**Transcript of**

**Pesticide Program Dialogue Committee Meeting**

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**P R O C E E D I N G S**

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**DAY ONE - SEPTEMBER 17, 2002**

MS. MULKEY: Good morning, all. Thank you very much for convening with us again for our Pesticide Program Dialogue Committee. That name for this committee was selected a long time ago, but I think it continues to serve us very well. We have been able to use this forum to focus on a lot of issues that are important to us programmatically. It has been a real dialogue, and we have had an opportunity to work with you and you are a truly wonderful bunch in many senses of that term

We've had an opportunity to work with you on issues that you're interested in and that you've asked us to focus on, but also on issues that are important to us and that we have identified as representing issues where we really need the benefit of your dialogue. So, both for the issues where we benefit because you saw the need for us to engage in a dialogue and issues where we benefit because we saw the need to engage in a dialogue. It has enriched us enormously.

I didn't count the number of these committee

meetings over the history of this committee, but it is a very significant number at this point and we are working very hard to build on the history of our meetings, and I think you'll see more and more evidence of that as we work through these two days so that there is a continuity and a foundation for our ongoing dialogue.

I'm looking forward to today. I don't want to take much of the agenda time with these opening remarks because there is a lot of meat and a lot of interesting things to hear. But I did want to take a minute or two to acknowledge some faces that will either be new to you or sitting in different places and/or are particularly important to acknowledge. If I can get her to pause in the middle of what she's doing, I wanted to take a special moment this morning to talk about our Designated Federal Official. Margie Fehrenbach, whom all of you interact with constantly as a result of this committee, is the Designated Federal Official for this committee. But I don't think any of us have any sense of just all that is involved in her performance of that function.

The amount of work necessary to plan and pull off a meeting like this to assure that all of you and all

of us are here ready, prepared and able to be effective, to troubleshoot all the problems and to do it in a way that makes all of us feel better, because she makes us feel better, is just a really special talent. So, I wanted us to take a little extra time today to acknowledge our Designated Federal Official.

**(Applause.)**

MS. MULKEY: I also want to take a moment to tell you about a couple of folks whom you will see today and tomorrow. One you know quite well, Kathleen Knox, but she's here in a new role. She is now acting as our Deputy Office Director for Management. And you will remember Joe Merenda who is taking on the position as Director of the Office of Science and Coordination Policy within the Office of Pollution Prevention of Pesticides and Toxic Substances. So, we're really delighted Kathleen is performing a role for us. She brings skill, experience, ability, grace and a lot of other things to taking on that responsibility.

And, actually, although tomorrow's topic on funding is not one that we asked her to have to step up and do in her, literally, first week doing this, she will

be here to hear feedback and will provide some continuity on that topic that, I think, will be important.

The other person I wanted to introduce to you is Steve Bradbury. Now, I saw Steve, but I don't know where -- my eyes -- do you want to stand up, Steve?

Steve Bradbury is Acting Director now of our Environmental Fate and Effects Division and has been doing so for several months now. He came to us from the Office of Research and Development. We'll get a chance to learn a little more about how much expertise, science, bona fide ease and talent he brings to the organization, but I wanted you to have a chance to put his face with his name as early as possible this morning.

Speaking of putting faces with names, this is the time in the program where we will take an opportunity for all of us to introduce ourselves. If I start with my left, then what will happen is when we get past Al, I will have an opportunity to introduce the folks who are going to take on the next little piece of the program. So, if we can operate that way with your permission. Gentlemen, we will start with Jim.

MR. JONES: I'm Jim Jones, I'm the Deputy of

OPP-for Programs.

MS. KNOX: I'm Kathleen Knox. Marcia just introduced me.

MS. ANDERSEN: Janet Andersen. I'm the Director of the BioPesticides and Pollution Prevention Division.

MS. ROSS: Lois Ross, the Director of Special Review and Reregistration.

MS. BOUVE: I'm Kate Bouve. I'm Chief of the Information Services Branch in the Information Resources and Services Division.

MR. QUINN: I'm Pat Quinn with the Accord Group here in town.

MR. SEIDLE: Troy Seidle with PETA, People for the Ethical Treatment of Animals.

MS. BAKER: Cindy Baker with Gowan Company sitting in for Allen James of RISE.

DR. LYNCH: Sara Lynch, World Wildlife Fund.

DR. HOCK: Win Hock, American Association of Pesticide Safety Educators.

MS. HARDER: Lori Harder, Yurok Tribe and Tribal Pesticide Program Council.

MR. LIBMAN: Hi, I'm Gary Libman, Emerald

BioAgriculture.

DR. LEWIS: Nancy Lewis from the University of Nebraska in Nutrition.

DR. SAUERS: Len Sauers from the Procter and Gamble Company.

MR. GRAY: Sean Gray from Environmental Working Group.

MR. ELWORTH: Larry Elworth, Center for Ag Partnerships. And, Marcia, when you were talking about history, you kind of looked over towards me and Steve.

**(Laughter.)**

MS. MULKEY: You're right. Pardon me.

MR. ELWORTH: I just tried not to take that personally.

FEMALE PARTICIPANT: Not ancient.

MR. ELWORTH: Ancient?

**(Laughter.)**

DR. BALLING: We were looking around trying to see anyone who had been here longer. Nope.

Steve Balling, DelMonte Foods.

MS. BRICKEY: Carolyn Brickey, the Institute for Environment and Agriculture.

MR. McCORMICK: Bill McCormick, Clorox Company.

DR. LOCKWOOD: Alan Lockwood, Chairman of Environment and Health Committee of Physicians for Social Responsibility.

MS. LIEBMAN: Amy Liebman filLing in for Ed Zuroweste from Migrant Clinicians Network.

MR. ROSENBERG: Bob Rosenberg, National Pest Management Association.

MR. NICHOLSON: Erik Nicholson with United Farmworkers of America.

MS. SPAGNOLI: Julie Spagnoli, Bayer Corporation.

DR. AMADOR: Jose Amador, Texas A&M, down in Weslaco, Texas.

DR. BERGER: Lori Berger, California Minor Crops Council, Visea, California.

MS. SASS: Jennifer Sass with the Natural Resources Defense Council.

MR. STICKLE: Warren Stickle, President of the Chemical Producers and Distributors Association.

MR. VICKERY: John Vickery, a consultant from Minnesota.

DR. CARROLL: Beth Carroll, Syngenta Crop Protection.

MR. BENEDICT: Phil Benedict, Vermont Department of Agriculture, Foods & Markets.

DR. KAWAMOTO: Melody Kawamoto, National Institute for Occupational Safety and Health.

MR. JENNINGS: Al Jennings, USDA.

MS. MULKEY: Go ahead and pick up the folks back here, too.

MR. BAILEY: Joe Bailey with (inaudible).

FEMALE PARTICIPANT: (Inaudible).

MR. JORDAN: Bill Jordan with the Office of Pesticide Programs.

FEMALE PARTICIPANT: (Inaudible).

MS. MULKEY: Thank you all very much. And we are fortunate and I, on behalf of the whole committee, thank Adam Sharp and Burleson Smith both for taking the time to spend time with us. They both insist that they believe that this is absolutely where they should be and that they're eager to be here, and that makes sense to me, too, because I know of their interest in this group and what it has to offer.

As you know, Burleson is at the U.S. Department of Agriculture and has taken on responsibility for this administration's leadership around pesticide issues for the Department. And Adam Sharp is our Associate Assistant Administrator and is taking on responsibility within EPA for a key point person for this administration's issues around pesticides and toxic substances in OPPTS.

So, they both have some remarks, and I assume you've figured out the order in which you want to go.

MR. SHARP: I'm going to be real brief. I just wanted to say welcome to everybody and pass on a welcome from Steve Johnson, my boss, of course, and he wants to make sure that he certainly values all of your input, as we all do up here for the next couple of days. It is a busy agenda as you've all seen. There's a lot of good items, I think, for you all, a lot of good information for you all to discuss, to hear about, ask questions about and provide input on. So, it is going to be a very busy couple days.

Myself, I'm committed to be here for the next two days because I certainly want to hear all the points

of views that you all have on this variety of issues, and I guess we do have a real good variety of issues, from animal testing to talking about our budget to cumulative risk assessment, et cetera, of things to cover.

I guess when I look back at some of the PPDC agendas, this is probably one of the more varied ones. It's a nice range of things to talk about and I know of interest to a lot of you around the table. So, I look forward to that discussion.

I want to also bring your attention, of course, to a couple of workshops that we have planned coming up and certainly invite you all to two public workshops. Of course, on Thursday, we're doing a workshop -- a public workshop on the Endangered Species Protection Program being developed by the agency, and then, of course, there's a workshop on worker risk at the end of next month. So, I want to invite you back to both of those meetings as well as they're going to be very important and a lot of good information, I think, also will be distributed at those.

So, with that, I'm going to go ahead and stop and say, thanks again for taking out the time to be here

for the next two days. Burleson?

MR. SMITH: Well, good morning and on behalf of the Department of Agriculture, thank you for your attention and cooperation here. It certainly is an opportunity for us to hear your ideas, comments and concerns with respect to the pesticide programs at EPA and we appreciate the opportunity to join EPA today at this. So, again, we appreciate your participation, look forward to it and keep the remarks short.

MS. MULKEY: Thank you. And we really do appreciate both of you being here. I notice we've been joined by Dr. Terry Troxell from Food and Drug Administration and by Jay Vroom of CropLife America. Did anybody else come in since we did the introductions?

(No response.)

MS. MULKEY: We seem to have a full house as it were. Everybody's at the table and that's exactly the way we like it.

We have been working on several enhancements to the PPDC approaches based on your feedback, and we continue to solicit your feedback to try to make this as effective as it can be. One of the enhancements is more

follow-through and continuity from meeting to meeting and over time with regard to the issues that we work through in this committee. And so, you will see, starting with the next agenda item, and again later in the day, that the four main subject matter areas for our last PPDC are again on this agenda, not necessarily in as comprehensive a way, but in an effort to make this continuity meaningful. So, we'll be asking throughout for your feedback about whether we're getting it about right with regard to level of continuity and follow-through involving those kind of topics.

As you know, you gave us a lot of positive feedback about the updates and amended approach, and we have continued with that. That allows us to touch upon a number of topics, but it -- these topics are not designed for robust, meaningful, sustained dialogue. So, again, to the extent that you find that among these topics you experience frustration for the absence of that opportunity, we welcome that feedback and we will look for ways of identifying more appropriately what kinds of things belong in that category and/or how to find other ways to give a more comprehensive approach for some of

those topics. But these topics were largely suggested by you for the update in a minute format, and so, we're assuming that we've gotten it about right in terms of what kind of topics belong in that section.

We also are finding our -- I'm sure this is not the right way to say it -- but our PPDC chatroom, maybe we should call it dialogue room, but our electronic dialogue opportunities to also enhance our ability to sort of know what you're thinking and we notice that you're not as eager on all days to engage as you are shortly after and shortly before these meetings, but we also would like feedback about whether that is a meaningful enhancement to our effort to make the dialogue committee.

We also have continued to try to bring into our discussions you, members of the committee or others other than the agency so that it's not just an agency talking heads committee comment, but that other people invest in preparation and interaction with the agency. And we're also learning to make more use of your input as we plan specifics, and as you will see, we have engaged with a group of you in planning the session for tomorrow on our

resource allocation and expenditures, and we've also been working with a group that came primarily from this committee and working on preparing our worker risk seminars, actually, as you will learn a little more about.

So, those are all ways in which we're trying to make this more meaningful, more interactive, more substantive, and have more continuity, and I would just encourage you to give us feedback as we go along and I will expressly solicit feedback at some point about whether these improvements are working and whether you have ideas for making things even better.

Well, one good way to make things even better is to get on schedule and stay on schedule. As you know, I'm a bit of a nag on the subject of keeping our breaks to the time allocated. I would ask you to commit yourself right now to really being conscientious about that today. But it will help that we're able to plunge into our first pair of follow-up topics a little early.

You will remember that we covered a range of electronic media related issues at the last session, everything from e-commerce to e-FOIA, but by far, the

most extensive dialogue was around electronic data submission issues. So, we've asked Kate Bouve, who works specifically in that subject matter area, to provide us with some update and continuity report in that area.

**(Brief pause.)**

MS. BOUVE: Let me get started. I think some of you may have picked up the handout. I think they were out in the -- yeah, very good.

As Marcia noted, we will be talking in future PPDCs about the advancements in the e-docket and the e-FOIA area, but for today, I'm going to be focusing on updating you on our electronic submission and review efforts in the Office of Pesticide Programs.

First, I want to review a little bit some of the standards that we've set for electronic submission and then talk specifically about our supplemental files pilot project, which was something I talked about with Clive Holder at the last PPDC, and then just a real quick touch on some of the upcoming meetings and further communication in that area.

I think it's important to recap some of the basic information about how we've been approaching our

electronic submission and review efforts. Our basic operating principle is that we have to strike a good balance between the needs of our registrant applicants and those of the reviewers in OPP. So, we had to find an electronic formatting standard that was easy and inexpensive for the registrants to put into place, but that it was also easy for our reviewers to learn how to use, and at the same time provided them powerful enough tools so that they could do the important work of reviewing studies and preparing their review documents more efficiently and more effectively.

We also felt it was important that we need to focus our efforts on the most resource-intensive work. There's all sorts of fun little things that we can do in electronic submission, but if we're going to go to this trouble, we thought reviewing studies, which is probably the most resource-intensive hunk of work that we do in OPP, that was the place to start.

Now, we have set standards for the submission and formatting of studies that are submitted electronically to the Office of Pesticide Programs. We're using Abode PDF. Not exactly brilliant, pretty

much a de facto standard. And they're coming into us on CD-ROM.

For the reviewers internally, they're using the full Adobe Acrobat software package, plus other tools like their word processing software, their spreadsheet software and the like, to use that as a way of evaluating the studies and preparing review documents. We established that standard last fall.

Electronic submissions are encouraged from our registrants and submitters, but it is not mandatory.

Now, we've got a couple of pilots that we're working on. As we finish a pilot and set a standard, then we move on to the next set of pilots. So, we've got two underway. One is the electronic submission and review of product label text, but the one I want to focus on today is talking about electronic submission and review of supplemental files that come along with our chronic toxicology studies.

First of all, a little clarification. What are supplemental files? We're talking about those files, the data that are generated, and, of course, some of the long term feeding studies. These generate a great deal of

data and the ability to analyze that data helps our reviewers better understand these studies. So, we're talking about chronic and sub-chronic studies, developmental, developmental neurotox, and there's a whole range of data sets that are produced in the course of these studies, food consumption, body weights, tumor data, clinical signs, clinical chemistry and the like.

Now, you may recall last time I was here Clive Holder from Bayer was my co-presenter, and Bayer stepped up to the plate on this project and worked very closely with the program to design the formats, to decide what data sets, how they should be organized, and we all decided to work with SAS Transport as the software, as sort of the truck to carry that data into the building. We built on the work that was done by the Food and Drug Administration. We felt that they've done such good work over the years and we felt that we could build on the foundation that they provided. And then we're also, as the Food and Drug Administration does, we're using JMP software by our reviewers in order to analyze the data.

So, in our first pilot effort, Bayer worked with their labs in the U.S. and overseas, so it was a real

challenge, and they submitted supplemental files in support of their chronic studies on 2 AIs? Our reviewers worked with it, a small number of them, obviously, were very enthusiastic about this process. They felt that they were better able to analyze the data much more efficiently than if they were trying to rekey data or reenter statistics or do that sort of work, and they felt that it greatly improved the quality of their evaluation of these studies. Of course, we're working with our toxicologists and the whole (inaudible) Division to do this work.

So, as a result of that very initial success, we're declaring this as a full-blown pilot now and we're encouraging more companies to submit these supplemental files. We've put together an extensive guidance document on what are the files, what are the data elements within the files, how to create the SAS transport, and that's posted on a website that we've built that has all of our guidance on how to submit studies electronically.

And then, internally, we've acquired more copies of the JMP software and the HED staff are being trained on the use of that software. JMP, just as a little

clarification, is part of a suite of softwares that's produced by SAS. SAS is the Statistical Analytical Software package and it's pretty much the standard throughout EPA.

Fortunately, registrants have shown interest in participating in this. We're very pleased about that. It's a real challenge for them to work with the many different labs that they deal with and that different sources of software that generate the data in support of these chronic toxicology studies. So, we're very appreciative of those efforts and we encourage more registrants to get involved.

Finally, just to let you know that there's continuing communication, both internal and external on these issues, we're going to be participating in an OECD workshop the first week in October in Ottawa. We're working with the Canadians PMRA on hosting this effort, and it's going to be an opportunity to share information on what kinds of tools and technology is being used in the United States, Canada, and in Europe for electronic submission and review.

And then in November, on the 19th and 20th, here

locally, there will be another -- the second workshop that was cosponsored with CropLife America and OPP, a real working session on electronic submission, with a wide variety of participation from different types of registrant groups. Hopefully, we'll get some lab people here as well. So, the continuation of this conversation is an important part of our work here.

Any questions?

(No response.)

MS. MULKEY: Thank you very much, Kate. As I said, we didn't plan for an extensive discussion of this, but it is worth noting what are the policy and programmatic implications of this kind of essentially techie exercise. We believe, and there are increasing data to support this, that this can have quite a material measurable effect on our productivity with the result that we can do more work with our existing resources. From the standpoint of new chemicals, obviously, which is where these submissions are going to be seen, that's presumably something that everybody has an interest in. So, that is sort of the macro significance of this.

You also heard a related issue, which is this

may also improve the quality of our capacity to understand very complex studies. That, of course, means that we will both do things faster and better, which is just about all you can ask for from any kind of new initiative.

We have not yet attempted to develop data on the extent to which this enhances productivity. But Canada has made some efforts to do that and I think FDA has, also, and there are data which do support the notion of more than marginal improvements in efficiency and productivity. So, that's an important sort of macro context for this topic.

The second topic that we wanted to spend some time on that is a carry-forward from a very extensive dialogue that we had at the last PPDC meeting had to do with issues around the adoption of biopesticides in agriculture, primarily agriculture. As you know, we had quite a discussion about barriers and factors and the nature of these products and a lot of things relating to them.

So, Janet Andersen, who is, of course, Director of our BioPesticides and Pollution Prevention Division

working with the team of folks that were involved in our work leading up to the last PPDC meeting and since then is going to give us a report on follow-up in that area.

MS. ANDERSEN: Thank you, Marcia. I want to acknowledge that Kathleen's name is here because she still -- this is probably like one of her last official acts in the BioPesticides and Pollution Prevention Division, but certainly has been important in the help we've had in putting this together.

Last May, as Marcia said, we did have a good robust discussion on the adoption of biopesticides, and coming out of that we took quite a bit of notes and put together a list of all of the barriers and suggestions we had.

Can I go ahead and have the first slide, Bill?

If I counted it up, I think we had 77 items in the list, and with that whole stack of things we tried to decide how we could best handle it. Working with the IR-4 group, we put together seven categories that we thought were appropriate for these various topics. They were industry, land grant universities, the USDA and its various agencies and parts, regulatory groups, commodity

groups and growers, food processors and independent crop consultants, and then the others. It's not that others weren't significant, it's just that there were so many diverse that we stacked them together.

We then arrayed this group into the various categories which have been sent out to you for you to look at it and go over. It's in your handouts. It also was sent electronically to the committee, to the whole PPDC, and what we're looking for today is for the discussion we'd like to have at the end of this short presentation, is something about how EPA could help facilitate in bringing to the attention of these groups and working with these various groups, some of these barriers and solutions that we might actually try and implement some ways of further adoption of biopesticides.

As I said, the list of barriers was provided to everyone and at the end of it there's a section that's the top 10 items that both IR-4 and BPPD identified as things that we thought we could really make improvements on. Now, this is a long-term list. It's not something we're going to have done in the next couple of months nor even probably the next couple of years, but real goals

for us to look at.

However, we have made some good progress and I want to just go through some of those for you. The very first item on the top 10 list is increase IR-4 funding for biopesticides research and IR-4 has done this. They've moved an additional $100,000 into their program. So, they've moved from $300,000 identified for biopesticide research to $400,000. This is really demonstration projects and also sometimes other research to help facilitate bringing products to market. But often, it's demonstration projects that really can be hands-on. So, we're really pleased to see that IR-4 has been able to do that and we're sorry, actually, Bob Holm couldn't be here today to make more of that presentation.

I'm going to move a little bit then onto some of the things that BPPD has been doing. Number two on the list of the top 10 was to the process for registration of biopesticides. So, let me go through some of the things we've been doing in the Division and show you that we are making some progress in this area.

We've developed a fast track team for biochemicals, and let me tell you for the jargon that you

might not know, a fast track action in the Office of Pesticide Programs is one that comes in with no data associated to it. That doesn't mean it should have data and it's missing. We get those, too. They aren't fast track. It's an action that is really just a simple amendment to an already existing product where they may be adding a new use cite but don't need to have any data to support that or an additional insect pest or something like that might be added. Those are examples of fast track amendments.

Also, there are some products that are fast track amendments. They're what we also refer to as ME-2s, they're identical products to what's already on the market but might be splitting up a label or something like that.

But these actions can pile up and really can help move the actions along better and have better products on the market with better labels, we believe, if we can have them acted on rapidly. So, that team has been up and working for several months and has really been making quite a difference, I think, in being able to get these actions out rapidly to our registrants.

The second one is a newly instituted group called the pheremone team, and we were just up and running this group. But the goals of this group is to provide better guidance to our registrants on how to actually make the submissions for pheremones. We've gotten a lot of problems with that over the last couple of years and we're really trying to provide some better guidance that will help us get packages in and be able to make decisions more rapidly.

We also, on our own side, want to improve our consistency in our reviews, not only our scientific reviews, but our label reviews for these products so that they can go to any one of the number of staff and have a quick and consistent review of their product.

We hope, overall, to be able to streamline and improve the speed at which we are actually able to make decisions on pheremones, and I'll get to the reason a little bit later of why we picked pheremones for this.

Some of you probably know that in the 2001 budget, I believe it was, we got a significant increase in our division in extramural funds for having contract reviews. It takes a while. You have to identify a

contract or put them in place, but you also have to train the contractor in how to do the reviews and work on it, and we've been doing a lot of effort on that lately and we really see that our contractors are improving and providing back to us reviews that are much more in line with what we need and fewer corrections we have to make as we go through our secondary review process. So, that's a good one.

And we are now screening all of our scientific reviews before we send them to contractors. That is, if the product has a set of data associated with it that is not going to be acceptable, we're identifying it right on, right early, and giving it back to the registrant to identify them. It doesn't go off to the contractor and four months later come back, goes through secondary review and we say, oh, well, you really need to redo this whole study, and they say, why didn't you tell me this six months ago. Well, now we're telling them right up front that there's a problem with their package, and we hope that that will also give us some better turnarounds. And we've improved our front end processing within our own division to speed that up.

Bill, next one.

But there are lots of other things on this list of 10 that we want to do and we are working on. Last year, we had a workshop in November on biopesticides and how to get them registered. We've had some suggestions for new topics and we're working right now to develop a workshop for hopefully this fall or early winter on some test methods regarding microbial pesticides that are causing us some difficulties, and we want to make some improvements there. And, also, there have been several requests for some more how-to instructions for biopesticide registrants in various topics and we'll be doing some small workshops in that area.

I think there will be more discussion a little bit later from some of the panel members from last time, but there's going to be a biopesticide session at the National IPM meeting that will be held next April and we think that that's really an important way to help us have a good dialogue with lots of people who are really in the field and doing real practical work in adoption of new pesticides.

I mention here, this is the pheremones that are

playing a role in transition. As we move from some of the organophosphates and carbamates into other more safer products, we are looking at the pheremones as one of the real key players in this, and we think that they have played a role in transition and can play even a greater role in transition if we help with some of the regulatory parts, that is including giving sprayable pheremones that are much easier than the twist-tie versions of these products, and also just bringing these products more rapidly to the market. So, that's why we have the team -- one of the reasons we really have the team.

Just so you know we really did pay attention at that session that we held in May, one of the things that was suggested in that meeting was that we put a list of all of the active ingredients we have for biopesticides and the trade names of those products associated with it and make that publicly available. We have now done that and put it on our website.

Next slide.

Another one on the list, it's number six on the list of top 10s, is talk about success stories for biopesticides. So, I'm going to want to give a little

success story here to you today, and that's talking about phermones. I know that a lot of you have heard good things from Gerber and DelMonte about them, using phermones over the last few years, but there are also other good stories. I just want to provide a little bit of information.

In California, it is estimated by the pheremone industry that over half of the fresh market of stone fruit receives at least one application of pheremones in a year for oriental fruit moth, and one of the pheremone companies we work with, Siterra (phonetic), has told me that their products alone are being used to treat over 100,000 acres of California crops in the year 2002, this year.

This company has also backed up what they got with new technologies. They are the registrant producing the puffer technology that's used in some of the orchards now and, also, they're moving quite rapidly into sprayable pheremones.

We do see an adoption of this technology, especially as the sprayables are coming along and receiving registration. Siterra is especially looking

for a new product that we hope to eventually -- that we will rapidly have in the market, we think, in the next few weeks, one on navel orange worm, another important pest in California.

Siterra is not unique in its aspect, but they are really very strong in research and development and they have committed to spend over a million dollars annually for phermone research. So, that kind of commitment by the industry, I think, is very important for us being able to see these products coming more rapidly into the market.

On the U.S. side, we also have with phermones been working with PMRA, who is represented here, too, and OECD to have the data requirements and the process that we use for phermone registration, that expedited process, have that be the standard for all OECD countries, and that system is in place as guidelines from OECD now.

So, I just wanted to give that little bit of brief overview of where we came from and we are going to continue to work on our top 10 list and others, and I also wanted to then go around to the people who were especially panelists last time with us and ask if they

have any specific comments, and I know the biopesticide industry is actually -- we've put some slides up for them, but if I -- as Bill switches from this presentation to theirs, maybe I could -- Win, do you want to add anything that you'd like to say as I go around the table? Would you like to add a comment?

MR. HOCK: I'd like to ask a question.

MS. ANDERSEN: Okay.

MR. HOCK: I'm just wondering how many -- I use the term kind of in quotes -- "registrants" might go for a Section 25B, in other words, a minimum risk exclusion for registration. Do you see this happening quite a bit in the future with phermones and other biopesticides?

MS. ANDERSEN: Phermones will not be 25B compounds.

MR. HOCK: Okay. I was wondering just, you know --

MS. ANDERSEN: No, they're registered in an expedited fashion. What he's referring to is, 25B is a section of the law of FIFRA that allows us to exempt specific active ingredients if they are determined to be extremely safe, very, very low risk. And EPA has done

this, did a final rule in '96 that put, I think, 31 compounds on that list and then also to then have a 25B pesticide product, you must have inerts that only on List 4A, so also extremely safe inerts. The process of 25B has us not actually reviewing those labels. The concept was they would be so safe that we would not need to do safety reviews of them. So, we do not review those labels. So, it's very hard for us to actually say how many products there are out there, but we know that there are quite a few.

MR. HOCK: Thank you.

MS. ANDERSEN: Gary, I think you are the next one. Gary Libman representing right now the Biopesticide Industry Alliance. If you want to --

MR. LIBMAN: If you could put up the next slide.

MS. ANDERSEN: It's the one that says top 10 list of BPIA.

MR. LIBMAN: We all had top 10 lists and these are ours, and we divided it into three different categories. First of all, thank you, Marcia, thank you, Janet, for this opportunity, and thanks to the whole PPDC for the opportunity to speak about biopesticides. It

really became a very interesting topic in May and it really helps the biopesticide industry to understand where people are coming from. It was very eye opening to say the least.

And we took the listing that came out last Thursday or Friday and we sort of culled it down to 10 items that are very important for industry. First of all, the three broad categories, our industry will demonstrate programs to show users that biopesticides fit into integrated pest management and other pest management practices. Janet Andersen already alluded to the IPM workshop. There's going to be a workshop in Indianapolis next April, and there's several of us from the industry who will be part of that. We'll be on a panel discussion, Fred Betts from Eden BioSciences and myself from Emerald Bio.

And another thing is showing the biopesticide success programs. Janet talked about the phermones. There's many microbial success stories whether it's gypsy moths or BTs or bavari basiana (phonetic) with thrips and aphids, and the biochemicals showing incredible yield improvements in California and other states. So, we

definitely have success programs and we need to get that word out because a lot of people, as I found out in May, were not aware of that.

We are going to have a website, the Biopesticide and Industry Alliances will have a website. We don't have it yet. We're a bunch of small little companies that are just all working diligently trying to stay afloat. But we are going to put together a website because we feel it's very important for us to have that so that people can look at that information and determine what is available.

As Janet indicated, the BPPD website does have a listing of the brand names of biopesticides and we would like to add some more information to that, including labels and so on.

Next slide.

Industry also wants to demonstrate that biopesticides are efficacious products. When I gave my presentation in May, we talked about the fact that there is a perception that some of the products are, in fact, snake oil type of products and that was probably a valid impression on some products a few years ago, but it

certainly is not the case now. So, we are working diligently towards a certification program so that when you see this Biopesticide Industry Alliance certification, people will know that it is quite an efficacious product as a stand-alone or an integrated pest management.

And then we need to do a better job, as clearly came out in several issues in the BPPD listing, to use advocates a little better, whether those advocates are PCAs or extension folks or other people in the universities and so on, we need to get the word out that people are not advocating the use of biopesticides as much as we'd like to see them being advocated.

We also want to work with the extension services. There's a tendency of the extension services to use this one-shot-kill-all type of things for synthetic chemicals, and we want to educate the extension services to objectively evaluate the benefits of the use of biopesticides.

That leads into the next stop which is just showing compatibility with other --

**(END OF SIDE A, TAPE 1)**

-- pest management tools.

Next slide.

The final broad category is we want to get biopesticides to be the product of choice, obviously, whether, again, as stand-alone or as part of an integrated pest management system. A lot of questions, a lot of points came up regarding cost effectiveness of biopesticides. They are, very often, more expensive than traditional synthetics. So, we recognize the importance of cost effectiveness to the growers and we have to do a better job and industry is aware of that and we are working towards that. As Janet said, on her top 10 list, these are not things that will happen overnight, but it's an evolving process.

We want to promote the environmental compatibility of biopesticides. Clearly, these biopesticides, in almost every case, fall into the reduced risk category and we are wearing the white hats, we like to say. We know that they are environmentally compatible. And then, finally, our products are available as a tool for organic growers, depending on what inert is in the formulation. We're working with the

USDA, the National Organic Program of the USDA and various other groups to move that process along.

MS. ANDERSEN: Thank you. I'm not expecting every panel to have had the slides. They got kind of a heads-up that everybody didn't get. But I'm going to turn to Steve Balling. So, the next one, as I go around, that was on the panel last year. Do you have anything you'd like to add?

MR. BALLING: Well, one thing I would continue to add, which I have many times, Gary, is that advocacy is very important, and I think it's critical in the world of growers to move information along. But for many of us, replicated data is what counts, and so, I'll continue to harp on that.

Gary also mentioned, and as you did, Janet, the IMP workshop next April in Indianapolis, and we will be, along with Gary and BPIA, the National Foundation for IPM Education will be helping to host a break-out group on overcoming barriers to biopesticides. I think it's a real critical opportunity for a lot of folks in various areas to come in and have a serious discussion about how we can move quality products through the system, and we

would really like to see a good turn-out for that. So, any of you who are interested, please join us.

That's all. Thanks.

MS. ANDERSEN: That's good. I'll just reiterate, I think that this replicated data, it will help to have the increased funding with IR-4, too. I think that's a good source for it.

Carolyn was on the group. Carolyn's got --

MS. BRICKEY: Well, I was really intrigued and interested in Gary's list because there's so much there. I mean, some of those items could take up pages and pages if you started listing all the steps that you had to do to make some of that stuff happen. But I definitely think that this is one of the panels that we've all gotten a lot of substance out of. So, I'm really glad to see the follow-up and I'm interested in continuing to work with you, Janet and Gary, to try to make some of these things happen.

MS. ANDERSEN: Great, thank you. Lori, do you want to add -- I hope I'm not missing anybody?

DR. BERGER: Well, I just wanted to say that all these goals are very reasonable and worthwhile. It

should be recognized that they all are predicated on efficacious products, and that's really the key I see, kind of the a priori assumption that all of these things will -- you know, the IR-4 Program, all of these other things, technology transfer, it's all based upon whether or not there's true efficacy there.

MS. ANDERSEN: Good point. Al Jennings?

MR. JENNINGS: Yeah, thank you. I would just like to emphasize the experimental use permit and the importance of that in terms of getting the product out to researchers so they can do demonstrations, so they can generate that hard data, and just how important the experiment use permit is in this process of getting products on the market and getting them accepted.

MS. ANDERSEN: And now, I think we'll turn it over to anybody else on the panel who would -- we've got a couple of minutes if anybody else wants to raise a flag.

MS. MULKEY: You mean on the PPDC?

MS. ANDERSEN: On the PPDC, right. Larry, you're first.

MR. ELWORTH: Janet, in the discussion for BPPD

actions, you talked about your processes to your division, I guess one of the questions I have is whether you can also expand work on your processes to what happens with HED since -- to the extent that you need tolerances or to the extent the inerts are important, what you're doing on that.

I actually wish Bob were here because I didn't know that IR-4 did demonstration projects until today and it certainly seems a little far afield from their initial charge in terms of doing data to support tolerances. I guess the thing I'd like to follow up a little bit on, Steve, is that on the list of BPIA -- I'm sorry, I'm having trouble keeping the acronyms right -- at some point, all of you folks are going to have to generate invoices and the people that help you generate invoices are PCAs and growers. So, it's important to have all of these organizations involved. But the hard thing for all of these companies, because of their size, is their ability to effectively market their products.

At some point, I think separate from everything else that you do, which is all fine, until that piece of it actually works out, you're still going to be

struggling, talking, a little bit preaching to the choir, people who wish you well, but are not going to go out and buy your products tomorrow.

MS. ANDERSEN: Well, Larry did ask a question. Just so that the panel understands, the Biopesticides and Pollution Prevention Division has both its science and its regulatory staff within the same organization, and we certainly do go to our colleagues in HED and EFED at times for help, and frankly, they come to us at times for help. But for our reviews, they're done predominantly in-house. Occasionally, we will get some -- actually, we've gotten some help from times from RD who also does some work. But mostly it's an in-house effort. I hope that helps explain.

MR. ELWORTH: Is that true for inerts as well?

MS. ANDERSEN: We will do some inert work, but we don't do -- the inerts work is typically done in RD, that's right.

Cindy?

MS. BAKER: I'm not sure if you guys have talked about this before. Is this topic and this kind of work something that you've taken the transition group within

CARAT, for example? Is that -- I mean, how do you integrate this into that whole discussion? I mean, we have two products. We have an azinderactid (phonetic) material and we have a pheremone material, and the thing that we found in trying to market and sell those things is exactly what Lori and Larry both alluded to, which is an efficacy thing. And I think that the only way that you get that done is to gradually move people through transition.

Because when you're dealing with something like oriental fruit moth or NOW, they've had a lot of success. But take on something like coddling moth in apples and pears in a year like they had this year and it's difficult to get people to move away from that, because the standards are so high for them when they're selling their fresh fruit, they just can't afford one moth, one worm, whatever, it turns out the whole thing is unsaleable for them.

So, I think there's a lot to this that you can't switch people overnight to biopesticides. There's a lot of pests that it's not as easily put together in a whole IPM program. But I think that people are working -- are

trying to work towards that and it takes steps. Can you maybe use certain chemistry early and then bring these other things in? Can you use it in combination at reduced rates, you know, those kinds of things? And I think that takes a lot of discussion and time and planning. And so, the more avenues that I think you can address this with, probably the better the success rate in getting people talking about it and using it because there are registrants that are trying really hard to sell these products, and it's strictly an efficacy deal.

I mean, it has got to work. Cost is certainly an issue, perception is certainly an issue. But the bottom line is that the grower's got to be able to use that season after season and understand that they're going to get control.

UNIDENTIFIED MALE: I think -- actually, if I could respond to that, yes. Cindy, I think that's a good point actually. A number of you sitting around the table are a part of the transition workgroup or the CARAT in general and, you know, I think that we're getting close, actually, to the point where we can start really talking about the specific programs. I mean, the focus of that

transition workgroup is, of course, looking at programs that USDA and EPA have that growers and such can take advantage of as we're talking about moving folks from Point A to Point B if they have a pest problem.

So, I think that this is definitely a good option and something we need to look at. So, I'll certainly take note and see if Jim or Janet have anything else to add.

MS. ANDERSEN: No, I thought that was great, very good. Thank you.

Bob is, I think, the next one.

MR. ROSENBERG: Yeah, I only have a question. Is there a requirement that efficacy data be submitted in conjunction with a registration application? And if so -- go ahead.

MS. ANDERSEN: The requirement is that a company have efficacy data for any claim they make on a label. We require that data to be submitted for public health pesticides, but we also have the right to require that data at any time. BPPD does, at times, say to potential registrants, we want to see the efficacy data before we actually spend all of our resources on this product

because we, frankly, don't believe it's maybe really going to work.

So, we have done that. We get some kickback from the companies at times, but we do have the right to do that and have.

MR. ROSENBERG: And I just -- the reason I ask that, I'm actually thinking about termiticides and public health products where there are efficacy requirements. It seems as if the credibility of the products stand to benefit from agency reviewed efficacy data, and have you considered making that an actual requirement for all registrations?

MS. ANDERSEN: Well, once upon a time, the agency had that as a requirement and then they took it away. So, I think in the case of considering it just for biopesticides, it's considered why would we require this for these products when we don't require it for others. However, with our partners at PMRA, they do -- and California, they do require this efficacy data as they do reviews. So, our registrants for both sides are very aware that they have to have the data for some of the other companies -- other countries and states in the case

of California.

Julie, I think you're next.

MS. SPAGNOLI: Bob kind of started where I think my questions were heading. Even if the data are not required to be submitted, maybe there would be some -- if efficacy is the issue and efficacy is part of what is necessary to kind of promote the product, maybe the registrant should be encouraged to submit efficacy data just so that there is a third party review, there's an independent review of it.

If the agency has deemed the product efficacious, then you can use that as part of establishing that credibility and/or looking at, you know, for certain critical uses, maybe that the agency should require the efficacy data, again, because I think that will help build that confidence with the growers that it has been looked at by the agency, that someone has evaluated the efficacy data, and that would give them more confidence in using the products.

MS. ANDERSEN: Let me let Gary respond first.

MR. LIBMAN: Mainly, I want to reiterate what Janet just said. It's true that we don't always submit

efficacy data, although sometimes it is required, and certainly in the case of public health products, it is required. But in order to get these state registrations in several states, not just California, but California probably being the most rigorous -- I mean, definitely being the most rigorous, but also New York, Florida, many other key states, you cannot put anything on your label unless you have shown extensive data, good trials and if you see a product that -- if it has a use registered in California, believe me, that has gone through a rigorous evaluation, particularly on the biochemical side, but also on the microbial side as well.

MS. ANDERSEN: Win, you have -- if we can be quick.

MR. HOCK: Yeah, just a quick comment kind of addressing something that Adam raised and a few others. The issue of using extension in the transition process, one way to get the message out to growers is through the extension service. The extension service works in every country virtually in the country and they deal with issues such as pest management, IPM, so forth. And I think, you know, if we're going to do a transition, if

we're talking about transition processes, we've got to include extension in that process.

Unfortunately, many extension services, and I certainly can give you an example of Pennsylvania, were actually cutting staff, we don't have the resources. So, again, if somebody -- when I say somebody, some company is wanting to promote a product, wanting to get it out into the transition stream, go to extension, it may be that they have to provide some fiscal support, but most extension researchers will be willing to put materials like this into their trials, but they need support to do it. That's one of the things. It's a basic thing. There just isn't the resource staff and the resource funds out there to take every product that comes along and throw it into a research program. But, again, extension could play a key role.

MS. ANDERSEN: All right, last word, Steve.

MR. BALLING: Well, if I could speak for PBIA in a couple senses, one is relative to efficacy data, why have two separate standards for normal chemicals, efficacy data is not required? Why would you require it for biopesticides? Let the marketplace determine that.

If DelMonte needs to see replicated data, then that's -- and other growers and other users need to see it, then that's going to force the companies to do that. I don't see that EPA needs to require that.

Secondly, relative to Win's point, extension is the problem. Extension has not shown great interest in biopesticides, and when they do, they plug it in as a straight substitute for compounds normally in the system. We know that typically biopesticides are not strict replacement compounds for what we've been using historically, and they have to be massaged. Timing is critically important. Use patterns are important and, historically, extension has not been willing to try to fit those into their programs. There are some places where that works out very well, but it's not nationwide.

Part of the goal of the workshop in April is to talk through those issues, in particular, with extension people to say, how do we better fit biopesticides into your programs.

MS. MULKEY: Okay. Pretend that was the next to last word because Jose (inaudible).

DR. AMADOR: Just briefly, because we've been

talking about extension and it is true what Win says. Extension -- we're seeing a reduction in force and a reduction in time. Very few states now have extension people who are 100 percent extension. They're going more and more to the joint appointments. So, one thing I have not heard mentioned here very much is the private consultants, particularly independent private consultants. I think that you're going to see a shift in which extension is going to depend more and more on private consultants to get the information out.

So, I think it's important that we keep that in mind and at the same time that we train and we talk about extension people, we also talk about the private consultants and the role they can play, because this is, to me, this is the way that things are going. I'm doing a review now particularly of extension (inaudible) in the United States and almost every state has had a reduction in force, FTY, you know, for people. So, this is a problem that I think we're going to see more and more in the future, and if we don't rely on the private consultants and the other people, I think we're missing the boat.

MS. MULKEY: It's really great to see the level of continued interest in this topic. We've apparently struck a chord. And it's also heartening to see another forum that can play a really important role in building on this interest through the transition workgroup of the CARAT. And so, for those of you who feel that you'd like to roll up your sleeves and get a little deeper into this, that may be available sooner rather than later.

So, with that, we'll turn to the next place in the agenda. Going through these updates in somewhat more than a minute, but nevertheless a pretty rapid pace, is a real challenge. So, that's why we asked Jim to chair this segment, so somebody else could crack the whip and keep us moving.

A reminder, to the extent that you actually want a discussion -- and we're actually in one of these, going to ask your opinion, we really can't have a meaningful discussion in this kind of context. So, we can take clarifying questions and those kinds of things, but we have some opportunities later in the agenda tomorrow to identify things that you really want to invest significantly more time in. So, keep that in mind if you

get frustrated.

Otherwise, Jim, take it away.

MR. JONES: Thanks, Marcia. As Marcia mentioned, this is a pretty robust list of topics we have here. Some of them are so robust, they are subject in and of themselves to special advisory committees. Some of them are so robust, we're having full day workshops on them. So, largely, we're going to be giving information out today. Try to keep your questions to clarifications as many of them have other forms for having dialogue on them.

There is one exception. We're going to be asking for some advice on one of these topics and that will become clear when we get to it. So, with that, I'm going to turn it over to Lois Rossi for our first update.

MS. ROSSI: Okay. In your handouts in your packet, there are three handouts related to the status of tolerance reassessment and reregistration. In meeting the FQPA August 3rd deadline, the agency reassessed, as of August 2nd, close of business August 2nd, reassessed 6,465 tolerances out of the 9,721 universe. And the handout that you have is as of August 2nd, because

actually, we're a little farther along even in the tolerance count than that, but I wanted to present the statistics as of August 2nd. There are a lot of statistics on this sheet that you're welcome to look at, and -- for example, over 70 percent of the Group 1 tolerances have had reassessment decisions comprising over 60 percent of the total reassessed tolerances, and you can look at those and you'll get a lot of statistics on that.

In the second handout entitled, Reregistration and Tolerance Reassessment Decisions, completed in fiscal year 2002, that outlines all the decisions that we made, five reregistration documents to date. We have another one or two that are probably going to be issued before the end of the fiscal year. We issued eight interim reregistration eligibility decisions, mostly on the OPs. We issued 18 what we call TREDs, Tolerance Reassessment Decisions.

These decisions were all in the work plan that many of you saw over the last year that we presented at the CARAT workgroup at the OP cumulative process. While my summary of one minute, which represents three years of

work, is reduced to --

**(Laughter.)**

MS. ROSSI: Is reduced to numbers and counts, I would like to remind everybody that these decisions represent a lot of input from stakeholders, a very robust public process, and more importantly, they represent a lot of risk reduction measures, and we are actually tallying those things up and will, at some point, present those in the appropriate forum. So, they do represent a lot.

With regard to reregistration as a whole, in stepping back and looking at the universe of 612, for those of you who have been in the reregistration game for as long as I have, we have completed, at this point, 212 reregistration eligibility decision documents and 21 IREDs that someday will become REDs. When you look at the total universe, we've got about 148 decisions to go in completing reregistration.

Also, in your packet, you have a sheet that summarizes the status of the organophosphates, and in that regard, we have four organophosphates to go, DDPB, dimethylate, malathion and methyl parathion.

Also, what are we doing now? On the web, we have announced previously candidates for our 2003 decisions. We basically have some 3,200 odd tolerances to go to meet the 2006 deadline and the remaining reregistration decisions to complete by 2006. We're in the process of working with our science divisions and coming up with a multi-year plan on this. As soon as that's ready, we'll be able to present that.

I would like to make two personnel announcements with regard to SRRD. I don't know -- is Betty Shackleford here yet? Okay, Betty Shackleford has been Acting Associate Director of the Special Review and Reregistration Division. And I know Rich Dumas is here. Rich, could you stand up? Rich has just taken on the job as special advisor in our division with a focus on use and usage and stakeholder outreach. So, in the coming months, I hope that a lot of the stakeholders will be talking to Rich about various concerns.

And that's it in a minute.

MS. MULKEY: Betty just walked in.

MS. ROSSI: Betty just walked in. Betty. There's Betty. And that's it in a minute, folks.

MS. MULKEY: Thank you, Lois.

MS. JONES: Any questions? One?

UNIDENTIFIED MALE: Lois, I just had a question concerning the tolerance reassessment of inerts. In the first trimester 87 were done, in the second trimester I think 287 were done. That represents about, I think, 47 percent of the roughly 800 food uses inerts, and I wondered where that might be reflected in your summary. Is it in there or is it something that should be added to it?

MS. ROSSI: It's part of the -- they're part of the count. I don't think we broke up -- we might not have broken them up. No, we just have the high hazard ones broken out.

MS. MULKEY: They're in group three.

MS. ROSSI: Most of them are in group three, that's right. But they're not individually identified.

UNIDENTIFIED MALE: Is there any way that --

MS. ROSSI: Yeah, we could identify them for you.

UNIDENTIFIED MALE: If we could identify them in the future, it would be helpful to chart the progress

over the years.

MS. ROSSI: Okay.

MR. JONES: All right. With that, Margaret?

MS. STASIKOWSKI: Good morning. Since our publication of the OP cumulative assessment in June, we've been continuing to work. You are familiar with the July meeting of the Science Advisory Panel where we discussed incorporation and how we incorporated FQPA safety factor in the assessment. We now have the SAP report and are analyzing and preparing our responses.

The public comment period of cumulative assessment was extended and just ended last week, September 9th. We received 50 pages of comments representing seven different commenters. We are now looking at the PDP data from 2001 as it becomes available and while we will be revising the assessment, we are looking at any impact of risk mitigation taken on the results of the cumulative assessment, as we see it in the PDP data.

We are also -- to the extent that we receive comparative cholinesterase inhibition studies, we will consider them and incorporate them in the next version of

the OP cumulative assessment.

Earlier this month, again last week, we received a lifeline version of the OP cumulative risk assessment performed by lifeline group. That assessment was performed using the same inputs as were used for the calendex version that was published in June.

Publication of that assessment is being considered as we look at the resolution of some of the issues that I've just discussed. Risk mitigation, Lois has mentioned, is continuing on several of the OPs, and as those risk mitigation activities are completed, we will incorporate them into the cumulative assessment. That's my minute.

Oh, no, I want to also add, our next cumulative assessment plan. Right now, we are working on the N-methyl carbamates. We are analyzing uses and available data. We also have made calls last year on triazines and chloro-acetyl analides and we're working on those.

MR. JONES: Thanks, Margaret. Any questions? Jay?

MR. VROOM: I think there was also a CARES risk assessment submitted also, along with the lifeline

cumulative risk assessment.

MS. STASIKOWSKI: That's right. We have the program, CARES, but we don't actually have the OP cumulative risk assessment run on CARES -- within CARES.

MR. VROOM: Really? We're pretty certain that you do.

MS. STASIKOWSKI: I will check maybe during the break.

MR. VROOM: Okay.

MS. STASIKOWSKI: But I just had a presentation on Lifeline last week and I did not have that presentation on CARES.

MR. JONES: Any other questions on Margaret's presentation?

(No response.)

MR. JONES: Okay. Bill Jordan is going to give us a couple of updates.

MR. JORDAN: The next two topics, the first one is the NRDC objections to various tolerance rules that EPA has issued. We sent out to PPDC members, and have available in your pamphlet and out on the desk in the hallway, a copy of the page that was posted on our

website summarizing the 14 different sets of objections that the Natural Resources Defense Council has filed on the final tolerance rules issued by EPA. The objections are lengthy and each set of objections raises a number of issues with regard to the tolerance rule. They are highly complex, factual, scientific, legal, policy questions, and it would be impractical to try to summarize them other than to say that they are all related to EPA's decisions with respect to the FQPA safety factor. That seems to be a common denominator for most of the issues raised in the objections.

As I indicated, we've made the objections available on the website, and in the upper right-hand corner, you will find information about how to access that.

In the Federal Register in June 19 of this year, we asked for public comment on the first eight sets of objections that we had received, and that comment period was scheduled to close today, but we are extending that for an additional 30 days in response to the request from some members of the public.

This particular topic is one that Jim referred

to about where we would like to get feedback from you. We're considering whether the issue of a Federal Register notice or use some other mechanism to solicit public comments on the next six sets of objections we have received from NRDC, and in the event that we receive more objections from any other party or from NRDC, we'd like to get your feedback on whether or not we should open up a public comment period on them as well.

I want to note that in the next six sets of objections, many of the issues that are raised are quite similar to the objections that appeared in the first eight sets, but there are a few issues that are chemical-specific. So, as I finish up this particular summary, think about whether or not it would be valuable to take public comments on those, and if so, how we would go about doing that.

I want to note that we are continuing to process applications, emergency exemption requests, tolerance petitions and so on for chemicals that are the subject of an objection filed by NRDC. To date, EPA has not issued any decisions involving such chemicals, but we do expect to decide on a case-by-case basis for pending

applications and emergency exemption requests whether there are sufficient data to support a decision.

Finally, I want to note that we do not have any particular schedule, nor does the statute create one, for resolving these issues, but we have been working on them since we received them several months ago and we are expecting to look closely at the public comments that we receive in response to the Federal Register notice as we go about making decisions. That's the first topic, the first minute.

MR. JONES: And just to add that we do not need to spend all of the rest of the time here in this session providing input on this. Your call can use the PPDC forum over the next 10 days, I'd say until next Friday, to give us your thoughts about whether or not we should be routinely seeking comment on objection received to these tolerances, or is there a sense of you or groups of you that, having looked at the first group, you don't feel the need to have -- to participate and comment on the subsequent ones.

So, I'll open it up for some comments. Carolyn?

MS. BRICKEY: Yeah. I guess I would want to

only take comment on something that's an issue, kind of a first impression. If the issues have been -- that the objections relate to have been raised in the rule-making, for example, then I don't see any need to take comment on the objections. They're really responding to the rule-making. But if it's an issue that's been raised that's not been a part of the rule-making and is kind of unique, then I think it would make sense to do it.

I do not think it would make sense to do this routinely because for those of us who do these comments, it would be like a nightmare to have to think about responding to all these different people's objections to different issues. And it's confusing. Pretty soon, you'll end up talking to yourself, you know, which is not a good thing for some of us.

MR. JONES: Jay? Thank you.

MR. VROOM: A question on both the issue of the objection authority under Section 408-G of FFDCA that you refer to in Bill's handout in the first paragraph. Is that limited only to objections or -- there is no provision, as I understand it, there for making comments that would be supportive of the petition, number one.

And, number two, on the topic I guess more germane to what we're discussing here is the question of how much public comment is appropriate and necessary on these objections? It's our understanding that there are like 7,000 virtually identical e-mail kinds of submissions on this range of objections that have been filed to the petition, and if the agency's traditional use of weight of evidence is going to be employed here, is agriculture missing an opportunity to weigh in with at least 7,001 virtually identical supportive -- contrary virtually identical e-mails, and where does this take us, Bill?

