We've been working internally with our own staff, going in detail over these proposals just to bring everybody up on the same page. That included some of our other counterparts, CAL EPA and Health Canada.

We started outreach with our stakeholder community with our May 158 workshop and we're continuing it with this meeting.

So, we think that the ILSI proposal is an important springboard. One consideration that we should

be looking at as we move forward to the next generation of requirements, but it's just one activity, we're looking at a number of activities, and Steve's going to talk to you a little bit about our computational program and how this proposal intersects nicely with that.

DR. BRADBURY: Before I start, I just wanted to take a couple of minutes and reflect back on Tina's introductory comments and sort of touch base again and make sure we're all in the same context. One of the challenges that was, I think, reflected in our discussion on performance measures and our goals is how to ensure that we're protecting public health and the environment and ensuring the benefits of the products, but how do we do that as efficiently as we can so we focus limited valuable resources as effectively as we can, so we maximize the use of all of society's resources in moving ahead and making these decisions.

So, we're sort of faced with a challenge of how

to ensure that we have sufficient credible information to make informed and proper decisions and use those limited resources wisely. The integrative testing, integrative assessment concept gets at how do we ensure that we're using all sorts of available information to help drive that decision-making and to help focus limited resources where they need to be focused?

So, in other words, in addition to just using in vivo testing in sort of today's world of toxicity testing in today's world of doing risk assessments, how do we start advancing the incorporation of other technologies -- it could be technologies that are coming out of the computer, it could be technologies that are coming out of cell lines or in vitro assays, to help inform us as to what questions are really critical for a given decision we need to make and how do we then focus resources, resources for the regulated community, resources for the government agencies and the regulatory agencies to ensure

that everyone's focusing those resources as fine tunely as we can?

One piece of the building blocks to advance this integrative testing and assessment paradigm relies on many of the principles that Vicki just talked about, how to maximize the information content for every animal that's used in a toxicity study, how can we take advantage of information that's learned in a classic, if you will, study to help support human health risk assessment, how can that same information inform our ecological risk assessment and improve our ability to extrapolate across species?

So, getting that more efficient, more diagnostic, more hypothesis driven in vivo testing protocol is a very important part of the evolution of this integrative assessment and testing paradigm.

But this funnel on the -- the funnel concept on this slide is trying to address the challenge of how do

we decide when, what and how are we going to do in vivo testing? How do we deal -- if we think about the agency as a whole and its challenge with a variety of chemical inventories, how do you take a look at those large chemical inventories and decide how to focus in on specific chemicals when you need to and what do you need to really learn about a given chemical, given your regulatory decision-making process? How do you move towards the use of the computer in silico-predictive models, as well as in vitro testing and other kinds of emerging technologies to help zero in on that question so that when you are doing your in vivo testing, it's focused on the likely drivers for that overall risk assessment? Or for a given chemical, how do we start thinking about, as Jim said, five, 10, 15 years down the road and zeroing in on what's the most likely adverse outcome for the chemical and can we use emerging technologies to help zero in on what the most likely

adverse outcome is for a chemical and move away from -- over time with the right science and the right public participation to a paradigm that instead of requiring testing for all possible in vivo tests and every possible outcome, how do we start to zero in on the efficiencies of doing that kind of testing?

So, one of the aspects that we're looking at with partners, not only in EPA, but across the Federal Government and internationally, is the use of a variety of in vitro techniques and computer techniques, quantitative structure activity relationships, for example, which take a look at a structure and try to predict biological potency, but also the development of omics (phonetic) technology, the emerging molecular biology technologies that are being used in drug discovery and in vivo chemical discovery, but also starting to be used in helping to understand what potential adverse outcomes may be associated with a

chemical structure.

So, the computational toxicology program in the EPA is a program that's trying to more aggressively and systematically take a look at those emerging technologies and see how that information and those techniques can start to be used in a risk assessment venue just as they are starting to be used in a drug discovery and an eco-chemical discovery concept. Again, the evolution of the process is, first, probably just how to help one better define your question and define information needs and how to better use information that we can be gathering in a number of contexts.

One of the reasons we're also taking a look at this is the realization that these kinds of technologies, computational toxicology, omics technology, genomics, proteonomics (phonetic), they're happening now in the industry and one can imagine over the coming years that information will be part of the information to help

interpret the potential risk of a compound. So, we want to be at the front end of that process with partners in the regulator community, academia and our international partners to be at the front end of that so that we're prepared to take advantage of that information as it starts to emerge.

So, I think it's a foregone conclusion that those technologies are happening and that information will emerge. How do we understand how to use that information in the risk assessment process?

And, again, as I was saying before, there's a number of different activities going on globally in terms of this whole matrix of tools and techniques that are coming into play. Vicki talked about the ILSI/HESI efforts. There's not only the efficient in vivo testing concept, but also efforts in the omics and how are those technologies going to start to play into the risk assessment process?

I mentioned EPA's computational toxicology program. Tina mentioned the National Academy of Science, the National Research Council addressing these issues as well. FDA, of course, is looking at toxico-genomics and how does that play into the risk assessment of drugs and understanding efficacy of drugs, and the OECD is also taking a look at this issue of how does one think about the information needs to make different kinds of decisions and how do we integrate these concepts of in silico, in vitro, and in vivo information to maximize information content, maximize efficiencies, but still make credible sound decisions?

Bill Diamond was talking just before the break, in part, about Part 158, and sort of the evolution of that testing requirement. If we use Part 158 as just an example of the evolution of the techniques that we're talking about, we're sort of at the stage now where we've gone over the last 15, 20 years the evolution of in vivo

assays and increasingly diagnostic information in in vivo assays and how those inform, in this case, pesticide risk assessments and pesticide decision-making. There's similar parallels in drug discovery, drug evaluations in other parts of our society.

What we're trying to do now is taking a look ahead and thinking about the test requirements, the risk assessment technologies of five years out, ten years out, and thinking about those kinds of technologies and being part of that research community science evolution and being aware of what's going on and being part of what's happening so that those technologies can be focused and efficient and helpful, say, in the realm of pesticide risk assessment and pesticide decision-making.

But it's clearly more than just a science activity. While science is part of it, it's just a part of it. The reason to have the visit today and some visits we've had in the past on computational toxicology

and related issues is to just keep you informed of the evolution right now, especially of the science and the science foundation for aspects of a potential paradigm shift in the way risk assessments are done, realizing, again, science is only part of it. As we go through the science development and the transition from different paradigms at the appropriate stages of the evolution of science, there's really important aspects of public participation and dialogue in terms of how is this information going to be used. How will these paradigms play out as we move from today to five years from now, 10 years from now, 20 years from now?

So, if we think about the Part 158 process and sort of our existing in vivo test methodology and how they're applied in cumulative risk assessments or other techniques, the very many and different types of public participation processes that were a very important part of that whole process, science was part of it, but there

was a lot else -- a lot of other activities that had to happen to make sure that we all understood how to use that science appropriately.

Obviously, those same kinds of discussions and dialogue and public participation will be playing out over the coming years as these technologies start to move their way from the research labs and the conceptual models into the peer review process and the scientific foundation and vetting process and this slide here, this figure here, is just trying to get across the point that as these technologies start to mature and the science becomes a bit more focused, having dialogue with stakeholders and the public in terms of thinking about these technologies as they evolve and how they can be appropriately used and interpreted in regulatory decision-making.

With that, I'll stop and we can field some questions.

MR. JONES: Carolyn?

MS. BRICKEY: I guess I support the concept behind this topic and I certainly support the notion of abbreviating studies if they don't work well or adding in new types of data and information that we don't look at now. The only cautionary thing --

(End of Tape 3, Side B)

UNIDENTIFIED MALE: We use the kinds of things that you have at the top of that chart to validate what we were seeing in animal testing and being able to apply it to humans, and the kinds of things that we were seeing animals, can it really happen in a human population? We use these in vitro -- these mechanistic studies to draw that link.

There's a real emphasis to sort of take away those two components, the animal testing and the human testing. We heard earlier today that we want to minimize human testing. We're talking about animal reduction, and

we're seeing a lot more emphasis on it. Vincent Cogliano (phonetic) at IARC (phonetic), just last year, wrote a paper where he proposed that you don't even need epidemiological studies or animal testing, the two-year chronic animal bioassay to declare something a human carcinogen just based on these kind of in vitro testing. Is that where you think that this is headed? It probably is okay for compounds that are truly contaminants and hazards like PCBs where if we invoke the precautionary principle, it's probably not a big deal. But when you're talking about evaluating a pesticide that has a positive aspect to it as well, eliminating something based strictly on some of these early testing, I just think there might be some real problems with that.

UNIDENTIFIED MALE: I think as Vicki was looking at the figure and circling efficient animal testing, I think thinking about how can some of these techniques -- like you were saying, understanding the mechanism of

action that are understanding some aspects of how there may be variability across species in a mechanism, that can inform the in vivo testing to ensure that that in vivo testing is designed in such a way that it's informing the overall understanding of the dose response curve, for example.

So, there's a lot of different possibilities to be thinking about in this kind of technology and as it evolves. I think most folks are thinking about how does this kind of information, in an integrated sense, help improve our understanding of the toxicological processes, help us improve dose-to-dose extrapolation, help us improve our understanding of species-to-species extrapolation or age class-to-age class extrapolation.

I think there are some concepts that are certainly playing out with this technology. If you're in the drug discovery or the agro-chemical discovery mode, where using some omics technology may help you as you're

sorting through 10,000, 15,000, 20,000 structures, how you may want to start even in the computer or in the cell study on your bench top, how you want to start to continue to streamline your discovery process. Over the next 15, 20, 25, 50 years, it will be sort of fascinating to talk again in 50 years and see where this is all going.

UNIDENTIFIED MALE: I guess my point is what's the decision here? Carolyn brought it up, but probably from a different perspective. We do a whole animal repro test and we're looking at neuro development and then you're going -- you're doing in vitro testing and you're looking at (inaudible) cells or whatever, and the whole animal study may not be telling us something, but the in vitro may be telling us something, but the in vitro may be telling us something because it doesn't happen in a whole animal. So, where is your decision point? We've got a lot of redundancy in a whole organism that you guys

are stripping away in the in vitro testing. So, it just -- from our perspective, being in this business for the last 20 years, it just seems like the decision point, the data that are going to be used for the decision point seem to be moving up higher on that chart that you have.

MR. JONES: Let me say from my perspective and what I've asked our team to do in this exercise is that any change in the system along these lines needs to increase our knowledge and not decrease our knowledge. So, if we -- in our research and the evolution of this -- if we get to a point where, you know what, Jim, we may be ready to move out with this approach versus this one, the first question is, are we gaining knowledge or are we losing knowledge? And the whole objective for us in it is about we think that there are ways to harness newer -- the newer science, new technologies in a way that we gain knowledge. That's what we're trying to do in our engagement and investment in this.

Jennifer?

MS. SASS: One of my points was actually that joint point there. I have three points and that was my second, which was how are you going to -- I mean, not how are you going to, just that we need to start all thinking about knowing that we need to begin to define thresholds or some way of knowing when we're going to make a regulatory decision on the data so that we're not generating data forever, saying, well, this test only shows us so much, we need to do the next. I think that -- I hope that what EPA is doing is not trying to revolutionize toxicology, but trying to streamline and enhance a registration process, which is different.

And IARC doesn't actually use almost all of -- IARC doesn't use this data to make its decisions because IARC doesn't use unpublished data. Almost all of this is unpublished data and mostly historically it has been crude and not that useful. No offense to the people that

have to do it. I know it's also expensive and time-consuming. So, I think the idea of streamlining this process is a good one and that will entail defining when to make a decision and -- that's number one -- that's number two, so back to number one.

I think that the ILSI/HESI/EPA report -- ILSI/HESI report -- I mean, I've skimmed through it, I haven't looked through it. It's fat, it's in three big white papers. But I have a question which is, where did the funding come from? And the reason why I'm concerned about that is because it wasn't really a stakeholder process. ILSI and HESI defines themselves as an academia/industry/government tripartite process. I've looked at the authors and almost all of the academic authors are also industry consultants, some of them substantially.

Many of them are the best in the field and they are the experts in that area, including the government

people, and I recognize that, but it wasn't a stakeholder process. So, that means that certain questions and certain concerns may not have been introduced early in the process, and late in the process, only tweaking usually gets done. For instance, in the Part 158 revisions, I handed in substantial comments and those concerns may have been germane had they gotten in early in the process, but I was not one of the people that was called by EPA to come and talk with them before that proposal was released. So, who foots the bills for number one?

Number two, the threshold issue, it's not a question, it's just something we need to keep on the table.

And number three, I think maybe this fits here, maybe in the computational toxicology section, but I'm concerned about whether there's also, in your conversations, concern about the nano materials and the

nano pesticides that are coming around the corner, and not quite around the corner, some of them have gone around the corner. So, I wonder if you have an inventory developed of the nano pesticides that have been registered or are applying for registration or whether you even distinguish them as that versus in their bolt component?

So, whether you've made a decision about whether these are new or existing chemicals, whether there's information that could be gathered for these nano pesticides that are -- is already available, very basic chemistry information that would be available without new testing because they would have to be available to develop a pesticide, and whether that's submitted, and also whether there's FIFRA 6(A)(2) requirements on any of that or whether it's just -- there's just no category yet, in which case, I want to suggest that one be made so that somebody can actually look at that.

And then, finally, to encourage you -- and I'm sure you're doing this -- to integrate that thought into these testing strategies, because it's not too early to begin to think about that.

MR. JONES: Steve, do you want to take the first couple and I'll --

STEVE: Sure. Which is first and which is second?

(Laughter.)

STEVE: The threshold -- I really appreciate Jennifer's comments about the threshold and she's exactly -- I appreciate those comments. Understanding how this information may or may not be used in different kinds of decision-making is part of the evolutionary process.

The nano technology, I can handle part of that. As many of you know, from Society of Toxicology to other venues, sort of the whole issue of how to assess the exposure and effects of nano materials is rapidly

expanding, and certainly, the Pesticide Program, as well as our colleagues in OPPT, the Toxic Substances part, are involved in those activities. The agency is -- I think it's about ready to finish up a white paper on starting to think about how to do risk assessments for nano technology. So, at least in that part of the question that you asked, we're certainly engaged in a number of activities to be -- with the science as it evolves --

UNIDENTIFIED FEMALE: Steve, some of us don't know what nano pesticides are.

STEVE: Well, nano technology would be -- and there's probably others around the table that can do better than I, but the use of -- the development, the chemistry development of very, very small particles, nano particles, that may have a variety of beneficial uses that we've never used that technology before, delivery of materials being looked at in the pharmaceutical area, being looked at in a number of different areas. But

micro-particles, nano particles.

MR. JONES: And we're not aware of any companies who have come to us with nano pesticides. We have heard, in the antimicrobial industry, some companies talking about some concepts that they've got, and it is an area that, I think, we need to do some thinking around. So, there are no nano pesticides that I'm aware of right now.

UNIDENTIFIED FEMALE: Thank you.

MR. JONES: And then the ILSI/HESI questions.

UNIDENTIFIED MALE: Go ahead, you can do that.

UNIDENTIFIED FEMALE: Well, HESI is funded by member companies. They pay dues.

MS. SASS: This project, I mean, sorry.

UNIDENTIFIED FEMALE: Are you talking about the (inaudible), is that what you asked?

MS. SASS: Yes.

UNIDENTIFIED FEMALE: Yeah, that's what I'm speaking to right now. But the way that you have to look

at this, that was a scientific project. It had a start, it has an end and then scientific publications will come out of it. Our process is separate from that. We have a different process and that's what we've been describing to you, where we'll look at all the relevant science that's out there as we move forward to improve how we assess human health risks. That's one that we'll look at it because it's a piece of science that was developed by this international group of experts and it's going to be published, and you can't turn a blind eye to any science. But as we mentioned, we realize there's some issues in those papers, some unresolved issues, but at least what's important about that is the thinking's beginning. People are starting to think about it and the dialogue's starting. It has provided a good foundation to get the dialogue started.

MR. JONES: The funding issue where --

UNIDENTIFIED FEMALE: I just mentioned that

they're funded by member companies. They pay dues.

MS. SASS: So, this product didn't get -- I mean, EPA Pesticide Office has hired ILSI --

MR. JONES: Yes.

MS. SASS: -- has contracted out to ILSI to do certain projects. So, my question was --

UNIDENTIFIED FEMALE: That's a different part of ILSI. That's the Risk Sciences Institute, and this is the Health Environmental --

MR. JONES: We didn't fund this project.

MS. SASS: Okay, that's what I was getting at. Thanks.

UNIDENTIFIED FEMALE: But there was sweat equity if you include that.

MR. JONES: Right. Although we didn't encourage them to make invitations to the public interest community, which they did, and the response back they got was that we don't have the capacity to participate in

this level of an activity --

MS. SASS: That's where cloning comes in. We're working on that.

MR. JONES: I won't comment on that, but we recognize that just -- we need to have some way to deal with that and it can't be just to say, well, you missed your chance. The fact that people can't participate because of resource issues doesn't mean that, therefore, they shouldn't be given consideration. We've got to figure out how to deal with that reality. So, we're aware of that reality. We've tried to do things about it and there are other things we still have to do because it's not an outcome that -- that's one of the reasons we're doing this.

Any test that we were going to ultimately rely on would, of course, go through things like our Science Advisory Panel which would be an opportunity for further participation.

Okay, I think I saw Pat and Troy.

MR. QUINN: I just -- I wanted to make a related comment. You know, I think to the extent I understand it, computational toxicology sounds like it holds enormous promise, and I want to get smarter about it, but people who work with it more closely than I do tell me its promise for regulatory institutions may be 10 years away. I guess alongside that, I want to make sure that the agency stays focused on low-hanging fruit, on things like acute toxicology where there are in vitro methods that have been developed, where there are other approaches that are available to us.

Now, one has come out of this group, it's this antimicrobial cleaning product alternative testing initiative that Tina has been working on with us and Jim has been working with ICFAM on, but it takes far too long, frankly, to get those approaches examined in a responsible manner so that they can be used for a narrow

regulatory purpose, and that's what I think we need to keep in mind is, identifying test methods of approaches that allows EPA to do its work in a responsible and scientifically sound manner, and not be beholden to broad validation exercises for every active ingredient in every product. So, I just wanted to offer that.

MR. JONES: Thanks. Troy?

MR. SEIDLE: Thank you. I would support what Pat said, of course, and with respect to low-hanging fruit, we are very supportive of the content of the ILSI/HESI ACSA and proposals. We do recognize, as do many people around the table, that the current testing and data requirements are anything but lean or efficient. There's a lot of redundancy and a lot of waste. I think those white papers go a long way to addressing those concerns.

With respect to the time table for Part 158, I guess a question/comment, is EPA, is OPP committed to

incorporating, to the greatest extent possible, some of the recommendations, the innovations that ILSI/HESI are recommending? Because if it's taken 20 years to get to this point with a proposed rule, it would be a shame to waste another 20 years and miss the boat to incorporate some of these things into Part 158.

MR. JONES: As it relates to Part 158, they won't be because they're not ready to be incorporated into 158. The commitment on our part is to pursue them along the lines that we've been talking about here, is that they need to get -- there are a number of issues that need to be sorted out, some pretty serious issues that need to be sorted out, to take them through additional peer review including, for example, the Scientific Advisory Panel. We see 158 as not a once-in-20-year exercise, but something that we should be doing on a routine basis and are committed to doing it on a routine basis, and hopefully, if we're to come back here

in 20 years, we will note that the 20-year lapse between the first one and the second one was the exception and not the rule, and the rule became that EPA was routinely updating its data requirements.

