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8 **Transcript of**
9 **Pesticide Program Dialogue Committee Meeting**
10 **Holiday Inn Select Old Town**
11 **410 King Street**
12 **Alexandria, Virginia**
13 **September 17-18, 2002**
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1 **P R O C E E D I N G S**

2 **- - - - -**

3 **DAY ONE - SEPTEMBER 17, 2002**

4 MS. MULKEY: Good morning, all. Thank you very
5 much for convening with us again for our Pesticide
6 Program Dialogue Committee. That name for this committee
7 was selected a long time ago, but I think it continues to
8 serve us very well. We have been able to use this forum
9 to focus on a lot of issues that are important to us
10 programmatically. It has been a real dialogue, and we
11 have had an opportunity to work with you and you are a
12 truly wonderful bunch in many senses of that term
13 We've had an opportunity to work with you on
14 issues that you're interested in and that you've asked us
15 to focus on, but also on issues that are important to us
16 and that we have identified as representing issues where
17 we really need the benefit of your dialogue. So, both
18 for the issues where we benefit because you saw the need
19 for us to engage in a dialogue and issues where we
20 benefit because we saw the need to engage in a dialogue.
21 It has enriched us enormously.
22 I didn't count the number of these committee

1 meetings over the history of this committee, but it is a
2 very significant number at this point and we are working
3 very hard to build on the history of our meetings, and I
4 think you'll see more and more evidence of that as we
5 work through these two days so that there is a continuity
6 and a foundation for our ongoing dialogue.
7 I'm looking forward to today. I don't want to
8 take much of the agenda time with these opening remarks
9 because there is a lot of meat and a lot of interesting
10 things to hear. But I did want to take a minute or two
11 to acknowledge some faces that will either be new to you
12 or sitting in different places and/or are particularly
13 important to acknowledge. If I can get her to pause in
14 the middle of what she's doing, I wanted to take a
15 special moment this morning to talk about our Designated
16 Federal Official. Margie Fehrenbach, whom all of you
17 interact with constantly as a result of this committee,
18 is the Designated Federal Official for this committee.
19 But I don't think any of us have any sense of just all
20 that is involved in her performance of that function.
21 The amount of work necessary to plan and pull
22 off a meeting like this to assure that all of you and all

1 of us are here ready, prepared and able to be effective,
2 to troubleshoot all the problems and to do it in a way
3 that makes all of us feel better, because she makes us
4 feel better, is just a really special talent. So, I
5 wanted us to take a little extra time today to
6 acknowledge our Designated Federal Official.
7 **(Applause.)**
8 MS. MULKEY: I also want to take a moment to
9 tell you about a couple of folks whom you will see today
10 and tomorrow. One you know quite well, Kathleen Knox,
11 but she's here in a new role. She is now acting as our
12 Deputy Office Director for Management. And you will
13 remember Joe Merenda who is taking on the position as
14 Director of the Office of Science and Coordination Policy
15 within the Office of Pollution Prevention of Pesticides
16 and Toxic Substances. So, we're really delighted
17 Kathleen is performing a role for us. She brings skill,
18 experience, ability, grace and a lot of other things to
19 taking on that responsibility.
20 And, actually, although tomorrow's topic on
21 funding is not one that we asked her to have to step up
22 and do in her, literally, first week doing this, she will

1 be here to hear feedback and will provide some continuity
2 on that topic that, I think, will be important.
3 The other person I wanted to introduce to you is
4 Steve Bradbury. Now, I saw Steve, but I don't know where
5 -- my eyes -- do you want to stand up, Steve?
6 Steve Bradbury is Acting Director now of our
7 Environmental Fate and Effects Division and has been
8 doing so for several months now. He came to us from the
9 Office of Research and Development. We'll get a chance
10 to learn a little more about how much expertise, science,
11 bona fide ease and talent he brings to the organization,
12 but I wanted you to have a chance to put his face with
13 his name as early as possible this morning.
14 Speaking of putting faces with names, this is
15 the time in the program where we will take an opportunity
16 for all of us to introduce ourselves. If I start with my
17 left, then what will happen is when we get past Al, I
18 will have an opportunity to introduce the folks who are
19 going to take on the next little piece of the program.
20 So, if we can operate that way with your permission.
21 Gentlemen, we will start with Jim.
22 MR. JONES: I'm Jim Jones, I'm the Deputy of

1 OPP-for Programs.
2 MS. KNOX: I'm Kathleen Knox. Marcia just
3 introduced me.
4 MS. ANDERSEN: Janet Andersen. I'm the Director
5 of the BioPesticides and Pollution Prevention Division.
6 MS. ROSS: Lois Ross, the Director of Special
7 Review and Reregistration.
8 MS. BOUVE: I'm Kate Bouve. I'm Chief of the
9 Information Services Branch in the Information Resources
10 and Services Division.
11 MR. QUINN: I'm Pat Quinn with the Accord Group
12 here in town.
13 MR. SEIDLE: Troy Seidle with PETA, People for
14 the Ethical Treatment of Animals.
15 MS. BAKER: Cindy Baker with Gowan Company
16 sitting in for Allen James of RISE.
17 DR. LYNCH: Sara Lynch, World Wildlife Fund.
18 DR. HOCK: Win Hock, American Association of
19 Pesticide Safety Educators.
20 MS. HARDER: Lori Harder, Yurok Tribe and Tribal
21 Pesticide Program Council.
22 MR. LIBMAN: Hi, I'm Gary Libman, Emerald

1 BioAgriculture.
2 DR. LEWIS: Nancy Lewis from the University of
3 Nebraska in Nutrition.
4 DR. SAUERS: Len Sauers from the Procter and
5 Gamble Company.
6 MR. GRAY: Sean Gray from Environmental Working
7 Group.
8 MR. ELWORTH: Larry Elworth, Center for Ag
9 Partnerships. And, Marcia, when you were talking about
10 history, you kind of looked over towards me and Steve.
11 **(Laughter.)**
12 MS. MULKEY: You're right. Pardon me.
13 MR. ELWORTH: I just tried not to take that
14 personally.
15 FEMALE PARTICIPANT: Not ancient.
16 MR. ELWORTH: Ancient?
17 **(Laughter.)**
18 DR. BALLING: We were looking around trying to
19 see anyone who had been here longer. Nope.
20 Steve Balling, DelMonte Foods.
21 MS. BRICKEY: Carolyn Brickey, the Institute for
22 Environment and Agriculture.

1 MR. McCORMICK: Bill McCormick, Clorox Company.
2 DR. LOCKWOOD: Alan Lockwood, Chairman of
3 Environment and Health Committee of Physicians for Social
4 Responsibility.
5 MS. LIEBMAN: Amy Liebman filLing in for Ed
6 Zuroweste from Migrant Clinicians Network.
7 MR. ROSENBERG: Bob Rosenberg, National Pest
8 Management Association.
9 MR. NICHOLSON: Erik Nicholson with United
10 Farmworkers of America.
11 MS. SPAGNOLI: Julie Spagnoli, Bayer
12 Corporation.
13 DR. AMADOR: Jose Amador, Texas A&M, down in
14 Weslaco, Texas.
15 DR. BERGER: Lori Berger, California Minor Crops
16 Council, Visea, California.
17 MS. SASS: Jennifer Sass with the Natural
18 Resources Defense Council.
19 MR. STICKLE: Warren Stickle, President of the
20 Chemical Producers and Distributors Association.
21 MR. VICKERY: John Vickery, a consultant from
22 Minnesota.

1 DR. CARROLL: Beth Carroll, Syngenta Crop
2 Protection.
3 MR. BENEDICT: Phil Benedict, Vermont Department
4 of Agriculture, Foods & Markets.
5 DR. KAWAMOTO: Melody Kawamoto, National
6 Institute for Occupational Safety and Health.
7 MR. JENNINGS: Al Jennings, USDA.
8 MS. MULKEY: Go ahead and pick up the folks back
9 here, too.
10 MR. BAILEY: Joe Bailey with (inaudible).
11 FEMALE PARTICIPANT: (Inaudible).
12 MR. JORDAN: Bill Jordan with the Office of
13 Pesticide Programs.
14 FEMALE PARTICIPANT: (Inaudible).
15 MS. MULKEY: Thank you all very much. And we
16 are fortunate and I, on behalf of the whole committee,
17 thank Adam Sharp and Burleson Smith both for taking the
18 time to spend time with us. They both insist that they
19 believe that this is absolutely where they should be and
20 that they're eager to be here, and that makes sense to
21 me, too, because I know of their interest in this group
22 and what it has to offer.

1 As you know, Burleson is at the U.S. Department
2 of Agriculture and has taken on responsibility for this
3 administration's leadership around pesticide issues for
4 the Department. And Adam Sharp is our Associate
5 Assistant Administrator and is taking on responsibility
6 within EPA for a key point person for this
7 administration's issues around pesticides and toxic
8 substances in OPPTS.
9 So, they both have some remarks, and I assume
10 you've figured out the order in which you want to go.
11 MR. SHARP: I'm going to be real brief. I just
12 wanted to say welcome to everybody and pass on a welcome
13 from Steve Johnson, my boss, of course, and he wants to
14 make sure that he certainly values all of your input, as
15 we all do up here for the next couple of days. It is a
16 busy agenda as you've all seen. There's a lot of good
17 items, I think, for you all, a lot of good information
18 for you all to discuss, to hear about, ask questions
19 about and provide input on. So, it is going to be a very
20 busy couple days.
21 Myself, I'm committed to be here for the next
22 two days because I certainly want to hear all the points

1 of views that you all have on this variety of issues, and
2 I guess we do have a real good variety of issues, from
3 animal testing to talking about our budget to cumulative
4 risk assessment, et cetera, of things to cover.
5 I guess when I look back at some of the PPDC
6 agendas, this is probably one of the more varied ones.
7 It's a nice range of things to talk about and I know of
8 interest to a lot of you around the table. So, I look
9 forward to that discussion.
10 I want to also bring your attention, of course,
11 to a couple of workshops that we have planned coming up
12 and certainly invite you all to two public workshops. Of
13 course, on Thursday, we're doing a workshop -- a public
14 workshop on the Endangered Species Protection Program
15 being developed by the agency, and then, of course,
16 there's a workshop on worker risk at the end of next
17 month. So, I want to invite you back to both of those
18 meetings as well as they're going to be very important
19 and a lot of good information, I think, also will be
20 distributed at those.
21 So, with that, I'm going to go ahead and stop
22 and say, thanks again for taking out the time to be here

1 for the next two days. Burleson?
2 MR. SMITH: Well, good morning and on behalf of
3 the Department of Agriculture, thank you for your
4 attention and cooperation here. It certainly is an
5 opportunity for us to hear your ideas, comments and
6 concerns with respect to the pesticide programs at EPA
7 and we appreciate the opportunity to join EPA today at
8 this. So, again, we appreciate your participation, look
9 forward to it and keep the remarks short.
10 MS. MULKEY: Thank you. And we really do
11 appreciate both of you being here. I notice we've been
12 joined by Dr. Terry Troxell from Food and Drug
13 Administration and by Jay Vroom of CropLife America. Did
14 anybody else come in since we did the introductions?
15 (No response.)
16 MS. MULKEY: We seem to have a full house as it
17 were. Everybody's at the table and that's exactly the
18 way we like it.
19 We have been working on several enhancements to
20 the PPDC approaches based on your feedback, and we
21 continue to solicit your feedback to try to make this as
22 effective as it can be. One of the enhancements is more

1 follow-through and continuity from meeting to meeting and
2 over time with regard to the issues that we work through
3 in this committee. And so, you will see, starting with
4 the next agenda item, and again later in the day, that
5 the four main subject matter areas for our last PPDC are
6 again on this agenda, not necessarily in as comprehensive
7 a way, but in an effort to make this continuity
8 meaningful. So, we'll be asking throughout for your
9 feedback about whether we're getting it about right with
10 regard to level of continuity and follow-through
11 involving those kind of topics.
12 As you know, you gave us a lot of positive
13 feedback about the updates and amended approach, and we
14 have continued with that. That allows us to touch upon a
15 number of topics, but it -- these topics are not designed
16 for robust, meaningful, sustained dialogue. So, again,
17 to the extent that you find that among these topics you
18 experience frustration for the absence of that
19 opportunity, we welcome that feedback and we will look
20 for ways of identifying more appropriately what kinds of
21 things belong in that category and/or how to find other
22 ways to give a more comprehensive approach for some of

1 those topics. But these topics were largely suggested by
2 you for the update in a minute format, and so, we're
3 assuming that we've gotten it about right in terms of
4 what kind of topics belong in that section.
5 We also are finding our -- I'm sure this is not
6 the right way to say it -- but our PPDC chatroom, maybe
7 we should call it dialogue room, but our electronic
8 dialogue opportunities to also enhance our ability to
9 sort of know what you're thinking and we notice that
10 you're not as eager on all days to engage as you are
11 shortly after and shortly before these meetings, but we
12 also would like feedback about whether that is a
13 meaningful enhancement to our effort to make the dialogue
14 committee.
15 We also have continued to try to bring into our
16 discussions you, members of the committee or others other
17 than the agency so that it's not just an agency talking
18 heads committee comment, but that other people invest in
19 preparation and interaction with the agency. And we're
20 also learning to make more use of your input as we plan
21 specifics, and as you will see, we have engaged with a
22 group of you in planning the session for tomorrow on our

1 resource allocation and expenditures, and we've also been
2 working with a group that came primarily from this
3 committee and working on preparing our worker risk
4 seminars, actually, as you will learn a little more
5 about.
6 So, those are all ways in which we're trying to
7 make this more meaningful, more interactive, more
8 substantive, and have more continuity, and I would just
9 encourage you to give us feedback as we go along and I
10 will expressly solicit feedback at some point about
11 whether these improvements are working and whether you
12 have ideas for making things even better.
13 Well, one good way to make things even better is
14 to get on schedule and stay on schedule. As you know,
15 I'm a bit of a nag on the subject of keeping our breaks
16 to the time allocated. I would ask you to commit
17 yourself right now to really being conscientious about
18 that today. But it will help that we're able to plunge
19 into our first pair of follow-up topics a little early.
20 You will remember that we covered a range of
21 electronic media related issues at the last session,
22 everything from e-commerce to e-FOIA, but by far, the

1 most extensive dialogue was around electronic data
2 submission issues. So, we've asked Kate Bouve, who works
3 specifically in that subject matter area, to provide us
4 with some update and continuity report in that area.
5 **(Brief pause.)**
6 MS. BOUVE: Let me get started. I think some of
7 you may have picked up the handout. I think they were
8 out in the -- yeah, very good.
9 As Marcia noted, we will be talking in future
10 PPDCs about the advancements in the e-docket and the e-
11 FOIA area, but for today, I'm going to be focusing on
12 updating you on our electronic submission and review
13 efforts in the Office of Pesticide Programs.
14 First, I want to review a little bit some of the
15 standards that we've set for electronic submission and
16 then talk specifically about our supplemental files pilot
17 project, which was something I talked about with Clive
18 Holder at the last PPDC, and then just a real quick touch
19 on some of the upcoming meetings and further
20 communication in that area.
21 I think it's important to recap some of the
22 basic information about how we've been approaching our

1 electronic submission and review efforts. Our basic
2 operating principle is that we have to strike a good
3 balance between the needs of our registrant applicants
4 and those of the reviewers in OPP. So, we had to find an
5 electronic formatting standard that was easy and
6 inexpensive for the registrants to put into place, but
7 that it was also easy for our reviewers to learn how to
8 use, and at the same time provided them powerful enough
9 tools so that they could do the important work of
10 reviewing studies and preparing their review documents
11 more efficiently and more effectively.
12 We also felt it was important that we need to
13 focus our efforts on the most resource-intensive work.
14 There's all sorts of fun little things that we can do in
15 electronic submission, but if we're going to go to this
16 trouble, we thought reviewing studies, which is probably
17 the most resource-intensive hunk of work that we do in
18 OPP, that was the place to start.
19 Now, we have set standards for the submission
20 and formatting of studies that are submitted
21 electronically to the Office of Pesticide Programs.
22 We're using Abode PDF. Not exactly brilliant, pretty

1 much a de facto standard. And they're coming into us on
2 CD-ROM.
3 For the reviewers internally, they're using the
4 full Adobe Acrobat software package, plus other tools
5 like their word processing software, their spreadsheet
6 software and the like, to use that as a way of evaluating
7 the studies and preparing review documents. We
8 established that standard last fall.
9 Electronic submissions are encouraged from our
10 registrants and submitters, but it is not mandatory.
11 Now, we've got a couple of pilots that we're
12 working on. As we finish a pilot and set a standard,
13 then we move on to the next set of pilots. So, we've got
14 two underway. One is the electronic submission and
15 review of product label text, but the one I want to focus
16 on today is talking about electronic submission and
17 review of supplemental files that come along with our
18 chronic toxicology studies.
19 First of all, a little clarification. What are
20 supplemental files? We're talking about those files, the
21 data that are generated, and, of course, some of the long
22 term feeding studies. These generate a great deal of

1 data and the ability to analyze that data helps our
2 reviewers better understand these studies. So, we're
3 talking about chronic and sub-chronic studies,
4 developmental, developmental neurotox, and there's a
5 whole range of data sets that are produced in the course
6 of these studies, food consumption, body weights, tumor
7 data, clinical signs, clinical chemistry and the like.
8 Now, you may recall last time I was here Clive
9 Holder from Bayer was my co-presenter, and Bayer stepped
10 up to the plate on this project and worked very closely
11 with the program to design the formats, to decide what
12 data sets, how they should be organized, and we all
13 decided to work with SAS Transport as the software, as
14 sort of the truck to carry that data into the building.
15 We built on the work that was done by the Food and Drug
16 Administration. We felt that they've done such good work
17 over the years and we felt that we could build on the
18 foundation that they provided. And then we're also, as
19 the Food and Drug Administration does, we're using JMP
20 software by our reviewers in order to analyze the data.
21 So, in our first pilot effort, Bayer worked with
22 their labs in the U.S. and overseas, so it was a real

1 challenge, and they submitted supplemental files in
2 support of their chronic studies on 2 AIs? Our reviewers
3 worked with it, a small number of them, obviously, were
4 very enthusiastic about this process. They felt that
5 they were better able to analyze the data much more
6 efficiently than if they were trying to rekey data or
7 reenter statistics or do that sort of work, and they felt
8 that it greatly improved the quality of their evaluation
9 of these studies. Of course, we're working with our
10 toxicologists and the whole (inaudible) Division to do
11 this work.
12 So, as a result of that very initial success,
13 we're declaring this as a full-blown pilot now and we're
14 encouraging more companies to submit these supplemental
15 files. We've put together an extensive guidance document
16 on what are the files, what are the data elements within
17 the files, how to create the SAS transport, and that's
18 posted on a website that we've built that has all of our
19 guidance on how to submit studies electronically.
20 And then, internally, we've acquired more copies
21 of the JMP software and the HED staff are being trained
22 on the use of that software. JMP, just as a little

1 clarification, is part of a suite of softwares that's
2 produced by SAS. SAS is the Statistical Analytical
3 Software package and it's pretty much the standard
4 throughout EPA.
5 Fortunately, registrants have shown interest in
6 participating in this. We're very pleased about that.
7 It's a real challenge for them to work with the many
8 different labs that they deal with and that different
9 sources of software that generate the data in support of
10 these chronic toxicology studies. So, we're very
11 appreciative of those efforts and we encourage more
12 registrants to get involved.
13 Finally, just to let you know that there's
14 continuing communication, both internal and external on
15 these issues, we're going to be participating in an OECD
16 workshop the first week in October in Ottawa. We're
17 working with the Canadians PMRA on hosting this effort,
18 and it's going to be an opportunity to share information
19 on what kinds of tools and technology is being used in
20 the United States, Canada, and in Europe for electronic
21 submission and review.
22 And then in November, on the 19th and 20th, here

1 locally, there will be another -- the second workshop
2 that was cosponsored with CropLife America and OPP, a
3 real working session on electronic submission, with a
4 wide variety of participation from different types of
5 registrant groups. Hopefully, we'll get some lab people
6 here as well. So, the continuation of this conversation
7 is an important part of our work here.
8 Any questions?
9 (No response.)
10 MS. MULKEY: Thank you very much, Kate. As I
11 said, we didn't plan for an extensive discussion of this,
12 but it is worth noting what are the policy and
13 programmatic implications of this kind of essentially
14 techie exercise. We believe, and there are increasing
15 data to support this, that this can have quite a material
16 measurable effect on our productivity with the result
17 that we can do more work with our existing resources.
18 From the standpoint of new chemicals, obviously, which is
19 where these submissions are going to be seen, that's
20 presumably something that everybody has an interest in.
21 So, that is sort of the macro significance of this.
22 You also heard a related issue, which is this

1 may also improve the quality of our capacity to
2 understand very complex studies. That, of course, means
3 that we will both do things faster and better, which is
4 just about all you can ask for from any kind of new
5 initiative.
6 We have not yet attempted to develop data on the
7 extent to which this enhances productivity. But Canada
8 has made some efforts to do that and I think FDA has,
9 also, and there are data which do support the notion of
10 more than marginal improvements in efficiency and
11 productivity. So, that's an important sort of macro
12 context for this topic.
13 The second topic that we wanted to spend some
14 time on that is a carry-forward from a very extensive
15 dialogue that we had at the last PPDC meeting had to do
16 with issues around the adoption of biopesticides in
17 agriculture, primarily agriculture. As you know, we had
18 quite a discussion about barriers and factors and the
19 nature of these products and a lot of things relating to
20 them.
21 So, Janet Andersen, who is, of course, Director
22 of our BioPesticides and Pollution Prevention Division

1 working with the team of folks that were involved in our
2 work leading up to the last PPDC meeting and since then
3 is going to give us a report on follow-up in that area.
4 MS. ANDERSEN: Thank you, Marcia. I want to
5 acknowledge that Kathleen's name is here because she
6 still -- this is probably like one of her last official
7 acts in the BioPesticides and Pollution Prevention
8 Division, but certainly has been important in the help
9 we've had in putting this together.
10 Last May, as Marcia said, we did have a good
11 robust discussion on the adoption of biopesticides, and
12 coming out of that we took quite a bit of notes and put
13 together a list of all of the barriers and suggestions we
14 had.
15 Can I go ahead and have the first slide, Bill?
16 If I counted it up, I think we had 77 items in
17 the list, and with that whole stack of things we tried to
18 decide how we could best handle it. Working with the IR-
19 4 group, we put together seven categories that we thought
20 were appropriate for these various topics. They were
21 industry, land grant universities, the USDA and its
22 various agencies and parts, regulatory groups, commodity

1 groups and growers, food processors and independent crop
2 consultants, and then the others. It's not that others
3 weren't significant, it's just that there were so many
4 diverse that we stacked them together.
5 We then arrayed this group into the various
6 categories which have been sent out to you for you to
7 look at it and go over. It's in your handouts. It also
8 was sent electronically to the committee, to the whole
9 PPDC, and what we're looking for today is for the
10 discussion we'd like to have at the end of this short
11 presentation, is something about how EPA could help
12 facilitate in bringing to the attention of these groups
13 and working with these various groups, some of these
14 barriers and solutions that we might actually try and
15 implement some ways of further adoption of biopesticides.
16 As I said, the list of barriers was provided to
17 everyone and at the end of it there's a section that's
18 the top 10 items that both IR-4 and BPPD identified as
19 things that we thought we could really make improvements
20 on. Now, this is a long-term list. It's not something
21 we're going to have done in the next couple of months nor
22 even probably the next couple of years, but real goals

1 for us to look at.