MR. JORDAN: Well, a couple of things. The first question is whether there's an opportunity to file comments in support of a final ruling. Of course, you can always write us and we're happy to receive letters saying you think we did the right thing, from any stakeholder.

The 408-G(2)(A) really kicks off a specific legal process described in the Food, Drug and Cosmetic Act for giving parties an opportunity to first contest before the agency and then eventually go to court with their disagreements with EPA's action. And it seems to

me that if you agree with what EPA has done, while we like the letters, you don't need to send it to us saying you support our actions.

With regard to the e-mail campaign that you referred to, we view the substance of the comments to be more important than the number of the comments. And so, what really matters is the scientific merits of the comments made, not how many people happen to share that opinion.

MR. VROOM: Thanks.

MR. JONES: Larry?

MR. ELWORTH: Two points of information. One is how many of -- at least on the handout that we've got here, how many of these are reduced risk active ingredients?

MR. JORDAN: I'm not sure of the exact count, but I know that several of them are.

MR. ELWORTH: Okay. It would be interesting if, at some point, people could tell us what reduced risk is.

Secondly, I wanted to follow up on Carolyn's thing. Were you asking us whether we thought there should be another additional comment period above and

beyond the opportunity to file objections? Is that what you were asking us or not?

MR. JORDAN: The question is, when someone files an objection to the final rule, should we open an opportunity for the public to comment on the ideas advanced in the objections.

MR. ELWORTH: So, would you have to the publish an opportunity for an additional comment period, is that -- you would?

UNIDENTIFIED FEMALE: (Inaudible).

UNIDENTIFIED MALE: Larry, we have before us a number of objections --

MR. ELWORTH: Right, right.

UNIDENTIFIED MALE: -- and we have gotten additional objections on different actions that raise basically the same issues, but not exactly the same issues.

MR. ELWORTH: Okay.

UNIDENTIFIED MALE: In that scenario, is there a desire to see us, each time we get objections that cover basically the same issues but maybe not exactly the same issues on different actions, is there a desire to see

additional public comment?

MR. ELWORTH: Oh, okay.

UNIDENTIFIED MALE: On the additional final actions.

UNIDENTIFIED MALE: That's easy for you to say.

MR. ELWORTH: Yeah, right.

UNIDENTIFIED MALE: You can provide a tutorial later.

MR. ELWORTH: I'm kind of like with Carolyn (inaudible).

MR. JONES: Jennifer?

MS. SASS: I hope this is a quick question. What do you see happening with the public comments? In other words, what do you see the function of a comment period for if this is an objection that's basically a legal process that's put into play, how do you see public comments being used and then why do it and then why extend it and then why double extend it?

MR. JORDAN: As I indicated, we think that the objections that NRDC has raised are pretty broad, go to a number of scientific, legal, factual policy questions, and getting the views of a variety of stakeholders on

those issues, we think, will help us make a better decision with regard to the merits of them. So, what we anticipate is if there is information provided to us for analysis of, I guess, legal questions, then we would consider it and see whether or not it shapes our particular choices.

We're not interested in prolonging the process just for the sake of taking a longer time. These are, in a number of cases, the first time that we've looked at some of these questions.

MR. JONES: Okay, Julie, and then I think we have to wrap this update up.

MS. SPAGNOLI: I think what I'm understanding from this is that the substance of the comments is really regarding policy or policy interpretations that the objections were based on. So, I guess I would say that if the basis of the objection is on an interpretation of a policy, then I think it would be appropriate to solicit public comments on that interpretation or on that policy if that's really what the basis of that objection is. If it's not just, you know, was it this number or that number, but it's more of a policy interpretation, I do

believe public comment is appropriate.

MR. JONES: Okay. And, again, we will engage additional dialogue on this through our PPDC forum and will be happy to have additional one-on-one conversations with anyone in PPDC who wants further clarification or to get a better understanding of what we're actually asking over the next couple of days.

We'll move on to the next update. Bill?

MR. JORDAN: Okay. This is an update on where EPA is with regards to the issue of consideration of human studies. First, let me start with the news and then go back over briefly our current situation here.

As you know, in December of last year, EPA asked the NAS to provide us advice on the circumstances in which the agency should accept, consider and rely upon third party human toxicity studies. The NAS agreed with our request and signed a contract with EPA September 5th.

The academy has been anticipating a signature on that contract and had been thinking about planning to move ahead quickly with it and in conversation last week, I learned that they have made excellent progress towards choosing a committee and they expect to post the names of

the provisional members of the committee early in October. They are expecting that the committee will come together and have the first of several public information gathering meetings probably sometime by the end of this year. The contract which we and the NAS signed calls for the completion of the NAS report around the end of next year, 2003.

As you probably recall, the press release that we issued in December of last year, explained that our approach during this interim period would be that the agency "will not consider or rely on such human studies in regulatory decision-making whether the study is previously or newly submitted." And we take that approach unless we're legally required to consider or rely on the studies.

Just to remind you to be really clear about it, the studies that are covered by this approach are third party studies, that is to say studies which are not conducted by or sponsored by a Federal agency subject to (inaudible) rule and it also is limited to studies which intentionally dose human studies with toxicants to identify or quantify the effects of the toxins.

We have, at EPA, never required or we certainly do not encourage studies of this sort. But we have, sometimes in the past, received studies that have been voluntarily submitted by regulated entities.

Other kinds of human studies are not affected by this December press release approach. We have long accepted, in some cases we've been required, other kinds of human research such as studies of applicator or reentry worker exposure, pharmacokinetic studies, repellant efficacy or reports of pesticide incidents or epidemiological investigations. We will continue to accept and consider these other kinds of human study data.

When we receive a human study that is not subject to this interim approach, EPA will review it, and where appropriate, we will rely on it. Obviously, our review will consider the scientific merits of the study. But because FIFRA also makes it unlawful to use a pesticide in a test with human subjects unless the subjects are fully informed and freely volunteer to participate, we'll also pay attention to these ethical aspects of the design and conduct of the research.

The last thing I want to mention is that in 2002, CropLife America and other entities sued EPA in U.S. Court of Appeals for the District of Columbia. They challenged, in that action, EPA's interim approach as articulated in the December press release. The Court of Appeals considered and dealt with a number of preliminary motions filed both by the government and by CropLife America and other parties, and having decided not to take any action on those motions, that is to say, not to (inaudible) the merits in dealing with those motions, the court has set a schedule for the parties to file briefs on the merits and they have also scheduled oral argument on the merits for March 17, 2003. So, that's where that stands.

MS. JONES: Any questions for Bill? Has?

DR. SHAH: Bill, thanks for the clarification of what's covered under the moratorium and what's not covered under the moratorium. We have heard that several times verbally. Is there a written clarification that the agency has issued or can issue so that this issue does not come up every time, it was covered, it was not covered even though based upon a verbal presentation? A

few people know here, but not everybody knows.

MR. JORDAN: The remarks that I made were taken, in a number of cases, verbatim from the press release issued on December 14, 2001, and that is available on EPA's website. I'd be happy to give you the reference for that if that would be helpful.

MS. MULKEY: The letter to NAS.

MR. JORDAN: And then we have a letter to NAS that's also part of that. I can provide that to you.

MS. MULKEY: Just tell him what (inaudible).

DR. SHAH: Okay. The letter to NAS, that would be helpful.

MR. JORDAN: Okay, thank you.

MR. JONES: Anne Lindsay is going to provide the next few updates.

MS. LINDSAY: Okay. The first thing I wanted to give you an --

**(END OF SIDE B, TAPE 1)**

MS. LINDSAY: -- policy. This is a policy that we originally published in the fall of 1999, and I'm sitting here realizing, oh, that's the last century already.

UNIDENTIFIED MALE: Anne, could you speak up? Get closer to the mic.

MS. LINDSAY: Okay, we'll see if this does better. More recently, we -- actually in August of this year, we published a Federal Register notice announcing the availability of two guidance documents related to that policy. One of them is a PR notice and you have it, I think, in your packets, and it's also out on the table for others, as well as an internal standard operating procedure.

The basic policy, without going into all of the details, tries to identify those circumstances in which a tolerance might not be required for a pesticide use in or on food, and it's essentially when we know with confidence that no residues have been detected and the estimated potential risk is at a level of no concern.

The PR notice describes sort of how you would actually go about requesting a threshold of regulation decisions by the agency. It's a fairly simple procedure. It applies both to the establishment of new tolerances, the reassessment of old tolerances, the issuance of the State 24C Special Local Need Registration or a Section

18, if it fits in -- for the particular chemical and the particular use in question.

We've created a special section of the Federal Register to install decisions that result from the application of the policy. It's actually, I think, 180.2010. That's all in the PR notice. You don't need to write it down.

And there are four -- when we get a request for a special regulation decision, there are four possible outcomes. The first is yes, this request does meet the criteria, the use is below the threshold of regulation and it also meets the FIFRA registration standard. So, it's a go both with regard to the lack of a need for a tolerance and for registration.

The second kind of decision we might make is that the use actually is above the threshold of regulation, but we can go ahead and establish a tolerance and a registration could also be a go under FIFRA.

The third possible outcome is that the use is above the threshold of regulation. It would need a tolerance, but we're not able for (inaudible) kind of concerns to actually establish the tolerance.

And then the fourth outcome would be that it's below the threshold of regulation for tolerance purposes, but the use for some other non-tolerance related reason poses an unreasonable risk under FIFRA. It might be an occupational issue or non-target species issue, in which case, at least initially we would not be able to grant a registration, even though the TOR, the threshold of regulation policy, was found to apply.

You'll see all of this laid out in the PR notice. It's on our website. We've had some, I would call them, sort of exploratory discussions with a number of registrants about the actual use of the threshold of regulation policy and we're hopeful that with the issuance of this other guidance in the PR notice and our own internal standard operating procedure that we'll see some more use of the policy.

MR. JONES: Any questions on TOR for Anne? Steve?

STEVE: Well, I submitted my response three years ago on that. I still think that if there's zero residues then zero times the hazard is still zero risk. But that doesn't seem to be EPA's policy on this.

Three years after the original notice, you're now providing guidance, which suggests to me there haven't been a lot of registrants knocking down the door for this particular opportunity. Yet, it really seems to represent a nice option, a nice tool for transition to move some of these products into the system, particularly for seed treatments and soil treatment at planting and some of those kinds of things.

What are you seeing in terms of participation requests, et cetera, and what do you think the barriers are to adopting?

MS. LINDSAY: We're not seeing what I would call a barrage of requests coming in the door. We've had these exploratory discussions with a number of different folks. I should note that we could actually receive requests -- and the PR notice makes this clear. It's not confined to a registrant. A grower group, some other organization could also, in a given case, actually request a threshold of regulation kind of decision from us.

So, we're not seeing a lot. We'd like to actually encourage some more use, because I think we

would agree with you that there are situations where it seems like it's a policy that has a niche to play. I would suspect that one of the issues is, though, that we, by design, crafted a policy that does actually require work. You have to really be able to demonstrate, based on reliable data, quality data, that there are no residues detected with a method that's sufficiently sensitive and to do the estimated potential risk well.

So, it's not -- this is not, I guess what I would call, in the no-brainer quality, to use a cliche. It requires -- it still requires real work to demonstrate that that test has been met.

STEVE: Well, wouldn't presumably the reduced risk compounds meet sort of the hazard portion of this so that if you found -- if you went down to a reasonable level of detection and found nothing there, then that would follow?

MS. LINDSAY: I would think that that would be a likely candidate pool, but I would suspect others around the table might be able to share with you. And I don't know that we're supposed to be getting into a deep discussion --

STEVE: Yeah, okay.

MR. JONES: Yeah, we've definitely got to move this along.

MR. ELWORTH: Well, this won't move it along.

**(Laughter.)**

MS. LINDSAY: I don't know whether I want to answer your question.

UNIDENTIFIED MALE: He's going to ask it anyway.

MR. ELWORTH: Well, at some point -- I understand the words, but in the Section 18 section, the last sentence on the section on Section 18s, the second paragraph it says, however, because of the time limit nature of the emergency exemption, EPA would grant an exemption, but would not propose to establish the emergency use as a TOR use under Part 180.

I understand what the words mean. I don't understand the logic. Why does the time limited nature of the 18 lead you to decide to just grant an exemption rather than threshold of regulation?

MS. LINDSAY: I think it's because they are, in fact, very time limited and the presumption would be that they'd be there and gone and you'd be taking back and

forth out of the CFR. They would not -- for an 18, they would not be a permanent --

MS. MULKEY: Simply because it's not registered. You wouldn't establish a permanent finding. I think it's not more (inaudible).

MR. ELWORTH: Right. It does the question of why it's not being -- why no one's seeking its registration.

MS. LINDSAY: But the analysis underlying it would be comparable.

MR. JONES: Okay. Bill, and then we'll wrap this (inaudible).

MR. McCORMICK: I just have a question about scope. Is this limited to actives only when you talk about pesticide chemicals or does it include inerts?

MS. LINDSAY: I don't think that there's anything in the policy, per se, that limits it to active ingredients. So, that may be another venue that should be explored a bit.

MR. JONES: Julie?

MS. SPAGNOLI: Prior to issuing this, I think the policy was essentially applied in some cases to

products that were just conceptually there, like baits that were contained in a bait station. Does this impact any, like, future products in those categories that were just more or less given that kind of status just on -- I almost want to say almost as though -- a logical basis. That if it's in a -- that if the product is contained in a bait station, put in inaccessible areas, that those -- do they need to go now through a more formal process than they did?

MS. LINDSAY: This isn't, I believe, asking anybody who's already gotten a decision from us to come back in and --

MS. SPAGNOLI: Well, and I'm thinking kind of from -- if you're coming in with a new bait product, do you really have to demonstrate that there are no residues or do you just -- you know, kind of the logic of it, just --

UNIDENTIFIED MALE: There's no tolerance link, Julie, so there would be no applicability to a bait product or --

MS. SPAGNOLI: Okay.

MS. LINDSAY: Yeah. But I would say in any

given case, depending on the use pattern proposed for the bait, because I know there are some bait use patterns that can raise questions about is a tolerance needed.

MS. SPAGNOLI: Right. I'm thinking of a bait that's like in a contained station.

MS. LINDSAY: Yes.

MS. SPAGNOLI: And that's put under sinks, you know, kind of thing.

MS. LINDSAY: But my standard answer would be, you'd always want to talk to the relevant registration division about the specifics in any given case as to what you really needed to do.

MS. SPAGNOLI: Okay, thanks.

MR. JONES: Okay, Marcia, you've got the next update.

MS. MULKEY: I obviously have to be fast in order to --

MS. LINDSAY: Jim, Jim, Jim.

MR. JONES: Oh, I'm sorry, I'm sorry. I jumped ahead.

MS. MULKEY: Actually, Anne does have another one. You're right.

MR. JONES: Freudian slip in my whip-cracking to move things along.

MS. LINDSAY: It's so quick.

MR. JONES: Pardon me, Anne.

MS. LINDSAY: It's so quick that he knew I needed no time.

On endangered species, there are, actually, a lot of things that I could be providing you an update on, but there's only one thing that I actually am going to provide an update on.

Members of the PPDC should have received from Margie, in an e-mail submission a couple of weeks ago, a heads up about a workshop that we're planning. This is a workshop that will occur on Thursday, this week, in this same hotel. I think literally in this same room. And Margie and Joe are just now passing out the agenda for this endangered species workshop. Its focus is on ideas for implementing the Endangered Species Act more systematically within the Office of Pesticide Programs. There are four broad topic areas that we've identified, approaches to consultation with the services, public participation at various points along the way, and ways

of doing public participation effectively, compliance assistance and enforcement labeling and bulletins.

This is a prelude to them actually developing a Federal Register Notice which we would put out by the end of this calendar year. The Federal Register Notice itself will be a proposal and will be subject to comment.

So, while we will be making various endangered species decisions in compliance with the schedules that we've agreed to, we're also going to be developing this proposal for more systematic implementation of the Endangered Species Act, and this is a sort of immediate opportunity to give us some input as we actually begin to draft that proposal for later publication. And that's it, Jim.

MR. JONES: Thanks, Anne. Any questions on that before we. . .

MR. ELWORTH: Jim, just real quickly. There's nobody from Fish and Wildlife or anything involved in this or NIMFS or any of those guys.

MS. LINDSAY: They're invited. You're just seeing the names of the EPA people who are sort of running the event.

UNIDENTIFIED MALE: Okay. But the proposal is going to be developed with --

MS. LINDSAY: By EPA, but it will have input from the services as well as from an array of folks.

UNIDENTIFIED MALE: Sounds like an interesting OMB discussion.

MR. JONES: Why don't we take one of the remaining three where we may have a time issue tomorrow and that's the new registrations, and then we'll put the remaining two on tomorrow afternoon's updates or we'll take the other two and then -- okay, we'll take the last one, the opportunity for public participation in biotech issues. Okay.

MS. ANDERSEN: That's not the -- there is some slides, but we'll see if we can do it in just -- in the interest of a break, we'll keep going.

There are lots of opportunities for the public to participate in discussions about biotechnology, and the Pesticide Program, obviously, we only deal with the pesticidal part of biotechnology, which is a small part overall of biotechnology in the United States, but I wanted to go over some of the opportunities that there

are for the public participation.

I'll begin with the National Academy of Sciences, which is doing a lot of work in biotechnology and continuing to do so, has for the -- several years in the past. They have right now a standing committee on agricultural biotechnology health in the environment. This is conducting a broad series of studies and workshops and what I've listed up there are the four that are actually going on in this year, and there are certainly more in the future. EPA has, itself, been especially interested in the first one, the environmental effects of transgenic crops, and the last one, unintended health effects of GE foods and that workshop is actually being held on the 23rd.

Then on to USDA, they do a lot of issues where they all have either a policy or a regulation that they're considering and they'll put it out for public comment through the Federal Register and take public comments on it. They, too, have advisory committees. They do rely quite heavily on the NAS, but they also have an Advisory Committee on Agriculture and Biotechnology which expired its FACA license if it -- in 2002 on

February, and now they are putting together a new advisory committee which they are calling the Advisory Committee on Biotechnology and the 21st Century Agriculture, and their acronym is just going to be AC21. They are now choosing their members and will be then moving forward to hold meetings and these are definitely something like this, all stakeholders involved.

FDA holds lots of public hearings and has been known to go out across the country and request comments from the public. They also issue their proposals for comment in the Federal Register, and probably one of the ones that have been most interesting to this organization or the PPDC would be the ones recently on food labeling.

The Center for Food Safety and Applied Nutrition, I did not write it out, but that's the Center for Food Safety and Applied Nutrition, has a biotechnology subcommittee under it's Food Advisory Committee. This group has recently been put together and they head a meeting in August on allergenicity that was very useful and we attended it, also. And their Center for Veterinary Medicine has a veterinary medicine advisory committee and all of these take public comments

and are open to the public.

For EPA, every action that we issue regarding a biotechnology activity, whether it's an EOP or an amendment to EOP or anything, they always get announced in the Federal Register. We hold public hearings to gather information and have done that in the past. We do lots of workshops on specific topics that are open to the public and invite public comment and participation, and we certainly do a lot of Scientific Advisory Panel meetings on biotechnology. Over the last three years, we have done over -- we've done seven SAP meetings.

What I will focus on a little bit is the BT crops reassessment, where we really emphasize public participation. We went back and reassessed all of the BT crops that have been registered to date and looked at whether or not we should allow those products on the market. We had an SAP meeting, but we also allowed the comments on the preliminary risk assessment and we also took comments on a paper that we drafted on what we might do with response to those products as well as just holding the public docket open for this one. As we continue to work through the products, with their new

compliance programs that need to be put in place, the public docket for that continues to be open and we, too, continue to get comments on it and work with them.

Just quickly, other forums where there is a chance for public participation, the CODEX Task Force on Biotechnology Foods is an international group, but it has a number of NGOs, which are actively participating. In fact, Alan Goldberg's international counterpart to his organization is an active member in that task force.

The National Institutes of Health and EPA have held workshops, and recently did last November, on allergenicity, which continues to be a very important topic in biotechnology products.

We -- in the United States Government, USDA and EPA, held -- hosted an OECD conference, also last November, on environmental effects and we have repeatedly national science societies, the Entomology Society, PHYTOPAT (phonetic) Society, et cetera, have symposiums which are -- invite the public to attend and are publicly available information, the proceedings of those that anyone can also see as well as do it.

And then the Office of Science Technology and

Policy, which is part of -- actually works out of the White House Staff, they have recently put out a Federal Register Notice for comment on a policy on adventitious presence that might be there by the -- that might be put in place by the various regulatory agencies, USDA, FDA, and EPA.

So, I did that, I know, very quickly because there was only a few minutes before your break is over --

**(Laughter.)**

MS. ANDERSEN: And I just wanted to let you know there are lots of places for the public to participate in biotechnology.

MR. JONES: Thanks, Janet. Okay, well, what we're going to do at this point is move on to our break. But to let you know, we have two remaining topics in this session, the FY '02 status of new registrations, we're going to pick up in the afternoon session where we're doing some follow-up from the May 2002 meeting, the 3:45 slot. So, that will start off -- that update will start off that session.

And then Marcia will do her update on the worker risk seminar at tomorrow's session on updates in a

minute. So, we will end this session right now.

MS. MULKEY: But a reminder, we have scheduled a 15-minute break. Let us keep it to that. The schedule has some room, you've made your panel. I think we'll be able to complete the day's work, but only if you're back by 10 after and not a minute later.

**(A brief recess was taken.)**

MS. MULKEY: We are eagerly waiting your return to your seats.

**(Brief pause.)**

MS. MULKEY: We are confident that with a little work, we can cover, over the course of the two days, the entire agenda, and in particular, we are confident that we will have the kind of full, comprehensive focus on today's major topic that everybody is interested in. We are mindful that we have about a half hour, actually a little less, to make up. The likeliest impact of that will be that there will be somewhat less time in the current framework of the agenda for discussion. But we anticipate that the public comment period rarely takes the full 30 minutes, and we anticipate acting in a very disciplined way this afternoon about our breaks, as we

have more or less just now succeeded in doing for this break. So, that's a good sign.

A special thank you to all of you who are in your seats. Of course, it's never the people who need to hear the message who get the negative vibes if you give it at the outset. So, we may try again before the lunch.

This next group, as you know, emerged from your midst; that is to say, a group of PPDC members who basically stepped up to this issue showed a keen interest in this issue, has been working more or less steadily since the last PPDC meeting with the agency to identify issues, to work through opportunities for engagement, and one such opportunity is this panel presentation.

Jack Housenger, who is currently serving as the Associate Director of our Anti-Microbials Division, but who comes here wearing one of our senior leadership hats around an issue that cuts across our entire organization, is going to chair this panel, and I'm going to turn it over to him.

MR. HOUSENGER: Thank you, Marcia. To be frank, this is an issue that I knew little about before we started on this endeavor, and I'm still learning as we're

going along.

Debbie Edwards and I convened this group of people sometime ago and -- can everyone hear me?

UNIDENTIFIED MALE: Um-hum.

MR. HOUSENGER: We've actually done it all by phone. So, even some of the people that are presenting today, I haven't met yet, which I hope to do sometime today. But we have seven presentations, there's quite a bit of material. So, at the end of the day, hopefully, you'll come away a little smarter than you were at the beginning of the day.

We've shared our presentations with one another and we haven't censored these at all. So, what's being presented are the thoughts of the people and not everyone necessarily agrees with what everyone's going to say, but we did want people to have the opportunity to say what they thought on the non-animal testing issue.

One of the things that we talked about very early on and got consensus on was that because this is such a huge topic, that we would discuss only the six-pack or the acute studies, not the beer, in our conversations. But you're going to see, some of the

slides go beyond the six-pack and, like I said, we didn't object to that.

Before we get started, we want to have Marcia talk a little bit about where the agency is on non-animal testing, and I'll turn it over to her now.

MS. MULKEY: My remarks will be brief, but I think they are important framing remarks. As you know -- and they are more or less on behalf of all of EPA, although because of the nature of the Pesticide Program, the amount of testing that we are able to require and need to require creates a dynamic in which we tend to be front and center around an issue like this. But we are certainly not the only part of EPA for which this is an issue.

I think it's important, and we always bear in mind that, first and foremost, our obligations are to assure that we analyze properly and completely the risk and hazards associated with the use of pesticides or any other substance for which EPA has regulatory responsibility. In other words, we must have sound answers to the important science questions to allow us to assure that pesticides meet the appropriate standards of

protectiveness. That is the ultimate framework within which we come to this dialogue.

And, of course, in order to get sound answers to those important science questions, we have to develop an understanding of how pesticides can affect people and wild animals and, of course, plants and domestic animals as well, so that we have a need to understand the effect of pesticides in all kind of animals, including the kind of animal that is gathered around this table today.

But I also want to make it very clear that we are very committed that testing to give us those sound answers and to help us answer the key science questions be done in a way that is cost-effective, that is efficient, that is not unduly burdensome, and in a way that is ethical. And the extent of use of animals in this testing is related to both of these issues. It is, in general, a costly and time-consuming way to develop answers to these science questions, and when you use living creatures for your tests and especially higher order living creatures, you face very real ethical considerations and constraints.

And so, we look forward to this as to other

opportunities to help us think through these considerations.

Today, we will not continue to emphasize the cost-effectiveness issue or the efficiency issue. The focus will be more on the ethical issue, but it does bear repeating that both considerations warrant care about the extent and frequency of animal testing.

For well in excess of a decade, EPA has openly and publicly embraced the principles for animal testing that were first set forth in the 19 -- well, maybe set forth before that, but at least a key time they were set forth was in the 1959 book, the principles of humane experimental technique. Those principles sometimes called the three Rs; replacement of animal testing where practicable, reduction of the number of animals and refinement of the way in which animals are tested to improve humaneness.

Our issues -- our involvement with these issues have been more than lip service. They have been manifested in a number of activities over time and they have been articulated primarily along with all of the U.S. Government articulation of its embracing of these

principles contained in the implementation of ICCVAM, which you will hear enough about, you don't need to hear from me about. But you will find as part of the documentation of its development and implementation, the articulation of these principles.

And you will also find EPA when the situation warrants, as we did in connection with a program called the High Production Volume Testing Program, an effort to try to understand more about some chemicals that are nowhere near as thoroughly tested as pesticides tend to be, as well as articles that have been written by professionals at EPA, including one just recently in the ILAR Journal, and I believe a copy of that has been made available to you, that article, and others. You will find us stating these principles.

Finally, I want to mention briefly work of our Office of Research and Development. The 2002 budget actually earmarks, as budgeteers use the term, or identifies $4 million for EPA to spend on research on enhanced use of alternative testing, and in particular in vitro testing for the -- and that monies -- those monies are being directed primarily to the endocrine disruptor

program, which is a program that was contemplated under FQPA, as well as the Safe Drinking Water Act, for the testing of substances, screening and other kinds of testing involving endocrine disruption.

Are Jackie McQueen and Robert Dyer here? If you could --

UNIDENTIFIED FEMALE: Bob Dyer's not here.

MS. MULKEY: Okay, Jackie is here, okay. Thank you very much for coming. She's with our Office of Research and Development and they came along in order to hear this dialogue and be available if any issues arise that they can be helpful with.

And in particular, with reference to the topic this morning and this afternoon where we have focused on the acute testing, I think in part because it's seen as a particularly productive area for thinking about alternative testing in the near term, EPA has placed $500,000 into an interagency agreement with NIEHS to focus on in vitro cytotoxicity validation project for acute toxicity. So, that's a very specific manifestation of our research commitment.

So, this PPDC dialogue is yet another

opportunity for us to make clear what our, EPA's approach is, context and committee is, as well as to hear the view of others, and we look forward to it. Thank you, Jack.

MR. HOUSENGER: Thank you, Marcia. Our first presentations are going to be made by EPA because we're running it, so we can be first.

**(Laughter.)**

MR. HOUSENGER: We thought it would be good to give a little background about what we currently do to reduce the number of studies and Mark Perry, who's a team leader with the Product Reregistration Branch and the Special Review and Reregistration Divisions, is going to be talking first about some of the acute tox studies and bridging and batching. Mark's been with the agency for 12 years. Like I said, he's a team leader for Product Reregistration Branch, which is the branch responsible for implementing all the various decisions that are made in the reregistration decision documents and reviewing data that comes in on acute testing to support the label hazards that are on those labels. Mark?

MR. PERRY: Can everybody hear me?

Good morning. As Jack said, I'm going to talk

about the strategies that OPP currently uses to reduce acute toxicity testing. (Inaudible).

I'll start with a little bit of background, basically. Those of you that are familiar with this, just try to bear with me. Those of you that don't know, there are six acute toxicity studies, the acute oral, the acute dermal, the acute inhalation, eye irritation, dermal irritation and skin sensitization.

The first three are systemic toxicity studies by the designated route, oral, dermal or inhalation. The next two, of course, are irritation studies for eye and skin, and the third one, dermal sensitization evaluates contact sensitization following repeated exposure.

Once the agency reviews these studies, they place each study into a category from I to IV with I reflecting the most severe results of the study and IV reflecting, basically, the least severe. The exception to that is the dermal sensitization which we don't really evaluate on a 1 to 4 scale. We just use a positive or a negative designation.

Once we do that, once we review all those studies, we get what we call the tox profile basically

for that product that was tested.

Let me go ahead and switch. We then take this tox profile and basically translate into product labeling. Since each category, I, II, III or IV, corresponds with specific labeling requirements, signal word, hazards to humans and domestic animals, which has the PPE in it, first aid section and the restricted-use classification, as well as child restraint packaging criteria.

Something we get asked all the time is why don't we just go ahead and use the acute data on the a.i. to support the end use product and there's a couple of pretty good reasons for not doing that.

First of all, a lot of inerts are very toxic and they're present in concentrations that are much higher than the active ingredient may be present (inaudible). Secondly, it's difficult to predict if there's going to be a synergy between the inerts and the active ingredient, which will result in an increased toxicity, and the third main reason that we don't just test the technical is that there can be significant physical differences between the technical and the end-use

products. You might have a technical material that's something like a waxy solid that, for example, cannot be tested by inhalation, but it might use products that are formulated with a solvent and that's dissolved in the solvent and then sprayed and (inaudible).

Moving on from that little bit of background on the acute, I want to talk about the two main strategies that we really use to reduce acute toxicity (inaudible) and those two things are waiving the data requirement and allowing data citation. Those are the two things.

I'm going to talk about data waivers first. Waivers can be kind of broken down into three different groups. You can have waivers that are based on existing knowledge that we have of extreme toxicity, waivers based on a lack of toxicity or irritation and waivers based on a lack of exposure potential by the route of concern.

The first route there, waivers based on extreme toxicity, a good example of that is when we have a pH of a product that's less than 2 or greater than 11.5. We have a really good idea that that's going to be corrosive to the eye and skin. What we do is just go ahead and waive the data requirement and place it in Category I.

We see all sorts of different scenarios here. People supply all sorts of different information trying to support a Category I classification. We're open to looking at anything like that to support such (inaudible).

The second group, waivers based on a lack of toxicity or irritation, we have situations sometimes where a registrant might come in and make an argument that they have a product with one a.i. and three inerts. They must provide information on all four of those components, demonstrating that there's not going to be a toxicity or irritation concern, there's not going to be any synergy. We'll look at that information, we'll consider it. We'll make a weight of the evidence call on that, and if we think it's appropriate, we'll waive it and place it in Category IV. And, again, with this, also, we're open to seeing all sorts of information. We consider information from the open literature, MSPS's old acute studies on just one of the inert components (inaudible).

And then the largest group of waivers that we see by far is probably the waivers that are based on a

lack of exposure potential, when people come in and they'll say, there's just no way there's going to be any inhalation exposure from the product. We may ask them to support that claim with something like an attrition study to see if the material is friable. An example -- yeah, like right here. If a product is a non-friable granular material, it's not going to break down at all, there's probably not going to be any inhalation exposure, so we'll probably go ahead and waive the inhalation -- the (inaudible) inhalation study.

Another example we see, for dermal and eye testing, we have a lot of products and tamper resistant bait stations, there's no way it can get out of the station. The station is very difficult to break open. We don't expect in those cases there to be any dermal contact or eye contact. So (inaudible) waive dermal toxicity, dermal irritation, eye irritation, dermal sensitization, possibly even inhalation.

That's kind of a summary of the types of waivers that we see.

Another main group of the main strategy that OPP uses to reduce acute testing is data citation. Bridging

and batching are the two things that pretty much make up data citation.

Bridging basically is using the available data to support multiple products, like taking the one set of data and trying to support many products, two or more products with that set of data. It requires us to make a determination if the material tested for the six-pack is similar to the product that wants to rely on that data. So, we do a lot of formulation comparisons. We look at all the inerts pretty exhaustively. We might do literature searches of the inert components and try to get good ideas. But still, if we think there's going to be a difference between the tox profiles between those two products in that situation.

A typical bridging example, you might have a product where the active ingredient percent is the same and it's citing a product that has different inerts that were -- there's data on the (inaudible) of the product that has different inerts. So, like I said, what we'll do is we'll do a pretty exhaustive check of the inerts, here in this situation, inert C. We might do a literature evaluation or search and make sure that

there's not any kind of acute concern associated with that inert. And if we feel comfortable with it, we'll go ahead and allow that product to rely on the data generated from the other product.

Another example I have is where you have the active ingredients differing quite a bit. You might have a 12 percent product relying or wanting to rely on a 35 percent a.i. product. Of course, there's going to be a lot more inert component in that 12 percent product, but we'll look at the differences (inaudible) the inert differences and everything across the board, and if we make a determine that there's not going to be a change in that acute tox profile, we'll go right ahead and allow that bridging to take place.

The other kind of type of data citation is batching, although it really just uses the same principles as bridging, except it's done for reregistration. Batching basically is where we look at all the products -- since we have reregistration, there's a chemical going through reregistration and we might have 150 products coming through for that chemical. We can look at all those products upfront, literally we get all

the (inaudible) out on the table and do a comparison to pretty much try to break it down to batches or groups that we think -- or groups of products that we think will demonstrate the same acute toxicity profile (inaudible) ask for one set of acute data for each of those groups. Not every product is going to get placed into a group, so we end up with a no-batch group sometimes.

Here's a typical example of a (inaudible) chemical going through (inaudible) 150 products. We might end up breaking down 127 of those products into 14 different batches. So, instead of getting 127 pieces or six-packs, we would just want 14 in that case, basically. And then there's going to be 23 in the no-batch. So, basically we're going from over, from 57 to 37 data sets that we would be asking for. Since it's reregistration, the vast majority of those 37 would probably be citing existing data that the agency already has.

Here's my final slide. We did kind of an unscientific estimation to try to get an idea of to what extent data waivers and data citations are used across OPP for acute submission. So, we looked at a couple of divisions, three or four divisions, and kind of took

close to a year's sample from each division and came up with some numbers for you to look at.

We divided the acute submissions into three groups. First of all, submissions containing only newly generated data, a whole new six-pack basically, or less, one of the six studies or up to six, submissions containing no newly generated data at all. So, it would be composed entirely of citations and waivers. And then the third group is submissions containing a mix of A and B. And you can see the breakdown that we came up with.

In reregistration, we see a lot more of citations and waivers and that probably elevates that number a little bit. But you can see, if you add C and B, it's close to -- it's over 70 percent containing citations and waivers to some extent. I'm sure (inaudible) pleased with that. That's a significant number.

With that, I'm going to go ahead and turn it back to Jack.

MR. HOUSENGER: Okay, thanks, Mark.

MR. PERRY: Sure.

MR. HOUSENGER: Are there any questions on

Mark's presentation?

UNIDENTIFIED MALE: I just have a comment.

MR. HOUSENGER: Yes?

UNIDENTIFIED MALE: I think one of the places where another uncounted area is when a registrant submits alternate formulas and there's not a call for a new tox data set being made, because there's a lot of times, at least on the anti-microbial side, where we may do products that look pretty different on shelf as a result of utilizing the same registration, but an alternate formula, and there's no call for a tox profile. So, in a way, that's another gain. I don't know how to count that exactly, but that's another area where you could say you're really saving a lot of animals by not calling for that toxicity profile to be repeated.

MR. PERRY: Right. That's another example of a situation (inaudible).

MR. HOUSENGER: Any other questions?

(No response.)

MR. HOUSENGER: If not, we'll move on to Debbie McCall. Debbie, prior to joining the agency, worked for 15 years doing various tox and hazard-related products in

contract management setting. Then in 1990, she became a tox reviewer in our Health Evaluation Division, and after three years of doing that, which is probably about the max that you can do --

**(Laughter.)**

MR. HOUSENGER: -- she was promoted to Branch Chief in the Technical Review Branch and Registration Division where she is today. That branch reviews all of the acute tox product chemistry studies for conventional pesticides and child packaging requests.

Debbie's going to talk about how test methods become guidelines and the ICCVAM process. Debbie?

MS. McCALL: Welcome, everyone. Basically, what I want to cover today is to answer the question, hopefully, of how do new test methods become guidelines in OPPTS. And I'm going to cover the role of ICCVAM and SAP, and then I'm going to briefly go over a case study which is the Up and Down Procedure.

On this slide, you'll see new test methods that we have taken through the ICCVAM process, and this is just recent. So, the Local Lymph Node Assay, which is an assay used for dermal sensitization, that has come

forward as a stand-alone assay in 2000. The In vitro Cytotoxicity, which is going to be used (inaudible) setting for the Up and Down Procedure, that came in September. And the Up and Down Procedure (inaudible) in December 2001.

We also have some future methods that are in the works (inaudible) and those are three in vitro methods for corrosivity, Corrositex, Episkin/Epiderm, which is (inaudible), and the Transcutaneous Electrical Resistance Assay or what they call as TER. Now, I would like to say that these last three are what are called proprietary test methods (inaudible) buy them as a kit, you know. And so, under the U.S. Federal Ethics Statute, whenever we use a proprietary test method, we have to have some type of performance measure behind that. So, we are working (inaudible) --

**(END OF SIDE A, TAPE 2)**

MS. McCALL: Basically, when a new test method comes forward in OPPTS, it comes forward to a group called the Test Method Group. This Test Method Group is comprised of various scientific disciplines and they usually have a member from the different organizations

across OPPTS. It sort of depends on where that guideline has potential for the largest impact in the program.

So, I can't give you a listing of exactly who's on that Test Method, it kind of changes by time frame. But there are certain folks that are (inaudible).

Sources of test guidelines, of course, are EPA working groups, people who are working all the time with industry, looking at different activities, other U.S. agencies bring forward (inaudible) industry scientists bringing forward to us research and OECD. We're very active in the OECD (inaudible) pass new methods to us. As far as (inaudible) OECD comes the other nations and, of course, the ICCVAM.

Now, the goals and the activities of the Test Method Group are really very basic. They're to address the new or maybe to review test methods, to help incorporate the scientific advances into the harmonized guidelines because we do have harmonized guidelines (inaudible). They asked us to establish test guidelines, methods and strategies that will generate credible scientific information (inaudible) and also consider alternatives that support the 3 Rs, replacement,

reduction and (inaudible).

Test Methods does consider the scientific validity, the regulatory applicability in the agency programs, how it fits into OECD and (inaudible) international harmonization.

So, basically -- oh, and also, it does provide a very nice forum for discussion for the science and any policy issues (inaudible).

Now I'd like to talk a little bit about ICCVAM, which is the acronym for the Interagency Coordinating Committee on the Validation of Alternative Methods, hence why we call it ICCVAM. That's way too much of a mouthful.

It was established in 1997 as an ad hoc group that would be implemented by NIEHS. But in 2000, the ICCVAM Authorization Act established and (inaudible) a permanent (inaudible) a permanent committee, and there are 15 agencies that interact. This is a list of the agencies. I would like to say a thank you to Bill Stokes who has allowed me to (inaudible) ICCVAM slides here and this is one of them.

The function of ICCVAM is mainly the

coordination step (inaudible). They help coordinate the development, looking at the validation, acceptance and (inaudible) the harmonization issues. Of late, what we've looked at have been test methods that have multi-agency interest. One of the other really nice functions of ICCVAM is to provide a way so that test recommendations can go back and forth in the agencies and to gain regulatory acceptance. There is a lot of (inaudible) and they provide guidance on the validation of test methods.

Now, ICCVAM is -- like I said, is being sponsored by NIEHS, which is located in (inaudible), and it's run by the National Toxicology Program (inaudible). I'll just refer to that as the center (inaudible). And their function is basically the operation and the technical support of ICCVAM. They help set up the peer reviews, they help do the information dissemination. They help communicate with the stakeholders and the partnerships, and they've also helped us in the past with workshops.

I've listed out on the slide there the website for ICCVAM for those (inaudible).

The goals of ICCVAM are just -- there's really two -- are really to promote scientific validation and regulatory acceptance of new methods, and the hope is that they will be more predictive of human health and ecological effects than current methods, and that they will use the three Rs where scientifically feasible.

Now, our hold is that they will -- the new methods will improve public health by having improved risk assessments and reducing injuries and disease from different chemicals.

(Inaudible). This is the schematic of the ICCVAM Evaluation Process. When I'm walking through the case study, we'll go over this in a little bit more detail. I believe it's pretty straightforward and you just follow the arrows. (Inaudible). Basically, what I want you to look at is on the left side of the screen there. Almost all of the work happens in the independent peer review panels and in the working groups (inaudible).

I thought this would lead into how EPA responds to ICCVAM recommendations (inaudible). Basically (inaudible) Test Methods Group, we examine the recommendation from an independent peer review report and

the working group. We look at the test methods for regulatory applicability and acceptability and see how that method will fit into the agency program. We also prepare recommendation and response back to ICCVAM on, you know, we've looked it over, we've discussed it, we've looked at the possible regulatory policy implications -- policy problems that may be (inaudible) our response back to ICCVAM.

Here are the factors that the Test Method Group looks at when we get the peer review report from ICCVAM. We believe that we gain a lot of experience by looking at interaction in the ICCVAM process. We get to look at their strengths, the limitations, the advantages and the disadvantages of each test method. Because of the way ICCVAM (inaudible) in the independent peer review report, we get a mix of everything that happens, good and bad, about the new test methods.

The other factors that we look at in the test method group are how (inaudible) contributes to animal welfare. One of the things that we found doing one of the other new methods were context in how it deals with chemical classes. Sometimes they don't -- new methods

don't interact well with all chemical classes that the agency regulates. We also look at the potential impact and the usefulness to the regulatory programs and the science and regulatory implementation issues.

This leads me into peer involvement. After we've taken the ICCVAM peer review report and sort of digested it, if we think it's a good method, we're going to circulate that draft protocol and guidelines out to the scientific community. If possible, we will convene workshops and interact with outside experts and bring everyone in to the process that we can for giving us input on the new method.

Then sort of the final step here is taking it to the SAP. FIFRA, our law, says that we (inaudible) requires (inaudible) peer review of all (inaudible). (Several sentences inaudible -- volume extremely low).

One of the things that I want to talk about later on is the workshops that we have (inaudible). These are (inaudible). One of the nice things about the workshops is that if it's a drastically changed method, at the workshop, we interact with industry as well and (inaudible).

We communicate our findings to the American Public by the SAP Report -- that's public notice -- Federal Register Notice, and other agency websites.

I have up here the equivalence of SAP and ICCVAM, and this is sort of a personal interpretation. I sort of believe that the ICCVAM and SAP are integrated very well together, so that once the scientific validity has been assessed by ICCVAM, the SAP can move on and look at the regulatory applicability of the test guideline (inaudible). So, it kind of pulls them very nicely together. That's (inaudible).

And, you know, instead of having everything go to the SAP for scientific validity, ICCVAM gets to look at it in large detail with our stakeholders and then coming to the SAP for the regulatory (inaudible). And then SAP (inaudible).

(Inaudible) I'm just saying that the SAP and the ICCVAM process are a coordination step with OECD (inaudible) all the reports. In the past we did the LLNA and (inaudible). Like I said in the beginning, our future methods are to incorporate these three in vitro methods as soon as we work through the proprietary test

methods (inaudible). Those are (inaudible) incorporated into (inaudible).

Now we'll go on to the case study. (Inaudible) the next slide.

This is the same schematic I showed you before. Basically, for the Up and Down Procedure, if you'll follow along with me on the schematic, we were -- EPA -- essentially the Up and Down Sponsor with (inaudible) and we sent it to the center, which is (inaudible). Now, the reason that that came about is there was a meeting in Rome in about 1998 and we took a real hard look at three new test methods. (Inaudible) and the Up and Down Procedure to look at those to see how well they fit for all chemicals, and we found that all three of those guidelines needed to be updated and modified.

So, we were charged with -- by OECD to take these on and to modify the protocols. So, we started going down through the ICCVAM process. So, we went, about in 1999 when we started the (inaudible) ICCVAM and having a lot of discussion about modifying the protocol. It wasn't (inaudible) OECD charged us with modifying (inaudible).

On the ICCVAM step, it's kind of a shame that's such a small box because for about a year and a half, we went -- we did all kinds of activities (inaudible). We were working with our counterparts (inaudible) great deal (inaudible). We were working (inaudible) all the time and (inaudible) guidelines. So, we were doing a lot of input and response, trying to modify these protocol to make them a much more vigorous (inaudible). We found that the Up and Down Procedure was the only one that would give us an (inaudible) 50 value. The others are not based on equality. So, that was the reason we choose to sponsor the (inaudible).

Then once we came forward, we came to make recommendations on test methods to the agencies. We talked with the agencies, worked it out and it went up back and forth in the working group, and ICCVAM, we had our first peer review meeting in July of 2000. They came back and said, wow, this is a really drastically changed (inaudible). You guys are going to need to develop some software so that the (inaudible) reasoning. So, in July of 2001, we had that finalized and that's (inaudible).

We had a second peer review panel meeting and

that was in August of 2001. (Inaudible) defined it now, we have taken into account what you said at the first peer review (inaudible) a second time, we think we're ready now to take it all the way (inaudible), which we did in December of 2001.

Can we go to the next slide?

Basically, here is the picture of the publication that is put out by the NIEHS (inaudible). It may seem like it took a long time in coming, but we think that we have a much better protocol guideline than we originally had in the beginning and we look -- we had a workshop in February of 2002 that dealt with (inaudible) and the Up and Down where we had industry there, we had contract (inaudible). We were there. We interacted back and forth trying to work out different issues, different (inaudible), the problems (inaudible) and we think we have all of that worked out (inaudible). Hopefully, we'll (inaudible). (Inaudible).

So, just a summary on (inaudible) OPPTS is advancing the three Rs. I see ICCVAM as playing a very positive role in facilitating the process (inaudible) and I think that the new test methods (inaudible) scientific

advances (inaudible).

MR. HOUSENGER: Okay, thank you, Debbie. Are there any questions? Yes?

UNIDENTIFIED MALE: Just one question. In the slide that talked about the goals for ICCVAM and then the NTP-based agency, it talks about the goal being to promote test methods that are more predictive of human health than current methods. With all the difficulties we face today in getting non-animal test methods accepted, why would we place such a hurdle on these methods? Why can't they be equally predictive to the current methods?

MS. McCALL: Well, I think that they are. That may be a fact of how -- that slide is from Bill Stokes. I believe that as time has gone along -- and 40 years ago, if you would look at the data we got then and the data that we're getting now, I think we're getting much better data now than we were 20 years ago, and I think it's just that slide and scientific advancement is what's meant there on that slide.

MS. MULKEY: Debbie, the question is, would ICCVAM handle a method that was simply comparable?

MS. McCALL: Yes.

MR. HOUSENGER: Are there -- yes?

UNIDENTIFIED MALE: Once you have a new guideline that has been -- gone through the whole process, how do the registrants know about it? What does EPA do? Do you notify each registrant or do you -- I'm just concerned because in the past there has been some mix-up in whether guidelines have been final or whether guidelines are coming out of a reviewer's drawer that are a draft, et cetera. But once we get to a final, which I've heard you say it here, what's the process for notification of the regulated community?

MS. McCALL: Generally, after the SAP happens and we enter the SAP comments, you'll see a Federal Register Notice that puts the new -- puts a notice out there saying that the new guideline is now available. And we'll also put on our website attention in the new column of the new guideline.

UNIDENTIFIED MALE: Thank you.

MR. HOUSENGER: Pat?

PAT: Debbie, maybe you can talk a little bit more about the value added of the SAP review. I was

struck, I guess, in looking at your slides about the extent to which there's a lot of give and take between the test method guideline group here at EPA and the ICCVAM players, and it's a broad group of players at ICCVAM, where you look at both the science and the regulatory implications. So, I'm wondering if you can just get to another level of detail about what SAP adds after all of that give and take and then peer review.

I guess maybe a related question is, I know there's a statutory requirement that you take things to the SAP, but is there -- you know, might that be satisfied in another way that you've looked at, I guess the scientific validity and regulatory applicability?

MS. McCALL: Well, with ICCVAM, we've looked at the -- we take a real hard look at the scientific validity and in the past, SAP was looking at scientific validity and regulatory applicability. And now, with the advent of ICCVAM, they've sort of had to just now -- if the method is very promising and very hopeful, then we will just come forward for the regulatory applicability. Have there been in the past? Probably some that we have taken not to the SAP but have gone forward with. There

may have been, I'm not sure.

But as far as -- and maybe some other folks can answer this. But before the advent of ICCVAM, we would have -- we could go to SAP one or two times talking about the scientific validity of a guideline.

And now, we can just go and say, we have discussed this, here's all the strengths, here's all the weaknesses, here's all the potential issues that surround it, and SAP will give us guidance on, well, we understand all that, but you're going to need to make this part easier and that was one of the comments on the Up and Down. We showed them the software program and they said, well -- they gave us comments on, well, you need to do a little bit more work on that so that when somebody downloads it, they know that they've downloaded the whole thing. So, it was like, oh, well, we hadn't thought about that. So, it will be that type of issue.

Have I answered your question?

UNIDENTIFIED MALE: Yeah. I guess it's, you know, not being as familiar with sort of the ICCVAM discussions that you have. It seemed like many of the obligations that you might have under FIFRA and many of

the things that you might want to think about from a regulatory implementation perspective could be thought through in the ICCVAM EPA exchange, and maybe you could -- you know, maybe you could eliminate that final step.

MS. McCALL: Of the SAP?

UNIDENTIFIED MALE: Yeah.

MS. McCALL: That would be up to management.

UNIDENTIFIED MALE: Okay.

MS. MULKEY: I think there is an option to seek a waiver of their review.

MR. HOUSENGER: Julie?

MS. SPAGNOLI: Just a question for clarification. When you're talking about peer review of guidelines by a scientific advisory panel, that's review of a guidelines that the agency intends to publish as OPPTS guidelines. So, that wouldn't necessarily apply to non-guideline or new protocols that may be being developed. I think we're looking at some types of processes for looking at -- you know, with innovative products or new types of guidelines. So, the requirement for it to go to an SAP is really only for guidelines that are intended to be published? And I'm not getting at

this, you know, outside of just toxicity testing as well.

MS. McCALL: I believe so.

MR. HOUSENGER: Okay. Well, let's move on to our next presentation. I was annoyed when I got here because I couldn't find a parking spot, but Dr. Dick Lewis came from England to talk to us today and I thought that he was here on other business, but he came expressly for this purpose. He joined Syngenta in 1988 and in the mid-nineties in in vitro alternatives research. He's currently the head of the Reproductive Development Toxicology and provides support and health assessments in the new Chemical Discovery Division. He's going to talk about alternatives for assessing acute endpoints.

DR. LEWIS: Well, first, I'd like to thank the organizers for inviting me and giving me the opportunity to give an overview of alternatives for assessing acute endpoints.

What I'd like to do is to look back over the last 20 years, assess where we are now, and then we'll look a little bit forward into the future and what are the challenges, which we (inaudible).

If we look at the last 20 years, they represent

really quite an intense period of activity, quite a number of acute endpoints. Inventing new tests, developing new tests. But the most interesting thing for me is that during the (inaudible) 20 years, we've also had to invent the framework for recognizing if a test (inaudible) purpose and if a test can be used; i.e., is it valid. So, during the last 20 years, we've not only had to invent and develop new tests, but we've also had to develop a mechanism for telling whether those tests were any good or not.

And certainly, when I look around the room today, coming back to the present, I've seen a number of colleagues that I've worked with over the last 10 to 15 years or so and the tests that we were using in-house, in our individual companies in those days, now are seen as valid tests and (inaudible) regulatory guidelines. So, there's some age (inaudible).