Okay, let's wrap this session up. Thank you to -- oops, do we have one more? Oh, sorry. Terry, I keep missing my peripheral vision.

DR. TROXELL: I have a, maybe, different perspective. I think your point about 10 years plus out for the omics is right on because -- and -- well, anyway, what I think we have with the omics is we're going to have tons of information. We're going to have thousands of genetic changes, thousands of protein changes, thousands of metabolic changes that you're going to be able to measure and that's going to lead us to information overload, and as a risk manager, you know, it's kind of frightening to think we're going to have all this information and how are we going to really relate

that to real concrete endpoints that are adverse?

We know that human beings, you know, every day, their systems are varying and changing, adapting and so on, and there are a lot of things that are happening that are going to be just simply adaptive effects to whatever you eat, breathe, drink, whether it be food component or residue of a pesticide or contaminant. But what we really want to know is what's -- which of those changes are concretely linked to adverse effects? That is the bridge that has to be made over the years so we can link things. In fact, in the end, of course, we're going to know so much more about human health, more about human health that doesn't even relate to contaminants, but also we'll understand so much more about individual variations and there are going to be things that we never imagined that we're going to discover and it's going to present many new challenges, but also -- but the key in the end is going to be to link those individual points in the

micro array lighting up to real effects that might be adverse for humans and that we have to be concerned about.

MR. JONES: That's a good point. Okay, let's wrap this session up. Thank you, Tina, Steve and Vicki. Thank all of you.

We're going to now move into sort of our last session associated with some of the worker issues that many of which, not all of them -- actually all of them, we have talked to this committee about before, and Bill Diamond is going to take us through a number of updates, basically, around our PRIA worker protection efforts, the Pesticide Safety Education Program and the National Assessment of Pesticide Worker Safety, and then my colleague from OECA, Jack Neylan, is going to give us a brief presentation about something hot off the press from that program, which is the Worker Protection Standard Program Review Final Report.

All right, Bill?

MR. DIAMOND: The three sessions that I'll be covering are the three topics. There will be two quick updates and one kind of more in-depth project overview. So, we'll move through those fairly quickly and spend most of the time on the third one here.

The first one that we've got here is the update on the Pesticide Safety Education Program. We've talked about those at the last couple of meetings in terms of issues for funding and improvements and some of those things.

What we were trying to do in terms of background here is we did conduct an overall review with a bunch of different stakeholders. That was primarily last year. We got some perspectives on different critical questions that needed to be addressed to have improvements in the program to maintain the value, but also to try and improve efficiencies, cost effectiveness and value in

terms of the outcomes there.

In the May meeting, we presented that in a report that was kind of a summary of here's areas you should focus on some more and we've been, over the last six months or so or five months, trying to follow up on that to get some of those things started here.

Broadly, the follow-up actions came in about five different areas. The first one that got a lot of attention was to try and improve the funding mechanism. There was an issue in terms of how effective and timely the distribution process was and also the issue of accountability that we've been talking about in a number of areas. What we're doing is we're establishing a stakeholder workgroup to explore some alternative funding mechanisms that will also consider some accountability needs, and I'll mention a little bit more on that in just a minute.

The second area was to try and set some training

priorities, recognizing the evolution of needs over time and that with the demands exceeding the ability to perform those -- all that training, that we have to work with certain people to try and identify what the top priorities were out of all those competing demands. At this past summer's National Certification and Training Workshop that we held, we worked with a number of different partners to try to identify that as a follow-up in terms of what are the most pressing areas, who might be able to provide those things, and what are the specific actions that would come out of that? So, we think we're in the process to move ahead in that area.

In terms of program efficiencies, the notion of, again, trying to get more bang for the buck out of that and also try to encourage regional and national collaboration on the material development, eliminate redundancies, maybe get some regional centers of expertise were some of the ideas that were tossed around.

In terms of following up on that and in terms of practice, we've already started doing some of those things. Development collectively of valid exams and manuals for both fumigation and aerial application are being initiated so that we can have standardized materials that everybody can use for those areas, for training and individual states and localities do not have to reinvent the wheel on that.

And a similar one in terms of trying to take advantage of work that's already been done out there, our EPA Region 5 had worked to develop a valid exam for structural applicators, and we're looking to see whether or not that has benefit to take nationally and transfer that information to other people.

In terms of the next area, expanding the scope and coverage of the certification regulations. I'm going to talk a little bit more about that later in this session here, but it was basically the notion that there

are some gaps in terms of people who are handling pesticides, that may be bringing them under the umbrella of certification and training requirements would make sense, and we've started to initiate some regulatory planning on that front.

The last one, the accountability measures, this goes to kind of like accountability in the small sense, not the mega sense of mission areas, but project-specific areas that would flow from those types of things, and how do we develop those measures specifically to demonstrate the results of these targeted or niche activities? How much benefit do you get from a certain investment in training or certification? So, at about a second or third tier level, we'll be looking with our partners in terms of how to demonstrate the value and contribution of this part of the program to achieving our overall objectives.

If you go to the next slide, this just gives you

an update in terms of where we are in terms of funds available and distributed for the Safety Education Training Program. In FY 05, we had $1.2 million, the same as the previous year, that were distributed through an IAG with USDA, the traditional mechanism that we've had over a period of time. That letter of credit was sent out in September for people to start funding them and notifying them of the availability of funding. So, that money is out and in the pipeline.

We expect that for Fiscal Year 06, we're going to be using the same distribution mechanism. We anticipate that we would have the same level of funding, barring some additional Congressional action that would affect our entire program. We're not targeting this one particularly, but the FY 06 process is clearly not closed yet, as Congress still has to reconsider that.

The critical actions here in terms of where do we move in the future is -- FY 06 would be the last year

for this cycle of the IAG. We've been talking to USDA and they've agreed that we ought to explore different alternatives for the funding mechanism to try and address some of those fundamental concerns. What we're doing is we're going to be working with a number of the stakeholders that were involved in that process of coming up with the action areas to try and determine what are the criteria and the mechanisms that we ought to consider in planning to follow up that new mechanism for the future.

Some of the criteria for us would be, obviously, we're not going to have a disruption in the mechanism availability to get that money out into the field, but also to try and anticipate what those needs are going to be to make it effective and give us the flexibility to plan for the future training needs, as well as maintaining the base that we've got in the past.

Before I move to the next topic, any questions

on that one?

MR. JONES: Amy?

AMY: Bill, who is on the stakeholder groups that will be working with you to -- beyond USDA, who's identified -- to establish the alternate funding mechanism?

MR. DIAMOND: This will be the same cast of characters that we had for the program review, basically the involved parties who were in training, and what you can expect is that over the next couple weeks and months, very near term, we'd be contacting people to explore their interest in doing that.

AMY: I would just encourage you to -- for those groups that you're expecting representation from, like APCO and AAPSE and APSCRO (phonetic), to actually contact the president of that organization to ask for who might be a good representative from their organization to be on that rather than hand-picking.

MR. DIAMOND: I think that's our plan. That's our plan.

AMY: That would be great.

MR. DIAMOND: I think, also, one of the things we'll explore with them is people who maybe were involved in some of the previous process. So, we've got the learning curve that's up there, but we're obviously going to consult with who they think is the most appropriate people to engage.

AMY: Okay, that would be good. Will there be more discussion of PSEP in your presentation to come? Because if so, I'll hold off on my other comment.

MR. DIAMOND: Only to the extent that some of the concerns that we heard were some of the same concerns that people are saying we ought to look at regulatory changes in terms of future coverage, for example, in terms of people who may need training and certification. So, it will be there, but it's not going to be

specifically broken out for the PSEP activities which is just, here's what we're doing to try and change and address that funding mechanism and programmatically, things as how we do specific manuals, for example.

AMY: Okay. Then I'm not sure if this comment is germane now or later, but I'll make it now and you can decide. The American Association of Pesticides Safety Educators or AAPSE did -- recently compiled a summary of data on the 2004 Pesticide Safety Education Programs, and we have that summary -- I have that summary with me today, so I'll just pass it out. I just want to bring your attention to one section where it talks about program efficiency because that has come up before and you were talking about sharing manuals and trying to decrease the number of materials that states actually have to develop for themselves. We do appreciate that.

The report confirms that most states do share multiple training resources that were developed outside

their state or they share between states, and that includes manuals, CDs, presentations, many, many more things. We share resources as far as people and presenters as well. So, there's a lot of information there on both quantity and quality of program.

MR. DIAMOND: I think that's very helpful. We recognize that there's some potential for efficiencies there in terms of collective development of materials. But, also, given the nature of the industry, that there's some that are going to have to be more targeted and it's appropriate for the people maybe locally who were informed about those to develop those. So, it's going to have to be a mix and we'd certainly like to see that so we can take advantage of that information.

AMY: Great.

MR. DIAMOND: Anything else on that?

(No response.)

MR. DIAMOND: Okay. Not seeing any, we'll move

along to the next one, which is the PRIA Worker Protection Resources. Again, this is kind of an update on that. Let me remind you of the background on this, that PRIA authorized funding to enhance worker protection activities, emphasis on enhance.

And the activities that are identified at the bottom of that page in terms of the objectives are, to try and look at existing activities and address and reduce the risks, but also to better characterize the risks because, again, information can inform your decisions on that, and then generate improved data that's useful not only for the communication aspects, but also in terms of the risk management aspects.

When we look at the program for worker protection, as we told you before, we kind of structure it in terms of four critical components: Effective prevention, improved ability to respond to incidents that do occur, the improved quality and usefulness of

information that's available on incidents and occurrences and to then utilize that information effectively on two tracks, one internally to make improved risk management decisions if we see some patterns or trends of levels of activities that helps us make better judgments in terms of our risk assessment and risk management processes, but almost as importantly, to make sure that that information's available in a usable fashion for all of the other interested stakeholders because the educational component is something that's very valuable, but also in terms of just program status, accountability and measurement as well.

So, those are the four major areas we try and bin things into when we look at our program management.

In terms of the strategic approach to how we move on these activities, some of the principles of using that additional fund was, again, to build on existing foundation and activities, to start new things that may

be enhancements, but not to start brand new areas. Obviously, to maximize risk reduction when we target the use of the funds, but also to advance all four of those different components because we think the combination of them is what achieves the protective safety net that we want out there in the field. Then, also, since it's kind of a short-term cycle of funding, to try and get some near term results out of that investment of money there.

What we've done -- this one is difficult to read. You've got the handout there, but this is just to try and give you a sense of two things. One, that we're trying to do some life cycle planning over the five-year window of the PRIA funding here and to distribute it over those range of different activities. You've got the -- at least on this page, you've got two of the large headings. On the next page of the matrix, you'll see the other ones.

What you've got here is that you've got, for

example, in terms of prevention and safety training, the notion in terms of the training element, but also the hazard communication elements as critical functions that are necessary to improve the prevention aspect of it, recognizing that you're not going to be able to prevent everything. Then you've got the response aspect so people can, once there is a potential incident or a real incident, they can have better treatment in a more effective manner. In that type of area, some of the emphasis that we've got on enhancements is in terms of the health care providers, making sure that they've got the materials necessary to do the appropriate things, but also that they can be aware of the potential incidents and those things, and we've got a couple of different activities that are involved there that would provide, again, strengthening those types of things.

You'll note that in some of these cases, it's kind of like a fixed funding over that five-year cycle.

In others, it's spot funding. That, again, goes to the notion of what the type of output is that we're trying to achieve as a result of this funding.

This one would be the sound data and the information/dissemination type of aspect of that. The credible reliable information on occupational incidents. We're trying to strengthen the database using the sensor database of information through the NIOSH project to expand the coverage of that to get a representative sample of potentially impacted agricultural workers, and then to utilize that information in terms of some of the -- the bottom one of better information on what the agricultural workers are. We've used that for a long period of time. That's to try to expand and enhance our information on those particular areas there.

I guess the point I would make on this type of stuff is now that we're in the second year or going into the third year of this funding, we think we've got a good

handle on it in terms of the funding mechanisms that we're going to be using, which is why we did some life cycle planning, so we didn't have to have downtime with getting that money out in the field. We expect to, hopefully, start seeing some of the results of that in terms of tangible products, but also in terms of improved understanding and education.

For example, the work in terms of hazard communication in terms of the Spanish Language Radio Network would be something that we think would be something that would be valuable in the real term. The HAZCOM communication area, we're putting pilots out there that this year will be in the field to test what's an effective means to reach the target audience and then what are some of the downsides, what are some of the benefits that we can use that may potentially be rolled into a regulation or may potentially be rolled into the field practices in the not too distant future?

Any questions on that update?

UNIDENTIFIED FEMALE: I have a clarification. What are the units in these charts, these tables, these money tables again?

MR. JONES: Hundreds of thousands of dollars.

MR. DIAMOND: Right, those are hundreds of thousands of dollars.

UNIDENTIFIED FEMALE: Times everything times 1,000, okay.

MR. JONES: Thousands, thousands.

MR. DIAMOND: Thousands of dollars. So, it's 400,000, for example, under that first one.

(Laughter.)

MR. DIAMOND: Our budget's going the other direction, so you're right. If it is, I've got some more expenditures I can make under these things.

Anything else?

DR. AMADOR: Bill, can you expand on the

training for farmworkers? The AFOP and AmeriCorps, are those the only ones that are doing the training? Is that where the money's going for or --

MR. DIAMOND: Back it up one. In terms of the first one, AFOP and AmeriCorps, those are the ones for -- it's one of our primary mechanisms to train farmworkers, train the trainer type of things, out in the field in terms of materials development, but also training delivery, and we've had a long-standing relationship with these parties in terms of their effectiveness to reach these people, and what we're doing under here would fall under the real category in terms of enhancement as was intended under the PRIA investments of quicker development of needed materials, expanded use in terms of targeting certain audiences.

DR. AMADOR: Well, where do the universities come in on this part here, training?

MR. DIAMOND: Excuse me?

DR. AMADOR: The universities, where do they come in?

MR. JONES: Jose, could you use the mic?

MR. DIAMOND: Under the first one there?

DR. AMADOR: Yeah, under the first one, where do the universities come in? Do they work with AmeriCorps or --

MR. DIAMOND: No, I don't think -- that's a direct grant to those organizations.

DR. AMADOR: Just to only?

MR. DIAMOND: Yes. That's not just a representative, so that's different.

Amy?

AMY: If you look at the summary sheet that AAPSE prepared in our report, there were 614,000 farmworkers who received training from PSEPs. Many of the states don't target farmworkers as one of their primary groups, but we do -- most states do train them

along with the other members -- the other groups that we train. So, we're not in that up there. Any training that we do of farmworkers comes outside of the EPA funds and is supported by state funds or registration fees or other fees that we bring in, grant funds or other fees that we bring in. But we do do farmworker training.

DR. AMADOR: But do you work with these two groups? You don't work at all with them?

AMY: Sometimes we do, but in a limited -- I mean, in our state we have -- both Mary Ellen Setting and I have worked with the AmeriCorps folks, but in, I would say, a limited setting. In other states, they may not.

MR. DIAMOND: This is clearly just a piece of the puzzle. What we're representing here is just the PRIA dollars that are invested for clarity. We've had other charts that try and mesh how it meshes with the rest of the program, but it's a little too busy to put up

here.

We've got base investments in all of these four areas, so this is truly an enhancement on top of that, and as Amy legitimately said, we've spent a lot of time with the group that came up with these recommendations trying to explore the practice and the reality that you've got a whole network of a lot of different providers for training for the certified applicators, but also to reach this group and we're trying to make sure that that meshes smoothly so we're not, one, being redundant, but we get the best efficiency out of the total contribution of everybody.

MR. JONES: All right, thanks, Bill.

MR. DIAMOND: We'll get into the third area of the -- National Assessment and Regulations, and we've got this on a separate file here, but let me just get started given the late time here.

Basically, to shift gears and spend a little bit

more time in terms of the worker safety activities, worker safety defined broadly as both the certified applicators and the agricultural worker protection programs. Last spring, we issued a report about our recent efforts to identify progress and gaps in those programs that had been developed over a number of years, and targeted areas for further exploration -- exploration in terms of both activities, training, education, but also rulemaking.

I wanted to focus in terms of here of what we're thinking about in terms of the potential scope and time frame for rulemakings, but I wanted to run quickly through a couple of slides that sets it in the context so people don't think of it as it's outside of our program. Just like the previous ones, we've got a -- this is one component or one plank in terms of the entire program that we're doing here.

This chart basically describes the breadth of

the program, activities when we're talking about worker safety. I think we don't have to spend much time on it, it does cover a bunch of things from our containment activities and storage and disposal to our traditional competency of applicators and minimizing exposure of occupational workers.

When you look at the activities, what we try and look at is all of the available tools, not just the tail end of it, the field component, which is what a lot of people think about in terms of how do we appropriately mix this blend of tools to try and address the different forms of risk, everything from adequate risk assessment, risk management, labeling activities, risk mitigation, what we think of as the field component, training, front line flexibility and some feedback, and then what we think is an important component as well is the individual activities, the citizen protecting themselves through understanding and making informed judgments, the citizen

being anybody that's the end exposed population there.

If you look at this, this is just a brief graphic or shorthand. What we have here is we've got a whole range of potential risks pathways that we've got to deal with and address and we've got that range of tools that we try and look at that from risk mitigation, individual actions, rulemaking and other activities that try to collectively protect a different range of populations. When we're talking about worker safety, we're clearly talking about the agricultural workers and handlers, we're talking about the pesticide applicators, to protect themselves, but as a vehicle, also, as a secondary benefit to protect the general public and vulnerable populations.

What we're trying to do with this program and our activities collectively is -- if you'd go to the next slide -- this is the rest of the components. Okay, we can move on to that one. Is to try to appropriately

expand that range of protection utilizing all of those different tools so that we have the right balance for all of those populations and get them the right protections that are part of our mandate, but part of the program already.

The background in terms of when we're shifting more to just the adequacy of the rules, start with what's on the books now, the Agricultural Worker Protection Rule was promulgated more than 12 years ago now. So, it's been out there for a period of time and it's time to try and take another look at it.

The Applicator Certification Rule is part of that protective web. It's been on the books for more than 30 years without an update. So, that's the base there and it's been a long time for both of those.

We think it's timely to review the adequacy of those rules in the light of both today's condition, but also today's information that's available in terms of the

effectiveness of those activities, but also in terms of the changing circumstances and what -- the process that's been in there for a number of years is that we've been looking at some of those activities and that we produced a couple of reports last spring that kind of summarized the complete suite of what people looked at and some of the recommendations that were potential there.

If you look at the next slide, those reports identified a number of things that were going well with both of those programs, but a number of potential deficiencies that needed to be addressed, and regulatory changes was one area that we were charged with exploring for filing some of those gaps. I'd note that in terms of some of those areas, that we're now plowing new areas, that some of the states, particularly, have taken extra steps already to fill some of those perceived gaps, and we think that that can provide us information, lessons and models for our consideration as we move into the

regulatory arena.

In terms of the next slide, some of the principles that we'll be looking at, it's the same we do for any regulatory development. We'll be following our standard goals and principles. In terms of openness, transparency, trying to move quickly through the regulatory process, but also to allow enough time for meaningful input from all the interested stakeholders.