2 However, we have made some good progress and I

3 want to just go through some of those for you. The very

4 first item on the top 10 list is increase IR-4 funding

5 for biopesticides research and IR-4 has done this.

6 They've moved an additional $100,000 into their program.

7 So, they've moved from $300,000 identified for

8 biopesticide research to $400,000. This is really

9 demonstration projects and also sometimes other research

10 to help facilitate bringing products to market. But

11 often, it's demonstration projects that really can be

12 hands-on. So, we're really pleased to see that IR-4 has

13 been able to do that and we're sorry, actually, Bob Holm

14 couldn't be here today to make more of that presentation.

15 I'm going to move a little bit then onto some of

16 the things that BPPD has been doing. Number two on the

17 list of the top 10 was to the process for registration of

18 biopesticides. So, let me go through some of the things

19 we've been doing in the Division and show you that we are

20 making some progress in this area.

21 We've developed a fast track team for

22 biochemicals, and let me tell you for the jargon that you

1 might not know, a fast track action in the Office of
2 Pesticide Programs is one that comes in with no data
3 associated to it. That doesn't mean it should have data
4 and it's missing. We get those, too. They aren't fast
5 track. It's an action that is really just a simple
6 amendment to an already existing product where they may
7 be adding a new use cite but don't need to have any data
8 to support that or an additional insect pest or something
9 like that might be added. Those are examples of fast
10 track amendments.
11 Also, there are some products that are fast
12 track amendments. They're what we also refer to as ME-
13 2s, they're identical products to what's already on the
14 market but might be splitting up a label or something
15 like that.
16 But these actions can pile up and really can
17 help move the actions along better and have better
18 products on the market with better labels, we believe, if
19 we can have them acted on rapidly. So, that team has
20 been up and working for several months and has really
21 been making quite a difference, I think, in being able to
22 get these actions out rapidly to our registrants.

1 The second one is a newly instituted group
2 called the pheremone team, and we were just up and
3 running this group. But the goals of this group is to
4 provide better guidance to our registrants on how to
5 actually make the submissions for pheremones. We've
6 gotten a lot of problems with that over the last couple
7 of years and we're really trying to provide some better
8 guidance that will help us get packages in and be able to
9 make decisions more rapidly.
10 We also, on our own side, want to improve our
11 consistency in our reviews, not only our scientific
12 reviews, but our label reviews for these products so that
13 they can go to any one of the number of staff and have a
14 quick and consistent review of their product.
15 We hope, overall, to be able to streamline and
16 improve the speed at which we are actually able to make
17 decisions on pheremones, and I'll get to the reason a
18 little bit later of why we picked pheremones for this.
19 Some of you probably know that in the 2001
20 budget, I believe it was, we got a significant increase
21 in our division in extramural funds for having contract
22 reviews. It takes a while. You have to identify a

1 contract or put them in place, but you also have to train
2 the contractor in how to do the reviews and work on it,
3 and we've been doing a lot of effort on that lately and
4 we really see that our contractors are improving and
5 providing back to us reviews that are much more in line
6 with what we need and fewer corrections we have to make
7 as we go through our secondary review process. So,
8 that's a good one.
9 And we are now screening all of our scientific
10 reviews before we send them to contractors. That is, if
11 the product has a set of data associated with it that is
12 not going to be acceptable, we're identifying it right
13 on, right early, and giving it back to the registrant to
14 identify them. It doesn't go off to the contractor and
15 four months later come back, goes through secondary
16 review and we say, oh, well, you really need to redo this
17 whole study, and they say, why didn't you tell me this
18 six months ago. Well, now we're telling them right up
19 front that there's a problem with their package, and we
20 hope that that will also give us some better turnarounds.
21 And we've improved our front end processing within our
22 own division to speed that up.

1 Bill, next one.

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

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

22 I mention here, this is the pheremones that are

1 playing a role in transition. As we move from some of
2 the organophosphates and carbamates into other more safer
3 products, we are looking at the pheremones as one of the
4 real key players in this, and we think that they have
5 played a role in transition and can play even a greater
6 role in transition if we help with some of the regulatory
7 parts, that is including giving sprayable pheremones that
8 are much easier than the twist-tie versions of these
9 products, and also just bringing these products more
10 rapidly to the market. So, that's why we have the
11 team -- one of the reasons we really have the team.
12 Just so you know we really did pay attention at
13 that session that we held in May, one of the things that
14 was suggested in that meeting was that we put a list of
15 all of the active ingredients we have for biopesticides
16 and the trade names of those products associated with it
17 and make that publicly available. We have now done that
18 and put it on our website.
19 Next slide.
20 Another one on the list, it's number six on the
21 list of top 10s, is talk about success stories for
22 biopesticides. So, I'm going to want to give a little

1 success story here to you today, and that's talking about
2 phermones. I know that a lot of you have heard good
3 things from Gerber and DelMonte about them, using
4 phermones over the last few years, but there are also
5 other good stories. I just want to provide a little bit
6 of information.
7 In California, it is estimated by the pheremone
8 industry that over half of the fresh market of stone
9 fruit receives at least one application of pheremones in
10 a year for oriental fruit moth, and one of the pheremone
11 companies we work with, Siterra (phonetic), has told me
12 that their products alone are being used to treat over
13 100,000 acres of California crops in the year 2002, this
14 year.
15 This company has also backed up what they got
16 with new technologies. They are the registrant producing
17 the puffer technology that's used in some of the orchards
18 now and, also, they're moving quite rapidly into
19 sprayable pheremones.
20 We do see an adoption of this technology,
21 especially as the sprayables are coming along and
22 receiving registration. Siterra is especially looking

1 for a new product that we hope to eventually -- that we
2 will rapidly have in the market, we think, in the next
3 few weeks, one on navel orange worm, another important
4 pest in California.
5 Siterra is not unique in its aspect, but they
6 are really very strong in research and development and
7 they have committed to spend over a million dollars
8 annually for phermone research. So, that kind of
9 commitment by the industry, I think, is very important
10 for us being able to see these products coming more
11 rapidly into the market.
12 On the U.S. side, we also have with phermones
13 been working with PMRA, who is represented here, too, and
14 OECD to have the data requirements and the process that
15 we use for phermone registration, that expedited process,
16 have that be the standard for all OECD countries, and
17 that system is in place as guidelines from OECD now.
18 So, I just wanted to give that little bit of
19 brief overview of where we came from and we are going to
20 continue to work on our top 10 list and others, and I
21 also wanted to then go around to the people who were
22 especially panelists last time with us and ask if they

1 have any specific comments, and I know the biopesticide
2 industry is actually -- we've put some slides up for
3 them, but if I -- as Bill switches from this presentation
4 to theirs, maybe I could -- Win, do you want to add
5 anything that you'd like to say as I go around the table?
6 Would you like to add a comment?
7 MR. HOCK: I'd like to ask a question.
8 MS. ANDERSEN: Okay.
9 MR. HOCK: I'm just wondering how many -- I use
10 the term kind of in quotes -- "registrants" might go for
11 a Section 25B, in other words, a minimum risk exclusion
12 for registration. Do you see this happening quite a bit
13 in the future with phermones and other biopesticides?
14 MS. ANDERSEN: Phermones will not be 25B
15 compounds.
16 MR. HOCK: Okay. I was wondering just, you
17 know --
18 MS. ANDERSEN: No, they're registered in an
19 expedited fashion. What he's referring to is, 25B is a
20 section of the law of FIFRA that allows us to exempt
21 specific active ingredients if they are determined to be
22 extremely safe, very, very low risk. And EPA has done

1 this, did a final rule in '96 that put, I think, 31
2 compounds on that list and then also to then have a 25B
3 pesticide product, you must have inerts that only on List
4 4A, so also extremely safe inerts. The process of 25B
5 has us not actually reviewing those labels. The concept
6 was they would be so safe that we would not need to do
7 safety reviews of them. So, we do not review those
8 labels. So, it's very hard for us to actually say how
9 many products there are out there, but we know that there
10 are quite a few.
11 MR. HOCK: Thank you.
12 MS. ANDERSEN: Gary, I think you are the next
13 one. Gary Libman representing right now the Biopesticide
14 Industry Alliance. If you want to --
15 MR. LIBMAN: If you could put up the next slide.
16 MS. ANDERSEN: It's the one that says top 10
17 list of BPIA.
18 MR. LIBMAN: We all had top 10 lists and these
19 are ours, and we divided it into three different
20 categories. First of all, thank you, Marcia, thank you,
21 Janet, for this opportunity, and thanks to the whole PPDC
22 for the opportunity to speak about biopesticides. It

1 really became a very interesting topic in May and it
2 really helps the biopesticide industry to understand
3 where people are coming from. It was very eye opening to
4 say the least.
5 And we took the listing that came out last
6 Thursday or Friday and we sort of culled it down to 10
7 items that are very important for industry. First of
8 all, the three broad categories, our industry will
9 demonstrate programs to show users that biopesticides fit
10 into integrated pest management and other pest management
11 practices. Janet Andersen already alluded to the IPM
12 workshop. There's going to be a workshop in Indianapolis
13 next April, and there's several of us from the industry
14 who will be part of that. We'll be on a panel
15 discussion, Fred Betts from Eden BioSciences and myself
16 from Emerald Bio.
17 And another thing is showing the biopesticide
18 success programs. Janet talked about the phermones.
19 There's many microbial success stories whether it's gypsy
20 moths or BTs or bavari basiana (phonetic) with thrips and
21 aphids, and the biochemicals showing incredible yield
22 improvements in California and other states. So, we

1 definitely have success programs and we need to get that
2 word out because a lot of people, as I found out in May,
3 were not aware of that.
4 We are going to have a website, the Biopesticide
5 and Industry Alliances will have a website. We don't
6 have it yet. We're a bunch of small little companies
7 that are just all working diligently trying to stay
8 afloat. But we are going to put together a website
9 because we feel it's very important for us to have that
10 so that people can look at that information and determine
11 what is available.
12 As Janet indicated, the BPPD website does have a
13 listing of the brand names of biopesticides and we would
14 like to add some more information to that, including
15 labels and so on.
16 Next slide.
17 Industry also wants to demonstrate that
18 biopesticides are efficacious products. When I gave my
19 presentation in May, we talked about the fact that there
20 is a perception that some of the products are, in fact,
21 snake oil type of products and that was probably a valid
22 impression on some products a few years ago, but it

1 certainly is not the case now. So, we are working
2 diligently towards a certification program so that when
3 you see this Biopesticide Industry Alliance
4 certification, people will know that it is quite an
5 efficacious product as a stand-alone or an integrated
6 pest management.
7 And then we need to do a better job, as clearly
8 came out in several issues in the BPPD listing, to use
9 advocates a little better, whether those advocates are
10 PCAs or extension folks or other people in the
11 universities and so on, we need to get the word out that
12 people are not advocating the use of biopesticides as
13 much as we'd like to see them being advocated.
14 We also want to work with the extension
15 services. There's a tendency of the extension services
16 to use this one-shot-kill-all type of things for
17 synthetic chemicals, and we want to educate the extension
18 services to objectively evaluate the benefits of the use
19 of biopesticides.
20 That leads into the next stop which is just
21 showing compatibility with other --
22 **(END OF SIDE A, TAPE 1)**

1 -- pest management tools.
2 Next slide.
3 The final broad category is we want to get
4 biopesticides to be the product of choice, obviously,
5 whether, again, as stand-alone or as part of an
6 integrated pest management system. A lot of questions, a
7 lot of points came up regarding cost effectiveness of
8 biopesticides. They are, very often, more expensive than
9 traditional synthetics. So, we recognize the importance
10 of cost effectiveness to the growers and we have to do a
11 better job and industry is aware of that and we are
12 working towards that. As Janet said, on her top 10 list,
13 these are not things that will happen overnight, but it's
14 an evolving process.
15 We want to promote the environmental
16 compatibility of biopesticides. Clearly, these
17 biopesticides, in almost every case, fall into the
18 reduced risk category and we are wearing the white hats,
19 we like to say. We know that they are environmentally
20 compatible. And then, finally, our products are
21 available as a tool for organic growers, depending on
22 what inert is in the formulation. We're working with the

1 USDA, the National Organic Program of the USDA and
2 various other groups to move that process along.
3 MS. ANDERSEN: Thank you. I'm not expecting
4 every panel to have had the slides. They got kind of a
5 heads-up that everybody didn't get. But I'm going to
6 turn to Steve Balling. So, the next one, as I go around,
7 that was on the panel last year. Do you have anything
8 you'd like to add?
9 MR. BALLING: Well, one thing I would continue
10 to add, which I have many times, Gary, is that advocacy
11 is very important, and I think it's critical in the world
12 of growers to move information along. But for many of
13 us, replicated data is what counts, and so, I'll continue
14 to harp on that.
15 Gary also mentioned, and as you did, Janet, the
16 IMP workshop next April in Indianapolis, and we will be,
17 along with Gary and BPIA, the National Foundation for IPM
18 Education will be helping to host a break-out group on
19 overcoming barriers to biopesticides. I think it's a
20 real critical opportunity for a lot of folks in various
21 areas to come in and have a serious discussion about how
22 we can move quality products through the system, and we

1 would really like to see a good turn-out for that. So,
2 any of you who are interested, please join us.
3 That's all. Thanks.
4 MS. ANDERSEN: That's good. I'll just
5 reiterate, I think that this replicated data, it will
6 help to have the increased funding with IR-4, too. I
7 think that's a good source for it.
8 Carolyn was on the group. Carolyn's got --
9 MS. BRICKEY: Well, I was really intrigued and
10 interested in Gary's list because there's so much there.
11 I mean, some of those items could take up pages and pages
12 if you started listing all the steps that you had to do
13 to make some of that stuff happen. But I definitely
14 think that this is one of the panels that we've all
15 gotten a lot of substance out of. So, I'm really glad to
16 see the follow-up and I'm interested in continuing to
17 work with you, Janet and Gary, to try to make some of
18 these things happen.
19 MS. ANDERSEN: Great, thank you. Lori, do you
20 want to add -- I hope I'm not missing anybody?
21 DR. BERGER: Well, I just wanted to say that all
22 these goals are very reasonable and worthwhile. It

1 should be recognized that they all are predicated on
2 efficacious products, and that's really the key I see,
3 kind of the a priori assumption that all of these things
4 will -- you know, the IR-4 Program, all of these other
5 things, technology transfer, it's all based upon whether
6 or not there's true efficacy there.
7 MS. ANDERSEN: Good point. Al Jennings?
8 MR. JENNINGS: Yeah, thank you. I would just
9 like to emphasize the experimental use permit and the
10 importance of that in terms of getting the product out to
11 researchers so they can do demonstrations, so they can
12 generate that hard data, and just how important the
13 experiment use permit is in this process of getting
14 products on the market and getting them accepted.
15 MS. ANDERSEN: And now, I think we'll turn it
16 over to anybody else on the panel who would -- we've got
17 a couple of minutes if anybody else wants to raise a
18 flag.
19 MS. MULKEY: You mean on the PPDC?
20 MS. ANDERSEN: On the PPDC, right. Larry,
21 you're first.
22 MR. ELWORTH: Janet, in the discussion for BPPD

1 actions, you talked about your processes to your
2 division, I guess one of the questions I have is whether
3 you can also expand work on your processes to what
4 happens with HED since -- to the extent that you need
5 tolerances or to the extent the inerts are important,
6 what you're doing on that.
7 I actually wish Bob were here because I didn't
8 know that IR-4 did demonstration projects until today and
9 it certainly seems a little far afield from their initial
10 charge in terms of doing data to support tolerances. I
11 guess the thing I'd like to follow up a little bit on,
12 Steve, is that on the list of BPIA -- I'm sorry, I'm
13 having trouble keeping the acronyms right -- at some
14 point, all of you folks are going to have to generate
15 invoices and the people that help you generate invoices
16 are PCAs and growers. So, it's important to have all of
17 these organizations involved. But the hard thing for all
18 of these companies, because of their size, is their
19 ability to effectively market their products.
20 At some point, I think separate from everything
21 else that you do, which is all fine, until that piece of
22 it actually works out, you're still going to be

1 struggling, talking, a little bit preaching to the choir,
2 people who wish you well, but are not going to go out and
3 buy your products tomorrow.
4 MS. ANDERSEN: Well, Larry did ask a question.
5 Just so that the panel understands, the Biopesticides and
6 Pollution Prevention Division has both its science and
7 its regulatory staff within the same organization, and we
8 certainly do go to our colleagues in HED and EFED at
9 times for help, and frankly, they come to us at times for
10 help. But for our reviews, they're
11 done predominantly in-house. Occasionally, we will get
12 some -- actually, we've gotten some help from times from
13 RD who also does some work. But mostly it's an in-house
14 effort. I hope that helps explain.
15 MR. ELWORTH: Is that true for inerts as well?
16 MS. ANDERSEN: We will do some inert work, but
17 we don't do -- the inerts work is typically done in RD,
18 that's right.
19 Cindy?
20 MS. BAKER: I'm not sure if you guys have talked
21 about this before. Is this topic and this kind of work
22 something that you've taken the transition group within

1 CARAT, for example? Is that -- I mean, how do you
2 integrate this into that whole discussion? I mean, we
3 have two products. We have an azinderactid (phonetic)
4 material and we have a pheremone material, and the thing
5 that we found in trying to market and sell those things
6 is exactly what Lori and Larry both alluded to, which is
7 an efficacy thing. And I think that the only way that
8 you get that done is to gradually move people through
9 transition.
10 Because when you're dealing with something like
11 oriental fruit moth or NOW, they've had a lot of success.
12 But take on something like coddling moth in apples and
13 pears in a year like they had this year and it's
14 difficult to get people to move away from that, because
15 the standards are so high for them when they're selling
16 their fresh fruit, they just can't afford one moth, one
17 worm, whatever, it turns out the whole thing is
18 unsaleable for them.
19 So, I think there's a lot to this that you can't
20 switch people overnight to biopesticides. There's a lot
21 of pests that it's not as easily put together in a whole
22 IPM program. But I think that people are working -- are

1 trying to work towards that and it takes steps. Can you
2 maybe use certain chemistry early and then bring these
3 other things in? Can you use it in combination at
4 reduced rates, you know, those kinds of things? And I
5 think that takes a lot of discussion and time and
6 planning. And so, the more avenues that I think you can
7 address this with, probably the better the success rate
8 in getting people talking about it and using it because
9 there are registrants that are trying really hard to sell
10 these products, and it's strictly an efficacy deal.
11 I mean, it has got to work. Cost is certainly
12 an issue, perception is certainly an issue. But the
13 bottom line is that the grower's got to be able to use
14 that season after season and understand that they're
15 going to get control.
16 UNIDENTIFIED MALE: I think -- actually, if I
17 could respond to that, yes. Cindy, I think that's a good
18 point actually. A number of you sitting around the table
19 are a part of the transition workgroup or the CARAT in
20 general and, you know, I think that we're getting close,
21 actually, to the point where we can start really talking
22 about the specific programs. I mean, the focus of that

1 transition workgroup is, of course, looking at programs
2 that USDA and EPA have that growers and such can take
3 advantage of as we're talking about moving folks from
4 Point A to Point B if they have a pest problem.
5 So, I think that this is definitely a good
6 option and something we need to look at. So, I'll
7 certainly take note and see if Jim or Janet have anything
8 else to add.
9 MS. ANDERSEN: No, I thought that was great,
10 very good. Thank you.
11 Bob is, I think, the next one.
12 MR. ROSENBERG: Yeah, I only have a question.
13 Is there a requirement that efficacy data be submitted
14 in conjunction with a registration application? And if
15 so -- go ahead.
16 MS. ANDERSEN: The requirement is that a company
17 have efficacy data for any claim they make on a label.
18 We require that data to be submitted for public health
19 pesticides, but we also have the right to require that
20 data at any time. BPPD does, at times, say to potential
21 registrants, we want to see the efficacy data before we
22 actually spend all of our resources on this product

1 because we, frankly, don't believe it's maybe really
2 going to work.
3 So, we have done that. We get some kickback
4 from the companies at times, but we do have the right to
5 do that and have.
6 MR. ROSENBERG: And I just -- the reason I ask
7 that, I'm actually thinking about termiticides and public
8 health products where there are efficacy requirements.
9 It seems as if the credibility of the products stand to
10 benefit from agency reviewed efficacy data, and have you
11 considered making that an actual requirement for all
12 registrations?
13 MS. ANDERSEN: Well, once upon a time, the
14 agency had that as a requirement and then they took it
15 away. So, I think in the case of considering it just for
16 biopesticides, it's considered why would we require this
17 for these products when we don't require it for others.
18 However, with our partners at PMRA, they do -- and
19 California, they do require this efficacy data as they do
20 reviews. So, our registrants for both sides are very
21 aware that they have to have the data for some of the
22 other companies -- other countries and states in the case

1 of California.
2 Julie, I think you're next.
3 MS. SPAGNOLI: Bob kind of started where I think
4 my questions were heading. Even if the data are not
5 required to be submitted, maybe there would be some -- if
6 efficacy is the issue and efficacy is part of what is
7 necessary to kind of promote the product, maybe the
8 registrant should be encouraged to submit efficacy data
9 just so that there is a third party review, there's an
10 independent review of it.
11 If the agency has deemed the product
12 efficacious, then you can use that as part of
13 establishing that credibility and/or looking at, you
14 know, for certain critical uses, maybe that the agency
15 should require the efficacy data, again, because I think
16 that will help build that confidence with the growers
17 that it has been looked at by the agency, that someone
18 has evaluated the efficacy data, and that would give them
19 more confidence in using the products.
20 MS. ANDERSEN: Let me let Gary respond first.
21 MR. LIBMAN: Mainly, I want to reiterate what
22 Janet just said. It's true that we don't always submit

1 efficacy data, although sometimes it is required, and
2 certainly in the case of public health products, it is
3 required. But in order to get these state registrations
4 in several states, not just California, but California
5 probably being the most rigorous -- I mean, definitely
6 being the most rigorous, but also New York, Florida, many
7 other key states, you cannot put anything on your label
8 unless you have shown extensive data, good trials and if
9 you see a product that -- if it has a use registered in
10 California, believe me, that has gone through a rigorous
11 evaluation, particularly on the biochemical side, but
12 also on the microbial side as well.
13 MS. ANDERSEN: Win, you have -- if we can be
14 quick.
15 MR. HOCK: Yeah, just a quick comment kind of
16 addressing something that Adam raised and a few others.
17 The issue of using extension in the transition process,
18 one way to get the message out to growers is through the
19 extension service. The extension service works in every
20 country virtually in the country and they deal with
21 issues such as pest management, IPM, so forth. And I
22 think, you know, if we're going to do a transition, if

1 we're talking about transition processes, we've got to
2 include extension in that process.
3 Unfortunately, many extension services, and I
4 certainly can give you an example of Pennsylvania, were
5 actually cutting staff, we don't have the resources. So,
6 again, if somebody -- when I say somebody, some company
7 is wanting to promote a product, wanting to get it out
8 into the transition stream, go to extension, it may be
9 that they have to provide some fiscal support, but most
10 extension researchers will be willing to put materials
11 like this into their trials, but they need support to do
12 it. That's one of the things. It's a basic thing.
13 There just isn't the resource staff and the resource
14 funds out there to take every product that comes along
15 and throw it into a research program. But, again,
16 extension could play a key role.
17 MS. ANDERSEN: All right, last word, Steve.
18 MR. BALLING: Well, if I could speak for PBIA in
19 a couple senses, one is relative to efficacy data, why
20 have two separate standards for normal chemicals,
21 efficacy data is not required? Why would you require it
22 for biopesticides? Let the marketplace determine that.