At the present, as I said, we are doing an implementation of this. The implementation is not without (inaudible) minor issues, and I think that harks back to the fact that we've been developing tests along with the framework of accepting those tests (inaudible)

it's not surprising that (inaudible) together.

In the future, I think we'll -- I hope that we'll do better on what we've learned in the past. There will be challenges in the future, and I've outlined some of those. The main challenge is the need for partnership and coordination, and I'm encouraged that I see that actually happening in some areas.

Here I've set out a schematic for the stages in the development of any new test, any new methods. It could be a method not involving animals. It could be a method involving animals. It's just new testing toxicology. And the earliest part of this is science-based and it's all about understanding basic mechanisms in biology, maybe normal mechanisms, maybe aberrant mechanisms. But when you've understood that, you've got to ask the question, do I have enough understanding here to enable me to use this information and devise tests. I will use (inaudible) animals (inaudible) procedures to which animals are exposed or does the way we use the animals conflict (inaudible). This is science-based. Once we've got the idea, we understand enough to make a test.

The rest of it is technology process based. Once we've got a test, is it robust, do you get the same results in different laboratories around the world, does it give us the same level of information, does it travel well?

And then at the end of it we have acceptance into legislation.

A couple of comments I like from ex and current colleagues of myself. (Inaudible) will be familiar (inaudible) community. The first one was from the Ian Purchase, and Ian really answer (inaudible) said, of course, industry, if it invested enough money would have replaced the use of animals many, many years ago, but (inaudible) is lacking to invest the money. And, of course, Ian's point was that, you know, science can't be driven to a timetable, it's dictated by money. You know, once you've got the right people and the right ideas, then the rest of the development of an idea, of course, is amenable to good management and the application of resources.

The second comment is more recent. It comes from Phil Botham, and Phil's perception was that the

final stage of our process for accepting (inaudible) alternative methods is driven as much by politics as it is by science. I think the background to this reflects the different starting positions, if we (inaudible) last 20 years. Most of the initiatives all the ones I'm going to talk about in the early stages were certainly led by the regulated community; i.e., they were led by industry.

I'm going to use three examples of the validation process and of the (inaudible) over the last 20 years or so and where we are at present. I'm not going to go into them in too much detail since I know the presenters later in the session will be going into more detail on some of these things.

The first one if the (inaudible), the Local Lymph Node Assay. A good example of reduction, it uses about half the number of animals as compared to the traditional Guinea Pig Maximization tests, and it's also a really good example of refinement because of the understanding of biology, the normal (inaudible) biology, we can concentrate here on the induction phase of the sensitization response. There's no need to challenge the animal, and as we know, it's during the challenge phase

that we have the greatest potential for adverse effects to be manifested.

So, it's certainly an example of reduction. It's a very good example of refinement. It's also a quantitative test as opposed to the subjective assessments, looking at guinea pigs, for example, and because it's quantitative, there's less chance of an equivocal outcome, because there's less chance of an equivocal outcome, there's less chance that we have to repeat the test and use even more animals.

How long did this all take? Again, a good example of something that's been industry driven. (Inaudible) Syngenta (inaudible) first publications in the early 1980s with Unilever in the UK and certainly with Procter and Gamble in the U.S. So, it was a European/U.S. initiative. Prevalidation and validation got going in the early to mid-1990s, and as you can see it's taken a full 20 years from the appreciation of basic biology and the idea that we could make a case out of this -- for this test to be accepted into regulatory guidelines.

The second example, we've heard quite a lot of

the details, so I'm going through this rather reasonably quickly. It's about Acute Systemic Toxicity testing. Now, the first OECD guidelines, which formalized this testing, are 20 years old and they included the now notorious 401, the LD50 test. As early as 1987, it was recognized by OECD and others that perhaps there was a way of conducting this test in a more refined manner, such that less potential adverse effects would be caused, and the idea was to reduce the highest dose level tested, the so-called limit dose, from 2,000 — from 5,000 milligrams per kilogram to 2,000. Since 1987, this is still the topic of some debate. I think it lies in the different hazard-based classification schemes that we have around the world.

In continuing effort through the '80s and '90s, a lot of it we've heard about the so-called Class Methods and the Up and Down Method. Let's move ahead.

With EPA and ICCVAM becoming involved, luckily. And, again, the time scale has been 15-odd years for some progress. 401 is now deleted in the OECD guidelines and it has been replaced by some of the alternative tests.

Just a very brief overview of what these tests

are. The first two tests, 420 and 423, are class methods. There are fixed doses -- 5,000 sort of crops upin there -- but they are fixed doses to which animals are exposed and the output of the test is a range, a range of LD50 values, which ideally should correspond to classification (inaudible).

425 is different. It gives a point estimate with some idea of a confidence interval around that point estimate. So, it gives you a number like the old LD50 did.

In terms of animal welfare benefits, I think these are clear. If we look at the next slide. The old LD50 test used up to 25 animals, by definition, up to half of those did not survive the study. 420, 423, the class methods, 420 has the endpoint of toxicity and not necessarily (inaudible), we can see they use far fewer animals, so we reduce the numbers and actually we refine (inaudible). More animals survive the procedure. 425, again, reduces and refines.

The last example I have is skin corrosion. We've heard a little bit about this. Again, quite a fruitful area for research over the last 20 years or so.

The animal test that's been used over the last number of years actually assesses the degree of full thickness skin destruction (inaudible). The alternative methods, there are quite a number here, some of which we've heard about, some refine and reduce, such as the Transcutaneous Electrical Resistance Test. This is really an ex vivo test. It uses skin disks from untreated rats, and what we assess here is the barrier function of skin, the flux of (inaudible) across the barriers of skin.

We've used this test in-house at Syngenta and all of its previous incarnations since the mid-1980s to guide humane testing of animals. We have not tested corrosion materials on the skin of animals for quite some time because we've (inaudible).

There are certainly replacement tests. We've heard about the reconstituted skin models. These are really (inaudible) cultures. They don't really have a barrier, but they are quite sophisticated in that (inaudible) have cellular integrity that can be evaluated.

Again, the chronology, the first prevalidation studies were done in the early 1990s, all the development

and scientific understanding would have predated that. It would have been in the 1980s. (Inaudible) validation including the activities of ICCVAM towards the end of the 1990s, and now with 2002, we have some of these tests adopted into regulatory guidelines.

How long has it taken? I just said that it's taken really about 20 years. And don't forget, we're talking about what we've imagined to be among the most simple endpoints in biology.

Okay, if we move to where we are in the present day -- I mean, I've mentioned that implementation is not without some difficulties, some issues. The Local Lymph Node, for example, the use of concurrent controls. Concurrent controls, as you know, are used to demonstrate the sensitivity of the test system under the conditions used. (Inaudible) Guinea Pig Maximization Test, I think the guidelines say we should do this about every six months or so. OECD made no mention of whether we should use concurrent positive controls, and fortunately, the recommendations from ICCVAM and EPA seem to suggest that we do need to use concurrent controls. So, there's a slight inconsistency. If we do, we'll use more animals.

Is it valid for testing formulations? Again, there's nothing in the data that we supplied that indicates that it is, especially for pesticide formulations. EPA's draft conclusions are that it is the method of preference for formulations. We know of no data that supports that. That doesn't mean it's wrong. We know of no data that supports it.

Acute systemic toxicity, the class -- this is an interesting one. The class methods, 420 and 423, are aligned to the new Globally Harmonized Scheme for hazard-based classification, which is great. Unfortunately, this hasn't been accepted into local legislation anywhere. It's in European law, but it hasn't been accepted by (inaudible) member state (inaudible).

So, while we have these nice methods that we use to refine, we can only really use one of them, 425, at the moment because the output of the others doesn't match with any hazard-based classification scheme.

Tests for skin corrosion, we'll move on. Again, is this for identifying a positive only or is it able to identify a negative? Again, there seems to be some confusion.

So, in summary on this, everybody is working toward the same common; reducing, refining, replacement (inaudible) use of animals in toxicology assessments. What's beginning to happen is a coordination in scientific review and a coordination in the outputs of tests with the purpose of knowing the number in the first place, which in this case is hazard-based classification. And those lessons are being learned, so it's not surprising that we find ourselves with minor inconsistencies since we didn't start at the same place.

Looking to the future (inaudible) other than acute endpoints. I think we've got both threats and opportunities. New endpoints in toxicology, the so-called catch-all protocols (inaudible) revised process for defining the reference (inaudible) leads to extra endpoints. This is going to make it more difficult to replace, refine and reduce the number of animals we use.

On the other hand, we may have some opportunity, biotech products, fewer traditional chemicals. (Inaudible) chance to challenge the testing paradigm. A lot of these chemicals, as we've heard this morning, (inaudible) for example, we can predict the way the

adverse effects (inaudible) for human health and concentrate on those. Do we really need to feed these to rats for two years? I don't know. Maybe we should think about that.

Greater emphasis on understanding mechanisms of toxicity. The relevance of animal models, I think we've been really successful over the last 30, 40 years in making the world a very safe place for rats. Does that always mean that those models are relevant to humans? The use of transgenics to humanize the test method (inaudible) and the use of generally in vitro and (inaudible) systems and so called in silico systems.

Of course, I'm a member of the public and I expect safer drugs, safer pesticides, safer chemicals, and I'd also like to reduce the number of animals we use.

Moving on on a positive note (inaudible) on what we've learned over the last 20 years and we've heard a little bit about this so far. There's quite a lot of work being done in Germany in (inaudible) Spielmann's group about understanding basic cytotoxicity and how that could help us in selecting the initial doses for testing, in the alternative acute tox (inaudible). And the closer

we are to the starting point, then the fewer animals we use, up to 40 percent fewer. So, that's something that's worth (inaudible) doing.

So, the question's being posed, can simple cytotoxicity tests guide the selection of a starting dose and then by definition reduce the number of animals we use.

We've heard a little bit about this, but this is (inaudible) a joint European union. (Inaudible) talks about to -- it's addressing two potential benefits here. The first one is guiding the testing so we use fewer animals. The second approach, which is on the right-hand side of the overhead, is about (inaudible). (Inaudible) move to different time scales. It's realistic to think in the next couple of years that we can use cytotoxicity tests to guide test chemical selection (inaudible) complete replacement in some way in the future.

So, just to conclude, there are a couple of overheads thinking about what's available in the future, what do we realistically expect to be able to achieve in the next two to three years and then in the longer term. I think we have tests for skin irritants. Certainly, in-

house, we've been using these types of tests for a number of years to aid in chemical design, for example, to detect chemicals which are the higher risk chemicals, stay away from those and develop safer chemicals. Human skin constructs, much the same types of systems that we are using for detection of corrosive materials, do have a lot of potential for detecting and quantifying an irritant response. And skin integrity and function tests (inaudible) developed by Syngenta, for example. The (inaudible) of (inaudible) endpoints are showing enormous promise.

Acute oral toxicity, I've talked about that. Dose level selection followed by complete replacement, but certainly not in this (inaudible) on a scale of three years.

Developmental toxicity screens to identify the chemicals that are more intrinsically toxic. Most of the industries, I know, have been using this type of technology. Certainly, we have for the last 15 years or so to prioritize what we test. (Inaudible) chemical design to make things more specific a pesticidal target and less specific to mammals. Things like whole embryo

cultures (inaudible) to avoid the use of living adult animals. Embryonic stem cells have even shown great promise. Some of these (inaudible) and things like micromass, the lymphatic types of assays. So, there's a lot of positive things there for the next three years or so.

In the longer term, (inaudible) replacement, acute toxicity, can it be replaced by cytotoxicity tests? I think we're approaching that in a coordinated way. So, I have some confidence that, again, it's going to be longer term than three years.

Skin and respiratory sensitization. Again, some of these endpoints are a little bit more esoteric, if you like, but again, pretty bad if you suffer from them, especially respiratory sensitization. Most (inaudible) tests, a lot of work being done on the basic biological processes going on, and things like kinetic and metabolism, target organ, systemic toxicity, chronic toxicity, total replacements for development and reproductive toxicity, non-genotoxic carcinogenesis, again, sometime in the future. And like the screening tests, where you can live with some degree of under-

prediction; i.e., false negatives, when you replace the animal tests with an alternative test, you can't live with any degree of under-prediction, any false negatives because the next species of tests might well be humans.

Okay, so I'd just like to conclude. When we look back over the last 20 years, we've seen this explosion of activity, especially around acute endpoints. And where were we to date, I think we've learned some good lessons in the past and I see us applying a lot of those (inaudible) lessons to what we intend to do in the future. So, thank you very much.

**(END OF SIDE B, TAPE 2)**

MR. HOUSENGER: Thank you, Dick.

**(Applause.)**

MR. HOUSENGER: You're going to notice that some of the handouts don't correspond with Dick's presentation. That's because Syngenta was brought in fairly late in this one. We decided we wanted an agricultural point of view on this whole thing, and Janice McFarland, who was on vacation and then in Switzerland, kind of pulled it together very quickly. So, thanks to her.

Are there any questions on Dick's presentation? Jennifer, yes?

MS. SASS: I actually just have a comment. Thank you. I actually thought that was the clearest presentation and most complete presentation on both the summation of the science of each of the tests as well as the utility, and I really appreciate that. The only thing that I would add, and I know that you're well aware of this, is that just because it's new to EPA doesn't really mean it's new. In other words, a lot of the tests that you're saying it took 20 years to develop really have been validated from a publication and scientific use point of view. And so, it's a regulatory step to put them into action. And it really shouldn't take as long or be as onerous, maybe, as anticipated.

But there's certainly -- I think there's a confidence level that's well-established in a lot of those.

DR. LEWIS: I take your point, and hopefully, in the future, things will go a little quicker. The important thing to note is that just because a test has been published doesn't mean that anybody can pick up that

methodology and use it. I think that's what regulatory (inaudible) are likely looking for, is that the outcome of tests conducted by labs around the world will be reliable and relevant; i.e., valid. So, that's why --

MS. SASS: And repeatable.

DR. LEWIS: -- you have to go through a validation, a formal validation step.

MR. HOUSENGER: Are there any other questions?

(No response.)

MR. HOUSENGER: If not, I guess we'll break for lunch now and reconvene in one hour and two minutes.

MS. MULKEY: We'll see everybody in our seats at 1:30.

**(A lunch recess was taken.)**

**AFTERNOON SESSION -- DAY ONE**

MS. MULKEY: Apparently, there is quite the fascinating cocktail hour at this hotel and it is purely coincidental that this is the only hotel that we know of in the area that invites people to bring their pet dogs to the cocktail hour. But it just somehow seemed to fit with our agenda beautifully. I'm just killing time here.

**(Laughter.)**

UNIDENTIFIED MALE: Is that every night that they bring the dogs?

MS. MULKEY: No, I think it's only Tuesdays, and I'm not even sure it's every Tuesday.

**(Brief pause.)**

MS. MULKEY: Well, thank you, again, for all of you being conscientious about being in your seats.

**(Brief pause.)**

MS. MULKEY: Those of you who have already made it back are probably not the people who need to hear from us, that we're cognizant that this topic we've embarked on is pretty dense and that it's difficult to plunge right into the policy issues without all this context, but that it is sometimes a tad tedious to wade one's way through all the context.

I'm hesitant to embarrass the one or two people who belong at the table who are not -- who are in the room, but are not at the table, to the exclusion of all the many who are not in the room and not at the table.

**(Brief pause.)**

MS. MULKEY: All right, well, let's take an opportunity to focus on our time management challenges. This panel still has quite a bit of really quite meaty material to include and it is -- frankly, it was obvious to them and I'm finding it obvious to me that it is difficult to have a meaningful dialogue on this relatively complex set of issues involving the adoption and actual use of alternative tests without a lot of this context, and we do look forward to an opportunity for dialogue.

It is important to remember that through these panelists, we, the agency, are hearing some variety of views. That even before we get to the opportunity of hearing from the PPDC, this is an opportunity from our point of view for a range of inputs. But this is a PPDC that has a lot to offer us and has not been given much opportunity yet for your points of view to emerge. We're

mindful of that. We're hopeful that we can make up for it this afternoon, and we're presuming that the panel is eager, similarly, to have a good discussion and will work toward that end.

So, I think without any further delay in our ability to get to that stage, I will ask Jack to put us back on track.

MR. HOUSENGER: Okay. Something happened to the right-hand side of the room here, the panel members. I'm not sure --

DR. AMADOR: I'm holding the fort on this side.

**(Laughter.)**

MR. HOUSENGER: Everyone on the left is here. All right.

The next three presentations are going to be made by Procter and Gamble. The first presenter is Katherine Stitzel. Kathy graduated from the University of California at Davis with a Doctor of Veterinary Medicine degree. In 1982, she joined Procter and Gamble as a veterinary clinical pathologist. She moved up through the management in the corporate human safety area to Associate Director in the Corporate Human Safety

Department. Kathy has since retired. She retired in 19 -- 2002 and she has a lot of credits to her name associated with non-animal testing. I won't get into all of them, but she is currently serving on the Board of Scientists Center for Animal Welfare.

She's going to be talking about an approach to risk assessment. Kathy?

DR. STITZEL: Thank you very much. I'm going to introduce Procter and Gamble's presentation and then the other two speakers will come in, Mike Robinson and Rosemarie Osborne, and then I'll end up at the very end.

Today, what I want to do is give Procter and Gamble's approach to risk assessment, and since we're here kind of encouraging EPA to think about new ways of doing things, we're going to -- I want to do this kind of historically. Where we were when we started and how we got to using very few animals for risk assessment, what types of changes we've made, how we've made them and why we've made them. So, if I can have the first slide, I'll begin at the beginning.

Back in the 1960's and 70's, as Dick also mentioned, we used to do a full set of animal tests for

every new product and new ingredient. At that time, we had a limited number of product categories and few really novel ingredients, but we didn't have very good safety data on these materials. That was early in industrial toxicology.

We did, however -- and I wasn't here then, but we had some pretty sharp people and even back then we started developing a database of all the toxicology testing we had done, and we continue that today. So, we do have access to all the testing that we've ever done.

We also, back in the 60's and 70's, didn't have near the understanding we do now on the habits and practices of our consumers. So, our ability to decide on exposures was much less than it is now.

Because we had little safety data and because of our limited understanding of habits and practices, we did do a full battery of tests on each product before it was introduced to the market. Next slide, please.

Now, the reasons that we've changed our way of doing toxicology are several. One is that we now have extensive data on all -- on most of our ingredients and many variations on our formulas. So, it became clear

that there was no real sense in retesting these things over and over again because we had already done the testing and we knew pretty well what the answer was going to be.

We had, like I said, 30 years of experience of how these materials fit together and how -- what's safe and what's not. And so, based on that we said, there's really no real good reason to continue to do these full batteries of tests. And also, we've really improved our exposure data. We understand the habits and practices much better than we did then and we also have, although it doesn't really -- we don't use it as proof of safety, we also have all the 800 numbers. We put 800 numbers on all our products in the United States and in many countries overseas, and so, we have kind of a check that we have been safe, but not only that we have been safe, but also that people are using the products the way we think they are.

So, in addition to that, something I didn't put on the slide, which is a very important mention, is that within the last 30 years, there have been tremendous advances in both the science of risk assessment and in

understanding the mechanism of toxicology. And without those, we would not have been able to change.

The most important thing has been that we have been under business pressure to change, not only because it's faster, less expensive to have to do all this animal testing, but also because our consumers wanted us to reduce animal use. So, it is the pressure to change that has really forced us to do this. Without pressure to change, I think that's what's somewhat difficult about getting a regulatory agency to change because there's not the similar business pressure that we have. Next slide, please.

Our current process, and I'm going to go through this real fast because Rosemarie and Mike will also talk about this, is to review what we know about the toxicology of ingredients and the formulas, review the habits and practices for the type of product that we're going to be putting on the market, do a preliminary risk assessment to decide whether or not we have enough data for a positive assurance of safety. If we do, we stop there. Of course, if we have data that indicates it's toxic, we also stop. If we don't have enough data, then

we would go to non-animal testing, which might be in vitro testing, might be computer testing, might be some physical chemical testing.

Then we reassess our risk assessment process and refine it and say, do we now have enough information to say that we have a positive assurance of safety. And it's only if we come back at that point that we would end up doing in vivo testing, and then we do our risk assessment -- we find our risk assessment and finalize it for market approval. Next slide, please.

Now, I haven't mentioned regulatory guidelines in there because what we're really trying to do is say, is the product safe. But you understand that if there were regulatory guidelines that were going to kick in, we would be thinking about those all the way through and doing tests that would meet regulatory guidelines at the appropriate step.

The other thing that our current process, of course, includes is continually monitoring our 1-800 data and any other data that we can get on consumer use, including that this confirms that we were right with our safety, but more importantly, calls attention to

unexpected exposure scenarios that we haven't thought about. Next, please.

The result is that at the current time, we use no animal -- we have had to use no animals to assure the safety of products released in the non-drug area for several years. We reserve the right to do that if we have a really new product or ingredient. All of our animal use at the current time for non-drug products is really driven by regulatory requirements. If we have to deal with regulatory requirements, of course, we have to do it, but otherwise, we haven't really had to do any of that. And one of our biggest uses of regulatory requirements is the anti-microbial registration for EPA, which is why we're here today.

This has resulted -- that is, not using this process for developing data on safety has resulted in significant savings in resources. For us, a big savings is time. We can get products to market much faster. Some of the tests are less expensive, which allows us to save money on testing, and also, of course, we save animals. And we also have, we think, continued to have an excellent record in protecting the health of humans

and the environment, even though we are using very few animals in our safety assessments. Next slide, please.

Our continuing goal is to eliminate the testing that's not necessary to support safety. Next slide.

Now, I want to talk about the three steps -- there probably are others -- but the three steps that we think are important and how we got from doing tests on every product to doing no animal testing on products.

The first is developing and adopting new methods. We now have alternative methods. They're not all in vitro methods. Some of them are. We find there are reduction methods available for almost every endpoint, the major ones, where we do not have any type of alternative or systemic toxicity, the sub-chronic, particularly.

It's important that our tests are mechanistically based. We can't develop new tests unless we understand the science of (inaudible). So, understanding the science of toxicology has allowed us to develop better tests for these endpoints.

Our tests are developed to predict human response. We really are trying to protect the health of

humans, in most cases, and for what we're talking about today, the tests are designed to protect human response.

Our tests are validated internally. I think Dick mentioned that a lot of the tests that are now being accepted internationally have been used in Syngenta for years and it's similar with P&G. We have a set of tests that we use internally. They've been validated internally. We know what types of materials that they will be correct for. We know that within our lab they're reliable and reproducible, so we have a good understanding for our materials. So, adopting new methods is important. Next.

Another thing that is very important is utilizing the data that is available, that are available. We have a toxicology database of all of the toxicology testing that we have done previously. We have added to that database all the data that's in UCLID (phonetic) and most of the data that's in RTEXT (phonetic), all the NTP studies, the Gold database, anyplace that we can find large quantities of toxicology data, and that really allows us to search for other data on protecting ingredients and for our own products on formulas.

We can search by chemical structure and by substructure, something which I know that EPA can do because they're very good at this in the environmental area, and we find it very useful in being able to go in and look for what data's available on very closely related chemicals and predict whether something is likely to be a problem or not. And then we use some of the commercially available software programs that do predictions based on chemical structures such as Derek and Medium.

It's important to understand that you really can't do this very well without understanding mechanisms. And so, again, these processes, being able to use the data to predict really -- to depend upon understanding the mechanisms of toxicity.

The third thing is to constantly rethink the process. Ask, why are we making this decision. What is it we really need to know? Ask, what information do we really need to answer the question that we decided we really need to know the answer to. And then how much information is really needed? And by doing that, we've really sharpened our purpose when we do toxicology

testing rather than just do a standard set of tests every time. Really what do I need to know this time or what data do I need and how much data do I need for the answer that I need to know today.

And at P&G all the toxicologists that come in, I think, by now have quickly learned that you don't come in with what you know in toxicology when you graduate from school and expect to do the same toxicology for the rest of your life. It's constantly changing, and constantly changing means constantly relearning. And it's just an expected part of toxicologists at P&G that they do not expect to do the same thing five years from now as they do now, and that's really important because change is hard for people and it really has to be built in that change is expected and you have to be able to deal with change. Next slide, please.

So, with that, I'm going to turn it over to Mike and Rosemarie, but I want -- they're going to talk about skin and eye testing, and I wanted to touch on the other tests in the six-pack that was presented earlier so you know where we are with those.

For the Acute Oral Toxicity test, as you heard,

we use the Up and Down Test. Primarily, if we have to do it, we do use a limit test most of the time because mostly we're dealing with materials that we know are not toxic. If we didn't know or have a good idea what the toxicity was, we would do a cytotoxicity to predict the starting dose. For Acute Dermal and Acute Inhalation, again, we usually use limit tests. We have no alternatives, but we support the development of alternative tests designed, just as we did with the Acute Oral Toxicity, and there are some attempts being made, particularly for dermal change, which is test design, as well. to reduce the amount of animals.

And for Skin Sensitization, we use the Local Lymph Node Assay for ingredients and we have a very active research program to develop an in vitro method for skin sensitization.

So, those are the four of the six tests and the other two will be discussed in more detail and we'll start with Mike. He's going to talk about skin.

MR. HOUSENGER: Let me just tell you about Mike while he makes his way to the podium. Mike graduated from Notre Dame with a Bachelor of Science, Masters of

Science, got his Ph.D. at the State University of New York at Buffalo, my alma mater, and now the home of the Al Quada terrorist cells.

**(Laughter.)**

MR. HOUSENGER: He joined Procter and Gamble in 1985 and he serves there as Principal Scientist working on a number of -- I can read these to you -- experimental clinical skin allergy, clinical skin irritation, a bunch of skin things. So, he certainly seems to be the correct person to be talking about skin irritation.

**(Laughter.)**

DR. ROBINSON: Thanks. Thanks for the invitation. What I'm going to do on skin irritation is really kind of go through a framework that we use. I think it's becoming adopted by many in industry with regards to their own particular frameworks. I will talk a little bit about ours. It really is a risk assessment motif. I know a lot of times we're talking about hazard identification and being able to check off boxes in different toxicity categories, but we've already heard some relationships of the importance of exposure. We've heard about waivers being offered for chemicals for which

there's not going to be any human exposure for various reasons. So, therefore, exposure does come into the context in a number of different places.

Our framework really begins with an assessment of what we know about any chemical and the formulation in which it's going to be employed. So, we all do a lot of homework before we even think about what testing may or may not have to be done.

I want to talk a little bit about skin corrosion. We've already heard from Dick and others, and we're going to hear more later, about what's been going on with the skin corrosion testing methodologies. It clearly is a shifting paradigm for how we approach that particular hazard endpoint. And I'm going to talk about options for skin irritation and skin compatibility testing. Of course, we wouldn't have any fun today if we couldn't be controversial.

So, we've already heard about an agency position with regards to human testing, whether it should ever be allowed or ever be used, and I think the point here is, when you talk about human testing, there are really two questions. One is, should it ever be done under any

circumstances, and if you give an allowance that maybe it can be done, the real question after that is, what should be done, how should it be done, what ethical protections are there for the subjects and how is that data to be generated and used in advancing a safety testing and risk assessment program.

I'll also be talking a bit about skin irritation testing, which we heard a little bit about, but it hasn't been touched on to any great extent, and I'll talk a little bit about where that is in terms of its development. Next slide, please.

Basically, everything I'm going to say today is a very cursory, a superficial overview of a paper that came out about last May, in Food and Chemical Toxicology, which goes into excruciating detail into a lot of the methodologies surrounding both in vitro and human -- various types of human test methodology, initially for skin corrosion, as well as for skin irritation testing, and how it can be employed in the risk assessment processes, both validation processes and methods -- methods that are currently in the process of being developed and validated, as well as methods that are used

within various organizations for their own purposes, including our own.

In putting together the authorship on this, we really looked to cover as broad a base as we could, while still keeping it in reason for the senior author to try to manage an international effort on getting this thing written and published. In addition to myself, Ed Whittle and Julia Fentem -- Julia is certainly well known to many in the alternatives area for the time she spent at ICCVAM coordinating all of the work on skin corrosion testing. They and I represent, of course, the broad-based consumer product companies. They come from Unilever. Catherine Cohen from a cosmetic company that most people know about called L'Oreal in Europe, Anne de Brugerolle from Novartis, also in Europe, and Mya Ponec, who is our academician on the panel is from Leyden University in the Netherlands.

You'll notice a fairly hefty European influence on this paper and that's not surprising. Clearly, Europe has been ahead of the curve on this method development standpoint. Really, only one of the methods that I'll talk about came out of P&G. It was a principally U.S.-

based effort. U.S.-based organizations have been involved in the validation effort, but a lot of the method development that's gone into these test methods came out of Europe and has been led by Europe, and that also includes internal methods that various organizations are using and trying to develop for their own purposes.

I've got about 10 or so copies of this with me, so if anyone's interested in a copy, I'll make them available. If you aren't able to get one and you really want one, just use the e-mail address, and if you want a paper copy, make sure you list your address so I can send it to you, or I can give it to you as an electronic version if you just want it that way as well. Next.

Actually, I guess you can read this. Probably not from the back of the room. It's in the handout and it's also in the paper. It really isn't meant to be read here. I do have a simplistic version in the slides that follow, but this really is sort of an overall flow chart of a risk assessment -- testing and risk assessment process, and I put this big one up mainly to illustrate a couple of -- identify a couple of points.

There are a whole variety of checkpoints during

the process of testing and assessment of your results. The point is that, oftentimes, we come up with a new ingredient, it may be such an insignificant change from a formulation that's already on the market, for example, but the decision may be that you don't need any testing and then you come all the way down here to complete your assessment and move into the marketplace. Other times, you may ask the question, do you need additional testing before the human exposures are allowed and, again, sometimes the answer is no. You can come right in and ask the question, do you need human testing. If not, then you go right around the risk assessment. If you do, then you go into various types of human testing that I'll talk about in a little bit. But if you do need additional information, then you go through a variety of other steps to generate the data that you need in order to determine whether or not this material is suitable to be put into exposure in humans.

This is the simplistic version of this, which is a little easier to read, and it really talks about the overall process of, again, some initial evaluation, the paper toxicology and I'll get into some of the details of

that in a minute, and then the question about whether you need additional testing prior to human exposure, the in vitro methods that are available if you do need that data, and then the question, is it safe to be put into humans and then any kind of human testing that may be necessary or wanted in order to move into the marketplace. Then a variety of human testing options to meet different kinds of needs. Not all of it is toxicity. A lot of it is compatibility and that relationship as well, and I'll talk about that. Next slide.

So, this is the paper toxicology, and again, it's just an assortment of things. There's a lot out there, a lot that we've generated internally, that many companies generate on their own, and we have, as Kathy said, a database of every chemical that's ever been put through acute testing or sub-chronic testing in our company. But there's also a lot of information in respositories and databases that belong in the public domain and are easily accessible either free or through a subscription. And so, that includes a lot of data, clinical data as well as animal in vitro, et cetera. I

think I'm losing my pointer here.

**(Brief pause.)**

DR. ROBINSON: Oops, I don't want to do that.

**(Laughter.)**

DR. ROBINSON: A lot of the information, physiochemical information, of course, a lot of questions around what the partition coefficient of a chemical is, how fast does it get into the skin, how well does it get into the skin, what's the pH, what's the reserve acidity or alkalinity, as Kathy indicated, there's a lot of information forthcoming now in structure activity -- quantitative structure activity relationships. There can be probably a lot more of that right now of value in the skin sensitization area than in skin irritation, but that's a developing area as well.

We talked about exposure scenarios. That's very important from the risk assessment standpoint and over the years we have developed a lot of information about the habits and practices of the products that we sell, not only the way they are intended to be used, but the creative way that consumers have of misusing our products, and we need to take that into consideration as

well.

And then finally, the marketplace experience, everything we sell becomes a benchmark against which we can evaluate new chemicals and formulations in the future, and we do that constantly by evaluating the new materials, the new materials against that for which we either have good or bad experience in our prior testing, and of course, in terms of the marketplace, the good experience that we have because we really have had a high degree of information coming back that our risk assessments have been good in protecting our consumers. Next slide.

I'm not going to spend a lot of time on the corrosion testing because most of this has already been stated before. Of course, the current basis for regulations is based on the Draize test that was developed in the '40s, mandated by the FHSA Act in the '60s and has been tweaked in a number of different ways by regulatory authorities in different parts of the world, and it's usually the speed of a corrosive result that defines the hazard either in terms of a packing group classification or a European labeling requirement

under the EC directive.

Of course, it's been the major focus, or a major focus of alternatives development, not only in terms of the animal welfare considerations, which are significant, but also issues that have been known for 25, 30 years about it's limited predictiveness, in particular, the various rabbit tests for human skin effects where they have been directly compared.

The new mechanistically based methods have all been developed and then validated through ECVAM-sponsored activities. We've already heard the names of all of them and, of course, the timeline of their development. The European Union, of course, two years ago adopted the TER and generic skin test methods. They did not define these actual products by name because of the implied endorsement of a corporate entity, so they basically said if you use anything that hasn't been validated, it's going to have to be validated with the data set that you submit. So, it kind of puts the onus back on people to use what has actually been through the validation process.

The OECD guidelines, of course, have been

recently approved by the new test guidelines with the in vitro methods incorporated, and again, mentioning that the ICCVAM process has just been concluded with the provision for the rabbit test, but again, with the provision that the test results are only used if a result is positive and a rabbit test is required to follow up a negative result.

This is just the one data slide on corrosion. This actually came out of the P&G methodology using the EpiDerm Cell Culture System that Rosemarie Osborne, Mary Perkins and their lab developed back in the early '90s. It was published in '96. And, again, it just shows the EpiDerm construct, which is just a differentiated epidermis with a stratam-corneum (phonetic) mon filter insert.

This is the way the cultures look sitting in the actual culture disk with the inserts in the center well. Test materials can be applied directly to an air interfaced stratam-corneum surface. The cultures are fed from underneath and then you can look directly at the cultures themselves for liability as well as other endpoints can be evaluated by looking at the culture

fluid for things like cytokines (phonetic), and then this was the actual test data differentiating corrosive and non-corrosive materials using the prediction model, which was set up at that time, which was a 50 percent residual viability after a three-minute exposure.

When the German lab, VGA, adopted this method and essentially tweaked it for ECVAM validation purposes, kind of a catch-up validation, they added an additional prediction model to it, which was a 15 percent residual viability after a one-hour exposure to try to increase a little bit the sensitivity of the method.

In vitro methods for skin irritation are still under development. Some of them actually have undergone an ECVAM-sponsored pre-validation effort. There is still work to be done, a lot of it having to do with inter-laboratory reproducibility, some of it having to do with sensitivity specificity. So, there really is no officially accepted in vitro skin irritation test at this point in time. A number of labs are actively developing methods, most of them based on some sort of skin equivalent model for both acute irritation as well as for cumulative and chronic skin effects, and these are

essentially used internally by different organizations. That review article that I mentioned upfront goes into a lot of those that different companies are using, including our own.

The challenge for a lot of these methods is to achieve, in these very short-term cultures, which usually are pretty much limited to 24, at the most 48 hours, sensitivity that is required for some of the longer term endpoints, particularly the cumulative or the chronic irritation, because obviously in clinical testing, some of those methods can go on for several weeks.

The focus of the regulatory effort, I think right now, is going to be more on the acute irritation, that irritation that is in the moderate to severe category and which shows up in just a few hours of exposure.

Now, we talk about human testing options, and, again, for non-corrosive chemicals -- and that's the provision, that obviously these things have to be evaluated for corrosivity before they ever go into a human test -- there are some human options available. The one I will talk about today is the prediction of

acute irritation potential. That's a fairly new method, or at least within the last seven or eight years. There are a variety of other methods that are available, which fall into the category of chronic or cumulative skin irritation. A lot of these are long-term patch test methods.

There are also a whole category of test methods which fall under the category of skin compatibility. A lot of these are use test methods that are used for final formulations with dilutions of product for things like skin hand soaking tests and just a variety of methods that different groups have employed, including different organizations with our own company to meet the needs of their particular product categories. And a number of these have been published over the years, both by industry as well as by academic dermatologists.

Again, when I talk about the true alternative, when you're really looking at an alternative method to replace an animal test, it's really the acute irritation endpoint that we're interested in here and so that's why I'm focusing today on this prediction of acute irritation.

This test method, the Human 4-Hr Patch Test, was initially developed by Unilever in the early '90s and first published in 1994. It basically involved a four-hour -- up to a four-hour exposure to potentially irritant chemicals under an occluded -- fully occluded patch test conditions. They usually tested very high concentrations, and if possible, 100 percent of the materials that they're interested in evaluating. The safety of the method was enhanced by a couple of procedures. One was very gradual subject enrollment into the study. You usually -- in the most conservative protocol, one person the first week and then four the second, up to 30 total with weekly increments.

There was also a graduated exposure, again, generally starting at 30 minutes, but it can be tweaked back to even shorter depending on what information is available about the test materials, and then ramping up to four full hours over these weekly intervals.

The skin reactions are graded for delayed response at 24, 48 and 72 hours after the patch removal on a simple grade of increasing erythema (phonetic). The point is that exposures were ceased at the first positive

response. So, it is the incidence of the sensitization responses, not their severity, which is the prediction model for this particular study, and the prediction model is based on a direct comparison to the results with a concurrent positive control, which is 20 percent sodium dodecyl sulfate, which was selected by Unilever because it is the labeling standard for surfactants in Europe based on conventional classification. So, it was not necessary to test 100 percent. They just used 20 percent as the labeling benchmark.

This just illustrates -- and this is from their original paper -- I'll draw a circle around it -- the degree of skin reactivity. Over the years that we've looked at this method, easily 90 to 95 percent of the reactions that occur are in this grade one category and I had to kind of draw a circle around this one to even see that the response was there. So, it is a very mild response, and again, it is the incidence of these reactions, not their severity, that defines the toxic endpoint for this particular test.

And this is just a representative figure from a paper published a couple of years ago when we were

comparing -- this is a -- actually, the focus of the study was comparing Unilever's results to our own. But this just shows two different endpoints, looking at three fatty acids with just -- with different chain links and showing the diversion of responses between them compared to distilled water. He's the positive control, SDS, to the fatty acids, the octanoic and the decanoic acids were more irritating than SDS and hence would be labeled, under this prediction model, as an R38 or irritating the skin. The dodecanoic acid and, of course, the distilled water were significantly less irritating than SDS and would be labeled as non-classified, again under the prediction model for this test.

In addition to that, we introduced a time course analysis which allows you to determine the time of response that would require for half of your panel of subjects to react over the time course, and what that has allowed us to do is to make a lot of comparisons using this test method, and we've done everything from racial comparisons to effects of seasonality, different geographies, different skin types. You name it, a number of things have been looked at in terms of understanding

some of the variability of human reactivity. The nice thing about that is, in spite of the variability that does occur in human skin irritation testing, the inclusion of 30 subjects in this method has ensured a high degree of reproducibility.

When we looked at these TR50 values between our lab and Unilever's in this study, they were within a couple of hundredths of an hour across the three test chemicals.

This is just an example of the comparison of results that have been generated -- this is out of Unilever's laboratory -- between the human irritation test results and the existing data that was available on those chemicals based principally on Draize test results. The bottom line here was that out of the 65 chemicals that were evaluated, 45 -- almost half of the classifications were wrong based upon human result.

All of the corrosive values were wrong. I mean, they were either irritant or they were non-classified. The irritant values here were correct. The non-classified values here were correct, but there were 23 irritant-labeled chemicals with the non-classified human

tests and then there were two that went the other way, that would be non-classified under the existing animal data that would have been irritating or R38 under the human results.

In addition to the chemical testing, we've also done some work with this method in formulation evaluation. Starting back in about 1995, the Soap and Detergent Association formed a task force on alternative methods and chose to use this method as a way to begin to look at detergent formulation for various categories. Over the last seven years, a number of tests have been done looking at products in a variety of detergent categories. The most irritating of those were mold and mildew removers. The least irritating were dish and laundry powders.

When we looked at multiple products, even between studies, their TR50 values were virtually identical. There was some seasonality of effects, wintertime studies, as you might expect with surfactant products, tended to be a bit more irritating than the studies done in the summertime. But, again, the classifications did not change. These have recently been

presented at the SOT meetings and the World Congress meetings of this year and we're expecting to publish the results of this sometime in early 2003.

And I'll just leave you with a case example. I put this up not because it's -- it's not a pesticide example, but it gets to the question of weight of evidence when you talk about data that's available and how you might use it. This is actually an internal situation where we have a product upgrade a few years ago where a product was going to have a chemical replaced with a near cousin of the chemical that was already in the product. But when the new chemical was tested, in order to meet base set notification requirements in the UK, where it was initially going to be submitted, it came up with a corrosive result. It would have carried an R34 label. This was the primary irritation index of 7.17 out of 8 in that study.

Well, that was viewed as a problem, obviously. Also, there was a question of whether it was a reliable result. And so, in vitro testing was done using the EpiDerm culture system to see whether or not we would reproduce the corrosivity and, in fact, we did not. The

test compound had a residual viability of 96 percent whereas the positive control in the corrosion test was 5 percent residual liability and highly corrosive.

So, let me put it into the Human 4-Hr Patch Test. This test was repeated at three different laboratories in the U.S. and Europe, and overall, we wound up with 90 percent of the subjects responding to the 20 percent SDS and only 13 percent of the individuals with irritant response to the chemical. So, clearly, in the human, it was a non-classified result as well.

The information was put before the (inaudible) in England and while they liked the data and certainly believed that the chemical was non-irritating, they were still going to require that the skull and crossbones go on the product. This happened to be a fabric softener, if I recall correctly, and since our competition at the time was marketing products with teddy bears and flowers, we thought it was probably not going to be a good idea to move ahead with that one.

**(Laughter.)**

DR. ROBINSON: But what it tells you is that we have, I think, moved the dime a little bit because it

would be nice to think that a similar submission today, something with a new EU requirements might get a little more attention in terms of being able to put this kind of information forward.

And finally, I just want to leave a set of recommendations that talk really about where we stand today and what we have available to us. Clearly, as a review article will also state, there is a current best approach out there. It's been tweaked by a number of different companies in a variety of different ways, but it can be used to make a full assessment of skin corrosion and irritation for new chemicals and maybe in new formulations obviating the need for animal test methods and flexible enough to meet a variety of different ingredient and product types.

It does used weight-of-evidence from a variety of sources, so it is not a checkbox approach. It does use existing data from a variety of sources, validated and qualified and accepted in vitro skin corrosion tests, in vitro skin irritation screening tests which again, right now, are limited to internal assessments since none have been validated and accepted by regulation at this

point. You can use human historical data as well as human irritation patch test data on both ingredients and formulations, and then, again, in our purposes, we do a lot of formulation testing, a lot of use testing in human subjects, as well, to confirm the safety of these materials and formulas once they've cleared all of the other batteries. Thank you.

MR. HOUSENGER: Thank you, Mike. Are there any questions before -- as Mike sits down. Yes, Steve?

STEVE: I'm just curious. With the ingredients, you presumably get this from some supplier. What are your expectations for the supplier to provide this kind of data or do you run it all yourself? Obviously, the formulation is your own product.

DR. ROBINSON: It works both ways. There are supplier data sets that we will get and we will use that information. We will also evaluate that information as to whether or not we agree with their assessment of the results. Again, some of that kind of stuff is grandfathered into existing chemicals. With brand new chemicals, if the suppliers aren't willing, we would have to make the assessment.

We have what's called a Tox Office within our organization. When I was in the safety organization, what would happen on an irritation question is, if there were new ingredients and the toxicologist out in our business unit would send me a piece of information about what they wanted, this material, what it was, what its structure was. It would go to a group of people who would do a computer search for any analog information, and then all of that information would come to me and I would take a look at it. I would go into RTEXT and CIR and a variety of different places and our own database to see what I could find. Oftentimes, there wasn't anything, in which case I would send a note back and say, we really don't know much about this. We're going to have to sit down and talk.

And, again, if it was something that they wanted to pursue and there was no data, that's what we would go through. But we would start in vitro. I mean, again, unless it was mandated that we needed to do the animal test to meet a registration requirement or something, there was no basis for us, from a risk assessment standpoint, to have to go down that route. We could

easily make the judgment based upon the tools at our disposal.

MR. HOUSENGER: Julie?

MS. SPAGNOLI: Maybe this was mentioned earlier, but I didn't catch it. I know sometimes these human patch tests are done for a lot of consumer products in Europe. What's the agency's position on these types of testing relative to their human testing position? I know they said applicator exposure and, you know, like repellents, but, you know, what about this type of testing?

MS. MULKEY: I think I'm going to reserve on that. I want to be sure I get it right.

MS. SPAGNOLI: Like I said, I wasn't sure if I just missed it when we were talking about it earlier.

MS. MULKEY: There's certainly a number of kinds of skin-applied human tests that we have regarded as outside the scope of this deliberate dosing, third party -- for purposes of --

**(END OF SIDE A, TAPE 3)**

MS. MULKEY: -- category. But I'm just not -- I don't feel close enough to it to say, in a definitive

way, whether the particular tests you heard about here designed for this purpose would meet the words of the things that we are consulting with NAS about, and I just don't -- I don't want to freelance.

MS. SPAGNOLI: Well, I would assume if we had, like an insect repellent product that was intended for direct human skin application, that that type of testing --

MS. MULKEY: Those, we have made it very clear, are not included in the category that we're consulting with the NAS about. My intuitive feeling is that this category is also not included, but before I say that, I'd rather be on a little bit firmer ground.

DR. ROBINSON: And to be fair, this has not been -- in Europe, this has met some really tough sledding, you know. Again, their regulations require that all the companies endorse it if it's going to meet an OECD guideline, for example, and it hasn't. It was written up as an OECD guideline draft about six year ago and it's failed, and it's because of a couple of countries that just simply will not consider it. And, again, it gets to that first point that I made. You have to say, first of

all, whether you're philosophically in agreement or not, and then you can talk about the details. Well, they aren't philosophically in agreement at this point. So, that's where it stands.

MR. HOUSENGER: Jennifer?

MS. SASS: Thank you for the presentation. I have some clarification points. I'm pretty naive on the developments in these areas. I'm not on the ICCVAM or anything, so this is me hearing about it.

Just to get the definitions straight, when you talk about an acute, you're talking about a single dose, single exposure.

DR. ROBINSON: Right.

MS. SASS: When you're talking about chronic, are you talking about a constant chronic exposure or a repeated exposure?

DR. ROBINSON: Yeah. I differentiate chronic and cumulative. Cumulative is based upon repeated exposures over a period of time. The chronic exposure is, generally speaking, a single prolonged application, it can be a very prolonged application. You know, you could argue that in some categories you could put

something on for say 24 hours and then you could have a progressive response over time. That would also be in the chronic category, but usually chronic just means long-term exposure whereas cumulative might be short-term, but repeated every day kinds of exposures.

MS. SASS: All right, good. And so, then that's capturing, you would think, the sensitization issues. When you use the word "sensitization" and I use it, I just want to make sure that we're talking about, like, somebody who has had an exposure and is no longer naive and is more likely to be hyper-sensitive. They could also habituate. It could go either way. But often with chemicals you become more sensitive to repeated exposures.

DR. ROBINSON: Yeah. Nothing I talked about here deals with sensitization. I mean, sensitization are cumulative procedures, repeat exposure procedures in order to first induce a sensitization response within the subjects and then if they elicit -- you know, you're eliciting a skin reaction in the secondary response. So, it is a different category. Certain chemicals can be both irritants and sensitizers, but this particular

framework was dealing specifically with the acute irritation, which is not an immunologically mediated process.

MS. SASS: So, one of my questions is going to be -- I guess now I'm getting into the questions part of it. You said on your last page, your recommendations, that there is a current best approach for skin corrosion. So, I have sort of a list of ticks it would cover, and one of them is the repeat. Is there something for repeat? And the other one is sensitization, habituation, can you deal with that issue, because it's the key. It's the top two issues of these kinds of (inaudible).

DR. ROBINSON: Yeah. Sensitization is not covered by this. It really is a separate endpoint that has to be dealt with, and again, we're not there yet. The Local Lymph Node Assay is a step in the right direction in terms of replacement and refinement, but we're not there for full replacement.

You know, corrosion, you could -- a material that's non-corrosive in a four-hour exposure could be corrosive if you put it on for 24 hours under occluded patch. So, when you define your irritation, it has to be

in the context, not only of the concentration that you're testing it, but also the time of exposure that you're using. So, there's no such thing as a cumulative corrosion test. Corrosion is a defined endpoint within a very short term window of exposure, and then if it's not corrosive at that point, it may be that you could put that into human subjects, again, depending upon the exposure scenario, and define it in terms of its acute irritancy potential, okay? But it would be non-corrosive by definition because it's non-corrosive in any of these in vitro methods.

MS. SASS: Yeah. I'm not concerned as much about the corrosive as I am about that repeat sensitization. I mean, this is the model of the workers who -- or like when I go to get my pictures developed, the guys in the photo lab don't smell the chemicals. Well, the chemicals are still damaging them and they might have smelled it at 8:00 a.m., but by 5:00 p.m., they're no longer smelling it, and they might not smell it by Friday, but when they come back to work on Monday, they smell it, and over years, they might actually become completely intolerant and become unable to do the job.

That's the scenarios.

And I'm not talking about years, but I'm talking about hours or days or weeks or months. That's the scenario. And that's the most real. Like I say, it's the key one or two when you're talking about sensitization.

DR. ROBINSON: And the test method -- when you're talking about product development from our standpoint, what we would try to do is we would try to capture all of those kinds of exposures, both anticipated and unanticipated or at least foreseen, in the context -- once we're beyond this acute testing or cumulative chronic testing, we would get into actual use scenarios so that we would understand exactly what people are going to be presenting with when they actually use the product.

MS. SASS: So, when you say a current best approach, we now have skin corrosion and acute skin irritation, acute short-term or single dose, maybe skin irritation?

DR. ROBINSON: Right.

MS. SASS: So, now my other questions are going to be are the tests transformed cell lines of any primary

cultures or are they synthetic or -- what's the state of the cells?

DR. ROBINSON: The test methods are all the ones you've heard about today. They are transcutaneous, electrical resistant and rat skin, they are a bio-barrier method, they are epidermal equivalent test method.

MS. SASS: So, the one that you showed, you're using as a representation. But, in fact, you would go -- like somebody suggested micromass cultures, that's the chick-wing bud (phonetic) standard culture or cell lines, transform cell lines, primary cultures, organ cultures, anything.

DR. ROBINSON: Yeah, they have not been validated for this endpoint. Again, they may be suitable or under-development for other toxicity endpoints, but not for this particular one.

MS. SASS: Okay. And the EpiDerm TM, these kinds of things, these are transformed cell lines?

DR. ROBINSON: No, these are normal human care tenacites (phonetic) that have been grown up in a sheet and then cut out in a lot of differentiated air interface which causes them to differentiate and form a multi-layer

and then ultimately give rise to a stratam-corneum. They do not have a barrier of normal skin. They do have some barrier properties. But they do form a fairly differentiated epidermal equivalent. It's very similar histologically to what the human skin would look like.

MS. SASS: To about three layers in the skin, right. And so, they would be primary cultures in some kind of defined growth medium?

DR. ROBINSON: Yes.

MS. SASS: Okay. So, given those limitations, I think you have a great system going. I don't think it's the last word, although it might be the first word or a really important primary screen or something like that. How do you feel? What's your sense of --

DR. ROBINSON: Like I say, if you look at the review article, you'll see what Novartis uses. Norvatis has a different approach than what we do and they rely a lot more heavily on the in vitro cultures for both their acute as well as their cumulative chronic irritation. L'Oreal has a different approach. I mean, everybody has kind of developed -- they have different kinds of chemicals, different kinds of formulations that they're

interested in. So, they all have developed -- I would call them similar, I would still call them processes, but they are different in the specifics of what they use once they've gotten beyond the currently validated and accepted methods. I mean, those are basically on the table for everyone and there's a very limited number of them.

But once you get beyond that, what are used internally by different organizations are the things that they're comfortable with, most of them or many of them are published because they want people to buy into them. But they're not -- certainly not validated in the sense of what we've talked about here as a process by which anybody would go through and say, yeah, these are methods that everybody can and should be using.

MS. SASS: Do you think that it's more valid to jump from these kinds of in vitro -- more synthetic and controlled and defined tests to a human skin test. And I'm not saying I'm averse to what you're doing, I'm just saying it seems to me that scientifically we've always had an in between stage and that has been an animal, and it wouldn't take a lot of animals and it's not a painful

test, it's not painful on the humans, and I'm certainly not talking about the Draize test, but I'm talking about the skin patch test that you were talking about where you get a red patch that you're claiming you almost can't see if it's a low level.