I want to hit now in terms of just the specific areas that we're going to try to be looking at as we initiate the rulemaking consideration here. I'm not going to hit everything. If you've read the report that we issued last year, you've already got a flavor for what's on the table, and what we're doing now is deciding what's realistic to be on the table and then how do we translate that into specific regulatory provisions to meet the goals I discussed earlier.

Here's just one example in terms of the

applicator certification of competency that was identified as part of these things, the thought in terms of under the supervision provision that we've got in the rules there. The original intent of that was to provide adequate supervision for the safe application of pesticides by people who are not certified at this time. What you've got in terms of practice out there is that it's probably not fulfilling the goal about how it's being practiced in the field.

You've got some potential there for employees using restricted use pesticides, for example, that under the current regulation, a company with maybe 500 employees can all apply that pesticide under the supervision of a single certified applicator. That ratio probably is behind the scope in terms of guaranteeing that that protective part of the program is fully in effect.

Another one is the notion in terms of what does

under the supervision mean. A lot of is, in practical common sense, means somebody is there in real-time to be able to do something. It varies. We've got one state that's been identified that the under the supervision can work if the person's up to five hours -- within five hours of the site of application, 150 miles away. That probably stretches the definition of what effective supervision is, and that's a gap that we probably ought to address. I'm not targeting this as just the only one we've got there, but we think there probably can be improvements in terms of that type of thing, just as an example.

Another type of example in terms of the competency that we're trying to get at is do we have the right scope and coverage in terms of the people who are handling potentially harmful materials here, should they have certification and training requirements here? For example, in terms of -- there's pesticides that are used

in schools, for example, here and that right now there's no nationally required certification of competence, whether it's training requirements, testing requirements, to ensure that that particular avenue of risk is assured that you've got the right people handling those materials in the right way.

Dealers are another area that people raised on the table for us in terms of they utilize, they handle a lot of these potentially high-risk pesticides. Half the states now have some requirements in terms of them being certified as competent. That's an area that we ought to be looking at and exploring in this exercise here.

When we look at applicator certification, the types of broad areas that we're looking at for potential exploration for regulatory changes here are basically to ensure that those who have -- present a potential risk in terms of -- to the public, have basically a standard set of training, competence, materials, whatever, to ensure

the adequate level of competency, and in other areas, it's basically just raise the competency standard appropriate to the level of risk. Those are kind of the principles we'd be looking at in those areas.

The other area would be to try and look at national consistency and improved program administration for efficient, cost-effective use of government resources. This would be the types of things in terms of accountability and standardizing some of the categories that people are certified in to, again, get some of the benefits that are out there.

Shifting to the worker protection side, we're going to be trying to develop two parallel sets of rulemakings, and at the same time, they would be two things that are moving through the pipeline, but distinct regulations, distinct Code of Federal Regulations processes. We think there's enough overlap there and commonality of interest to move them through the process.

Just procedurally, it helps us somewhat in terms of moving them in tandem as well. If we have to break them apart because of the nature of the issues, we will, but right now, that's what our thinking is to start ahead of this type of thing.

Shifting to the agricultural worker side here, similar examples of some of the potential deficiencies that were identified that might be addressed through regulatory activities, some of the ones we've got identified up here. The nature of the risk information that's available to agricultural field workers is not specified now. This would mesh with some of the type of stuff we talked to a little bit earlier about the use of some of those PRIA dollars to identify what is effective, hazard communication, what's information that's valuable and meaningful and then what's the delivery mechanism to do that. That would feed into this process as we move ahead here.

Also, and then meaningful training. What is meaningful training? Right now, there's a requirement every five years to have a retraining. We think that that's -- given the turnover in terms of the worker population, in terms of the types of information that's --

(End of Tape 4, Side A)

MR. DIAMOND: -- of training to be effective to achieve the public health protective goal. And then just the bottom line administrative type of improvement there is if you're reading through that worker protection regulation itself, it's very complex. It doesn't communicate well. That may not be important in terms of the people in the field who are not going to be out there reading the regulation, but certainly the people who have to try to implement it, understand it, and then carry out its protections. So, one of the areas we're going to be looking at is to try and simplify and make it clearer and

make it more user-friendly to the people out there to, again, enhance the level of protection through better understanding.

Some of the areas that we've be looking at are regulatory changes and, again, some of the other areas are increased training, better materials, this would be the regulatory component of it, is to identify what would be the parameters of effective information that are needed to allow self-protection there. Simply some of the complex regulatory language so it's better to understand, and then, again, improve the administrative aspects of the worker protection program to ensure cost effective things in terms of -- there's some potential savings there that we can take advantage of, state plans for worker protection that are already on the books out there.

That's the scope. You get a sense for what we're talking about here is parameters because we haven't

decided, here's the specific provisions of how we're going to be doing this forward. I'll get to it in a minute in terms of how you might get involved in this process.

The current process to kick off the rulemaking schedule was started earlier this year. When we finished up those reports, we moved quickly to start getting the -- it in the queue for regulatory development. You've got a lot of overhead and paperwork to just tee it up.

In June, we did our first draft of the regulatory blueprint, which defines the scope so people inside the agency can understand the potential reach of what you're looking at. In September, we went through a tiering process which says, what level of scrutiny does it have to have inside the agency? There's three tiers. This has been tiered, both of them, as a tier two, a lot of important issues, large potential impacts, but not the highest or the lowest type of tier. It basically is how

many people inside the agency are interested and want to play in this rulemaking?

Now that we've been tiered up, in November, we'll identify who else in the agency would be participating, specifically representatives from the usual cast of the characters, research and development, our enforcement colleagues, our general counsel. Regions and states would be probably participating along with tribes on that workgroup to develop our internal drafts and considerations.

We'll be publishing in the November reg agenda the Federal Register Notice in terms of the projected time frame for what we'd be moving ahead on this, and the first critical step would be we're looking to have a proposal in the spring 2007 time frame for both of these rules.

The last thing here is that what level of engagement the PPDC would like to have in these rules.

There's been a high level of interest in terms of both of these areas over the last couple of years. We think that it's probably appropriate, similar to some of our other rulemaking activities that we have a PPDC subgroup on worker safety, on these rules that's self-selected, and the process would be the same that we've worked through some of these other things.

Unlike -- we don't think this is kind of like a registration review example where we had people from the git-go involved with that rule package because there was truly a rule package that came out of the need to develop a program. All of the work that's been done over the last number of years with broad stakeholder engagement and a lot of public participation and outreach, we think we're already beyond that. So, we think that the model is more in terms of we've got some concepts now, what does the rule, itself, have to do? So, it's not brainstorming, it's more with these issues, how do we

move forward?

That would be information exchange at critical points and then input at critical points when we have particular early drafts of rules, for example, and then, obviously, the standard notice and comment under the Administrative Procedures Act. And then even if we -- whether or not we have a subgroup on these rules, we would have something where we'd have regular updates if people are interested to the full PPDC. And I guess that's what we'd like to throw out for you. Does that process make sense? Is there any interest? What the level of interest is? And if so, then we'd be inviting interest expressed over the next couple of weeks to us because we are going to be starting to get started on this.

If we go to just the last slide, for people to get back to Kevin Keaney, who will be running this out of his organization, or myself, in the next month or so to

express interest in doing that. So, I guess we'd throw it open now to either questions on the scope issues or the process type of issues. Bob, I'll start with you.

BOB: You know what, I apologize, I think there's probably not any organization that probably supports what the agency has done to enhance certification and training more than NPMA. I think we've twice successfully lobbied the U.S. Senate to pass legislation to require training for anybody who applies a pesticide in a school, have actually sort of succeeded in getting language in FQPA that later got watered down that defines maintenance applicators and service technicians, with the goal of having the requirement that those people be trained.

So, I say all that as a prelude to say that I slightly object to the use or the citation of the study about the 25 children over a five-year period. I think that was -- I think anybody that looked at that study

closely would arrive at the same conclusion, more or less. Trying to use that statistic as a basis for further regulation is, in my opinion, well, not a good thing for the agency to do. It was 2,500 children that had reported -- there were reports to poison control centers over a five-year period of which 90 percent plus were asymptomatic. I mean, the numbers weren't especially compelling out of 66 million school kids.

My only point is I just -- we don't think that's a particularly credible study and wish the agency wouldn't use that as the basis for justifying expansion of training requirements for people to make application of pesticides in schools. We think that's a good idea to expand those and we support it fully, we just wish you wouldn't use that study.

Secondly, we'd love to participate, and I think most applicator groups would love the opportunity to participate and continue to participate in what you're

doing.

MR. DIAMOND: Okay, Becky?

MS. FREEMAN ADCOCK: I guess on your structure for the evolution of the rule or the process, I was just wondering if you could describe where USDA is involved and at what point, and also, I think, yes, I know my organization would be interested in participating, obviously, in a subgroup through PPDC or whatever venue you think appropriate.

MR. DIAMOND: All right. We worked closely, obviously, with USDA on this and we plan to work closely with them in terms of throughout this process. That's both in terms of our developmental work -- we anticipate that USDA would be part of the initial workgroup and then, obviously, as part of our rulemaking process, as you know, they get formal reviews at critical junctures of proposal and final. So, it was an oversight if we didn't list them up there. We don't -- we plan to have

them there.

MS. FREEMAN ADCOCK: I was assuming that they'd probably be in the November meetings because it would probably help you head off a lot of things that, you know --

MR. DIAMOND: No, we think that's a valuable thing and we anticipate that, yeah.

MR. JONES: Julie and then Allen and then Amy.

MS. SPAGNOLI: I guess just a clarification on scope and I remember working with Bob on that school legislation. I think one of the things that clearly came out of it in looking at scope was, you know, how are you defining a pesticide that's subject to this? I think -- you know, they, clearly, in that legislation, did not include disinfectants as being subject to that. I guess looking, also, at the definition of a pesticide, dealers, are they looking at, you know, every 7-Eleven just because they might, you know, have some toilet bowl

cleaner or something in the store? So, you know, I guess -- I'm not saying that there's not some efforts that should be underway here, but I think you, obviously, have to very clearly define the scope.

MR. DIAMOND: Yeah, we appreciate that. Some of the issues that were discussed, obviously, over the number of years in terms of we're not trying to have a blanket, everybody, everything, and we're not going to try and start from scratch some of those discussions that we've had over time that have informed our judgment. And, also, maybe I moved through it too quickly, we're looking at knowledge as the scope of potential coverage of users and what makes sense to require versus how broadly you go, but also that you wouldn't require the same levels of certification or training of whatever would come out of there to try and tailor something that's appropriate to the potential risks. Not all of these things would require the same things as restricted

use pesticides, but on the other hand, maybe some minimal improvement. So, those scope issues are critical to defining not just the rules, but the outcomes of what we try to do.

MS. SPAGNOLI: And I think that's good. I mean, just for janitorial workers, I think there's good basic training that should be -- that, obviously, is different than for restricted use pesticides.

MR. JONES: Thanks. Allen?

ALLEN: Thank you. I think our industry -- I think you'll find the supplier industry, especially on the non-agricultural side, extremely supportive of what you're trying to do. I would like to reemphasize what Bob said about the study that was cited. We will actually be taking some more direct action relative to communicating with the agency on the inadequacy of that study and its many, many shortcomings. We were disappointed to see that the agency has even given it the

light of day so far. So, it was just a bad study that shouldn't be used for any purpose in our view. And so, we'll be sending some further information to the agency on our viewpoints about that study.

MR. JONES: Okay, Amy Brown and then Amy Liebman and then Melody.

MS. BROWN: How will the certification and training advisory group process fit into this stakeholder -- the new PPDC workgroup and what will be the connections and how will things we --

MR. DIAMOND: Well, we've obviously worked closely with that group in terms of getting to this point. We expect to continue to use that as a venue, just as we would this, as we try and develop and refine ideas.

MS. BROWN: Well, I'll certainly be happy to volunteer to be on the PPDC subgroup.

MR. JONES: Amy Liebman?

MS. LIEBMAN: I would like to volunteer, too, to work on any subgroup. I also just wanted to -- you're doing a lot of work on this, so thank you. But I wanted to just mention some things that I think are missing from here, and I do -- I'm an educator, I'm a trainer, I do believe that training is the cornerstone to effective worker protections. But I would like to see a lot more language about enforcement and reporting in here. That is also as critical as training. So, the reporting needs to be happening on a number of levels, and I say this at every meeting, but it needs to be said again. We need a national reporting system for pesticide exposure problems. Then the enforcement part about that is just as critical as any training's going to be. So, please get that back in there.

MR. JONES: Thank you. Melody?

DR. KAWAMOTO: I'd like to volunteer for the subgroup, also. I think what Amy said about the

reporting is really important because, at this point, you know, as Bob's concerned about the accuracy of the data, I think without such a reporting system and I think there's a lot of under-reporting, that we won't really know what's out there. So, it's really important to consider that.

MR. JONES: Okay. Mary Ellen? Thanks, Melody.

MS. SETTING: As a state lead agency for pesticide regulations, I agree that a PPDC workgroup on this issue would be appropriate and I would certainly like to be a part of that. I think you can use a lot of the models already provided in state regulations for enhancing some of the federal programs. We're looking forward to have the federal regs be brought up to the standard that many of the states have had in place for a number of years.

MR. JONES: Thank you. Jose?

DR. AMADOR: I'd just like to second what a lot

of people have said. I think this is very appropriate that we look at where we are on the farmworker training part of the program. In my own state, it's being done, but I don't think it's being done with the intensity that it was done in the past, and I'd like to volunteer, too, for the subgroup.

MR. JONES: Thank you. All right, John, you'll have the last word on this topic.

JOHN: I just wanted to -- I'd repeat what some folks have said and just sort of add our support for the JAMA studies, just to put it on the record that the PPDC was not universally opposed to the agencies in that study, and until we have a sufficient reporting mechanism, I think that's one of the better things we have. So, we need to reinstate an incident reporting system.

MR. JONES: Okay. We are now going to move on to a very related topic. A number of you have, over the

years, frankly, asked me, asked us at the EPA to please invite our colleagues from the Enforcement Office. OECA is the acronym we use in the EPA. So, we did and they have been gracious enough to agree to participate in this meeting. We are quite fortunate that just a few days before this meeting, a report that many of you have been waiting for for some time was released by that office. So, not only are they here, they're on the agenda.

So, Jack Neylan from our Office of Assurance and Compliance -- Enforcement and Compliance Assurance is here.

MR. NEYLAN: Yeah, that's a mouthful. When Steve Johnson suggests you come to these meetings, I guess it's a strong incentive as well.

MR. JONES: Who?

(Laughter.)

MR. NEYLAN: In your package, you should have the full program review report. I don't have a

PowerPoint because of the late signing of this and coming to this. This was a review of the Worker Protection Standard Compliance and Enforcement Program, which was basically spurred by kind of two events, I guess, to some degree.

In 1998, the Children's Health Protection Advisory Committee issued a report that suggested that it was time for a review of the Worker Protection Standard, and then in 2000, what are they called now, the Government Accountability Office also issued a report that suggested that, among other things, that there should be improved oversight of the implementation of the Worker Protection Program.

So, I guess coincidentally, around the same time, the agency was looking at reviewing various programs, and because of these two things, it sort of popped up high on the radar screen for a review. So, we started one. The review was done by a person in OECA

that was not connected, in any respect, with any of the Worker Protection Program, a fellow by the name of Dan Palmer.

They basically set a couple of goals, I guess, early on. One was to assess the effectiveness of headquarters, regional, state and tribal efforts to ensure compliance with the Worker Protection Standard, and also to assess our efforts at implementing the Worker Protection Standard.

The review began in 2000. It continued through 2001. The review process, itself, was fairly complicated. In the appendices, there's some information about how the review process was supposed to be conducted. It's got information about when different regions and some states were reviewed and so forth.

There were various review teams. They were composed of headquarters, regional, state or tribal people, and all that's in here.

The review, itself, when you read it, suggests that -- came out with basically seven general findings and recommendations. I'll just read very carefully. One was we needed a clear strategic vision for this program. I'm talking again about the compliance and enforcement program. Accountability at all levels should be improved. Communication between EPA and states and with workers and growers should be enhanced. More training for co-regulators was needed to enhance implementation. Better information for measuring the success of the program was needed. The level of and the utilization of resources are issues that are hampering implementation. And last, implementational levels should be strengthened, from headquarters all down through the states and tribes.

If you -- when you read the report, you'll see that some of this is echoed in the National Assessment that the Program Office did as well, so you'll see some commonality between the two.

Now, as you can see, there's been some time lapse between when this review was done and when this report was signed, and one of the other things we've decided to include in there is something we're calling progress since the review. So, you will see, following a lot of the findings and recommendations, some things that have happened in the program that we've done to try and address the findings and recommendations, because we were relatively well-aware at some point along the time, where this report was sort of showing the need for some program improvement. So, you'll see that.

Now, we're looking at this, along with the worker safety thing, to kind of go and start improving the program, and one of the first things we've done since -- or most recently, was we met with a number of the state pesticide regulatory managers the week of September 12th and we're starting to begin kind of looking at this report and developing a strategy and an action plan to

implement these review recommendations. So, we're kind of looking to the future and seeing what more needs to be done to move along.

I think a lot has -- as you'll see when you look at some of this, a lot has happened to -- in terms of improving things. But, obviously, I think that probably still more needs to be done. One of the things is probably getting some better measures of success in this program, which is one of the things we're lacking.

MR. JONES: I appreciate it, Jack. I know the report just came out, and although we made efforts to get it to you, you may not have had an opportunity to digest all of it. But if you have any questions for Jack, this would be a good place to start. I expect that this is an area that we'll probably come back to at this meeting as the agency and its co-regulators have some opportunity to do the kinds of things that Jack just described. This certainly won't be the last opportunity.

MR. NEYLAN: And I'm sure some of this will feed into the efforts at rulemaking.

MR. JONES: Right. So far, although I didn't make an announcement, so I'm going to do it now, no one has signed up for making public comments, but since I didn't make an announcement to that effect, you wouldn't have known what to do. So, if there is anyone the general public, outside of the committee, who would like to make a comment, you just make yourself known and we'll -- okay.

All right, well, very good. It's been quite a day here. I know I need some time to digest the many things that I heard over the course of this day and I'm going to start my evening by spending an hour on a soccer field with a bunch of eight-year-olds coaching.

(Laughter.)

UNIDENTIFIED FEMALE: Jim, may I make a suggestion on the process?

MR. JONES: Yes, please.

UNIDENTIFIED FEMALE: I wonder if, instead of leaving the public comments to the very end of the day, especially when we go late and maybe people can't stay, I don't know, if maybe just maybe three times, maybe like before each break, before lunch and maybe after. So, we could just do like a five-minute option (inaudible).

MR. JONES: Okay.

UNIDENTIFIED FEMALE: And just make them shorter, but more often.

MR. JONES: I think that's a good idea. All right, we'll try that.

Amy?

AMY: If we're making general comments for the future, could I make a plea for a list of acronyms? You know, I actually do know most of them, but sometimes I get confused. I think there are some people who don't.

MR. JONES: Sure. We should, on our part, try

very hard to avoid acronyms and when we use them, to follow them right away with what they mean. And then if, on your part, you could help enforce that and call us on it when we use it, it's -- they're pervasive in this town. It's very hard for people to understand.