1 If DelMonte needs to see replicated data, then that's --
2 and other growers and other users need to see it, then
3 that's going to force the companies to do that. I don't
4 see that EPA needs to require that.
5 Secondly, relative to Win's point, extension is
6 the problem. Extension has not shown great interest in
7 biopesticides, and when they do, they plug it in as a
8 straight substitute for compounds normally in the system.
9 We know that typically biopesticides are not strict
10 replacement compounds for what we've been using
11 historically, and they have to be massaged. Timing is
12 critically important. Use patterns are important and,
13 historically, extension has not been willing to try to
14 fit those into their programs. There are some places
15 where that works out very well, but it's not nationwide.
16 Part of the goal of the workshop in April is to
17 talk through those issues, in particular, with extension
18 people to say, how do we better fit biopesticides into
19 your programs.
20 MS. MULKEY: Okay. Pretend that was the next to
21 last word because Jose (inaudible).
22 DR. AMADOR: Just briefly, because we've been

1 talking about extension and it is true what Win says.
2 Extension -- we're seeing a reduction in force and a
3 reduction in time. Very few states now have extension
4 people who are 100 percent extension. They're going more
5 and more to the joint appointments. So, one thing I have
6 not heard mentioned here very much is the private
7 consultants, particularly independent private
8 consultants. I think that you're going to see a shift in
9 which extension is going to depend more and more on
10 private consultants to get the information out.
11 So, I think it's important that we keep that in
12 mind and at the same time that we train and we talk about
13 extension people, we also talk about the private
14 consultants and the role they can play, because this is,
15 to me, this is the way that things are going. I'm doing
16 a review now particularly of extension (inaudible) in the
17 United States and almost every state has had a reduction
18 in force, FTY, you know, for people. So, this is a
19 problem that I think we're going to see more and more in
20 the future, and if we don't rely on the private
21 consultants and the other people, I think we're missing
22 the boat.

1 MS. MULKEY: It's really great to see the level
2 of continued interest in this topic. We've apparently
3 struck a chord. And it's also heartening to see another
4 forum that can play a really important role in building
5 on this interest through the transition workgroup of the
6 CARAT. And so, for those of you who feel that you'd like
7 to roll up your sleeves and get a little deeper into
8 this, that may be available sooner rather than later.
9 So, with that, we'll turn to the next place in
10 the agenda. Going through these updates in somewhat more
11 than a minute, but nevertheless a pretty rapid pace, is a
12 real challenge. So, that's why we asked Jim to chair
13 this segment, so somebody else could crack the whip and
14 keep us moving.
15 A reminder, to the extent that you actually want
16 a discussion -- and we're actually in one of these, going
17 to ask your opinion, we really can't have a meaningful
18 discussion in this kind of context. So, we can take
19 clarifying questions and those kinds of things, but we
20 have some opportunities later in the agenda tomorrow to
21 identify things that you really want to invest
22 significantly more time in. So, keep that in mind if you

1 get frustrated.
2 Otherwise, Jim, take it away.
3 MR. JONES: Thanks, Marcia. As Marcia
4 mentioned, this is a pretty robust list of topics we have
5 here. Some of them are so robust, they are subject in
6 and of themselves to special advisory committees. Some
7 of them are so robust, we're having full day workshops on
8 them. So, largely, we're going to be giving information
9 out today. Try to keep your questions to clarifications
10 as many of them have other forms for having dialogue on
11 them.
12 There is one exception. We're going to be
13 asking for some advice on one of these topics and that
14 will become clear when we get to it. So, with that, I'm
15 going to turn it over to Lois Rossi for our first update.
16 MS. ROSSI: Okay. In your handouts in your
17 packet, there are three handouts related to the status of
18 tolerance reassessment and reregistration. In meeting
19 the FQPA August 3rd deadline, the agency reassessed, as
20 of August 2nd, close of business August 2nd, reassessed
21 6,465 tolerances out of the 9,721 universe. And the
22 handout that you have is as of August 2nd, because

1 actually, we're a little farther along even in the
2 tolerance count than that, but I wanted to present the
3 statistics as of August 2nd. There are a lot of
4 statistics on this sheet that you're welcome to look at,
5 and -- for example, over 70 percent of the Group 1
6 tolerances have had reassessment decisions comprising
7 over 60 percent of the total reassessed tolerances, and
8 you can look at those and you'll get a lot of statistics
9 on that.
10 In the second handout entitled, Reregistration
11 and Tolerance Reassessment Decisions, completed in fiscal
12 year 2002, that outlines all the decisions that we made,
13 five reregistration documents to date. We have another
14 one or two that are probably going to be issued before
15 the end of the fiscal year. We issued eight interim
16 reregistration eligibility decisions, mostly on the OPs.
17 We issued 18 what we call TREDs, Tolerance Reassessment
18 Decisions.
19 These decisions were all in the work plan that
20 many of you saw over the last year that we presented at
21 the CARAT workgroup at the OP cumulative process. While
22 my summary of one minute, which represents three years of

1 work, is reduced to --

2 **(Laughter.)**

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

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

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

1 Also, what are we doing now? On the web, we
2 have announced previously candidates for our 2003
3 decisions. We basically have some 3,200 odd tolerances
4 to go to meet the 2006 deadline and the remaining
5 reregistration decisions to complete by 2006. We're in
6 the process of working with our science divisions and
7 coming up with a multi-year plan on this. As soon as
8 that's ready, we'll be able to present that.
9 I would like to make two personnel announcements
10 with regard to SRRD. I don't know -- is Betty
11 Shackleford here yet? Okay, Betty Shackleford has been
12 Acting Associate Director of the Special Review and
13 Reregistration Division. And I know Rich Dumas is here.
14 Rich, could you stand up? Rich has just taken on the job
15 as special advisor in our division with a focus on use
16 and usage and stakeholder outreach. So, in the coming
17 months, I hope that a lot of the stakeholders will be
18 talking to Rich about various concerns.
19 And that's it in a minute.
20 MS. MULKEY: Betty just walked in.
21 MS. ROSSI: Betty just walked in. Betty.
22 There's Betty. And that's it in a minute, folks.

1 MS. MULKEY: Thank you, Lois.
2 MS. JONES: Any questions? One?
3 UNIDENTIFIED MALE: Lois, I just had a question
4 concerning the tolerance reassessment of inerts. In the
5 first trimester 87 were done, in the second trimester I
6 think 287 were done. That represents about, I think, 47
7 percent of the roughly 800 food uses inerts, and I
8 wondered where that might be reflected in your summary.
9 Is it in there or is it something that should be added to
10 it?
11 MS. ROSSI: It's part of the -- they're part of
12 the count. I don't think we broke up -- we might not
13 have broken them up. No, we just have the high hazard
14 ones broken out.
15 MS. MULKEY: They're in group three.
16 MS. ROSSI: Most of them are in group three,
17 that's right. But they're not individually identified.
18 UNIDENTIFIED MALE: Is there any way that --
19 MS. ROSSI: Yeah, we could identify them for
20 you.
21 UNIDENTIFIED MALE: If we could identify them in
22 the future, it would be helpful to chart the progress

1 over the years.

2 MS. ROSSI: Okay.

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

4 MS. STASIKOWSKI: Good morning. Since our

5 publication of the OP cumulative assessment in June,

6 we've been continuing to work. You are familiar with the

7 July meeting of the Science Advisory Panel where we

8 discussed incorporation and how we incorporated FQPA

9 safety factor in the assessment. We now have the SAP

10 report and are analyzing and preparing our responses.

11 The public comment period of cumulative

12 assessment was extended and just ended last week,

13 September 9th. We received 50 pages of comments

14 representing seven different commenters. We are now

15 looking at the PDP data from 2001 as it becomes available

16 and while we will be revising the assessment, we are

17 looking at any impact of risk mitigation taken on the

18 results of the cumulative assessment, as we see it in the

19 PDP data.

20 We are also -- to the extent that we receive

21 comparative cholinesterase inhibition studies, we will

22 consider them and incorporate them in the next version of

1 the OP cumulative assessment.

2 Earlier this month, again last week, we received

3 a lifeline version of the OP cumulative risk assessment

4 performed by lifeline group. That assessment was

5 performed using the same inputs as were used for the

6 calendex version that was published in June.

7 Publication of that assessment is being

8 considered as we look at the resolution of some of the

9 issues that I've just discussed. Risk mitigation, Lois

10 has mentioned, is continuing on several of the OPs, and

11 as those risk mitigation activities are completed, we

12 will incorporate them into the cumulative assessment.

13 That's my minute.

14 Oh, no, I want to also add, our next cumulative

15 assessment plan. Right now, we are working on the N-

16 methyl carbamates. We are analyzing uses and available

17 data. We also have made calls last year on triazines and

18 chloro-acetyl analides and we're working on those.

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

20 Jay?

21 MR. VROOM: I think there was also a CARES risk

22 assessment submitted also, along with the lifeline

1 cumulative risk assessment.
2 MS. STASIKOWSKI: That's right. We have the
3 program, CARES, but we don't actually have the OP
4 cumulative risk assessment run on CARES -- within CARES.
5 MR. VROOM: Really? We're pretty certain that
6 you do.
7 MS. STASIKOWSKI: I will check maybe during the
8 break.
9 MR. VROOM: Okay.
10 MS. STASIKOWSKI: But I just had a presentation
11 on Lifeline last week and I did not have that
12 presentation on CARES.
13 MR. JONES: Any other questions on Margaret's
14 presentation?
15 (No response.)
16 MR. JONES: Okay. Bill Jordan is going to give
17 us a couple of updates.
18 MR. JORDAN: The next two topics, the first one
19 is the NRDC objections to various tolerance rules that
20 EPA has issued. We sent out to PPDC members, and have
21 available in your pamphlet and out on the desk in the
22 hallway, a copy of the page that was posted on our

1 website summarizing the 14 different sets of objections
2 that the Natural Resources Defense Council has filed on
3 the final tolerance rules issued by EPA. The objections
4 are lengthy and each set of objections raises a number of
5 issues with regard to the tolerance rule. They are
6 highly complex, factual, scientific, legal, policy
7 questions, and it would be impractical to try to
8 summarize them other than to say that they are all
9 related to EPA's decisions with respect to the FQPA
10 safety factor. That seems to be a common denominator for
11 most of the issues raised in the objections.
12 As I indicated, we've made the objections
13 available on the website, and in the upper right-hand
14 corner, you will find information about how to access
15 that.
16 In the Federal Register in June 19 of this year,
17 we asked for public comment on the first eight sets of
18 objections that we had received, and that comment period
19 was scheduled to close today, but we are extending that
20 for an additional 30 days in response to the request from
21 some members of the public.
22 This particular topic is one that Jim referred

1 to about where we would like to get feedback from you.
2 We're considering whether the issue of a Federal Register
3 notice or use some other mechanism to solicit public
4 comments on the next six sets of objections we have
5 received from NRDC, and in the event that we receive more
6 objections from any other party or from NRDC, we'd like
7 to get your feedback on whether or not we should open up
8 a public comment period on them as well.
9 I want to note that in the next six sets of
10 objections, many of the issues that are raised are quite
11 similar to the objections that appeared in the first
12 eight sets, but there are a few issues that are chemical-
13 specific. So, as I finish up this particular summary,
14 think about whether or not it would be valuable to take
15 public comments on those, and if so, how we would go
16 about doing that.
17 I want to note that we are continuing to process
18 applications, emergency exemption requests, tolerance
19 petitions and so on for chemicals that are the subject of
20 an objection filed by NRDC. To date, EPA has not issued
21 any decisions involving such chemicals, but we do expect
22 to decide on a case-by-case basis for pending

1 applications and emergency exemption requests whether
2 there are sufficient data to support a decision.
3 Finally, I want to note that we do not have any
4 particular schedule, nor does the statute create one, for
5 resolving these issues, but we have been working on them
6 since we received them several months ago and we are
7 expecting to look closely at the public comments that we
8 receive in response to the Federal Register notice as we
9 go about making decisions. That's the first topic, the
10 first minute.
11 MR. JONES: And just to add that we do not need
12 to spend all of the rest of the time here in this session
13 providing input on this. Your call can use the PPDC
14 forum over the next 10 days, I'd say until next Friday,
15 to give us your thoughts about whether or not we should
16 be routinely seeking comment on objection received to
17 these tolerances, or is there a sense of you or groups of
18 you that, having looked at the first group, you don't
19 feel the need to have -- to participate and comment on
20 the subsequent ones.
21 So, I'll open it up for some comments. Carolyn?
22 MS. BRICKEY: Yeah. I guess I would want to

1 only take comment on something that's an issue, kind of a
2 first impression. If the issues have been -- that the
3 objections relate to have been raised in the rule-making,
4 for example, then I don't see any need to take comment on
5 the objections. They're really responding to the rule-
6 making. But if it's an issue that's been raised that's
7 not been a part of the rule-making and is kind of unique,
8 then I think it would make sense to do it.
9 I do not think it would make sense to do this
10 routinely because for those of us who do these comments,
11 it would be like a nightmare to have to think about
12 responding to all these different people's objections to
13 different issues. And it's confusing. Pretty soon,
14 you'll end up talking to yourself, you know, which is not
15 a good thing for some of us.
16 MR. JONES: Jay? Thank you.
17 MR. VROOM: A question on both the issue of the
18 objection authority under Section 408-G of FFDCA that you
19 refer to in Bill's handout in the first paragraph. Is
20 that limited only to objections or -- there is no
21 provision, as I understand it, there for making comments
22 that would be supportive of the petition, number one.

1 And, number two, on the topic I guess more germane to
2 what we're discussing here is the question of how much
3 public comment is appropriate and necessary on these
4 objections? It's our understanding that there are like
5 7,000 virtually identical e-mail kinds of submissions on
6 this range of objections that have been filed to the
7 petition, and if the agency's traditional use of weight
8 of evidence is going to be employed here, is agriculture
9 missing an opportunity to weigh in with at least 7,001
10 virtually identical supportive -- contrary virtually
11 identical e-mails, and where does this take us, Bill?
12 MR. JORDAN: Well, a couple of things. The
13 first question is whether there's an opportunity to file
14 comments in support of a final ruling. Of course, you
15 can always write us and we're happy to receive letters
16 saying you think we did the right thing, from any
17 stakeholder.
18 The 408-G(2)(A) really kicks off a specific
19 legal process described in the Food, Drug and Cosmetic
20 Act for giving parties an opportunity to first contest
21 before the agency and then eventually go to court with
22 their disagreements with EPA's action. And it seems to

1 me that if you agree with what EPA has done, while we
2 like the letters, you don't need to send it to us saying
3 you support our actions.
4 With regard to the e-mail campaign that you
5 referred to, we view the substance of the comments to be
6 more important than the number of the comments. And so,
7 what really matters is the scientific merits of the
8 comments made, not how many people happen to share that
9 opinion.
10 MR. VROOM: Thanks.
11 MR. JONES: Larry?
12 MR. ELWORTH: Two points of information. One is
13 how many of -- at least on the handout that we've got
14 here, how many of these are reduced risk active
15 ingredients?
16 MR. JORDAN: I'm not sure of the exact count,
17 but I know that several of them are.
18 MR. ELWORTH: Okay. It would be interesting if,
19 at some point, people could tell us what reduced risk is.
20 Secondly, I wanted to follow up on Carolyn's
21 thing. Were you asking us whether we thought there
22 should be another additional comment period above and

1 beyond the opportunity to file objections? Is that what
2 you were asking us or not?
3 MR. JORDAN: The question is, when someone files
4 an objection to the final rule, should we open an
5 opportunity for the public to comment on the ideas
6 advanced in the objections.
7 MR. ELWORTH: So, would you have to the publish
8 an opportunity for an additional comment period, is that
9 -- you would?
10 UNIDENTIFIED FEMALE: (Inaudible).
11 UNIDENTIFIED MALE: Larry, we have before us a
12 number of objections --
13 MR. ELWORTH: Right, right.
14 UNIDENTIFIED MALE: -- and we have gotten
15 additional objections on different actions that raise
16 basically the same issues, but not exactly the same
17 issues.
18 MR. ELWORTH: Okay.
19 UNIDENTIFIED MALE: In that scenario, is there a
20 desire to see us, each time we get objections that cover
21 basically the same issues but maybe not exactly the same
22 issues on different actions, is there a desire to see

1 additional public comment?
2 MR. ELWORTH: Oh, okay.
3 UNIDENTIFIED MALE: On the additional final
4 actions.
5 UNIDENTIFIED MALE: That's easy for you to say.
6 MR. ELWORTH: Yeah, right.
7 UNIDENTIFIED MALE: You can provide a tutorial
8 later.
9 MR. ELWORTH: I'm kind of like with Carolyn
10 (inaudible).
11 MR. JONES: Jennifer?
12 MS. SASS: I hope this is a quick question.
13 What do you see happening with the public comments? In
14 other words, what do you see the function of a comment
15 period for if this is an objection that's basically a
16 legal process that's put into play, how do you see public
17 comments being used and then why do it and then why
18 extend it and then why double extend it?
19 MR. JORDAN: As I indicated, we think that the
20 objections that NRDC has raised are pretty broad, go to a
21 number of scientific, legal, factual policy questions,
22 and getting the views of a variety of stakeholders on

1 those issues, we think, will help us make a better
2 decision with regard to the merits of them. So, what we
3 anticipate is if there is information provided to us for
4 analysis of, I guess, legal questions, then we would
5 consider it and see whether or not it shapes our
6 particular choices.
7 We're not interested in prolonging the process
8 just for the sake of taking a longer time. These are, in
9 a number of cases, the first time that we've looked at
10 some of these questions.
11 MR. JONES: Okay, Julie, and then I think we
12 have to wrap this update up.
13 MS. SPAGNOLI: I think what I'm understanding
14 from this is that the substance of the comments is really
15 regarding policy or policy interpretations that the
16 objections were based on. So, I guess I would say that
17 if the basis of the objection is on an interpretation of
18 a policy, then I think it would be appropriate to solicit
19 public comments on that interpretation or on that policy
20 if that's really what the basis of that objection is. If
21 it's not just, you know, was it this number or that
22 number, but it's more of a policy interpretation, I do

1 believe public comment is appropriate.
2 MR. JONES: Okay. And, again, we will engage
3 additional dialogue on this through our PPDC forum and
4 will be happy to have additional one-on-one conversations
5 with anyone in PPDC who wants further clarification or to
6 get a better understanding of what we're actually asking
7 over the next couple of days.
8 We'll move on to the next update. Bill?
9 MR. JORDAN: Okay. This is an update on where
10 EPA is with regards to the issue of consideration of
11 human studies. First, let me start with the news and
12 then go back over briefly our current situation here.
13 As you know, in December of last year, EPA asked
14 the NAS to provide us advice on the circumstances in
15 which the agency should accept, consider and rely upon
16 third party human toxicity studies. The NAS agreed with
17 our request and signed a contract with EPA September 5th.
18 The academy has been anticipating a signature on
19 that contract and had been thinking about planning to
20 move ahead quickly with it and in conversation last week,
21 I learned that they have made excellent progress towards
22 choosing a committee and they expect to post the names of

1 the provisional members of the committee early in
2 October. They are expecting that the committee will come
3 together and have the first of several public information
4 gathering meetings probably sometime by the end of this
5 year. The contract which we and the NAS signed calls for
6 the completion of the NAS report around the end of next
7 year, 2003.
8 As you probably recall, the press release that
9 we issued in December of last year, explained that our
10 approach during this interim period would be that the
11 agency "will not consider or rely on such human studies
12 in regulatory decision-making whether the study is
13 previously or newly submitted." And we take that
14 approach unless we're legally required to consider or
15 rely on the studies.
16 Just to remind you to be really clear about it,
17 the studies that are covered by this approach are third
18 party studies, that is to say studies which are not
19 conducted by or sponsored by a Federal agency subject to
20 (inaudible) rule and it also is limited to studies which
21 intentionally dose human studies with toxicants to
22 identify or quantify the effects of the toxins.

1 We have, at EPA, never required or we certainly
2 do not encourage studies of this sort. But we have,
3 sometimes in the past, received studies that have been
4 voluntarily submitted by regulated entities.
5 Other kinds of human studies are not affected by
6 this December press release approach. We have long
7 accepted, in some cases we've been required, other kinds
8 of human research such as studies of applicator or
9 reentry worker exposure, pharmacokinetic studies,
10 repellant efficacy or reports of pesticide incidents or
11 epidemiological investigations. We will continue to
12 accept and consider these other kinds of human study
13 data.
14 When we receive a human study that is not
15 subject to this interim approach, EPA will review it, and
16 where appropriate, we will rely on it. Obviously, our
17 review will consider the scientific merits of the study.
18 But because FIFRA also makes it unlawful to use a
19 pesticide in a test with human subjects unless the
20 subjects are fully informed and freely volunteer to
21 participate, we'll also pay attention to these ethical
22 aspects of the design and conduct of the research.

1 The last thing I want to mention is that in
2 2002, CropLife America and other entities sued EPA in
3 U.S. Court of Appeals for the District of Columbia. They
4 challenged, in that action, EPA's interim approach as
5 articulated in the December press release. The Court of
6 Appeals considered and dealt with a number of preliminary
7 motions filed both by the government and by CropLife
8 America and other parties, and having decided not to take
9 any action on those motions, that is to say, not to
10 (inaudible) the merits in dealing with those motions, the
11 court has set a schedule for the parties to file briefs
12 on the merits and they have also scheduled oral argument
13 on the merits for March 17, 2003. So, that's where that
14 stands.
15 MS. JONES: Any questions for Bill? Has?
16 DR. SHAH: Bill, thanks for the clarification of
17 what's covered under the moratorium and what's not
18 covered under the moratorium. We have heard that several
19 times verbally. Is there a written clarification that
20 the agency has issued or can issue so that this issue
21 does not come up every time, it was covered, it was not
22 covered even though based upon a verbal presentation? A

1 few people know here, but not everybody knows.
2 MR. JORDAN: The remarks that I made were taken,
3 in a number of cases, verbatim from the press release
4 issued on December 14, 2001, and that is available on
5 EPA's website. I'd be happy to give you the reference
6 for that if that would be helpful.
7 MS. MULKEY: The letter to NAS.
8 MR. JORDAN: And then we have a letter to NAS
9 that's also part of that. I can provide that to you.
10 MS. MULKEY: Just tell him what (inaudible).
11 DR. SHAH: Okay. The letter to NAS, that would
12 be helpful.
13 MR. JORDAN: Okay, thank you.
14 MR. JONES: Anne Lindsay is going to provide the
15 next few updates.
16 MS. LINDSAY: Okay. The first thing I wanted to
17 give you an --
18 **(END OF SIDE B, TAPE 1)**
19 MS. LINDSAY: -- policy. This is a policy that
20 we originally published in the fall of 1999, and I'm
21 sitting here realizing, oh, that's the last century
22 already.