Why go right to the human? Why not go to --

DR. ROBINSON: It's a fair question.

MS. SASS: -- you know, the hind limb of a rat?

DR. ROBINSON: Yeah, it's a fair question. Number one is I don't believe the rat is going to tell me any more or the rabbit is going to tell me any more from a predictive standpoint than the culture does.

MS. SASS: Maybe that they'll volunteer quicker for the experiment probably.

DR. ROBINSON: And it's -- you know, again, we have to be real careful because, you know, volunteers are paid for their participation, but they can only be paid for their inconvenience not as an inducement. So, the ethics of this -- I wrote a review article with the Unilever group about a year ago that really went through 20 pages of ethics on this methodology, and it really did hit hard on all these kinds of questions.

And part of it is the experience. I mean, you know, we relied on what they had done when we got into it, between the two organizations, and now a number of other groups have gotten into it in formulation testing. The SDA Task Force that I mentioned has representatives from over a dozen U.S. companies. We've approached this, we've approached it very carefully and I think the track record has been that it's both safe to do, and we would believe, ethical to do, and if I took a piece of cellophane tape and went around the room and took one swipe off of everybody's forearm, I would get more reactions than what we typically see with these patch tests. That's just the facts. And more accurate representation.

Again, you know, the human -- by definition, humans are variable, but the human response is, by definition, the correct one. No one is going to validate a new rabbit test based upon the human response.

MS. SASS: Right. But all those same arguments that apply to why it's important to take that test to that level of human, that you get the response in a complex whole and verbal articulate organism that can

respond, are all the same deficiencies -- I don't want to use deficiencies, but the limitations of the in vitro testing. So, I mean, I think they're all really key and really important, and I think they all could be used to be red flags or indicators or begin to hone and be more specific about those final tests. But --

DR. ROBINSON: No, I don't know if I agree. I think the human testing in practice has proven to be very, very reliable. It's been reliable across and between laboratories. It's been reliable between studies. It's being used as the benchmark for human data for developing the in vitro tests in Europe through the ECVAM process. So, there's a lot going on it in terms of its reliability at this point. Again, that's all I can really say about it.

MS. SASS: Thank you.

MR. HOUSENGER: Okay. I think we have one last question from Alan.

DR. LOCKWOOD: Just to set the record -- one item to set the item straight. Yesterday, on my way to the Buffalo airport, I didn't see any terrorists, I didn't see any snow.

**(Laughter.)**

UNIDENTIFIED MALE: They're hiding.

DR. LOCKWOOD: It was 75 degrees. Relative humidity was about 50 percent. It was partly cloudy. It was a beautiful day.

UNIDENTIFIED MALE: Give it another week.

DR. LOCKWOOD: One of the other things that's happening in Buffalo is a major emphasis on genomics and bio-informatics, and I'm surprised I'm not hearing anything about that in the development of contemporary risk assessment strategies. Certainly, one example that might be applicable to this committee is the fact that there's a genetic determinant of the level of peroxinase, which is an enzyme that's involved in the metabolism of some of the organophosphate pesticides, so that there are cohorts of people who are going to be more or less sensitive to compounds depending upon their genetic make-up. We're also not hearing anything about differences in sensitivity at different stages of development.

I wonder if you could comment on some of those issues.

MS. MULKEY: Let me observe that one reason you

may not be hearing this is because of the decision of this group to focus on this really quite small subset of overall testing, that is the acute testing of the end use products and there's no questions that these larger issues arise when you look across the broad range of testing, and we could definitely have had a multi-day dialogue on some of that. I think that's the primary reason.

MR. HOUSENGER: Okay. Our last presenter from Procter and Gamble is Rosemarie Osborne, who's a Principal Scientist there. She received her undergraduate degree in biochemistry from Skidmore College and her Ph.D. in pharmacology from Harvard University. Her expertise is in cell culture, and her work at P&G is focused on non-animal alternatives for eye and skin irritation testing.

DR. OSBORNE: Thank you. I'd like to start by thanking the committee for the invitation to come here today and tell you a little bit about what we're doing to develop non-animal methods for eye irritation testing. What I'd like to do is to overview the general process that's used by consumer product companies to determine

the eye irritancy of our products and ingredients; then talk a little bit about the specific test methods and how they work; and then end up by showing you an example of a risk assessment using a bridging approach that incorporates both historical data as well as in vitro data. Next slide, please.

A lot of what I'll be discussing today is based on a workshop that was held at the Institute for In Vitro Sciences close by here in Gaithersburg, Maryland. Participants in this workshop included Procter and Gamble, Colgate-Palmolive, Gillette, J&J, L'Oreal, S.C. Johnson and Unilever.

At this workshop, we discussed some of the common approaches that we use for eye irritation assessments, as well as specific differences in test methodologies. Nonetheless, a lot of the examples that I'll be discussing today are based on ones that were presented at this workshop that we're currently in the process of writing up as a manuscript for a submission later this year. Next slide, please.

This is the basic approach that we are all using for our eye irritation assessments. It's very similar to

the one that Mike was just showing for skin irritation. First of all, starting with human exposure estimates, then getting into a review of historical data. After that, taking all of this information into account, it might be possible to go into an eye safety assessment if it's a minor change in a formulation relative to currently marketed product. If there's new traditional information, then it goes into an in vitro testing mode and then all of this information is taken into account in the overall eye safety assessment process.

As Kathy indicated, there's also post-market surveillance that's conducted via our 1-800 contact number or e-mails or faxes, letters, whatever we're able to gather. We use that both as a check on the pre-market assessment that was made, as well as to gain information on the sorts of scenarios in which people accidentally splash our products into their eyes. This is the basic process.

What I'd like to do is talk about the review of historical data and then get into the in vitro methodologies. Next slide, please.

Again, similar to what we saw for skin

irritation, the eye exposure estimates are based on the intended use and foreseeable use or misuse of the product, and known habits and practices. So, the types of ways that our consumers use the product and scenarios in which they might actually get product in their eye. That allows us to assess whether certain types of products might have the potential for accidental exposures and also to estimate the amount that folks might get in their ideas.

We have a large database in-house of existing either rabbit or human exposure information and irritation information based on assessments that have been done over the last 50 years or so. That's a very rich source of information for a toxicologist in making these sorts of assessments. In addition, we have links into government and trade associations and other types of online databases that we use as a source of information for the ingredients and analyze. Next, please.

The standard eye irritation test that's been used for the last 50 years in industry and is the basis for regulations around the world is the Draize Rabbit Eye Irritation Test that was developed at the Food and Drug

Administration back in the 1940s. The procedure incorporates placement of a 0.1 ml of test material into the lower eyelid of albino rabbits. The eye is held shut for a fix period of time, generally about one second, and then the responses are scored using a subjective scoring scale. The observations are made on the cornea, which is the transparent tissue in the front of the eye, inflamation of the iris, which is the pigmented part of the eye, the blue or brown, as well as the conjunctiva, which is the membrane that lies overtop of the square, which is the white part of the eye.

From an EPA FIFRA standpoint, classifications are based not so much on individual tissue scores acutely, but how rapidly those heal. So, for example, Category I, which would be the most aggressive materials, would be those that take greater than 21 days to heal when the material is instilled once into a rabbit's eye. Category II, 8 to 21 days to heal; Category III, as we're getting into milder materials, less than seven days; and Category IV materials are those that would clear within 24 hours. Next, please.

Now, we tried to develop alternatives to using

rabbits for assessing eye irritation. There's been a number of different approaches. First of all, reducing the numbers of animals per test. I use as an example there the change in the FIFRA guidelines 870 that now requires three rabbits instead of the original six as a part of the standard protocol.

There have been refinements to the in vivo test. Those include modified procedures, such as the low volume eye test, which was a modified procedure to try to more closely model the types of exposures and responses as they occur in human eyes as opposed to rabbit eyes, and also objective measurement of responses in rabbit eye tests.

And then also, replacement of the rabbit eye irritation tests with either ex vivo or in vitro alternative tests. And I'd like to tell you a little bit about those types of methodologies.

I inserted here -- what you'll see in your packet -- a couple of slides I brought from Roger Curran and Joe Harvell from Institute for In Vitro Sciences that I thought gave a really nice picture of the types of systems that are used as alternative methods.

If you think about the eye, the tissues of greatest concern from an accidental splash standpoint are the tissues that are right in the front of the eye, that are accessible to the test chemical or the product, and of particular concern is the cornea, which is right in the front, it's the transparent tissue that acts as a barrier and also acts to transmit light back through the lens and back on to the retina.

If a chemical is splashed onto the cornea and causes it to become damaged, such that it swells, it becomes opaque. So, then it's not possible for light to be transmitted through there and there's a decrease in visual acuity. So, a lot of the alternative tests have focused on trying to understand what might happen to the cornea if there is an exposure to a test chemical.

So, methods that involve -- if I could go to the next slide, please. Methods have involved either use of an intact eye, such as nucleated rabbit eyes or chicken eyes, these are eyes that are derived from slaughterhouse animals that are part of the human food chain. In addition, there are methodologies that use excised corneas, such as the bovine cornea method. Bovine cornea

opacity and permeability method, the BCOP, that's a widely used method. Or an emerging method is the human corneal model, and the goal there is to try to model just the isolated cornea to see if it's possible to measure changes in the isolated tissue that would be similar to what we would see either in rabbits or humans.

Now, on the surface of the cornea -- you see over on the right there is the epithelium. That's a protective barrier right on the surface that's exposed to -- potentially exposed to test chemicals if they were to test chemicals, if they were to be splashed into the eye. So, there's been a lot of work trying to develop three dimensional tissue constructs or monolayer culture systems that would model the changes as they might occur in the epithelium.

And if we look at these test systems, they try to model the sort of range of responses as they might occur to a whole range of test chemicals. So, for example, over here on the left, if we're looking at very corrosive materials, severely irritating materials, it's been found that methods that have intact eyes or intact corneas, such as the isolated rabbit eye test, the

isolated chicken eye test or the bovine cornea test, have the greatest degree of sensitivity for these severe materials. In fact, these tests have been accepted within the EU as screening tests for eye corrosives.

Now, on contrast, if you have very mild materials, such as some of our cosmetic products, they wouldn't be detected or distinguished by using these intact eyes or cornea tests. However, the tissue constructs or some of the cell culture systems are very sensitive to differences in these types of materials.

So, what we found in our workshop is that companies tend to use a combination of tests. So, depending on what types of products they're interested in, be they severe materials or mild materials, they would either use a tissue construct for the mild materials and then some sort of isolated eye test or excised cornea test for the more severe materials. So, usually these types of tests are used in combination. Next, please.

I'd like to go through some examples of a nucleated eye test, an isolated cornea test and then get into cell culture methodology. What we're looking at

here is an isolated rabbit eye. In this case, you can see an opacity that's formed on the surface of the cornea. What we're looking at here is actually a plastic Petri dish. Here's a Teflon dosing ring that's lying on top of an actual rabbit eye. Again, these were slaughterhouse derived tissues.

The tissue becomes opaque, but it's possible to examine the eye more closely by using microscopic techniques, such as confocal microscopy. What we're looking at here is the eye essentially looking down at us through the bottom of a confocal plate and you can see the opening of the iris here. There's the surrounding tissue. Next please.

Now, if we look at these tissues under confocal microscopy using fluorescent stains that indicate either live or dead cells, we can look at responses to various different types of test materials. And for example, on the left here is a 5 percent solution of sodium laurel (phonetic) sulfate. This is a surfactant that's commonly been used in liquid dishwashing detergents or shampoos.

And what we're looking at here is actual individual cells. You can see, for the most part, these

are green. This is actually looking at the surface of a rabbit cornea. This is the epithelial cells, and you can see that there's just a very slight damage. Most of the cells that are there are alive, but you'll see areas where it seems that cells might actually be missing, and that's what this very mild treatment does. It causes cells to actually slough off the surface of the epithelium. So, if you shampooed this morning and got a little bit of the shampoo solution in your eye, this is what your cornea looked like earlier this morning. By now, since we're after lunch, it's had time to renew itself, it's now, again, an intact epithelium. It's a very mild response.

But in contrast, if an eye were exposed to a severe material, such as a cationic (phonetic) surfactant, you can see here that the barrier has a lot of red cells in it. These are a lot of damaged cells. And not only that, but there's this almost like a crater that's formed where the epithelium is completely denuded off the surface of the cornea. This would be the sort of response that you'd see to a much more severe material such as (inaudible).

Even inside the damaged area here, you can see some small red areas. Those are actually the connective tissue cells within the stroma of the cornea, and it turns out that if you have very deep injuries to the cornea, it doesn't heal. There's too much of a crater, if you will, for the epithelium to renew itself over the surface of the lesion. So, this would be a non-healing injury that would result in a permanent opacity in the cornea, which is an irreversible or Category I type of a response.

Now, there's been a lot of work using this basic approach of confocal microscopy to understand the fundamental mechanisms by which eyes become irritated. It turns out that this damage, this cytotoxicity, is a primary step in the response, things like an increase in opacity or swelling or the cornea are secondary to this cellular damage. Next, please.

You can see here, too, in the black bars, we're looking at the depth of damage into the stroma of the cornea that's on the Y-axis versus a range of different test materials, going from mild on the left here to very severe materials. And one of the things I'd like you to

appreciate here is that if you have severe materials and you're using an intact eye test such as this, there's a lot of sensitivity to extinguishing the severe materials versus less severe materials. I want you to kind of remember that because later on we'll be looking at a different type of test that has much more sensitivity for distinguishing very mild materials. But this is an important basis for an ex vivo test, looking at depth of injury and cytotoxicity as the primary mechanism of response. Next slide, please.

This is a different type of approach, but very complimentary. It's looking at bovine corneas, and you can see here a response to a corrosive test material causes an opacity on the isolated cornea. This is the exact same lesion as is evaluated in rabbit eye tests. Next, please.

Now, instead of using animal derived tissues, an emerging area is the use of reconstructed human corneas, and this is growing out of the medical community where these types of corneas are being developed for transplantation to patients who have corneal injuries. And on the left here is shown a backlighted human cornea

that's an eye bank tissue, and it's backlighted so the square here appears black, and there's a letter E put behind it to try to mimic an eye chart type of approach. What you can appreciate here is actually the eye bank cornea is more opaque than what you see over here, which is the reconstructed cornea, which is much more transparent. If I could have the next slide.

This shows the two tissues in cross section. On the left here is the eye bank cornea. It has the outermost epithelium, which is the protective barrier on the front of the cornea, a large stromal element, and then a single layer of endothelial cells. So, there are three different cells types to the cornea.

Over here is the reconstructed cornea that contains immortalized epithelial cells that are co-cultured with stromal keratinocytes (phonetic) which are the connective tissue cells, and again, there's an inner layer of endothelial cells. This is a fully reconstructed cornea that's based on immortalized, but not transformed, cells that are grown together. Next, please.

In the upper left here, you can see an excised

human cornea, this is the control cornea and this is a cornea that was treated with a cationic surfactant solution. You can see that the area by the pointer here has become opaque. And similarly, in the reconstructive cornea, there's a control cornea, it's transparent; however, areas of opacity develop upon exposure to these severe types of materials.

Over on the right here it shows -- if you can appreciate the reddened area here, that the area of opacity contains damaged cells. The non-opaque area, the transparent area, has living cells.

In the bottom here, we're looking at changes in light transmission through the cornea as it becomes opaque, and the point of all these is -- over on the right here is human corneas from eye bank tissues that are relatively insensitive to these types of materials, ranging from mild materials to those that are more severe and drastically decrease the amount of light that's transmitted through the cornea and to opacity.

Over on the left here, you can see that rabbit corneas are much more sensitive to these types of materials, and the reconstructed corneas provide a sort

of happy medium that provide a safety factor relative to human corneas but are still not quite as sensitive or (inaudible) predictive as what's been seen with the rabbit corneas.

So, that's the newly emerging human corneal cultures. A surrogate that's been used for the past couple of years for actual ocular cells is skin-derived cells that are grown on filter membranes, such as on the right here, and this is very similar what Mike was showing for reconstructed skin cultures. This is actually sort of a reconstructed mucosal epithelium. It has several layers of epithelial cells, but without a stratam-corneum. This is a model system that, again, has an epithelium and a stroma, so it's two cells types in co-cultures. These systems have been used for topical application types of assessments, looking at cytotoxicity as an endpoint. Yes?

UNIDENTIFIED MALE: Those of us who are drifting off here, can you explain -- I mean, not drifting off asleep, but like not catching on.

**(Laughter.)**

UNIDENTIFIED MALE: What is a reconstructed --

UNIDENTIFIED MALE: We drift for a lot of things.

UNIDENTIFIED MALE: What -- can you define two terms for those of us who don't know what they mean.

DR. OSBORNE: Okay.

UNIDENTIFIED MALE: Reconstructed tissue and immortalized. I'm especially interested in immortalized.

DR. OSBORNE: Okay.

**(Laughter.)**

DR. OSBORNE: (Inaudible) immortalized part on behalf of our tissue culture expert over here. I'll start with reconstructed, and what that means is as you're trying to develop a tissue that you might want to transplant back into a person's body, what you do is you take the isolated cells, and in isolation, you put them back together.

So, for example, I'll just use the cornea as an example. It has three different cell types, and if you were wanting to cure that person's problem with their cornea, you need to put all three cell types back in there. But you have to put them back in the right confirmation so that they mimic the actual tissue, so

they mimic cornea. Now, it turns out the way the cornea is constructed is that it has like endothelium on one side, it has a stroma in the middle and then epithelium on the surface. So, in cell culture and isolation, you can put all those back together in that right confirmation and then take that construct and put it back in a person's eye. That's called a reconstruction or reconstruct or construct. That's that kind of terminology.

Now as far as immortalization, that has to do with how you treat the cells when you're growing them to make sure that you can maintain them in cultures so you have a big enough supply, so when you start to put these tissues back together, you have enough to actually do the work. And so, what -- if we could, right now, take part of your skin and put it in a nutrient culture medium, which is kind of a nutrient broth, grow it up on Petri dishes, and expand it out so we'd have many millions of cells, we could freeze those down and for years to come we could be using your cells with your skin construct.

UNIDENTIFIED MALE: (Inaudible) skin cancer, right.

UNIDENTIFIED FEMALE: (Inaudible).

**(Laughter.)**

DR. OSBORNE: But those would be primary cultures. If we take them right off the body and put them into cultures, those are primary cultures. We can treat those with protease and expand those out, and those would be like secondary or tertiary cultures.

But what if we wanted them to go on forever? We want to use them today, but we want to develop a test method that's useful in 10 years. We want to have a stable cell life. So, what we do -- what we could do is to treat those cells with a virus that causes them to immortalize. So, it's almost like a step in the cancer process, but it allows us to maintain those cells in culture for a longer period of time, still with a differentiated -- you know, they will still be like skin cells and still like corneal cells, but we'll be able to maintain them for a longer period of time.

Did that explain --

UNIDENTIFIED MALE: Yeah, that's great.

DR. OSBORNE: Okay. So, that's reconstruction and immortalization. If you have any questions like

that, please ask. I'm sorry (inaudible) jargon.

Here's a reconstructed mucosal epithelium, which taking actual human skin cells and growing them on the inserts, they're stratified. We put test materials on the surface and then look at cytotoxicity endpoints and relate those to eye irritation. If I could have the next slide, please.

This shows a comparative -- a comparison of in vitro responses on the X-axis here relative to historical rabbit data on the Y-axis. This is very typical for the relationship between a non-animal test and it's data set relative to the animal test. It's a sort of bi-phasic relationship as you can see here. This is what we would refer to as a validation data set, and this is from some of our in-house work. (Inaudible) roughly 100, 120 or so materials that have been tested in historical rabbit eye irritation tests and we took those very same materials and evaluated those in a non-animal method and then we're able to develop this sort of plot.

What this allows us to do is to take new test materials and put them into the context of our historical database. So, for example, if we have a new shampoo, we

would expect it to fall in the same range of other shampoos that have been tested previously, such as those that are shown here in the black spot. If we have strongly irritating materials, they would fall up in this range and have very low in vitro values. They'd be very potent. In contrast, things like cosmetic products or liquid hand soaps or that sort of thing are very mild and so they'd end up on the far right of the curve.

What I wanted to focus on in this next example is some of our anti-microbial hard surface cleaners that are shown here in the black triangles, and those would be on kind of the high of this innocuous to slight categorization.

This is a case study looking to predict the human eye safety of a new liquid household cleaning product, HSCL is that (inaudible) designated. The strategy was to use the in vitro tests that we just looked at, as well as three marketed hard surface cleaning products that we used as internal benchmarks for comparison. These historical benchmarks had low eye irritation in the historical rabbit (inaudible) eye test, as well as in consumer accidental exposures based on the

marketplace experience.

So, we're taking the new product and we're going to compare it to three marketed products in in vitro methodology. Next, please.

You can see here the responses to the three benchmarks based on the historical rabbit data. These are all really quite low. MAS on this scale is measure of eye irritation and (inaudible) 110 scale. So, you can see the responses here are really quite low. And also, the days to clear are really quite fast. So, these would be either a Category IV or a Category III, I guess based on the FIFRA classifications.

Also, in the in vitro method, you can see that the response is really quite high, indicating that these are mild materials, and our new hard surface cleaner would fall in the mid-range of these. So, based on the similarity of formulation of this new material relative to the marketed standards, as well as the historical data that we're using for bridging and the in vitro data, our assessment is that this new formulation has innocuous to slight irritancy and that's similar to the previously marketed products.

In fact, this product was marketed and the low irritancy was later confirmed by the marketplace experience, which showed that had very low irritation, that any exposures healed very rapidly in consumers. Next, please.

So, the lessons from what we've learned from use of alternative methods for eye assessments is that the alternatives can be used in the assessments as long as validation has occurred. So, we have this range of historical data that we can use for perspective. That any new test materials are similar to those that have been evaluated previously and for which we have validation data, that we use benchmark controls in our in vitro tests so that we can bridge new data to existing historical, be it rabbit or marketplace, experience data, and that we use this overall weight of evidence approach in taking into account historical data, SAR, all of the arguments that we've heard, in addition to any new in vitro data.

So, the state of the art is that within industry, in vitro tests are used to assess small, well defined classes of chemicals and formulations, such as

the anti-microbial hard surface cleaners. This approach has allowed consumer product companies to end finished product testing in vivo in rabbits.

The weight-of-evidence assessment process is the same across companies. That's what we found in our workshop, although specific in vitro methodologies used might be different between companies. Nonetheless, the way that we use those tests for benchmarking and for bridging is the same across companies.

And also, I just wanted to reiterate the point that some of these methods have been accepted within the EU for screening for corrosive chemicals. Next slide, please.

So, the recommendation coming out of all this work is that the weight-of-evidence assessment process, as we've described it, be accepted for the anti-microbial cleaning products, such as hard surface cleaners. Thank you.

DR. STITZEL: I just have two or three things I wanted to summarize on behalf of P&G. I know we're running late, so I'll be real brief. I don't know (inaudible).

We have five issues that we saw are core issues that we think are core issues that we think are important, specifically for anti-microbial regulations. One is that we think there should be more support for development of new test methods, and particularly both internationally and nationally to have direction setting. Because as you have seen, every company is going out and doing their own kind of test development. We really need to have better coordination.

We need to have a multiplicity of endpoints, tests for each endpoint, and we need to have the regulatory agency understand that there's a multiplicity of tests and be able to deal with that.

More importantly, we need to have the agency personnel aware of what's going outside and involve not doing a development, but understand what's going in development and have some consultation input into how these tests are developed and what kind of test methods and endpoints are used.

Our second issue has to do with validation. Validation still needs continuous improvement. I think that's partly -- the example of the corrosion test is a

good example because those tests were validated against a prediction model which did not fit the United States, which is why they're not being accepted in the United States as final tests, and that's just a learning that we need to change and not do that again.

Validation is extremely resource intensive the way it's set up right now and we need to work on trying to save that, and we need a process to allow the agencies to understand about these internal tests that companies are using. If they validate it internally, then they have a lot of faith in it. Somehow, the agencies have to be able to also judge this data and say, is this really a good test, does this company -- does this internal validation set -- is this the right data, did they do this right, and so they can also have some faith in these tests, because we're not going to be able to take all these many, many tests through ICCVAM or ECVAM. ICCVAM and ECVAM do not have enough resources to look at all these different kinds of tests.

Finally, there's also the issue of acceptance. We think the process is still too slow. We realize that the agency is working rapidly on it and just learning how

to do this because they've only had a few tests that have gone through ICCVAM, but we're hoping the process will speed up. We think that the use of the SAP is duplicative and increases our work. We're hoping that we can reduce that as much as possible. We're particularly concerned that the use of new methods should increase the time that it takes for approval of new processes. For industry, times means money. We need to get these products out on the market as soon as possible. And if it seems like it's going to slow down the process to use alternative tests, then industry is likely to say, well, we just won't use them because it's faster to use animal tests.

So, we really need the agency to not make it slower if you submit alternative data, and we also need them to not say, okay, we'll accept your alternative data, but we will increase -- we'll just knock it up one labeling classification. That, also, won't help us because we want to have the lowest labeling that we can. So, we need to have these tests accepted for what they are, as replacement tests.

And we definitely need a way to prework the use

of bridging data, alternative data and waivers, so we know before we turn in -- this is for anti-microbial registration, I'm talking about, particularly before we go and turn in our packet of materials that these things -- not that they're going to accept the data necessarily, but the test method would be acceptable. So, we'd like to have a way of coming in and preworking some of this so it would go as fast as possible once it's accepted.

Issue number four is the data requirements. We really think the agency needs to rethink the six-pack. Do we really need to do all these tests every time? Our two examples that I'm sure all of you are -- I would be surprised if some of you at least haven't used Tide with Bleach and Mr. Clean, and understandably, we went to put anti-microbial labels on those products, even though they had been on the market, we had to do the six-pack of tests. We were allowed to get by without doing the eye test, but otherwise, we had to go back and test for acute dermal toxicity for those tests, even though those products had been on the market and you and I had been using it all this time.

So, we really need to rethink this. We need to

be able to validate alternative methods. We need to be able to use historical data. We need to be use structure activity approaches and we need to be able to use exposure considerations.

And, finally, we realize that facilitating change is difficult. The primary thing is there must be a reason for people to change and we understand that that's difficult. We need training that is -- we realize that agency people need training on new methods. We need -- in order to have faith in these new methods, people really need to understand learnings in toxicology and that means continuing education. We understand that that's a problem for agency people, and however we can help to provide not just us, but the industry in general, provide continuing education, we really need that, and we need to understand better each other. We're constantly learning reasons why the agency needs different kinds of data than we think they do, and I'm sure you're constantly learning what we're doing. So, the more that we can talk to each other and learn each other's needs, the better we can develop new test methods.

My final is, toxicology is changing and we all

must change with it, and I think the genomics is -- it will be a few years before it ever gets (inaudible) but we're all going to have to learn to live with these new approaches and so we've got to learn how to change. Thank you very much.

MR. HOUSENGER: Very good.

**(Applause.)**

MR. HOUSENGER: All right. We have a little time for questions. We won't be taking on how to immortalize Larry's skin, though.

**(Laughter.)**

MR. HOUSENGER: If not, let's move on to our final presenter. Since graduating with Honors Health Sciences Degree, Troy Seidle has served as the director and consultant to numerous animal protection organizations in Canada and internationally. He is a former member of the Canadian Council on Animal Care, the national peer review body that sets monitors and establishes standards for the care and use of animals in Canadian laboratories. He currently serves as Science Policy Advisor to the People for the Ethical Treatment of Animals, and is active in the development of non-animal

chemical testing strategies in North America, Europe and OECD.

MR. SEIDLE: Thank you very much. Give that we've had some excellent technical presentations, I'm going to shift gears here and focus more on a policy-oriented talk and take a step backwards to where we've been and make some projections as to where we can go.

The process began back in 1959, as Marcia said, with the publication of the Principles of Human Experimental Technique, and the first major progress we saw was in 1969 in the UK with the formation of the Fund for the Replacement of Animals in Medical Experiments, or FRAME. Twenty years later, Germany followed suit with the formation of ZEBET, and the first major progress we saw in the United States from Federal agencies was in 1993 with the NIH Revitalization Act and specific language calling for the development of three Rs methods or alternatives.

1994 saw the formation of ECVAM, the sister organization to ICCVAM in the U.S., and the Netherlands Centre for Alternatives, and that's when we really started to see some concerted development of non-animal

test methods. And then in 1996, the OECD, Organization for Economic Cooperation and Development, organized a workshop --

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MR. SEIDLE: -- non-animal test methods. The following year, ICCVAM was created as a standing committee and in the year 2000, ICCVAM, under the ICCVAM Authorization Act, became a Congressionally mandated entity as has been discussed. In 2001, we saw the first Congressional appropriation of $4 million in support of the development of non-animal test methods by the EPA, and in 2002, some of the best activity we've seen so far, a second OECD validation conference was held in Stockholm, OECD National Coordinators endorsed three non-animal test guidelines for phototoxicity, skin corrosion and percutaneous absorption, and the OECD Task Force on Endocrine Disruptor Testing and Assessment established a dedicated Validation Management Group for non-animal test methods, which was quite a precedent. Next, please.

To date, we have seen some non-animal methods that have achieved validation. Most of these, as previous speakers have said, have come from Europe. We

have phototoxicity, four methods for skin corrosion, several options for vaccine testing. But what does this mean in the context of pesticide tests? Unfortunately, not a lot.

40 CFR 158 prescribes numerous animal tests protocols, very few of which are addressed by current validated non-animal test methods. So, we have an enormous challenge ahead of us if EPA is fully implement reductions, refinements, and ultimately replacements of animal use in its pesticide programs. Next, please.

So, today, as we've heard, we're dealing with the six-pack, and if you hit it three more times, for visual aides of exactly which tests we're talking about, skin irritation, eye irritation, and lethal poisoning. So, the effects, I think, should be pretty clear at this point. Next.

I'll just skim over these, as they've been dealt with in a great deal of detail. Acute systemic toxicity in the U.S. is still involving mortality or moribundity as an endpoint, and this is almost universally condemned, and it's something that really needs to -- we need to move beyond as a matter of urgency. In addition, the

reliability and the relevance to humans of acute systemic toxicity tests have not been established, and two factoids, to come from a multi-center evaluation of in vitro cytotoxicity study, published in 1999, demonstrate that rat and most LD50 are not necessarily self-predictive, much less predictive of human lethal doses. Next.

As replacement methods that have been (inaudible) two of the more promising ones are normal human keratinocytes and mouse fibroblast cell lines. The battery that was examined in the MAEK (phonetic) study of three of these assays found them to be highly predictive of human lethal blood concentrations. The R squared was 0.79. When a blood brain barrier biokinetic was added to the equation, the predictivity increased to 0.83. This isn't quite -- well, they're significantly better than the LD50 predictions, and given additional R&D, we are quite hopeful. In addition, the MAEK study recommended the addition of ADME parameters looking at absorption, distribution and metabolism, and these are also under development.

In October 2000, NIH asked that ICCVAM organize

an international workshop in acute toxicity testing and the use of alternative methods for this purpose. They concluded that it in vitro cytotoxicity assays are ready for us now as a starting dose prediction for acute toxicity studies. Researchers at ZEBET in Germany predicted that animal use could be reduced by up to 40 percent by using this methodology, and earlier this year, OPPTS issued a guidance to participants in the HPD program for the use of in vitro methods for starting dose calculation.

Participants in this workshop also concluded, as Dick had pointed out earlier, that if the political will was there, within two to three years, we could potentially have a validated replacement on our hands. However, two years have already passed and we're already -- we're just at the point where a joint U.S. and EU validation study is beginning. So, clearly, there are political, among other forces, that are perhaps going to extend these timelines.

Eye irritation, largely the same issues ethically speaking. Three bullets, I'll let you look at on the slides in your handouts, but the predictivity of

the Draize eye irritation test is nothing to write home about. The inter-laboratory variability back in 1971 was found to range from 42 percent to 117 percent. Now, bearing in mind that this was prior to the establishment of good laboratory practice, previous -- or subsequent research, rather, has found that these numbers haven't changed substantially. So, these are certainly, by no means, a gold standard by which to validate non-animal methods or even a reliable basis for human health risk assessment.

Many of the non-animal methods that have been invented to date have already been identified by Rosemarie. This is just another iteration, including below each of the major bullets the jurisdictions in Europe that have accepted these as screening methods for severe irritation. Next.

Skin irritation, same issues, we can skip over this.

Actually, let's just skip over all of these. We've already covered these. Let's move onto factors affecting progress, and there are five. Not to go into too much detail because Kathy's raised many of these.

But provision of adequate resources for test method development and validation -- actually if you want to skip -- there are a few regulatory bodies in North America that have committed resources to develop, validate and utilize non-animal test methods for risk assessment. As I mentioned, the $4 million appropriation Congressionally mandated for EPA for non-animal methods, has been (inaudible) to genomics which one could consider a good or a bad thing. It certainly isn't focused on endpoint-specific non-animal method development, which is a concern. Next.

International coordination of R&D efforts. We have substantial cultural differences that we've encountered. On one hand, Europe and Japan are definitely the leaders when it comes to in vitro method development, whereas North America is the stronger proponent of in silico, or QSAR, methods.

ECVAM, in May of this year, published a very comprehensive report on the status of alternative methods. However, until that time, there was no internationally recognized review document that covered all of the major endpoints in pesticide and other

chemical risk assessment and there really wasn't a roadmap from which to proceed. This has been a major deficiency. And although international coordination through ECVAM tends to focus on Europe only, efforts coordinated through the OECD have always focused on animal tests, and we really don't have a mechanism between government agencies, between industries and other stakeholders in North America, much less worldwide, to coordinate these efforts. As Kathy pointed out, there's a lot of money going into it, but it's very fragmented and it is stunted progress. Next.

Availability of trained personnel and experienced laboratories, another problem. We found that many laboratories like to tweak protocols rather than following a standardized methodology, and this is a major problem for validation. Next.

Availability of high quality human reference data. This has come up again and again in reference to validation studies, where animal data has been used as the default, but given that no animal test has been validated for its relevance to humans, much less its reproducibility between laboratories, one example being

the Draize test, the results have been across the board and it's been almost impossible, largely for this reason, to validate a replacement method for this test.

Likewise, at the OECD Stockholm conference earlier this year, it was recognized and recommended quite clearly that an expert meeting be organized to either create a human health effects database or some opportunity or some mechanism to gather reliable human data for validation purposes, recognizing in many cases animal tests have unknown validity or none. Next, please.

And finally, as Kathy pointed out, regulatory acceptance of scientifically valid non-animal methods and testing strategies. There are definitely political undertones to this process moreso than the validation process itself. Non-animal methods are quite consistently held to a higher standard of scientific excellence than animal tests. We believe OECD admits this in numerous of its discussion documents.

And even in some cases, non-animal methods that have undergone successful validation in one jurisdiction are not accepted in another, and the most recent examples

are the skin corrosivity assays which were validated by ECVAM in the late 1990s. The ECVAM Scientific Advisory Committee issued a statement of their validation in 2000. They were accepted by the EU in the same year, accepted by the OECD earlier this year, and still ICCVAM in the U.S. is requiring that negative results be followed up by an animal test as part of an in vivo weight-of-evidence (inaudible). So, we still have a ways to go politically. Next.

So, returning to the current challenges, we've got, already, a laundry list of animal tests that need to be revisited. Next.

In addition to these, we have a number of emerging challenges, among them a disruption in pesticide reevaluation for aggregate and cumulative effects, a trend towards perpetual new animal testing. New endpoints are being raised all the time. Reference was made to the EPA reference dose, reference concentration document, which outlines a number of proposed methodologies, none of them validated, some having the potential to reduce animal use, some proposing new endpoints, which could substantially increase it.

And unfortunately, the current trends we're seeing tend to be more focused on the increase in animal tests as opposed to the reduction or replacement, and this, in the grand scheme of things, undermines the 3Rs. Next.

So, some of the action items that we would like to see are the establishment of a subgroup of the PPDC to continue to monitor the progress of non-animal method development, formulate recommendations and report back to this body on a regular basis. Some of the issues for discussion have already been raised. I won't spend much time on them, but they deal with the percutaneous absorption test, in vitro that has been accepted by the OECD, the use of the (inaudible) embryonic stem cell test to screen for development toxicity, the use of in vitro genotoxicity tests as a stand-alone when combined with metabolism studies, and the potential to use genotoxic data as the screen for carcinogenicity in lieu of the rodent bioassay. Next.

And finally, back to the funding. There needs to be far more coordination and far more human and financial resources dedicated not only by EPA's ORD but

also by industry in a coordinated manner to start looking at some of the longer term endpoints. It's taken us 20 years to look at acute and local toxicities. It's going to take us a whole lot longer to look at these. So, there's no time like the present. Thank you.

**(Applause.)**

MR. HOUSENGER: Okay, thank you, Troy. Are there any questions for Troy?

UNIDENTIFIED FEMALE: Larry has one.

MR. HOUSENGER: Oh, I'm sorry.

MR. ELWORTH: This isn't my issue, so what are the political -- you mentioned that the political issues were in play on this. What are the political issues that are involved in either -- in preventing people or institutions from moving to non-animal testing?

MR. SEIDLE: Some of them in the regulatory community are just the fact that when you have animal tests that are prescribed under regulations. It's difficult, at the best of times, to get those changed. But the flexibility that Kathy alluded to that toxicology is always evolving and the methodologies have to evolve along with it, and this -- what we found to be an

inherent mistrust in non-animal test methods and also a belief that just in the terminology that's used that they are simple methods, that, you know, by implication they are less robust, less relevant, and even in the presence of a successful validation study, some of those attitudes persist. So, it really is that cultural belief that animal tests are inherently more relevant than the non-animal tests and that sees to be politically or philosophically based as opposed to scientific.

MR. HOUSENGER: Are there any general comments, questions that people want to raise?

UNIDENTIFIED MALE: I was wondering just if you would address something, Troy. It seems like all the discussion today has been in the sense of animals being used in order to protect humans, but you could also argue to protect animals, we actually need to do more animal testing because many of these species and other high order groups are not even being tested at all. And if you wanted to know what the effect of a compound is, pesticides are a good example, you would have to say there would have to be a lot more animal testing just those species groups and also different types of

endpoints, toxicological and others that are now totally neglected.

MR. SEIDLE: I'll respond to your question first. From an ethical point of view, we don't draw a line ethically between if you put an animal in a laboratory, the animal's interests somehow matter less than a wild animal. As far as we're concerned, from a pain and suffering point of view, it's complete equivalence, that killing one animal to protect another is not an ethical position to take whether we're looking at non-human or human animals as part of the equation. So, we're looking at specifically non-animal test methods across the board for that reason.

In terms of the ecotoxicity studies, to which I guess you're referring, it is a different animal in some cases from the human health risk assessment where you're looking at extrapolating to a population, and there are limitations there as well in terms of the validity. We went around and around in Stockholm on how you validate the data for one species to -- say one avian species to all others. Is that -- can you generalize -- can you make valid generalizations in so doing? And even though

there's a belief that within one taxonomic group there may be the same or similar ADME, that's not necessarily the case. And in the absence of proper validation, I think the scientific question is -- you know, it's a mute point and, you know, none of these methods have been validated to date.

MR. HOUSENGER: Jay.

MR. McALLISTER: I'm Jay for an afternoon. I'm Ray McAllister filling in for Jay. Earlier -- late this morning, Deborah McCall described to us the progress that has been made in validating methods by OPP, by OPPTS, using the ICCVAM procedure and I commend the agency for that progress that's been made there. If I understood right, you're describing primarily the validation of new methods, the new alternatives to animal testing, but from time to time the agency promulgates new guidelines for animal testing and makes revisions to the current guidelines for animal testing, whether it's on a permanent basis, from now on you're going to do this test differently, or perhaps on an ad hoc basis, for this circumstance, you need to do this test differently.

I wanted to ask, to what extent EPA does now or

plans to validate such changes in the animal testing, and would those changes in the animal tests go through the same involvement of ICCVAM or meeting the ICCVAM criteria before they are required of registrants?

MS. MULKEY: Well, I think the answer to that is essentially -- at least the primary answer to that is essentially case-by-case. Before we establish new guidelines for animal testing, there is always robust peer review engagement of some sort. The most frequent would probably be the scientific advisory panel. But many of these are not new, they are modifications. Now, I don't know if Margaret or somebody is here that would feel comfortable speaking at the level of detail that you raised the issue, but the short answer is that while the formal ICCVAM process is not typical for the additional animal testing or modified animal testing, peer review certainly is.

Can you think of anything beyond that?

MR. HOUSENGER: Julie?

MS. SPAGNOLI: I think, you know, looking at -- if we're focused on acute toxicity testing, which I think was the -- where this was really supposed to be looking

at and how the agency classifies products. They are categorized. And what you're really trying to do in this testing is determine a category and a lot of these categories are fairly broad. I think in the area of like acute oral toxicity, a Category III is anywhere from 500 to 5,000 milligrams per kilogram.

So, you know, the point of the acute six-pack is really just to categorize a product, and I think we've seen in a number of experiences that there's a lot of way that you can probably categorize these products based on available data. And I think we've heard -- I've heard over and over again about looking at weight-of-evidence, and some of the actions that the agency's already taking in the area of batching and bridging, and I think we can do more there. And a couple of personal experiences that I've been involved with, where we took batching even to a further standpoint of doing sub-batching where we'd say, okay, for certain types -- for like, acute oral, dermal inhalation, we can even combine some of these batches and do one set of tests for four or five batches and then only do fewer tests on the individual batches.

We also -- and Debbie's group was very much

involved with this and it resulted in the issuance of -- I think it was PR Notice 20012 where -- actually, where looking at criteria for formulations, what the active ingredient toxicity was, what level it was at in the formula, what the, you know, components were, that you could make a very clear determination of what category -- again, we're not looking for the exact LD50, but I think in most cases, a judgment could be made that, okay, if it's a fraction of a percent of a Category III active ingredient on fertilizer, we know what it's going to be. We don't need to look at the toxicity of fertilizer over and over again.

And I guess I would think that there's probably opportunities to look at other types of product categories and other types of formulations to see if we can't make those similar kind of judgments. I know what we did in the case of the granular fertilizer and granular pesticide products, we looked at all of the existing products and tried to make correlations between active ingredient toxicity and end-use product toxicity, and after you look at about 100 or so formulations, it starts to become fairly clear.

I'm just wondering if there might not be other opportunities for other types of formulations that are -- you know, outside of just the substantial are similar. Do we know enough about certain types of formulations that based on the formulation type and the active ingredient that we can probably make a pretty clear, you know, indication of what category, not an exact LD50, but what category it would fit into.

MR. HOUSENGER: Erik?

MR. NICHOLSON: I just had more of a general comment I'd like to share. Representing the farmworker community, I guess in terms of context, our membership and our constituency are regularly exposed to pesticides on almost a daily basis, and then often are the subjects of studies to look at what are the impacts of those pesticides on their physical well-being.

So, in that context, I'm very much concerned that while we strongly agree with the move towards getting away from animal testing, that this not be a back door to increase human testing. In fact, I would use the phrase I've often heard before that, humans are animals, too, and that we indeed keep humans within the scope of

the three Rs and not expose more humans to pesticides as part of the toxicological data.

MR. HOUSENGER: Bill?

BILL: Yeah, I have a couple of questions for Troy and then some for Procter. Troy, forgive me for these. I'm not trying to ply you on this, but I really do want to know this.

When -- what's PETA's position in terms of -- when we're looking at this idea of animal replacements? Like where would you focus more on? Is it on tests that are -- sort of like the eye irritation tests, which seem pretty cruel, or the idea of number reduction? Do you guys make a -- do you divvy it that way?

MR. SEIDLE: We do and we don't. How's that for a non-answer?

BILL: Well, I'm just thinking about if we're going after something for a reason, you know, and you had to make choices.

MR. SEIDLE: Well, as far as our priority targets, then, we do -- we're most concerned, I would say, about the heavy duty tests, if you're looking at repro, development, carcinogenistic, chronic, they are

long-term, involve large numbers.

The reason that we chose to focus on acute today is because the methods are more developed and, you know, they provide, we thought, very tangible case studies for which there's a ton of data to document the readiness of some methods and the near readiness of others to be used as total replacements. But as far as our priorities for R&D and agency attention and industry attention, we would focus on the longer term, larger number aspects.

BILL: And would you draw a distinction in a sort of -- I don't mean this necessarily either, but a hierarchy of animal-like, you know, a bacteria to a fish or a daphnia to a fish to a rat to a dog to a chimp kind of thing?

MR. SEIDLE: We generalize within the vertebrate kingdom, that if they've got a backbone, they're of very high concern. Certainly, if we look at -- some of the nastiest tests are conducted on the smallest animals. So, our concern is no less for a rat than it is for a dog.

BILL: Okay, thanks. I was really impressed with the whole day's presentation. There was a lot of

deep science in this and I want to commend everybody, particularly from Procter, for being willing to share all of their work, which is pretty incredible.

One of the things that concerns me, though, is the idea of broad applicability of the philosophies of how Procter does risk assessment to every registrant. Have you thought about -- I think Kathy you gave a pretty impassioned advocacy of a position and a new way of thinking. Have you thought about it for companies or ma and pa registrants who may not have the resources that Procter has at its disposal to doing alternatives?

DR. STITZEL: There's several parts of that, and it doesn't have to do with anti-microbial testing, but let me just tell you that for cosmetic testing and cosmetic companies, that has been an issue and there has been an attempt by all the bigger companies, particularly in Europe, to try and provide training for the smaller companies and to get this information out.

What I was trying to say for -- that I think is important for EPA for right now is to understand and be able to evaluate data that's come in to them so they can somehow judge what information has been generated by one

of these companies that does have a good database.

I mean, as Rosemarie said, there's a whole group of companies that have been doing this sort of thing for a long time and most of them have a lot of data, and the trick is to be able to understand and look at that data and say, yes, this is the data we mean, here's what a validation study should look like, here's some positives, here's some negatives, and here's importantly some in between, because if you just have positives and negatives, you can make a nice straight line, and that sort of data and we just need to, as an industry probably, help train people -- IVS is good resource for that -- into how to look at this data and say, this is good data or not. Providing training for smaller companies is something we probably need to do on an industry-wide basis.

BILL: Thanks.

DR. STITZEL: And we have been doing -- I mean, this stuff has all been presented many times, but I understand about the mom and pop stuff is harder.

UNIDENTIFIED MALE: Right. And I think the publications are also a part of that. Mike's publication

that he presented on the skin is very comprehensive on how to do this and Rosemarie and all of her friends are putting together a similar paper on eye.

UNIDENTIFIED MALE: Yeah, I think we try to -- one that does is it levels the playing field in terms of -- a lot of the resources at P&G and at Unilever and a number of these other companies can put against these programs is because we do have those resources and we can develop the methods. But once the methods are developed, we don't view toxicology as proprietary information. So we really have promoted our own effort to get this stuff out. And then people can pick and choose. Like I said, there are many methods in the reviews that other companies, small companies can look at and say, this is the way I would like to approach it.

UNIDENTIFIED MALE: Thanks. I think my last comment on this is that probably there may be a way to do this if we just look at the problem differently, and I think Julie was trying to get at that a little bit, too. I mean, when you boil down the why are we doing the six-pack and what does it translate to, and it translates into labeling decisions and presumably those labeling

decisions are for people who read the label and understand that they're being warned. You know, there's a lot of assumptions about what a label is and the CLI tried to get into that a little bit.

But I think if we examined the why are we doing this and what its value is and what decisions get made on a practical basis, which is, I think, a labeling decision, you know, we may not have to do a six-pack. We may not have to study to study replace all six. I mean, there could be some new evaluation scheme that gets at good warning and is sort of formulaically based but doesn't have to do all this testing.

MR. HOUSENGER: Win?

DR. HOCK: This is kind of directed to everyone really. I need some enlightenment about MSDSs. The question I have -- or at least the statement -- I'll make the statement first. To the best of my knowledge, every chemical that's used in the United States or marketed in the United States, in one way or another, I understand there has to be an MSDS prepared. And I'll give you an example. White-Out, I understand there's an MSDS for White-Out. In fact, I've given it to my secretary so she

can hold me responsible.

But at any rate, on an MSDS, you generally see things like toxicity information, corrosiveness, skin and eye irritation and other information like that, and I guess the question I have simply is that in developing an MSDS, are animals used in every case to develop the database? Does the six-pack come into play in every one of these products? I don't know, that's why I'm asking. And then I guess the other thing is what Federal agencies requires MSDSs? I'm guess it's not entirely or maybe it's not EPA. But what Federal agencies require MSDSs to be prepared --

UNIDENTIFIED MALE: OSHA.

DR. HOCK: I thought it was OSHA or NIOSH (phonetic) or one of those, right. But it's that kind of thing. What is the role or where do we come in with all this toxicological testing in an MSDS? How does that all blend together? Don't all answer at once.

UNIDENTIFIED MALE: It's an OSHA form and OSHA's put out -- there are regulations on how to fill out an MSDS and what you're supposed to consider and what data is required to be on there. Recently -- or not so

recently, but there's a pretty full requirement now that if you don't have tox on the formula, if you have tox on the components, then that's got to be on there. So, some MSDSs, there's no tox on the formula that you're looking at, but there's tox on all the ingredients there. So, you'll get a whole mixture of approaches to that.

Some people, there are software programs that will write an MSDS, other ones are handcrafted. So, there's a wide variety on how they're authored and the approaches taken by folks. But if you want how that's done or what's supposed to be included, that's in the OSHA regs.

UNIDENTIFIED FEMALE: And just your first question, I think, about -- MSDSs are generally required for, I think, almost all commercial products. In fact, I wrote the MSDS for SOS Soap Pads, which, I guess, now is one of Bill's products.

UNIDENTIFIED MALE: And my first MSDS I wrote was for a tape dispenser for 3M.

**(Laughter.)**

UNIDENTIFIED FEMALE: And as -- if you didn't -- what you have to identify in an MSDS are any hazardous

components by OSHA's hazard classification and any hazardous components in that formulation have to be identified.

DR. HOCK: Okay. Is the identification, though, done through animal testing? I guess that's the question.

UNIDENTIFIED MALE: Sometimes.

UNIDENTIFIED FEMALE: Probably of the individual components, yeah.

DR. HOCK: Of the individual components, yeah, yeah. Thank you.

MR. HOUSENGER: Beth?

UNIDENTIFIED FEMALE: I don't think that's necessarily true. I mean, I think there are companies who (inaudible) that will develop an MSDS based on what they are and if they are a technology. So, they don't do any testing at all. They say that the safety is based on historical data and if they don't know (inaudible) classification. But (inaudible).

MR. HOUSENGER: Okay, Beth?

DR. CARROLL: I was prompted by Ray's question, and there may not be an answer for this yet, but as I

look back over the morning's presentation, ICCVAM agencies are quite diverse from Consumer Product Safety to Department of Ag to Department of Interior, Department of Transportation, EPA, Food and Drug and OSHA. Has anybody thought a lot about whose data quality guidelines ICCVAM is going to use? Because it seems to me when I read through those, they're all different.

UNIDENTIFIED FEMALE: Can I answer that?

DR. CARROLL: Um-hum.

UNIDENTIFIED FEMALE: The data quality guidelines that ICCVAM is using were set up -- are based on some data quality guidelines that were developed by what was called IREG, which was Interagency Group of Regulatory Agencies back in the late '80s, right? And they're pretty strict.

Data is supposed to have been done under GLPs. Because we're using a lot of historical data, some of it will get by, you know, in the spirit of GLPs. But you have to be able to find the data and look at the data. When we sent the Local Lymph Node Assay in, they went back and they asked us to give us the original data for these tests just randomly and we had to go find the lab

notebooks and copy the data. So, they're pretty strict on quality, and that's really was set up by a group of -- the predecessor to ICCVAM, which was IREG.

DR. CARROLL: And are those available like on the web, the guidelines?

UNIDENTIFIED FEMALE: They're on the NIEHS website, the ICCVAM website.

DR. CARROLL: Okay, great, thank you.

UNIDENTIFIED FEMALE: They were adopted by OECD as well, so they're pretty well universal guidelines.

MR. HOUSENGER: Ray again?

MR. McALLISTER: If those data quality guidelines you're talking about date from the 1980s, how do they compare to the now developing data quality guidelines under the OMB regulations?

UNIDENTIFIED FEMALE: I have no idea. I don't know anything about OMB regulations. Are you talking about (inaudible)?