So, with that, I think we are wrapped up for today. We're going to return tomorrow, I think 9:00, Margie, is that right? Is that our starting time? 9:00 tomorrow.

It is important to take any valuables with you, but you can leave the papers here. They're very valuable, but they can be replaced, and we will have replacements. But anything that you don't want taken that we can't replace, which would be anything other than these papers, please take them with you. I hope you all have a good evening and we'll see you tomorrow morning.

(Whereupon, the meeting was adjourned.)

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Transcriptionist

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Pesticide Program Dialogue Committee

Georgetown University Conference Center

3800 Reservoir Road, N.W.

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Washington, D.C.

October 20-21, 2003

Day 2

ROSTER - PESTICIDE PROGRAM DIALOGUE COMMITTEE

Jim Jones	Director, Office of Pesticide Programs, OPPTS, Chairperson
Margie Fehrenbach	Designated Federal Officer, OPP
Lori A. Berger	Ph.D., Director of Technical Affairs, California Minor Crops Council
Robert Rosenberg	Director, Government Affairs, National Pest Management Association, Inc.
Bill Tracy	National Cotton Council of America
Rebeckah Freedman Adcock	Director, Congressional Relations, American Farm Bureau Federation
Dr. Steve Balling	Director, Agricultural Services Del Monte Foods
Carolyn Brickey	Executive Director, Protected Harvest
Erik Olsen	Senior Attorney, Natural Resources Defense Council

ROSTER - PESTICIDE PROGRAM DIALOGUE COMMITTEE

Michael Fry	Director of Pesticides and Birds Program, American Bird Conservancy
Amy Liebman	Environmental Health Consultant, Migrant Clinician Network
Troy Seidle	Director, Science Policy, People for the Ethical Treatment of Animals
N. Beth Carroll, Ph.D.	Senior Stewardship Manager, Syngenta Crop Protection
Allen James	President, Responsible Industry for a Sound Environment
Stephen Kellner	Senior Vice President and General Counsel, Consumer Specialty Products Association
Dr. Hasmukh Shah (Day 2 only)	Managing Director, American Chemistry Council
Julie Spagnoli	Executive Director, Regulatory Affairs, Clorox Services Company
Jay Vroom	President & CEO, CropLife America

ROSTER - PESTICIDE PROGRAM DIALOGUE COMMITTEE

Gary Libman	Vice President, Regulatory Affairs and Quality Assurance, Emerald BioAgriculture Corporation
Alan Lockwood, M.D.	Chair, Environment Committee, Physicians for Social Responsibility
Dr. James Roberts	Associate Director of Pediatrics, Medical University of South Carolina
Dr. Nancy Lewis	Associate Professor, Department of Nutrition and Health Science, University of Nebraska
Mary Ellen Setting	Assistant Secretary, Office of Plant Industries & Pest Management, Maryland Department of Agriculture
Dr. Jose Amador	Director, Agricultural Research & Extension Center, Texas A&M
Amy Brown	Coordinator, Pesticide Safety Education Program, UM

ROSTER - PESTICIDE PROGRAM DIALOGUE COMMITTEE

Larry Elworth	Executive Director, Center for Agricultural Partnerships
Dr. Robert Holm	Executive Director, IR-4 Project
Patrick Quinn	Principal, The Accord Group
John D. Schell, Ph.D.	Vice President/Toxicologist, BBL Sciences
Dr. Terry Troxell	Director, Office of Plant and Dairy Foods, CFSAN, FDA
Allen Jennings	Director, Office of Pest Management, USDA
Dr. Melody Kawamoto	National Institute for Occupational Safety and Health, Centers for Disease Control & Prevention
Jennifer Sass	(Portion of Day 1)
John Kepner	Beyond Pesticides
Frank Gasparini	(Day 2)
Maureen Serafine	New York
Nancy Golden	
Craig Thomson	EPA, Region VII

P R O C E E D I N G S

DAY TWO - OCTOBER 21, 2005

MR. JONES: Just a quick review of the morning agenda, which I'm going to do simply to buy a little time so you can get yourselves situated.

Okay, so we will start this morning with a half-hour update from the work group -- the PPDC workgroup on PRIA process improvements. Then we're going to spend an hour on an issue that, as I mentioned yesterday, over the last, at least, two years, maybe longer, numerous amongst you have asked that we spend some substantive time on, and that is spray drift.

Right before the break, I'll take Jennifer Sass' idea of having public comment for five minutes. So, there's a little bit closer alignment between when we're talking about an issue and people having an opportunity in the general public to give us some comment if they so choose.

We'll take a short break and then we'll come back and wrap up the morning with a little bit of administrative work associated with the renewal of our charter and membership of the PPDC and then our usual

planning for the next meeting. I've already identified a number of follow-up items from yesterday and I expect I'll be adding at least one from today that we can review at the end of the morning. And then, again, we'll have a short public comment process and we'll wrap the meeting up.

Just as a brief introduction around the PRIA Process Improvement Workgroup, this committee advised us soon after PRIA passed, probably in the spring meeting after PRIA passed, that there wasn't broad interest in participation in the PRIA Process Improvement Workgroup. However, you suggested that we have such a workgroup for interested parties, but again, as I mentioned yesterday, before the Agency got too far down the road with implementing these process improvements, that we would seek the advice of the PPDC, which we've been doing at each of these meetings. It tends to be a relatively short part of the presentation.

So, this morning, Marty Monell and, I believe, Greg Watson and Elizabeth Leovey are going to give us an update on where that workgroup is. All right, Marty?

MS. MONELL: Thanks, Jim. I'm just going to

briefly give you the background. This is the statutory provision in PRIA, the Pesticide Registration Improvement Act, fondly known as PRIA, that provides for the Agency to take a look at its processes in its registration activities, and to the greatest extent possible, to come up with some improvements that basically will enable us to make certain that we meet the time frames without harming, in any way, our risk assessment, risk management process.

So, that's sort of the purpose of this statute, to make sure that we have processes that are effective to bring home the registration actions.

What we have done and what we did do for the last PPDC meeting was to really look at each registering division and the science divisions and go through some streamlining efforts, and you heard at this meeting last spring, some of those efforts from each of the registering divisions. At the last PPDC Workgroup Meeting, we -- the members heard from the science divisions, as well as updating from the registering divisions. They heard from the science divisions on some of their efforts to better engage and more efficiently

engage in their scientific reviews. We will be bringing that information back to the next PPDC meeting. We thought that, for this PPDC meeting, we would focus on a couple of items that were -- on which we've done a lot of work and which were of major importance to everyone.

So, I'll turn it over now to Greg Watson, who has graciously agreed, on behalf of the workgroup, to do a little presentation, and I want to also reintroduce -- for those of you that don't know Elizabeth Leovey. Elizabeth Leovey is the Senior Advisor to the Office Director for PRIA implementation, and she's been doing this since Rick Keigwin left about nine months ago. So, I want to thank her very much.

MR. WATSON: Thank you, Marty. I also want to thank Marty and Elizabeth for their contributions to the slide set. So, I appreciate all the help in getting that set up.

The first priority that the workgroup decided to work on that was an issue statement or problem statement that came both from EPA, as well as the Industry FEE Coalition was the labeling. I guess that shouldn't be a surprise given that labeling has been an issue under

discussion for quite a few years. In fact, there's some people in this room that have been involved in the Consumer Labeling Initiative to try to make labeling of consumer-oriented products more simple and understandable, and there have been PR notices over time. PR Notice 83-3 was actually a label improvement program. There were follow-ons from that in 84 and 87. So, again, it wasn't really a surprise that this was an area of interest.

After a lot of discussion within the group, OPP moved to establish a Labeling Committee. That will be a standing committee that represents or have representatives from the registering divisions, which are, of course, the registration division, the anti-microbial division and BPPD. SRRD is also represented, as well as FEAD. Again, that makes perfect sense given FEAD's alliance to the states. And the enforcement and compliance is also a needed component of that group because, again, labeling obviously has strong linkages to enforcement questions, as well as compliance with FIFRA and, again, hence the involvement of OGC.

I think it's important to recognize within this

labeling team that it's not the intention to concentrate on product-specific items. As is pointed out here, the purpose is to look at labeling policy and not specific examples within products.

And I think that the other part of that is also the intention for internal as well as external communication and we'll mention that again as we go through -- particularly as we talk about the Label Review Manual.

One of the charges, the first component, again, as I just mentioned, was the Label Review Manual. That actually is posted on EPA's website. This is really the most comprehensive document that's available both to those within OPP that are responsible for working in the registering divisions, as well as for the registrant community. So, it was seen to be, not only by the label team and the FEE Coalition and the PRIA WorkGroup, as a very important document and one that needed to become living or evergreen. So, it's, again, an important part of the effort.

As you can see, a website also will be established within the plan and that will be, also,

again, a way of communicating decisions to the registrants, as well as general public. There actually is already a database that is a conversation point between the state regulatory authorities and the EPA called the Slits (phonetic) Database, and that actually has been recommended by the FEED Coalition as a place where we could look for further items for the OPP Labeling Committee to look for for other things that need to be worked on.

Just to give some more concrete examples of what the Labeling Committee has been working on, you can see the list there, and again, the underlying theme is an emphasis on non-product-specific questions.

And, again, to do the list the converse way, there's also a list of things that are -- the Committee is not going to be working on. I think, again, the key emphasis here is if there is a product-specific issue that has arisen through a registration decision, that the intent is that that would still remain within the appropriate registering division, and I think that's an important component. However, I think it's also important that the labeling team provide a framework in

the guidance that they're working to provide so that there will be a consistent approach on -- when there's, again, these general issues that -- so they can be -- again, set the frame. And, again, that's mainly consistency and a fairness issue that's trying to be managed.

Some logistical information about the work the group is doing. These are really some of the operational things. To set an internal procedure document, the establishment of an email box where questions can be posed to the Committee, and the website for the, as we mentioned, the two-way communication. The website name even is actually named after a website that exists within BPPD and, again, that is -- seemed to be the best working model. And, again, the approach on the Labeling Committee has been not -- in terms of the Label Review Manual, has, again, to create a separate subgroup that will work on, again, keeping that -- the Label Review Manual up to date.

Again, some examples of the specific label language. Part of the important questions as a point of sometimes controversy is mandatory versus advisory label

language. To give you an example, a mandatory statement within -- as it's defined within PR Notice 2005 it uses words like "must" or "shall" in its recommendations or its statements on labeling.

Advisory statements seem to be recommendations. So, for example, if a product label says, you must apply this product using nozzle XYZ, that's a mandatory statement. If the label statement is we recommend that you apply this product using nozzle XYZ, then that's an advisory statement.

However, it's always not that simple. If you have -- there are several statements on labels that say "do not" versus the word "avoid." And, again, I think that's part of the issue that the Label Committee is trying to work through, is to get a little more clarity there.

One of the components within that topic that is of interest particularly to industry is we've asked for consideration of a creation of labeling statements that will allow stewardship of products toward intended audiences or customers bases without going to a restricted used classification. Now, we recognize that's

a potentially difficult topic, but, again, it's important to industry to provide, again, a stewardship tool to make sure the intended uses of products are there.

The second area that is of -- that's, again, more of an issue is warranty statements, and these are placed on labels by the registrant and their real intention is to outline and state as clearly as they can, the liability limits that are intended for that specific product by industry. One of the reasons that's been an issue for us is that when you're doing product development work on a new product, you cannot do research that will cover all the agronomic and all these conditions regarding advocacy and expected performance of product. So, that's another area that's being worked on within the Committee.

Regarding next steps, again, the intention is that the next PRIA FACA meeting that will be held in January of 2006, or planned to be held, is to present the work that the group has made so far on the topics we've mentioned, and to come forward with the recommendations or -- that we have given from the industry side to the Committee, as well as the ones they've developed for the

Labeling Review Manual. And, again, the for sale statement there is, again, the aforementioned, we're trying to create this category that allows the use of stewardship for intended customer use.

Switching gears completely, that was a pretty quick overview of the work the Labeling Committee is doing, to another initiative that is being taken up within the framework of the Committee, and certainly, the cornerstone of PRIA is that there must be a complete application when it is submitted to EPA. Without that foundation, all the time lines and all the work and the registrant expectations cannot be met.

So, there have been some initiatives within particularly AD, or Antimicrobial Division, with industry that works on registering products in that area, and there also has been some work within BPPD.

There have been some discussions regarding the registration division. Our feeling is that within RD, the spectrum of registrants within that area is very diverse and that may require more dedicated thought and effort on the best way to provide guidance. For example, there are several companies that have registrations

within the registration division that have only one product in registration, as compared to R&D-based companies who have several hundred.

Another initiative that's being worked on within OPP, within the group or within the committee is the Blue Book, and you can see the title on that document. I have to sort of smile about this one because my version of the Blue Book -- I've been working in Regulatory Affairs for over 14 years and my copy is more gray than blue on the cover because of the many times it's been copied and xeroxed. So, I think that's a welcome initiative to try to look at the guidance and, again, it will be focused toward providing a complete application.

As far as topics for the next meeting workgroup, again that's planned for January of 2006, a key thing, as I think I've mentioned in previous presentations to this group, is to look at the next topic that the group needs to take up in earnest. Hopefully, you can see from the presentation that there's been a lot of work and effort and progress made on the labeling issue and we need to look at that now being more in an implementation phase, the next issues that we want to move forward on.

With that, I will close, and if there's any questions or comments from the floor, I will let Elizabeth or Marty answer them.

(Laughter.)

MR. JONES: Go ahead, Steve.

STEVE BALLING: In the discussion about labels and warranties, I'm wondering if the issue of liability waivers ever came up and whether that's appropriate to that particular discussion. And if it's not appropriate, then I would suggest to Jim and Anne that maybe we ought to have that discussion at some point.

MR. WATSON: It actually has been put as sort of a parking lot issue. For minor crops, and particularly within the IR-4 program, there frankly has been a lot more concentration on residue information as compared to product use. But it was felt because, frankly, some of the legal precedents that are now being established, that probably this should be parked there, okay, until we get --

STEVE: Well, it's being more than parked right now.

MR. WATSON: But, again, to have an OPP Labeling

Team pick that up as a topic until --

STEVE: True.

MR. WATSON: -- it proceeds further and there's more clarity --

STEVE: I see.

MR. WATSON: -- is probably something we said we need to know -- keep track of where it's going and what's happening, but to put it as a topic that we're going to put front and center, it's been the decision not to or recommendation.

MR. JONES: Sort of a related procedural issue is that the process improvements this group has been working on that are, to me, very clearly process improvements, I think you need a labeling committee, good idea, you should do it, you should help us improve applications, good idea, we should do it. The Blue Book needs to be updated, process improvement, ITIM, information technology, good. Getting into the policy resolution of some of the labeling issues I don't think is necessarily appropriate for the process improvement workgroup. I think we need to find a different forum for dialogue around the --

STEVE: No, that makes more sense.

MR. JONES: -- substance of any of the issues that then get identified by the Labeling Committee.

STEVE: But maybe we could add that to an agenda item for the next PPDC meeting.

MR. JONES: Erik?

MR. OLSEN: Yeah. I just wanted to raise a cautionary flag about that issue. It sounds like you're already raising it. But my question is, for warranty statements, I'm just curious, what does EPA do now for warranty statements that are placed on a label? Do you approve the warranty statement basically as part of the label?

MR. JONES: Where's our registering master?

MR. WATSON: I can answer for the registering. There actually is a portion of the Label Review Manual that provides direction.

MR. JONES: Greg, give us an example of a warranty statement.

MR. WATSON: Oh, gee, you don't have that much time.

MR. JONES: They're that long?

(Laughter.)

MR. WATSON: That's the Syngenta one in small print, okay? It takes up a full printed page almost and, yes, it is written by lawyers here. So, it's --

ANNE LINDSAY: Elizabeth could supplement this or update this, but I believe that, at least traditionally, the warranty statement is something that is typically drafted by the company who's seeking the registration and by their attorneys. I think when we're reviewing the label for purposes of assuring that it reflects the registration that we're likely to grant, we'll look at that warranty statement to make sure that there's not something in the warranty statement itself that would conflict with or undermine other portions of the label that have to do with use instructions, necessary precautions, that would cause a user to go astray in following the label.

If we're satisfied that the warranty statement is not going to cause those kinds of problems, I think we generally treat it as a statement that the company wants to make with regard to their product. So --

MR. OLSEN: I mean, in terms of liability, I

would think it's important for EPA to be somewhat hands off on that. I presume you are, but I was surprised to hear this was --

MS. LINDSAY: Well, that's why I'm trying to describe --

MR. OLSEN: -- raised as --

MS. LINDSA6Y: We're just looking at it to see that it's not accidentally conflicting.

MR. OLSEN: But you're not -- there's no implied endorsement of the labels by EPA --

MS. LINDSAY: No, no.

MR. OLSEN: -- when you review the warranty?

MR. WATSON: I think that's clear. And, again, the comments, if you look at -- as Anne has just described, that's exactly what the guidance that the Label Review Manual provides, and frankly, our comment, Erik, if you recall in the last meeting you attended from industry's side is this was clearly an issue that was in the hands of OGC, the folks that are on the Labeling Team that are doing that.

MR. OLSEN: Okay. I would just want to make sure that that was clear. One other question is this

idea of for commercial use only, not for residential use, for professional use only. Would that be enforceable if it's on a label?

MR. JONES: I think that that's why that's such a challenging issue. Some of those may be enforceable and there are other aspects of it that may not be, and that's what we struggle with in making sure that if we're going to do something like that, we do it in a way that is enforceable.

MR. OLSEN: Yeah. So, the question is, is this a substitute for restricted use or not? I guess I have an issue with it if EPA is going to assume that there's full compliance with, say, for restricted -- I mean, for professional use -- I don't even know what that means, for professional use -- but for professional use only. If EPA then says, well, okay, we're going to assume that it's only used by registered -- you know, by somebody that's actually trained, blah, blah, blah, and therefore, it's safe and allows a fairly risky product on the market or to continue being marketed, there is a statutory process for that, which is restricted use, and if the product is dangerous enough to require some kind of

training before you use it, et cetera, it would seem that you have an approach to doing that, which is the law, and that ought to be pursued.

I'm not discouraging companies from trying to be responsible in saying, you know, this product should have additional precautions. But once it's on the label, in our view at least, it ought to be enforceable.

MR. JONES: And I think we would agree with that last statement. If it's on the label, it needs to be enforceable.

MR. COLBERT: And from the enforcement -- primarily the states' perspective -- many of these aren't enforceable. They don't know who the class is that is supposed to be -- that sales are supposed to be limited to. So, that's one of the issues, is it enforceable? In terms of what the purpose of it is, from our perspective, I don't have the answer. I mean, there are restrictions on restricted use, but from the enforcement side is, is it enforceable, and some of these classes are not well-defined. Like you said, who is professional only.

MR. JONES: I will give you one example that we've been struggling with right now and it has to do

with the remediation of bio-contaminated facilities, as in the anthrax context. It's pretty clear that the kind of training that you would get as restricted use as a certified applicator is totally irrelevant. It's not totally irrelevant. It doesn't help you do that application effectively, and yet, you want people to be trained specifically in that kind of -- you know, how we decontaminated the Hart Building or how you decontaminated the building in Florida or the other post offices.

So, one of the things that we struggle with is, is there a way in which you can make sure people receive appropriate training for a VERY specific application that they're not going to get just by being a certified applicator, and that's something we're right in the midst of right now struggling with in the context of how would you potentially label something for that kind of a use? I mean, that was one example of what we're struggling with now.