1 UNIDENTIFIED MALE: Anne, could you speak up?
2 Get closer to the mic.
3 MS. LINDSAY: Okay, we'll see if this does
4 better. More recently, we -- actually in August of this
5 year, we published a Federal Register notice announcing
6 the availability of two guidance documents related to
7 that policy. One of them is a PR notice and you have it,
8 I think, in your packets, and it's also out on the table
9 for others, as well as an internal standard operating
10 procedure.
11 The basic policy, without going into all of the
12 details, tries to identify those circumstances in which a
13 tolerance might not be required for a pesticide use in or
14 on food, and it's essentially when we know with
15 confidence that no residues have been detected and the
16 estimated potential risk is at a level of no concern.
17 The PR notice describes sort of how you would
18 actually go about requesting a threshold of regulation
19 decisions by the agency. It's a fairly simple procedure.
20 It applies both to the establishment of new tolerances,
21 the reassessment of old tolerances, the issuance of the
22 State 24C Special Local Need Registration or a Section

1 18, if it fits in -- for the particular chemical and the
2 particular use in question.
3 We've created a special section of the Federal
4 Register to install decisions that result from the
5 application of the policy. It's actually, I think,
6 180.2010. That's all in the PR notice. You don't need
7 to write it down.
8 And there are four -- when we get a request for
9 a special regulation decision, there are four possible
10 outcomes. The first is yes, this request does meet the
11 criteria, the use is below the threshold of regulation
12 and it also meets the FIFRA registration standard. So,
13 it's a go both with regard to the lack of a need for a
14 tolerance and for registration.
15 The second kind of decision we might make is
16 that the use actually is above the threshold of
17 regulation, but we can go ahead and establish a tolerance
18 and a registration could also be a go under FIFRA.
19 The third possible outcome is that the use is
20 above the threshold of regulation. It would need a
21 tolerance, but we're not able for (inaudible) kind of
22 concerns to actually establish the tolerance.

1 And then the fourth outcome would be that it's
2 below the threshold of regulation for tolerance purposes,
3 but the use for some other non-tolerance related reason
4 poses an unreasonable risk under FIFRA. It might be an
5 occupational issue or non-target species issue, in which
6 case, at least initially we would not be able to grant a
7 registration, even though the TOR, the threshold of
8 regulation policy, was found to apply.
9 You'll see all of this laid out in the PR
10 notice. It's on our website. We've had some, I would
11 call them, sort of exploratory discussions with a number
12 of registrants about the actual use of the threshold of
13 regulation policy and we're hopeful that with the
14 issuance of this other guidance in the PR notice and our
15 own internal standard operating procedure that we'll see
16 some more use of the policy.
17 MR. JONES: Any questions on TOR for Anne?
18 Steve?
19 STEVE: Well, I submitted my response three
20 years ago on that. I still think that if there's zero
21 residues then zero times the hazard is still zero risk.
22 But that doesn't seem to be EPA's policy on this.

1 Three years after the original notice, you're
2 now providing guidance, which suggests to me there
3 haven't been a lot of registrants knocking down the door
4 for this particular opportunity. Yet, it really seems to
5 represent a nice option, a nice tool for transition to
6 move some of these products into the system, particularly
7 for seed treatments and soil treatment at planting and
8 some of those kinds of things.
9 What are you seeing in terms of participation
10 requests, et cetera, and what do you think the barriers
11 are to adopting?
12 MS. LINDSAY: We're not seeing what I would call
13 a barrage of requests coming in the door. We've had
14 these exploratory discussions with a number of different
15 folks. I should note that we could actually receive
16 requests -- and the PR notice makes this clear. It's not
17 confined to a registrant. A grower group, some other
18 organization could also, in a given case, actually
19 request a threshold of regulation kind of decision from
20 us.
21 So, we're not seeing a lot. We'd like to
22 actually encourage some more use, because I think we

1 would agree with you that there are situations where it
2 seems like it's a policy that has a niche to play. I
3 would suspect that one of the issues is, though, that we,
4 by design, crafted a policy that does actually require
5 work. You have to really be able to demonstrate, based
6 on reliable data, quality data, that there are no
7 residues detected with a method that's sufficiently
8 sensitive and to do the estimated potential risk well.
9 So, it's not -- this is not, I guess what I
10 would call, in the no-brainer quality, to use a cliche.
11 It requires -- it still requires real work to demonstrate
12 that that test has been met.
13 STEVE: Well, wouldn't presumably the reduced
14 risk compounds meet sort of the hazard portion of this so
15 that if you found -- if you went down to a reasonable
16 level of detection and found nothing there, then that
17 would follow?
18 MS. LINDSAY: I would think that that would be a
19 likely candidate pool, but I would suspect others around
20 the table might be able to share with you. And I don't
21 know that we're supposed to be getting into a deep
22 discussion --

1 STEVE: Yeah, okay.
2 MR. JONES: Yeah, we've definitely got to move
3 this along.
4 MR. ELWORTH: Well, this won't move it along.
5 **(Laughter.)**
6 MS. LINDSAY: I don't know whether I want to
7 answer your question.
8 UNIDENTIFIED MALE: He's going to ask it anyway.
9 MR. ELWORTH: Well, at some point -- I
10 understand the words, but in the Section 18 section, the
11 last sentence on the section on Section 18s, the second
12 paragraph it says, however, because of the time limit
13 nature of the emergency exemption, EPA would grant an
14 exemption, but would not propose to establish the
15 emergency use as a TOR use under Part 180.
16 I understand what the words mean. I don't
17 understand the logic. Why does the time limited nature
18 of the 18 lead you to decide to just grant an exemption
19 rather than threshold of regulation?
20 MS. LINDSAY: I think it's because they are, in
21 fact, very time limited and the presumption would be that
22 they'd be there and gone and you'd be taking back and

1 forth out of the CFR. They would not -- for an 18, they
2 would not be a permanent --
3 MS. MULKEY: Simply because it's not registered.
4 You wouldn't establish a permanent finding. I think it's
5 not more (inaudible).
6 MR. ELWORTH: Right. It does the question of
7 why it's not being -- why no one's seeking its
8 registration.
9 MS. LINDSAY: But the analysis underlying it
10 would be comparable.
11 MR. JONES: Okay. Bill, and then we'll wrap
12 this (inaudible).
13 MR. McCORMICK: I just have a question about
14 scope. Is this limited to actives only when you talk
15 about pesticide chemicals or does it include inerts?
16 MS. LINDSAY: I don't think that there's
17 anything in the policy, per se, that limits it to active
18 ingredients. So, that may be another venue that should
19 be explored a bit.
20 MR. JONES: Julie?
21 MS. SPAGNOLI: Prior to issuing this, I think
22 the policy was essentially applied in some cases to

1 products that were just conceptually there, like baits
2 that were contained in a bait station. Does this impact
3 any, like, future products in those categories that were
4 just more or less given that kind of status just on -- I
5 almost want to say almost as though -- a logical basis.
6 That if it's in a -- that if the product is contained in
7 a bait station, put in inaccessible areas, that those --
8 do they need to go now through a more formal process than
9 they did?
10 MS. LINDSAY: This isn't, I believe, asking
11 anybody who's already gotten a decision from us to come
12 back in and --
13 MS. SPAGNOLI: Well, and I'm thinking kind of
14 from -- if you're coming in with a new bait product, do
15 you really have to demonstrate that there are no residues
16 or do you just -- you know, kind of the logic of it,
17 just --
18 UNIDENTIFIED MALE: There's no tolerance link,
19 Julie, so there would be no applicability to a bait
20 product or --
21 MS. SPAGNOLI: Okay.
22 MS. LINDSAY: Yeah. But I would say in any

1 given case, depending on the use pattern proposed for the
2 bait, because I know there are some bait use patterns
3 that can raise questions about is a tolerance needed.
4 MS. SPAGNOLI: Right. I'm thinking of a bait
5 that's like in a contained station.
6 MS. LINDSAY: Yes.
7 MS. SPAGNOLI: And that's put under sinks, you
8 know, kind of thing.
9 MS. LINDSAY: But my standard answer would be,
10 you'd always want to talk to the relevant registration
11 division about the specifics in any given case as to what
12 you really needed to do.
13 MS. SPAGNOLI: Okay, thanks.
14 MR. JONES: Okay, Marcia, you've got the next
15 update.
16 MS. MULKEY: I obviously have to be fast in
17 order to --
18 MS. LINDSAY: Jim, Jim, Jim.
19 MR. JONES: Oh, I'm sorry, I'm sorry. I jumped
20 ahead.
21 MS. MULKEY: Actually, Anne does have another
22 one. You're right.

1 MR. JONES: Freudian slip in my whip-cracking to
2 move things along.
3 MS. LINDSAY: It's so quick.
4 MR. JONES: Pardon me, Anne.
5 MS. LINDSAY: It's so quick that he knew I
6 needed no time.
7 On endangered species, there are, actually, a
8 lot of things that I could be providing you an update on,
9 but there's only one thing that I actually am going to
10 provide an update on.
11 Members of the PPDC should have received from
12 Margie, in an e-mail submission a couple of weeks ago, a
13 heads up about a workshop that we're planning. This is a
14 workshop that will occur on Thursday, this week, in this
15 same hotel. I think literally in this same room. And
16 Margie and Joe are just now passing out the agenda for
17 this endangered species workshop. Its focus is on ideas
18 for implementing the Endangered Species Act more
19 systematically within the Office of Pesticide Programs.
20 There are four broad topic areas that we've identified,
21 approaches to consultation with the services, public
22 participation at various points along the way, and ways

1 of doing public participation effectively, compliance
2 assistance and enforcement labeling and bulletins.
3 This is a prelude to them actually developing a
4 Federal Register Notice which we would put out by the end
5 of this calendar year. The Federal Register Notice
6 itself will be a proposal and will be subject to comment.
7 So, while we will be making various endangered
8 species decisions in compliance with the schedules that
9 we've agreed to, we're also going to be developing this
10 proposal for more systematic implementation of the
11 Endangered Species Act, and this is a sort of immediate
12 opportunity to give us some input as we actually begin to
13 draft that proposal for later publication. And that's
14 it, Jim.
15 MR. JONES: Thanks, Anne. Any questions on that
16 before we. . .
17 MR. ELWORTH: Jim, just real quickly. There's
18 nobody from Fish and Wildlife or anything involved in
19 this or NIMFS or any of those guys.
20 MS. LINDSAY: They're invited. You're just
21 seeing the names of the EPA people who are sort of
22 running the event.

1 UNIDENTIFIED MALE: Okay. But the proposal is
2 going to be developed with --
3 MS. LINDSAY: By EPA, but it will have input
4 from the services as well as from an array of folks.
5 UNIDENTIFIED MALE: Sounds like an interesting
6 OMB discussion.
7 MR. JONES: Why don't we take one of the
8 remaining three where we may have a time issue tomorrow
9 and that's the new registrations, and then we'll put the
10 remaining two on tomorrow afternoon's updates or we'll
11 take the other two and then -- okay, we'll take the last
12 one, the opportunity for public participation in biotech
13 issues. Okay.
14 MS. ANDERSEN: That's not the -- there is some
15 slides, but we'll see if we can do it in just -- in the
16 interest of a break, we'll keep going.
17 There are lots of opportunities for the public
18 to participate in discussions about biotechnology, and
19 the Pesticide Program, obviously, we only deal with the
20 pesticidal part of biotechnology, which is a small part
21 overall of biotechnology in the United States, but I
22 wanted to go over some of the opportunities that there

1 are for the public participation.
2 I'll begin with the National Academy of
3 Sciences, which is doing a lot of work in biotechnology
4 and continuing to do so, has for the -- several years in
5 the past. They have right now a standing committee on
6 agricultural biotechnology health in the environment.
7 This is conducting a broad series of studies and
8 workshops and what I've listed up there are the four that
9 are actually going on in this year, and there are
10 certainly more in the future. EPA has, itself, been
11 especially interested in the first one, the environmental
12 effects of transgenic crops, and the last one, unintended
13 health effects of GE foods and that workshop is actually
14 being held on the 23rd.
15 Then on to USDA, they do a lot of issues where
16 they all have either a policy or a regulation that
17 they're considering and they'll put it out for public
18 comment through the Federal Register and take public
19 comments on it. They, too, have advisory committees.
20 They do rely quite heavily on the NAS, but they also have
21 an Advisory Committee on Agriculture and Biotechnology
22 which expired its FACA license if it -- in 2002 on

1 February, and now they are putting together a new
2 advisory committee which they are calling the Advisory
3 Committee on Biotechnology and the 21st Century
4 Agriculture, and their acronym is just going to be AC21.
5 They are now choosing their members and will be then
6 moving forward to hold meetings and these are definitely
7 something like this, all stakeholders involved.
8 FDA holds lots of public hearings and has been
9 known to go out across the country and request comments
10 from the public. They also issue their proposals for
11 comment in the Federal Register, and probably one of the
12 ones that have been most interesting to this organization
13 or the PPDC would be the ones recently on food labeling.
14 The Center for Food Safety and Applied
15 Nutrition, I did not write it out, but that's the Center
16 for Food Safety and Applied Nutrition, has a
17 biotechnology subcommittee under it's Food Advisory
18 Committee. This group has recently been put together and
19 they head a meeting in August on allergenicity that was
20 very useful and we attended it, also. And their Center
21 for Veterinary Medicine has a veterinary medicine
22 advisory committee and all of these take public comments

1 and are open to the public.
2 For EPA, every action that we issue regarding a
3 biotechnology activity, whether it's an EOP or an
4 amendment to EOP or anything, they always get announced
5 in the Federal Register. We hold public hearings to
6 gather information and have done that in the past. We do
7 lots of workshops on specific topics that are open to the
8 public and invite public comment and participation, and
9 we certainly do a lot of Scientific Advisory Panel
10 meetings on biotechnology. Over the last three years, we
11 have done over -- we've done seven SAP meetings.
12 What I will focus on a little bit is the BT
13 crops reassessment, where we really emphasize public
14 participation. We went back and reassessed all of the BT
15 crops that have been registered to date and looked at
16 whether or not we should allow those products on the
17 market. We had an SAP meeting, but we also allowed the
18 comments on the preliminary risk assessment and we also
19 took comments on a paper that we drafted on what we might
20 do with response to those products as well as just
21 holding the public docket open for this one. As we
22 continue to work through the products, with their new

1 compliance programs that need to be put in place, the
2 public docket for that continues to be open and we, too,
3 continue to get comments on it and work with them.
4 Just quickly, other forums where there is a
5 chance for public participation, the CODEX Task Force on
6 Biotechnology Foods is an international group, but it has
7 a number of NGOs, which are actively participating. In
8 fact, Alan Goldberg's international counterpart to his
9 organization is an active member in that task force.
10 The National Institutes of Health and EPA have
11 held workshops, and recently did last November, on
12 allergenicity, which continues to be a very important
13 topic in biotechnology products.
14 We -- in the United States Government, USDA and
15 EPA, held -- hosted an OECD conference, also last
16 November, on environmental effects and we have repeatedly
17 national science societies, the Entomology Society,
18 PHYTOPAT (phonetic) Society, et cetera, have symposiums
19 which are -- invite the public to attend and are publicly
20 available information, the proceedings of those that
21 anyone can also see as well as do it.
22 And then the Office of Science Technology and

1 Policy, which is part of -- actually works out of the
2 White House Staff, they have recently put out a Federal
3 Register Notice for comment on a policy on adventitious
4 presence that might be there by the -- that might be put
5 in place by the various regulatory agencies, USDA, FDA,
6 and EPA.
7 So, I did that, I know, very quickly because
8 there was only a few minutes before your break is over --
9 **(Laughter.)**
10 MS. ANDERSEN: And I just wanted to let you know
11 there are lots of places for the public to participate in
12 biotechnology.
13 MR. JONES: Thanks, Janet. Okay, well, what
14 we're going to do at this point is move on to our break.
15 But to let you know, we have two remaining topics in this
16 session, the FY '02 status of new registrations, we're
17 going to pick up in the afternoon session where we're
18 doing some follow-up from the May 2002 meeting, the 3:45
19 slot. So, that will start off -- that update will start
20 off that session.
21 And then Marcia will do her update on the worker
22 risk seminar at tomorrow's session on updates in a

1 minute. So, we will end this session right now.
2 MS. MULKEY: But a reminder, we have scheduled a
3 15-minute break. Let us keep it to that. The schedule
4 has some room, you've made your panel. I think we'll be
5 able to complete the day's work, but only if you're back
6 by 10 after and not a minute later.
7 **(A brief recess was taken.)**
8 MS. MULKEY: We are eagerly waiting your return
9 to your seats.
10 **(Brief pause.)**
11 MS. MULKEY: We are confident that with a little
12 work, we can cover, over the course of the two days, the
13 entire agenda, and in particular, we are confident that
14 we will have the kind of full, comprehensive focus on
15 today's major topic that everybody is interested in. We
16 are mindful that we have about a half hour, actually a
17 little less, to make up. The likeliest impact of that
18 will be that there will be somewhat less time in the
19 current framework of the agenda for discussion. But we
20 anticipate that the public comment period rarely takes
21 the full 30 minutes, and we anticipate acting in a very
22 disciplined way this afternoon about our breaks, as we

1 have more or less just now succeeded in doing for this
2 break. So, that's a good sign.
3 A special thank you to all of you who are in
4 your seats. Of course, it's never the people who need to
5 hear the message who get the negative vibes if you give
6 it at the outset. So, we may try again before the lunch.
7 This next group, as you know, emerged from your
8 midst; that is to say, a group of PPDC members who
9 basically stepped up to this issue showed a keen interest
10 in this issue, has been working more or less steadily
11 since the last PPDC meeting with the agency to identify
12 issues, to work through opportunities for engagement, and
13 one such opportunity is this panel presentation.
14 Jack Housenger, who is currently serving as the
15 Associate Director of our Anti-Microbials Division, but
16 who comes here wearing one of our senior leadership hats
17 around an issue that cuts across our entire organization,
18 is going to chair this panel, and I'm going to turn it
19 over to him.
20 MR. HOUSENGER: Thank you, Marcia. To be frank,
21 this is an issue that I knew little about before we
22 started on this endeavor, and I'm still learning as we're

1 going along.
2 Debbie Edwards and I convened this group of
3 people sometime ago and -- can everyone hear me?
4 UNIDENTIFIED MALE: Um-hum.
5 MR. HOUSENGER: We've actually done it all by
6 phone. So, even some of the people that are presenting
7 today, I haven't met yet, which I hope to do sometime
8 today. But we have seven presentations, there's quite a
9 bit of material. So, at the end of the day, hopefully,
10 you'll come away a little smarter than you were at the
11 beginning of the day.
12 We've shared our presentations with one another
13 and we haven't censored these at all. So, what's being
14 presented are the thoughts of the people and not everyone
15 necessarily agrees with what everyone's going to say, but
16 we did want people to have the opportunity to say what
17 they thought on the non-animal testing issue.
18 One of the things that we talked about very
19 early on and got consensus on was that because this is
20 such a huge topic, that we would discuss only the six-
21 pack or the acute studies, not the beer, in our
22 conversations. But you're going to see, some of the

1 slides go beyond the six-pack and, like I said, we didn't
2 object to that.
3 Before we get started, we want to have Marcia
4 talk a little bit about where the agency is on non-animal
5 testing, and I'll turn it over to her now.
6 MS. MULKEY: My remarks will be brief, but I
7 think they are important framing remarks. As you know --
8 and they are more or less on behalf of all of EPA,
9 although because of the nature of the Pesticide Program,
10 the amount of testing that we are able to require and
11 need to require creates a dynamic in which we tend to be
12 front and center around an issue like this. But we are
13 certainly not the only part of EPA for which this is an
14 issue.
15 I think it's important, and we always bear in
16 mind that, first and foremost, our obligations are to
17 assure that we analyze properly and completely the risk
18 and hazards associated with the use of pesticides or any
19 other substance for which EPA has regulatory
20 responsibility. In other words, we must have sound
21 answers to the important science questions to allow us to
22 assure that pesticides meet the appropriate standards of

1 protectiveness. That is the ultimate framework within
2 which we come to this dialogue.
3 And, of course, in order to get sound answers to
4 those important science questions, we have to develop an
5 understanding of how pesticides can affect people and
6 wild animals and, of course, plants and domestic animals
7 as well, so that we have a need to understand the effect
8 of pesticides in all kind of animals, including the kind
9 of animal that is gathered around this table today.
10 But I also want to make it very clear that we
11 are very committed that testing to give us those sound
12 answers and to help us answer the key science questions
13 be done in a way that is cost-effective, that is
14 efficient, that is not unduly burdensome, and in a way
15 that is ethical. And the extent of use of animals in
16 this testing is related to both of these issues. It is,
17 in general, a costly and time-consuming way to develop
18 answers to these science questions, and when you use
19 living creatures for your tests and especially higher
20 order living creatures, you face very real ethical
21 considerations and constraints.
22 And so, we look forward to this as to other

1 opportunities to help us think through these
2 considerations.
3 Today, we will not continue to emphasize the
4 cost-effectiveness issue or the efficiency issue. The
5 focus will be more on the ethical issue, but it does bear
6 repeating that both considerations warrant care about the
7 extent and frequency of animal testing.
8 For well in excess of a decade, EPA has openly
9 and publicly embraced the principles for animal testing
10 that were first set forth in the 19 -- well, maybe set
11 forth before that, but at least a key time they were set
12 forth was in the 1959 book, the principles of humane
13 experimental technique. Those principles sometimes
14 called the three Rs; replacement of animal testing where
15 practicable, reduction of the number of animals and
16 refinement of the way in which animals are tested to
17 improve humaneness.
18 Our issues -- our involvement with these issues
19 have been more than lip service. They have been
20 manifested in a number of activities over time and they
21 have been articulated primarily along with all of the
22 U.S. Government articulation of its embracing of these