MR. McALLISTER: Well, that's data quality across the board.

MS. MULKEY: I don't think any of us know the instrument.

MR. McALLISTER: Okay.

MR. HOUSENGER: I guess considering all the presentations that everyone's heard, we have heard some general comments regarding guidance at the agency, how we could do a better job. Does the panel have any further guidance, recommendations based on what you heard today?

(No response.)

MS. MULKEY: Are we ready for a -- oh, excuse me.

UNIDENTIFIED MALE: I'd just say that, you know, there's been some discussion here of a more systematic approach by the agency, by OPP in particular, with the assistance and input from stakeholder groups to look at how alternative methods can be used and developed. I would support that. I think we need that approach, whether it is this group in particular that forms a subgroup, I'm not sure that's the best one because our toxicology experts on the panel today are invited. They're not permanent members of the group. So, I don't know that we have expertise to address those questions. But perhaps there's another forum within the agency to address that.

MS. MULKEY: (Inaudible) in the corner.

MR. HOUSENGER: Okay.

UNIDENTIFIED MALE: Yeah, I'd like to echo that. It's interesting. Marcia, you said earlier that it's a case-by-case basis, and I think really in a lot of these cases from our stakeholders, from a registrant perspective, it is case-by-case. I think it exemplifies how important preregistration meetings are. Because in point of fact, during preregistration meetings, you can talk about what toxicology data you'd like to generate, what you'd like to use from the literature, what you'd like to use as an alternate kind of thing. I mean, we've done things as simple as reduce fly testing by doing HPLC analysis. Well, that's reducing an animal test, I guess, in some small way.

So, it is a case-by-case basis really, and I still think the preregistration meetings become key because of that.

MR. HOUSENGER: Anyone else?

(No response.)

MS. MULKEY: All right. Well, it works quite well for us to take a 15-minute break at this point. To

induce your return, let me remind you that in addition to the follow-up issues that you were planning, that you will hear about this year's registration activity and that is a topic which ought to be keenly interesting to everybody. We also have public comment and I think we all want to be sure that this advisory committee complies with the meaningful public input portion of our charter.

So, while I'm sure everybody will enjoy this break and be back right at 4:00, I'm equally sure everybody will be back, and as I tell some of you, the cocktail hour at this hotel on Tuesday nights features the -- anyone who chooses to bring his or her pet dog. And I gather it's quite charming and a pleasant atmosphere to hang out with some very much beloved animals, citizens of Alexandria. So, I think we can all make it till then. We can have that little uniqueness. See you at 4:00.

**(A brief recess was taken.)**

MS. MULKEY: -- to our timetable.

**(Brief pause.)**

MS. MULKEY: It's not entirely consistent who can be counted on to be back at the end of the moment.

But we very much appreciate those who are consistently back in the moment. This was, I know, a long hard afternoon's work, not hard in the unpleasant sense, but in the -- I don't know what time they arrive, about 5:30, I think.

**(Brief pause.)**

MS. MULKEY: I'm ready for cocktail hour, I'll give you that, with or without dogs.

**(Brief pause.)**

MS. MULKEY: We really appreciate all the work and effort that has brought you this far today. We are mindful that we have not called upon the full committee to be as actively advisory as we have in some other sessions. But it's certainly a key subpart of the committee, which invested heavily in our ability to have the kind of input that we have gone through on this topic.

Several of you said to me in sidebars on the brief break that you're very mindful that in order to offer any kind of perspective on a topic like we just have heard about, you have to invest a fair amount in the learning curve, if you will, if you're not already

engaged in a topic like that. And we're mindful that not everybody is prepared to do that on every topic. But we're really grateful for those of you who understand the context in which we operate to take the opportunity to give this level of investment in order to share with us a topic like this, which definitely is relevant to us and can have, at least, a marginal impact on the more particularized interests that some of you have with regard to our work.

As you can tell, I'm trying to fill time with something other than merely sitting or whining. What we have left to do is actually quite a lot and I want to be sure that we maximize people's return because I think there's going to be an interest in all the pieces of it. Let me have you take out your agendas and let me sort of frame the remainder of the day.

We had planned follow-up from two other of major topics from May, the Section 18 revisions, reforms on which you got a report in May, and we have an update, and you will remember the examples of the non-isolated misuse that we were experiencing in last year's season and we were going to give you sort of an update around that --

those particular problems and that kind of problem.

At the request of an active one of the members who is interested in being present for that discussion and in light of our need to triage time, we're actually going to move that to the updates in a minute tomorrow, but you will remember that we retained from this morning's updates in a minute the registration activity. That is important in and of itself and it also gives you some information that I think you will find relevant in tomorrow's discussion of the way we spend our money and allocate our resources in OPP, not directly, but not that indirectly either. So, that should be of value.

And I also wanted to take -- we have public commenters, we have at least two -- more than that, Margie?

MS. FEHRENBACH: (Inaudible).

MS. MULKEY: And finally, I wanted -- because so many special guests were here for our presentations, but who don't seem to have made it back, probably because they are -- maybe they rushed to the cocktail hour after their ordeal but --

**(Laughter.)**

MS. MULKEY: Okay.

UNIDENTIFIED MALE: Dogs to test.

MS. MULKEY: If I learn that they're likely to be around -- but I wanted to give a little feedback about next steps around this issue today because I thought there might be attendees today who would not be here tomorrow. Normally, tomorrow would be the more obvious time to do that. So, we'll do a little bit of that.

All right, then I suggest that we go to this follow-up issues by turning to Debbie Edwards' presentation on behalf of all of our registering division, the Registration Division, the Anti-Microbials Division and the Biopesticides and Pollution Prevention Division, and get a report on this year. For us, that means October 1 to September 30 activities.

MS. EDWARDS: Thanks, Marcia. As Marcia pointed out, this is a -- normally you would report the Registration Division the registration program outputs for the entire office for the fiscal year, which ends on September the 30th. It is today September 17th and we're all working very hard to continue to meet the goals and hope to get a lot done in the next two weeks.

But anyway, I will -- you should each have in your package a piece of paper that starts with registration division outputs, it actually says. You might want to follow along there because I don't think I should be spending your time and my time reading through each and every chemical that we've registered this year, but rather, I'll kind of try to make a summary of what we've achieved.

And also, as Marcia pointed out, I'll be covering the outputs for conventional chemicals, biochemicals, microbial pesticides and plant-incorporated protectants and anti-microbials.

So, on the first page there, you'll see that, just for context, in FY 2001, the new active ingredient registration total that we registered this last year was 12. The goal for the current year, 2002, was again 12. To date, we have registered six new active ingredient chemicals in the registration --

**(END OF SIDE A, TAPE 4)**

MS. EDWARDS: And two additional ones to total -- the two additional ones are signed but not yet registered. That means it's a sure thing and it will

happen by September 30th.

Of these eight chemicals that are essentially registered, four of them are reduced risk chemicals. They achieved a reduced risk status, one of them as well is an OP alternative chemical. In addition to that, we have established some import tolerances, two of which actually are for new chemicals, one being Iprovalicarb on grapes, and the other Tolyfluanid, which is a new active ingredient for several commodities listed there.

Finally, I would say that we are still working on five active ingredients, working through issues, trying to get these looked at, and I'm hopeful that we will get four of them registered by the end of the fiscal year, which would allow us to achieve our goal of 12.

If you move to new uses, which should be on the next page, for convention chemicals, last year in FY 2001, 204 new uses were registered. The goal for fiscal year 2002 was 230 new uses, and as of September 13th, we had registered 124 new uses, of which 62 are reduced risk, 30 were OP alternatives and 59 were IR-4 or minor uses. You can see there's some overlap there. Often, IR-4, in particular uses, are reduced risk uses.

We also have signed, which again that means it's a done deal for the year, 61 additional new uses. That takes us pretty close to our goal, and we're working on and we're pretty certain we're going to get an additional 45 new uses by the end of the fiscal year, which will allow us to achieve our goal of 230.

In addition to new chemicals and new uses, we have cleared nine new food use inerts, as well as five food use polymers through the polymer exemption, and as well, 69 new non-food use inerts this year. We're not anticipating doing any more in the next two weeks, but we did achieve those this year. And you'll see, also, a table that shows our progress over the years in Section 18s. I think the numbers are looking pretty similar throughout the years, but as you can see there, the average response time is continuing to go down. This year, the average response time for Section 18s is 33 days.

And then you'll see there in the footnotes that many of these exemptions and several of the crises exemptions this year were related to the anthrax incidents that occurred in buildings here in D.C. and

other areas.

Moving on now to the Biopesticides and Pollution Prevention Division, last year, they had two new active -- I'm sorry, seven new active ingredient registrations and this year the goal was to register nine additional ones. To date, they have registered four biochemicals listed there, three microbial pesticides, and one plant-incorporated protectant, which takes you to a total of eight, and they are anticipating completing three more which will exceed their goal by two. So, they'll have a total of 11 probably for the year.

As far as new uses go, last year they registered in the Biopesticide Pollution Prevention Division a total of 90 new uses. This year, they are registering a total of 80, 61 microbials and 19 biochemicals.

And finally, the Anti-Microbial Division outputs, FY 2001, the Anti-Microbial Division measured one new active ingredient, new chemical. The goal for FY 2002 was two new active ingredients, and this year they've actually exceeded their goal by one. They've registered three new active ingredients.

Also, in the new use area, last year a total of

nine new uses were registered in the Anti-Microbial Division. The goal for this year was 13, and again, that goal has been exceeded. They registered 17 new uses in the Anti-Microbial Division. And as always, Frank Standers and his management, with Jack Housenger on his team now, continues to meet all FQPA timelines for all anti-microbial registration actions. So, that's a summary of outputs for this year.

Any questions?

UNIDENTIFIED MALE: Marcia, what drives the number of the goal, 230? Why not 240 or 220?

MS. MULKEY: Those goals are part of the budget process and they're worked out as part of the -- originally the President's budget that's submitted to the Congress and then I guess they're revised. When the agency gets its budget and establishes its operating plan, it's tracked under the Government Performance and Results Act. It's reported on to Congress, in the agency's public documents. I think there's a colloquy with OMB around those goals.

UNIDENTIFIED MALE: We also try to -- when resources are stable, to always have a goal that's equal

or better than the previous year's goal because we have an expectation that we're enhancing our efficiency and productivity as a general expectation. And so, that goal -- that number has actually crept up rather dramatically over the last six years because we've been enhancing our efficiencies around how we do new uses.

UNIDENTIFIED MALE: Debbie, how does this relate to any backlog within those divisions as a percent? Do you have any idea?

MS. EDWARDS: I can't really speak, I don't think, right now for the -- maybe Janet can from BPPD, she's here. But for the Registration Division, I would say that an equal number of new chemicals, maybe 18 to 20, are in the cue, next year's -- candidates for next year, but the goal will probably be 12 again. We always have to have more candidates, you know, than we issue. And then I would say another between 16 and 20 are in backlog over and above that candidate list.

MS. MULKEY: Janet, do you (inaudible)?

MS. ANDERSEN: We have 32 pending active ingredients right now in the Biopesticides and Pollution Prevention Division. We know that some of those will not

actually make it next year. Our goal is 12. And there's a couple of them that are sort of (inaudible) that we might exceed that depending on how the data goes when we actually see it. So, 32 new active ingredients are pending.

STEVE: Who's next?

MS. EDWARDS: Steve?

STEVE: Debbie, I couldn't help but wonder about sucrose as a wood preservative. It seems like it might attract ants or something, huh?

But Carolyn actually had a good solution, if you used chlordane as an inert, it would probably work for --

**(Laughter.)**

UNIDENTIFIED FEMALE: (Inaudible) animal testing (inaudible).

STEVE: No, no. Yeah, but the Clordane is fine. And I was also wondering about the -- when you consider 12 new AIs in the Registration Division, when two of them are import tolerances, I wouldn't announce that necessarily to the American farming public. That almost flies in our face as promoting your efforts when, in fact, it's what they use overseas and we don't get to use

it here.

MS. EDWARDS: Actually, the goal of 12 does not include the imports.

STEVE: Okay.

MS. EDWARDS: So, you'll notice here I'm listing eight -- in total, I'm listing 11 as done, if you include the -- I guess 10 as done if you include the imports. But our goal is actually to register 12 new chemicals, and that means register, not establish tolerances.

STEVE: You still have a couple more you're trying to get through.

MS. EDWARDS: Those are over and above that goal.

STEVE: Okay.

MS. MULKEY: Debbie, do you want to talk a little bit about how it happens that we work on those import tolerances and sort of a little bit about what the dynamic is?

MS. EDWARDS: Sure. Well, I mean, for the most part, the reason that we're working on import tolerance registrations, it would be two different reasons. One, they may need the active ingredient there and they don't

-- in another country and it's not needed here, in which case the company just has no interest in pursuing the registration here. And so, to prevent any trade barriers from developing, we would go ahead and review those applications.

I know a recent case actually where a company came to us with a -- wanting us to participate in a NAFTA project where the -- there would be an import tolerance for the United States, but the product would be actually registered in Mexico, and it's just simply not needed here and the company is claiming that. And I think that the growers are in agreement. We had a meeting where many of the growers came along to substantiate.

So, that's one of the main reasons why we do end up working in import tolerances.

MS. MULKEY: Would these typically be registrant priorities? Is that how they got to --

MS. EDWARDS: Right. I'm sorry, that's true as well.

STEVE: So, they've established that as a priority?

MS. MULKEY: Right.

MS. EDWARDS: Right.

STEVE: Still, it's not something to brag to American growers about.

MS. MULKEY: But we're transparent.

MS. EDWARDS: Yes.

STEVE: Good for you.

**(Laughter.)**

MS. EDWARDS: Julie?

MS. SPAGNOLI: Yeah, two questions. One, is the agency still on track for issuing their 2003 work plan in the October time frame? I think that was kind of the goal.

MS. EDWARDS: I would say that it's likely to be around the first week in November.

MS. SPAGNOLI: Okay.

MS. EDWARDS: More likely. It's been delayed slightly.

MS. SPAGNOLI: And then the second question is, you know, you indicated that the review times for the Section 18s have continued to (inaudible). How are the review times for both conventional and reduced risk AIs and new uses, are they -- what's the trend there? Are

they staying stable? Are they increasing, decreasing? Is there any trend or is it -- that you can see?

MS. EDWARDS: I would say that they're staying stable. I mean, particularly for reduced risk, we're trying to meet the shortened time frame. As far as I know, they're staying stable. Actually, I don't have it at my fingertips now, but a lot of -- I don't know if Anne Lindsay has them with her, but we've just put together a whole lot of statistics about that, which I actually intend to present at the CLA Registration Committee meeting in about a month.

But, Anne, do you have any of that information with you?

MS. LINDSAY: (Inaudible).

MS. EDWARDS: Great. No, okay. This is for new conventional chemicals, so I'm strictly talking about Registration Division actions right now. For reduced risk or OP alternatives, we're averaging 23 and a half months. For work shares, reduced risk, OP alternatives, 20 months. For reduced risk, OP alternatives that are not joint reviews or work shares, 22 months. And for new chemicals which are not reduced risk or OP alternatives,

39 months.

MS. MULKEY: Is that actual review times?

MS. EDWARDS: Now, that is over -- no. It's actual review time -- probably it's close to average review time possibly for many of the ones that are joint reviews and things like that. But the 39 months date, it represents probably at least as year of Q time. They don't get as high a priority typically.

MS. SPAGNOLI: Thanks.

MS. MULKEY: Any other -- (inaudible)?

UNIDENTIFIED MALE: Debbie, I wanted to ask a question dealing with the expedited review portion. You've given a very good, detailed summary of the new active ingredients and new registrations. I wondered where we were on the expedited review, the ME-2 (phonetic) labels, the ME-2 products and the label changes, and as to where we are, perhaps, in meeting the 90-day deadline, which the agency has been meeting, I guess, over the last couple of years. I wondered if you could simply update some of those numbers.

MS. EDWARDS: I don't actually have the specific numbers with me. It's my understanding that we're -- at

the end of this fiscal year, we will have a zero backlog on fast-tracks. So, that is good news, I hope.

UNIDENTIFIED MALE: Where's --

MS. EDWARDS: On the non-fast-tracks, it probably doesn't look as good.

UNIDENTIFIED MALE: Are we still under the 90 days? I would assume that we are, but --

MS. EDWARDS: Yeah.

UNIDENTIFIED MALE: Okay. In the past, you've done anywhere from 1,000 to 1,500 ME-2s and between 3,500 and 4,000 simple label changes. Are those ballpark numbers or are they up or down?

MS. EDWARDS: The last time I looked at the numbers, they were continuing to kind of trend along, not really going up, but not going down.

UNIDENTIFIED MALE: Okay.

MS. EDWARDS: Anyone else?

MS. MULKEY: Anything else on this?

(No response.)

MS. MULKEY: Thank you, Debbie. And now Dan Rosenblatt is going to provide us a continuation of our earlier discussion about some issues around Section 18.

If you'll remember, we talked through some areas for reform and revision at the last PPDC meeting, and this is an update on that.

MR. ROSENBLATT: Hi. This is just a brief recap and sort of progress report on where we are on a project that the PPDC heard about in May. This will sort of summarize what we're calling the Section 18 Process Revision Project, and we're moving at least forward with an upcoming Federal Registry notice, which the policy shop is busy drafting and is here in the back, taking a short break from drafting that. I'll put a schedule around what's ahead and for the Section 18 season in 2003, how we will be integrating, at least in part, the new ideas that we developed for you in May.

Okay. This slide, sort of in a qualitative fashion, summarizes what this project is about. We are putting these proposals forward in sort of a good government spirit. Can we get to a decision point on a Section 18 faster and with less paperwork while still maintaining the standards of FQPA and the standards of the regulations for health and safety protection.

For folks who are involved in the Section 18

process, I'm sure you're familiar with sort of the very high degree of time pressure connected to each and every application. So, I think we're very proud of the numbers and our average turn-around time, but at the same time, we know that with each application, there really is a high degree of time sensitivity. So, we're looking to integrate efficiencies where we can.

As I said, the way we're moving this forward is bringing -- sorry about that -- a Federal Register notice and we've got three areas where the notice will be specifically covering. One will be in terms of a streamline application for repeat Section 18s and specifically dealing with second and third year requests. We're proposing a manner for the applicant, in most all cases, a state lead agency, to provide a certification about the continuing nature of the emergency in the new -- sort of the battery of data that would be required under the regs, Part 166.

Concerning this first bullet, the streamline application process, I want to make clear that although the applicant will be providing less data, the information that EPA is in control of will continue to

re-reviewed and reassessed each year. So, specifically concerning risk alternatives and progress towards registration, those areas will be reevaluated each year in the second and third year cycle where we're offering sort of this abbreviated opportunity to submit an abbreviated Section 18 package.

Further on this point, the exemptions that are eligible for this streamline treatment are selected by EPA. The criteria are going to be laid out in the Federal Register notice that we'll be publishing soon. But in a nutshell, we are going to be asking ourselves, and the State needs to ask themselves, whether this sort of emergency that we're facing is one that is likely to be ongoing. A classic example would be sort of the identification of a new pest and as a problem for a certain group and we would sort of anticipate that retrenching and gaining sort of pest management tools, or something along those lines, would be an ongoing emergency.

Concerning the second point, the tiering pilot for the assessment of significant economic loss, the established sort of precedent here is for EPA to look at

historical data, usually five years' worth of information and to evaluate whether the request and the pest problems in this year fall outside the baseline that has been generated by the five-year track record.

In the spirit, sort of, again of getting to the decision point quicker, we were looking at putting forward a tiered process whereby it's very likely that many exemptions would not need to travel through sort of this historical net revenue approach, but rather, we could do an assessment, as a first try, yield information, next try would be revenues and then finally would be profit. So, as an application would work its way through the process, more and more data would be needed until you get to tier three, which approximates the existing procedures. Our economists have done an evaluation of past 18s under the old paradigm, and in an analytical sense, rolled out the tiered processes, and the important bottom line finding was that there were not likely to be any difference in the likelihood of EPA finding in support of an emergency using the historic and established net revenue method versus the tier method, and the up-side, of course, is that we could get there

with a lot less paperwork and a lot less analytical time.

In terms of the economic analysis and the tiered approach, that's a feature that the states, themselves, are going to opt into when they see that it may be to their advantage. There will be plenty more on that in the Federal Register notice, and I think we'll be available to sort of clarify that if there remain questions.

This third area, a proposal for potential resistance management exemptions, it's a policy notion that we are wrestling with, and in the notice that's coming out shortly, we are at least tentatively stepping into the arena of more aggressively facilitating resistance strategies, and at the moment, the Section 18 program takes sort of a passive posture in connection to resistance management in that you can sort of backdoor your way into an emergency if the registered pesticide lacks efficacy to the degree that you are facing a significant economic loss, whereas the proposal that we'll be putting forward sort of moves the bar to a different spot and puts the emergency exemption process sort of in as a tool for resistance management.

There's an implementation section in the Federal Register notice and that's going to describe what we're open for business for in the 2003 Section 18 season. We do want to take a narrow -- begin a narrow pilot project for Section 18s in the 2003 season, and at this time, we're limiting the universe to reduce risk pesticides. The first process, the emergency exemptions eligible for the streamline application process, that's -- we will, as part of the Federal Register itself, have some companion documents that are in the docket, and we'll I.D. the 18s that we saw this year, in 2002, that we think are candidates for this steamlined application process.

The second point, if you're a state lead and you're in the audience, it's one. If you want to opt in and try for the -- making a significant (inaudible) finding based on the new tiered process, that's for you to raise your hand and send your application forward in that fashion.

Regarding resistance, again, it's presented here as a parenthetical. Resistance management is not in the pilot for 2003. For this upcoming season, the status quo policies for resistance management connected to Section

18s will be in place. There's some pretty substantive policy ideas that we'll be putting forward on resistance management, and for that reason, we thought we need to take comments on the program that we've got in the FRN.

Federal Registry notice is well drafted and in the final stages. We're expecting the Assistant Administrator to sign it shortly in the upcoming weeks, and it will likely publish in October of 2002. It's going to have a 60-day comment period on it, so please, if you're interested in this topic, give us your feedback. We will also launch this limited pilot for the '03 Section 18 season and give us some sense of whether we are on track with the ideas for the streamlined application for repeats and a tiered process for the significance of (inaudible). That's it.

MS. MULKEY: Thank you. Any feedback, reactions?

UNIDENTIFIED MALE: I have a question.

MS. MULKEY: Okay.

UNIDENTIFIED MALE: Will that FR notice be in the form of a proposed regulation?

MS. MULKEY: It's not set up as a rule. It's

set up as a -- I don't know that the styling is a PR notice, but an approach. One of the issues that we may ask for comment on with regard to, especially the resistance management piece, is whether people believe that it requires a rule or would be better done by rule. I think the other two, I think, we feel pretty comfortable are just guidance-like, if you will.

Julie?

MS. SPAGNOLI: Just a couple of questions for clarification. I guess the pilot program, the streamline application, that would be for repeat Section 18s, so this is just for repeat Section 18s. As far as the reduced risk, I'm not -- does the agency make a reduced risk for a Section 18 so that it would be a repeat -- so it would have to be a chemical for which there's an existing Section 3 registration, that was considered reduced risk? Because sometimes they actually will make a -- that a use will be considered reduced risk even though the chemical might not have previously. So, this would be for chemicals that were considered reduced risk for some Section 3 registration, and then this would be for a repeat Section 18?

MR. ROSENBLATT: Right, that's right. It is intentionally (inaudible) --

MS. SPAGNOLI: I just want to make sure I understand the criteria.

MR. ROSENBLATT: -- criteria to get us some traction and some degree of record with the 2003 season.

MS. SPAGNOLI: Okay. I just wanted to make sure I understood that right. Okay, thanks.

MS. MULKEY: Erik?

ERIK: Yeah, unfortunately, I missed the last PPDC meeting at which this was originally presented. But, frankly, we're deeply troubled by this proposal for several reasons. One, it seems like it's a solution without a problem. In my 12 years of monitoring pesticides in the State of Oregon, which is a major Section 18 requester, I'm not aware of any crop loss whatsoever due to the current Section 18 program.

And, also, we just heard the report from the folks in the Section 18 -- turnaround time has been reduced this fiscal year. So, the first part of my question is, I'm not sure what the problem is we're trying to fix.

Second, if a review of the current Section 18 program -- it's ripe with abuse. We've tracked a 14-years consecutive Section 18 approval in the State of Oregon with no evidence ever submitted showing movement towards a full Section 3 registration and we're in the tens of pesticides right now over the five-year bar without similar documentation.

So, we're concerned about the streamlining process simply expediting a Section 18 process when the current program is, in our opinion, not adequately policed.

And then, finally, I think the Environmental Working Group did a good job in their report several years ago of really asking the question, what is an emergency. So, again, if we're streamlining this, in our perspective, this is going to make a bad situation only worse.

So, my question, specifically, what is the problem we're trying to fix in terms of concrete crop loss data as a result of a Section 18 program not meeting current needs?

MR. ROSENBLATT: Those are some strong points

and I think we -- it is sort of a double-edged sword in the sense that we have -- we are very proud of the turnaround time, and it is low. I think at the same time, we do acknowledge and I think we foresee that some of these streamlinings will be non-trivial for the State lead agencies and they'll facilitate a diversion, to a small degree, of EPA resources. I think the other thing that is motivating the agency here is we're responding explicitly to some (inaudible) recommendations about the Section 18 process.

MS. MULKEY: But, of course, your comments are wholly appropriate for the comment period, among other places. That's why we propose these kinds of things, to be sure that all these points of view do get heard.

Well, thank you -- yes, Steve?

STEVE: One quick question. Relative to the shortening of the time period that you get or that you -- the turnaround time, I guess it is, have you had a chance to analyze the number of repeat Section 18s relative to previous times? In other words, one would assume that if it's the same Section 18 application as last year, you don't require the same amount of work to review it, which

would shorten your overall time. Where the problem occurs, particularly, from an emergency standpoint, is the first year. After that, presumably, the commodity knows their problem and can generate sufficient and proper data in an effort to get it to you in a timely manner. So, it's that first year.

So, (inaudible) just take the first year data and say what's your turnaround time on that and have you been able to decrease that and does this streamlining help that.

MR. ROSENBLATT: Right. That is an astute way of looking at it. There's often -- with first time Section 18s, since FQPA, we need to do the tolerance to cover that. There is, you know, an awkward weeks potentially or hopefully there's a convergence of use in the field with no tolerance established just yet.

STEVE: Trust me, I know that all too well. We were the first.

MR. ROSENBLATT: In terms of volume, the number of 18s that we've gotten over the past years has been about 550, plus or minus, and in general, 70 percent or so are repeat uses.

MS. MULKEY: We've done some analysis of this issue you've described and I think we are achieving significantly shorter time between registration and tolerance setting, and I suspect we're seeing fewer first-time -- well, maybe not, maybe not. Lori?

DR. BERGER: There were seven other reforms that were proposed, I believe, and several of those actually were -- seemed to make the process more prohibitive in how you could request a Section 18 or how you could use it, and I'm just curious to know what happened to those.

MR. ROSENBLATT: The short answer is that we've been in ongoing dialogue with APCO (phonetic). This project, the reforms, actually came up as an idea and something that people were working on prior to FQPA. In March of 2002, APCO actually shortened their list of priority policy areas, and these are the three that are there.

DR. BERGER: There were several members amongst this committee that actually expressed interest in some of those other reforms at the last meeting. So, will that be maybe looked at again or --

MS. MULKEY: Anne, do you want to --

MS. LINDSAY: Just real briefly. I think that when the Federal Register notice comes out, there will be a brief sort of report about all seven of the original recommendations so you can see what happened. One that comes to mind, there was a request, could state lead agencies do an effective regional 18, and I think that that's an approach the Registration Division has been able to incorporate into its existing process. So, it, in effect, got done several years ago.

I've certainly been to State lead agency meetings where states have talked about working together to develop the basis for a Section 18 request. But all of them, there will be some, at least, brief discussion on sort of what happened to them.

MS. MULKEY: Thank you. Well, we --

UNIDENTIFIED FEMALE: There's one more here, Marcia.

MS. MULKEY: Oh, I'm sorry.

DR. HOCK: Just a real quick one.

MS. MULKEY: Win.

DR. HOCK: What happened to the multi-year possibility of a Section 18? I think that was one of the

ones that was discussed. Wasn't there one that we had a multi-year -- am I wrong about that?

MS. MULKEY: That's what this first one is. Repeat is --

DR. HOCK: Repeat is -- that will be --

MS. MULKEY: Multi-year is, I guess, in the eye of the beholder. But this first one is -- that's the evolution of the multi-year idea was that the applying agency could certify the continuation of the -- as you heard it described.

DR. HOCK: Okay, I think I understand. In other words, what's happening is you'll still approve it every year. You wouldn't give, for instance, a -- I'm just going to use an example. You wouldn't give a Section 18 for 2003 through 2005 carte blanche?

MS. MULKEY: Right. That's not what this (inaudible). And I think there are issues relating to the regulations, among other things on that issue.

DR. HOCK: Okay, thank you.

MS. MULKEY: Well, we do have two public commenters. I did want to take a moment before we call on them to do two things. One is to thank you all and

invite you to provide any feedback that you think would make a difference between today and tomorrow about how the meeting has gone, is going, and our approach to the meeting. But in particular to think about an opportunity to provide that feedback tomorrow, as you spend the evening.

In light of the fact that we do appear to have most of the folks who participated in the panel -- the big panel today have already left, except for those who are PPDC members, and I assume will be present again tomorrow, we will take an opportunity again tomorrow to talk a little bit about our feedback to that group and some next steps so that you don't feel like we're letting that fall through the cracks.

We are, to some I think pretty modest extent, the victim of our collective ambition about the scope of what we would cover, bearing in mind that much of what's included here came from you. And we have deferred, I think it's two topics, from today until tomorrow. So, it will require us to exercise continued self-discipline tomorrow.

Let me just take an opportunity, before we hear

the public comment, to see if any of you want to react to issues relating to trying to enhance the quality of the remainder of this meeting. I don't mean today, I mean today and tomorrow.

Yes, Win?

DR. HOCK: Is there any chance you could give about a 30-second update tomorrow on the DRIFT PR notice and what the status of the DRIFT -- I think it was probably a Federal Register notice, actually a Federal Register notice, where it stands and when it might be reissued?

MS. MULKEY: I think we could probably say something on That tomorrow.

UNIDENTIFIED FEMALE: Um-hum.

DR. HOCK: I mean, just a quick overview.

UNIDENTIFIED FEMALE: Uh-huh.

MS. MULKEY: All right. We have two commenters who, at least I can guess from the organization of one of them, have appeared particularly because of interest in the topics that we have tackled today. We look forward to hearing from both of them. Roger Curran from the Institute for In Vitro Sciences.

MR. CURRAN: Thank you. I'd like to compliment the OPP in beginning to look at a subject that's very dear to my heart and close to my heart that we've worked at in our organization for quite a while, and I'd also like to compliment the audience for making a number of cogent comments about in vitro and the alternative testing that is going on.

I'll try and make the presentation short once it brings it up here.

**(Brief pause.)**

MS. MULKEY: Yeah, why don't we do that? Why don't we ask Fred Smith --

MR. CURRAN: (Inaudible) start.

MS. MULKEY: It's really part of a joint presentation, in effect. Technology, it's wonderful and occasionally frustrating.

MR. CURRAN: Okay. I represent the Institute for In Vitro Sciences. We were founded in 1997 although it didn't make it on the (inaudible) chart. We're a not-for-profit 501C(3) organization dedicated to the advancement of in vitro methods for safety evaluation and determination of biological activity.

We have two sections to what we do in our company, one is an actual hands-no conduct of in vitro tests for companies throughout the United States, Europe, Japan, throughout the world. That means a lot of what we talk about and what we do is a science-based activity. Essentially, we test in our laboratories well over 1,000 chemicals, products per year in in vitro tests. So, we have a reasonable knowledge of how these tests work, how they can be applied, how you would use them in day-to-day working. That's the hands-on technical side.

We also have -- conduct an educational program and an interaction program with organizations throughout the world, including regulatory agencies here in the United States, NIEHS, EPA, FDA and so forth. And I'm on slide two right now.

The last (inaudible). We provide general information and actual hands-on instruction to people, to groups who want to learn about in vitro methods, and this includes industry, government, academia, animal welfare. We've had hands-on presentations -- we've had one major one every year and actual EPA representatives have taken advantage of our programs, come to our laboratories to

see how some of the in vitro methods work, and how the data can be applied to some of their questions.

We also work closely with the animal welfare groups, and what we try and do is promote situations where we can have dialogue between animal welfare groups, industry and government, and that's occurred several times within our facilities where sometimes these disparate groups have been able to sit down in a neutral territory and be able to discuss issues that are very substantive and very important to them. Next slide.

We commonly work with about 100 clients, more or less, per year, and the reason I put that up is to say that I'm speaking not just for myself, but for a lot of companies within the United States. When I do that, I'm saying that industry routinely is using in vitro tests. This isn't something that's a bit obscure that Procter and Gamble and Syngenta were talking about today. It's a process that hundreds of companies use around the world. These companies range -- and to address a question that came up earlier, these companies range from a P&G, a L'Oreal, multi-billion dollar companies, to single person cosmetic companies who are churning something up in their

backyard or smaller companies of 10 and 20 people.

So, we're able to utilize non-proprietary information that we gain from some of the larger companies to help out the smaller companies in the process. They use these methods for a lot of things. It's not just screening methods for early safety, but it's all the way from early product development to final safety decisions.

Why do they do it? Why do they use these methods? As Kathy said earlier, time and money savings is one thing. The tests are often much more sensitive. They're able to determine biological activity at much lower levels than some of the animal tests. Ethical considerations and mechanistic information. So, it's not entirely let's replace animals. That is a very important component of it. It's also, let's get better scientific information. Luckily, the tests are able to do both.

How can we use these tests? Well, also spoken of by Procter and Gamble, private internal evaluations of products, constructino and uses of databases, benchmarking, there are a number of ways. You don't use any -- you shouldn't use any toxicological test by itself

and you don't use in vitro tests by itself. It's a combination of information. Next slide, please.

One of the things we do is to develop tests not just to replace animals again, but to facilitate getting information. One example is an ocular irritation. We use, very often, a test that Rosemarie talked about for a minute, called the bovine cornea test where we use discarded cow corneas. But we found out that although this test didn't work perfectly in some of the earlier validations of it, there were some reasons why, and so we've, along with others, modified the protocol so that it can give more mechanistic information.

One of the things is to be able to actually look at histopathology, something that animal toxicologists always like. Next slide, please.

And in this situation, I'm just quickly showing that you can now do cross sections and look at a mild material. You can see that cells are damaged by a slightly more aggressive material and that a highly aggressive material completely tears up the epithelial level of this cornea. So, not only do you have some biochemical measures, but you can also see some of the

damage. And this gives us a little more comfortable feeling with how to apply some of these tests. Next slide, please.

And one of the reasons I put this up is because a very important thing is ingredient interaction, one of the important questions that I think a lot of manufacturers ask themselves, and that's applications certainly to pesticides. I used the -- we used the same example here of the bovine cornea in cross section and what I'm showing is a series of studies conducted by John Harvell in our label and S.C. Johnson as one of our clients, and there's nothing proprietary here. This is already published information.

But they were able to show, to investigate two ingredients of a formulation, a base material and then sodium hydrochloride -- yes, we do know a lot about sodium hydrochloride. We see some just superficial damage of epithelium. We look at the base plus a sodium hydroxide concentration and, again, see just a superficial denudation of the upper layer of the cornea. But the combination of the ingredients is much more than either one can be seen together.

Here you combine this into the final formulation and you see some very deep tissue injury, you see the epithelium completely separated from the stroma down here, and you begin to see dead cells.

**(END OF SIDE B, TAPE 4)**

MR. CURRAN: -- important to both regulators and companies, mechanistic information and interactions can be seen with in vitro tests. Next slide.

But from our point of view, do we think there are things that could be done to help facilitate the speeding up of acceptance of in vitro methods? Within the regulatory community, it would be nice to see more proactive situations so that regulators and management can build familiarity on the scientific basis of the assays and the performance of the products and ingredients that are of special interest, those things, how the assays work with chemicals and formulation of your interest.

The validation process can be accelerated by adding a key that we're often missing, and that's good, reliable reference data. And if agencies, FDA, EPA can provide historical animal data in situations where we're

going to have to use animal data, this will enable us to have a little better idea of setting the target, and that includes both knowing how the animal test works with individual materials, but what the reproducibility of the animal test is, which has been one of the criticisms, certainly, in some of the acute areas.

If the agencies could express a positive attitude towards the use of alternative methods, by perhaps providing a means to capture and review parallel data submissions, this is part of a learning process where in vitro information comes in in parallel with animal information (inaudible). And at the same time, to begin the dialogue with test developers regarding what specific toxicological needs of the agency exist.

Sort of a combination of these two, it would be nice if there was some type of preregistration, presubmission situation or a company who had suggested the types of in vitro testing that they might want to use, and then determine if it's even feasible that this could be reviewed by the agencies. I have one more slide.

That's what I think some of the agencies can do.

What can we do? Our organization -- and we have a good background in in vitro testing, we can help -- we agree to commit resources to interact directly with the U.S. EPA in any way (inaudible) with U.S. EPA and its clients or directly with ICCVAM as we do right now, so that technical details of these in vitro assays can be communicated and understood in the context of the EPA's regulatory needs.

MS. MULKEY: Thank you very much. Fred Smith from Cyrad (phonetic), Inc. Is Fred Smith still here?

(No response.)

MS. MULKEY: Well, how about that? Thanks to Fred's bailing out, we are right on time.

**(Laughter.)**

MS. MULKEY: Well, thank you all. I know it's been a long day. It's been a very dense -- in the good sense of that term -- rich, information dense.

UNIDENTIFIED MALE: Robust.

MS. MULKEY: Yeah, robust -- I've always loved that adjective, that sort of personalizes it -- day. So, I think tomorrow will be, too. So, we appreciate the work that went into it and we look forward to tomorrow.

Bye.

**(The meeting was adjourned.)**

**Day Two - September 18, 2002**

For The Record, Inc.
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MS. MULKEY: Greetings. It's nice to see so many of you so close to your seats. It's another beautiful day in the neighborhood. I'm personally very fond of this part of the D.C. Metro area, so I hope those of you who have had a chance to hang out in Alexandria have been enjoying it.

Well, as I said, thank you all for returning. Thank you, Adam and Burleson, for being with us again today. I think we all collectively appreciate that very much. I don't want to distract any more from our ambitious agenda. I promise you that you will find a lot of today interesting.

I want to ask all of you to bear with us, to be with us in the early afternoon. This is the phase where we begin to look forward to issues that we want to tackle together, and while I understand the temptation to allow lunch to be the natural breaking point, it's really important to us to get your feedback and reaction as we talk through the next steps. So, a special plea to see you after lunch.

Okay, Jim is again going to march us through another raft of updates in a minute, including -- I

think it's two issues left from yesterday -- three -- three issues left from -- two from last and one added at request.

MR. JONES: Well, we will finish with the last three and start with the first one on the printed agenda, which is the NAFTA TWG five-year plan.

Okay, one of the documents that you should have received, I think ahead of time, was the draft NAFTA Technical Working Group five-year plan, and I just want to walk people through a few of the highlights.

Probably the most important take-home message is it's a draft document at this point. It's been developed by all three countries, Mexico, Canada, U.S. We actually have Janice Hopkins from Canada with us for the whole meeting, so it represents a collective perspective by the governments of the three countries. It was built both on the previous five-year plan, which is drawing to a close this year, as well as significant input from the last full NAFTA Technical Working Group meeting, which was held in Mexico about a year ago or nine months ago now.

It's a very high-level document. It does not go into all of the detail of everything that is either

ongoing right now or might start in the next five years. It's that way by design. It's meant to be a kind of high-level guidance, but to allow flexibility over time for either the governments themselves or for our many stakeholders to come forward and propose some redirections, new activities, time to finish off, wrap something up. So, it's built with a fair amount of flexibility in it.

It maintains the two basic goals of the original plan, which is to make work sharing the routine way of business between the governments of the three countries, and I guess work sharing is a term we may have coined in the NAFTA context, but it means just literally what it sounds like, which is to share the work of regulation in all the many ways that it may be appropriate to do so.

The second is to develop and maintain and broaden a North American market for pesticides that also maintains and, where possible, improves the high levels of protection of public health and the environment and in a way that supports the principles of sustainable development. So, I think we're trying to have our cake and eat it, too, with the goals, but those are the same

basic goals that we have had for the first five years. They seem appropriate for the next five.

One of the things I'd mention, though, is we spent -- the Government spent some time doing a little visionary brainstorming, and so it actually articulates a vision which I don't think we did in our previous plan, and the vision is that the North American region could come to serve as a model for excellence for the whole world in the realm of safe food, safe pesticides, training and protection of the pesticide labor force, and that to the extent that we're able to do it, we really want to integrate all of our activities, both governmental and non-governmental, into a life cycle approach to pesticide management that would actually help us achieve this high standard of excellence.

So, we've deliberately set ourselves a vision that we think is very high, but we also feel like at the governmental level that it's attainable and that it's the sort of vision that all of us are likely to be able to subscribe to, though in any individual case and with regard to any individual activity, we may have a difference of perspective as to its relative priority and

importance in achieving that standard. So, I want you to keep that vision in mind.

It tries to hit in all the sort of areas that we've heard so far that were important to people. We're talking about broadening Mexican participation within the NAFTA Technical Working Group for the first five years. To a very large extent, a lot of the actual work was done between the U.S. and Canada, with Mexico in what I would call more of an observer capacity, and so in this next five years, we're trying to develop what I would call a full trilateral partnership.

We're actually in the process of embarking on a trilateral review of a new active ingredient with Mexico. It's been sort of specially designed and crafted so that it will take advantage of Mexican strengths, not over-tax them in areas where they don't have the same capacity that the U.S. and Canada does. A registrant was actually very critical in helping select a viable candidate for this trilateral review. So, we actually have very high hopes for that.

We'll be working on minor use issues in the North American venue. It's already been started, IR-4

showing a lot of leadership in that arena. Canada has some new developments that I think will enhance their capabilities pretty significantly, so I think minor use will be a clear focus of the NAFTA TWG.

As always, there's the harmonization of MRLs, and here we're counting on growers and others to actually help us identify where real trade irritants and problems are occurring because of differences in MRLs, and we're also going to be doing our own analysis of the situation. So, that is underway, and I think later on, from a government perspective, we'll be able to present a better picture of progress in that arena.

The last thing I might mention is the NAFTA label. We've talked about that for a number of years in various different venues. The good news I have to report is there actually is one approved NAFTA label. It's approved only for use in Canada. That was the registrant's choice, so that for the U.S. they have stuck with a U.S. ePA only label, but in Canada, they've got a NAFTA label. So, U.S. growers can go up to Canada, purchase the product there if they so choose and bring it back into the U.S., and they'll be fully in compliance

with U.S. requirements. The label doesn't need to change.

We also have another proposed NAFTA label pending with one of the new active ingredients that is part of Registration Division's workload for the coming year, 2003. So, I'm hopeful by the time the Registration Division makes a decision on this new active ingredient, it will actually become the second and in this case I hope fully utilized NAFTA label between the U.S. and Canada.

In addition, Mexico, who originally felt a little hesitant about the concept of a NAFTA label, has decided that the time is right for them to begin to entertain that idea. We've been going through an analysis with Mexico of differences between the labels. We don't think that they're so substantial that it would prevent actually having a NAFTA label with Mexico.

And I think the other piece of good news is we have a new industry group, the Non-agricultural -- Warren, help me -- Working Group, thank you, NAWG is its acronym, and they're at least exploring the concept of using NAFTA labels for different kinds of

non-agricultural products and I think may, during the course of the year, have some interesting proposals to present to the NAFTA TWG.

So, I'm going to stop talking about the specifics of the plan, but what I'd like to encourage all of you to do is to take a look at it in a little more depth, think about what you want this Technical Working Group to be focusing on. Have we hit the right mix of things? Are there some things that are really missing, some things that from your perspective maybe need to get a heightened priority or a lessened priority, because we're not going to be able to do everything that everybody wants. Give us comments. We're asking comments to come to us by the 15th of October.

If you're a U.S. citizen, you can send them to U.S. ePA, to Verace Altero and Tyler Wayne (phonetic) who are our NAFTA secretariat. If you're Canadian, send them to PMRA, and if you're Mexican, send them to Sequa Plafest (phonetic), to Salude (phonetic). We need them by around the 15th of October so that the document can be revised, translated in our three respective official languages and to be ready for the next full NAFTA

Technical Working Group meeting, which will be the 5th of December in New Orleans.

The U.S. is the host this year. We have chosen New Orleans not only because it's a fun place to be, but because we actually thought it did a good job of representing our North American cultural heritage in a way that no other U.S. city probably did quite so well. So, that's it for NAFTA.

SPEAKER: And I may have missed the nuances here. Are you saying that the NAFTA label would actually be accepted by the Sequa Plafest now in Mexico?

MR. JONES: What the Mexican Government has said is that they are willing to entertain the idea of a NAFTA label. I think that there's a lot of specifics that need to be worked through for any individual case, but they now want to pursue that.

SPEAKER: So, that one particular label you're talking about, they would not recognize it right now, then.

MR. JONES: No, that one label that's been approved was done between the U.S. and Canada, so it doesn't reflect work that -- and I, in fact, do not even

know if that particular product is approved for use in Mexico or would have a use in Mexico.

SPEAKER: Okay. Well, I think this is great stuff. I'm very encouraged by the whole concept, and congratulations. A couple questions.

One, has anyone entertained the idea of bringing in the independent republic of California into this harmonization process? Too bad Toby Jones isn't here to help represent -- and actually, that really is a problem. I know you've been working a lot on harmonization with California, but I truly hope that California is involved at least peripherally in these discussions so that they understand the issue.

What's the time frame? I realize there are probably multiple time frames depending on the issue. Is it going to be within anyone's lifetime here at the table that some of these things can be accomplished, because this is a huge undertaking it seems to me.

MR. JONES: Well, from my perspective, there are a lot of things that have already been accomplished, and when this five-year initiative is finalized, we will attach to it a list of the specific things that the three

countries believe we've accomplished. There are a lot of actual joint reviews that have been done between the U.S. and Canada. They're complete. They're done with -- Debbie Edwards yesterday actually sort of made reference to a time frame.

There are MRLs that were identified as causing real trade problems, and they have been harmonized. We have not had a lot actually identified as causing active trade problems, but where we have had those identified, we feel like we've largely been able to move forward and adjust things so that it works.

SPEAKER: Right. Well, I would suggest that the MRLs are clearly the most important in this whole process, trying to ease trade restrictions. This is by far the most important. Labels are great, to have similar labels, but you're still going to -- that's less important to trade and simple movement across borders, so --

MR. JONES: I think the joint review and the work sharing that's gone on, particularly between the U.S. and Canada, has done a lot to what I would call sort of equalize access for growers to products so that you're

having -- getting access to the same product at basically the same time.

SPEAKER: Right.

MR. JONES: And so whether or not it's got a NAFTA label, the product becomes available, and we've chosen to focus on reduced risk products, alternatives to OPs, methyl bromide in that program, so not only are you giving equal access, but it's got kind of a safer component to it.

SPEAKER: Yeah, that's great, great.

SPEAKER: Steve, there's quite an active stakeholder involvement in those processes, including grower involvement, so you may want to --

STEVE: And we ought to.

SPEAKER: Yeah.

SPEAKER: Just another meeting to go to.

Erik?

MR. OLSON: Thanks for your presentation. I would caution the agency not to look past issues of enforcement. Our Mexican counterparts have filed a complaint under NAFTA alleging failure of the state and Federal Government, specifically in Washington, not

enforcing health and safety regulations, and that complaint has been upheld after its initial hearing. So, I think the issue of enforcement is critical here in the United States and also in our -- in the counterpart countries of NAFTA.

SPEAKER: Okay, good.

SPEAKER: A couple questions. One is, will the NAFTA labels be trilingual, will they be bilingual? How will you handle the language issue? I know Canadian labels currently are both in -- I believe in English and French, and I'm just wondering how that's going to be handled. If you get all three languages on there, it's going to be a rather voluminous document.

The other issue or the other question I have is how are you going to handle -- and I'll call it rogue states or rogue provinces -- and Steve, I'm not talking about California now, don't -- but just an example, I read recently that Quebec is going to ban all non-agricultural pesticides by the year 2005. That means all, if you want to call it, cosmetic materials. How do you integrate that kind of situation into a "NAFTA label," which is supposed to be kind of broad and

covering, you know, all three countries.

MS. LINDSAY: I don't know if you're suggesting we have a special program for California, Quebec and, I don't know, for Mexico, which state it would be, and Janice, I don't know if you have any perspectives you want to share on the particular situation.

When -- I think each -- three countries always has to pay attention to what its individual states or provinces are doing, and that will remain sort of a national responsibility and prerogative.

If we've got insights to sort of offer each other as to how to handle those issues, we do that, and we will continue to do that. I actually think that to the extent that people see that their federal governments are working together and that they're working together with this sort of sustainable development reduced risk focus, it actually can help deal with the more particular issues that might surface in a state or a province, because they have greater confidence in what their federal governments are doing.

You also asked the language question about the labels, and yeah, we have a requirement that English is

the language, although we can also have Spanish labels already in the U.S. So, for a NAFTA label, you will be looking at either bilingual or trilingual, depending on the market range of the product. I think we think it obviously adds a layer of complexity, but it's not something that's insoluble.

SPEAKER: Folks, we are 15 minutes into our allotted 45 minutes on this one topic with three more cards up. If there's this much interest in the issue, you all may want to think about this in your feedback to us this afternoon, but we'll roll through these last cards and move on.

Larry?

MR. ELWORTH: I'll just raise the issues, because one of them actually could take a fair amount of time.

Number one, can you tell us a little bit more about this chemical for joint review, what it is, what it's used -- what crops it's used on?

MS. LINDSAY: The trilateral one?

MR. ELWORTH: Yeah, yeah.

MS. LINDSAY: Actually, literally, I can't. My

brain cells have aged, Larry, to the point that I can't remember its name.

MR. ELWORTH: Okay. Do you remember the -- well --

SPEAKER: We can get that to you.

MR. ELWORTH: Yeah, that --

MS. LINDSAY: It's possible to tell you more about it.

MR. ELWORTH: Right, right.

Second, and this may be to Jim's point, that it -- are you dealing with inerts in this trilateral issue as well?

MS. LINDSAY: There -- yes, and there is discussion about just exactly what form and shape that would be. There's been a lot of I think informal work that actually Kerry Leifer has done with PMRA over the years. They have got an inerts or formulants policy very similar to ours, so...

MR. ELWORTH: Okay. I think maybe Jim's right, this is something we probably want to look at a little bit more.

The last thing is I hope that's a canola

registration that you've got that NAFTA label for.

MS. LINDSAY: I don't think that it was, actually, unfortunately.

SPEAKER: Okay, the draft five-year plan was appended or supposed to be appended to Margie's e-mail Friday, and I'm just looking at my printout, and I realize I don't have it here. I don't know whether my printer ran out of paper or maybe all of us didn't get that, but I would just make sure that we all do have a copy of it.

MS. LINDSAY: It's also on our website, on the NAFTA homepage, so...

SPEAKER: Jose?

DR. AMADOR: Are you familiar with the work the Texas Department of Agriculture is doing with Mexico on pesticides and Mr. Rojas?

MS. LINDSAY: Um-hum, yeah, we actually work with TDA on some of the activities, especially activities relating to enforcement and inspector training, also safety training for applicators and farm workers. So, a number of U.S. states, and Texas is probably the premier one, are very active participants.

DR. AMADOR: Good, I'm glad that you know, because they are doing a lot of work, particularly in the pesticide safety area.

MS. LINDSAY: Yes.

DR. AMADOR: They have done a lot of work there.

SPEAKER: Okay, next -- Denise, you have the next two.

SPEAKER: In a minute.

MS. KEEHNER: I'll try to stay with my script so that we get done in a minute.

I'm sure that most of you are familiar with the fact that the Montreal Protocol provides for the phase-out of methyl bromide by 2005. My guess is that you're also familiar with the provision of the Protocol that allows for the granting of exceptions through a critical use exemption process to that phase-out requirement of 2005.

What I'd like to do is quickly update people here today on where we are in terms of designing and implementing the critical use exemption program for methyl bromide, because the Office of Pesticide Programs is working very closely with the Office of Air and also

with USDA to design a critical use exemption program for those uses that are believed to be critical needs in terms of continuing to have methyl bromide available beyond 2005.