MR. OLSEN: I think that's a really good question. It doesn't seem like that's a procedural sort of improvement issue.

MR. JONES: I would agree with that. Right.

MR. OLSEN: So, if we start getting into those, I think we need a broader discussion about that.

MR. JONES: No, I would agree that those are the kinds of things we need to sort of bring back into a broader policy kind of forum, like the full committee. Bob, I think you wanted to respond to something as part of that discussion and then I'll pick up.

MR. ROSENBERG: Well, we're not going to draw attention to the late arrivers again, are we?

(Laughter.)

UNIDENTIFIED MALE: You already did yourself.

BOB: I just want to respond to Erik and say that I have some experience with two examples of that kind of restrictive label language. The first, I think, time it was attempted was when the agency wrote its PR Notice 96-7 relating to termiticides, and then, again, with adulticide for area-wide application labeling. The issue was the toxicity characteristics of the products did not match the criteria for them being deemed restricted use products, but there were compelling reasons why they ought not to be sold to persons who were

not commercial applicators.

And in the case of termiticides, it was simply the difficulty of application, having to drill into holes and trench down four feet around the perimeter of a house.

I'd also say that there's been some mixed success with enforcement. In the case of termiticides, there were some pretty high visibility examples of, I think, Lowe's and Home Depot both retailing PCO Only products back in the nineties, and about maybe a third of the states felt as if they had sufficient leverage to enforce the label. And, actually, did --

UNIDENTIFIED MALE: Did they say PCO Only?

BOB: They say, I think, certified applicator. But, I mean, the intent was PCO. I would agree when we grappled with the issue the first time in '96, we probably didn't come up with the right set of words to create enforceable label language and think that it's worth taking another look and seeing if there isn't a better set of words that would give the states more unambiguous authority to do that kind of enforcement.

BETH: This is not necessarily specific to just

this, but it would be really nice -- I know you go up to the deadline on these overlays, but it would be really nice to have them in our packets prior to the meeting or available outside. There's a lot of information here, and I know you'll post it at some point, likely, but it just would be really nice to have them ahead of time.

MR. JONES: I agree with that. This example that -- it was the workgroup who was responsible for pulling these together, so yes, I think as a general matter, it's useful to have these things in advance.

Julie?

MS. SPAGNOLI: You know, Greg's saying about the Blue Book, and I think I really dated myself when we had that meeting and I brought up the mission statement from the original labeling unit and everyone -- how many people remembered that?

One of the questions that's come up with the group that's working on consumer labeling, we had a conference call earlier this week, is the real -- I think where we're at on the consumer labeling is we've come up against a lot of policy questions, especially with changing labels for environmental stewardship information

or safe use information. And so, we've sort of run up against some policy issues and I guess the question is, is now, how do we coordinate or where does this consumer labeling workgroup then go to the labeling committee, you know, with some of these policy questions, and that was something that came up just this week as to what that relationship -- again, because the -- we're not looking at the labeling committee as part of the PRIA Process Group. It's really a separate entity that's now been established to deal with labeling policy issues.

MR. JONES: Those are good questions and we need to think about how to integrate all of that.

MS. SPAGNOLI: Just as these things have developed.

MR. JONES: Yes.

MR. WATSON: Just to quickly follow up on that comment. That was exactly the original intention because the intended use pattern that's being requested in the application is exactly what you're trying to define on the label, hence the question. Again, I agree with the statements that it probably needs to move out of arena, but that's where it's started.

MS. SPAGNOLI: You know, just to add to Bob's comments. When I was with Bayer, with the termiticide product, one of our concerns was these products were showing up on these do-it-yourself websites and, again, the products really were never intended for just home application because of the special equipment that's required.

MR. JONES: Ray?

RAY MCALLISTER: I have a couple of points for clarification. As I've followed, kind of at a distance, this discussion about the professional application only, I think I understand that while we want to restrict the use to a certain class of applicators, that the definition -- the legal definition of restricted use -- doesn't quite fit the reasons why a registrant wants to sell only to a particular market. Is that correct? Is it a matter of the legal definition of restricted use and the class of --

MS. LINDSAY: I don't have perfect recall, and if Bill Jordan's actually around, he might do better with this. I think the statute gives us latitude to restrict products for a number of reasons, one of which is the set

of reasons that Bob articulated around toxicity. But I think, also, if we look at a particular product that's proposed for us and we look at it and say, this requires highly specialized knowledge, it requires access to equipment that you would never expect the homeowner on the weekend to be able to purchase, you know, because of cost, because of -- you don't even know where to go to get it. If you got it, you wouldn't know what to do with it.

So, if it's just a highly complex, very specialized use pattern that requires really significant training or if we have evidence of widespread misuse under current conditions of registration, and after examining that, we realize that the misuse might be related back again to the level of sophistication that the user needs to have and the level of equipment sophistication necessary, and that these misuses are causing significant either environmental or human health problems. We have the ability to restrict.

So, it's not a -- it's not totally driven by toxicity, although I think classically and historically we've looked at toxicity as sort of driving or leading

characteristics, so that if you've got something really highly toxic, even if it actually might be simple to apply, you just don't want people like me to have access to it for -- because of the possible consequences of misuse. So, there's a range of reasons you can restrict.

The other piece, though, that the Agency always has to think about in doing that is the point that Jim made earlier, which is if you restrict something but there are no training categories out there in the states and, you know, APSEE, for instance, may not have done training manuals for it or other kinds of training material, you can restrict it, but the applicators that then are eligible to use it are no more better educated or trained than I might be or -- I don't know if you're a certified applicator -- you might be. And so, you haven't actually achieved much.

So, when you're actually talking about restricting something for whatever set of reasons, you also need to be thinking about the sort of implementation in the field and do you have the wherewithal to achieve what you want. It's actually kind of an illustration of the issue Bill Diamond was raising yesterday and Marty

with our strategic planning, that the field program has to be integrated into the registration decision in order to be able to make it work.

MR. JONES: Ray?

MR. MCALLISTER: In a situation like this where this workgroup has discovered a concern which requires a policy decision at a different level than they're working at, and it probably requires some significant technical input that this group may not be immediately prepared to provide, but does need some stakeholder input, how would you go about resolving it?

MR. JONES: Well, I think we need to think about what would be the appropriate process for bringing resolution to it. Having watched this committee struggle with labeling issues before, I'm not sure this is the right forum, but whatever we do, it's not going to be divorced from having public participation. Like any kind of labeling issue that we've struggled with over the last 10 years, we're going to bring some public process to it.

So, in the back of my mind, I am thinking about the PPDC as the place, but I'd like to see this committee have a little more success around issues like that. We

do have the consumer labeling workgroup that I was about to pull the plug on at this meeting, but they were resuscitated just before the meeting, and so, we're going to give them a shot to show their stuff at the next meeting, and maybe you'll all convince me that actually these are the kinds of issues, labeling issues, that this committee would be effective at.

But we need to think of a forum to tee them up. It needs to have broad stakeholder participation and there needs to be broader public participation as well. So, I've noted that issue.

Michael, unless you want to talk about the process issues, which is what this ostensibly is about, I think we've clearly identified that there the process workgroup got a lot of good process moving forward, and stumbled into a policy area. We're going to make sure that we do not have the process implementation workgroup starting to resolve some of these policy issues. I think, once again, this showed the interest in this committee around substantive issues, although I really don't want to diminish the importance of this process improvement workgroup. I think they've identified a

number of very important issues that are strictly process that are going to make the process better and I'd like to see them continue down that vein. I think it's been pretty effective and would like to keep them plugging away at those kind of things.

Speaking of a substantive issue, as I've said a number of times over the last day -- thank you to the team who presented the PRIA process improvements, Greg, Elizabeth and Marty.

Spray drift is an issue that we've struggled with for a number of years in the pesticide program, probably since we've been a program. We've had a number of efforts in the last five years, which have been highly controversial. This committee has, as I've stated, repeatedly asked that we, as a group, focus on some of them. Now, I have the combination of the committee asking for some focus on it and my boss. That's a very powerful combination when the two of you line up together. And so, we are going to do some focus on spray drift and Anne is going to tee the issue up for us.

MS. LINDSAY: Okay. And I don't feel at all squeezed between a rock and a hard place. Before I

actually launch into drift, I'd like to make an introduction. This is Allison Wiedeman. She is a Branch Chief in our Office of Water and has significant responsibilities with the NPDES Permit Program here at headquarters, and we've gotten to know each other quite well over the last year or two since OPP and the Office of Water have been spending a lot of time on the intersection between the Clean Water Act and FIFRA.

There are a couple of topics I want to cover in this session quickly, and Allison is actually going to help me with some of the FIFRA-NPDES portion. So, before we got started, I wanted to make sure you knew who she was, and she's been listening to you in the last session. I assured her that you were the world's best FACA Committee. So, you need to live up to that billing or she's going to doubt my every word. I said you don't pull your punches, you ask hard questions, but you are really constructive and helpful. So, make me a truth teller today.

There are a couple of topics that I want to cover quickly, but we've only got, I think, an hour allotted for this and we've started a little bit late.

But I do want to save some time at the end to see if you can start sharing with us some specific issues that you would like us -- as we've set up this workgroup, we've talked about -- that you'd like this workgroup to be focusing on.

Before we get there, I want to talk a little bit with you about our progress on the drift reducing technologies project, that's the overhead here. I want then to move to -- describe to you one of our current efforts to integrate and coordinate FIFRA and Clean Water Act activities, and then finally to talk more specifically about the formation of this subgroup and what issues it might actually take on board, which will probably also lead then back to the kind of labeling questions that we were just talking about at some point.

So, if you focus for the moment on this flowchart, we, that is OPP and ORD, recently won an innovation grant from the Agency, from EPA, to develop this drift reducing technologies process, and the idea, if you remember back from May, is fairly simple. Can we identify specific application technologies and then test them and measure and verify that, in fact, when you use

these application technologies, you reliably achieve drift reduction and you actually have a sense of what is the magnitude of the drift reduction when you use this specific kind of technology, so that it's not just anecdotal or best professional judgment. You actually have scientific data that underlies that and you know with confidence that you're achieving a real degree of risk reduction?

This process that we're launching on with ORD is a process that's actually been developed by a specific branch within our Office of Research and Development. I think it's called the Environmental Technology Verification Branch. And they've used this model process on a whole array of different technologies. I don't think any of them have been associated with pesticide use in the past. This is sort of the first pesticide trial application. An example, I've been told, is they've used this on some diesel engine technology improvements, but I'm not an expert in diesel engines, so I can't actually tell you more about that.

But it starts out with the funds that we got from the innovation grant, we've been able to hire a

contractor who, at this point in time, is going out and gathering information from -- frankly, globally, about existing application technologies and, also, methodologies that may exist, measure the reduction associated with those technologies, data and information about how much they reduce drift, all kinds of relevant information. I think of this almost as a survey of the field paper. So, it will pull together in one place pretty much everything that has been published or is known about drift reduction technologies and ways of measuring that, and I think the expectation is that this paper would be done probably by the end of this calendar year.

If you go then to the next box where it says develop verification programs, this is envisioned as a stakeholder process, and so, all kinds of people would be engaged at this point, folks who actually use this application technology currently, real users, I think manufacturers of application technology, pesticide manufacturers, public interest groups, anybody who actually has a care and concern for this issue. In working with the White Paper, the expectation is that

this group and the Agency team would ultimately identify one or two specific technologies that ought to be piloted through the rest of the process, and not only the actual specific technology, but if there are (inaudible) methodologies for measuring the drift reduction, sort of what those are and whether they can be used as is for conducting the pilot test, which takes place in the third box, or whether there's additional work with those methodologies that need to be done.

And one of the other important kind of implicit reasons for the stakeholder process is that you actually hope that you're beginning to create incentives and ideas in people's minds about, okay, if I were actually going to adopt and use such technology, what are the other sorts of barriers that I would have to overcome. There's always, I think, a cost issue for farmers and other users. Can they afford to purchase new equipment if they've already got an investment? But there may be all kinds of other barriers and obstacles in addition to the cost one. I don't know how to use it, I haven't been trained to use it, education issues.

So, you start identifying, even in box two, what

some of those other barriers are and you start getting people interested in addressing those barriers and figuring out how to get around them. In box three, you're actually going to do the measurement process and verify the performance of these one or two technologies.

Assuming that they actually come out of that verification process with, yeah, they really do reliably achieve risk reduction, in the fourth box, EPA would take that information and actually incorporate into our drift models the use of these pilot drift reduction technologies and validate and peer review that.

And then you would go to the nominate pesticides/use box, and ideally, at this point, you might have a specific use or set of uses and pesticides in mind where you would then -- let's do sort of a strawman risk assessment to see if all the users of this particular pesticide for this particular use, use this new technology, what kind of risk reduction would you achieve? And, ultimately, then you might get to the stage of looking at label options where it says give credit or maybe reduce use restrictions. If you had a buffer zone in place that was large, maybe you could

reduce the buffer zone if it was tied to that specific technology.

You could also then look at cost savings analyses. If people were able to use this technology and had a reduction -- a lessening of a restriction because you knew it was no longer necessary in order to mitigate risk -- would that lead to cost savings ultimately for the grower, user and others, and then you would also be looking at grower education. So, this is a draft process with the basic high level steps laid out.

Jay Ellenberger, who's sitting behind me, and Norm Birchfield are the two principal people within the Office of Pesticide Programs who are in charge of this project. They are, as I'm talking, thinking about how to set up the stakeholder process that's in box two, and I think those of you around the table who may have an interest in this process, think you might want to be engaged or think you know people who would want to be engaged, it would be very valuable if you would get in touch with Jay and let him know your level of interest, because we would hope that a year from now, we'd be able to, for instance, come back here or be in other venues

where we could report what I hope will be the success of this project, or certainly, where we are with it and what we think we're learning from it.

If this works, it obviously has broader application than just for the selected pilot technology, and you'd have to figure out how to do this more broadly.

So, let me pause here and see if there are any brief questions about this project, because I think it's quite different than the next set of issues that I want to talk about.

Carolyn?

MS. BRICKEY: Yeah, describe real quickly what the pilot technology is and then give me some idea what others are. Is this closed system application that we're talking about?

MS. LINDSAY: The pilot technologies haven't been selected, but, for example, I know that there's a certain kind of air blast, what is it --

UNIDENTIFIED MALE: Aerosys (phonetic) sprayer.

MS. LINDSAY: An Aerosys sprayer that some people think might really reduce drift. So, we'll be looking at some very particular application equipment and

technologies. This is a fairly technical stakeholder process, as I understand it. It's not the kind of policy group that this group is. I don't know if that helps you any. You're looking at me puzzled still.

MS. BRICKEY: Yeah. I'm just wondering, is this closed system application or what is -- I mean, what's a sprayer to do? I mean, I don't understand.

MS. LINDSAY: Closed systems, I think, are actually designed to try to protect the applicator as they're applying.

MS. BRICKEY: Right, right.

MS. LINDSAY: This is about when you've got the pesticide coming out of the nozzle into the world.

MS. BRICKEY: Yeah.

MS. LINDSAY: Depending, for instance, if you've got an airplane, the way you set the nozzles on the airplane --

MS. BRICKEY: I know about airplanes.

MS. LINDSAY: Okay, okay. Well, but that's a type of technology, and depending on how you do it, you can cause drift to occur over large areas or you can reduce the amount of drift that occurs, both the amount

and the distance over which drift can occur. And the same is true for different kinds of land application technologies. This is about what comes out of the application equipment and how can you reduce -- make sure that more of it goes on target.

MS. BRICKEY: Okay.

UNIDENTIFIED MALE: A closed system would be a greenhouse. Is that what you're talking about?

MS. LINDSAY: So, Larry, I think you're next. You're holding your head.

UNIDENTIFIED MALE: Well, Larry's been here all of three minutes. (Inaudible).

(Laughter.)

MR. ELWORTH: Which will not prevent me from asking an insightful and probing question, and maybe you've already said this. What is the cross connection between USDA on at least two different areas, one is with conservation programs --

(End of Tape 1, Side A)

MS. LINDSAY: -- all of that would actually be incorporated through this stakeholder process. I understand, from talking with Pat Cimino and others, that

some of the NRCS programs actually might be used in conjunction with --

MR. ELWORTH: Are currently being used.

MS. LINDSAY: Okay. And so, the effort would be to get that incorporated into this pilot, so we're not doing something separate, but we're taking advantage of what's going on.

MR. ELWORTH: It would also be really useful to talk to somebody fairly senior at ARS to make sure there's kind of a regular connection back with them, because, you know, they're spread all over the country. They could be doing exactly what you want to be doing in --

MS. LINDSAY: Right.

MR. ELWORTH: -- you know, Missouri or somewhere.

MS. LINDSAY: Right. So, this is not meant to actually duplicate other activities; it's meant to incorporate it effectively.

Ray?

RAY: What time frame are you working on with this grant and what's the end part of the grant?

MS. LINDSAY: My understanding is we'd like, by a year from now, to have worked our way pretty much through this process with one or two pilot technologies. I don't know whether we'll succeed, but that's the expectation.

John?

JOHN SCHELL: Anne, you may not have the answer to this yet, but in one of the earlier boxes, you talk about verifying performance, do they achieve risk reduction. Do you have any sense of sort of a threshold risk reduction for a technology to be a candidate? Is it a two-fold risk reduction, an order of magnitude or --

MS. LINDSAY: I don't think we've gotten to that point.

JOHN: You haven't gotten to that far? And will you do a cost benefit once you do that?

MS. LINDSAY: Yeah.

JOHN: Okay.

MS. LINDSAY: That's how we make these kinds of decisions. So, Jose?

DR. AMADOR: First, I'd like to thank you because I guess I was one that brought up the issue of

drift a lot of times to the PPDC and wanted to have something done on it. This is a problem in my area, I know. There's a lot of people being sued and being contested because of drift, so I'm glad to see that we're doing it.

One question that I have, on this environmental technology verification, is that a very involved thing? Are we going to look at the impact that the drift pesticide is going to have on the environment all the way to water and soil and animals, wildlife? I mean, who's going to do that? Are you going to have the contract -- I mean, I'm not familiar with the terminology, I'm not familiar with the technology.

MS. LINDSAY: This project is focusing on application technology. the project, itself, is not doing the kind of broad brush work that I think you're describing. We, ourselves, when we do risk assessments are, and we continue to be, looking at the whole range of potential exposures that might occur in the environment as the result of drift and doing appropriate risk assessment analyses to make a call as to whether there's a level of risk there that merits when you factor in the

benefits, risk mitigation, risk management decisions on our part.

But this is just narrowly focused on technologies that might be capable of reducing drift and developing information about how much -- when you use the application technology the right way, how much does it actually reduce drift? Which is something right now I don't think we, at least in a regulatory sense, actually know. So, it's getting scientific and getting data about another piece of that whole process of pesticide use and application that I think has largely been absent.

DR. AMADOR: Well, I commend you for bringing this to the forefront because I had a feeling that maybe we didn't want to tackle the drift issue because it was too complicated, we didn't know what we had and all that. So, I assume this is going to be an ongoing part of the Office of Pesticide Programs from now on, right?

MS. LINDSAY: Yes. Rebeckah, I think you're hiding in the corner, but next.