1 principles contained in the implementation of ICCVAM,
2 which you will hear enough about, you don't need to hear
3 from me about. But you will find as part of the
4 documentation of its development and implementation, the
5 articulation of these principles.
6 And you will also find EPA when the situation
7 warrants, as we did in connection with a program called
8 the High Production Volume Testing Program, an effort to
9 try to understand more about some chemicals that are
10 nowhere near as thoroughly tested as pesticides tend to
11 be, as well as articles that have been written by
12 professionals at EPA, including one just recently in the
13 ILAR Journal, and I believe a copy of that has been made
14 available to you, that article, and others. You will
15 find us stating these principles.
16 Finally, I want to mention briefly work of our
17 Office of Research and Development. The 2002 budget
18 actually earmarks, as budgeteers use the term, or
19 identifies $4 million for EPA to spend on research on
20 enhanced use of alternative testing, and in particular in
21 vitro testing for the -- and that monies -- those monies
22 are being directed primarily to the endocrine disruptor

1 program, which is a program that was contemplated under
2 FQPA, as well as the Safe Drinking Water Act, for the
3 testing of substances, screening and other kinds of
4 testing involving endocrine disruption.
5 Are Jackie McQueen and Robert Dyer here? If you
6 could --
7 UNIDENTIFIED FEMALE: Bob Dyer's not here.
8 MS. MULKEY: Okay, Jackie is here, okay. Thank
9 you very much for coming. She's with our Office of
10 Research and Development and they came along in order to
11 hear this dialogue and be available if any issues arise
12 that they can be helpful with.
13 And in particular, with reference to the topic
14 this morning and this afternoon where we have focused on
15 the acute testing, I think in part because it's seen as a
16 particularly productive area for thinking about
17 alternative testing in the near term, EPA has placed
18 $500,000 into an interagency agreement with NIEHS to
19 focus on in vitro cytotoxicity validation project for
20 acute toxicity. So, that's a very specific manifestation
21 of our research commitment.
22 So, this PPDC dialogue is yet another

1 opportunity for us to make clear what our, EPA's approach
2 is, context and committee is, as well as to hear the view
3 of others, and we look forward to it. Thank you, Jack.
4 MR. HOUSENGER: Thank you, Marcia. Our first
5 presentations are going to be made by EPA because we're
6 running it, so we can be first.
7 **(Laughter.)**
8 MR. HOUSENGER: We thought it would be good to
9 give a little background about what we currently do to
10 reduce the number of studies and Mark Perry, who's a team
11 leader with the Product Reregistration Branch and the
12 Special Review and Reregistration Divisions, is going to
13 be talking first about some of the acute tox studies and
14 bridging and batching. Mark's been with the agency for
15 12 years. Like I said, he's a team leader for Product
16 Reregistration Branch, which is the branch responsible
17 for implementing all the various decisions that are made
18 in the reregistration decision documents and reviewing
19 data that comes in on acute testing to support the label
20 hazards that are on those labels. Mark?
21 MR. PERRY: Can everybody hear me?
22 Good morning. As Jack said, I'm going to talk

1 about the strategies that OPP currently uses to reduce
2 acute toxicity testing. (Inaudible).
3 I'll start with a little bit of background,
4 basically. Those of you that are familiar with this,
5 just try to bear with me. Those of you that don't know,
6 there are six acute toxicity studies, the acute oral, the
7 acute dermal, the acute inhalation, eye irritation,
8 dermal irritation and skin sensitization.
9 The first three are systemic toxicity studies by
10 the designated route, oral, dermal or inhalation. The
11 next two, of course, are irritation studies for eye and
12 skin, and the third one, dermal sensitization evaluates
13 contact sensitization following repeated exposure.
14 Once the agency reviews these studies, they
15 place each study into a category from I to IV with I
16 reflecting the most severe results of the study and IV
17 reflecting, basically, the least severe. The exception
18 to that is the dermal sensitization which we don't really
19 evaluate on a 1 to 4 scale. We just use a positive or a
20 negative designation.
21 Once we do that, once we review all those
22 studies, we get what we call the tox profile basically

1 for that product that was tested.
2 Let me go ahead and switch. We then take this
3 tox profile and basically translate into product
4 labeling. Since each category, I, II, III or IV,
5 corresponds with specific labeling requirements, signal
6 word, hazards to humans and domestic animals, which has
7 the PPE in it, first aid section and the restricted-use
8 classification, as well as child restraint packaging
9 criteria.
10 Something we get asked all the time is why don't
11 we just go ahead and use the acute data on the a.i. to
12 support the end use product and there's a couple of
13 pretty good reasons for not doing that.
14 First of all, a lot of inerts are very toxic and
15 they're present in concentrations that are much higher
16 than the active ingredient may be present (inaudible).
17 Secondly, it's difficult to predict if there's going to
18 be a synergy between the inerts and the active
19 ingredient, which will result in an increased toxicity,
20 and the third main reason that we don't just test the
21 technical is that there can be significant physical
22 differences between the technical and the end-use

1 products. You might have a technical material that's
2 something like a waxy solid that, for example, cannot be
3 tested by inhalation, but it might use products that are
4 formulated with a solvent and that's dissolved in the
5 solvent and then sprayed and (inaudible).
6 Moving on from that little bit of background on
7 the acute, I want to talk about the two main strategies
8 that we really use to reduce acute toxicity (inaudible)
9 and those two things are waiving the data requirement and
10 allowing data citation. Those are the two things.
11 I'm going to talk about data waivers first.
12 Waivers can be kind of broken down into three different
13 groups. You can have waivers that are based on existing
14 knowledge that we have of extreme toxicity, waivers based
15 on a lack of toxicity or irritation and waivers based on
16 a lack of exposure potential by the route of concern.
17 The first route there, waivers based on extreme
18 toxicity, a good example of that is when we have a pH of
19 a product that's less than 2 or greater than 11.5. We
20 have a really good idea that that's going to be corrosive
21 to the eye and skin. What we do is just go ahead and
22 waive the data requirement and place it in Category I.

1 We see all sorts of different scenarios here. People
2 supply all sorts of different information trying to
3 support a Category I classification. We're open to
4 looking at anything like that to support such
5 (inaudible).
6 The second group, waivers based on a lack of
7 toxicity or irritation, we have situations sometimes
8 where a registrant might come in and make an argument
9 that they have a product with one a.i. and three inerts.
10 They must provide information on all four of those
11 components, demonstrating that there's not going to be a
12 toxicity or irritation concern, there's not going to be
13 any synergy. We'll look at that information, we'll
14 consider it. We'll make a weight of the evidence call on
15 that, and if we think it's appropriate, we'll waive it
16 and place it in Category IV. And, again, with this,
17 also, we're open to seeing all sorts of information. We
18 consider information from the open literature, MSPS's old
19 acute studies on just one of the inert components
20 (inaudible).
21 And then the largest group of waivers that we
22 see by far is probably the waivers that are based on a

1 lack of exposure potential, when people come in and
2 they'll say, there's just no way there's going to be any
3 inhalation exposure from the product. We may ask them to
4 support that claim with something like an attrition study
5 to see if the material is friable. An example -- yeah,
6 like right here. If a product is a non-friable granular
7 material, it's not going to break down at all, there's
8 probably not going to be any inhalation exposure, so
9 we'll probably go ahead and waive the inhalation -- the
10 (inaudible) inhalation study.
11 Another example we see, for dermal and eye
12 testing, we have a lot of products and tamper resistant
13 bait stations, there's no way it can get out of the
14 station. The station is very difficult to break open.
15 We don't expect in those cases there to be any dermal
16 contact or eye contact. So (inaudible) waive dermal
17 toxicity, dermal irritation, eye irritation, dermal
18 sensitization, possibly even inhalation.
19 That's kind of a summary of the types of waivers
20 that we see.
21 Another main group of the main strategy that OPP
22 uses to reduce acute testing is data citation. Bridging

1 and batching are the two things that pretty much make up
2 data citation.
3 Bridging basically is using the available data
4 to support multiple products, like taking the one set of
5 data and trying to support many products, two or more
6 products with that set of data. It requires us to make a
7 determination if the material tested for the six-pack is
8 similar to the product that wants to rely on that data.
9 So, we do a lot of formulation comparisons. We look at
10 all the inerts pretty exhaustively. We might do
11 literature searches of the inert components and try to
12 get good ideas. But still, if we think there's going to
13 be a difference between the tox profiles between those
14 two products in that situation.
15 A typical bridging example, you might have a
16 product where the active ingredient percent is the same
17 and it's citing a product that has different inerts that
18 were -- there's data on the (inaudible) of the product
19 that has different inerts. So, like I said, what we'll
20 do is we'll do a pretty exhaustive check of the inerts,
21 here in this situation, inert C. We might do a
22 literature evaluation or search and make sure that

1 there's not any kind of acute concern associated with
2 that inert. And if we feel comfortable with it, we'll go
3 ahead and allow that product to rely on the data
4 generated from the other product.
5 Another example I have is where you have the
6 active ingredients differing quite a bit. You might have
7 a 12 percent product relying or wanting to rely on a 35
8 percent a.i. product. Of course, there's going to be a
9 lot more inert component in that 12 percent product, but
10 we'll look at the differences (inaudible) the inert
11 differences and everything across the board, and if we
12 make a determine that there's not going to be a change in
13 that acute tox profile, we'll go right ahead and allow
14 that bridging to take place.
15 The other kind of type of data citation is
16 batching, although it really just uses the same
17 principles as bridging, except it's done for
18 reregistration. Batching basically is where we look at
19 all the products -- since we have reregistration, there's
20 a chemical going through reregistration and we might have
21 150 products coming through for that chemical. We can
22 look at all those products upfront, literally we get all

1 the (inaudible) out on the table and do a comparison to
2 pretty much try to break it down to batches or groups
3 that we think -- or groups of products that we think will
4 demonstrate the same acute toxicity profile (inaudible)
5 ask for one set of acute data for each of those groups.
6 Not every product is going to get placed into a group, so
7 we end up with a no-batch group sometimes.
8 Here's a typical example of a (inaudible)
9 chemical going through (inaudible) 150 products. We
10 might end up breaking down 127 of those products into 14
11 different batches. So, instead of getting 127 pieces or
12 six-packs, we would just want 14 in that case, basically.
13 And then there's going to be 23 in the no-batch. So,
14 basically we're going from over, from 57 to 37 data sets
15 that we would be asking for. Since it's reregistration,
16 the vast majority of those 37 would probably be citing
17 existing data that the agency already has.
18 Here's my final slide. We did kind of an
19 unscientific estimation to try to get an idea of to what
20 extent data waivers and data citations are used across
21 OPP for acute submission. So, we looked at a couple of
22 divisions, three or four divisions, and kind of took

1 close to a year's sample from each division and came up
2 with some numbers for you to look at.
3 We divided the acute submissions into three
4 groups. First of all, submissions containing only newly
5 generated data, a whole new six-pack basically, or less,
6 one of the six studies or up to six, submissions
7 containing no newly generated data at all. So, it would
8 be composed entirely of citations and waivers. And then
9 the third group is submissions containing a mix of A and
10 B. And you can see the breakdown that we came up with.
11 In reregistration, we see a lot more of
12 citations and waivers and that probably elevates that
13 number a little bit. But you can see, if you add C and
14 B, it's close to -- it's over 70 percent containing
15 citations and waivers to some extent. I'm sure
16 (inaudible) pleased with that. That's a significant
17 number.
18 With that, I'm going to go ahead and turn it
19 back to Jack.
20 MR. HOUSENGER: Okay, thanks, Mark.
21 MR. PERRY: Sure.
22 MR. HOUSENGER: Are there any questions on

1 Mark's presentation?
2 UNIDENTIFIED MALE: I just have a comment.
3 MR. HOUSENGER: Yes?
4 UNIDENTIFIED MALE: I think one of the places
5 where another uncounted area is when a registrant submits
6 alternate formulas and there's not a call for a new tox
7 data set being made, because there's a lot of times, at
8 least on the anti-microbial side, where we may do
9 products that look pretty different on shelf as a result
10 of utilizing the same registration, but an alternate
11 formula, and there's no call for a tox profile. So, in a
12 way, that's another gain. I don't know how to count that
13 exactly, but that's another area where you could say
14 you're really saving a lot of animals by not calling for
15 that toxicity profile to be repeated.
16 MR. PERRY: Right. That's another example of a
17 situation (inaudible).
18 MR. HOUSENGER: Any other questions?
19 (No response.)
20 MR. HOUSENGER: If not, we'll move on to Debbie
21 McCall. Debbie, prior to joining the agency, worked for
22 15 years doing various tox and hazard-related products in

1 contract management setting. Then in 1990, she became a
2 tox reviewer in our Health Evaluation Division, and after
3 three years of doing that, which is probably about the
4 max that you can do --
5 **(Laughter.)**
6 MR. HOUSENGER: -- she was promoted to Branch
7 Chief in the Technical Review Branch and Registration
8 Division where she is today. That branch reviews all of
9 the acute tox product chemistry studies for conventional
10 pesticides and child packaging requests.
11 Debbie's going to talk about how test methods
12 become guidelines and the ICCVAM process. Debbie?
13 MS. McCALL: Welcome, everyone. Basically, what
14 I want to cover today is to answer the question,
15 hopefully, of how do new test methods become guidelines
16 in OPPTS. And I'm going to cover the role of ICCVAM and
17 SAP, and then I'm going to briefly go over a case study
18 which is the Up and Down Procedure.
19 On this slide, you'll see new test methods that
20 we have taken through the ICCVAM process, and this is
21 just recent. So, the Local Lymph Node Assay, which is an
22 assay used for dermal sensitization, that has come

1 forward as a stand-alone assay in 2000. The In vitro
2 Cytotoxicity, which is going to be used (inaudible)
3 setting for the Up and Down Procedure, that came in
4 September. And the Up and Down Procedure (inaudible) in
5 December 2001.
6 We also have some future methods that are in the
7 works (inaudible) and those are three in vitro methods
8 for corrosivity, Corrositex, Episkin/Epiderm, which is
9 (inaudible), and the Transcutaneous Electrical Resistance
10 Assay or what they call as TER. Now, I would like to say
11 that these last three are what are called proprietary
12 test methods (inaudible) buy them as a kit, you know.
13 And so, under the U.S. Federal Ethics Statute, whenever
14 we use a proprietary test method, we have to have some
15 type of performance measure behind that. So, we are
16 working (inaudible) --
17 **(END OF SIDE A, TAPE 2)**
18 MS. McCALL: Basically, when a new test method
19 comes forward in OPPTS, it comes forward to a group
20 called the Test Method Group. This Test Method Group is
21 comprised of various scientific disciplines and they
22 usually have a member from the different organizations

1 across OPPTS. It sort of depends on where that guideline
2 has potential for the largest impact in the program.
3 So, I can't give you a listing of exactly who's
4 on that Test Method, it kind of changes by time frame.
5 But there are certain folks that are (inaudible).
6 Sources of test guidelines, of course, are EPA
7 working groups, people who are working all the time with
8 industry, looking at different activities, other U.S.
9 agencies bring forward (inaudible) industry scientists
10 bringing forward to us research and OECD. We're very
11 active in the OECD (inaudible) pass new methods to us.
12 As far as (inaudible) OECD comes the other nations and,
13 of course, the ICCVAM.
14 Now, the goals and the activities of the Test
15 Method Group are really very basic. They're to address
16 the new or maybe to review test methods, to help
17 incorporate the scientific advances into the harmonized
18 guidelines because we do have harmonized guidelines
19 (inaudible). They asked us to establish test guidelines,
20 methods and strategies that will generate credible
21 scientific information (inaudible) and also consider
22 alternatives that support the 3 Rs, replacement,

1 reduction and (inaudible).
2 Test Methods does consider the scientific
3 validity, the regulatory applicability in the agency
4 programs, how it fits into OECD and (inaudible)
5 international harmonization.
6 So, basically -- oh, and also, it does provide a
7 very nice forum for discussion for the science and any
8 policy issues (inaudible).
9 Now I'd like to talk a little bit about ICCVAM,
10 which is the acronym for the Interagency Coordinating
11 Committee on the Validation of Alternative Methods, hence
12 why we call it ICCVAM. That's way too much of a
13 mouthful.
14 It was established in 1997 as an ad hoc group
15 that would be implemented by NIEHS. But in 2000, the
16 ICCVAM Authorization Act established and (inaudible) a
17 permanent (inaudible) a permanent committee, and there
18 are 15 agencies that interact. This is a list of the
19 agencies. I would like to say a thank you to Bill Stokes
20 who has allowed me to (inaudible) ICCVAM slides here and
21 this is one of them.
22 The function of ICCVAM is mainly the

1 coordination step (inaudible). They help coordinate the
2 development, looking at the validation, acceptance and
3 (inaudible) the harmonization issues. Of late, what
4 we've looked at have been test methods that have multi-
5 agency interest. One of the other really nice functions
6 of ICCVAM is to provide a way so that test
7 recommendations can go back and forth in the agencies and
8 to gain regulatory acceptance. There is a lot of
9 (inaudible) and they provide guidance on the validation
10 of test methods.
11 Now, ICCVAM is -- like I said, is being
12 sponsored by NIEHS, which is located in (inaudible), and
13 it's run by the National Toxicology Program (inaudible).
14 I'll just refer to that as the center (inaudible). And
15 their function is basically the operation and the
16 technical support of ICCVAM. They help set up the peer
17 reviews, they help do the information dissemination.
18 They help communicate with the stakeholders and the
19 partnerships, and they've also helped us in the past with
20 workshops.
21 I've listed out on the slide there the website
22 for ICCVAM for those (inaudible).

1 The goals of ICCVAM are just -- there's really
2 two -- are really to promote scientific validation and
3 regulatory acceptance of new methods, and the hope is
4 that they will be more predictive of human health and
5 ecological effects than current methods, and that they
6 will use the three Rs where scientifically feasible.
7 Now, our hold is that they will -- the new
8 methods will improve public health by having improved
9 risk assessments and reducing injuries and disease from
10 different chemicals.
11 (Inaudible). This is the schematic of the
12 ICCVAM Evaluation Process. When I'm walking through the
13 case study, we'll go over this in a little bit more
14 detail. I believe it's pretty straightforward and you
15 just follow the arrows. (Inaudible). Basically, what I
16 want you to look at is on the left side of the screen
17 there. Almost all of the work happens in the independent
18 peer review panels and in the working groups (inaudible).
19 I thought this would lead into how EPA responds
20 to ICCVAM recommendations (inaudible). Basically
21 (inaudible) Test Methods Group, we examine the
22 recommendation from an independent peer review report and

1 the working group. We look at the test methods for
2 regulatory applicability and acceptability and see how
3 that method will fit into the agency program. We also
4 prepare recommendation and response back to ICCVAM on,
5 you know, we've looked it over, we've discussed it, we've
6 looked at the possible regulatory policy implications --
7 policy problems that may be (inaudible) our response back
8 to ICCVAM.
9 Here are the factors that the Test Method Group
10 looks at when we get the peer review report from ICCVAM.
11 We believe that we gain a lot of experience by looking at
12 interaction in the ICCVAM process. We get to look at
13 their strengths, the limitations, the advantages and the
14 disadvantages of each test method. Because of the way
15 ICCVAM (inaudible) in the independent peer review report,
16 we get a mix of everything that happens, good and bad,
17 about the new test methods.
18 The other factors that we look at in the test
19 method group are how (inaudible) contributes to animal
20 welfare. One of the things that we found doing one of
21 the other new methods were context in how it deals with
22 chemical classes. Sometimes they don't -- new methods

1 don't interact well with all chemical classes that the
2 agency regulates. We also look at the potential impact
3 and the usefulness to the regulatory programs and the
4 science and regulatory implementation issues.
5 This leads me into peer involvement. After
6 we've taken the ICCVAM peer review report and sort of
7 digested it, if we think it's a good method, we're going
8 to circulate that draft protocol and guidelines out to
9 the scientific community. If possible, we will convene
10 workshops and interact with outside experts and bring
11 everyone in to the process that we can for giving us
12 input on the new method.
13 Then sort of the final step here is taking it to
14 the SAP. FIFRA, our law, says that we (inaudible)
15 requires (inaudible) peer review of all (inaudible).
16 (Several sentences inaudible -- volume extremely low).
17 One of the things that I want to talk about
18 later on is the workshops that we have (inaudible).
19 These are (inaudible). One of the nice things about the
20 workshops is that if it's a drastically changed method,
21 at the workshop, we interact with industry as well and
22 (inaudible).

1 We communicate our findings to the American
2 Public by the SAP Report -- that's public notice --
3 Federal Register Notice, and other agency websites.
4 I have up here the equivalence of SAP and
5 ICCVAM, and this is sort of a personal interpretation. I
6 sort of believe that the ICCVAM and SAP are integrated
7 very well together, so that once the scientific validity
8 has been assessed by ICCVAM, the SAP can move on and look
9 at the regulatory applicability of the test guideline
10 (inaudible). So, it kind of pulls them very nicely
11 together. That's (inaudible).
12 And, you know, instead of having everything go
13 to the SAP for scientific validity, ICCVAM gets to look
14 at it in large detail with our stakeholders and then
15 coming to the SAP for the regulatory (inaudible). And
16 then SAP (inaudible).
17 (Inaudible) I'm just saying that the SAP and the
18 ICCVAM process are a coordination step with OECD
19 (inaudible) all the reports. In the past we did the LLNA
20 and (inaudible). Like I said in the beginning, our
21 future methods are to incorporate these three in vitro
22 methods as soon as we work through the proprietary test

1 methods (inaudible). Those are (inaudible) incorporated
2 into (inaudible).
3 Now we'll go on to the case study. (Inaudible)
4 the next slide.
5 This is the same schematic I showed you before.
6 Basically, for the Up and Down Procedure, if you'll
7 follow along with me on the schematic, we were -- EPA --
8 essentially the Up and Down Sponsor with (inaudible) and
9 we sent it to the center, which is (inaudible). Now, the
10 reason that that came about is there was a meeting in
11 Rome in about 1998 and we took a real hard look at three
12 new test methods. (Inaudible) and the Up and Down
13 Procedure to look at those to see how well they fit for
14 all chemicals, and we found that all three of those
15 guidelines needed to be updated and modified.
16 So, we were charged with -- by OECD to take
17 these on and to modify the protocols. So, we started
18 going down through the ICCVAM process. So, we went,
19 about in 1999 when we started the (inaudible) ICCVAM and
20 having a lot of discussion about modifying the protocol.
21 It wasn't (inaudible) OECD charged us with modifying
22 (inaudible).