We have been working within the Biological and Economic Analysis Division with the Department of Agriculture and the Office of Air to set up this process, and USDA has been very forthcoming in identifying technical experts in the field to work with us in the technical review of the incoming applications. You have in front of you a summary table that lists out all 54 applications that we have received as of 9/11 or so, I think actually it might be up to the 13th of September.

Our first order of business in looking at these applications that have come in is to see if there are any data gaps that need to be filled. Our objective early in the process is to see what we can do jointly working with USDA to fill in any gaps that might exist in terms of information or data on the biological or economic feasibility of alternative compounds or practices for methyl bromide for each of these uses, because that technical review is a critical part of the

decision-making process ultimately on what the United States is going to send forward to the international petite panel, which is ultimately where these critical use exemptions have to be reviewed and accepted.

We've seen quite an amount of variability in the depth to which individual applicants have addressed the issues of biological or economic feasibility of alternatives. So, there's some applications that have come in that are quite thorough. There are others that are going to require a little bit more effort on the part of both USDA and BEAD to fill in those gaps.

We expect to be fully into the application review process after having filled in and taken whatever reasonable steps we can take to fill in gaps by the mid to late November time frame, and it will be at that point that our review panels that will be made up of BEAD people as well as USDA technical experts will forward the results of the evaluation to the Office of Air.

Subsequent to the forwarding of the technical review results, there will be the convening -- there will be the formulation of an EPA position and then a formulation of a U.S. government position that will be

brokered by the State Department with full participation of Department of Agriculture and also EPA in basically deciding what is going to go forward into the international arena.

So far, in terms of establishing the process, it's been a very good and collaborative relationship with the Office of Air, and also we've been working very well with the Department of Agriculture, and so we're very optimistic that we'll be able to meet basically the next four-month deadline of getting ready for the submission of the packages to the international panel.

I'll stop there on methyl bromide. That's sort of the one-minute update on where we are, if anybody has any questions.

SPEAKER: I have a quick question. Is there any internal agency effort to identify gaps in applications, more or less, is the agency trying to determine if there's a commodity, for instance, that probably needs an exemption but for which no exemption was applied for?

MS. KEEHNER: One of the positive aspects of how we're approaching this is that there is a second bite at the apple. So, we do know that there are some commodity

groups that -- like particularly during the last week or so, you know, September 2nd to around the 9th, we're saying, gee, we just found out that we need to do this. There is a second bite at the apple which will start in mid-2003.

So, it's not too late to apply, and that's kind of the direction that we've been giving people, is that with what we have right now, we feel like we've got a pretty full plate to get through what we have. In addition to working through these applications, we remain available to work with other commodity groups and other user groups who have -- didn't make this first round of applications, to help them prepare for the next round, which will be, as I say, around -- in mid-2003.

SPEAKER: Gabrielle?

GABRIELLE: Denise, I just want to make sure I understood this correctly. What you're saying is that BEAD and USDA take a first cut and review and summarize their assessment of the applications, and then that gets handed over to the Office of Air for them to review?

MS. KEEHNER: Correct. We're doing the technical review. The Office of Air doesn't have a lot

of experience in agriculture, and the Office of Pesticide Programs, particularly BEAD, as well as USDA obviously has a lot of technical expertise in biology as well as agricultural economics, and so the concept is that we try to conduct an objective technical scientific review of what's come in, and then those -- the results of that evaluation are then forwarded to the Office of Air and Radiation, and clearly there will be a continuing need for dialogue between Air and OPP so that we're sure that there's a good understanding of what it is that we're sending over to them in terms of the technical review.

GABRIELLE: Thank you.

SPEAKER: All right.

MS. KEEHNER: Okay, my next topic is to just quickly update and alert you to the fact that there is a scientific advisory panel meeting coming up October 1st involving the Biological and Economic Analysis Division. We are going to be presenting to the scientific advisory panel a proposed new statistical methodology for projecting percent crop treated for tolerance re-assessment purposes for use in the dietary risk assessment.

We have used a process in the past that has taken sort of a weighting of historic percent crop treated for particular commodity chemical combinations, where we would weight more recent statistics on what the percent crop treated was more heavily than historic use rates, and what we have found in looking at the various statistical approaches that one might use to doing trend analysis is that there are what look to be some better statistical approaches that provide a more accurate representation of what those future percent crop treated might be for particular commodities and chemical combinations.

So, this is sort of a program -- it started as sort of a programmatic review kind of thing, where we said let's see how accurate we have been in the past in projecting percent crop treated, and then what are the other statistical methods that might be able to be used and how accurate are they in projecting percent crop treated, and does it look like there's a better method than the method that -- the statistical approach that we've used historically?

It turns out that a method called exponential

smoothing seems to give us a better and more accurate projections of percent crop treated, particularly in cases where there has either been a downward or upward trend in use or if things have been bumping around a little bit.

What we plan to present to the SAP is the statistical methodology. Of course, there are always follow-up issues of, you know, how do you introduce the new methodology into the process and what kind of approaches you are going to take to -- from a policy standpoint to introduce that, but this particular scientific advisory panel meeting is really on the statistical issue of given the kind of data that we have available and the length of time that we have data available for particular commodities and crops, does this process, the statistical technique of exponential smoothing, is that the appropriate statistical technique? Is that a better statistical technique to use?

We will talk a little bit about what we've done in the past. We'll talk a lot about what the alternatives are from a statistical standpoint to better project, present crop treated, and we will be presenting

some case studies of what difference it makes in the projections of percent crop treated using this particular method versus the method that we have historically used, and that will give people I think a pretty good feel at least at the initial level for, you know, how much of a difference might this make.

It is on October 1st. It's from 9:00 to 5:00, and it's at the Sheraton Crystal City hotel, and you should have copies of the FR notice in your packages on your tabletops here that includes a description of what's going to be presented.

SPEAKER: Beth?

DR. CARROLL: Yeah, Denise, I just wondered if you're going to draw or if you're even going to discuss the sources of data. You remember the old Leonard Seepud (phonetic) days when we --

MS. KEEHNER: Right.

DR. CARROLL: -- discussed this ad nauseam, and it seemed like every database that was used, there was something that wasn't quite what you needed.

MS. KEEHNER: Right. We're going to -- as part of the presentation, there's going to be a background on

DONE (phonetic) and also on NASS (phonetic), and the data that we're using is -- are from those statistical databases.

DR. CARROLL: And is this going to cover water as well? You said dietary --

MS. KEEHNER: Well, I should say food.

DR. CARROLL: Okay.

SPEAKER: Larry?

MR. ELWORTH: Is the agency going to make those case studies available so that we can look at them? I mean, I don't need to see them before the --

MS. KEEHNER: Yes, actually, the analysis is part of the paper that's in the docket for the SAP, and I can certainly get you a copy of that if you would like.

MR. ELWORTH: Yes, I would like to see it.

MS. KEEHNER: Sure.

MR. ELWORTH: The other -- can I just follow up on Beth's question a little bit, and not in any depth. It's not just the source of the data but the accuracy of the data that matters a great deal, and I would hope that whatever statistical approach you take accounts for the fact that the time series may or may not be

representative and may or may not be really -- representative of what actually happens, nor --

MS. KEEHNER: Right.

MR. ELWORTH: -- and that you actually talk about the bounds of confidence and accuracy around the data.

MS. KEEHNER: Right, and we have looked at that.

MR. ELWORTH: Okay.

MS. KEEHNER: And we've looked at -- I mean, what we're dealing with really is -- this is the current approach, which has all its warts and pimples and things associated with it because of the nature of the data, and then is there an approach that, in fact, seems to provide a more accurate -- and it's -- the interesting thing, when you look at the case studies, is that it's not -- you know, it's not the case that out of the 17 cases that we looked at that, you know, 16 out of 17 result in higher and, you know, only one results in lower. It really does -- it's fairly even as to how it comes out based on the use of this particular method.

The other thing that I would like to add is that regardless of what statistical approach that you use,

analysts and the agency have to take a look at what's in front of them at the end of it and ask other questions, like is there something going on otherwise that we anticipate is going to have some impact on the percent crop treated for this particular chemical/commodity combination? For example, if you happen to know that, you know, some phase-out is going to come in place, you know, in two or three years, looking at historical trends in percent crop treated, that's not the full story, and you need to use some judgment and build that into your sort of post-statistical analysis determinations.

MR. ELWORTH: Yeah, that's important, especially -- because that may not be abundantly obvious to someone who basically has a statistical background.

MS. KEEHNER: Right. We can't -- you just can't flip a program switch and then have it spit it out and use it without thinking about what you're looking at.

SPEAKER: Jay?

SPEAKER: Yeah, and Larry, we looked at this ad nauseam in SEEPUD, and Denise was in on that. You know, there's a lot of them. One database will be accurate, one will be precise, one won't be available until

whatever, so that we discussed a lot of that, and I hope that that historical information is available either from Leonard or somebody else, because there was a lot of discussion on that.

SPEAKER: Jay?

MR. VROOM: Thanks.

Denise, three questions kind of in sequence. Number one, how many and what percent approximately of the risk assessments that have been done since you've been having access to this kind of percent of crop treated data have been employed, in other words? And then, what impact does that have, as I recall, in triggering the FQPA requirement that when you have that kind of data, that it kicks in the five-year registration and renewal requirement?

Secondly, you issued an information collection request a few years ago for public comment and input on percent of crop treated, and I'm wondering sort of where that input will be examined by the SAP when they meet.

And then thirdly, do you think there will be any new data requirements or guidelines that might be published for public comment following -- I'm not asking

you to anticipate or tell us what you think the SAP will say, but do you think it might result in that kind of an action step?

MS. KEEHNER: Let me start by -- preface my remarks with saying that our focus right now has been much on sort of the technical, scientific, statistical issue of what methodologies, the physical methodologies, might be more or less appropriate given what the question is that's being asked and given the nature of the data that we have.

So, there are issues that have to be dealt with in terms of the policy implications of whatever comes out of the SAP. If the scientific advisory panel, that's basically a group of statisticians and agricultural economists that are going to be looking at this and saying, you know, here's what we think about it from a standpoint of the appropriateness of that particular methodology for what it is that you're trying to do.

So, I do envision a period after the SAP where we have to engage with the policy and risk management sort of side of the program within OPP about, okay, where do we move with this methodology? What are all the other

issues that we need to address, and maybe some policy paper or something like that might have to be looked at.

In terms of the relevance of percent crop treated and how it's used in dietary risk assessments, as we have gotten more and more PDP data and market basket kind of data, the importance for tolerance re-assessment purposes has gone down somewhat, but there are still issues where it does play a role in projecting, for example, for detections or levels of pesticide below the limit of detection. There still is a need for that sort of extrapolation to percent crop treated.

So, our customers in the Health Effects Division as well as in the Registration Division are very interested in moving percent crop treated methodology forward, and incidently, not just for tolerance re-assessment purposes but also in the context of registration decisions, sort of the projections of, without any historical data, what do we expect a particular crop and pesticide combination to ultimately result in in terms of the percentage of the market that it might fill?

So, what I would say is that there is -- it

seems to be meaningful enough and it's playing enough of a role that there is a lot of interest in seeing what we can do to improve the methodology for tolerance re-assessments purposes, and also there is interest for new registration-related decisions and improving that approach as well.

MR. VROOM: Okay, and maybe the question then about triggering the five-year registration/renewal question may not be appropriate for you, but I don't know if, Jim or Marcia, you know. Is that a driver or is that sort of an afterthought factor in terms of initiating, you know, that five-year registration/renewal process?

MS. MULKEY: Well, maybe I'm -- I think that the five-year revisiting of the percent crop treated is a little different from the 15-year registration review process, although obviously you can and should integrate them.

MR. VROOM: Yeah.

MS. MULKEY: We have begun to do some work to figure out the five-year issue, and we also have, by a notice of proposed rulemaking and some other things,

involving the 15-year registration review. I don't know that either of those has crosswalked to the other yet.

MR. VROOM: Okay.

SPEAKER: Erik?

MR. OLSON: Actually, Jay asked part of my question, but my -- I wonder, I guess we're now six years past the enactment of FQPA, and I would -- if I went back in my memory, if memory serves, there were several pesticides for which percent of crop treated started to be used not that much after the Act was passed. Have you started doing the five-year reviews yet? Are you going to be using this new methodology to do the percent of crop treated? And also, you know, we've continually raised the issue about -- congressional concerns about using this for acute as opposed to chronic. Is this new methodology going to continue to apply to acute, pesticides with acute effects, where that's the effect of concern?

SPEAKER: Erik, we have identified the use of percent crop treated as well as the other one that's relevant is the use of anticipated residues, both have the five-year clock on them, and actually, we -- the

number of -- affected in the year -- between '96 and '97 is very small. There was actually very little activity that first year after FQPA.

So, we have done the identification work and have begun to work at what information we need for the verification and the recertification on both anticipated residues and percent crop treated.

On the second question, we do continue to expect to be using percent crop treated for acute as well as chronic effects in the --

MS. MULKEY: Probabilistic.

SPEAKER: Probabilistic, yes.

MR. OLSON: Pardon?

SPEAKER: Probabilistic, percent crop treated and our probabilistic acute risk assessments.

SPEAKER: All right, Al.

MR. JENNINGS: All right, IPM symposium, and I will keep within the minute.

As mentioned several times yesterday, there is an IPM symposium coming up April 8, 9 and 10 in the year 2003 to be held in Indianapolis. There is a website that has a lot of information on it, and I did not bring that

with me, but what I will do is give that to Margie and ask her to get it out to all of you electronically.

Again, it's going to cover a full range of typical pest management topics, and in my mind, IPM and pest management are becoming one and the same, and there is really no difference between the two. It's been a while. This is advertised as the fourth national IPM symposium. I remember one other, so I'm not sure how long ago that was. Steve probably remembers since he's reacting, but --

STEVE: You're so young.

MR. JENNINGS: Yes, I know.

But this is just a good opportunity. We haven't met and talked for a while, so it's getting the IPM practitioners and interested folks together for three days. Certainly part of this will be a follow-up to the GAO report of somewhat over a year ago in which the Department did acknowledge that we needed to get together and sit down and talk about goals and priorities and those sorts of things.

Some of you will recall that a number of years ago, a USDA employee set a goal saying it was a good idea

that we achieve 75 percent IPM acreage by the year 2000 --

SPEAKER: That would have been the Secretary of Agriculture.

MR. JENNINGS: Oh, excuse me. That employee is no longer with us, but his spirit lingers.

No, we are past the year 2000, and of course, we met that goal, but anyhow, it is time to sit down and try to figure out --

SPEAKER: Depending on how you define it.

MR. JENNINGS: Yes. Well, anyhow, where are our IPM programs, and more importantly, where are we going with them? So, that will be an important part of that symposium, or at least if we don't solve it all there, it will be a start of that process of discussing goals and measures and where are we headed. So, anyhow, certainly I hope those of you who are interested will be able to join us, and as I said, I will get the website information to Margie, who will hopefully then transfer it on out to you folks.

Questions? Great.

SPEAKER: Kathleen?

DR. CARROLL: I was going to say if anybody wants it today, I've got it.

MR. JENNINGS: Oh, okay. If you want the information today, Beth has it. Yes, there is a very active planning committee going on right now, so...

SPEAKER: Kathleen?

MS. KNOX: Okay, IPM in schools, just a brief update. At your places, there's a brochure which we published I believe -- I think we got it out in June. We are on our second printing. The first printing was sent to school districts and all of our mailing lists. The second printing was done recently. It's got a lot of information, web addresses, things like that.

The second thing is that in 2001, we funded two pilot technical resource centers for IPM in schools to investigate whether a center -- a virtual center that could provide tools, training and technical support to the states would be effective in providing the kind of support needed to folks who were interested.

We funded these competitively through grants. The intention was that the program would become sustainable when our grant funding ran out. We are

rapidly approaching the time when that funding is running out. So, we're in the process of starting to do an evaluation of the effectiveness of the two centers. They're both mentioned in here, and the states they cover are mentioned in here. They both have websites, so we will be evaluating whether there is an effective tool to basically facilitate the implementation of IPM in schools.

The third thing is something that we are not sponsoring, but the National Foundation for IPM Education is having a very focused facilitative workshop predominantly with a relatively small group of IPM in schools practitioners, many of whom are PESP partners, our Pesticide Environmental Stewardship Program, partners. That's on October 3rd, and the hopes, at least the intention of the Foundation when they planned this, was to try to bring together the folks who are doing the work and talk about what will it take to move it forward or to further implement, lots of discussion of tool development. There are manuals, there are technique, there are things that work. There are a variety of things. Many people feel that you don't need to start

from the basics and develop a whole new manual to do this, so these folks who have been doing this for some time are going to sit in a room and talk about what kinds of things could improve implementation in the future. So, that's my update in maybe two minutes or three minutes, so...

SPEAKER: One question, the October 3rd National Foundation facilitative meeting, is there a list of invitees that's available to the committee?

MS. KNOX: I don't have it. Steve --

STEVE: I'm sorry?

MS. KNOX: Bob asked if there's a list of invitees available for the workshop, and I know schools isn't your issue, but --

STEVE: I can get it to you, yeah.

Allen?

MR. JAMES: That was basically my question as well.

MS. KNOX: Okay.

MR. JAMES: How we get more information.

MS. KNOX: You'd contact the National Foundation for IPM Education.

MR. JONES: Kerry?

MR. LEIFER: Back in May, a presentation --

MR. JONES: I'm sorry, Kerry.

John, did you have a question for Kathleen?

MR. VICKERY: Yes.

MR. JONES: I'm sorry.

MR. VICKERY: You mentioned there was a meeting coming up to identify some of the things for the next -- I was wondering if you could share some of your own ideas based on what you know about maybe offering two or three examples of things that you think are critical needs or next steps.

MS. KNOX: Well, I think one of the things that we will do is see what the outcome from the workshop is and try and see how that -- how we could facilitate that. I mean, we don't have a large program supporting this. In fact, our internal work group is cross-divisional, but we don't have anybody working full-time on this. So, the idea is how can we build the kind of -- how can we facilitate the kinds of networks out there to provide the support that the states need to do this.

So, I think we're looking forward to the outcomes from the workshop, and in terms of our internal work, we're really going to evaluate whether these pilots have provided significant support.

(End tape 1-A.)

They were fairly small, each grant was $100,000, and again, they were competitively granted with the idea -- part of the proposal had to be a plan for sustainability, so that the center could continue after our grant funding ran out, so --

MR. JONES: Yeah, if I could add, there have been lots of independent efforts in California, in Monroe Schools in Indiana, in Las Vegas School District area --

MS. KNOX: New York City.

STEVE: -- New York City, the tribes have shown great interest in IPM in schools, and so the thought was let's bring together the leaders in all these different areas and see if we can begin to develop some coordination and some interaction and reduce the redundancy and the -- where everyone has the same learning curve, get everyone up along the same curve, and then discussion -- further discussions about some sort

of -- does it make any sense to have some centralization of information so that -- so that everyone can use a central location as a resource, so that all school systems can go to that location, get all the materials they need to develop an IPM-in-schools system.

Monroe County and Mark Lane who's at Purdue -- no, University of Indiana -- Indiana University --

MS. KNOX: That's right.

MR. JONES: -- have been very progressive in this whole issue and have really driven a lot of this, and I think for those of us at the IPM Foundation and in IPM in general feel like this is not only the obvious advantage of less exposure and better use of pest management systems in the school system, it also helps the public understand what integrated pest management is and helps draw IPM -- there will be a pull from the consumer side for IPM in agriculture, as well. So, it also helps just get the word out about what integrated pest management is all about.

DR. HOCK: Yeah, just to follow up on what Steve said, a little different wrinkle, in Pennsylvania, our State Department of Education actually passed a basic

curriculum requirement -- in other words, in addition to the three Rs, teachers are now required to actually teach or have a segment of their curriculum in IPM. It's a totally different wrinkle from the standpoint that it will be taught in schools as part of the basic core curriculum.

MR. JONES: Okay, Kerry.

MR. LEIFER: Back in May, a presentation was made to the PPDC that was essentially kind of a pre-release overview of a new risk assessment methodology, primarily to be used for pesticide inert ingredients, really to deal with many of the issues that we were faced with under FQPA. That methodology, the proposed guidance documents, was released on June 7th and is posted to OPP's website. The Federal Register notice of availability was published on June 13th. That's also available on EPA's website. That notice pointed to the methodology and basically asked -- solicited comments on four questions that included was this methodology a workable, logical approach; would it produce an efficient, productive process. The methodology talked about a number of sources of information for evaluating

these substances, and we asked if we had missed anything, were there other sources that we should be considering in evaluating these types of materials. And lastly, the document provided guidance to the regulated community, and we wanted to know if there were any additional information that would be helpful to the regulated community.

Now, the comment period was to be September 11th, that's been extended now to October the 11th. So, the comment period for this guidance document is October the 11th. OPP will, of course, review and consider these comments that we receive after the close of the comment period.

As we stated at the PPDC meeting and as noted in the Federal Register Notice of Availability. OPP has been piloting this new methodology, and in fact, we have been looking and using this in various iterations for about a -- almost a year now, and some of the things that we have done have included the re-assessment of about 442 substances using this new methodology, including 152 lower toxicity active ingredient tolerance exemptions, as well as about 290 inert ingredient

tolerance exemptions.

We are also utilizing, again on a pilot basis, this process, and it has resulted in the establishment of tolerance exemptions for four new inert ingredients.

MR. JONES: Troy?

MR. SEIDLE: Thank you. My question is more procedural. We are very pleased with the pre-release of the strategy, and my question relates to the proposed revisions to Part 158 and whether those will go through a similar process and opportunities for public comment.

MR. LEIFER: Yes.

MS. MULKEY: Absolutely. That's actually a rulemaking, so it's a full-blown Administrative Procedure Act notice and comment.

MR. JONES: Bill?

MR. TRACY: Yeah, Kerry, what I found in the guidance is that it gets a little vague about the tier approach and how one -- do you want submitters to select the tier if they're going in to propose, let's say, a new inert? Are they -- I would appreciate I guess greater guidance on the tiering process, and are you planning to do something like that? Are you finding that an outage

so far?

MR. LEIFER: Well, we have been mostly utilizing this for the existing chemicals, existing inert ingredients for tolerance re-assessment purposes, and essentially it's been predominantly an agency process where we've been putting the information together. These tiers are basically just pathways to -- for risk assessment purposes. I mean, I think we certainly would appreciate as part of the comments to get any comments about where you think that is, if that's not really clear to the regulated community.

Yeah, I mean, in essence we are or we would be expecting that in the case of new submissions or submissions on the re-assessment that the submitter would be essentially identifying where they fell into this process and essentially identifying substances particularly that are of particularly low toxicity.

MR. JONES: Warren?

DR. STICKLE: One of the things that is something that I think needs to be addressed very rapidly is really an updating of the inert list. As you may very well know, it was -- initially came out in May of 1995,

and since 1995, a lot of actions have taken place. About 250 inerts have been removed from the list. I think 87 were done for the first trimester for re-assessment, and then for the second trimester, there were I think 287 or something like that, and of course, during the period from 1995 to today, there have been a number of products that have been added to that list, they are polymers, et cetera.

The question ultimately is that right now, the regulated community, the general public and perhaps even people and product managers at EPA, are somewhat lacking in a definitive list, and I know the agency has been working very hard on it. In fact, I know Kerry's been working very hard on it, but I wondered if you might be able to give us a -- perhaps an update and a timetable by which that updated list might be made publicly available.

MR. LEIFER: Well, we're actually -- we've just been in the process -- as you know, we have been working quite hard on the tolerance re-assessment front to meet the August 3rd mandate. We have now begun to kind of go back and account for the actions that we've made and what

they mean in terms of reclassification for many of the inerts that were re-assessed, be it to List 4-B or 4-A. That's predominantly where they moved to.

So, we have now pretty much completed that process, and we are beginning to put that all together. We have already -- have internally captured all of the, quote unquote, the "new" inert ingredients that have been added since '95. So, I think we are very, very close, hopefully within a matter of weeks, of having an updated listing of all the inert ingredients with their corresponding list classification on the website.

And on a related matter, I guess we're going to be looking into making publicly available in some form the substances that have been re-assessed under this process as well.

MR. LEIFER: Do you want to handle the next three of yours, the drift issues -- I'm sorry, the nonisolated --

MS. LINDSAY: Which one do you want me to do next? I was going to do inerts disclosure.

MR. LEIFER: Start with inerts disclosure, and then take the two carryover issues.

MS. LINDSAY: Okay. This group a number of years ago commissioned a work group, the Inerts Disclosure Stakeholder Work Group, which labored long and hard to look at ways of making information on inert ingredients more available to the public while still being mindful of the FIFRA requirements and the CBI concerns that are relevant.

The group actually submitted its report to the full committee in April this year, and we also opened a public comment period on that report which closed at the end of July. We did not get a lot of comments, I'd say in the neighborhood of a dozen or so, most of which were of the sort of postcard variety, but there were two that actually were substantive, one from the Minnesota Department of Agriculture that was quite I think soundly in support of improved disclosure of information while being mindful of a number of the issues that are surrounding doing that. It went on to describe actually some very concrete and different sorts of situations than the group itself had looked at, of difficulties they actually have in doing their pesticide regulatory job because of the current state of affairs.

The other letter was from the American Pet Producers -- no, American Pet Product Manufacturers Association that, again, went through some of the issues that were developed by the work group.

The actual report ended up not, of course, with a single set of recommendations but with three different proposals. One discussed the creation of a voluntary program to create releasable non-CBI summaries. Another proposal recommended rulemaking to modify labeling requirements to require the name of each inert ingredient be included on pesticide products. And a third proposal also proposed a rulemaking to modify labeling requirements to require the name of each inert ingredient to be on pesticide product labels, but also this third proposal directed EPA to determine up front or to substantiate up front any CBI claims that were made for a particular formulation.

Then the report actually also had a number of other suggestions kind of embedded in it beyond the three specific proposals. One concerned strengthening databases that contain information for health care providers. The current systems are voluntary, and they

don't necessarily include all information. It talked about disclosure of inerts on labels using general descriptors, such as surfactants or fragrances rather than very specific chemical names, standardizing nomenclature of inert ingredients, and then finally, develop ways to provide recognition to those registrants who actually voluntarily disclose all inert ingredients. So, build a kind of incentive program.

We're now in the mode of actually looking at all three of the proposals, the comments that we got through the comment process, these other suggested initiatives that are embedded in the report, and would expect over the next several months to be able to elaborate some directions forward in this arena, and when we do that, we will have public process around those ideas as part of our roll-out of them. We're being a little bit deliberately vague at this point about what that public process might be, because there are a number of different directions we could take that. So, that's it.

MR. JONES: Bill?

MR. TRACY: Anne, I think you have a yeoman's task on this one, and you know it.

I guess my question is a little bit about EPA's process on this and who is it that's working on it, not individuals but what entities, and do you have ODC or some sort of legal folks or what's your team look like and who are you going to vet process with?

MS. LINDSAY: Unless the team who supported the Inerts Disclosure Stakeholder Work Group refuses to do this anymore, because they have done yeoman's work, I would expect that to be the core team. So, for instance, Kerry Leifer from Registration Division was a critical member. I've got some staff. Our General Counsel's Office was always a main player. And I think they will be the core group that moves things forward.

MR. JONES: I'm sorry, Bill, were you --

MS. LINDSAY: I may need to create an incentive program for them.

SPEAKER: That was a tough job. I was part of that. Thanks.

I just want to make sure -- and I think Bill asked the question, but just to emphasize that any program, any project that we move forward with take into consideration the statutory authority in FIFRA and FOIA.

I thought the letter that Marcia sent to the petitioners was particularly good, because it did lay out the legal authority. Without getting into that here, I think that's really critical and important.

We had some problems laying that on the table during the proceedings, because I think the leaders and everyone wanted to move forward to see what we could agree on, if anything, but I think it is critical that the Office of general Counsel be very involved in anything that finally comes out as a proposal.

MR. JONES: Julie?

MS. SPAGNOLI: A number of registrants have, you know, initiated their own kind of voluntary activities in this area, and I think one of the problems that we've run into is, you know, a number of stumbling blocks with some of the states and just trying to I guess have some guidance on -- and this would, of course, all be voluntary at this point, and I guess I would be asking, what is -- does the agency have any kind of more immediate plans maybe to facilitate some type of guidance to registrants who are looking for ways to, you know, to -- maybe to voluntarily provide this kind of information,

particularly on consumer labels I think is where the main focus has been, and maybe to try to eliminate some of the stumbling blocks that we've encountered in voluntary disclosure.

MS. LINDSAY: Okay, that's an interesting suggestion. We'll look at that.

MR. JONES: Did you want to go ahead and --

MS. LINDSAY: Yeah, I was going to talk about misuse next. At the last of the PPDC meetings, we had a panel discussion. Phil Benedict was part of that, Jay Vroom, and a number of other people who I think are not in the room today.

What I want to do is just a very brief update. The misuse cases that we were discussing then were pretty significant, pretty -- not focused in any one specific region of the country. Most of them seemed to involve use of a product registered for one crop on a crop for which it was not registered, though in at least one case I think there was a pending registration.

I'm happy to say, after having done sort of an informal poll of our regional offices, Registration Division, our state lead agencies and others, that we're

not seeing reported to us these kind of significant patterns of misuse that we saw in the past couple of years, so I think that's actually very good news, that the sort of egregious kinds of situations that we were looking at don't seem to be occurring.

I will say that in doing this little poll in preparation for the meeting, I did get what I would call some anecdotal information in some areas that we might think about. The first is actually the use of pesticide products in a manner in which they were not intended to be used, as bait for nuisance animal control, and then the second area is the sort of -- I'm not quite sure what to call it, sort of like a copycat 24-C situation. If, for instance, Phil Benedict had issued a 24-C in Vermont and in a neighboring state they didn't have the 24-C but the grower knew about it, the grower in the state without the 24-C may just go ahead and do what Phil's growers are quite legally doing.

So, both of those are anecdotal. I don't have what I would call hard, concrete information about the extent of those kinds of problems, but to me what it suggests is that there's a reason to keep a bit of a

focus on the issue of proper use and misuse, because the temptations are always out there, without maintaining some level of focus.

I think Jay actually has a little bit to add.

MR. VROOM: Yeah, thanks, Anne.

At the May PPDC meeting in that panel discussion, I think we talked a bit about the fact that there was some legal hurdle to get over at that point in time to get published what turned out to be two sort of parallel editorial pieces that Steve Johnson and I separately authored, and those have now been cleared by the -- all the lawyers and have been published fairly widely in the ag trade media, probably a little later than we would have preferred in the growing cycle for this particular crop year, but nonetheless, I think they have gotten good attention.

I have actually been quite surprised with the amount of e-mail response that I've gotten from growers, extension agents, university folks around the country. I think there have been five major ag farm media that have picked both of those editorials up, and a number of them have republished them, and others have put them on their

websites. That's led to requests from I think the Oregon Extension Service Newsletter asked to republish these articles. So, I think all that's been very positive.

It also has probably contributed to the anecdotal survey that you referred to, which does seem to indicate that people have been reminded through, you know, these articles and other communication from the agency and the industry that the label is the law, and that's something that you need to follow.

Lastly, I think it's elevated a few problems that need to be addressed. One of them is the definition of hay, for instance, and I think this is still a continuing problem, Phil, in your state and some other parts of the Northeast, and it probably relates more directly to milk-producing areas where people are more critically concerned about residues in milk than in meat animals that would be consuming hay, but it is an area that we have raised informally now, this definition of hay crop and residue concern.

I think that the agency staff are addressing it, but I wanted to make sure, Marcia, you and Jim were aware of that, because it is something that while it is a

fairly minor use category, it is one that apparently has been a persistent problem. Phil has talked about it, and I don't know, Phil, if you want to speak to it again, but if it hasn't received your attention at the highest levels in the program, we would like to ask that you look into it.

MR. BENEDICT: I still think it's a Northeast problem and probably broader than that. I really think it's not just hay, though, it's forages, it's mixed stands is what it really is.

MR. VROOM: I stand corrected, sorry.

MR. BENEDICT: That's fine. It took us a long time to figure out what it was, actually, according to the rules.

MS. LINDSAY: If I could just add, I actually do think that Jim anyway, I know that Jim and I have talked about this issue and sort of our internal plan of attack, so it's had high-level attention and continues to have.

MR. JONES: Okay, next topic, Anne?

MS. LINDSAY: Spray drift, and here I'm doing my imitation of my associate, Jay Ellenberger, and he was kind enough to actually give me his official Power Point

presentation to crib from, so I may actually get things correct.

Win, you had asked for sort of an update on the spray drift issue --

MR. HOCK: Yes, thank you.

MS. LINDSAY: -- we put out -- this is just background -- draft guidance in the form of a draft PR notice in August 2001. We had what amounted to a very long comment period. It ran from August to end of March 2002. Ultimately, after a couple of extensions, we got a very significant number of comments, 5249, with a total of individual comments, which I think this is significant, 1771. These are not campaign letters. They're really, you know, letters that people sat down and wrote to us about the issue. So, obviously the topic of spray drift has -- really touches a lot of different nerves and I think in a lot of different ways.

Just a run-down, 56 percent of these were individual grower comments; 17 from ag retail business; 6 percent from private citizens. Although that's a very small percentage, I again find that very significant, because we almost never, at least in my experience, get

comments from just like real people, not that you're all not real people, but it's pretty amazing when just an ordinary person takes the time to actually file a comment in a Federal Government comment sort of process. 4 percent from associations; 1.4 percent from environmental groups; 1 percent from applicators; and 0.3 percent registrants.

The one missing category, Phil, in the official comments were states, and that actually surprised me since APCO had been a significant partner in developing the ideas. That were ensconced in that draft.

Anyway, primary issues. Recommended application within the range of the three to ten miles per hour wind speed was viewed as being unrealistic by a number of the commenters. The height of the application is a concern. I think we talked about ten feet above whatever it is, and a lot of the aerial applicators gave us very specific examples of why that was totally loony and wouldn't work.

Orchard growers -- like telephone poles and rolling countryside and that sort of stuff.

Orchard growers were concerned that the orchard blast spray technology that seemed to be sort of

ensconced in the PR notice was unrealistic. Concerns about economic hardship to small farmers due to new equipment costs, so that even though there might be equipment out there that was really good and would help with drift control, it wasn't necessarily accessible to everybody.

Then, enforcement concerns, and those would be really from the -- I think the state agency perspective. There were some of what we're calling special issues around forestry applications and also adult and larvaside applications for mosquito control. And my favorite one of all, the beekeepers and protection of bees during aerial spray programs.

But the vast majority of programs did come from farmers and the ag community broadly and were quite unfavorable I think is a fair way to characterize it. Those who favored the revisions tended to include the private citizens, that 6 percent that wrote to us, especially those that have actually experienced spray drift personally in their life and believe that they suffered adverse effects from those, because they live near the treated fields, and environmental groups and

organic farmers. So, it's kind of I think a classic split.

What we're doing right now and what we have been doing all through the comment period and since the comment period closed is doing a lot of I would say very informal getting out there, listening and talking with people in all different directions. I know that, Adam, you and Steve and Jay made a trip to.

DR. LEWIS: In the height of the summer, ideal vacation time in.

DR. LEWIS: . Jay will actually be going shortly to a very large conference in Texas about vegetation management with lots and lots of folks there who care about the ag drift issues.

But we're also in the midst of planning some more specific workshops, and our current thoughts are that we would have probably three workshops, one on the East Coast, probably most likely in Washington, one in the middle and one on the West. Actual time frames, specific dates and locations aren't crystallized enough yet to sort of give you a better feel for it than that, but we're really looking forward to the workshops. We

actually think we have got enough interest in the issue that we're going to get some very constructive input, and I think eventually we'll find a way forward that is reasonable, practical and also protective.

Assuming that I'm right about my expectations of our success in the dialogue, and I see Adam is looking at me a little -- he's smiling at me now, this is better -- the expectation would be that we would probably do another draft PR notice -- or not probably, but that we would do another draft PR notice, and that would go out for comment, and then obviously, depending on what that comment showed us, we would decide what our next steps are. So, that's it.

MR. JONES: Julie?

MS. SPAGNOLI: Just for clarification, kind of what is the scope of these workshops? Is it going to be to solicit stakeholder input or to discuss the various issues, I guess just kind of what is the agenda idea for these workshops?

MS. LINDSAY: Well, broadly obviously we want to discuss with stakeholders, and I think we want to make sure that we actually get a full range of stakeholders at

the workshops. I think we're going to have to look at the issues that have come out of the public comment period and use those issues to properly frame discussion at those workshops. I think also we're open to suggestions from all of you as to, you know, what might make those workshops be good and useful.

MR. JONES: Win?

MR. HOCK: First of all, thank Jay Ellenberger and Anne, I appreciate that very much. The expectation of another PR notice, that's probably going to be after the workshops, am I --

MS. LINDSAY: Oh, definitely.

MR. HOCK: Definitely?

SPEAKER: Well after the workshops.

MR. HOCK: Because I thought, yeah, you know, you'll go through this whole thing again, you know, so you'll incorporate those comments and suggestions and so forth into the new PR notice.

I guess you're really looking about, what, nine months away, something like that, an expectation?

MS. LINDSAY: I would say that that's a very aggressive estimate on your part.

MR. HOCK: All right, we will look for the workshops.

MR. JONES: Erik?

MR. NICHOLSON: For what it's worth, I had to evacuate my family from our house, which borders a strawberry field, this summer. I have a two-year-old daughter. When the grower applied unknown chemical, preharvest application, to strawberries in a field that sits about 30 feet behind our house, we just had to get out of the house as quickly as possible.

In terms of enforcement, we have had such a bad experience with the Oregon Department of Ag, I didn't even bother filing a complaint. My concern was the safety of my family.

MS. LINDSAY: Thanks.

MR. JONES: Adam, did you want to --

MR. GOLDBERG: Yeah, actually, I just wanted to chime in a little bit on spray drift. It really has been a lot of varied comment, I think very constructive comment that we've received over the last six months from folks, and it's really been informative. I just wanted to back up kind of what Anne was saying. I think we're

going to have some very constructive workshops aiming at the level of interest that we've had in this, and it has been a lot more than possibly expected I think and from a lot wider range of folks. So, I think it's going to be a good discussion. I think we are going to have good workshops on those, and we look forward to your continued comment and input from everybody. Thank you.

MR. JONES: Next I am going to introduce Don Wood, who I don't think most of you have met previously. He is with the Senior Budget Office in the assistant administrator's office, and Don is going to give us an update on EPA's strategic plan revision.

MR. WOOD: Thanks, Jim.

Good morning, everybody, nice to see you. This is our current strategic plan, the EPA strategic plan dated September 2000. This is not a document, I can guarantee you from personal experience, that sits on the shelf. We use this document a lot in the budget office, and in fact, it is sort of the brooding omnipresence of our budget work, because every time we gin up a budget for the next fiscal year, we need to go back and show Congress and show the public and show you all how we're

doing against our explicitly stated goals in the strategic plan.

This is our second strategic plan. Each one is to last five years, and we're now starting the cycle to begin a new strategic plan that is to be in effect from FY 2003 through the end of FY 2007, five years. We have in the past and will continue to very strongly encourage public participation in the formation of the strategic plan.

What we'll be doing in OPPTS and OPP in particular is to seek public input over the next year in three ways. The first thing will be coming up very quickly, and that will be a letter from Steve Johnson which is now in gestation and we hope to have finished by next week that will lay out a series of questions that we'll be asking the public and our stakeholders about the strategic plan and providing input, asking input into our next plan, and that letter will be out next week and will direct folks to the EPA e-docket, and the e-docket will be the way that we and OPPTS will be seeking your input on the strategic plan.

The major portion of the strategic plan and the

thing that really drives our budget are the objectives and sub-objectives, and I would like to read a couple of sample objectives and sub-objectives to you to show you how specific the strategic plan is and also show you what -- ask you how you can help us with our next round of objectives and sub-objectives.

For example, in the current plan, one of our sub-objectives is by 2006, residues of carcinogenic and cholinesterase-inhibiting neuro-toxic pesticides on the foods most frequently eaten by children will be reduced by 50 percent from baseline levels in 1994. That's in our current plan, and every year we need to demonstrate how we're doing against that particular sub-objective.

Another one is by 2005, reduce by 50 percent from 1995 levels the number of incidents and amounts of mortality to terrestrial and aquatic wildlife caused by 15 pesticides currently responsible for the greatest mortality of such wildlife.

Those are the kinds of specific drivers that we have in the budget, and those are just two of several that we will be asking folks to help us update and provide new objectives and sub-objectives as we face the

next five years.

We'll also be asking what are the organizational difficulties that our stakeholders and you are facing that we can help through planning over the next five years. So, look for the letter from Steve Johnson next week. We'll be sending it out through our very comprehensive mailing lists, and we'll make sure to give Margie that letter. That letter should point you to the e-docket where we will have the specific questions that we really would appreciate your help on.

Then, two other opportunities to take a bite out of the apple will be in the beginning of December when we will have draft objectives and sub-objectives out for public comment, and then in the beginning of March of 2003, we'll have an entire revised strategic plan available for comment, and that will not only include the work in the pesticides program but, in fact, throughout the entire agency. That will be early March of 2003. Then our final plan is due to be finished and sent to Congress at the end of fiscal year 2003, which is September 2003.

So, again, I very much encourage you to continue

your help, as you did in the last strategic plan, by providing us input in the next revision. Thank you.

MR. JONES: Larry?

MR. ELWORTH: Is the -- is OPPTS or the agency or both doing an evaluation and publishing that of performance at -- from -- to a certain point on performance in meeting those objectives, because I think it would be a little difficult to comment on a strategic plan without having some sense of what had happened to date in achieving whatever objectives you had.

MR. WOOD: That's a very good question. Every year we are required by GPRA and would be by good management practices anyway to report how we've done on our strategic plan, and in fact, we have annual reports that come out every year, and right now we're starting the 2002 annual report, and those are all available on the EPA Office of Chief Financial Officer website, epa.gov/ocfo I believe is the address, and those reports will indicate how we've been doing against the goals and measures that are in the strategic plan.

MR. ELWORTH: So, when is the 2002 report on the website?

MR. WOOD: The 2002 report we're starting now, and I'm not exactly sure when the release date is, but it's earlier than it has been in recent years.

MR. ELWORTH: Okay.

MR. WOOD: It will be out I would imagine -- probably not in time for Steve's letter, but certainly in time -- in late December or early January to use to comment when we come out with the draft objectives and sub-objectives.

MR. ELWORTH: Well, I would encourage you -- and maybe this is one of the forums to do it -- is some opportunity for discussion as well and not -- in addition to whatever response, to letters or e-mail, maybe if this is worth bringing up later as something we could discuss as part of this group's discussions, that would be helpful.

MR. JONES: Would you give that website again, please, the addition to the epa.gov?

MR. WOOD: The website for the annual performance reports -- and I'm doing this from memory -- is epa.gov/ocfo, and another way to do it is just go to the epa.gov and look for the Office of Chief Financial

Officer link, and they are very good about putting up all of the annual performance reports, the strategic plans and the yearly budgets. The yearly budgets, by the way, also have our annual performance measures and progress toward the -- annual performance goals and progress towards those goals every year.

MR. JONES: Okay, Marcia, you have the last update.

MS. MULKEY: And responsible as I am for the entire agenda, I am motivated to make this very quick.

As you know, there's been a lot of interest in worker risks and worker risk assessment -- oh, I'm sorry, Phil.

MR. BENEDICT: I'd like to talk from a state perspective now. We have the Office of Pesticide Programs, and we also have the other branch or another of the agency that funds a major component of the pesticide program, that's the enforcement grants, and to me somehow there's a disconnect in the way the agency does its planning if you don't look at both what's going on in OPPTS and OECA for talking about the pesticide program, you're only painting part of the picture, and I think the

agency has historically done that.

So, I would hope this time around that you would take a more holistic look at the pesticide program and deal with both sides of the agency, because it's -- what you're putting out in reality is really an agency plan, of which OPPTS is part of, but if you don't combine what's going on in OECA, you don't really paint a very good picture. The pesticide program in my opinion is unique. It's the only one where Congress delegated use to the states, and in all of the other programs, the delegation has been by the agency, but in doing that, it has really created a program that is really a true partnership, and I think the strategic plan ought to better reflect that personally.

MR. WOOD: Well, you're right, and of course, the Office of Research & Development, not so much from a state perspective but in other ways, it's also critical to understanding the entire pesticide program.

MS. MULKEY: With regard to our update in a minute, more or less, on worker risk and worker risk assessment, there has been in this forum and in the CARAT quite a lot of very strong stakeholder interest in more

attention, more detailed attention and more specific attention to issues relating to estimates of worker risk, the actuality of worker risk, means of worker risk management issues, the whole range of those kinds of things, and out of those requests -- actually, the Deputy Administrator made a commitment that there would be some increased stakeholder engagement around this issue, and out of that commitment, along with your and your counterparts' keen interest, we developed an idea to try to do some kind of forum that would meet those criteria.

We were mindful that our efforts in the past to be more transparent and more comprehensive in our dialogue had not met all the hopes and expectations, and so we embarked this time first on a planning activity. We invited a group that is drawn primarily from this but also from CARAT, Cindy Baker, Melody Kawamoto, Richard Finsky (phonetic), who's actually on neither but specializes in research in this area, Lori Berger, Dan Botts, Larry Ellworth, Sherry Davis and Al Jennings convened with us. We spent a full -- almost a full day and a subsequent conference call in an attempt to plan

this kind of thing.

What came out of it was the fact that we had more than two days needed for such a forum and that the topics were both -- were wide-ranging -- they had both depth and breadth elements, and so we have basically attempted to plan two such what we're calling workshops, for lack of a better word, each about two days, the first of which is dominated by but not exclusively focused on OPP's approach to estimating worker risk, both handlers and post-application exposure in fields, along with some other topics that are related directly to measurement of the risk of workers, including some portions of Dr. Finsky's work and some new data development that's going on in the industry and a new study that has been sponsored over the last 10 or 12 years, so it's not very new, but some newly emerging information from studies by the National Cancer Institute.

There's a copy of that agenda in your folder. The planning group is continuing to work toward the second session, and so its agenda is not as refined, but it's likely to include such things as what kind of technological improvements can we identify and pursue

regarding worker protection; what kind of information can we derive from epidemiological data, measurements of worker body burden, all the -- sort of the science -- the medical/occupational health science of worker -- pesticide -- workers exposed to pesticides in fields; and a range of other topics of keen importance, the omission of which shouldn't signal anything in this remark.

So, that group, the planning group, which has worked very hard, is going to continue to work so that we hopefully hit the mark with these two sessions. The first one is October 29 and 30 in the D.C. area, so mark your calendars. We hope to did I say gorge all the information about how we do risk assessments that you ever wanted to know, along with some other really important and valuable information.

Erik?

MR. NICHOLSON: I appreciate the agency's interest in pursuing these issues further, and I'm heartened to hear about the second seminar. Frankly, the second agenda is not as -- representing someone who represents the most farm workers in the United States,

this agenda really doesn't get at very many of the issues at all that we have in terms of worker risk, so I would really encourage the agency to please not forget in particular the issue of farm worker children.

I think the General Accounting Office study came out several years ago, was very critical to the agency, especially the pesticide program, obtain their oversight of farmer worker children, specifically referring to children who incur occupational exposure who are under 12 years old who are continuing to work in the fields. That, among other issues, I think are critical to be raised in this forum. I look forward to seeing the agenda for the second meeting.

MS. MULKEY: And we welcome any input you have to the planning for it. Thank you. Anybody else?

All right, let's -- Jim, do you have any wrap-up of your segment?

MR. JONES: No, I don't.

MS. MULKEY: Well, we have a time challenge, but it's not an insurmountable one, I think. You've probably noticed that the agenda never planned a break for this morning's session. Some of you are probably mildly

uncomfortable, literally, with that. I think we need to do one, but equally, we really need not to have a full break or we can't keep going. So, what I suggest is that people take care only of the necessities, which I understand to include coffee, and that we return literally in ten minutes, 15 'til, to our seats so we can cover these important issues.

**(A brief recess was taken.)**

MS. MULKEY: Thank you again for returning to your seats. If you will model that behavior ahead of your colleagues, we will actually succeed. Thank you, Beth and Phil. We very much appreciate everybody's attention to this.

This next segment I think many of you will find extremely interesting. You do have a handout at your seats. Don't spend too much energy reading forward. You really do need to hear the verbal context setting.

This next topic is one that we have had a request for and actually attempted to respond to pretty much every other PPDC meeting, some version of we would like to know how you're spending your money at EPA on pesticides. We have attempted to answer it. We have

brought in the budget people. We have revealed the budget numbers. And for whatever reason, we have managed to choose a language and a format and a level of detail for those presentations such that nobody ever went away feeling they got the question answered, and it was -- I assure you, it was never for any lack of intention on our part to be as utterly transparent as we could be, but we did sort of get it that we were not being able to convey information about our resources in a way that was meeting people's needs, and so we attempted two things that in some ways were fundamentally different this time.

One is we attempted to get some feedback from some of you and others who were interested in our program at what I would call the macro level but whose needs were not being met by our previous attempts and who could help us understand what kind of information it was that was desired and that would be in an accessible way. So, that was one thing we did, and I very much appreciate the folks, including Wesley Warren, who I believe is president of NRDC -- I'm not sure of his title, but I know he's the big gun, Jay Vroom, who is also a big gun, Phil Klein and Allen James and Carolyn Brickney, who was

there by phone and Adam Goldberg. So, we had an excellent group to help us figure out whether we've gotten this right or right enough that it's a meaningful exchange with you. So, I wanted to give you that context.

The other thing -- and for this, I am hopeful that everybody who is going to hear this session will join us, so is there anybody out there -- outside we need to push in here?

SPEAKER: (Inaudible.)

MS. MULKEY: Yeah, I noticed that, because this next few remarks that I want to do for stage setting are pretty critical to your understanding what this is and isn't, so the last thing we need is for somebody to hear the rest, not having heard this part.

Yeah, I can't whistle personally, so I need to get one of those piercing types. Good line. You win the prize for the best line of the day.

As you've picked up some hints from the colloquy we've just had, EPA gets from Congress certain monies that are in certain categories of the larger EPA budget, and into those categories come monies for pesticides.

That, for those of you who are budget gurus, are in goal three and -- all of goal three almost and a portion of goal four, but EPA's pesticide program consists of entities and work outside of Crystal City and the two laboratories that we in OPP manage. The pesticide program's budget includes monies that go to the -- that is, the pesticide budget, pesticide work budget, includes monies that go to the Office of Research & Development, monies that go to the Office of General Counsel, monies that are retained by the infrastructure of the agency to pay our approximate pro rata share of the overhead and operations of the agency, our administrator's office and our budget office and all of the infrastructure that supports not only the pesticide program but other parts of the agency. There are enforcement monies which are not in those two goals but which are dedicated to work on, among many other things, the pesticide program and so forth.

At the end of the day, there is -- and then it comes to the -- our assistant administratorship, Steve Johnson, and he then allocates it within that organization. In that case, it's actually a very small

fraction that is taken for the operation of his office, sort of our pro rata share, if you will, of Steve and Adam and Susie and their immediate staff, and then the remainder goes through to the Office of Pesticide Programs.

The information we're going to supply today is about the money that makes it across the river, if you will, makes it to the Office of Pesticide Programs. You'll get some indication of the fraction that does not make it there, it's somewhere around 12 to 15 percent, and that doesn't include a lot of the ORD money, but that's sort of the money that is operational, programmatic money. So, this information is about the money that we have.

The money comes in certain colors, if you will, as you will learn, basically three in our case. One is called S&T, science and technology. It is money that can only be used for certain narrow functions. In our case, it's almost entirely the operation of our laboratories. We have two laboratories.

There is the FIFRA fee money, and that money is designated -- it's the maintenance fee money I guess is

what it was, and it sort of has a new name in the last two appropriations, but it's money that is designed to pay for certain things, and as you will learn, it goes to pay for those things. It's essentially the salaries or the -- to the extent it can cover them -- of about 200 people who work on re-registration.

Then finally, there is everything else. The everything else money is the general appropriated funds, and it is divided, as you will see, primarily between money to pay the salaries of our people, and relative to many EPA programs, we are a people-expensive program. So, the overwhelming majority of the money we receive goes to pay the salary, the over -- the benefits and everything that goes with fully funding our people.