MS. FREEMAN ADCOCK: Only because we're having a little group meeting probably and this subject will come up later today. I just want to sort of seek some

clarification based on the questions that have been asked. Am I understanding this process basically to be an identification process for technologies that reduce risk and that you really haven't put any other boxes around it other than that yet and you're going to draw from existing information --

MS. LINDSAY: Yes.

MS. FREEMAN ADCOCK: -- and existing technologies and try to figure out and sort out, in the end, is there anything out there that really we can tell people on the label or otherwise, or give them an option to say, if you use this, then your risk will go down this much and you might even be able to use the product differently perhaps.

MS. LINDSAY: Yes.

MS. FREEMAN ADCOCK: That that will be factored in.

MS. LINDSAY: You've captured it, I think, quite well. I would also emphasize it's not just the identification of these types of existing technologies, but then assuming that they pan out, what can be done to create incentives --

MS. FREEMAN ADCOCK: Are they reasonable?
MS. LINDSAY: -- for broader adoption and use.
MS. FREEMAN ADCOCK: Right.
MS. LINDSAY: And forming that --
MS. FREEMAN ADCOCK: That would be for agricultural and non-agricultural use? I would assume that there would be a --
MS. LINDSAY: I think right now, in my mind, we're focused on ag, but it obviously would be relevant to any kind of pesticide use.
MS. FREEMAN ADCOCK: It could be broadened, I'm assuming.
MS. LINDSAY: Yeah.
MS. FREEMAN ADCOCK: Okay. And you're saying this is a stakeholder group or eventually that you're going to want some --
MS. LINDSAY: By the time we get to box two -- and Jay is telling me he needs to get to box two soon -- we need to have some kind of a stakeholder process that adequately brings people with the right technical expertise into it and gets us the sort of balanced array of people.

MS. FREEMAN ADCOCK: Would it help to have an actual user? I don't mean like me representing a user, but an actual user around.

MS. LINDSAY: I believe it would very much help to have real users because if real users aren't engaged from the get-go, I don't know you develop the -- so, that's why I know I'm the wrong kind of person to be there. And I think Bob Rosenberg, the political scientist, he's not necessary either. But he'd be welcome.

(Laughter.)

MR. ROSENBERG: I've met real users.

(Laughter.)

MS. LINDSAY: Lori?

DR. BERGER: What types of crops do you anticipate looking at?

MS. LINDSAY: I think this would have to depend on the selection of the technology first that you're going to run through the pilot. But I don't think we're at the point where we're talking about crops. The first part of it is looking at the technologies.

DR. BERGER: Well, that's going to drive some if

it.

MS. LINDSAY: Um-hum.

DR. BERGER: So, I think that's something that really needs to be considered up front.

MS. LINDSAY: Okay.

DR. BERGER: You know, orchard crops, row crops, field crops.

MS. LINDSAY: Right.

DR. BERGER: That's just going to really confound things, and I think it's definitely a very worthwhile project and our group is very willing to help out and provide people and resources. I do think a year is a very aggressive schedule for this series of projects here.

MS. LINDSAY: You know, Jim is a real task master, and just like he drives you to get back here and sit down at the table, he asked us to set ourselves stiff goals, but he also -- the emphasis is on doing it right. So, if we get into this process and we feel like we've got a good process going, but it's clear that it's got to go longer than a year, I'm confident that we'll adjust the schedule accordingly.

Gary?

MR. LIBMAN: Lori sort of took my thunder on the year thing, too. I agree with that, too.

One other thing, you're talking about agricultural, but I'm not sure how you can do this, but you might want to incorporate some of the forestry applications into this as well, not to -- maybe even public health on rivers and things, but certainly forestry where there's a major problem with this. I'm not sure how you can get that into the matrix, but I think it would be very useful.

MS. LINDSAY: Okay, that's a good suggestion. Let me, if it's okay, move on to the rest of our presentation because I do want to save some time for some further discussion.

My second topic which I wanted to bring to your attention, an activity that started within the Pesticide Program, that we believe will help really much better integrate activities under the Clean Water Act and activities under FIFRA. I think you've heard Jim talk about one of his personal goals that he's made actually a programmatic goal for all of us in the Pesticide Program

is essentially to make decisions under FIFRA in such a way that we're not, however inadvertently, setting, say, a user up for possible Clean Water Act problems. In other words, we want to make our two statutes work together to achieve the goals.

We believe the goals are very complementary and consistent between these two statutes, but we need to actually make sure that our individual decision-making, as we grant registrations or reevaluate registrations -- and in the future that will be through registration review -- lead to appropriate outcomes under both statutes. And users, for sure, need to have the guarantee that when they're using pesticides correctly, that they're going to be in compliance both with FIFRA and the Clean Water Act, that they're not inadvertently being put in the position of possibly violating one or the other statutes.

So, as part of our planning for the coming registration review program, we've been working primarily with our EPA regional colleagues, at this point, to develop an internal standard operating procedure for addressing water bodies that may be impaired by

pesticides in the registration review process. Now, there are other reasons water bodies can be impaired, but sometimes pesticides are identified as being one of the causes of impairment. And our goal in this internal project is really that we have a process that would allow for the systematic inclusion of impaired water body information into our risk assessment processes and our risk management process for registration review.

If you're talking about the new use of a pesticide, it doesn't seem to make sense because you haven't actually authorized the use yet.

As we've been having some of the discussions that I've referred to in introducing Allison between OPP and the Office of Water, this is actually one of the issues that I think, quite logically, has come up, which is, well, if you're trying to figure out the appropriate relationship between those two statutes, are we, in fact, taking a look at what's going on in the real world, the information we have there from the 303D program and incorporating it back into our FIFRA process, or has that perhaps not been done systematically.

Drift would not be the only factor that might

lead to impairment, obviously, but drift could be one of the contributing factors. As we're envisioning the process, we would start with the identification of 303D listed water bodies where pesticides were actually identified as the cause of the impairment. So, the first thing would just be systematic identification of that. We would hope that largely our regional staffs could be working with state officials, tribal officials, local officials, to actually gather for us the data that was the basis for the 303D listing, because that data right now does not systematically come into the pesticide program and I think it's because, frankly, there hasn't been a clear, obvious process for doing that either within the agency or externally. So, if you don't have a process, you're not going to be able to sort of systematically get it.

Such data that we got through this process would go into the docket for public comment at the initiation of a registration review for an individual pesticide. Now, remember, from all of our registration review discussions that sort of the start is the creation of a docket where we put all relevant information associated

with that pesticide. So, this would become a piece of relevant information where there is a 303D listing and would go in there from the beginning, and be available for everyone to look at and provide the agency comment on, according to the procedures that we've outlined for registration review.

During the risk management process in registration review, we would expect that the pesticide program, in collaboration with our regional colleagues in the Office of Water, would be looking at this information. Where it was appropriate we would be thinking about should there be monitoring plan options developed as a condition of continuing registration that would allow us to establish the extent to which additional water bodies, beyond the ones that are listed, might actually be impaired, because I think one of the underlying issues is monitoring can be spotty.

You can have data from one place and it shows you have a problem, but you may not have data from a lot of other similar circumstances and you simply don't know whether the impairment is also occurring there or it's not occurring because there are other factors at work.

And so, some of the risk management options that we might look at, if these concerns are substantiated, would be appropriate monitoring options.

And then, finally, we would issue our registration review decision, and if we had judged that risk mitigation was appropriate, whether it was monitoring plans or other risk mitigation measures, that would be part of the decision. Once the decision was made, then we would, obviously, follow up with the implementation of the decision appropriately.

So, all of this is a plan for the future. The SOP is actually still under development, but that's kind of the process that we're envisioning for ourselves, and we'll be taking this SOP probably to the November SFIREG Water Quality Committee Meeting so we can discuss it with our state officials. So, those are public meetings. There's an opportunity for other people who are interested to come -- State FIFRA Issues Research and Evaluation Group. Thank you for the help. November 1 is the actual date and it will be in D.C. But don't think that that's the only opportunity to talk to us and interact with us. Steve Bradbury, Debbie Edwards and

Bill Diamond are the Division Managers who are sort of working on this process. So, you should feel very free to talk with them about this, ask your questions, get clarification, add in your good ideas.

Let me go on now to talk more specifically about the formation of a PPDC subgroup that would focus on what I will call drift policy issues. We're not envisioning this group to look at the kind of very technical issues that I talked about in the drift reduction technology project. In May, we solicited interest from this group and Margie actually got the names of several PPDC members, and let me just remind you who they are. Because you named yourself doesn't mean that you continue to have to name yourself. You're always able to take your name out of consideration. You're also able to add your name if you didn't do it.

But the people who expressed interest to Margie were Carolyn Brickey, Michael Fry, Ray McAllister, Lori Berger, Dan Botts, and then we've got three other people who are not PPDC members but have held up their hand. Dave Scott -- and for those of you who don't know Dave, he is actually from Indiana, a state official there.

He's very knowledgeable and very experienced on drift issues and actually chairs AAPCO's, which is the state's professional organization, Off-Target Pesticide Movement Committee. So, he has been identified by AAPCO as their representative to the subgroup. And George Wichterman.

So, from the world of kind of pesticides and PPDC, that's what we've got right now, and as I say, those of you who held up your hand can change your mind, although I hope you don't, and those of you that didn't, but think you might be interested, you can add your name. Just let Margie know. You can let me know, too, but I forget things and Margie doesn't.

MR. ELWORTH: Anne, a quick question, going back to Gary's comment.

MS. LINDSAY: Yes.

MR. ELWORTH: I bet the Forest Service people haven't thought about this, maybe a little outreach to people on the forestry side would be helpful.

MS. LINDSAY: Okay.

MR. ELWORTH: Because they wouldn't even know about that. If you all want to do that -- Burleson or Al?

MS. LINDSAY: Yes. I actually think of forestry as an agricultural activity and that's --

MR. ELWORTH: We do, too. Forest Service doesn't always.

MS. LINDSAY: Anyway, we'll work with Al to get -- because, obviously, I think on this -- even though I don't think at our last meeting USDA held up their hand, I would hope --

UNIDENTIFIED FEMALE: We'll raise it for them.

UNIDENTIFIED MALE: I can hold up somebody else's hand.

MS. LINDSAY: We know that we need them.

UNIDENTIFIED MALE: And mosquito abatement districts, also, should be brought in.

MS. LINDSAY: Well, that's where we'll have George. Anyway, in addition, we've been having some internal discussions with the Office of Water about whether they would actually like to be very active participants with the pesticide program in this subgroup, and I'm very happy to say that they're very interested in doing this, which is why I'm asking you all to impress Allison today.

The Office of Water is actually, right now, going through some internal thinking and cogitating about how to get some appropriate, I'll call them, people from the world of water, because right now, these are people that are from the world of pesticides and really know the pesticides, which doesn't mean you don't know anything about water.

But we'd like to have, for instance, at least one state official who has, at the state level, more direct responsibilities for Clean Water Act implementation. We think that would be appropriate. From public interest groups who work that end of things, from other folks that I actually don't know who would bring relevant experience, expertise and responsibilities, so that we end up having a workgroup that both knows pesticides and who actually knows water quality issues very broadly.

So, Allison and other folks within the Office of Water are working on that right now. I think we're hoping to end up with a group that I would say would be in the range of 10 to 15. It doesn't mean it can't be a little bigger or a little smaller, but we want to try to

keep it to a size where it can really work because we would expect this to be a working workgroup.

Our current plans are that we would like to actually start this up and have an initial kick-off session, I'll call it, early in the new calendar year. We know that drift is actually -- and the policy issues, in particular, are very controversial. There is, no matter how you look at it, no matter where you stand, there is a lot of implications to where you come out on the policy issues, and so, I think neither OPP nor OW is expecting that this group would come to consensus recommendations. Obviously, if the group did, we'd be likely to be very happy. I always have to reserve judgment.

(Laughter.)

MS. LINDSAY: You could come to consensus on something and we'd go, oh, no, although I think we'd be hard-put if the group came to consensus not to figure out a way to deal with recommendations. But we do expect that what we could have is what I would call just a very serious constructive dialogue, frankly, kind of like the dialogue we had yesterday morning on that other very

controversial policy issue, human studies. So that, first and foremost, those of us who work at the agency could be sure, both in the pesticide program and in the water program, that we really understood key issues, and not just what the key issues are, but where the various stakeholders really stood on those issues and sort of why you stand where you do. We can think we know that, but that doesn't mean that we necessarily do know that, and I think the subgroup could help us ensure that kind of confidence in our knowledge.

We do also expect to get, what I would call, good, constructive ideas about ways to effectively address the key issues that the group identifies and maybe at least what I would call some cleaning out of the underbrush, so that where there are issues, that the group at least comes into kind of a common perspective, if not full consensus, we would know that and some issues might become less challenging to deal with and we would know more clearly what were the big ticket issues.

Possible topics that I've thought about for this group and kind of starting places are, first of all, and this is a question -- this begins the kind of questions

for you to give us some reaction to -- education. Because we would have this blended group that we've not put together, do we need to plan on education both around drift, around pesticide issues, around water issues to make sure that there's some kind of common level playing field within the group members? And, actually, we may discover that the agency learns something from it, too. So, should there be education at the beginning and kind of what might those broad educational topics be?

Are there policy issues associated with label enforcement around drift that ought to be considered? Particularly since we're looking at the sort of intersection of NPDES, Clean Water Act and FIFRA, do we need to have some certainty around enforcement and what are those policy issues?

Would this group think it important to look at label incentives that would serve to reduce drift, for example? Picking up some of the stuff from the project, not the technical piece, but possible policy labeling issues that you might see. And then, of course, the whole NPDES/FIFRA intersection, we're engaged -- and Allison will tell you a little bit more about that in a

moment -- in a rule-making, but it doesn't apply -- the rule-making underway does not apply broadly to agricultural operations, although we've made very clear that our practice -- our historical practice and current practice is not to require permanence for agricultural operations.

I'd like to let Allison have a few minutes to talk with you and then open it up for some discussion, specifically around what issues you think the subgroup should really be dealing with.

MS. WIEDEMAN: Thank you, Anne. I'm very grateful to be in front of such a distinguished group of people and very happy to be able to talk about this issue and try to move it forward, which has been a challenge, because we don't know the answers. So, the purpose of forming this group is to find those answers.

A little bit about me so you know where I'm coming from. I'm in the Office of Water at EPA and I'm specifically in the Water Permits Division. Our mission in the Water Permits Division is to look at situations and develop policies for situations that would require a national pollutant discharge elimination system permit,

NPDES permit.

And to do that, we ask ourselves the following questions: If a situation needs to have a permit, there must be a discharge of a pollutant to navigable waters of the United States and from a point source. So, those are four of the criteria that need to happen, one or all, it's not inclusive, before we determine whether or not something needs an NPDES permit.

I think you're probably aware that the recent rule-making -- well, the rule-making that we are involved in finalizing that was proposed earlier this year when we were finalizing a rule-making and working with the Office of Pesticides is the two situations where we have determined that pesticide applications do not need an NPDES permit, and that is where they are applied over water, such as on canopies, to eradicate forest pests, and also on water to eradicate waterborne pests. So, either over or on water as long as these applications are applied in accordance with FIFRA, a NPDES permit is not necessary, the programs are complimentary, the FIFRA program takes care of any environmental concerns that we have. But more importantly, we made the legal

determination that an application of pesticides in these cases is not a pollutant. So, it doesn't trigger one of the requirements for an NPDES permit.

And during this process, we have been working very closely with the Office of Pesticides. It's been a great process to integrate our programs and to learn about each other's programs and know that we need to continue to do this and we plan on doing that in very specific and intentional ways. That rule-making will be coming out as final sometime in January, I hope.

But there is one situation where we have said in that rule-making we will not address and that is the one of drift. And the reason we are not addressing whether or not drift needs a permit is because -- while we don't say it this way in the preamble -- we don't know enough about the situation to make that determination and we are going on to say that we are going to be forming a FACA process to look into that situation. And in a nutshell, the question is, does drift require an NPDES permit? And this could be drift generally over land applications or it could be associated with water applications as well.

A couple of things I wanted to talk about in

terms of questions that I would like this group to consider, and again, let me stress that we're very grateful that we could say in the preamble that this situation is going to be dealt with through this committee. It gives us a perfect and logical next step that I think the public will accept, and I know that going through this process, we will be able to objectively look at all sides.

Some of the questions that I see we need to look at are obviously within the realm of does pesticide drift need an NPDES permit or is drift -- it's both a technical and a legal analysis and that would involve asking ourselves the questions, is drift a pollutant? Pollutant and discharge and point source are all defined in our permit regulations. So, we have clear definitions for what those are. And does the situation for drift fall under any of those categories? Is drift a pollutant? Is drift a discharge? Is drift a point source?

And if not, then what are the other mechanisms by which we can control drift is the next question. Do we use labeling and additional verbiage on labels? Are the current labels okay? Do we need to talk about

requiring additional best management practices? These kinds of things we need to look into.

You all wouldn't be starting from scratch. There's a lot of information that we have put together on this issue already. We've done considerable legal analysis of court cases across the country on this. There are a handful of court cases that have dealt with the subject of drift and they span the spectrum of yes, they do need a permit and, no, they don't need a permit. And we can provide that type of legal analysis to you. We can provide the technical information on drift that we have been able to gather so far. We can provide information on situations where drift occurs so that you all have a launching pad on which to be able to gear up and move forward with this issue.

I basically covered the points I wanted to say, but I did want to also add one thing and reiterate what Anne was saying about the environmental technology verification program. I was working with that program when it started in 1997 and, at that time, we were looking at septic systems and verifying different septic systems. Basically, a niche like this has been necessary

for a very long time. There are entrepreneurs out there that are developing technologies, but they don't have the resources to verify them, and this program -- you know, to verify the performance of a technology can cost upwards of $100,000 with all the sampling and the reporting that's required. This type of program can subsidize that for the developer and allows us then to promote innovation and to find those technologies that we may not otherwise have access to.

So, I think it is an extremely beneficial program and has grown by leaps and bounds over the years and I'm glad to see they're going into the pesticides arena as well.

MS. LINDSAY: Okay. One comment before I turn the floor over to you. It could be tempting to folks, or at least some of you, to actually want to talk with us about the rule that Allison gave you a status report on. I'd like to encourage you, though, not to go down that path. We're actually at that point in the rule-making where it's not really appropriate for us to be having large discussions. The comment period is closed and it's also not the purpose of this session. So, Allison's

given you some good background, but I will try to be very firm in keeping us from going in that direction and you actually will do the best job of helping me do that if you do it yourselves.

MS. WEIDEMAN: Yeah, because I'm supposed to be impressed with this group, right?

MS. LINDSAY: That's right. And you don't want to cause Allison more problems.

The other piece is, I think, with regard to some of Allison's suggestions for possible topics or issues, I am not thinking of this group as a group to do extensive legal analysis. It may be that there is some legal analysis or understanding of the operation either of the Clean Water Act or of FIFRA that the group will need to get started right, but I'm viewing that more as background operation. So, those of you who have expressed an interest in it, but who may not be attorneys or who may be attorneys but occasionally like to do something other than legal analysis, we're not going to be asking you to actually do legal analysis in the group.

And with that, I'll stop and ask for some reaction. Beth, is your -- your card's been up for a

long time.

DR. CARROLL: Yeah.

MS. LINDSAY: Are you number one?

DR. CARROLL: I think so.

MS. LINDSAY: Okay.