1 On the ICCVAM step, it's kind of a shame that's
2 such a small box because for about a year and a half, we
3 went -- we did all kinds of activities (inaudible). We
4 were working with our counterparts (inaudible) great deal
5 (inaudible). We were working (inaudible) all the time
6 and (inaudible) guidelines. So, we were doing a lot of
7 input and response, trying to modify these protocol to
8 make them a much more vigorous (inaudible). We found
9 that the Up and Down Procedure was the only one that
10 would give us an (inaudible) 50 value. The others are
11 not based on equality. So, that was the reason we choose
12 to sponsor the (inaudible).
13 Then once we came forward, we came to make
14 recommendations on test methods to the agencies. We
15 talked with the agencies, worked it out and it went up
16 back and forth in the working group, and ICCVAM, we had
17 our first peer review meeting in July of 2000. They came
18 back and said, wow, this is a really drastically changed
19 (inaudible). You guys are going to need to develop some
20 software so that the (inaudible) reasoning. So, in July
21 of 2001, we had that finalized and that's (inaudible).
22 We had a second peer review panel meeting and

1 that was in August of 2001. (Inaudible) defined it now,
2 we have taken into account what you said at the first
3 peer review (inaudible) a second time, we think we're
4 ready now to take it all the way (inaudible), which we
5 did in December of 2001.
6 Can we go to the next slide?
7 Basically, here is the picture of the
8 publication that is put out by the NIEHS (inaudible). It
9 may seem like it took a long time in coming, but we think
10 that we have a much better protocol guideline than we
11 originally had in the beginning and we look -- we had a
12 workshop in February of 2002 that dealt with (inaudible)
13 and the Up and Down where we had industry there, we had
14 contract (inaudible). We were there. We interacted back
15 and forth trying to work out different issues, different
16 (inaudible), the problems (inaudible) and we think we
17 have all of that worked out (inaudible). Hopefully,
18 we'll (inaudible). (Inaudible).
19 So, just a summary on (inaudible) OPPTS is
20 advancing the three Rs. I see ICCVAM as playing a very
21 positive role in facilitating the process (inaudible) and
22 I think that the new test methods (inaudible) scientific

1 advances (inaudible).

2 MR. HOUSENGER: Okay, thank you, Debbie. Are

3 there any questions? Yes?

4 UNIDENTIFIED MALE: Just one question. In the

5 slide that talked about the goals for ICCVAM and then the

6 NTP-based agency, it talks about the goal being to

7 promote test methods that are more predictive of human

8 health than current methods. With all the difficulties

9 we face today in getting non-animal test methods

10 accepted, why would we place such a hurdle on these

11 methods? Why can't they be equally predictive to the

12 current methods?

13 MS. McCALL: Well, I think that they are. That

14 may be a fact of how -- that slide is from Bill Stokes.

15 I believe that as time has gone along -- and 40 years

16 ago, if you would look at the data we got then and the

17 data that we're getting now, I think we're getting much

18 better data now than we were 20 years ago, and I think

19 it's just that slide and scientific advancement is what's

20 meant there on that slide.

21 MS. MULKEY: Debbie, the question is, would

22 ICCVAM handle a method that was simply comparable?

1 MS. McCALL: Yes.
2 MR. HOUSENGER: Are there -- yes?
3 UNIDENTIFIED MALE: Once you have a new
4 guideline that has been -- gone through the whole
5 process, how do the registrants know about it? What does
6 EPA do? Do you notify each registrant or do you -- I'm
7 just concerned because in the past there has been some
8 mix-up in whether guidelines have been final or whether
9 guidelines are coming out of a reviewer's drawer that are
10 a draft, et cetera. But once we get to a final, which
11 I've heard you say it here, what's the process for
12 notification of the regulated community?
13 MS. McCALL: Generally, after the SAP happens
14 and we enter the SAP comments, you'll see a Federal
15 Register Notice that puts the new -- puts a notice out
16 there saying that the new guideline is now available.
17 And we'll also put on our website attention in the new
18 column of the new guideline.
19 UNIDENTIFIED MALE: Thank you.
20 MR. HOUSENGER: Pat?
21 PAT: Debbie, maybe you can talk a little bit
22 more about the value added of the SAP review. I was

1 struck, I guess, in looking at your slides about the
2 extent to which there's a lot of give and take between
3 the test method guideline group here at EPA and the
4 ICCVAM players, and it's a broad group of players at
5 ICCVAM, where you look at both the science and the
6 regulatory implications. So, I'm wondering if you can
7 just get to another level of detail about what SAP adds
8 after all of that give and take and then peer review.
9 I guess maybe a related question is, I know
10 there's a statutory requirement that you take things to
11 the SAP, but is there -- you know, might that be
12 satisfied in another way that you've looked at, I guess
13 the scientific validity and regulatory applicability?
14 MS. McCALL: Well, with ICCVAM, we've looked at
15 the -- we take a real hard look at the scientific
16 validity and in the past, SAP was looking at scientific
17 validity and regulatory applicability. And now, with the
18 advent of ICCVAM, they've sort of had to just now -- if
19 the method is very promising and very hopeful, then we
20 will just come forward for the regulatory applicability.
21 Have there been in the past? Probably some that we have
22 taken not to the SAP but have gone forward with. There

1 may have been, I'm not sure.
2 But as far as -- and maybe some other folks can
3 answer this. But before the advent of ICCVAM, we would
4 have -- we could go to SAP one or two times talking about
5 the scientific validity of a guideline.
6 And now, we can just go and say, we have
7 discussed this, here's all the strengths, here's all the
8 weaknesses, here's all the potential issues that surround
9 it, and SAP will give us guidance on, well, we understand
10 all that, but you're going to need to make this part
11 easier and that was one of the comments on the Up and
12 Down. We showed them the software program and they said,
13 well -- they gave us comments on, well, you need to do a
14 little bit more work on that so that when somebody
15 downloads it, they know that they've downloaded the whole
16 thing. So, it was like, oh, well, we hadn't thought
17 about that. So, it will be that type of issue.
18 Have I answered your question?
19 UNIDENTIFIED MALE: Yeah. I guess it's, you
20 know, not being as familiar with sort of the ICCVAM
21 discussions that you have. It seemed like many of the
22 obligations that you might have under FIFRA and many of

1 the things that you might want to think about from a
2 regulatory implementation perspective could be thought
3 through in the ICCVAM EPA exchange, and maybe you could
4 -- you know, maybe you could eliminate that final step.
5 MS. McCALL: Of the SAP?
6 UNIDENTIFIED MALE: Yeah.
7 MS. McCALL: That would be up to management.
8 UNIDENTIFIED MALE: Okay.
9 MS. MULKEY: I think there is an option to seek
10 a waiver of their review.
11 MR. HOUSENGER: Julie?
12 MS. SPAGNOLI: Just a question for
13 clarification. When you're talking about peer review of
14 guidelines by a scientific advisory panel, that's review
15 of a guidelines that the agency intends to publish as
16 OPPTS guidelines. So, that wouldn't necessarily apply to
17 non-guideline or new protocols that may be being
18 developed. I think we're looking at some types of
19 processes for looking at -- you know, with innovative
20 products or new types of guidelines. So, the requirement
21 for it to go to an SAP is really only for guidelines that
22 are intended to be published? And I'm not getting at

1 this, you know, outside of just toxicity testing as well.
2 MS. McCALL: I believe so.
3 MR. HOUSENGER: Okay. Well, let's move on to
4 our next presentation. I was annoyed when I got here
5 because I couldn't find a parking spot, but Dr. Dick
6 Lewis came from England to talk to us today and I thought
7 that he was here on other business, but he came expressly
8 for this purpose. He joined Syngenta in 1988 and in the
9 mid-nineties in in vitro alternatives research. He's
10 currently the head of the Reproductive Development
11 Toxicology and provides support and health assessments in
12 the new Chemical Discovery Division. He's going to talk
13 about alternatives for assessing acute endpoints.
14 DR. LEWIS: Well, first, I'd like to thank the
15 organizers for inviting me and giving me the opportunity
16 to give an overview of alternatives for assessing acute
17 endpoints.
18 What I'd like to do is to look back over the
19 last 20 years, assess where we are now, and then we'll
20 look a little bit forward into the future and what are
21 the challenges, which we (inaudible).
22 If we look at the last 20 years, they represent

1 really quite an intense period of activity, quite a
2 number of acute endpoints. Inventing new tests,
3 developing new tests. But the most interesting thing for
4 me is that during the (inaudible) 20 years, we've also
5 had to invent the framework for recognizing if a test
6 (inaudible) purpose and if a test can be used; i.e., is
7 it valid. So, during the last 20 years, we've not only
8 had to invent and develop new tests, but we've also had
9 to develop a mechanism for telling whether those tests
10 were any good or not.
11 And certainly, when I look around the room
12 today, coming back to the present, I've seen a number of
13 colleagues that I've worked with over the last 10 to 15
14 years or so and the tests that we were using in-house, in
15 our individual companies in those days, now are seen as
16 valid tests and (inaudible) regulatory guidelines. So,
17 there's some age (inaudible).
18 At the present, as I said, we are doing an
19 implementation of this. The implementation is not
20 without (inaudible) minor issues, and I think that harks
21 back to the fact that we've been developing tests along
22 with the framework of accepting those tests (inaudible)

1 it's not surprising that (inaudible) together.
2 In the future, I think we'll -- I hope that
3 we'll do better on what we've learned in the past. There
4 will be challenges in the future, and I've outlined some
5 of those. The main challenge is the need for partnership
6 and coordination, and I'm encouraged that I see that
7 actually happening in some areas.
8 Here I've set out a schematic for the stages in
9 the development of any new test, any new methods. It
10 could be a method not involving animals. It could be a
11 method involving animals. It's just new testing
12 toxicology. And the earliest part of this is science-
13 based and it's all about understanding basic mechanisms
14 in biology, maybe normal mechanisms, maybe aberrant
15 mechanisms. But when you've understood that, you've got
16 to ask the question, do I have enough understanding here
17 to enable me to use this information and devise tests. I
18 will use (inaudible) animals (inaudible) procedures to
19 which animals are exposed or does the way we use the
20 animals conflict (inaudible). This is science-based.
21 Once we've got the idea, we understand enough to make a
22 test.

1 The rest of it is technology process based.
2 Once we've got a test, is it robust, do you get the same
3 results in different laboratories around the world, does
4 it give us the same level of information, does it travel
5 well?
6 And then at the end of it we have acceptance
7 into legislation.
8 A couple of comments I like from ex and current
9 colleagues of myself. (Inaudible) will be familiar
10 (inaudible) community. The first one was from the Ian
11 Purchase, and Ian really answer (inaudible) said, of
12 course, industry, if it invested enough money would have
13 replaced the use of animals many, many years ago, but
14 (inaudible) is lacking to invest the money. And, of
15 course, Ian's point was that, you know, science can't be
16 driven to a timetable, it's dictated by money. You know,
17 once you've got the right people and the right ideas,
18 then the rest of the development of an idea, of course,
19 is amenable to good management and the application of
20 resources.
21 The second comment is more recent. It comes
22 from Phil Botham, and Phil's perception was that the

1 final stage of our process for accepting (inaudible)
2 alternative methods is driven as much by politics as it
3 is by science. I think the background to this reflects
4 the different starting positions, if we (inaudible) last
5 20 years. Most of the initiatives all the ones I'm going
6 to talk about in the early stages were certainly led by
7 the regulated community; i.e., they were led by industry.
8 I'm going to use three examples of the
9 validation process and of the (inaudible) over the last
10 20 years or so and where we are at present. I'm not
11 going to go into them in too much detail since I know the
12 presenters later in the session will be going into more
13 detail on some of these things.
14 The first one if the (inaudible), the Local
15 Lymph Node Assay. A good example of reduction, it uses
16 about half the number of animals as compared to the
17 traditional Guinea Pig Maximization tests, and it's also
18 a really good example of refinement because of the
19 understanding of biology, the normal (inaudible) biology,
20 we can concentrate here on the induction phase of the
21 sensitization response. There's no need to challenge the
22 animal, and as we know, it's during the challenge phase

1 that we have the greatest potential for adverse effects
2 to be manifested.
3 So, it's certainly an example of reduction.
4 It's a very good example of refinement. It's also a
5 quantitative test as opposed to the subjective
6 assessments, looking at guinea pigs, for example, and
7 because it's quantitative, there's less chance of an
8 equivocal outcome, because there's less chance of an
9 equivocal outcome, there's less chance that we have to
10 repeat the test and use even more animals.
11 How long did this all take? Again, a good
12 example of something that's been industry driven.
13 (Inaudible) Syngenta (inaudible) first publications in
14 the early 1980s with Unilever in the UK and certainly
15 with Procter and Gamble in the U.S. So, it was a
16 European/U.S. initiative. Prevalidation and validation
17 got going in the early to mid-1990s, and as you can see
18 it's taken a full 20 years from the appreciation of basic
19 biology and the idea that we could make a case out of
20 this -- for this test to be accepted into regulatory
21 guidelines.
22 The second example, we've heard quite a lot of

1 the details, so I'm going through this rather reasonably
2 quickly. It's about Acute Systemic Toxicity testing.
3 Now, the first OECD guidelines, which formalized this
4 testing, are 20 years old and they included the now
5 notorious 401, the LD50 test. As early as 1987, it was
6 recognized by OECD and others that perhaps there was a
7 way of conducting this test in a more refined manner,
8 such that less potential adverse effects would be caused,
9 and the idea was to reduce the highest dose level tested,
10 the so-called limit dose, from 2,000 — from 5,000
11 milligrams per kilogram to 2,000. Since 1987, this is
12 still the topic of some debate. I think it lies in the
13 different hazard-based classification schemes that we
14 have around the world.
15 In continuing effort through the '80s and '90s,
16 a lot of it we've heard about the so-called Class Methods
17 and the Up and Down Method. Let's move ahead.
18 With EPA and ICCVAM becoming involved, luckily.
19 And, again, the time scale has been 15-odd years for some
20 progress. 401 is now deleted in the OECD guidelines and
21 it has been replaced by some of the alternative tests.
22 Just a very brief overview of what these tests

1 are. The first two tests, 420 and 423, are class
2 methods. There are fixed doses -- 5,000 sort of crops
3 upin there -- but they are fixed doses to which animals
4 are exposed and the output of the test is a range, a
5 range of LD50 values, which ideally should correspond to
6 classification (inaudible).
7 425 is different. It gives a point estimate
8 with some idea of a confidence interval around that point
9 estimate. So, it gives you a number like the old LD50
10 did.
11 In terms of animal welfare benefits, I think
12 these are clear. If we look at the next slide. The old
13 LD50 test used up to 25 animals, by definition, up to
14 half of those did not survive the study. 420, 423, the
15 class methods, 420 has the endpoint of toxicity and not
16 necessarily (inaudible), we can see they use far fewer
17 animals, so we reduce the numbers and actually we refine
18 (inaudible). More animals survive the procedure. 425,
19 again, reduces and refines.
20 The last example I have is skin corrosion.
21 We've heard a little bit about this. Again, quite a
22 fruitful area for research over the last 20 years or so.

1 The animal test that's been used over the last number of
2 years actually assesses the degree of full thickness skin
3 destruction (inaudible). The alternative methods, there
4 are quite a number here, some of which we've heard about,
5 some refine and reduce, such as the Transcutaneous
6 Electrical Resistance Test. This is really an ex vivo
7 test. It uses skin disks from untreated rats, and what
8 we assess here is the barrier function of skin, the flux
9 of (inaudible) across the barriers of skin.
10 We've used this test in-house at Syngenta and
11 all of its previous incarnations since the mid-1980s to
12 guide humane testing of animals. We have not tested
13 corrosion materials on the skin of animals for quite some
14 time because we've (inaudible).
15 There are certainly replacement tests. We've
16 heard about the reconstituted skin models. These are
17 really (inaudible) cultures. They don't really have a
18 barrier, but they are quite sophisticated in that
19 (inaudible) have cellular integrity that can be
20 evaluated.
21 Again, the chronology, the first prevalidation
22 studies were done in the early 1990s, all the development

1 and scientific understanding would have predated that.
2 It would have been in the 1980s. (Inaudible) validation
3 including the activities of ICCVAM towards the end of the
4 1990s, and now with 2002, we have some of these tests
5 adopted into regulatory guidelines.
6 How long has it taken? I just said that it's
7 taken really about 20 years. And don't forget, we're
8 talking about what we've imagined to be among the most
9 simple endpoints in biology.
10 Okay, if we move to where we are in the present
11 day -- I mean, I've mentioned that implementation is not
12 without some difficulties, some issues. The Local Lymph
13 Node, for example, the use of concurrent controls.
14 Concurrent controls, as you know, are used to demonstrate
15 the sensitivity of the test system under the conditions
16 used. (Inaudible) Guinea Pig Maximization Test, I think
17 the guidelines say we should do this about every six
18 months or so. OECD made no mention of whether we should
19 use concurrent positive controls, and fortunately, the
20 recommendations from ICCVAM and EPA seem to suggest that
21 we do need to use concurrent controls. So, there's a
22 slight inconsistency. If we do, we'll use more animals.

1 Is it valid for testing formulations? Again,
2 there's nothing in the data that we supplied that
3 indicates that it is, especially for pesticide
4 formulations. EPA's draft conclusions are that it is the
5 method of preference for formulations. We know of no
6 data that supports that. That doesn't mean it's wrong.
7 We know of no data that supports it.
8 Acute systemic toxicity, the class -- this is an
9 interesting one. The class methods, 420 and 423, are
10 aligned to the new Globally Harmonized Scheme for hazard-
11 based classification, which is great. Unfortunately,
12 this hasn't been accepted into local legislation
13 anywhere. It's in European law, but it hasn't been
14 accepted by (inaudible) member state (inaudible).
15 So, while we have these nice methods that we use
16 to refine, we can only really use one of them, 425, at
17 the moment because the output of the others doesn't match
18 with any hazard-based classification scheme.
19 Tests for skin corrosion, we'll move on. Again,
20 is this for identifying a positive only or is it able to
21 identify a negative? Again, there seems to be some
22 confusion.

1 So, in summary on this, everybody is working
2 toward the same common; reducing, refining, replacement
3 (inaudible) use of animals in toxicology assessments.
4 What's beginning to happen is a coordination in
5 scientific review and a coordination in the outputs of
6 tests with the purpose of knowing the number in the first
7 place, which in this case is hazard-based classification.
8 And those lessons are being learned, so it's not
9 surprising that we find ourselves with minor
10 inconsistencies since we didn't start at the same place.
11 Looking to the future (inaudible) other than
12 acute endpoints. I think we've got both threats and
13 opportunities. New endpoints in toxicology, the so-
14 called catch-all protocols (inaudible) revised process
15 for defining the reference (inaudible) leads to extra
16 endpoints. This is going to make it more difficult to
17 replace, refine and reduce the number of animals we use.
18 On the other hand, we may have some opportunity,
19 biotech products, fewer traditional chemicals.
20 (Inaudible) chance to challenge the testing paradigm. A
21 lot of these chemicals, as we've heard this morning,
22 (inaudible) for example, we can predict the way the

1 adverse effects (inaudible) for human health and
2 concentrate on those. Do we really need to feed these to
3 rats for two years? I don't know. Maybe we should think
4 about that.
5 Greater emphasis on understanding mechanisms of
6 toxicity. The relevance of animal models, I think we've
7 been really successful over the last 30, 40 years in
8 making the world a very safe place for rats. Does that
9 always mean that those models are relevant to humans?
10 The use of transgenics to humanize the test method
11 (inaudible) and the use of generally in vitro and
12 (inaudible) systems and so called in silico systems.
13 Of course, I'm a member of the public and I
14 expect safer drugs, safer pesticides, safer chemicals,
15 and I'd also like to reduce the number of animals we use.
16 Moving on on a positive note (inaudible) on what
17 we've learned over the last 20 years and we've heard a
18 little bit about this so far. There's quite a lot of
19 work being done in Germany in (inaudible) Spielmann's
20 group about understanding basic cytotoxicity and how that
21 could help us in selecting the initial doses for testing,
22 in the alternative acute tox (inaudible). And the closer

1 we are to the starting point, then the fewer animals we
2 use, up to 40 percent fewer. So, that's something that's
3 worth (inaudible) doing.
4 So, the question's being posed, can simple
5 cytotoxicity tests guide the selection of a starting dose
6 and then by definition reduce the number of animals we
7 use.
8 We've heard a little bit about this, but this is
9 (inaudible) a joint European union. (Inaudible) talks
10 about to -- it's addressing two potential benefits here.
11 The first one is guiding the testing so we use fewer
12 animals. The second approach, which is on the right-hand
13 side of the overhead, is about (inaudible). (Inaudible)
14 move to different time scales. It's realistic to think
15 in the next couple of years that we can use cytotoxicity
16 tests to guide test chemical selection (inaudible)
17 complete replacement in some way in the future.
18 So, just to conclude, there are a couple of
19 overheads thinking about what's available in the future,
20 what do we realistically expect to be able to achieve in
21 the next two to three years and then in the longer term.
22 I think we have tests for skin irritants. Certainly, in-

1 house, we've been using these types of tests for a number
2 of years to aid in chemical design, for example, to
3 detect chemicals which are the higher risk chemicals,
4 stay away from those and develop safer chemicals. Human
5 skin constructs, much the same types of systems that we
6 are using for detection of corrosive materials, do have a
7 lot of potential for detecting and quantifying an
8 irritant response. And skin integrity and function tests
9 (inaudible) developed by Syngenta, for example. The
10 (inaudible) of (inaudible) endpoints are showing enormous
11 promise.
12 Acute oral toxicity, I've talked about that.
13 Dose level selection followed by complete replacement,
14 but certainly not in this (inaudible) on a scale of three
15 years.
16 Developmental toxicity screens to identify the
17 chemicals that are more intrinsically toxic. Most of the
18 industries, I know, have been using this type of
19 technology. Certainly, we have for the last 15 years or
20 so to prioritize what we test. (Inaudible) chemical
21 design to make things more specific a pesticidal target
22 and less specific to mammals. Things like whole embryo

1 cultures (inaudible) to avoid the use of living adult
2 animals. Embryonic stem cells have even shown great
3 promise. Some of these (inaudible) and things like
4 micromass, the lymphatic types of assays. So, there's a
5 lot of positive things there for the next three years or
6 so.
7 In the longer term, (inaudible) replacement,
8 acute toxicity, can it be replaced by cytotoxicity tests?
9 I think we're approaching that in a coordinated way. So,
10 I have some confidence that, again, it's going to be
11 longer term than three years.
12 Skin and respiratory sensitization. Again, some
13 of these endpoints are a little bit more esoteric, if you
14 like, but again, pretty bad if you suffer from them,
15 especially respiratory sensitization. Most (inaudible)
16 tests, a lot of work being done on the basic biological
17 processes going on, and things like kinetic and
18 metabolism, target organ, systemic toxicity, chronic
19 toxicity, total replacements for development and
20 reproductive toxicity, non-genotoxic carcinogenesis,
21 again, sometime in the future. And like the screening
22 tests, where you can live with some degree of under-

1 prediction; i.e., false negatives, when you replace the
2 animal tests with an alternative test, you can't live
3 with any degree of under-prediction, any false negatives
4 because the next species of tests might well be humans.
5 Okay, so I'd just like to conclude. When we
6 look back over the last 20 years, we've seen this
7 explosion of activity, especially around acute endpoints.
8 And where were we to date, I think we've learned some
9 good lessons in the past and I see us applying a lot of
10 those (inaudible) lessons to what we intend to do in the
11 future. So, thank you very much.
12 **(END OF SIDE B, TAPE 2)**
13 MR. HOUSENGER: Thank you, Dick.
14 **(Applause.)**
15 MR. HOUSENGER: You're going to notice that some
16 of the handouts don't correspond with Dick's
17 presentation. That's because Syngenta was brought in
18 fairly late in this one. We decided we wanted an
19 agricultural point of view on this whole thing, and
20 Janice McFarland, who was on vacation and then in
21 Switzerland, kind of pulled it together very quickly.
22 So, thanks to her.