Then there is a final amount, and as you will see, depending on which way you look at it, $30 or $40 million which is available to spend on things other than merely salaries, and that's sort of the context of what you're going to see and hear today.

Doug Weik is our budget person responsible for what we call budget execution, I've always found that sort of an amusing term, and he is very, very good at it,

and he assures that we not only spend our money in the, you know, legally correct and proper way but that we're smart, that we're not wasteful, that we monitor it, that we know at all times where we are, that we spend it all, which is very important, but that we not overspend, which is also important. So, he is just I think the optimal person to provide you with this information.

The slides he's using are numbered. They will prompt questions in your minds. Please make notes on the slides as you go along. If we -- we really need to go through the whole thing in order to both make our timetable and make the dialogue meaningful, but we will have comment time.

We're going to run at least until noon and maybe until 12:15 before our lunch break, and I think that will make this session sufficiently comprehensive.

Doug?

MR. WEIK: Thank you, Marcia.

Okay, the first slide is just kind of laying out what we'll be talking about. We're going to start with just a very brief definition of some of the sorts of funds. We'll move on to some of the historical trends.

Then, as you can see, we're going to delve into the 2001 year specifically, that's the last complete year that we have, starting with major programs and working our way down into some more specific views of some of the registration, re-registration issues that may be of interest.

Flipping to page 1, I won't spend much time on the definitions. Authorizations just allow us to legally receive funds. The key one here is the appropriation. Without the appropriation, you are not allowed to spend whatever money you may be authorized to spend. Jumping down, you probably may find of interest the fact we have a mixture of administrative funds that support other areas of the program, not specifically directly science reviews and things, such as training, supplies, equipment, relatively small part of the budget, and then the programmatic funds are the ones that support the program activities, such as the risk assessments, processing of registration applications.

Before we move on to looking at the resources, I just wanted to make a note of what a full-time equivalent or FTE, you are going to see this term, and what it

represents is 2088 hours. So, it doesn't always equate to an on-board person. There's an example here showing that if you had a work team of five people that worked four hours a week all year long, that would only use a little less than half of an FTE worth of the 2088 hours. So, that's just to set the context.

Flipping over to page 2, Marcia's pretty well covered this section. This kind of gives you a breakout of our four major pots of money, if you will. Environmental program management is by far the largest. That's the one that Marcia referred to as covering about everything else. It's a two-year appropriation. We can use it for contracts, grants, salary, travel, just about everything.

The S&T, science and technology appropriation, is only $4 and a half million out of the total of $130.7. Again, a two-year appropriation primarily dedicated to the laboratories.

Marcia didn't really mention the STAG, the State and Tribal Assistance Grants Program. This is a regional program. We do have $13 million. Of that, virtually everything goes right out to the states. We have about

$1.3 million that is sent out a little bit later out of the headquarters operating plan, but through the year, all this money goes straight out to the states and regions.

The last thing is the FIFRA Revolving Fund, which in 2001, we spent $16.8 million, all on salaries and -- yes?

SPEAKER: Would it be appropriate just to ask a couple of clarifying question?

The two-year appropriation reference for the first two categories is -- can you explain that a little bit more --

MR. WEIK: Sure, sure.

SPEAKER: -- and the -- for instance, the $96.3 million for the EPM amount is an annualized amount as opposed to whatever the two-year appropriation designation is.

MR. WEIK: Correct, correct, that's correct. Let's take EPM as an example, and since we're talking -- and that was another reason for using the 2001 year, because the 2001 appropriation, this $96.3 million, was actually available to us to spend throughout 2001 and

throughout 2002, and frequently we will refer to it in the budget world as '01-'02 money, and that's the two years that it's alive and we are allowed to use that money.

The 2001 money will expire in about two weeks, September 30th of this year, and we will no longer be able to commit those funds for 2001. So, we're virtually -- that's another reason we used this, because we had virtually completed spending of the 2001-2002 dollars, and each year we get an annual appropriation that will be, you know, roughly that same amount, so in 2002, we got another additional $96 or $97 million, and that's available for expenditure during 2002 and 2003.

So, in any given year, you usually have two years of EPM dollars that are available for spending, but quite honestly, the first year they're available, virtually all of them are committed. It's a very small -- you know, less than 10 percent remain uncommitted after the end of a fiscal year.

SPEAKER: So, a two-year appropriation designation means that you just have more expenditure flexibility over the use of that money and --

MR. WEIK: Right.

SPEAKER: -- you don't have the same kind of pressure to have to sort of spend it or lose it at the end of a given fiscal year. You've got more like two years to do that.

MR. WEIK: Right, and it gives you a little better planning horizon, and sometimes there are circumstances that will prevent you from getting something committed in a given time frame. Some of these monies arrive with earmarks, they are designated for certain things, and they will have to go through certain vehicles to get committed and funded. So, it allows you that flexibility to get all the money spent properly.

Now, and the other two, the no-year appropriations, those monies do not expire. They are usually re-issued -- you know, they go back and get re-issued each year. It's not like we can just go and roll them over and respend them. We will be given a target that we use to spend at certain levels each year, but the money does not expire.

For the FIFRA Revolving Fund, for example, for a number of years when we first started, we would carry

balances over. We have now gotten to a point where we are no longer carrying balances over, we're really on a cash-and-carry basis, but if there is any money left over, it just rolls over to the next year and is available for spending.

Okay, we'll move on to number 3, and this is just trying to break out the $130.7 million into some general categories. As Marcia mentioned, nearly 60 percent of the headquarters funds go into salaries and benefits. The next largest category are the (inaudible) contracts and grants, and the $13 million, 10 percent that goes right out is the state grant money. Then smaller percentages go into our working capital fund, the administrative expenses I mentioned earlier, and then less than 1 percent for travel.

We will move on to the next slide, slide 4. This just tries to present an historical picture of our FTEs since 1980, and the shading represents the beginning of the FIFRA Revolving Fund, 1989 and beyond, and it shows you the breakdown between the appropriated funds and the fee-supported FTEs.

Oh, I might -- yeah, move on to the next one.

This is really what has contributed to the fact that we can only support the payroll out of the FIFRA Revolving Fund. Since 1982, the average cost of salaries and benefits have increased from less than $40,000 up to nearly $100,000 this year, and these basically just reflect the annual 3 to 4 percent increases in the GS schedule.

On to the next. And a breakdown of a typical FTE in 2002, base salary of $76,800 and then your retirement and other benefits on top of that get the subtotal for salary and benefits up to about the $100,000 level, and that's what's actually in the payroll account. We have added another line here showing the working capital fund. This is a significant amount of money that we put into communications, computers, mainframe, infrastructure support that's handled centrally by the agency, and it amounts to about $6,300 per FTE for us in 2002.

The next one. Okay, this is starting to get into how we have split out our FTEs into the major program areas, and how we derived this data, we have a time accounting information system, and our Science

Divisions and our Special Review and Registration Divisions report into the system, so it gives us an idea of how the hours are spent and the different categories. We'll get into more detail on how the registration and the re-registration break out, but it shows you roughly an equal split between re-registration and registration, with about 10 and 11 percent for field programs and information and program management.

Slide number 8. Now we're going to look a little more specifically at the registration FTEs: 326 of the FTEs were devoted to registration in 2001; 75 percent of those went to conventional pesticides, with 14 percent-plus to biopesticides, which includes microbials, biochemicals, transgenics and pesticides in plants, and 10 percent to anti-microbials.

Slide number 4 -- I'm sorry, 9, yes, my number is a little sketchy here. Looking at the conventional pesticide part of registration, we estimate about 245 of the FTEs went into support conventional pesticides, and as you can see, about 25 percent of that went into either fast track or nonfast track me-toos, and that would be the registration of new or amending existing products,

and then another 25 percent to new AI and almost 20 percent into tolerances, with lesser percentages for the other registration categories.

SPEAKER: Can I ask a clarifying question?

MR. WEIK: Sure.

SPEAKER: Does this also include, then, this is the FTEs for the scientific review of data associated with these various actions?

MR. WEIK: Yes.

SPEAKER: So, that 24.8 percent also includes all the science reviews? Okay.

MR. WEIK: The science reviews going for new AI, right, and there will be science reviews for some of the other categories also.

SPEAKER: Okay.

MS. MULKEY: One thing that -- new AI overlap some with tolerances and things -- and so does new uses, so if you really look at -- if you distribute the tolerance work between new AIs and new uses, you get a sense of the total going to new registration activity for the most part.

MR. WEIK: Right, right.

MS. MULKEY: I mean, that oversimplifies it, but --

SPEAKER: Can you clarify that -- Marcia --

MS. MULKEY: Remember, this is registration of conventionals.

SPEAKER: Right.

MS. MULKEY: So, the tolerance piece of the pie is mostly about either new AIs or new uses.

SPEAKER: Okay, okay, that's what I thought --

MS. MULKEY: So, if you want to think about how much is going to new AI and new uses, you really need all three of those pieces of pie.

SPEAKER: Okay.

SPEAKER: So, if a science reviewer, if they account it to a tolerance, then it goes to a tolerance. If they're accounting it just to a new AI, then it goes to a new AI.

MS. MULKEY: Right.

SPEAKER: So, it's just really how it's accounting for it.

MS. MULKEY: Right.

MR. WEIK: It's really a reflection of how they

actually report it, the people that are doing the work, yeah.

Moving on to slide number 10, this is just looking at the biopesticides portion of the registrations, and again, the new AIs and the two me-too categories make up a significant portion. We do have a fairly large other category, and in that we've -- that includes such things as pre-application meetings, work planning, policy development related to registration, PR notices, efficacy, guidelines, such things as managing joint reviews with Canada, California, NAFTA work, also managing the public docket, maintaining the website, addressing data compensation issues, just as some examples, since it's a fairly large category, of what's in the "other" application review category.

MS. MULKEY: There's a clarifying question.

MR. WEIK: I'm sorry.

SPEAKER: Is there a breakout or are you going to discuss a breakout of how this -- within the biopesticides, how it breaks out, like the transgenics or the PIPs or the microbials or biochemicals? It would be kind of interesting to know how much of that budget is

actually on the plan-incorporated pesticides, for example.

MS. MULKEY: We don't have the data broken out that way, and I don't think it's available to break out that way using this methodology, which is deriving it from the reporting -- the worker reporting. So, what you have to do is get a -- sort of an informed judgment estimate by the management team or something to -- to get a handle on that.

MR. WEIK: I don't know if Kathleen has a sense of that. I don't know, it seems like it's probably a disproportionate amount, perhaps, on the plan-incorporated pesticides.

MS. KNOX: We do think that probably in that other application review category, particularly because this was 2001, that a lot of those hours that were reported did relate to the plan-incorporated protectants, and that, again, is because we had several SAP meetings. There were a lot of the activities that fall into that other category going on with your biotech products that year, but we really don't track that. We would have to go back and do an individual-by-individual summation of

the year's worth of records, and I'm not sure that that would be very useful.

MS. MULKEY: But there is no question that a significant portion --

MS. KNOX: They are costly.

MS. MULKEY: -- of the work under biopesticides is attributable to PIPs. I don't know -- disproportionate is in the eye of the consumer, if you will, but a significant portion. I don't think there's any question about that.

SPEAKER: Can I ask a quick question, and this may -- it may be a dumb one, but why is other application review for biopesticides so high versus --

SPEAKER: Yeah, good question.

SPEAKER: -- versus conventional?

MS. KNOX: Well, again, particularly for the year 2001, where there were a whole lot of things going on in the biotechnology arena, we did hold I think at least three SAPs that year. They would be counted in here and all the preparation for them. We do a lot more pre-registration meetings with our registrants, a lot more data requirement, particularly in the microbial

area, defining what the testing will be. The nature of our pesticides is different from conventionals, so we do a lot of -- a lot more of the kinds of things that fall under this category.

SPEAKER: So, do you expect this or do you believe that this may be an abnormally high number as you get more comfortable with --

MS. KNOX: I'd really have to go back and look at the year 2000 to find out whether 2001 was abnormally high. Again, it could have been just because of the biotech issues that we were dealing with in 2001.

MS. MULKEY: It's just a guess, but it's entirely possible that the people filling out their forms, working on these pesticides, sort of resorted to the other category more readily than the people filling out their forms working on the other pesticides. It could be as simple as that, or it could be that they had a disproportionate share of work that just wasn't easy to categorize.

Remember, when you're talking about a fraction of a 48 doing SAPs is a much bigger fraction of the total than it is of the 245 or on the re-registration side.

MS. KNOX: John just reminded me, the reporting form was designed for accounting reasons, and it was designed for conventional chemicals. So, when the Biopesticide Division was created, we sort of split off some categories, but I think using the data for this exercise, we need to go back and revisit that and make sure that if we're going to use those data for this kind of thing, we need to probably refine the form a little bit more and make sure that we know a little bit better that the people are putting down the categories that really apply.

SPEAKER: I have a clarifying question about the me-too designation. Are these just fast track and non-fast track amendments as opposed to me-toos?

MR. WEIK: No, both, it's both amendments and --

MS. KNOX: New products.

MR. WEIK: -- and new products.

SPEAKER: Right, so the idea that it's me-toos is a bit of a misnomer as a category, correct?

MR. WEIK: It's adding the two together.

SPEAKER: Right.

MS. MULKEY: He's talking about amendment -- yeah.

MR. WEIK: I don't think it's misleading, because they are me-toos in the sense that when they are new products, they are identical to something that's already out there. They are identical or substantially similar in their formal construction. So, the point is that they are thoroughly precedented decisions, and whether they happen to be a new product or an amendment to a previously registered product, the most important thing that -- we thought, for purposes of these pie charts -- was to distinguish the ones that did require science review, in other words, the non-fast tracks, from the ones that didn't, which were perfect matches for something that didn't require any science review.

MS. MULKEY: But you're right, it's wholly new products or amendments of products that might be added use or a formulation or something.

SPEAKER: I just -- to me, "me-too" means you're doing a new registration, getting a new registration number for a me-too product, but I'm assuming and you're confirming that in that fast track

and non-fast track, me-too slices -- that's also amendments with data or without data.

MR. WEIK: That's correct.

SPEAKER: That's all.

MR. WEIK: That's correct.

Now to slide 11, this is the split-out of the anti-microbial slice, and as you can see, the me-too categories we were just talking about combined make up nearly 80 percent of these, with the rest of it falling out into the new AIs, new uses and other applications, but very much so on the existing.

Number 12, now we're moving over to the re-registration FTEs, approximately 320 of them, and it's kind of a Pacman chart with the conventionals virtually eating up the whole pie and 7 percent going to anti-microbials and less than 1 percent to the biopesticides.

Slide 13 gets into a little more detail on the re-registration FTE distribution. Now, these are categories that on our time accounting reporting, the largest one is the current red production. This includes such things as issuance of the re-registration

eligibility documents, the reds, information updates, data reviews for the current fiscal year, reds, public docket development. The next largest slice, product re-registration, is a very busy part of it now that we're in the waning years of re-registration. Then the DCIs in red pipeline makes up the other significant portion of the breakdown of the red re-registration FTE distributions.

Okay, we are going to move over to the non-payroll side now. Slide 14 is an historical trend chart showing the non-payroll dollars. The big spike in 1989 is an influx of storage and disposal money we got that was specifically earmarked, primarily I believe for Dyna 7 (phonetic), 2-4-T Sovex (phonetic) works, so that was not something that had an impact on the rest of the program at all, but if you look at it, there really are roughly three trends here.

You have got the pre-FIFRA 88 at lower levels, and there was a bump-up with the passage of FIFRA 88, and then another bump-up with the passage of FTPA in '96, and then it's, you know, reasonably stable around those three tiers.

Slide 15 is a breakout by major program activity of those -- of just the headquarters and contract -- contracting grant funds, that's about $30 million. The re-registration makes up about a third. The field programs and communications, about a third. Registration, a little less than a fourth of that, and the rest is the information/program management slice.

Slide 16 -- yeah? Oh, I'm sorry.

SPEAKER: I actually want to ask a clarifying question. When we say headquarters contract and grant, we mean for within OPP.

MR. WEIK: Right.

SPEAKER: We are not including enforcement.

MR. WEIK: That's correct. This is OPP only, as Marcia made clear earlier.

SPEAKER: Because there is a separate allocation of money that runs through our Office of Enforcement.

MR. WEIK: This is only what we spend through OPP, right. Thank you again.

Slide 16 splits out the large field program slice into the general areas just to give you a better flavor of where this money goes. Communications

outreach, certification and training, PSP has been included here also, we have got a tribal program, groundwater, worker protection, endangered species, and this kind of gives you a feel for the field program slice and communications.

SPEAKER: So, this is only over a couple of divisions, then?

MR. WEIK: This -- right. It's primarily the field enforcement --

SPEAKER: It's the field --

SPEAKER: Field PPD.

SPEAKER: -- field PPD and IRSD. You see the FOIA dockets and --

SPEAKER: Okay, okay.

MR. WEIK: So, it's pulling in from some of those, but it's --

SPEAKER: Primarily just this.

MR. WEIK: Right, right.

Slide 17 shows the breakout of the registration contracting grant dollars. As you can see, nearly -- almost 60 percent goes to data review. Information management's about a fifth, and guidelines and methods,

less than 10 percent. Data acquisition, a couple of percentage points, and other is 11 percent. In the other category here, we've got some intern programs. They've got a senior environmental employee program, and we tried to attribute those to registration and re-registration, but we weren't comfortable splitting that below that category, so that's what makes up a large part of that other.

SPEAKER: Do you have a --

MS. MULKEY: So you understand that, those are essentially people who come and work in our midst, through a grant program, senior employees or interns. So, in effect, they are more like salary dollars than they are like grants and contracts dollars.

SPEAKER: So, these aren't contract reviewers?

MS. MULKEY: No, not the 11 --

MR. WEIK: Not the other. I was talking about the other. No, the reviewers are in data review.

SPEAKER: Would you have this -- and I don't need it right now, but can you break this out in terms of HED reviews, registration reviews?

MR. WEIK: We have it by division.

MS. MULKEY: You mean HED versus EFED?

SPEAKER: Right, right, right.

SPEAKER: Right.

MR. WEIK: Right, I mean, it can be broken out by contracts, by division, right.

Slide 18 is the re-registration portion of the contract grants, about $10 million, and data review makes up more than half of all the re-registration contract dollars. A significant portion goes to information management. A lot of the tracking of the data and things is supported by our information management, and again, the data acquisition guidelines and other fall out about the same percentages as they did in registration.

Right, right, as John pointed out, data acquisition is a little bit larger, because we purchased usage data more for the re-registration.

That's the formal slides, and we have allowed some time for further discussion.

MS. MULKEY: Yeah, all right. Okay, Larry?

MR. ELWORTH: Well, first of all, thank you very much for doing this. I mean, we have been talking about this a lot. This is nicely done, and I appreciate the

information.

Two quick questions. One is, how do you use this in budgeting, or does this have any -- does this kind of information have a use in budgeting or what other ways do you use it in management?

MS. MULKEY: Well, we have an operating plan each year in which we make decisions about sort of large categories, registration, re-registration and so forth, and so obviously we plan so that this is what comes out at the end.

Our planning process is a combination of the agency operating plan and internal decision-making that is at a somewhat more particularized level, which is -- on FTE doesn't tend to involve major movement. On dollars, a little bit more from year to year, decision-making about where the dollars need to go, but we do quite a detailed amount of planning that sort of leads to having this kind of result, and actually at a higher resolution than this.

MR. ELWORTH: Also, I would be interested in looking at slide 11 on anti-microbials for 2002, given what you folks were doing with the anthrax stuff, it

probably is -- is another one of those Pacman pie charts --

MS. MULKEY: Well, on 2002, you would have seen a big Section 18 section there.

MR. ELWORTH: Oh, really? Right, right.

MS. MULKEY: Which you didn't see in 2001 at all, you did on registration. So, that would be an example of a very significant change, but that's unusual.

MR. ELWORTH: Right, right.

MS. MULKEY: These things are pretty -- the macro is very stable from year to year, the division between registration and re-registration, for example. Even at this level of resolution, it's pretty stable from year to year. You'll see trends. You heard some regarding product re-registration growing and -- but that is an example of one where you would have seen a pretty meaningful shift.

MR. ELWORTH: Would it be possible at some point to see the data review on contracts broken out, I mean -- by HED versus -- on 17 and 18? Right.

MS. MULKEY: You're talking about within registration and/or re-registration, broken out --

MR. ELWORTH: On slides 17 and 18 where you had the contract for data review --

MS. MULKEY: And you want it broken basically by support of the HED work versus EFED work?

MR. ELWORTH: Yeah, and I don't want to give you a whole lot -- I'm just generally interested, if it's --

MS. MULKEY: That's probably doable.

MR. ELWORTH: I'd be interested. Thanks.

MS. MULKEY: Yeah. You would want to look at the split for re-registration and registration, because they may be making different choices about FTE versus contract approach.

MR. ELWORTH: That's a good point.

MS. MULKEY: Jose?

DR. AMADOR: My question is related to, you know, his question on budgeting, how you use this information. The way I see it, in budgeting, in how much money you actually get, there's four forces that come into play here, right? One is the OPP, what you plan and you decide you're going to need. Then that has to mesh with the agency, with what the agency thinks, you know,

you're going to have. Then the administration I guess decides, you know, how much they're going to go forward. Then Congress decides.

How do you work all those four things into -- what is the play there?

MS. MULKEY: Whoa.

DR. AMADOR: And which one is --

MS. MULKEY: I mean, at the risk of seeming to be unresponsive, we really did want to sort of keep the scope of this dialogue today to the expenditure side and OPP specifically. Now, I'll try to make at least a broad brush answer to your question, but this issue -- you know, there is budget planning. There's everything that wraps up to the President's budget, and that's -- your questions seem to go to that issue, which is how does the Executive Branch develop the Government that the President reports to the Congress? And you're right, there's initially an internal to the AAship, which we include our regions and we involve the states and some of our sort of customers and partners like OECA and ORD, and we develop an approach for the internal dialogue.

Then there's the agency-wide dialogue, in which

the administrator makes some choices about priorities, basically what kind of things are going to grow, what kind of things are going to shrink and what the total -- they're given a mark by OMB. So, she's not allowed to just pick an amount of money and ask for it. So, within that mark, she then makes agency-wide decisions. That then goes to OMB. The Executive Branch -- OMB on behalf of the President and the Executive Branch develops a package for the entire federal budget. So, there are trade-offs made at that level.

Then the budget is submitted to the Congress, it's the President's budget, and the Congress just passes it. No, the Congress obviously makes decisions about what to actually appropriate, and I mean, how do we do all that? By a series of annual exercises that involve all of the key players, the green eye shade types and the macro programmatic types.

(End tape 2-A.)

MS. MULKEY: And everybody in between.

DR. AMADOR: Yeah.

MS. MULKEY: Okay? I mean, that's really the best I can do with the question for this forum.

DR. AMADOR: And that really goes on year-round, right?

MS. MULKEY: Every year there's a cycle and a season by which it goes on, and of course, it builds on previous years. I mean, things don't just sort of start in a vacuum.

DR. AMADOR: The slide that you showed with the three different areas, that's very illustrative of what -- you know, what goes on, you know, the FIFRA time, then what happened after FIFRA, then what happened after FQPA. You can really see the levels there and how --

MS. MULKEY: If you look at the slide on number of FTEs and the slide on dollars, that really gives you a sense of what scale of program we have, what kind of change-over time, degree of stability.

DR. AMADOR: Are these real dollars or are these dollars for every year, right?

MS. MULKEY: These are -- they are --

MR. WEIK: They're not adjusted.

DR. AMADOR: They are not adjusted for inflation.

MS. MULKEY: They are not adjusted. They are

absolute dollars.

MR. WEIK: Right.

DR. AMADOR: The fact that from '97 to 2000 higher in real dollars compared to pre-FIFRA, there may not be that much difference.

MR. WEIK: That's true.

MS. MULKEY: Well, especially when you have some big inflation years in there.

MR. WEIK: That's true.

DR. AMADOR: Thanks.

MS. MULKEY: I believe Stephanie had her card up, and then I will come back over here. I'm really -- let me get my classes on. Lori I was looking at and seeing S T E P and trying to put -- Steve had his card up. My apologies.

STEVE: Could you go back to I think it's slide 7?

MR. WEIK: Which is --

STEVE: We talked about the working capital fund of $6,300 per FTE. Could you explain that again? Shouldn't that be in a capital account or -- that's 6, sorry.

MS. MULKEY: It's a term of art that EPA uses. Doug, why don't you explain the working capital fund.

MR. WEIK: Yeah, I think it was about three or four years ago, they established the working capital fund. I think EPA is one of several agencies that was an initial pilot, and it's like a revolving fund. It's to try to support all of our communications, postage, such things as desktops for all our computer desktops, the LAN, our local area network, all of these kind of infrastructure communications, computer type of things, and it -- in 2001, I think it was about $5.2 or $5.3 million that OPP had to put in as our share to support that, and that's what made up that $6,300 per FTE.

MS. MULKEY: Let me try and add a little bit to that. There's overhead, as I explained, the agency takes some things off for overhead. A portion of what used to be treated as overhead is now being managed by the agency by setting up that function but funding it by the purchase, buying into it, of the various customers for that subset of overhead. So, we in effect have to either go out on our own with our own money and buy these functions, some of which are not really -- you can't.

MR. WEIK: We can't, right.

MS. MULKEY: Or we have to pay the price that the agency is charging us to get those functions performed. So, we, and I expect the entire rest of the agency, pays the per capita cost to the suppliers of that subset of overhead in order to get it. It's just a different way of keeping the overhead books.

SPEAKER: Okay, thank you.

MS. MULKEY: Now we will come back over here to Erik, now that I've got my glasses on.

MR. NICHOLSON: I was wondering if you've -- have you done a careful analysis of roughly what percentage of the cost of reviews and re-registration reviews is paid for by the registrant fees as opposed to comes out of, you know, general revenue?

MS. MULKEY: Yeah, why don't you put the chart --

MR. NICHOLSON: I saw the general overview numbers, but do you have that on --

MS. MULKEY: Well, those fees are assigned to people working on fast track and re-registration, and for a while they paid the salaries and benefits --

associated benefits for 200 people. Now they pay it for --

MR. WEIK: It's probably closer to about 170 we're able to support.

MS. MULKEY: 170.

MR. WEIK: Just because of the cost.

MS. MULKEY: Because of the cost, and those people are all working on re-registration and/or fast track.

MR. NICHOLSON: But you have other people working on that as well, presumably.

MS. MULKEY: Well, if you look at the numbers on FTE -- put up the one on re-registration, for example.

MR. WEIK: Yeah, where is that?

SPEAKER: (Inaudible) where we have got 38 percent of 833 --

MS. MULKEY: Well, you have got one that actually has the number on it.

SPEAKER: (Inaudible.)

MS. MULKEY: If you look at the chart, 320 FTEs --

MR. NICHOLSON: I was kind of doing the mental

math, but it seems like it's a -- what's the ballpark, 20 percent, 25 percent?

MS. MULKEY: Well, it looks like it's closer to maybe -- but not all 170 are working on re-registration, because some are working on fast track, so that's about --

MR. WEIK: Traditionally, when FIFRA 88 passed, it was set up so it was supposed to be roughly split between the two appropriated versus fees, and for some years it ran about 50/50, would waiver between 51/49, either way. Now, because we don't have enough fees to cover, I think the appropriated portion has, you know, moved up into the 55, you know, 56 range, and --

MS. MULKEY: Probably higher than that.

MR. WEIK: And it's getting higher each year.

MR. NICHOLSON: I was trying to do the mental math, and I don't think you can do it from the stuff that's here.

MR. WEIK: Right, right.

MS. MULKEY: Well, a very crude estimate would be subtracting 17 -- I mean, what portion is 170 of 320?

MR. WEIK: Right, right, but since the funds are

interchangeable, I mean, we can use appropriated or FIFRA funds, we don't even really look at the color of the money other than we -- the FIFRA funds we always make sure that we are looking at folks who have reported they're working on re-registration. We have to make sure that they -- the fee monies support that, but other than that, I mean, it doesn't really matter and we don't try to send fee monies to one division versus another or anything like that. We just try to --

MR. NICHOLSON: I just think it would be useful for this committee and others to see EPA's actual numbers on that, what percentage over time has gone, you know, of the fee has been paid for by fees as opposed to by general revenue.

MS. MULKEY: Contracts and grants just -- I think we can do that calculation. Doug can do it, just add up the cost of the FTE and the cost of the contracts and grants, but because of fast track, that confuses it a little bit.

MR. NICHOLSON: There are a lot of complications. I don't think it's -- you can't just sit and look at this, I don't think, and answer the question.

MS. MULKEY: Right, right.

MR. NICHOLSON: My other question is, I thought this was really useful. I'm wondering if perhaps we could get something -- Burleson, whether there might be an opportunity to get something like this from USDA, in particular looking at what percentage of USDA's funds go to SARA (phonetic) and to various pesticide-related activities, just because I think it would be really interesting for us in viewing how the money is being spent over at USDA. I don't know if you guys have ever done that kind of presentation.

SPEAKER: There are various cuts that are given looking at some of the program-related areas. The problem is is that as you start getting into the details, as with most of the accounting systems, they're set up primarily for management of either program areas but not necessarily subsets of the program areas, and so it's difficult to cut out some of the details, to split them out rather, but there are aspects of that that are ongoing.

MR. NICHOLSON: Well, do you have, for example, estimates of how much of the USDA funding is going

towards AIPM/SARA/those -- whatever we're calling it these days versus other expenditures? I'm assuming you've already done this. I --

SPEAKER: Personally, I do not. Yes, there are estimates of those within each of the mission areas, and part of it would be a matter of collecting it and pulling it in, so...

MR. NICHOLSON: I at least think it would be very interesting for this committee to at some point hear about that, because I know a lot of the dialogue between EPA and USDA is specifically on these issues, and it would be really interesting to see some kind of information about that. Maybe it is a CARAT issue, I just heard somebody say that over there, but it does seem like it would be very useful information.

MS. MULKEY: You know, most parts of EPA would have difficulty providing these kind of pie charts, because they don't have time accounting systems for their workers. Now, the dollar ones, grants and contracts, you can -- everybody in EPA could do with very good precision, but the ones that -- the FTE part, time and accounting systems are -- we're sort of unusual at EPA

in having it. Now, the Super Fund program has them.

Warren?

DR. STICKLE: I really had two questions. If you go back to chart number 2, it breaks out the amount of dollars that were put into the revolving fund, realizing that the monies come from two different sources there, maintenance fees on one hand and also the tolerance fees on the other, also realizing that some years you raise more money than you're allocated and sometimes you raise less, that it goes up and down over the years. It would be interesting to see a breakout of how much money's been collected in maintenance fees and how much money has been collected in tolerance fees over the years.

MR. WEIK: Over the -- I don't have it for over the years, but in 2001, we collected $15.4 million in maintenance fees and $1.4 million in tolerance fees, and you'll notice we actually spent more or about -- I'm sorry, that was the -- that was just about right on, okay. So, basically we were in a cash-and-carry situation. That's virtually what we spent.

DR. STICKLE: Well, and the number of

maintenance fees has gone up and down over the years, and in 2001, for example, it was $14 million. So, really you were able to collect $15.4 million of that --

MR. WEIK: I'm sorry, I'm sorry, we collected -- yeah, I misread my note here. We collected $15.4 million in total, $14 million maintenance fees, $1.4 million tolerance. I was misreading my note here.

DR. STICKLE: That doesn't get to 16.8.

MR. WEIK: That's right. So, we had a little bit of a carryover going into 2001.

MS. MULKEY: We were spending previously collected --

DR. STICKLE: I don't understand that. See, that's the point I was trying to get to.

MR. WEIK: Yeah, 2001 was probably the last year we were able to carry any kind of substantial amount from a previous year.

DR. STICKLE: It would be worthwhile if it was actually broken out on a year basis just to see the ebb and flow of how those finance fees are collected.

MS. MULKEY: I think it's all ebbed.

DR. STICKLE: But it is -- but in the very

beginning, it was -- you were collecting less than you were supposed to, so...

The second question I have deals with chart number 9, and on the conventional pesticides, you break out the amount of inert clearances and work done on inerts, but on the next two charts, for biopesticides and for anti-microbials, there is in breakout on costs for inerts, and I was just trying to get a better handle on the total amount of monies spent on inerts, and that was not reflected -- it's probably buried in there someplace, but I wondered if we could clarify that.

MS. MULKEY: Well, remember that what drives this is what people reported on their time sheets.

DR. STICKLE: Right.

MS. MULKEY: For starters, but most of the inert work is done in the Registration Division.

DR. STICKLE: Right, I understand.

MS. MULKEY: So, in all likelihood, if they were doing inert work on a chemical that was an anti-microbial chemical, it was showing up in this conventional category under inerts, would be my guess.

MR. WEIK: Or those two divisions just were not

reporting work on --

MS. MULKEY: Right, that they were reporting it some other way. It's either a difference in reporting --

DR. STICKLE: Right, right, I understand.

SPEAKER: (Inaudible.)

MS. MULKEY: But a lot of the inerts cut across chemical classes, and most of that work is done in RD, so it's probably most of the work done on inerts anywhere is showing up on this one pie chart.

Julie?

MS. SPAGNOLI: A lot of work has been done over the years on trying to -- like the rejection rate analysis and streamlining efforts and different things to try to I guess reduce cycles and increase efficiency. Has there been any analysis done to look at, you know, like kind of the numbers of actions versus the FTE equivalents put to that, are we seeing a reduction in, let's say, the amount of hours or FTEs that go into, you know, any -- like per fast track action or per new registration, just to see, are we seeing a trend in some kind of increase maybe in efficiency due to some of

these -- I guess like trying to reduce cycles and reduce rejections?

MR. WEIK: It's been a number of years since we've done a real systematic analysis along those lines, probably -- actually, it was pre-FQPA for certain --

SPEAKER: '94.

MR. WEIK: -- and a lot of that work was done specifically around the beginning of the creation of the Anti-Microbials Division, because you're trying to figure out how large the division ought to be, but it's been pre-FQPA since we have done something along those lines.

MS. MULKEY: If you had enough confidence in these data and you produced them year to year -- and remember, these data are derived by the time and accounting system, and that is the FTE data as opposed to the other dollars. Then you obviously could overlay them with production.

The problem is that a year's outputs are not necessarily the same as that year's input. This measures inputs in that year. Now, for fast tracks, probably matching it with the same year would work very well.

MS. SPAGNOLI: Or if you were going to look for

trends.

MS. MULKEY: Even for me-toos, but I think you probably could derive, at sort of a crude level, some sense of how much you're spending for how many outputs.

MS. SPAGNOLI: I think just to see are we seeing some positive impacts or --

MS. MULKEY: I will tell you this, new use outputs are up dramatically, and new use inputs are pretty stable, so there's one where I think there's not much question.

SPEAKER: (Inaudible) Section 18s are very clearly the efficiency gains have been dramatic in the last five years.

MS. MULKEY: I mean, you can sort of see that without much further analysis.

Jay?

MR. VROOM: I'd like to echo the comments that several people like Erik have made, that I think this is -- represents a lot of forward progress and is serving the needs of -- kind of the larger interests that many of us are engaged in forward looking on, you know, how to advocate that the Congress continue appropriations as

well as wrestling these various difficult fee issues.

One of the things that occurs to me is that the best detail here that feels to me like it's new and comprehensive is embedded in these pie charts, and what seems to be lacking to me, though, is any kind of historic perspective, in other words, they are one-year snapshots in a vacuum, and I would ask that you get us comparative prior year and '03 budget projection parallel pie charts for each one of these.

I don't know when you're going to close FY '02, I mean the fiscal year ends September 30, so when do you think reasonably you could give at least a reasonable forecast, comparative detail, for each of these pie charts for FY '02 do you think?

MS. MULKEY: Doug, do you have a sense of that?

MR. WEIK: Well, they close what they call the 13th month or whatever around the 4th of -- no, it would be about the 4th of November, it's about 30 days afterwards. So, I mean, we would have some figures at that point. Obviously, since the 2002 appropriation will still be alive all through 2003, there will be further spending going on, and those numbers would change

somewhat, but probably we'd have 9 -- at least 90-plus percent spent, probably higher this year, because we seem to be more strapped.

MS. MULKEY: Well, the FTE part would be very -- the FTE -- how about just the FTE piece of it, the piece that's dependent on the TIAAs?

MR. WEIK: That would probably be about four weeks also, because --

MR. VROOM: Because the sooner we have that for, you know, our fees working group, whether or not it's '02 accurate or just the '99 and '00 so that we have some kind of perspective just to get a sense of the comparative trend lines in some of these accounts I think will help us get a better feel for driving down detail around advocating both resource appropriations and fee decisions the Congress will be looking at hopefully very soon.

MS. MULKEY: You are putting us slightly -- so, we will be happy to do this in the interest of transparency.

MR. VROOM: Right. On the working capital fund issue, Doug, you mentioned that EPA is one of several

federal government departments that have switched to this or been either told by OMB to switch to this kind of cost accounting.

MR. WEIK: The capital funds?

MR. VROOM: Yeah.

MR. WEIK: I don't know if we were necessarily told. I think we were -- officially we volunteered, but we probably were told.

MR. VROOM: What are the other agencies, and have you done any comparison in terms of, you know, the benefit or --

MR. WEIK: See, I have -- we really have not. It's centrally run through EPA. They may have some things -- it's actually its own enterprise really, supposedly a self-supporting group, the working capital fund.

MR. VROOM: So, do you serve on an agency-wide committee that oversights this or is this a black hole in the administration.

MR. WEIK: I believe there is a representative on my staff that participates and there is an executive committee that oversees it.

MR. VROOM: So, 4 percent or $6,300 per FTE for the FY '01 that we're looking at here, how does that compare to FY '00 or '02? Do you have any --

MR. WEIK: It's staying pretty steady. The dollar amount itself has been growing slightly, so if anything, it may be inching up a little bit, and I think that's just -- you know, it's supporting staff down there as well as the systems themselves. So, I mean, it's probably a reflection just of their costs kind of inching up a little bit. I think it was 5.2 or 3 million in '01. We are looking at probably $5 and a half million for '02.

MR. VROOM: Yeah. So, it's only $5 million, but I would think, Erik, you, Wesley, Carolyn and I and others that are working on this fee initiative with Steve probably would be interested in a lot more comparative kind of detail, because that's, you know, $5 million is real money in the context of what we're trying to get at here.

MS. MULKEY: But remember, Jay, it's just a portion of what is overhead, and the rest of it doesn't show up in our budget at all, because it never gets

there.

MR. VROOM: The $5 million does, though.

MS. MULKEY: The $5 million does, but I'm saying it's just a portion of the total agency overhead.

MR. VROOM: Yes, but then there's another 2 and a half percent for administrative expenses, right, if I'm understanding --

MR. WEIK: That's correct.

MR. VROOM: -- that slice on slide number 3.

MR. WEIK: That's correct.

MR. VROOM: So I mean there's another piece that agency overhead, you know, is carving out.

MS. MULKEY: That's our overhead, though. That's our overhead.

MR. VROOM: That's yours.

MR. WEIK: That's our training, our furniture, supplies.

MS. MULKEY: Everything else except --

MR. VROOM: So, the only money going to the administrator's office is the 4 percent.

MS. MULKEY: Well, going back to some other fraction of the agency. The administrator's -- the

operation of the administrator's office is not included in the working capital fund.

MR. VROOM: Okay.

MS. MULKEY: It -- that's why I'm cautioning you. It has certain functions in it --

SPEAKER: Telecommunications, we would have to pay for our own phone system if we were not paying into this, which would not be cheap. We would have to pay for our own LAN system if we were not paying into this, those kinds of things.

MS. MULKEY: But it's a subset of agency-paid overhead, and whatever's in it is in it, and even comparing the other agencies, you would have to first find out what did they put into that function?

MR. VROOM: True.

MS. MULKEY: So, that's just the caution. I mean, it's relevant, but you want to be sure that -- if what you're thinking about is overhead -- agency overhead, then that's a piece of it, and so is the piece that never gets to us.

MR. VROOM: Yeah, okay.

SPEAKER: (Inaudible.)

MS. MULKEY: Right.

SPEAKER: The working capital fund, $6,300, comes to us and then we get it back.

SPEAKER: That's logical.

MR. VROOM: On the slides, I think it's 12 and 13 -- no, 11 and 12, the pie charts that talk about re-registration -- 12 and 13, re-registration, FTE distribution. Anyway, the reference to 320 FTEs, most of what we've been operating off of was the assumptions that 200 FTEs are paid for out of -- by the maintenance fees, so of the other 120 FTEs, are they funded, then going back to slide 2, out of EPM or science and technology account or both? How do you make those allocations?

MS. MULKEY: First of all, as we said earlier when talking to Erik, it's closer to 170 whose salaries can be paid. The rest are EPM --

MR. WEIK: And there are some S&T where the labs report that they're --

MS. MULKEY: A few, but not much.

MR. WEIK: -- that they're supporting re-registration. Again, it's based on how they report their --

MS. MULKEY: Right.

MR. VROOM: So, you are going to work at trying to give us more of that kind of detail then, right? Okay.

MS. MULKEY: The specific question of the fraction of re-registration and fast track --

MR. VROOM: Right.

MS. MULKEY: -- that are paid with fees and the fraction that are paid with appropriated funds, I mean that's essentially the question.

MR. VROOM: Yeah, right.

Another issue that's come up as we're looking at the maintenance fee question for the new fiscal year is the oversight of some amount of charge for rent that hadn't been accommodated in FY '02, I forget how much it was, but it's some millions of dollars --

MS. MULKEY: For the labs, is that --

MR. WEIK: No, no, that's the OARM piece that is taken off. That's the agency overhead equivalent coming out of the FIFRA fund.

MS. MULKEY: Oh.

MR. WEIK: About $1.9 million a year.

MS. MULKEY: Doug can explain that.

MR. WEIK: That would never come to us. It was like, you know, you'd collect so many fees, and then there would be about $1.8, $1.9 million would go toward supporting those FTEs. Again, this would be the equivalent of the agency overhead we don't see in the EPM side.

MR. VROOM: And this attributed to rent?

MR. WEIK: Largely to rent, goes into the office of OARM, I think it's the administrative resources management group that handles the leasing of the buildings and that type of thing.

MR. VROOM: So, can you get us a slide that would sort of capture that, then? That's something new for FY '02.

MR. WEIK: No.

MR. VROOM: No?

MR. WEIK: No, it's been going on ever since the fund was initiated.

MR. VROOM: Okay. So, where is that -- in the slides that we've got here --

MR. WEIK: It's not money that we see. It never

comes to us, and I don't even know how -- it goes -- I know the amount after the fact. We will get a report from the Comptroller's Office, how much was spent, but there's no way that I see it during the year or anything like that.

MS. MULKEY: Just in the interest of keeping this within the scope of what we brought, for things that don't come through to OPP, let us take it back to Steve's budget office and express your interest in a better understanding of that, okay?

MR. VROOM: Okay, but it is material here to the issue.

MS. MULKEY: To your issue, absolutely.

MR. VROOM: Let's see, my last question, just as an example, we talked yesterday about cumulative risk assessment and the Life Line cumulative risk software development, which was done pretty much with -- by outside contractors. Where will that money be? How much is it over the string of years that it's been in process? And have you spent the last contract dollars on Life Line, or is it continuing, et cetera?

MR. WEIK: I believe it falls under the

guidelines and methods slice is where that is picked up. The -- and I'm not sure what the status of --

MS. MULKEY: On any particular investment, we can give you very precise accounting. So, if Life Line is what you're interested in --

MR. VROOM: Yeah, specifically I am, but I'm also interested in sort of as an example context here, so that's great.

MS. MULKEY: If you are interested in what fraction is going for that kind of thing, in '01 it was this 6 percent here, and it was a comparable number in registration, and some of that's because some of this work is for both.

MR. VROOM: How do you make that decision?

MS. MULKEY: Well, we -- this is -- was our attempt, remember, to be transparent about what we actually spent. When we go and buy a Life Line, we don't see, all right, what fraction of this are we buying for re-registration, and what fraction are we buying for registration?

MR. VROOM: Um-hum.

MS. MULKEY: So, you don't buy it --

MR. VROOM: You say you don't do that?

MS. MULKEY: No, you don't buy it asking yourself that question. You buy it because you have a need to have a capacity which will be used initially in a re-registration context in that example, and over time in both.

MR. VROOM: But then subsequent --

MS. MULKEY: What we did was sort of an after-the-fact effort --

MR. VROOM: Right.

MS. MULKEY: -- to attribute guidelines work to the appropriate piece of the pie, and we did some of it pro rata, we did some of it where we thought it was primarily one or the other, but --

MR. VROOM: And those kinds of contract expenditures for a capital good, whether it's computer software or bricks and mortar, whatever it is, but that is strictly attributable to OPP are expensed every year. They are not like in a private sector business capitalized and depreciated over time or anything.

MS. MULKEY: They are expensed when you pay for them.

MR. VROOM: Right.

MR. WEIK: Right.

MR. VROOM: So, some of that -- those kinds of decisions may end up being incorrect in terms of the arbitrary decisions you might make between allocation against registration and re-registration?

MS. MULKEY: Remember that, you know, we keep careful books, but we don't necessarily keep them around these pie charts.

MR. VROOM: Yeah.

MS. MULKEY: And this was designed for your needs, and so we did some things around some issues like that in order to work in the pie chart.

MR. VROOM: Sure. Yeah, great. Thanks.

MS. MULKEY: Bill?

MR. TRACY: Yeah, on the FTE distribution pie charts, these are look-backs based on reporting based on time charts and all that. To what extent -- I assume -- did you collect this just for the purposes of this group and reporting out, or -- and were there any "ah-has" in looking at those distributions, and will you use that information to guide or re-allocate people to

different efforts? I mean --

MS. MULKEY: Let's back up.

MR. TRACY: Or is this just a report out, yeah, this is what we did --

MS. MULKEY: The accounting information is collected for a lot of purposes, so it wasn't obviously collected just so we could do this presentation. This particular, exact template for looking at the information we did do for this presentation. We had not done exactly this template before.

MR. TRACY: And were there any "ah-has" for you on that?

MS. MULKEY: Were there any "ah-has"?

SPEAKER: Well, I mean, we had --

MS. MULKEY: Mostly it was just what I thought, thank God.

MR. WEIK: We have done this type of analysis over the last ten years multiple times.

MS. MULKEY: Right.

MR. WEIK: So, I think most of us on the senior team have looked at various versions of this over the last ten years, and as Marcia said, it sort of comported

with our last recollection.

MS. MULKEY: Yes. I mean, we hadn't done exactly this exercise using exactly these input data, but we pay very close attention to such issues as a basic split between registration and re-registration, and you know, you know where you're spending your dollars and you know where your FTEs are sitting and you know what they're working on, and this was largely -- I would say that there were a few -- I don't know that there were "ah-has." There were a few subtleties that some of you have keyed on, that you sort of said, well, that's interesting, what do we think is going on here?

I found, for example, the first time I saw the pie chart, they had communications and outreach or information, had a pretty big chunk, and I thought, wow, what is that all about? Then when I learned that included FOIA, it included the grant that we give to the National -- the 1-800 number, NBTN, then, oh, yeah, all right. So, there was a little of that kind of thing, but I didn't -- did you experience any "ah-has"? Did you guys when you saw this?

SPEAKER: We are, though.

MS. MULKEY: Actually, I have picked up some conventional wisdom on the outside that there had been some major torque, for example, away from registration toward re-registration, and I was quite confident there had not, but, you know, this kind of thing helps you sort of be transparent about that, and you can pick up that perception if some -- you know, if three people who work on X start working on Y, that can become conventional wisdom that we've redirected all the resources from X to Y, and so I think it's been really useful in that regard, and I agree with Jay, that you want to look at more than one year just in case you didn't pick some sort of oddly anomalous year, but we're also quite confident we didn't do that.

MR. TRACY: Right. And I guess my only other question, on some -- I'm sort of confused on the accounting of -- when you have like BPPD -- the self-contained units, like anti-microbials and BPPD, how you look at things like re-registration and fast track and allocation when you go to some of these re-registration -- like the pie chart on 13, is that a cumulative, all-division kind of breakout, or is that

just R&D?

MS. MULKEY: All of them are cumulative, all division. So, it's at least theoretically possible that you'll get some work done outside of BPPD and AD for the anti-microbial pie chart and the biopesticide pie chart.

MR. TRACY: Right.

MS. MULKEY: And in fact, we're pretty sure you may be getting a little RD work on biopesticides that are not managed -- not -- that's a term of art -- on biological, we're pretty sure we're not --

MR. WEIK: What we do is the product re-registration happens in Registration Division AD, BPPD and SRD. I mean, everyone who does work in the program has the same form. It doesn't matter where they are, they're all looking at the same form, and they're -- every other week, they fill out what they did.

MR. TRACY: Got it, okay.

MR. WEIK: So, it doesn't really matter where you sit. It matters what you actually were working on.

MS. MULKEY: And yes, they are all cumulative. BEAD is showing up everywhere, but the self-contained divisions I would guess is very high percent comes from

within them.

John, did you --

JOHN: With respect to this particular chart, which is numbered 13, because the sliver for re-registration (inaudible) was so small, we didn't break them out. This is everybody. This is the undifferentiated --

MS. MULKEY: Oh, I see.

JOHN: -- (inaudible) for re-registration by (inaudible). If you take that 9 -- (inaudible) break it down like this (inaudible). BPPD and AD presumably did not conduct any special reviews (inaudible), but for the three big sites, it's almost certainly about the same.

MR. TRACY: Okay, thanks.

MS. MULKEY: Okay, Steve.

MR. BALLING: Okay, this is exhausting.

MS. MULKEY: But you're interested.

MR. BALLING: Of course. We're always interested in budgets.

SPEAKER: (Inaudible.)

MR. BALLING: Tell me about it, with an E on it.

Slide 3, 24 percent of total OPP funds go to

contracts and grants, and if you look back at one of these other slides, 60 percent of that is data review. I'm curious, have you had any -- and I think your answer to Julie probably suggested you don't have this information -- but have you had any opportunity to look at sort of productivity on a cost or on -- cost on a per unit productivity basis, so you have some sense whether going out to contracted reviewers is more or less efficient on a cost basis?

MS. MULKEY: Well, we don't use our contract reviewers, for the most part, the same way we use our internal reviewers, so there's a difficulty in comparing apples to oranges. We did do an exercise this year about what kind of our work was susceptible -- that's being done by employees now is readily susceptible to being done by contract, and there were some analyses conducted in connection with thinking that through.

There are -- over time, there have been a number of analyses done about what it costs to have a government worker do something versus what it costs to have a contractor do something. The real truth is it depends on how immediately useful the contractor-produced

work is, and the higher order the work goes, the more complex it goes, the more it requires an understanding of how it fits with the rest of it, the less immediately useful it is. So, it's -- you have to find some way to compare apples to apples.

We might have the capacity to do that, where we have pockets of doing the same exact sort of sit at the desk, review work that we're contracting out that we are still doing internally, but even that, because it's pockets, it might be being done by our more inefficient people, and that's -- I mean, there are -- you know, I think it would be very hard to --

MR. BALLING: And there is always intangibles, I understand that.

MS. MULKEY: Right.

MR. BALLING: But I --

MS. MULKEY: But there is no question that we need to pay attention whether what we're contracting for is being done smart, in a smart way.

MR. BALLING: Yeah. Well, the reason I asked is that if you look two slides over, page 5, and you look at the average cost of salary per FTE over time --

MS. MULKEY: Right.

MR. BALLING: -- I don't know, Doug, you mentioned that was just cost of living raises, but it sure seems faster than we would expect at Del Monte. We wouldn't want to see something like that. It -- I think it reflects an age structure issue, that you have a lot of senior people.

MR. WEIK: Yeah, I think that certainly is a factor.

MS. MULKEY: That's part of it. Part of it is we've been hiring pretty -- part of it's this function of contracting. The more routine work you contract out, the more it becomes important that you fill your work force with --

MR. BALLING: Senior people who are --

MS. MULKEY: -- senior -- or, you know, pricier people. Part of it's what's happening with regard to support staff, and this must be happening in the private sector, too. We don't have typists and keyboarders and data inputters. I mean, we have very, very few people in the grade 5, 7, 9, even 11 range, and that used to be a very high percentage of the federal

work force, because the -- you know, the functions that were associated to that are now done by the higher graded people and/or by machines. So, there's a lot of factors that drive this.

What might give you a handle on how pricey is OPP is how do we compare per capita with other parts of EPA headquarters, and we're on the high end. We're not through the roof, the top. We're above the 50th percentile.

MR. WEIK: We're in the top third, I think.