DR. CARROLL: I have two questions.

MS. LINDSAY: Sure.

DR. CARROLL: One is, what's your time frame for this subcommittee or subgroup?

MS. LINDSAY: I think that -- well, I told you we'd like to get it started early in the new year. Although the issues are hard and complicated, I would really like to have the group be able to -- because, of course, it has to report back to this full committee. I would like it to be able to have a substantive report back to what would be the next PPDC meeting, and although Margie hasn't scheduled that yet, that would be in the springtime, I would expect. I don't know whether it will be the week we actually move to our new building, but, you know, it could be the May/June time frame. That doesn't mean it would necessarily declare itself finished. But I would like to see it work in a fairly

intensive fashion.

DR. CARROLL: And is the intent to develop additional rule-making?

MS. LINDSAY: That's something the Agency's not decided upon.

DR. CARROLL: Okay. And then, finally, just for clarification, if I could go back to the collection of data for registration review, where is that coming from? Is there -- and I'm just not familiar necessarily with how they report 303D. How far back are you going? Is it anecdotal? Is it recorded somewhere?

MS. LINDSAY: No, there is -- this probably illustrates that you're telling me there's a need for some --

DR. CARROLL: Education.

MS. LINDSAY: -- basic education. But there is, under the Clean Water Act, a whole 303D listing process and states list water bodies that are impaired for a variety of reasons. But one of the reasons could be for pesticides and there's a whole reporting system that goes with that and they base their decisions on data and other relevant information, and we want to get that data and

information into our system so it's not merely an anecdotal process.

DR. CARROLL: So, it resides in the state, it doesn't reside in Office of Water?

MS. WIEDEMAN: Well, in terms of impairments?

DR. CARROLL: Right.

MS. WIEDEMAN: No, we have all that -- we have that information as headquarters as well in EPA.

DR. CARROLL: So, would that not be the logical place to go for it as opposed to collecting it from --

MS. WIEDEMAN: Are you speaking with respect to the drift issue?

DR. CARROLL: No, the 303D listing and re-registration or registration review.

MS. WIEDEMAN: Okay. Well, any information that you all need on impairments from -- that are on the 303D list --

DR. CARROLL: I mean, I understood you to say you were going to get it from the regions, and if it already sits here --

MS. LINDSAY: I think --

MS. WIEDEMAN: It's readily available.

MS. LINDSAY: But we need to actually, Beth -- you know like the previous discussion on PRIA process improvements, we need to make the process of getting that information into OPP's registration review really operational and streamlined, and to be very candid with you, historically, it's not been. So, if it's already at headquarters, we would use it. We also, though, believe that there is information that our regions can help us access. But we will be taking it from the most efficient available way.

Let's see, Bob, I think you were next.

MR. ROSENBERG: Yeah, and I just had two questions. Allison, you had mentioned the initiation of a FACA process. Is that something different from the PPDC workgroup?

MS. WIEDEMAN: No, I'm sorry, that's the same thing.

BOB: And the second question, this is probably just a reflection of my naivety about all this. You had said something about the Water Office needing to make a determination as to whether drift constituted a point source discharge of a pollutant.

MS. WIEDEMAN: Yes, right.

BOB: Isn't it correct -- maybe it isn't -- that drift is not permissible, in some broad sense, on a label and would be an enforceable FIFRA violation and is it necessary to go beyond that?

MS. WIEDEMAN: Well, that's the question we want you to answer.

MS. LINDSAY: But, Bob, you'd have to look, and I know that our state official at the table would back me up on this, you would have to look, in any particular case, at what the label actually said. So, in some cases --

BOB: So, it's a labeling problem --

MS. LINDSAY: -- I think we've got labels where we've made it fairly clear what's enforceable and a state official like Maureen would be able to take action. If it were violated, I am afraid, unfortunately, that there may be other labels where it's less clear and our state officials may have challenges when they think that harm has occurred in making their case.

BOB: Don't you feel that you've made some headway on that issue, at least in a narrow sense, with

the revised language that was contained in the adulticide PR notice?

MS. LINDSAY: You're right. For the mosquito adulticides, when that labeling gets in place on labels, I believe that will be a substantial improvement in the quality of labeling. But that's one specific use pattern and our country is a wide and varied place.

I'm not sure who literally is next, so Erik -- I'm going to kind of go this way because I'm not doing a good job of keeping track of which one. . .

MR. OLSEN: Yeah, I just want to follow up on the whole enforceability and enforcement issue. I'm assuming that the Enforcement Office will be part of this negotiation also, is that right?

MR. WIEDEMAN: We work very closely with our enforcement folks.

MR. OLSEN: Would they be part of this group?

MS. WIEDEMAN: Good question. I think that the formation of the group is something that we still have yet to decide.

MR. OLSEN: I would strongly encourage that just because they're the ones that are going to be stuck with

whatever ends up coming out of that.

MS. LINDSAY: Can I clarify something, though? It's not a negotiation.

MR. OLSEN: I understand that.

MS. WEIDEMAN: Right.

UNIDENTIFIED MALE: Okay, sorry.

(Laughter.)

MS. LINDSAY: Some people may want it be --

MR. OLSEN: None of these are negotiations, whatever.

MS. LINDSAY: -- a negotiation, but we -- OPP and OW are asking the PPDC if they would be willing to have a subgroup to give us advice on these issues, and I think that there are a set of enforcement policy questions and I have confidence that whether they're direct members on the group or they're actually -- usually we have what I would call kind of a shadow group, just like we did with registration review. There was a team within OPP in that case who provided the support and interacted with the subgroup of the PPDC. I would expect we would have that kind of internal team that supports our interaction with the PPDC subgroup and it would have

appropriate enforcement involvement, and I think our Pesticide Enforcement Division Director wants to say something on this point.

MR. COLBERT: I think the question would be -- and it's a little early maybe to know -- is the scope and the goals of exactly what questions you want to answer and in what order. Enforcement will come up, it always does. For us, the question is, is it too early? We don't want to get in necessarily too early, but, of course, we don't want to get in too late. But I think that's one of the things that will have to go into it. It may be that right off the bat you'll say, enforcement is going to be a key player in this. I can't tell.

MR. OLSEN: Well, this is just part of a broader issue which is, to us, one of the big issues with drift is problems with the label specificity and enforcement of the label. You know, that really seems to be a crucial central issue. I'm not sure a negotiation over label enforcement is a good idea. But, you know, I think that's important. For example, on the soil fumigants that are injected into soil, is that drift if it gets out? You know, there are issues like this where there

have been incidents where there was no enforcement taken apparently because of some questions. I'm not sure that's a good example, but that would be something I'd hope.

The last point I wanted to make is on the 303D listings, that's extremely spotty. I mean, some states are pretty good about collecting data on pesticides and doing 303D listings and a lot of states are not. They just don't have the resources to go out and do comprehensive pesticide testing, as we found out with plenty of examples. I won't name any chemicals, but there are a lot of chemicals where we know -- you know, intensive monitoring shows up significant water quality issues, but a lot of states have just never done the monitoring. Therefore, they've never listened and, therefore, if you're building a whole house of cards on 303D listing based on lack of monitoring, you know, just flagging that issue I think is important.

MS. WIEDEMAN: Yeah, I think that's a good point, and you also don't know the source of the pesticides as well. So, it's one tool in the toolbox, one source of information.

MS. LINDSAY: Another thing just on your first part of sort of what's inclusive in the term drift, I'm not going to use the right technical language, but we're trying to focus on the movement -- the off-target movement of the pesticide that occurs at the time of application. So, volatilization, after it's applied, for instance, or other terms that you might use, are not, as we're looking at it, part of what we would ask this group to look at, which is not to say that --

MR. OLSEN: Why would that be? Because that's one of the big problems that we've had repeatedly.

MS. LINDSAY: Well, I was getting ready to say, it's not to say that there aren't issues there and that there wouldn't be opportunities to discuss them, but we see this as sufficiently different that we want to keep them separate.

Jose, I think you had some stuff you wanted to say.

DR. AMADOR: Yeah, my name is not Sue, but I cannot find my card. I don't know what happened to it.

(Laughter.)

UNIDENTIFIED FEMALE: A boy named Sue.

MS. LINDSAY: Well, you know what, Jose, I actually can't see what it said at all, it was just your face I recognized.

DR. AMADOR: That's why I highlighted this so you could see it, but it says Sue. I can't find mine.

(Laughter.)

DR. AMADOR: I got a question and a comment and a suggestion. The question, Allison, could you repeat again what NPDES stands for? I'm not too good at acronyms.

MS. WEIDEMAN: Sure. National Pollutant Elimination -- sorry, National Pollutant Discharge Elimination System, NPDES permits.

DR. AMADOR: Thank you. The comment, I'm glad you put education at the top of the list because there's a lot of education that is needed on this issue. There's a lot of questions. And the suggestion that I have, Anne, yesterday, there was a subgroup that was formed on farmworker safety. I think there should be somebody from that group on this committee. Some of the issues that I deal with are application of chemicals when there's people working out in the field either by air, that is

sprayed directly on the people, or sometimes just by drift, people who are working in an adjacent field. I think that the farm safety factor should be included in this subgroup. Whoever Kevin or Bill Diamond think is the best person maybe ought to be in this group, too.

MS. LINDSAY: That's a good suggestion, and actually, I hope that maybe we get some folks that represent that community to --

MS. WIEDEMAN: What community is that?

MS. LINDSAY: Farmworker.

MS. WIEDEMAN: Okay.

MS. LINDSAY: And we actually have some folks on our committee here who, unfortunately, this turned out to be a bad time for them and they weren't able to actually be here. But if not them, I think we can look in other quarters.

DR. AMADOR: That's some of the complaints that I often here from people, that they put chemicals on while they are in the field working.

MS. LINDSAY: Pat?

MR. QUINN: So, as I understand it, the questions you'll be trying to deal with, in part, will be

is drift a pollutant, is it a point source and is it a discharge. So, for those -- and if it's one of those, then it might require an NPDES permit. So, can you kind of give the group a feel for what one goes through in obtaining an NPDES permit and how that would apply to a pesticide application?

MS. WIEDEMAN: And, you know, it has been -- there are folks across the country -- applicators across the country that actually want to be able to get a permit so that it gives them clear authority to apply and gives them protection against citizen litigation. But to get a permit, one supplies a permit application to the state permitting authority. That application generally goes through a public review process, and after that process and after any changes are made, then the permit is granted.

MR. QUINN: How long does that take?

MS. WEIDEMAN: Well, that varies between state. That's a very good question and a very good concern, and it could take, you know, a matter of weeks and it could take a matter of several months. So, that is an issue that we need to look at.

MS. LINDSAY: Pat, this may actually be what I would call a --

MS. WIEDEMAN: One more thing.

MS. LINDSAY: Sure.

MS. WIEDEMAN: Sorry. One of the things that EPA has -- a program that EPA has instituted years and years ago to --

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MS. WIEDEMAN: -- under that general permit, and depending on the way the states operate, a notice of intent is often enough to go ahead and have coverage.

MR. QUINN: And that kind of standardization may make sense in these kinds of circumstances. I just wanted to have you illustrate that it can be a fairly lengthy, cumbersome process which can take quite a bit of time to resolve public concern.

MS. LINDSAY: That may actually -- your question may actually be a topic that it would profit the group early on to get some -- Allison only has a minute or two to give you a very thumbnail sketch to actually provide more information about what it's really like.

Maureen?

MS. SERAFINE: Anne, simply to provide a state's perspective on applying for a SPEEDIES (phonetic) permit, I am told in New York State it will take about six years, and you can verify that. Although I don't work in the Office of Water, our SPEEDIES people and permitting process is extremely cumbersome.

MR. ELWORTH: That's really a misnomer.

MS. LINDSAY: Well, I think we're not going to ask New York to come to this group.

(Laughter.)

MS. LINDSAY: But, no --

MS. SERAFINE: You need to really evaluate in deciding that drift, although it is unintentional, is actually a pollutant because that would negate the rule-making that you have just made or are in the process of making and require all aquatic applicators then to just move ahead and ask for a SPEEDIES permit because they never know if drift will occur.

MS. WIEDEMAN: Well, I guess I don't see it quite that way. We're clear on the policy that the application of pesticides, in accordance with FIFRA, does not need a permit, that it is it not a pollutant, that it

is a product used for a beneficial purpose. So, the situation with drift and there's other situations like, well, what happens if there's residuals left, with the breakdown products. Those are all issues that we have to look at to make the determination if those are pollutants or not.

But I think there are two different situations. Even though I know that drift can occur, when the application occurs, we just have to draw the line and say that, at this point, the application of pesticides is not -- proper application is not a pollutant.

MS. SERAFINE: Okay. I would honestly say that would be dependent upon the definition that you come up with for drift. If you're talking about causing harm, then you have to relate it to what detection limit of that pesticide would be determined to cause harm.

UNIDENTIFIED FEMALE: Good point.

MS. LINDSAY: Larry?

MR. ELWORTH: I realize I'm still a little bit confused. How are you using the 303D list?

MS. LINDSAY: I'll try again, but I may not succeed. If a state has listed a water body as impaired

because of pesticide use, then what we would like our standard operating procedure to be is that we have a process working with our regional colleagues, with our Office of Water, to get the underlying information upon which that impairment decision was based and any other relevant information.

MR. ELWORTH: Then you would use that information to --

MS. LINDSAY: Yeah, the same way we would use any other information from the real world in our risk assessment process.

MR. ELWORTH: Why wouldn't you use the TMDL list?

MS. LINDSAY: Why would we?

MR. ELWORTH: Why wouldn't we?

MR. JONES: Basically, Larry, if the state has identified a water body as impaired by a pesticide, I think we need to know that.

MR. ELWORTH: Sure, sure.

MR. JONES: And I think we need to consider it in our characterization the way we consider all kinds of data. Now, my understanding is that a TMDL is done only

if you have impairments. So, the impairment is going to be the broader universe. I want to know if there are impairments and I want to make sure that we're dealing with that knowledge appropriately. As Erik said, I recognize that that doesn't define the entire universe, although I do think it's sort of a missing piece to the puzzle if we don't even know it and, therefore, are in no position to evaluate what it tells us.

What we do about it depends on what we've learned. If you look at that data and you realize the underlying basis of it was very weak, you may not do anything. If you look at that data and you realize that, you know what, it's only the tip of the iceberg, it may lead you down a different track. I think it's very dependent on what you've learned from. To me, it's just adding one more piece to the puzzle to get a clear picture of what's going on as it relates to a pesticide in the environment.

MR. ELWORTH: The reason I ask --

MR. JONES: It's pretty straightforward.

MR. ELWORTH: -- is kind of going back to Erik's question, because the TMDL information is very, very

specific. You can really figure out this stretch of water for this chemical.

MS. LINDSAY: Okay. Michael?

DR. FRY: I understand the need for having the FIFRA permit for the aquatic applications of pesticides, but I have a question, and that is, how far downstream does the pesticide in the water remain beneficial and where does it become a pollutant? Methoprene used for -- as a larvicide when it goes downstream and starts killing lobster larvae, it's obviously a pollutant at that point.

UNIDENTIFIED FEMALE: That's a residual issue.

MS. LINDSAY: That actually is kind of a concrete example of one of the issues that the Agency has been focused on. I don't actually think we have a specific bright line answer for you here nor time to go through it today. But it is one of the sub-issues that we've been talking about, and that this subgroup, when it gets up and running, may want to examine. So, thanks for the example.

Rebeckah?

MS. FREEMAN ADCOCK: I think I would like to build a bit on Maureen's response to defining what would

be considered off-target application. I think, you know, from my mind, the notion of drift has already achieved such negative status that that's automatically the assumption that drift is bad. Off-target or non-target, perhaps, application of a pesticide, I think, is something, by the Agency's own, at least verbal admission, is unavoidable. You can't say I'm going to spray something here and that it wouldn't get on a blade of grass here.

The unfortunate consequence that the user community, whether ag or non-ag, is experiencing is that there is a campaign, according at least to Internet sources, of folks going around the country with cotton swabs looking for that sort of defining detail on whether somebody's doing something appropriately or not and putting -- at least my folks believe -- unfair pressure on people who are doing things and following the label, and those are some very fundamental threshold questions that are going to be very challenging for the group, but that we are going to have to determine, within some flexible bounds, I would assume, because the labels are different and the chemicals are different, what is the

policy at the Agency on non-target drift or whatever we're going to call it, you know, maybe making one a more negative term and one a more positive term, but realizing that the more positive term is going to occur. That's what the label is considering as included in the use of the product.

The other thing, if these discussions are going to lead to a larger OPP policy or some sort of guidance -- I don't mean that necessarily in the formal term -- but in some way giving instruction to the label and registration process for non-target applications, spray drift, whatever we're going to call it, we have so many other challenges. The users are seeing so many other challenges and so much pressure on other issues, water included, species issues included, which hopefully will be addressed somewhat through the counterpart rule, but they still remain, and then the worker issues as well. If we're going to knock out the beast, we're going to have to knock out the beast because the people with their tails hanging out are the people who are using the products and think that they're doing what they need to do to cover their tails. Right now, they're finding that

that's not the case.

MS. LINDSAY: That is actually one of the things that I hope, ultimately, with the advice that we get from the PPDC, that we'll be able to improve --

MS. FREEMAN ADCOCK: So, we can discuss those other issues as well. Would that be appropriate?

MS. LINDSAY: I don't want to have this be an endangered species group.

MS. FREEMAN ADCOCK: Right, right, no, I understand that.

MS. LINDSAY: But it's got to stay focused on drift.

MS. FREEMAN ADCOCK: So, we are focusing on water and drift and not the other issues and drift or do we know yet?

MS. LINDSAY: I see this as focused on water and drift. If I hear from enough different quarters that there's some other pieces that should be fitted in there or if it's very obvious that you need to take something else up, then we can consider if that's appropriate to do. We may also learn something from this process that then would be applicable in other situations. But if we

take on the whole universe of drift-related issues, I think it's a very -- it's very big.

MS. FREEMAN ADCOCK: Right. I guess my only concern is we've seen situations from at least farm user perspective where we've done something within the purview of the water issue that may have exasperated something on -- and this is by example, not necessarily exclusive to pesticides, but we've seen a situation where we gave people guidance on how to improve their practices relating to water protection and we exacerbated their practices relating to air protection or air improvement.

And I would hope that as we're moving, if we are just going to deal with water, that at least in the back of our minds, we're not making it worse for the other ones.

MS. LINDSAY: Yeah, and I would say if in the course of this group's working it comes up with, well, this would improve this situation, but we have a concern that it's going to exacerbate, then this subgroup can certainly advise the full group before you go down that road or before the Agency goes down that road, that other set of issues needs to be examined because we're just

pushing the problems from one media to another, we have not done what we ought to be doing.

Terry:

DR. TROXELL: Do I get the last word?

MS. LINDSAY: It looks like it.

DR. TROXELL: A dimension of this, it doesn't relate to water, but a possible dimension on this is FDA's enforcement on tolerances. It provides somewhat of a bound, possibly.

UNIDENTIFIED MALE: Oh, don't go there.

(Laughter.)

UNIDENTIFIED FEMALE: Is that advice?

UNIDENTIFIED MALE: It's advice Anne has given to me many a time.

UNIDENTIFIED MALE: Phone call for you, Terry.