1 Are there any questions on Dick's presentation?
2 Jennifer, yes?
3 MS. SASS: I actually just have a comment.
4 Thank you. I actually thought that was the clearest
5 presentation and most complete presentation on both the
6 summation of the science of each of the tests as well as
7 the utility, and I really appreciate that. The only
8 thing that I would add, and I know that you're well aware
9 of this, is that just because it's new to EPA doesn't
10 really mean it's new. In other words, a lot of the tests
11 that you're saying it took 20 years to develop really
12 have been validated from a publication and scientific use
13 point of view. And so, it's a regulatory step to put
14 them into action. And it really shouldn't take as long
15 or be as onerous, maybe, as anticipated.
16 But there's certainly -- I think there's a
17 confidence level that's well-established in a lot of
18 those.
19 DR. LEWIS: I take your point, and hopefully, in
20 the future, things will go a little quicker. The
21 important thing to note is that just because a test has
22 been published doesn't mean that anybody can pick up that

1 methodology and use it. I think that's what regulatory
2 (inaudible) are likely looking for, is that the outcome
3 of tests conducted by labs around the world will be
4 reliable and relevant; i.e., valid. So, that's why --
5 MS. SASS: And repeatable.
6 DR. LEWIS: -- you have to go through a
7 validation, a formal validation step.
8 MR. HOUSENGER: Are there any other questions?
9 (No response.)
10 MR. HOUSENGER: If not, I guess we'll break for
11 lunch now and reconvene in one hour and two minutes.
12 MS. MULKEY: We'll see everybody in our seats at
13 1:30.
14 **(A lunch recess was taken.)**
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22 **AFTERNOON SESSION -- DAY ONE**

1 MS. MULKEY: Apparently, there is quite the
2 fascinating cocktail hour at this hotel and it is purely
3 coincidental that this is the only hotel that we know of
4 in the area that invites people to bring their pet dogs
5 to the cocktail hour. But it just somehow seemed to fit
6 with our agenda beautifully. I'm just killing time here.
7 **(Laughter.)**
8 UNIDENTIFIED MALE: Is that every night that
9 they bring the dogs?
10 MS. MULKEY: No, I think it's only Tuesdays, and
11 I'm not even sure it's every Tuesday.
12 **(Brief pause.)**
13 MS. MULKEY: Well, thank you, again, for all of
14 you being conscientious about being in your seats.
15 **(Brief pause.)**
16 MS. MULKEY: Those of you who have already made
17 it back are probably not the people who need to hear from
18 us, that we're cognizant that this topic we've embarked
19 on is pretty dense and that it's difficult to plunge
20 right into the policy issues without all this context,
21 but that it is sometimes a tad tedious to wade one's way
22 through all the context.

1 I'm hesitant to embarrass the one or two people
2 who belong at the table who are not -- who are in the
3 room, but are not at the table, to the exclusion of all
4 the many who are not in the room and not at the table.
5 **(Brief pause.)**
6 MS. MULKEY: All right, well, let's take an
7 opportunity to focus on our time management challenges.
8 This panel still has quite a bit of really quite meaty
9 material to include and it is -- frankly, it was obvious
10 to them and I'm finding it obvious to me that it is
11 difficult to have a meaningful dialogue on this
12 relatively complex set of issues involving the adoption
13 and actual use of alternative tests without a lot of this
14 context, and we do look forward to an opportunity for
15 dialogue.
16 It is important to remember that through these
17 panelists, we, the agency, are hearing some variety of
18 views. That even before we get to the opportunity of
19 hearing from the PPDC, this is an opportunity from our
20 point of view for a range of inputs. But this is a PPDC
21 that has a lot to offer us and has not been given much
22 opportunity yet for your points of view to emerge. We're

1 mindful of that. We're hopeful that we can make up for
2 it this afternoon, and we're presuming that the panel is
3 eager, similarly, to have a good discussion and will work
4 toward that end.
5 So, I think without any further delay in our
6 ability to get to that stage, I will ask Jack to put us
7 back on track.
8 MR. HOUSENGER: Okay. Something happened to the
9 right-hand side of the room here, the panel members. I'm
10 not sure --
11 DR. AMADOR: I'm holding the fort on this side.
12 **(Laughter.)**
13 MR. HOUSENGER: Everyone on the left is here.
14 All right.
15 The next three presentations are going to be
16 made by Procter and Gamble. The first presenter is
17 Katherine Stitzel. Kathy graduated from the University
18 of California at Davis with a Doctor of Veterinary
19 Medicine degree. In 1982, she joined Procter and Gamble
20 as a veterinary clinical pathologist. She moved up
21 through the management in the corporate human safety area
22 to Associate Director in the Corporate Human Safety

1 Department. Kathy has since retired. She retired in 19
2 -- 2002 and she has a lot of credits to her name
3 associated with non-animal testing. I won't get into all
4 of them, but she is currently serving on the Board of
5 Scientists Center for Animal Welfare.
6 She's going to be talking about an approach to
7 risk assessment. Kathy?
8 DR. STITZEL: Thank you very much. I'm going to
9 introduce Procter and Gamble's presentation and then the
10 other two speakers will come in, Mike Robinson and
11 Rosemarie Osborne, and then I'll end up at the very end.
12 Today, what I want to do is give Procter and
13 Gamble's approach to risk assessment, and since we're
14 here kind of encouraging EPA to think about new ways of
15 doing things, we're going to -- I want to do this kind of
16 historically. Where we were when we started and how we
17 got to using very few animals for risk assessment, what
18 types of changes we've made, how we've made them and why
19 we've made them. So, if I can have the first slide, I'll
20 begin at the beginning.
21 Back in the 1960's and 70's, as Dick also
22 mentioned, we used to do a full set of animal tests for

1 every new product and new ingredient. At that time, we
2 had a limited number of product categories and few really
3 novel ingredients, but we didn't have very good safety
4 data on these materials. That was early in industrial
5 toxicology.
6 We did, however -- and I wasn't here then, but
7 we had some pretty sharp people and even back then we
8 started developing a database of all the toxicology
9 testing we had done, and we continue that today. So, we
10 do have access to all the testing that we've ever done.
11 We also, back in the 60's and 70's, didn't have
12 near the understanding we do now on the habits and
13 practices of our consumers. So, our ability to decide on
14 exposures was much less than it is now.
15 Because we had little safety data and because of
16 our limited understanding of habits and practices, we did
17 do a full battery of tests on each product before it was
18 introduced to the market. Next slide, please.
19 Now, the reasons that we've changed our way of
20 doing toxicology are several. One is that we now have
21 extensive data on all -- on most of our ingredients and
22 many variations on our formulas. So, it became clear

1 that there was no real sense in retesting these things
2 over and over again because we had already done the
3 testing and we knew pretty well what the answer was going
4 to be.
5 We had, like I said, 30 years of experience of
6 how these materials fit together and how -- what's safe
7 and what's not. And so, based on that we said, there's
8 really no real good reason to continue to do these full
9 batteries of tests. And also, we've really improved our
10 exposure data. We understand the habits and practices
11 much better than we did then and we also have, although
12 it doesn't really -- we don't use it as proof of safety,
13 we also have all the 800 numbers. We put 800 numbers on
14 all our products in the United States and in many
15 countries overseas, and so, we have kind of a check that
16 we have been safe, but not only that we have been safe,
17 but also that people are using the products the way we
18 think they are.
19 So, in addition to that, something I didn't put
20 on the slide, which is a very important mention, is that
21 within the last 30 years, there have been tremendous
22 advances in both the science of risk assessment and in

1 understanding the mechanism of toxicology. And without
2 those, we would not have been able to change.
3 The most important thing has been that we have
4 been under business pressure to change, not only because
5 it's faster, less expensive to have to do all this animal
6 testing, but also because our consumers wanted us to
7 reduce animal use. So, it is the pressure to change that
8 has really forced us to do this. Without pressure to
9 change, I think that's what's somewhat difficult about
10 getting a regulatory agency to change because there's not
11 the similar business pressure that we have. Next slide,
12 please.
13 Our current process, and I'm going to go through
14 this real fast because Rosemarie and Mike will also talk
15 about this, is to review what we know about the
16 toxicology of ingredients and the formulas, review the
17 habits and practices for the type of product that we're
18 going to be putting on the market, do a preliminary risk
19 assessment to decide whether or not we have enough data
20 for a positive assurance of safety. If we do, we stop
21 there. Of course, if we have data that indicates it's
22 toxic, we also stop. If we don't have enough data, then

1 we would go to non-animal testing, which might be in
2 vitro testing, might be computer testing, might be some
3 physical chemical testing.
4 Then we reassess our risk assessment process and
5 refine it and say, do we now have enough information to
6 say that we have a positive assurance of safety. And
7 it's only if we come back at that point that we would end
8 up doing in vivo testing, and then we do our risk
9 assessment -- we find our risk assessment and finalize it
10 for market approval. Next slide, please.
11 Now, I haven't mentioned regulatory guidelines
12 in there because what we're really trying to do is say,
13 is the product safe. But you understand that if there
14 were regulatory guidelines that were going to kick in, we
15 would be thinking about those all the way through and
16 doing tests that would meet regulatory guidelines at the
17 appropriate step.
18 The other thing that our current process, of
19 course, includes is continually monitoring our 1-800 data
20 and any other data that we can get on consumer use,
21 including that this confirms that we were right with our
22 safety, but more importantly, calls attention to

1 unexpected exposure scenarios that we haven't thought
2 about. Next, please.
3 The result is that at the current time, we use
4 no animal -- we have had to use no animals to assure the
5 safety of products released in the non-drug area for
6 several years. We reserve the right to do that if we
7 have a really new product or ingredient. All of our
8 animal use at the current time for non-drug products is
9 really driven by regulatory requirements. If we have to
10 deal with regulatory requirements, of course, we have to
11 do it, but otherwise, we haven't really had to do any of
12 that. And one of our biggest uses of regulatory
13 requirements is the anti-microbial registration for EPA,
14 which is why we're here today.
15 This has resulted -- that is, not using this
16 process for developing data on safety has resulted in
17 significant savings in resources. For us, a big savings
18 is time. We can get products to market much faster.
19 Some of the tests are less expensive, which allows us to
20 save money on testing, and also, of course, we save
21 animals. And we also have, we think, continued to have
22 an excellent record in protecting the health of humans

1 and the environment, even though we are using very few
2 animals in our safety assessments. Next slide, please.
3 Our continuing goal is to eliminate the testing
4 that's not necessary to support safety. Next slide.
5 Now, I want to talk about the three steps --
6 there probably are others -- but the three steps that we
7 think are important and how we got from doing tests on
8 every product to doing no animal testing on products.
9 The first is developing and adopting new
10 methods. We now have alternative methods. They're not
11 all in vitro methods. Some of them are. We find there
12 are reduction methods available for almost every
13 endpoint, the major ones, where we do not have any type
14 of alternative or systemic toxicity, the sub-chronic,
15 particularly.
16 It's important that our tests are
17 mechanistically based. We can't develop new tests unless
18 we understand the science of (inaudible). So,
19 understanding the science of toxicology has allowed us to
20 develop better tests for these endpoints.
21 Our tests are developed to predict human
22 response. We really are trying to protect the health of

1 humans, in most cases, and for what we're talking about
2 today, the tests are designed to protect human response.
3 Our tests are validated internally. I think
4 Dick mentioned that a lot of the tests that are now being
5 accepted internationally have been used in Syngenta for
6 years and it's similar with P&G. We have a set of tests
7 that we use internally. They've been validated
8 internally. We know what types of materials that they
9 will be correct for. We know that within our lab they're
10 reliable and reproducible, so we have a good
11 understanding for our materials. So, adopting new
12 methods is important. Next.
13 Another thing that is very important is
14 utilizing the data that is available, that are available.
15 We have a toxicology database of all of the toxicology
16 testing that we have done previously. We have added to
17 that database all the data that's in UCLID (phonetic) and
18 most of the data that's in RTEXT (phonetic), all the NTP
19 studies, the Gold database, anyplace that we can find
20 large quantities of toxicology data, and that really
21 allows us to search for other data on protecting
22 ingredients and for our own products on formulas.

1 We can search by chemical structure and by
2 substructure, something which I know that EPA can do
3 because they're very good at this in the environmental
4 area, and we find it very useful in being able to go in
5 and look for what data's available on very closely
6 related chemicals and predict whether something is likely
7 to be a problem or not. And then we use some of the
8 commercially available software programs that do
9 predictions based on chemical structures such as Derek
10 and Medium.
11 It's important to understand that you really
12 can't do this very well without understanding mechanisms.
13 And so, again, these processes, being able to use the
14 data to predict really -- to depend upon understanding
15 the mechanisms of toxicity.
16 The third thing is to constantly rethink the
17 process. Ask, why are we making this decision. What is
18 it we really need to know? Ask, what information do we
19 really need to answer the question that we decided we
20 really need to know the answer to. And then how much
21 information is really needed? And by doing that, we've
22 really sharpened our purpose when we do toxicology

1 testing rather than just do a standard set of tests every
2 time. Really what do I need to know this time or what
3 data do I need and how much data do I need for the answer
4 that I need to know today.
5 And at P&G all the toxicologists that come in, I
6 think, by now have quickly learned that you don't come in
7 with what you know in toxicology when you graduate from
8 school and expect to do the same toxicology for the rest
9 of your life. It's constantly changing, and constantly
10 changing means constantly relearning. And it's just an
11 expected part of toxicologists at P&G that they do not
12 expect to do the same thing five years from now as they
13 do now, and that's really important because change is
14 hard for people and it really has to be built in that
15 change is expected and you have to be able to deal with
16 change. Next slide, please.
17 So, with that, I'm going to turn it over to Mike
18 and Rosemarie, but I want -- they're going to talk about
19 skin and eye testing, and I wanted to touch on the other
20 tests in the six-pack that was presented earlier so you
21 know where we are with those.
22 For the Acute Oral Toxicity test, as you heard,

1 we use the Up and Down Test. Primarily, if we have to do
2 it, we do use a limit test most of the time because
3 mostly we're dealing with materials that we know are not
4 toxic. If we didn't know or have a good idea what the
5 toxicity was, we would do a cytotoxicity to predict the
6 starting dose. For Acute Dermal and Acute Inhalation,
7 again, we usually use limit tests. We have no
8 alternatives, but we support the development of
9 alternative tests designed, just as we did with the Acute
10 Oral Toxicity, and there are some attempts being made,
11 particularly for dermal change, which is test design, as
12 well. to reduce the amount of animals.
13 And for Skin Sensitization, we use the Local
14 Lymph Node Assay for ingredients and we have a very
15 active research program to develop an in vitro method for
16 skin sensitization.
17 So, those are the four of the six tests and the
18 other two will be discussed in more detail and we'll
19 start with Mike. He's going to talk about skin.
20 MR. HOUSENGER: Let me just tell you about Mike
21 while he makes his way to the podium. Mike graduated
22 from Notre Dame with a Bachelor of Science, Masters of

1 Science, got his Ph.D. at the State University of New
2 York at Buffalo, my alma mater, and now the home of the
3 Al Quada terrorist cells.
4 **(Laughter.)**
5 MR. HOUSENGER: He joined Procter and Gamble in
6 1985 and he serves there as Principal Scientist working
7 on a number of -- I can read these to you -- experimental
8 clinical skin allergy, clinical skin irritation, a bunch
9 of skin things. So, he certainly seems to be the correct
10 person to be talking about skin irritation.
11 **(Laughter.)**
12 DR. ROBINSON: Thanks. Thanks for the
13 invitation. What I'm going to do on skin irritation is
14 really kind of go through a framework that we use. I
15 think it's becoming adopted by many in industry with
16 regards to their own particular frameworks. I will talk
17 a little bit about ours. It really is a risk assessment
18 motif. I know a lot of times we're talking about hazard
19 identification and being able to check off boxes in
20 different toxicity categories, but we've already heard
21 some relationships of the importance of exposure. We've
22 heard about waivers being offered for chemicals for which

1 there's not going to be any human exposure for various
2 reasons. So, therefore, exposure does come into the
3 context in a number of different places.
4 Our framework really begins with an assessment
5 of what we know about any chemical and the formulation in
6 which it's going to be employed. So, we all do a lot of
7 homework before we even think about what testing may or
8 may not have to be done.
9 I want to talk a little bit about skin
10 corrosion. We've already heard from Dick and others, and
11 we're going to hear more later, about what's been going
12 on with the skin corrosion testing methodologies. It
13 clearly is a shifting paradigm for how we approach that
14 particular hazard endpoint. And I'm going to talk about
15 options for skin irritation and skin compatibility
16 testing. Of course, we wouldn't have any fun today if we
17 couldn't be controversial.
18 So, we've already heard about an agency position
19 with regards to human testing, whether it should ever be
20 allowed or ever be used, and I think the point here is,
21 when you talk about human testing, there are really two
22 questions. One is, should it ever be done under any

1 circumstances, and if you give an allowance that maybe it
2 can be done, the real question after that is, what should
3 be done, how should it be done, what ethical protections
4 are there for the subjects and how is that data to be
5 generated and used in advancing a safety testing and risk
6 assessment program.
7 I'll also be talking a bit about skin irritation
8 testing, which we heard a little bit about, but it hasn't
9 been touched on to any great extent, and I'll talk a
10 little bit about where that is in terms of its
11 development. Next slide, please.
12 Basically, everything I'm going to say today is
13 a very cursory, a superficial overview of a paper that
14 came out about last May, in Food and Chemical Toxicology,
15 which goes into excruciating detail into a lot of the
16 methodologies surrounding both in vitro and human --
17 various types of human test methodology, initially for
18 skin corrosion, as well as for skin irritation testing,
19 and how it can be employed in the risk assessment
20 processes, both validation processes and methods --
21 methods that are currently in the process of being
22 developed and validated, as well as methods that are used

1 within various organizations for their own purposes,
2 including our own.
3 In putting together the authorship on this, we
4 really looked to cover as broad a base as we could, while
5 still keeping it in reason for the senior author to try
6 to manage an international effort on getting this thing
7 written and published. In addition to myself, Ed Whittle
8 and Julia Fentem -- Julia is certainly well known to many
9 in the alternatives area for the time she spent at ICCVAM
10 coordinating all of the work on skin corrosion testing.
11 They and I represent, of course, the broad-based consumer
12 product companies. They come from Unilever. Catherine
13 Cohen from a cosmetic company that most people know about
14 called L'Oreal in Europe, Anne de Brugerolle from
15 Novartis, also in Europe, and Mya Ponec, who is our
16 academician on the panel is from Leyden University in the
17 Netherlands.
18 You'll notice a fairly hefty European influence
19 on this paper and that's not surprising. Clearly, Europe
20 has been ahead of the curve on this method development
21 standpoint. Really, only one of the methods that I'll
22 talk about came out of P&G. It was a principally U.S.-

1 based effort. U.S.-based organizations have been
2 involved in the validation effort, but a lot of the
3 method development that's gone into these test methods
4 came out of Europe and has been led by Europe, and that
5 also includes internal methods that various organizations
6 are using and trying to develop for their own purposes.
7 I've got about 10 or so copies of this with me,
8 so if anyone's interested in a copy, I'll make them
9 available. If you aren't able to get one and you really
10 want one, just use the e-mail address, and if you want a
11 paper copy, make sure you list your address so I can send
12 it to you, or I can give it to you as an electronic
13 version if you just want it that way as well. Next.
14 Actually, I guess you can read this. Probably
15 not from the back of the room. It's in the handout and
16 it's also in the paper. It really isn't meant to be read
17 here. I do have a simplistic version in the slides that
18 follow, but this really is sort of an overall flow chart
19 of a risk assessment -- testing and risk assessment
20 process, and I put this big one up mainly to illustrate a
21 couple of -- identify a couple of points.
22 There are a whole variety of checkpoints during

1 the process of testing and assessment of your results.
2 The point is that, oftentimes, we come up with a new
3 ingredient, it may be such an insignificant change from a
4 formulation that's already on the market, for example,
5 but the decision may be that you don't need any testing
6 and then you come all the way down here to complete your
7 assessment and move into the marketplace. Other times,
8 you may ask the question, do you need additional testing
9 before the human exposures are allowed and, again,
10 sometimes the answer is no. You can come right in and
11 ask the question, do you need human testing. If not,
12 then you go right around the risk assessment. If you do,
13 then you go into various types of human testing that I'll
14 talk about in a little bit. But if you do need
15 additional information, then you go through a variety of
16 other steps to generate the data that you need in order
17 to determine whether or not this material is suitable to
18 be put into exposure in humans.
19 This is the simplistic version of this, which is
20 a little easier to read, and it really talks about the
21 overall process of, again, some initial evaluation, the
22 paper toxicology and I'll get into some of the details of

1 that in a minute, and then the question about whether you
2 need additional testing prior to human exposure, the in
3 vitro methods that are available if you do need that
4 data, and then the question, is it safe to be put into
5 humans and then any kind of human testing that may be
6 necessary or wanted in order to move into the
7 marketplace. Then a variety of human testing options to
8 meet different kinds of needs. Not all of it is
9 toxicity. A lot of it is compatibility and that
10 relationship as well, and I'll talk about that. Next
11 slide.
12 So, this is the paper toxicology, and again,
13 it's just an assortment of things. There's a lot out
14 there, a lot that we've generated internally, that many
15 companies generate on their own, and we have, as Kathy
16 said, a database of every chemical that's ever been put
17 through acute testing or sub-chronic testing in our
18 company. But there's also a lot of information in
19 respositories and databases that belong in the public
20 domain and are easily accessible either free or through a
21 subscription. And so, that includes a lot of data,
22 clinical data as well as animal in vitro, et cetera. I

1 think I'm losing my pointer here.

2 **(Brief pause.)**

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

4 **(Laughter.)**

5 DR. ROBINSON: A lot of the information,

6 physiochemical information, of course, a lot of questions

7 around what the partition coefficient of a chemical is,

8 how fast does it get into the skin, how well does it get

9 into the skin, what's the pH, what's the reserve acidity

10 or alkalinity, as Kathy indicated, there's a lot of

11 information forthcoming now in structure activity --

12 quantitative structure activity relationships. There can

13 be probably a lot more of that right now of value in the

14 skin sensitization area than in skin irritation, but

15 that's a developing area as well.

16 We talked about exposure scenarios. That's very

17 important from the risk assessment standpoint and over

18 the years we have developed a lot of information about

19 the habits and practices of the products that we sell,

20 not only the way they are intended to be used, but the

21 creative way that consumers have of misusing our

22 products, and we need to take that into consideration as

1 well.

2 And then finally, the marketplace experience,

3 everything we sell becomes a benchmark against which we

4 can evaluate new chemicals and formulations in the

5 future, and we do that constantly by evaluating the new

6 materials, the new materials against that for which we

7 either have good or bad experience in our prior testing,

8 and of course, in terms of the marketplace, the good

9 experience that we have because we really have had a high

10 degree of information coming back that our risk

11 assessments have been good in protecting our consumers.