MS. MULKEY: Yeah, so that helps you get at it.

MR. BALLING: Well, that's not really what I'm getting at necessarily. What I'm thinking is with that age structure, that age distribution you have, you're probably going to be seeing a fair number of retirements in the next decade.

MS. MULKEY: We are watching that very closely.

MR. BALLING: And do you go to contracted outside work or do you try to bring it internal? That thing will probably flatten out a little bit in the next decade, I presume, because of the retirement --

MS. MULKEY: I don't know, benefits are going up

11 percent.

MR. BALLING: That's true.

MS. MULKEY: The private side is going up 11 -- what I pay is going up 11 percent next year. I assume the Government side is going up at least comparable, so I don't know about that, but --

MR. BALLING: Okay, but if that was just a salary distribution --

MS. MULKEY: Okay, well, you're assuming a rational model about the way people --

MR. BALLING: I know, assuming rationality is foolish, but --

MS. MULKEY: -- but as you know, there are FTE caps in government, and ours have been declining; that is, EPA-wide and OPP. So, while you can go below your cap, you can't go above it. So, you can never make the decision to hire more people no matter how much more efficient it is to hire people than it is to contract, and you can never make the decision to hire two cheap people instead of one expensive person.

MR. BALLING: Right, right.

MS. MULKEY: So, you have those constraints in

the system which make it harder for you to think through those things. We're in a declining FTE mode, so we are by definition not replacing everybody who leaves and making choices about how to get the work done that include more aggressive use of contracting where we have dollars available.

Within that, we have made -- and we did it thinkingly -- the choice that we should maintain a full work force and pay the salary costs associated with that, and we made that based upon some of these analyses about whether we have viable functions that are readily shiftable away from the federal work force and decided that as a practical matter we did not.

But other than that, there's not a lot of choice in that system, between those two kinds of expenditures.

MR. BALLING: Actually, I am not a big proponent of contracted services. It hasn't worked real well for us necessarily, but I know those kinds of pressures are going to come to bear.

With re-registration, you know, presumably winding down over the next three-plus years, will you find the need for FTEs declining?

MS. MULKEY: Well, registration review is built into FQPA, that contemplates a 15-year cycle, and the first pesticides that would -- have not gone through re-registration date from 1984 --

MR. BALLING: About 15 years from --

MS. MULKEY: -- which is, what, 17 years and counting, and the complexity, the science, the issues for reworking pesticides doesn't seem to me to be likely to be cheaper for the next 15-year cycle than it was the re-registration cycle, although it's possible. It's possible to have some kind of major breakthrough where you have a lot less data, because you have genomics or, you know, it's possible you will get to some place where the level of effort necessary to revisit the database and the risk of a pesticide changes, but that certainly doesn't seem to be true in the sort of first wave of the post-'84s.

MR. BALLING: Of course, we're also seeing new targets, end points that we have to keep looking at, which also --

MS. MULKEY: But that's part of the -- it's the science changing complexity and all that goes with it,

you know, what kind of data you look at, what issues they present, not to mention a few little things like aggregating exposures and accumulating common mechanism groups and so forth.

MR. BALLING: Okay, thank you.

MS. MULKEY: Oh, I'm sorry, Pat.

MR. QUINN: I think I was also interested in the break between contract dollars and FTEs, and I guess I was surprised, looking at chart number 17, I just want to make sure I'm understanding that, that data review, contract data review, according to that chart, is only about $4 million a year. Is that right?

MS. MULKEY: That's for registration.

MR. WEIK: This is only registration.

MR. QUINN: Just registration.

MS. MULKEY: And then the --

SPEAKER: (Inaudible.)

MR. QUINN: Right. I guess still I'm a little surprised by that and sort of wondered if you could comment, looking out, which you just have to some degree, you know, whether or not you see that trending --

MS. MULKEY: Shifting to --

MR. QUINN: -- and I mean, I know that the Anti-Microbial Division's re-registration strategy is heavily premised upon contract dollars.

MS. MULKEY: Right, and in Biopesticides and Pollution Prevention Division, we shifted what in absolute dollar terms was a very modest sum, less than a million dollars, but in fact, we'll make a fairly material shift in their balance between FTE and contract use, so yes, it -- the margins, you see there is a trend.

But the other limiting factor is that we don't have an infusion of contracting grant dollars either, so if you were to go dramatically into data review, that either has to come from salary or it has to come from other expenditures of contracting grant dollars.

MR. QUINN: Right.

MS. MULKEY: And those are basically your choices. So, you would have to decide that contracted data reviews were a higher priority than either what else you're spending your contracting grant money on or what you're spending -- or your work force.

MR. QUINN: Generally, I mean, Jay is trying to

look ahead at, you know, the 2002 kind of data. Are you able to give us back years as well? Is it --

MS. MULKEY: Yes.

MR. QUINN: Is that available in this kind of format with this template?

MS. MULKEY: Yes.

MR. QUINN: Is it? Okay.

MS. MULKEY: I mean, I think the request to at least look one year back and one year forward --

MR. QUINN: I guess one thing --

MS. MULKEY: -- is not a terribly burdensome thing that I can contemplate doing. I don't know if I want to commit to a 15-year --

MR. QUINN: Right, no. I guess one thing that does surprise me, again, you know, just looking at the anti-microbial side of things is chart number 12, which would indicate that you've got 24 FTEs, roughly, working on re-registration, which just -- I don't know, it doesn't feel right, you know, doesn't --

MS. MULKEY: Well, the wood preservatives are all in that, and we did some -- that was one where we actually did ask ourselves, what does this mean?

MR. QUINN: Right.

MS. MULKEY: The wood preservatives are all in that. All the methods development we have been engaged in, and that started in 2001, to wrap up to do a re-registration program is included in that, and we had some other thoughts about what might explain that, but I actually think that looked a little high to me, too.

MR. QUINN: Unusual, yeah.

MS. MULKEY: Not extraordinarily, because it may include some work that's not being done in the Anti-Microbials Division, it's being done in labs or in BEAD. I mean, we had a whole team that went beyond that organization to sort of think through the anti-microbials re-registration program.

MR. QUINN: I guess I just want to echo some things that others have said, that it's really a nice piece of work, and thank Doug and John and everybody who were involved in it.

MS. MULKEY: Win, is your card up from before or --

MS. MULKEY: Wow, we got around, and not a whole lot worse than I promised you for your lunch. Now, of

course, you have to be back right at 1:00 -- no, not quite, but if we could reconvene at 1:15 and make it real, we can still make our end-of-day schedule, and we look forward to it.

Thank you for all your interaction with us on this topic.

**(Whereupon, a lunch recess was taken.)**

**AFTERNOON SESSION**

. MS. MULKEY: All right, thank you very much for returning. We look forward to finishing up what I hope you think has been a very productive session.

We have -- do we have any public commenters -- is Margie here yet?

SPEAKER: She's outside.

MS. MULKEY: Margie, do we have any public commenters signed up?

MARGIE: No.

MS. MULKEY: Okay, well, that's good news. We recognize that there's going to be an interest in as early a wrap-up as possible. We also recognize that there are relatively few of you left, and while I expect at least a handful of you aren't here yet, we are mindful that there would be some loss.

We did manage to complete the agenda that we were planning to complete by noon, but we have learned a lesson, which is that we have been overly ambitious about our capacity to cover this many updates in the kind of time that we've allocated to it. So, one of the things I'll be asking for feedback is are there updates you're

getting you can live without, or are we going to have to consciously devote more of the total to updates?

And in connection with that question, as you know, updates come at the expense of real dialogue. So, there are real issues around whether you want to turn this into the periodic update meeting or not. So, I don't think it's an easy question, so yeah, if you want to speak to that now, that would be good.

Go ahead, Allen.

ALLEN: Well, my question is -- it's a question that will lead to the comment. Were most of the updates on topics requested by the members or were they a combination or were they strictly updates that the agency decided we ought to do?

MS. MULKEY: They were a combination, but I think most -- and in fact, I think the overwhelming majority were requested. Margie would be able to --

ALLEN: Then that makes it not as simple. I mean, if it had all been agency decision, we could have said, let us tell you what we want to hear, but if that's what you went by --

MS. MULKEY: Right. In one or two instances,

the request may have come from only one person and not been -- but in fact, if we thought a request was too esoteric, we didn't include it, and IPM, for example, was something that several people wanted a vastly more robust range of updates, and we specifically chose to focus on just two little pieces of it, the symposium and the development in schools, and I would say the NAFTA piece was probably one we put on, the strategic plan was one we put on. I'm not sure anything else was other than requested. The endangered species workshop we probably put on, but the endangered species issues were almost certainly included in the requests, so it's a real dilemma.

So, as we wrap up and those of you who are hearty enough to stay around and give us our last advice if you have further thoughts on this.

Steve?

MR. BALLING: Well, I was just thinking, I know the threshold of regulation issue was my request, and I probably was the only one who requested it.

MS. MULKEY: Um-hum, I think that's probably right.

MR. BALLING: But it also seemed like something that should come to light for everyone as well. I mean, people should know that there is this mechanism --

MS. MULKEY: And that's one reason why we --

MR. BALLING: -- here that isn't being used.

MS. MULKEY: Exactly.

MR. BALLING: And some understanding of why it isn't being used might be of some value, particularly -- and maybe it's better for CARAT relative to the transition issues at CARAT, I don't know, but --

MS. MULKEY: Well, I thought the best thing that came out of not that topic but the -- I guess it was the biotech topic, one of the best things was this is a topic that deserves some attention in the CARAT transition work group, and so unless you do surface issues -- I think you were right, that you were the only one who requested it, but we certainly thought it was appropriate for inclusion, and --

MR. BALLING: But then again, you might just make the argument, push back and say, hey, listen, Steve --

MS. MULKEY: Right, nobody else is asking.

MR. BALLING: -- you're the only one who's interested, go call Anne, and she'll tell you -- fill you in on the latest and leave it at that.

MS. MULKEY: Well, the other thing that -- I believe our chat room, our dialogue room -- Jim calls it our forum, which gives it a nice elevated sound -- but is also creating a dynamic in which people actually do push back on each other a little bit, you know, I really don't think we need to do that. So, I think that if you use that as a discussion, there is an opportunity to use that to sort of manage down, but it's not like it had been that long since we had a meeting. We had one in May. So, there's going to be demand for something similar to this volume. Well, I wanted to put that issue out there while we gathered the critical mass. Now that we have the critical mass -- yes, Steve?

MR. KELLNER: I think it really does -- I'm sorry, I think it does serve a good function to have a -- just a couple minute review. I know sometimes we go beyond it, but you have such a diverse group here that I think it's a help just to jag your mind that, oh, yeah, this is coming up or this is important, et cetera. So, I

do think it serves a good function, and I think it's very worthwhile.

MS. MULKEY: Okay, well, the feedback last meeting was that you really liked -- I know that they're not in a minute. Maybe we'll start calling them -- I think it was Burleson who said call it in a moment, that will help us to be other than literally inaccurate anyway. Quick updates might be another way.

We could introduce some more discipline on ourselves to cut down the time, but the truth is you have multiple presenters, you have people with different presentation styles. There's only just so much of that that you can do, and we do practice and try to manage it. Okay, well, as we come to the end, I'll look for that.

This afternoon, there are on your agenda five topics, four of which have been requested in most instances by more than one or we know that there's broader interest. With the exception of the one that wasn't requested, which is the data quality guidelines, and I'll go into a little bit about why that's there, none of these are topics, frankly, that there's some agency thrust or new agenda or special reason for

encouraging as a topic at PPDC. I don't mean to imply we don't want to do them, but they're not really driven by any agency sort of need to have a forum and a discussion that we identified independent of your requests.

The strategic plan discussion in a minute prompted a level of interest and even a suggestion, so I'm adding that, so if you will mentally add that as your sixth bullet for this discussion, we can work through each of these one by one a little bit.

I also noticed quite a bit of energy around the NAFTA -- I'm not sure whether it was around the NAFTA five-year strategic plan or whether it was around some sub-issues on that, like maybe the NAFTA label or movement of products across borders or tolerance, MRL, harmonization, but some interest around at least one of those issues that I was picking up as maybe people wanting to engage in a dialogue. So, we can add that.

Then I'll say one other thing, and then we will open it up to general discussion on this whole list, and then if that doesn't prompt enough attention to individual ones, we will find a way to do that.

One of the issues for us is not whether these

things are worth talking about but whether this is the right forum, and I -- and an example of that is the various issues surrounding plant-incorporated protectants, and frankly, one of the reasons why we did the update in a minute around opportunities for public participation on that set of issues was that there are so many other fora that are very sort of stakeholder-rich, many of which are much broader than just the pesticidal biotech, but many of the issues people want to talk about are broader than pesticide biotech. They are, for example, allergenicity, which has to do with any agricultural or food-related biotechnology and maybe even non-food-related for all I know.

So, you know, depending on people's interest -- now, so, what I think I would say is that if we embark on a use of this forum to talk about PIPs, it really ought to be something that's about PIPs, some issue that really is focused on BT, for example, or something involving -- that is not more generic by owetech, because there are all these other forums, and the NAFTA TWG has -- that whole process has an enormous amount of stakeholder mechanism around it, which frankly is underutilized by

many types of stakeholders.

Environmental groups are practically never engaged in that fora in the U.S. There's a little bit more engagement in Canada and actually more in Mexico than here. The non-ag industry wasn't but now is. The ag users are engaged, but it tends to be a different set of players than we see in this forum and in CARAT, not entirely different but some -- a little bit more grass rootsy version I would say of the ag users are involved there, and academia is -- I mean, the -- you know, like people interested in children's health issues are generally not engaged here -- there, and the farm worker advocacy community has not been very evident there, although you would think that would be just a real obvious place because of the Mexico-U.S., you know, the labor flow and so forth. So, there's sort of an under-participation of stakeholders.

I would say that the ag chemical industry is the exception to that. They've been very engaged, although as you know, Jay, it tends sometimes to be a different subset, and there even is a disconnect between the way in which the ag chemical industry engages there and the way

you do with us in other contexts.

So, one of the things on my mind there is not so much do we talk about it -- maybe it would be a good thing to bring it into this -- but how do we vitalize that? So, having made those opening comments, and I don't think any of these other topics sort of scream out for the "why don't you go to another place to talk about them" issue -- actually, the strategic plan sort of does, because there are going to be all these stakeholder processes around the strategic plan, although I don't think they're nearly at robust as the ones around biotech or NAFTA.

Okay, well, then let's open up this whole subject matter and see if that works, and if not, we'll identify some of the particular ones.

Steve?

MR. BALLING: Well, it struck home when you mentioned that many of the points that you have on this list are not issues that are of particularly great impending importance to OPP, and that's something I've struggled with all along in this whole process, is we're supposed to be an advisory committee to the Office of

Pesticide Programs, yet you're always asking us what we want to talk about, and I always thought it should be the opposite, you know, we're advising you, what are your problems, what are your issues, what can we provide advice on, and when you ask us, we end up with a lot of somewhat arcane, very generic issues that may not be appropriate for the PPDC, and I think some thought needs to be given about how to bring those back within the confines of what you guys need out of this group.

MS. MULKEY: Well, how important do you think it is for stakeholders like this to help set our agenda? Because I mean the flip side of that is that because you raise the profile of issues, it may become important to us in ways that wouldn't have but for your attention to it.

MR. BALLING: Well, one would presume that as the discussions proceed, they'd become important, and that's part of the give and take in P -- and you would realize that this is an important issue and in turn make it important internally, internalize it in some fashion, but I just think sometimes we really kind of get offline with this whole process, not unlike the CARAT group as

well, where I think we get offline fairly frequently on what, in fact, the role of that group is. So, just a thought.

MS. MULKEY: That's helpful.

Larry?

MR. ELWORTH: Well, the other thing that we tend to do is when you ask us about issues, all of us tend to respond based on the issue that we find most either immediate or important or vexing at the moment, and I think it's hard to pull together an agenda for 25 people's vexing issues or pressing issues, but I think a mixture of those issues is probably a good idea. I think the update -- you identified the update issue, probably a little more -- either fewer or more time or both, maybe not try to do it in a minute.

I think it's -- and I did not anticipate that I would ever say this -- but the stuff on non-animal testing was really interesting. The presentations were really good, and from an educational point of view, like reading a magazine article you wouldn't have looked at ordinarily, it was really interesting and well done, and I like the idea of this -- I mean, it's useful to me to

learn about things I don't know about. So, everything doesn't have to be immediately relevant to something that I have to deal with every day.

But I think it's also real important to have topical issues, and when you look at some of the updates that I think are important that aren't necessarily transparently obvious where you folks end up six months from now on ESA I think would be both topical and interesting, and interesting not just because of its effect on pesticides but the way that there's interaction on both different statutes and different agencies and how they resolve those kind of problems.

At least in agriculture, we keep running into situations where we're dealing with multiple agencies now who don't always look at us the same way. So, I think that kind of issue would be a useful issue.

I also -- and maybe everybody here already knows about it -- but I think it would be helpful if on a semi-regular basis, as new members come on, for the agency to talk about what FIFRA is. I mean, I happen to think it's a great statute, you know, found it very interesting, but maybe everybody here knows what the

difference between Section 6-C and Section 6-F and when somebody -- when you were talking about Section 28. It's a really interesting statute, and I think it would be useful to -- maybe a one-hour primer on part of FIFRA would be a useful thing. I mean, maybe not.

Well, I just think it's a fun law. I just love it.

MS. MULKEY: Well, you know, Larry, I would do that, but --

MR. ELWORTH: I know you would, but -- so, that's why it's easy for me to say this, but I think everybody here is being asked to look at pesticide issues and the level of background information and knowledge may be really variable --

MS. MULKEY: Maybe we need a series of breakfast seminars -- I'm only half joking -- before PPDC meetings, and people could attend or not.

SPEAKER: Yeah, that's a good idea.

MS. MULKEY: You actually sort of like that, huh?

MR. ELWORTH: Yeah, yeah.

SPEAKER: I mean, I think it's a great law, too,

but I don't necessarily need a primer on it.

MR. ELWORTH: Well, I know. Well, I don't -- I don't think everybody does, but I think it would be helpful to the discussion here if people at least had the same kind of basic information. It's a service that the agency can provide through this outreach group that really informs the public.

The other thing that I'd be real interested in seeing from the agency is how OPP is dealing with the methyl bromide issue, and it's not just critical use exemptions. It's how you're working with the Air Office, where it surfaces as a priority in the agency's registration priorities, and how the agency interacts with USDA. I think it would be a good issue.

I would also at some point like to hear about the agency's international programs, maybe not where there's a NAFTA thing, and as you said, there's a well-developed stakeholder group, but the agency's involved in a lot of international issues. I mean, we were talking in the hallway, POPs, I mean, there's a lot of things you folks have been doing, prior informed consent. Again, maybe you don't have to do an afternoon

on prior informed consent, but there's a lot of leadership this country has taken in international pesticide regulation, international pesticide safety, some of the Latin American projects you all have had, which I think people would be really interested in.

MS. MULKEY: Well, as usual, pretty rich mix of things.

Bob?

MR. ROSENBERG: Mine is like actually specific, and actually Julie understands the issue so much better than I do. Can I defer to her first? Am I allowed to do that?

MS. MULKEY: Of course.

MS. SPAGNOLI: Well, first, just in general, I think that as far as topics to be taken on, I think it's a mixture of -- the agency could -- we're not the only group of stakeholders that's going to give input to the agency on what they have issues with, and I think a lot of different groups bring issues to the agency, and I think it's somewhat -- if the agency sees an opportunity because of an issue that's been brought to them by anyone and saying this would be a good thing to take to the

PPDC, then I think that's probably that they bring -- that the agency brings that issue to the PPDC, and then vice versa, as we see issues we believe might be appropriate for the group, then we can bring them. So, I think you could have both. I think it doesn't all have to come from one group or the other.

The particular issue that I had brought up and wanted to I guess have for consideration in this group has to do with product claims, especially for alternative claims or -- and I'm going to say reduced risk claims, but it might not necessarily be reduced risk, but more and more we're seeing that the agency has a lot of initiatives and a lot of encouraging the use of, you know, lower risk products, reduced risk products.

As a marketer of these products, though, we're very, very limited in how we can present them, and I know it's -- there's -- it's a Pandora's box to -- you know, to completely open up and not allow people to say products are environmentally friendly or environmentally safe, but I think it could be something that -- to look at, are there good factual ways that we could present information on label and label claims that would help --

especially I think to consumers to help them make, you know, informed decisions? You know, if a product has been shown to not be toxic to bees, you know, shouldn't we be able to say on our label, "Will not harm bees," you know, something along that line.

Then I think with alternatives, especially as new alternatives to some of the older chemistries become available, one of the difficulties we've faced is trying to communicate to the public that these alternatives are available, and I know I had a personal experience of registering a new insect repellant product, and one of the difficulties we had bringing it to market was how to convince the retailers to put this -- you know, or the marketers to put this product out when they could not call it an alternative to D, they could not make that claim, yet you are going to have a higher-priced product that you couldn't really distinguish in any way, and I think that there's -- like I said, without misleading the public or providing, you know, I want to say trying to do scare tactics or any other way, I think there must be a way that we should be able to try to better communicate, you know, the attributes of these preferable

products to the public.

MS. MULKEY: Well, I think you've done a good job of framing that issue. I'll add just a couple of tidbits to the context.

We have a regulation that is pretty prescriptive -- as you know, FIFRA doesn't have many regulations. That's another one of the arcania of people who operate in this law, but we do have labeling regulations, been on the books a very long time, labeling regulations on the issue of claims, safety claims or claims that are really quite strictly drawn. Now, that doesn't mean there's no room without regulation changes for some rethinking, but that sort of context, and it's not just that the regs say this, but sort of the history of the thinking about pesticide labeling, which predates actually almost all of us, despite the long in the tooth crowd that has gathered here, has been very -- rigid I think would not be an overstated word in terms of labeling.

So, you are talking about opening a dialogue that would revisit that long-standing and pretty dug-in mind set. I don't mean by that in people, I mean just in

the infrastructure, you know, in the existing labels and so forth.

Having said that, we are in a very different era where we know a lot more about products, we have had these reduced risk initiatives, and there is -- there is definitely an argument that the past should not be prologue in this area and that there should be sort of a completely fresh opportunity.

Then there's the incrementalist who could say, well, let's be careful here and not rush all the way, but what if we open up this door? And then actually, we did open up one very small door recently, which has to do with the labeling of products that are -- that contain only the substances that the Organic Standards Board had certified as appropriate for organic gardening. So, now -- not gardening -- well, farming, organic growing. So, there will be now a pesticide label opportunity, as we finish that exercise, that was proposed and so forth that does that. So, very narrow, as you said, very factual. So, we sort of opened one little door.

So, I just wanted to add a little bit so when people react to your idea, they have a little sense of

this context, and this is one where it's not like somebody is sitting in OPP right now and saying, boy, this is the year we're going to embark on the initiative, because it's frankly a pretty high cost subject to try to figure out. Maybe if you did a little tiny piece, that wouldn't be too high cost, but to figure it out and to engage all the people who matter. I think we would have to understand the FTC's thinking on an issue like this, we would have to certainly understand our enforcement office's issue on -- you know, because -- and there would be all kinds of questions about just how much the agency should manage it, how much it should be left to industry to manage.

So, it's just even a difficult topic, but I think if there's a general sense, especially from a multitude of perspectives, that this is a topic that warrants the agency sort of dusting off that historic approach and putting some energy into rethinking, that you can make the case that sort of the time has come for an opportunity for the consumer to obtain some of this kind of information which may be driven by market positioning but may also have benefits beyond the market

--

MS. SPAGNOLI: Yeah, and we have also seen I guess from the retail side that the retailers, you know, kind of -- they want this, because even how they make their decisions on offerings to the public, and so I think there's a multitude of levels. I think from also -- and I think that Bob is going to reflect on it -- from his industry's perspective, too, because they have to make product choices for their uses, too.

MS. MULKEY: Well, this would seem to be a good time to call on Bob.

MR. ROSENBERG: About as good as any, and I think FIFRA's fun also, just for the record. This is I guess a corollary to what Julie's talking about and probably even less directly within the domain of the agency, but the long in the tooth crowd will remember that back in the early nineties, there were congressional hearings about the lawn care industry, and as a result of those, the agency convened a lawn care advisory committee which produced a set of draft lawn care advertising guidelines which were, to the best of my knowledge, never adopted but have become a de facto standard throughout

the United States upon which state attorneys general and state lead agencies rely and often make regulatory decisions.

The upshot of that is that they are actually pretty good. I mean, I'd have to go back and take a hard look to say that I love them, but they were actually pretty well done, but what they didn't allow for was the making of any kind of health, safety or environmental claim. So, if there are pest control operators or lawn care operators who do, in fact, use reduced risk products or do provide IPM or do embrace reduced risk strategies, there isn't any way for them to differentiate their product from someone who sprays baseboards, for instance.

If it's the agency's goal to try to move the applicator community in the direction of embracing those reduced risk strategies, I think revisiting that set of advertising guidelines would be a worthwhile endeavor.

MS. MULKEY: I know -- people may have had their card up for a while, but if people want to talk to this specific topic, it would probably be a good idea for them to call on them before, so -- I'm pointing to Carol.

SPEAKER: I thought you put it down. I'm sorry.

MS. BRICKEY: I think this is a good idea, and I'm very interested in it. I think it would be a good -- it is a good time for the agency to explore it, so I agree with Julie.

MS. MULKEY: Bill, you were on this topic, too? They have had their cards up for a while.

MR. TRACY: Well, I actually had something else, but a tie-in may be, and looping back to the presentation we had yesterday, you know, on a lot of shampoo products or, you know, cosmetic products, you see no animals were killed for this product kind of deal, and then, you know, I can envision the day where, you know, if people are embracing alternatives and we have a new structure for that, that would be a claim that people would like to have on their products as well.

MS. MULKEY: You can leave it up if you have something else you want to talk about later, but while we're on this topic, Larry?

MR. ELWORTH: Well, I just thought your initial analysis of why this is the way it is with labeling was really important. I mean, the whole -- one of the

primary foundations of FIFRA was a label -- a quality assurance for growers that they were actually getting X percent of X -- of Y chemical in the bag when they bought the pesticide. So, it's not coincidental that it started out -- that it's this prescriptive, this strict from the beginning. So, it -- I would be interested in hearing how the attorneys look at this, as well.

MS. MULKEY: Win, are you on this topic, on this sub-topic? Okay, because I wanted to get back to those who -- but Erik is, okay.

ERIK: It strikes me that it's probably worth having that conversation. I think it needs to be had very carefully, and the doors should not be swung wide open, but there are probably opportunities to make some reasonable changes that are probably worth discussing. It makes me nervous just because I know some of that history, and I know about some of the enforcement actions that have been taken by state attorneys general and so on. So, I think it would be key to bring in state AGs as well as enforcement folks and others, but I -- you know, I think if a legitimate and scientifically credible argument can be made that there may be reason to

authorize some fairly narrow provisions like that.

MS. MULKEY: Anything else on this topic?

Okay, Jose, you've been very patient.

DR. AMADOR: I let the other guys talk.

I've got a couple of things. The first one is the remark that Larry made on the international programs. I don't know if we've done enough of that in the past, and I'd be very interested in learning more about what the agency is doing, because, you know, living two or three miles from the border, because that's important to us, and I know that the Texas Department of Agriculture had a program on that, and I kind of would like to explore that a little more.

Then, in talking about the state programs, I think the assumption that Phil referred to in the morning, I don't know if this is the same disconnect that he was talking about or not, but we had a lot of activities from OPP, and I think that OPP has done a tremendous job on worker protection standards, but I don't hear much about what the states are doing or how the states are carrying on the programs, and it would be interesting for me to find out, you know, what is it

they're doing.

In talking to Anne earlier on this morning, the enforcement part of it is not part of your group here, and I wonder if it might not be good sometime to have somebody from enforcement to come to us and bring us up to date, you know, how are they doing and follow up on the things that OPP say needs to be done.

I've been thinking back, and I've been one of the guys who have been around for quite a while, I'm not as ancient as Larry is, and I don't want myself to go and crowd you or anything like that, I mean, one Larry is enough, but I can't think back to when we had that kind of conversation with somebody from enforcement. Maybe we had, I don't know, I can't remember, but I think it might be good to visit that and see how they're carrying on the -- and I'm not talking only about my state but I'm talking about all the states.

I know the level of activities in this area varies a lot, you know, from the heavy agricultural states, Florida. California and Texas, but I would like to see what the picture is for the whole United States. I would like to see how this is being enforced.

MS. MULKEY: Well, this planning group that's been working on these two worker risk workshops, there's been some discussion in that group about whether enforcement-related or state implementation-related issues fit in that dialogue. So, that -- we can take that as input to that as well.

DR. AMADOR: But I think it fits in it, because, you know, what good does it do to do all of that if it doesn't get out to the end of it?

MS. MULKEY: Well, certainly the issue of whether there's compliance with labeling or the standards, I think that the planning group definitely felt there was a need for some focus on that, which is not to say it's not sort of for this forum, too.

Beth?

DR. CARROLL: Well, first I'd like to say this is the third meeting I've been to, because I started with this new round, and you know, we go to so many meetings, this is a meeting I would not miss, because we do communicate and talk about so many different topics, and a lot of them may not be for everybody on that day, and we kind of had that discussion yesterday, but, you know,

a lot of it is really enlightening, and I do like the breakfast idea. I mean, maybe some of the animal testing -- because it did get a little long -- could have been accomplished, you know, early, and then the discussion could have ensued during the meeting.

But having said that, I don't know about all of these that have been put forth for the next meeting, but it may be that some of them could be taken care of in a shorter time frame than -- it seems like we have one main thing that comes on board, like the animal testing, electronic submissions, whatever --

MS. MULKEY: One or two, maybe three.

DR. CARROLL: -- but maybe there could be some that in your updates in a minute session, maybe you kind of already know it's going to take five minutes, and those are set up a little differently. I don't know, I'm just thinking out loud there.

Then I would like to echo Larry's suggestion about a discussion on ESA. The data quality guidelines, I'm wondering if since it's come up recently if we shouldn't think about during that discussion, or doing it separately, have IRIS and ORD come in and talk about the

IRIS database. It would be nice to know what their future plans are for updating it, how it -- you know, how they work with you guys in OPP to get this done, and I think probably some of the members would like to present some of the problems they've had with the database, and I think that database certainly is going to pay into the Data Quality Act guidelines. So, that's another one I'd like to suggest.

And I don't want to blindside Charlene Matten (phonetic), because she and I have talked a lot about this voluntary resistance management labeling, which with the exception of maybe one product that's in a category by its own I don't think has happened. We at Syngenta have some problems with it from -- that I think it might be helpful to air with this group, because some of them represent the grower community, and this is going to be -- I mean, the problems we have it are not that we can't put it on our label, but what it translates to when it gets out into the field is an issue, and what happens if my -- if the Syngenta labels have it, and our sales force is put out there, and the other guy's label doesn't have it. I know that pushes towards mandatory, but it

would be nice if we could all kind of agree that this is a good idea, and we need to get this information on our labels.

MS. MULKEY: But it has been interesting. We were lobbied pretty heavily at one point by some of the big grower -- I mean, I don't remember whether it was corn or wheat, but, you know, some of the big ones to move this issue, and we moved -- you know, we did what we did. We haven't heard much from them either. So, I'd also like to know, you know, what is the energy behind this, because, it's -- I think it's mandatory in Canada, isn't it?

DR. CARROLL: It is mandatory -- well, I'm not sure the date's kicked in yet, but we have had some meetings on it, but we all kind of keep talking around the same points, and we don't resolve them.

MS. MULKEY: Okay, well, that's helpful, um-hum.

DR. CARROLL: And I'd like to see it happen. I mean, it's critical for the longevity of a lot of these products and, you know, we keep -- we've been sticking it out there for glyphosate but haven't seen much more on other labels, so -- and then last, I just had a

question. I don't understand what the decision process and time line for how companies manage R&D pipelines -- what does that topic mean?

MS. MULKEY: Well, that topic came -- I can't remember from whom, it might have been Larry, but --

SPEAKER: Probably was.

SPEAKER: Bob Holm.

MS. MULKEY: Was it Bob Holm?

SPEAKER: Yeah. So, this is sort of a mischaracterization.

MS. MULKEY: Fair enough. The interest was in understanding what's going -- having a better understanding of how R&D decisions are being made.

SPEAKER: Actually, it was -- I think it was bigger than that. It was, you know, the consolidation of the industry, the shrinking investment in discovery research, both by the industry and also all research, which really could involve the National Coalition for Ag Research, which is active, and USDA has got a stake in that, so you can make this however large or small you --

MS. MULKEY: Fair enough. I mean, I heard several different things. One is just sort of what's in

the pipeline and is it shrinking or growing.

SPEAKER: Right.

MS. MULKEY: Then I thought there was some interest and a little bit more in how are decisions made, what kind of products are pursued, and the interests seemed to be more around what's driving it in the marketplace and economically than what's driving it with regard to environmental impact, and those things --

SPEAKER: It both ties to the resource question and a looking forward through OPP so that you know what to expect in terms of workload.

MS. MULKEY: Right, that's -- I mean, it's inartfully worded for sure, but that was the topic.

DR. CARROLL: That helps.

MS. MULKEY: Win?

MR. HOCK: Before I go into my dissertation, which will be brief, I have a suggestion. I think that the agency should produce a button, "I love FIFRA." After all, you go to New York or you go to any other place, there's always an "I love whatever," so I think --

MS. MULKEY: How about "I love FQPA," do you

think everybody would wear that?

MR. HOCK: We have a mutual admiration --

SPEAKER: All you guys would.

MS. MULKEY: Bring back Delaney.

DR. HOCK: No, wait a minute, let's not go too far about Delaney.

You know, we talk about a lot of EPA regulatory activities, and you know, I look at EPA as much more than just a regulatory/enforcement agency. I really look at EPA as doing a lot of outreach, and in fact, something -- it was Larry's comment, and boy, Larry, you have made an historic comment about this, when he said about international safety programs. The bottom line is, you know, international safety programs, but we have a lot of domestic safety programs, and I guess I just wonder if it would help the group to get a feel for what kind of "outreach programs" you people do have.

I mean, you know, I'm familiar with most of them because that's the area I work in, but thinking in terms of the support that EPA gives to USDA, to the EPA regional offices, the state lead agencies, cooperative extension, we all work very closely with the state lead

agencies. I think Phil and Jose, they would confirm that. We work closely with them but not strictly in an enforcement/regulatory capacity. Often it is an educational capacity in some way or form.

I think of the support for the SLAs, cooperative extension. You have a very strong CNT program here. The CNT program encompasses worker protections. That's largely I look at as a lot of outreach. The Endangered Species Act is really an educational program. It's not strictly an enforcement program, but it's to educate people, educate people on changes to the label or these endangered species bulletins.

I'm just wondering if it would help the group -- and I think most of the group here probably has not been engaged in, if you will, outreach type of education -- if it would help them to realize the magnitude of the programs that you really do sponsor, if you will, that you support, that you aid in promoting pesticide safety education.

So, I'm just throwing that out as a thought, because you know, even our industry people here, they take a major role in many cases in pesticide outreach

education, to their growers, to the general public. We have a lot of that going on, and I guess I would like to see -- you know, I want to say -- think a little outside the box, that yes, you're considered a regulatory agency, yes, you do enforcement, but yes, you also do a lot of outreach education either directly or indirectly, and we support that.

MS. MULKEY: Okay, Erik?

ERIK: I wanted to support what Jose had suggested actually, and in particular, I think it's -- we spend so much time debating what goes on labels and what the PHIs are, et cetera, and re-entry intervals and so on, and one thing, I think some of it is a worker issue, but I think there's sort of a broader compliance with label issue that I would certainly be interested in hearing what hard data the agency has, what data there are generally on compliance with labels and compliance generally with the agency's regulatory requirements.

You know, I'm not -- I think part of that might have to come not from OPP but from your enforcement and from state folks, but I think it would be a really interesting exercise to hear about what data you have on

that issue and whether a lot of the sound and fury over label changes and so on really ends up making it out into the field.

MS. MULKEY: All right, Lori?

MS. HARDER: I'm not sure if this is the right forum for this, but I think it would be interesting to discuss cross-media issues with the Office of Water, Office of Air and how they may challenge or uphold the registration -- pesticide registration process and label and those kind of issues.

MS. MULKEY: There certainly have been some obvious ones, like the methyl bromide exemption process and the NPDS permitting intersection with HOLSAD (phonetic) application.

I believe Warren and then Jay.

DR. STICKLE: I would like to make three quick comments. The implementation of the Data Quality Act on October 1st I think is going to have a significant set of ramifications for a whole variety of issues and programs in a lot of federal agencies, including EPA and including OPP. So, it might be worth taking some time at the next meeting to sort of focus on the impact that the Data

Quality Act might have on various programs and what its real impact is going to be.

Secondly, you know, I think Larry's really touched on an interesting concept of dealing with the various international efforts that the agency is making. I think a lot of us are cognizant of some of those, but no one's really put together a whole package of where EPA is taking the leadership in the international arena, and that would be good to just look at and review.

And thirdly, over the next six months or so, there's going to be a number of decision points on inerts, and whether that includes the new risk assessment model and the comments that are due on October 11th or the development of a data compensation scheme where there's going to be a meeting in late September or whether there's an impact on international harmonization with NAFTA or, for that matter, work on the 450 tolerances that are going to be worked on over the next four years, plus the update of the inert list. So, there are a lot of things happening in the next six months, and that might be a viable topic for the next meeting as well.

MS. MULKEY: Okay, Jay?

MR. VROOM: I have three suggestions for our next meeting, two of which would be continuations of things that we've done, and the third will be I think a relatively new idea topic-wise.

Number one is Endangered Species Act and its many implications or ramifications --

(End tape 3-A.)

MR. VROOM: -- with particularly interest in getting someone here from both Fish and Wildlife and NIMPS. I think that kind of dialogue opportunity for senior representatives of those two groups and perhaps even someone higher from Interior, in the Secretary's office, that we might be able to illustrate, you know, the level of expertise and outside advice that OPP gets as is embodied around this table ought to give some benefit to those programs, to understand the magnitude of the involvement plus USDA's involvement at this table as well.

Secondly, I think we will continue to have fees and resources and performance and strategic plan as kind of an integrated topic. I think it ought to be a

permanent agenda item for this committee, and in particular, I -- new subcategory opportunities to explore. Ray just informed me that he's a member of something called the Chemicals and Pesticides Results Measures Advisory Stakeholder Group to OPP. I didn't even know he was doing this, so I come here and learn something from my staff colleagues, but obviously there's a lot more detail around your strategic plan as it relates to GPRA goals and accomplishments and all of that that I think would be very rich further topic opportunity for this committee.

Lastly, I'd suggest that it be considered to put a topic on the next agenda strictly focused on benefits. Almost everything we've discussed has related to risks except for the conversation yesterday around efficacy data. USDA's got a lot of information that could be composited under this kind of a topic for future PPDC meeting. Certainly BEAD does, and I think the industry is bringing together, along with university sources, a lot of new information, and I think it would be an opportunity for us to put some focus on that, and also dialogue and give advice to the agency about how you are

pursuing that part of the statutory authority under FIFRA for benefits consideration.

MS. MULKEY: Bill?

MR. TRACY: I'd like to second and third the concept that's talking about the field programs along with the registration program and how they benefit each other, and in the field programs, I guess I'm talking about CNT, there's disposal programs going on out there, there's the groundwater issue, there's the surface water issue, and there's enforcement I think, and we used to talk, at least at SFIREG (phonetic) about the field data plan, which was supposed to support the registration process as kind of a check on the system. I honestly think some dialogue about all of those kinds of programs around this table and how they work with or don't work with the registration process is important. I really view the program as being a national registration program and then kind of a disperse program on implementation out in the field, and I think just focusing a little about where we connect well and where we don't would be real beneficial, and I think this group could give some input into that.

MS. MULKEY: In addition to or in the absence of a complete sort of integrated tackling of that topic, do you think some subparts of that lend themselves to this update approach so that at least they get, you know --

MR. TRACY: Well, I think endangered species has been talked about a number of times. That's kind of come back up on -- it looks to me on the plate, and that's part of that whole performance, but, you know, we have dealt with groundwater issues for a long time, we have skirted the surface water issue for a long time, and there is this whole -- this linkage between what's going on in the field found through enforcement.

Even more important than enforcement, where do you have troubles in the field when you're following the label? Where do you have environmental concerns or health-related concerns when you're actually following the label directions? That's probably even a bigger issue, because that's legally used with consequences, which we're not supposed to probably talk about or have, but it does seem to happen occasionally, so...

MS. MULKEY: Okay, thank you.

Well, all of this -- oh, excuse me, I'm sorry.

Nancy, I'm sorry.

DR. LEWIS: That's okay.

On future topics --

MS. MULKEY: I don't know, I think it's the light or something, I've got to --

MR. LEWIS: -- I consider myself very much a beginner in the whole pesticide area, and because of that, the primer idea does appeal to me a lot, and also maybe even a primer on your office and structure and to give me some sort of an umbrella of where to put these different topics as they come up. I think that would have helped with the language, too. A lot of new terms every meeting for me. I'm sort of getting there, but I could still use a lot more help on that.

MS. MULKEY: Well, let me make an offer -- that I hope I don't live to regret -- that for any of you who really feel that you would like some specialized help on sort of getting up to speed in a fairly basic area, like structure or -- if you just ask, through Margie, we will actually do some one-on-one tutoring here for some people's needs, and that's not to say in lieu of some kind of, if you like, breakfast session, but we obviously

do have a range, and what happens is that there will be somebody who sits among us -- Troy might be an example, he's not here -- who has a very keen interest in one area but who wouldn't have had any reason to have sort of developed mastery in other areas, but who if he's going to sit around the table with us might really add value in some of these other areas if there was an opportunity to do so.

So, I imagine there's a handful of you like that who are here because of a pretty narrow role, but who might welcome -- and we might do some one-on-one for that kind of thing if that would be helpful.

Well, we're doing great on time, because I assume we still have no public commenters, and we have 15 minutes left under our schedule. So, I would like to use that by asking for -- back up.

We heard you on all this. What's interesting is that the activity-based REIs, which I know Lori Berger has brought up and I thought several others of you had, and so while we don't have to know now, it's sort of interesting there was no mention of that in this discussion, but we are going to continue to use our chat

room. We have heard you. We actually -- the fact that I'm not taking notes doesn't mean we're not hearing you. We actually have very careful notes prepared and presented to us very shortly, and there is a transcript of this proceeding, so we'll actually be able to use this input that you just gave us.

We may frame it up for you a little bit so that on the -- in the chat -- in the e-dialogue, you can refine your thinking. Some of you may want to -- and, in fact, vote for topics that you didn't say something about this time or not. So, there will be an opportunity for some of that. I think this was actually very rich input, an opportunity to plan both some of the more comprehensive kinds of things and some more targeted kinds of approaches for our meetings or other -- even other forums.

Having said that, the one thing that we are really doing differently than what we had done until maybe two meetings ago is put together these, for lack of a better word, panels, this group of people who sometimes fairly loosely, sometimes in a quite integrated way, who invest in preparations and then have the opportunity to

have a sustaining involvement on that issue with us. The biopesticides industry and marketing issue is an example of that, and as you can see, although it's not a highly structured work group with a lot of meetings, there is a certain continuing cohesiveness of that group.

The group that was working on alternative testing seems to have a strong self-generated desire to maintain and continue to invest in that issue and engage with us. We are finding it helpful. It would be even more helpful if there were a couple of other perspectives. We sort of drafted Syngenta into that group, and they clearly have added something a little different from the consumer products industry perspective that was already there.

So, that's sort of going to take -- and I don't know whether we'll dub it a work group or keep it somewhat less formalized, but it does appear to have the desire, works for us, a potential to sort of -- so, there are some of these kind of topics which lend themselves to that kind of approach, and we're finding that useful, because it takes some of the work off of us for one thing. It gives you a multitude of perspectives

instead of just agency talking heads.

It can be other parts of the agency, you know, or other parts of the Government. It wouldn't have to always involve the private sector or participants from this -- from among you. So, we will think about that as we think about these topics, and we'll ask you to, too, which kind of topics lend themselves to that approach, because we find that richer for us in terms of having a topic be more than just our preparing and then hearing your reactions.

So, I think that in choosing among topics, the fitness of some -- of an issue like that -- I mean, of an issue for that kind of approach will help inform our thinking about what issues to engage in. So, having offered that, having asked you the questions I asked you throughout the day yesterday as well as now, what I would like to do is to get your general reactions to what's working, what's not, what you want to see. If you want to give feedback on this meeting now, fine; if not, you can do it in the electronic forum, and just sort of your last word kind of thing.

In particular, I encourage any of you and all of

you who haven't been saying a whole lot in particular to be sure that we hear your perspective if you have something you feel you want to offer.

Bill?

MR. TRACY: I want to talk a little bit about meeting format. I really like the in-depth, you know, four-hour examination of an issue. It gives an opportunity to really go deep and think that should be maintained for each meeting, have one of those, because they're very educational, and probably in contrast to a lot of people, I loved yesterday, but I come in from a tox background. So, I knew what all those words meant, so it was fun for me.

The minute updates seem a little -- they are not poorly managed, but they're not a minute update, and I -- and one of the things I think we need to do about -- I think they're great. I like getting, you know, a rapid sort of update on everything. I think a little bit about -- I don't know if we need to establish some game rules about that, but, you know, I'm sort of struggling about commenting when they're minute updates, and they can easily turn into half hour, and I know we don't want

to do that.

So, I don't know if we need to think about what they are exactly and are we just supposed to sit here, you know, or are you asking for a reaction, and so those -- we need -- I think we need to do something about how we do that, and maybe they need to be a little longer. I don't know. So, those are my only two comments.

MS. MULKEY: Okay. Beth?

DR. CARROLL: Well, I love the minute updates. I don't disagree that sometimes when we're -- we get into something and there's other comments, you kind of feel like, well, maybe I should just wait and put it on the web, but maybe there's a way to figure out which ones are going to generate most discussion and have a little more -- which ones are just informational, because some of them are, they're -- this is going to be published on this day in the Federal Register and we're working on this or whatever, and others that might be more to the group with we would want to make some comments, but I think we cover a lot of territory with those things, and I think they're great.

MS. MULKEY: Maybe we could parking lot the ones

that seem to want discussion and come back to them later. I'm not sure we can predict. We wouldn't have batted a thousand I'm predicting for this one, I'll tell you that. We might have gotten over 300 or whatever is a good average in baseball.

Warren?

DR. STICKLE: I think the updates are really excellent, because they give you a broad range of issues and a snapshot of what's happened on a particular issue.

I'd like to suggest two things you might want to consider. One, the House of Representatives sort of works under a five-minute rule, and you might want to consider not one minute but perhaps five minutes as a way of giving a little bit of an in-depth analysis on a short topic.

Then secondly, if there's any way to one week ahead of this meeting put together sort of a discussion or an outline on these topics so people can digest that information and then come prepared with a question or two, that might create more of a dialogue on these issues, but again, do it very, very quickly.

MS. MULKEY: We are trying to get relevant

information out. I know we've had mixed success. So, any feedback on both the up and the downside of what we've achieved would be welcome.

Julie?

MS. SPAGNOLI: I likewise share I think the comments that I think the updates are very, very helpful. I think maybe there might be some ways to organize them into ones that are just -- that are just informational, such as, you know, if there's a group of upcoming workshops, maybe just present all those as, you know, here's some upcoming activities that we're doing and kind of present them all together, and that's more informational.

I think when you -- as we know from yesterday, you know, with the topic of the objections to the tolerances that had been filed where the agency was actually looking for input, there obviously that wasn't an update in a minute type topic, and so again, I think if we kind of look at them and say -- maybe how we organize them, and what are we trying -- are we trying to look for feedback versus just provide information, and then we might be able to manage them a little better.

MS. MULKEY: Yeah, we definitely drafted on our solicitation at the 11th hour, and that was probably a mistake.

Nancy?

MR. LEWIS: I agree, I like the one-minute updates, too, and I did like the in-depth science as well, but some of it got a little long, so that the time limit there might be useful, too, 15 to 20 minutes might be enough for each topic.

I had a couple other general comments, thinking last night about what did I get out of this meeting. One thing that struck me yesterday was the comment on attitude, a couple of different times people mentioned attitude, and I'm not sure what the real message was, but I think for myself it is really critical to maintain an open attitude, and I don't know if that was the message that was trying to be conveyed or not, but I just remember hearing that more than once. So, I think there was a message there.

The other thing, since being on this group, I've noticed media more on pesticides, and it seems that every time I read it, it's negative, and it makes me think I

know there's a lot of good things, and is there any way of capitalizing on that and trying to put forward more of what it's really doing for us that's good?

MS. MULKEY: You're talking about negative about the products themselves?

MR. LEWIS: Well, like the pictures of the frogs with three legs, the kind of thing that gets the fear up in consumers.

MS. MULKEY: Okay, yeah. I thought you were talking about coverage of government's role.

MR. LEWIS: No, no. No, negative as to pesticides.

MS. MULKEY: You're talking about products, I understand, exactly.

All right, others? We have a public comment process, so we'll just allow you to participate in that if you will go to the mike and identify yourself.

SPEAKER: My name is Larry Hammond, I'm with -- a consultant to the 240 task force, and I just want to make a couple of comments perhaps for the itinerary. One is to echo what was said earlier about IRIS. I think that IRIS is woefully behind; however, we do know that

there's some interaction going on at this time between crop life and industry to try to update that, but that should be something that perhaps is discussed.

A second one, I don't think I heard it here, was about (inaudible) disruption. NSAX (phonetic) is kind of behind us, but the son of NSAX is very current, and where are they on the validation of the methodology and what can we expect on that, because it's a soft issue, but it keeps coming up about different compounds, and we need to know kind of where the agency is at at this point in time.

MS. MULKEY: Thank you very much.

Any other public comment that didn't sign up but we wanted to hear? Very good.

Well, we're in good shape. You've been terrific. You've worked hard. So have we. It's -- we really appreciate all the positive feedback, and there has been a lot of positive feedback, but we equally appreciate your suggestions about how to not only get this meeting better but to get all our work better, and we hear a lot of that in this context, and we welcome that, too.

SPEAKER: Are we going to talk about a next date kind of thing?

MS. MULKEY: A date? I think that's a good idea. I was contemplating taking a deep breath, but it's probably better to do that -- to start that here. We were going to do that on the list.Serve obviously, but do we have some perspectives on that at the table?

SPEAKER: The question is --

MS. MULKEY: The next meeting time frame.

SPEAKER: Are we looking at January possibly?

MS. MULKEY: My own thinking is probably January is the earliest to be looking at. There are some issues around January, travel and weather issues. There's also the CARAT -- at least the CARAT transition work group which, you know, has issues around scheduling that intersect with this.

On the other hand, if you go much beyond February, you've sort of created too long a gap.

SPEAKER: Yeah.

MS. MULKEY: Do you -- are you eager enough that if we could pull it off, you'd want to see December or January?

SPEAKER: Not December.

MS. MULKEY: Not December.

SPEAKER: January.

MS. MULKEY: Good.

SPEAKER: Not December.

MS. MULKEY: Yeah, so the other thing is the second of these worker risk workshops needs to be scheduled, and one of the -- I mean, it would be four days, because this is probably likely to be two days, but one of the opportunities is co-scheduling -- how do people feel about that? Is co-scheduling basically more a good thing than a bad thing or more a bad thing than a good thing, because you wind up with too many days?

SPEAKER: Good thing.

MS. MULKEY: More a good thing.

SPEAKER: It's a long way from California.

MS. MULKEY: We consciously scheduled the endangered species workshop for tomorrow, and I take it you're saying that's a good thing.

SPEAKER: Yes.

SPEAKER: Yes.

MS. MULKEY: Any contrary point of view? So,

what you're saying is relatively sooner rather than later, you're liking January, and if it were co-scheduled with something like the transition work group or the worker risk, you'd welcome that. Is that what we're hearing?

Great, we'll see what the story is on hotels and such -- like -- well, thank you. Thanks for --

SPEAKER: It's too bad we can't have one on Halloween, because that's the last dog day downstairs, and they bring them in costume they tell me.

MS. MULKEY: Oh, wow. Well, I had great fun with the dogs, and I never would have gotten over here if it hadn't been for this meeting, so that's great. Well, thank you all. It's been fun.

**(The meeting was concluded.)**

CERTIFICATE OF TRANSCRIPTIONIST

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We, Elizabeth M. Farrell and Susanne Bergling, 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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