DR. TROXELL: No, it's never been our intention to take enforcement action against a no-tolerance pesticide being on a commodity due to drift from what's applied using, what shall I say, good application practices. As a matter of fact, I don't know what the levels are likely to be on some of the crops when they're harvested when we might see them and if -- if we're

actually catching in the FDA snare lots of products because of this kind of situation. Also, what kinds of non-good application practice situations might ultimately be caught in that FDA snare if there's excessive drift?

I think we'd like to know a lot more about that and how that affects, including by the way, the situation you don't want to deal with, where the pesticide is lifted off of one field and moves over to another. Because we look to pretty low levels and, you know, while a pesticide may be applied weeks prior to harvest, which helps a lot, it's still possible that if there's excessive drift, we may ultimately catch some situations and farmers may be unnecessarily impacted even if the pesticides are being applied appropriately.

MS. LINDSAY: Okay, thanks. As I said to Rebeckah, I think we want to keep it, at this point, focused on drift as I described it and the water -- the Clean Water Act/FIFRA intersection, but I also believe that as the group goes through, if we come up with -- if we get good advice that helps us resolve some of those issues constructively, I think it will have broader application and we will also, I think the group, itself,

and the Agency, be mindful that if we make changes to deal with one problem and we haven't thought about inter-related issues, we will need to do that, because our goal is not just to push environmental problems around, but actually to improve them in a way that will also improve the ability of farmers and other pesticides users to do their business.

So, I think we've overrun our time. I feel my boss' anxiety on my left quarter.

MR. JONES: All right, well, that was a very good session. Actually, we're going to take a break right now and we're going to start with public comments if there are any public commenters. Right now, no one has signed up, but if you want to, we're going to, when we get back at quarter after, start with that and I will have an abbreviated committee status session.

All right, 15 minutes.

(A brief break was taken.)

MR. JONES: As I mentioned yesterday, the Federal Register Notice appeared yesterday requesting nominations of qualified candidates who wish to be considered for one or two-year terms. This is required

under FACA. It's not meant to be some signal to any or all of you. Also, required under FACA is if you are interested in serving for another term, you need to apply and the FR Notice describes what it is you need to do. It's pretty straightforward. Send an email to Margie, name, address, telephone number, and actually, a brief description as to what you bring to this exercise.

We do get a lot of applications for appointment to the PPDC every other year when we go through this exercise. So, it's something that people do take notice of, which isn't that surprising. I think it's viewed as an important way to get advice to the Agency. So, I particularly just want to raise that to your attention that it is important if you want to continue to serve -- to be appointed again, that you would need to submit an application. Again, it would go to Margie. The FR Notice tells you exactly how to do that and it's pretty straightforward.

As has been the case, I believe, the entire 10 years of this committee's existence, our goal is to have a broad representation with a balanced committee and hold two to three meetings a year, which I think is what we

have been doing and plan on continuing to do.

Nominations are due by November 7th, so three weeks or so, email, fax, regular mail. I would discourage regular mail myself because it takes us so long to actually process it.

UNIDENTIFIED FEMALE: And it comes fried.

MR. JONES: Our next PPDC we're tentatively scheduling for March, actually, before our move and we'll get some details around that shortly. So, those are just some things I wanted to make sure I spent a little bit of time on so that you weren't caught unaware. I'm sure the charter is less interesting to you than is the process for applying to serve.

Burleson just submitted his application. I have to say, Burleson, you, like me --

(Laughter.)

MR. JONES: -- are -- I will bring a -- oops, I don't really want to tell you what he thinks he's going to bring to the -- no.

(Laughter.)

UNIDENTIFIED MALE: So, technically, you could deny the application.

MR. JONES: No, the government representation here is what it is.

DR. AMADOR: Are you asking for an up or down vote on that?

(Laughter.)

MR. JONES: No, there's a different process for our participation that isn't so transparent.

(Laughter.)

MR. JONES: That goes also for our colleagues from the services and from FDA and our colleagues from OECA and NIOSH and EPA regions.

UNIDENTIFIED MALE: I think Steve wants a different FDA regulation.

(Laughter.)

MR. JONES: So, to spend a little bit of time on a couple of things that I've noted, which I would not claim to be all-inclusive in terms of follow-up, but some of the highlights. Actually, the transcript of this entire meeting -- it's not if you're Anne Lindsay who speaks in clear, articulate sentences all the time. So, when she reads the transcript, I'm sure she feels very good about it. When I see the transcript, I'm like,

where did I get my education, this is remarkable.

But the point being that we capture what the advice is that we're getting here and we go through that and we make sure that we are following up with the kinds of things that are important to follow up on. I've captured a handful -- a little more than a handful of things that I just wanted to relate to you that I'm committing now to have some follow-up around.

The first was an issue that came up very early yesterday morning. We've already had some discussions with our senior team, even though it seemed like we were here all day yesterday, which we were, but we're, you know, figuring out other ways to work with our management around the edges. That is sort of a feeling amongst a number of you that there needed to be some dialogue as it related to the 40-odd chemicals that we're going to be doing tolerance reassessment and re-registration on between now and August 3rd. We will internally spend some time thinking about what would be useful, but it would also be very helpful to get your thoughts, not necessarily now, I think we did a little bit of that yesterday, but off-line about what you think would be

useful around that.

I would, again, repeat one of the things I said yesterday, which is that you'll find out what's useful by spending some time with those risk assessments. That's where you're going to see issues that you think may deserve either a CARAT or discussion at the PPDC. We'll spend some time internally thinking about what would be valuable, both from the Agency's perspective in getting advice and also to stakeholders for some dialogue or discussion around those issues.

So, again, as you think of things, please let us know and that will certainly help inform the thinking at the Agency.

On our second point, on the strategic plan, we're going to come up with some mechanism to get to this committee some more specificity with respect to how the goal four is going to be characterized as it relates to our work before it's so far down the line that it gets very hard to make any meaningful change. The Agency is looking for, as Marty described yesterday, a way to get more stakeholder input and they actually think that the PPDC is a very effective way to do that.

I'm not sure if our next meeting may be a little too late, so we may actually have a conference call sometime between now and March if it turns out that March is a little too late to really have meaningful feedback around that, and you'll have much more specific language to react to. We should be able to get it to you several days in advance, have either a conference call or a discussion here at the PPDC. Again, it depends on the Agency schedule whether we need to have a conference call around that or we can actually use this forum when we get back together again. So, we will be definitely doing that.

We heard from the performance measures workgroup that the workgroup is going to next look at human health measures that we have identified and ecological and environmental measures, and I'm really just saying that as a reminder, that that commitment has been made by that workgroup and that's next on their agenda.

Around the worker and certification and training issues, a number of you expressed interest in the formation of a workgroup as we begin to think through how to take some of the recommendations that came out of

pretty meaningful stakeholder processes into potential regulatory changes and Bill Diamond has taken that as a task he needs to put together, a PPDC group to provide advice around some of those issues.

A number of you have already identified an interest. Margie will follow up with another email note to you all saying, you know, we're about to get this going, if you're interested and you did not express interest, let me know and we'll move out on that.

I mentioned earlier today that we were about to pull the plug on the Consumer Labeling Committee. I've said it a number of times over the last two years. This works -- this advice works when people are willing to invest in the time necessary to really vet an issue, and many of the issues that we struggle with are not amenable to an hour-long meeting to get that advice. And the consumer labeling, we had some interest in further evaluating and framing some issues and then coming back to the full committee with some advice. It seemed to be languishing there for a while. I was ready to pull the plug, but I got word from Lin Moos, who's been leading it on our end, that that committee has gotten resuscitated

in the last month or so, and so, they've had a meeting a couple of weeks ago, they're going to be having another one before our next meeting and will be on the agenda at our next meeting in March, if that's when we're having it.

So, that activity is still ongoing. If there are people who are interested in participating who have not been heretofore, Lin Moos is the appropriate contact. Of course, you can let Margie know and she'll hook you up with Lin.

Let's see. Spray drift, sort of being the last concrete specific issue. We have a list of those of you who are interested in participating in this sort of joint water-pesticides activity. It is going to be bureaucratically, in the world of FACA land, that this is going to be the FACA that it's going to report back to, but we are going to supplement our membership with people who are water stakeholders. We'll look to the Office of Water, as well as you to help identify who those groups are to make sure we have appropriate balance. Many of you have already expressed interest. Again, have that open for a while.

Anne had mentioned that we'd like to have a kick-off meeting around that at the beginning of the new year, the new calendar year as opposed to the fiscal year, and we will keep you posted. Again, if you haven't expressed interest and you think you would be, let Margie know.

Those are some of the highlights of the things that I know, without even having to talk with anybody, we are going to be following up on. As we get back to the office and slog through our notes and transcript, we'll likely identify additional things.

The final item is to just throw out a few ideas and I have more ideas than we will have time. So, I both want to hear your feedback about the ideas for the next meeting agenda as well as any additional ideas that you have. Some of these came up as we went through the day-and-a-half. Some of them, I think, may have been identified just by myself as we went through the meeting, either way.

The first one is something -- we thought about talking about it at our last meeting, but we decided not to because there is another FACA that EPA has that is

working on it, and that's nanotechnology. But I do think that there is some need for us to begin to -- at least begin educating ourselves about what it is and what is the potential interface with pesticides, and perhaps, we could have a representative from that other FACA, which is actually managed out of the toxics office -- our sister office -- come and talk with us.

That's an area where I think it we would all be, I think, informed. I'm not sure we necessarily need to task ourselves with anything, but I think some education around that may be useful for us. So, that's something we may want to do.

I heard yesterday, and I think it makes some sense, that some analysis around PRIA would be something the group is interested in. I said yesterday, we're going to continue to work performance measures and we want to do it with the advice of this committee, and so, we're committed to continuing to work it and committed to getting advice from all of you. So, that is something that I'm very interested in having on the next agenda.

Spray drift, I expect that there will be some report out. I doubt by March we'll have any consensus or

solution, but there will be an expectation that after the initial meeting or maybe a couple of meetings, there will be a report as to, this is so far what we've done, even if it's a status report, there will be some desire, on my part, to have a report out from that.

Again, the Consumer Labeling Workgroup, I expect we'll have a report out from that. Depending on how much has occurred, there may or may not be some report out from this Worker Protection C&T Workgroup that I mentioned.

I certainly will keep at the forefront of my mind that there is an interest in having more dialogue around the old chemical issues for '06. Again, I think we need to figure out how to have that dialogue and if this is the right forum or if it should be something like the CARAT. So we'll keep it on the agenda until we figure out which way to go on that.

I think it may be useful, I'm not sure, I'm going to put it out there though, as we get close to finalizing this SOP that Anne talked about as it relates to working with the Office of Water as it relates to impaired water bodies, of actually bringing that here to

have a more robust discussion around that.

So, those are some things that I think may be populating the next agenda. Again, I'll open it up now for thoughts about those things or other topics that you think are important for us to give consideration to as a committee.

Bob?

MR. ROSENBERG: This isn't a topic suggestion, you know, this is more of a format discussion. I'm trying to think of how to say this. Well, two things. One, Jim, you had said yesterday that the Agency was growing increasingly reliant on or was valuing the work that was being done by workgroups of this committee, and kind of unrelated, but related, is the fact that I probably suffer from a fairly severe case of attention deficit disorder and I find eight-hour meetings really challenging, even ones at which I don't actually have to do anything and it must be even that much worse for you.

I'm kind of wondering if it might be kind of a good idea to think about whether maybe we could look at changing the format to where maybe we meet from sometime, 9:00 to 1:00 or 2:00 on the first day and then actually

break out into workgroups for the afternoon and then resume on the second day, which would sort of break it up a little bit, provide some opportunity for the workgroups to work and, you know, just have some virtue to it.

MR. JONES: I think we've got a number of workgroups now. I know that some met -- I think two of them may have met Wednesday. That is something, I think, worth giving consideration to. So, you'd sort of make it a two-day meeting with at least one half day, maybe two half days where you're in the workgroups. That's something we should give thought to.

UNIDENTIFIED FEMALE: Jim, for those that may be on more than one workgroup, maybe dividing --

MR. JONES: Right.

UNIDENTIFIED FEMALE: You know, doing some staggering (inaudible).

MR. JONES: The logistics of sort of if you're participating on more than one workgroup, which I really do want to do things that encourage workgroup participation and not discourage it. So, that's something we'd need to give thought to.

Gary?

MR. LIBMAN: First of all, I second that idea. I think it's a great idea, especially for those of us who have to come from outside the Beltway. In my case, I'm considerably outside the Beltway. It would be nice, instead of having the workgroup the day before, which most of us can't get to, then it would be nice to have it the same day. So, I recommend that, too.

One other topic for your thoughts is something we talked about a little bit yesterday and it's something that just keeps on rearing its head all the time. I won't say its ugly head, but at least its head, and that's inerts. I know we're getting closer to the FQPA deadline of 2006 on the inerts, but there's still so much confusion about what they're doing and what's not being done. I would love to see some more of a clarification on this thing, because it's very important for those of us as a registrant.

MR. JONES: Okay.

UNIDENTIFIED MALE: I'd like to second that because some of the inerts are actually industrial products as well and it makes it a very confusing thing in terms of TMDLs and 303D.

MR. JONES: Okay. Julie?

MS. SPAGNOLI: I guess this is a request for the Consumer Labeling Workgroup, that if perhaps the Agency could look to see if we could get somebody from OGC to help us because I think where we keep coming to kind of a standstill is a lot of ideas have been developed or a lot of ideas have been put forward in suggestions, but then it's, well, how could we do this? Is it going to take rulemaking -- is it going to be no way, we can't do it without changing the law? Is it well we can maybe do it, but it's going to take rule-making? Is it a PR notice? Is it a policy change?

We really need some guidance, I think, to find out what recommendations can we come forward with and how -- not only what are the recommendations, but how do we recommend it be implemented and I think that would be real helpful.

MR. JONES: Okay, all right, I'll take that back. Melody?

DR. KAWAMOTO: NIOSH has been working on nano-technology. We have a group that's working on it and I think they've been working on it for over a year now.

MR. JONES: Okay, thanks. Erik?

MR. OLSEN: I'd like to support the concept since Bob and I always agree on everything --

(Laughter.)

MR. OLSEN: I wanted to support the concept of maybe trying to squeeze in some of the workgroup meetings right afterwards. I think it would be useful for everybody.

I also apologize for not being here yesterday afternoon, but one issue is these potential performance measures, and it sounded like, from the report back I got, that you guys didn't totally resolve everything in that conversation yesterday.

(Laughter.)

MR. OLSEN: I'm being diplomatic. You know, one thing that, to us, would be important to raise is most people, I think, in the public would think that if you said what's EPA's potential performance measure for success in the pesticide program, probably at the top of the list would be are they protecting public health and the environment, which doesn't really leap out at me from this.

So, I think some way to figure out how to discuss risk reduction in a way that EPA can actually try to measure it might be a worthwhile discussion for us to have or maybe you just want to think about that between now and then.

MR. JONES: A little clarification around that, because this is something that we've struggled with quite a bit, not exactly that point, but there are three areas that we're attempting to develop performance measures, protecting human health, protecting the environment and then this group that we're calling other benefits. Now, when we started doing this three years ago, I consciously kept our team away from other benefits and on human health and the environment because I knew, analytically, the latter is the easiest to do, and that the harder -- way much more difficult analytically is trying to do the first two. So, I'm like, let's keep this in abeyance because we're going to need less time because it's more straightforward and there's more data. And we struggled along, struggled along, struggled along on those other two and then, finally, I'm like, well, we've got to start working on this because we need to have -- there are

three important parts of this and we have to start working.

Well, even though they started a year-and-a-half later, of course they got farther ahead because analytically it is more straightforward. Strategically, I would have preferred to have put forward the human health one first, but as I said, analytically, it's so much more difficult. It's easy to do my part of it, which is to articulate the goal. Actually coming up with the measure is incredibly difficult for both human health and the environment.

So, I would recognize that strategically that wasn't the most masterful move, but that was the group that was the furthest ahead, even though we had tried to set it up so that the human health and the environment would have been further along. I think that confused people. You know, why are you talking in your performance measures about benefits? I think people who participated in the meeting -- in the workgroup became clear because they spent, you know, five hours on it and it became -- and they could understood it. But people who were then just at the PPDC got very sort of why are

you leading with this.

So, that's the story behind the story there. It really does get to the analytics behind human health measurements in our work and environmental measurements are just so much more difficult because the data sources are just not as available, so --

MR. ELWORTH: And what we've done is queue up protecting human health for the next meeting.

MR. JONES: Those are the next two that are being done.

MR. OLSEN: That was exactly my point was that I think that we need to have that discussion on what the -- how you're going to measure that because you're not going to be able to measure dead bodies necessarily, you're going to look at something else.

MR. JONES: It is very, very hard. Well, I expect we're going to have some very meaningful pet measures the next time we measure pet health from some of our actions last year, which some of you may not have focused on, but -- okay, appreciate it.

Pat?

MR. QUINN: I think given the level of interest

in the human studies issue yesterday and the fact that you will have issued a final rule four or six weeks in advance of the next meeting and you'll probably be doing things like selecting and announcing the members of the HSRB and everybody will be scrambling to try to understand what their role is on both the front end and the back end of the review process, it might not be a bad idea to have another session on human studies.

MR. JONES: I don't know how that slipped my list.

(Laughter.)

MR. JONES: I can't even imagine how that didn't -- you're probably right, that's very good advice, Pat.

Okay, well, in closing, I just want to relate one of my stories from talking to my kids, who give me some of the greatest insights about my work. This morning, my daughter -- I'm home a little later because these meetings start remarkably late for my schedule and so I'm hanging out with the family in the morning. Usually, I'm not around to talk too much and to wake them up. So, my daughter said, so, what are you doing today, Dad? Why are you here, basically is her question.

I said, well, I'm -- this is a stupid answer, but I said it anyway. I said, well, I'm meeting with some stakeholders today.

(Laughter.)

MR. JONES: And she's like, what are you talking about? So, I tried to describe it to her and as I'm walking out the door, she says, well, have fun with your work friends today.

(Laughter.)

MR. JONES: I said, these are not my friends -- no, I'm just kidding.

(Laughter.)

MR. JONES: And like, oh, what she's saying is not have fun so much, but you're going to be with a community today and you need to sort of take advantage of being with the community and that, I think, is something important for all of us to remember, is that we are part of a community and it's the broad community of this nation. It's not that we are a pesticide community, but we are a community and it's important for us to remember that. I think, actually, the way in which we have engaged each other as a community in the last day-and-a-

half, I think, has been very positive in a way that allows issues to evolve and move on. Whether you think it's forward or backward, it allows issues to move on.

I really do want to thank everyone for the professionalism with which you've all brought your perspective to this meeting so that the Agency is able to avail itself of your advice. So, I very much appreciate the degree to which we have operated as a community over the last day-and-a-half, and frankly, over the last 10 years. So, I thank you very much for that. And I hope you all have safe travels wherever you're going and a good weekend. Thanks.

(The meeting was concluded.)

CERTIFICATE OF TRANSCRIPTIONIST

I, Elizabeth M. Farrell, do hereby certify that the foregoing transcription was reduced to typewriting via audiotapes provided to me; that I am neither counsel for, related to, nor employed by any of the parties to the action in which these proceedings were transcribed; that I am not a relative or employee of any attorney or counsel employed by the parties hereto, nor financially or otherwise interested in the outcome of the action.

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ELIZABETH M. FARRELL

Transcriptionist