12 Next slide.

13 I'm not going to spend a lot of time on the

14 corrosion testing because most of this has already been

15 stated before. Of course, the current basis for

16 regulations is based on the Draize test that was

17 developed in the '40s, mandated by the FHSA Act in the

18 '60s and has been tweaked in a number of different ways

19 by regulatory authorities in different parts of the

20 world, and it's usually the speed of a corrosive result

21 that defines the hazard either in terms of a packing

22 group classification or a European labeling requirement

1 under the EC directive.

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

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

22 The OECD guidelines, of course, have been

1 recently approved by the new test guidelines with the in
2 vitro methods incorporated, and again, mentioning that
3 the ICCVAM process has just been concluded with the
4 provision for the rabbit test, but again, with the
5 provision that the test results are only used if a result
6 is positive and a rabbit test is required to follow up a
7 negative result.
8 This is just the one data slide on corrosion.
9 This actually came out of the P&G methodology using the
10 EpiDerm Cell Culture System that Rosemarie Osborne, Mary
11 Perkins and their lab developed back in the early '90s.
12 It was published in '96. And, again, it just shows the
13 EpiDerm construct, which is just a differentiated
14 epidermis with a stratam-corneum (phonetic) mon filter
15 insert.
16 This is the way the cultures look sitting in the
17 actual culture disk with the inserts in the center well.
18 Test materials can be applied directly to an air
19 interfaced stratam-corneum surface. The cultures are fed
20 from underneath and then you can look directly at the
21 cultures themselves for liability as well as other
22 endpoints can be evaluated by looking at the culture

1 fluid for things like cytokines (phonetic), and then this
2 was the actual test data differentiating corrosive and
3 non-corrosive materials using the prediction model, which
4 was set up at that time, which was a 50 percent residual
5 viability after a three-minute exposure.
6 When the German lab, VGA, adopted this method
7 and essentially tweaked it for ECVAM validation purposes,
8 kind of a catch-up validation, they added an additional
9 prediction model to it, which was a 15 percent residual
10 viability after a one-hour exposure to try to increase a
11 little bit the sensitivity of the method.
12 In vitro methods for skin irritation are still
13 under development. Some of them actually have undergone
14 an ECVAM-sponsored pre-validation effort. There is still
15 work to be done, a lot of it having to do with inter-
16 laboratory reproducibility, some of it having to do with
17 sensitivity specificity. So, there really is no
18 officially accepted in vitro skin irritation test at this
19 point in time. A number of labs are actively developing
20 methods, most of them based on some sort of skin
21 equivalent model for both acute irritation as well as for
22 cumulative and chronic skin effects, and these are

1 essentially used internally by different organizations.
2 That review article that I mentioned upfront goes into a
3 lot of those that different companies are using,
4 including our own.
5 The challenge for a lot of these methods is to
6 achieve, in these very short-term cultures, which usually
7 are pretty much limited to 24, at the most 48 hours,
8 sensitivity that is required for some of the longer term
9 endpoints, particularly the cumulative or the chronic
10 irritation, because obviously in clinical testing, some
11 of those methods can go on for several weeks.
12 The focus of the regulatory effort, I think
13 right now, is going to be more on the acute irritation,
14 that irritation that is in the moderate to severe
15 category and which shows up in just a few hours of
16 exposure.
17 Now, we talk about human testing options, and,
18 again, for non-corrosive chemicals -- and that's the
19 provision, that obviously these things have to be
20 evaluated for corrosivity before they ever go into a
21 human test -- there are some human options available.
22 The one I will talk about today is the prediction of

1 acute irritation potential. That's a fairly new method,
2 or at least within the last seven or eight years. There
3 are a variety of other methods that are available, which
4 fall into the category of chronic or cumulative skin
5 irritation. A lot of these are long-term patch test
6 methods.
7 There are also a whole category of test methods
8 which fall under the category of skin compatibility. A
9 lot of these are use test methods that are used for final
10 formulations with dilutions of product for things like
11 skin hand soaking tests and just a variety of methods
12 that different groups have employed, including different
13 organizations with our own company to meet the needs of
14 their particular product categories. And a number of
15 these have been published over the years, both by
16 industry as well as by academic dermatologists.
17 Again, when I talk about the true alternative,
18 when you're really looking at an alternative method to
19 replace an animal test, it's really the acute irritation
20 endpoint that we're interested in here and so that's why
21 I'm focusing today on this prediction of acute
22 irritation.

1 This test method, the Human 4-Hr Patch Test, was
2 initially developed by Unilever in the early '90s and
3 first published in 1994. It basically involved a four-
4 hour -- up to a four-hour exposure to potentially
5 irritant chemicals under an occluded -- fully occluded
6 patch test conditions. They usually tested very high
7 concentrations, and if possible, 100 percent of the
8 materials that they're interested in evaluating. The
9 safety of the method was enhanced by a couple of
10 procedures. One was very gradual subject enrollment into
11 the study. You usually -- in the most conservative
12 protocol, one person the first week and then four the
13 second, up to 30 total with weekly increments.
14 There was also a graduated exposure, again,
15 generally starting at 30 minutes, but it can be tweaked
16 back to even shorter depending on what information is
17 available about the test materials, and then ramping up
18 to four full hours over these weekly intervals.
19 The skin reactions are graded for delayed
20 response at 24, 48 and 72 hours after the patch removal
21 on a simple grade of increasing erythema (phonetic). The
22 point is that exposures were ceased at the first positive

1 response. So, it is the incidence of the sensitization
2 responses, not their severity, which is the prediction
3 model for this particular study, and the prediction model
4 is based on a direct comparison to the results with a
5 concurrent positive control, which is 20 percent sodium
6 dodecyl sulfate, which was selected by Unilever because
7 it is the labeling standard for surfactants in Europe
8 based on conventional classification. So, it was not
9 necessary to test 100 percent. They just used 20 percent
10 as the labeling benchmark.
11 This just illustrates -- and this is from their
12 original paper -- I'll draw a circle around it -- the
13 degree of skin reactivity. Over the years that we've
14 looked at this method, easily 90 to 95 percent of the
15 reactions that occur are in this grade one category and I
16 had to kind of draw a circle around this one to even see
17 that the response was there. So, it is a very mild
18 response, and again, it is the incidence of these
19 reactions, not their severity, that defines the toxic
20 endpoint for this particular test.
21 And this is just a representative figure from a
22 paper published a couple of years ago when we were

1 comparing -- this is a -- actually, the focus of the
2 study was comparing Unilever's results to our own. But
3 this just shows two different endpoints, looking at three
4 fatty acids with just -- with different chain links and
5 showing the diversion of responses between them compared
6 to distilled water. He's the positive control, SDS, to
7 the fatty acids, the octanoic and the decanoic acids were
8 more irritating than SDS and hence would be labeled,
9 under this prediction model, as an R38 or irritating the
10 skin. The dodecanoic acid and, of course, the distilled
11 water were significantly less irritating than SDS and
12 would be labeled as non-classified, again under the
13 prediction model for this test.
14 In addition to that, we introduced a time course
15 analysis which allows you to determine the time of
16 response that would require for half of your panel of
17 subjects to react over the time course, and what that has
18 allowed us to do is to make a lot of comparisons using
19 this test method, and we've done everything from racial
20 comparisons to effects of seasonality, different
21 geographies, different skin types. You name it, a number
22 of things have been looked at in terms of understanding

1 some of the variability of human reactivity. The nice
2 thing about that is, in spite of the variability that
3 does occur in human skin irritation testing, the
4 inclusion of 30 subjects in this method has ensured a
5 high degree of reproducibility.
6 When we looked at these TR50 values between our
7 lab and Unilever's in this study, they were within a
8 couple of hundredths of an hour across the three test
9 chemicals.
10 This is just an example of the comparison of
11 results that have been generated -- this is out of
12 Unilever's laboratory -- between the human irritation
13 test results and the existing data that was available on
14 those chemicals based principally on Draize test results.
15 The bottom line here was that out of the 65 chemicals
16 that were evaluated, 45 -- almost half of the
17 classifications were wrong based upon human result.
18 All of the corrosive values were wrong. I mean,
19 they were either irritant or they were non-classified.
20 The irritant values here were correct. The non-
21 classified values here were correct, but there were 23
22 irritant-labeled chemicals with the non-classified human

1 tests and then there were two that went the other way,
2 that would be non-classified under the existing animal
3 data that would have been irritating or R38 under the
4 human results.
5 In addition to the chemical testing, we've also
6 done some work with this method in formulation
7 evaluation. Starting back in about 1995, the Soap and
8 Detergent Association formed a task force on alternative
9 methods and chose to use this method as a way to begin to
10 look at detergent formulation for various categories.
11 Over the last seven years, a number of tests have been
12 done looking at products in a variety of detergent
13 categories. The most irritating of those were mold and
14 mildew removers. The least irritating were dish and
15 laundry powders.
16 When we looked at multiple products, even
17 between studies, their TR50 values were virtually
18 identical. There was some seasonality of effects,
19 wintertime studies, as you might expect with surfactant
20 products, tended to be a bit more irritating than the
21 studies done in the summertime. But, again, the
22 classifications did not change. These have recently been

1 presented at the SOT meetings and the World Congress
2 meetings of this year and we're expecting to publish the
3 results of this sometime in early 2003.
4 And I'll just leave you with a case example. I
5 put this up not because it's -- it's not a pesticide
6 example, but it gets to the question of weight of
7 evidence when you talk about data that's available and
8 how you might use it. This is actually an internal
9 situation where we have a product upgrade a few years ago
10 where a product was going to have a chemical replaced
11 with a near cousin of the chemical that was already in
12 the product. But when the new chemical was tested, in
13 order to meet base set notification requirements in the
14 UK, where it was initially going to be submitted, it came
15 up with a corrosive result. It would have carried an R34
16 label. This was the primary irritation index of 7.17 out
17 of 8 in that study.
18 Well, that was viewed as a problem, obviously.
19 Also, there was a question of whether it was a reliable
20 result. And so, in vitro testing was done using the
21 EpiDerm culture system to see whether or not we would
22 reproduce the corrosivity and, in fact, we did not. The

1 test compound had a residual viability of 96 percent
2 whereas the positive control in the corrosion test was 5
3 percent residual liability and highly corrosive.
4 So, let me put it into the Human 4-Hr Patch
5 Test. This test was repeated at three different
6 laboratories in the U.S. and Europe, and overall, we
7 wound up with 90 percent of the subjects responding to
8 the 20 percent SDS and only 13 percent of the individuals
9 with irritant response to the chemical. So, clearly, in
10 the human, it was a non-classified result as well.
11 The information was put before the (inaudible)
12 in England and while they liked the data and certainly
13 believed that the chemical was non-irritating, they were
14 still going to require that the skull and crossbones go
15 on the product. This happened to be a fabric softener,
16 if I recall correctly, and since our competition at the
17 time was marketing products with teddy bears and flowers,
18 we thought it was probably not going to be a good idea to
19 move ahead with that one.
20 **(Laughter.)**
21 DR. ROBINSON: But what it tells you is that we
22 have, I think, moved the dime a little bit because it

1 would be nice to think that a similar submission today,
2 something with a new EU requirements might get a little
3 more attention in terms of being able to put this kind of
4 information forward.
5 And finally, I just want to leave a set of
6 recommendations that talk really about where we stand
7 today and what we have available to us. Clearly, as a
8 review article will also state, there is a current best
9 approach out there. It's been tweaked by a number of
10 different companies in a variety of different ways, but
11 it can be used to make a full assessment of skin
12 corrosion and irritation for new chemicals and maybe in
13 new formulations obviating the need for animal test
14 methods and flexible enough to meet a variety of
15 different ingredient and product types.
16 It does used weight-of-evidence from a variety
17 of sources, so it is not a checkbox approach. It does
18 use existing data from a variety of sources, validated
19 and qualified and accepted in vitro skin corrosion tests,
20 in vitro skin irritation screening tests which again,
21 right now, are limited to internal assessments since none
22 have been validated and accepted by regulation at this

1 point. You can use human historical data as well as
2 human irritation patch test data on both ingredients and
3 formulations, and then, again, in our purposes, we do a
4 lot of formulation testing, a lot of use testing in human
5 subjects, as well, to confirm the safety of these
6 materials and formulas once they've cleared all of the
7 other batteries. Thank you.
8 MR. HOUSENGER: Thank you, Mike. Are there any
9 questions before -- as Mike sits down. Yes, Steve?
10 STEVE: I'm just curious. With the ingredients,
11 you presumably get this from some supplier. What are
12 your expectations for the supplier to provide this kind
13 of data or do you run it all yourself? Obviously, the
14 formulation is your own product.
15 DR. ROBINSON: It works both ways. There are
16 supplier data sets that we will get and we will use that
17 information. We will also evaluate that information as
18 to whether or not we agree with their assessment of the
19 results. Again, some of that kind of stuff is
20 grandfathered into existing chemicals. With brand new
21 chemicals, if the suppliers aren't willing, we would have
22 to make the assessment.

1 We have what's called a Tox Office within our
2 organization. When I was in the safety organization,
3 what would happen on an irritation question is, if there
4 were new ingredients and the toxicologist out in our
5 business unit would send me a piece of information about
6 what they wanted, this material, what it was, what its
7 structure was. It would go to a group of people who
8 would do a computer search for any analog information,
9 and then all of that information would come to me and I
10 would take a look at it. I would go into RTEXT and CIR
11 and a variety of different places and our own database to
12 see what I could find. Oftentimes, there wasn't
13 anything, in which case I would send a note back and say,
14 we really don't know much about this. We're going to
15 have to sit down and talk.
16 And, again, if it was something that they wanted
17 to pursue and there was no data, that's what we would go
18 through. But we would start in vitro. I mean, again,
19 unless it was mandated that we needed to do the animal
20 test to meet a registration requirement or something,
21 there was no basis for us, from a risk assessment
22 standpoint, to have to go down that route. We could

1 easily make the judgment based upon the tools at our
2 disposal.
3 MR. HOUSENGER: Julie?
4 MS. SPAGNOLI: Maybe this was mentioned earlier,
5 but I didn't catch it. I know sometimes these human
6 patch tests are done for a lot of consumer products in
7 Europe. What's the agency's position on these types of
8 testing relative to their human testing position? I know
9 they said applicator exposure and, you know, like
10 repellents, but, you know, what about this type of
11 testing?
12 MS. MULKEY: I think I'm going to reserve on
13 that. I want to be sure I get it right.
14 MS. SPAGNOLI: Like I said, I wasn't sure if I
15 just missed it when we were talking about it earlier.
16 MS. MULKEY: There's certainly a number of kinds
17 of skin-applied human tests that we have regarded as
18 outside the scope of this deliberate dosing, third party
19 -- for purposes of --
20 **(END OF SIDE A, TAPE 3)**
21 MS. MULKEY: -- category. But I'm just not -- I
22 don't feel close enough to it to say, in a definitive

1 way, whether the particular tests you heard about here
2 designed for this purpose would meet the words of the
3 things that we are consulting with NAS about, and I just
4 don't -- I don't want to freelance.
5 MS. SPAGNOLI: Well, I would assume if we had,
6 like an insect repellent product that was intended
7 for direct human skin application, that that type of
8 testing --
9 MS. MULKEY: Those, we have made it very clear,
10 are not included in the category that we're consulting
11 with the NAS about. My intuitive feeling is that this
12 category is also not included, but before I say that, I'd
13 rather be on a little bit firmer ground.
14 DR. ROBINSON: And to be fair, this has not been
15 -- in Europe, this has met some really tough sledding,
16 you know. Again, their regulations require that all the
17 companies endorse it if it's going to meet an OECD
18 guideline, for example, and it hasn't. It was written up
19 as an OECD guideline draft about six year ago and it's
20 failed, and it's because of a couple of countries that
21 just simply will not consider it. And, again, it gets to
22 that first point that I made. You have to say, first of

1 all, whether you're philosophically in agreement or not,
2 and then you can talk about the details. Well, they
3 aren't philosophically in agreement at this point. So,
4 that's where it stands.
5 MR. HOUSENGER: Jennifer?
6 MS. SASS: Thank you for the presentation. I
7 have some clarification points. I'm pretty naive on the
8 developments in these areas. I'm not on the ICCVAM or
9 anything, so this is me hearing about it.
10 Just to get the definitions straight, when you
11 talk about an acute, you're talking about a single dose,
12 single exposure.
13 DR. ROBINSON: Right.
14 MS. SASS: When you're talking about chronic,
15 are you talking about a constant chronic exposure or a
16 repeated exposure?
17 DR. ROBINSON: Yeah. I differentiate chronic
18 and cumulative. Cumulative is based upon repeated
19 exposures over a period of time. The chronic exposure
20 is, generally speaking, a single prolonged application,
21 it can be a very prolonged application. You know, you
22 could argue that in some categories you could put

1 something on for say 24 hours and then you could have a
2 progressive response over time. That would also be in
3 the chronic category, but usually chronic just means
4 long-term exposure whereas cumulative might be short-
5 term, but repeated every day kinds of exposures.
6 MS. SASS: All right, good. And so, then that's
7 capturing, you would think, the sensitization issues.
8 When you use the word "sensitization" and I use it, I
9 just want to make sure that we're talking about, like,
10 somebody who has had an exposure and is no longer naive
11 and is more likely to be hyper-sensitive. They could
12 also habituate. It could go either way. But often with
13 chemicals you become more sensitive to repeated
14 exposures.
15 DR. ROBINSON: Yeah. Nothing I talked about
16 here deals with sensitization. I mean, sensitization are
17 cumulative procedures, repeat exposure procedures in
18 order to first induce a sensitization response within the
19 subjects and then if they elicit -- you know, you're
20 eliciting a skin reaction in the secondary response. So,
21 it is a different category. Certain chemicals can be
22 both irritants and sensitizers, but this particular

1 framework was dealing specifically with the acute
2 irritation, which is not an immunologically mediated
3 process.
4 MS. SASS: So, one of my questions is going to
5 be -- I guess now I'm getting into the questions part of
6 it. You said on your last page, your recommendations,
7 that there is a current best approach for skin corrosion.
8 So, I have sort of a list of ticks it would cover, and
9 one of them is the repeat. Is there something for
10 repeat? And the other one is sensitization, habituation,
11 can you deal with that issue, because it's the key. It's
12 the top two issues of these kinds of (inaudible).
13 DR. ROBINSON: Yeah. Sensitization is not
14 covered by this. It really is a separate endpoint that
15 has to be dealt with, and again, we're not there yet.
16 The Local Lymph Node Assay is a step in the right
17 direction in terms of replacement and refinement, but
18 we're not there for full replacement.
19 You know, corrosion, you could -- a material
20 that's non-corrosive in a four-hour exposure could be
21 corrosive if you put it on for 24 hours under occluded
22 patch. So, when you define your irritation, it has to be

1 in the context, not only of the concentration that you're
2 testing it, but also the time of exposure that you're
3 using. So, there's no such thing as a cumulative
4 corrosion test. Corrosion is a defined endpoint within a
5 very short term window of exposure, and then if it's not
6 corrosive at that point, it may be that you could put
7 that into human subjects, again, depending upon the
8 exposure scenario, and define it in terms of its acute
9 irritancy potential, okay? But it would be non-corrosive
10 by definition because it's non-corrosive in any of these
11 in vitro methods.
12 MS. SASS: Yeah. I'm not concerned as much
13 about the corrosive as I am about that repeat
14 sensitization. I mean, this is the model of the workers
15 who -- or like when I go to get my pictures developed,
16 the guys in the photo lab don't smell the chemicals.
17 Well, the chemicals are still damaging them and they
18 might have smelled it at 8:00 a.m., but by 5:00 p.m.,
19 they're no longer smelling it, and they might not smell
20 it by Friday, but when they come back to work on Monday,
21 they smell it, and over years, they might actually become
22 completely intolerant and become unable to do the job.

1 That's the scenarios.
2 And I'm not talking about years, but I'm talking
3 about hours or days or weeks or months. That's the
4 scenario. And that's the most real. Like I say, it's
5 the key one or two when you're talking about
6 sensitization.
7 DR. ROBINSON: And the test method -- when
8 you're talking about product development from our
9 standpoint, what we would try to do is we would try to
10 capture all of those kinds of exposures, both anticipated
11 and unanticipated or at least foreseen, in the context --
12 once we're beyond this acute testing or cumulative
13 chronic testing, we would get into actual use scenarios
14 so that we would understand exactly what people are going
15 to be presenting with when they actually use the product.
16 MS. SASS: So, when you say a current best
17 approach, we now have skin corrosion and acute skin
18 irritation, acute short-term or single dose, maybe skin
19 irritation?
20 DR. ROBINSON: Right.
21 MS. SASS: So, now my other questions are going
22 to be are the tests transformed cell lines of any primary

1 cultures or are they synthetic or -- what's the state of
2 the cells?
3 DR. ROBINSON: The test methods are all the ones
4 you've heard about today. They are transcutaneous,
5 electrical resistant and rat skin, they are a bio-barrier
6 method, they are epidermal equivalent test method.
7 MS. SASS: So, the one that you showed, you're
8 using as a representation. But, in fact, you would go --
9 like somebody suggested micromass cultures, that's the
10 chick-wing bud (phonetic) standard culture or cell lines,
11 transform cell lines, primary cultures, organ cultures,
12 anything.
13 DR. ROBINSON: Yeah, they have not been
14 validated for this endpoint. Again, they may be suitable
15 or under-development for other toxicity endpoints, but
16 not for this particular one.
17 MS. SASS: Okay. And the EpiDerm TM, these
18 kinds of things, these are transformed cell lines?
19 DR. ROBINSON: No, these are normal human care
20 tenacites (phonetic) that have been grown up in a sheet
21 and then cut out in a lot of differentiated air interface
22 which causes them to differentiate and form a multi-layer

1 and then ultimately give rise to a stratam-corneum. They
2 do not have a barrier of normal skin. They do have some
3 barrier properties. But they do form a fairly
4 differentiated epidermal equivalent. It's very similar
5 histologically to what the human skin would look like.
6 MS. SASS: To about three layers in the skin,
7 right. And so, they would be primary cultures in some
8 kind of defined growth medium?
9 DR. ROBINSON: Yes.
10 MS. SASS: Okay. So, given those limitations, I
11 think you have a great system going. I don't think it's
12 the last word, although it might be the first word or a
13 really important primary screen or something like that.
14 How do you feel? What's your sense of --
15 DR. ROBINSON: Like I say, if you look at the
16 review article, you'll see what Novartis uses. Norvatis
17 has a different approach than what we do and they rely a
18 lot more heavily on the in vitro cultures for both their
19 acute as well as their cumulative chronic irritation.
20 L'Oreal has a different approach. I mean, everybody has
21 kind of developed -- they have different kinds of
22 chemicals, different kinds of formulations that they're

1 interested in. So, they all have developed -- I would
2 call them similar, I would still call them processes, but
3 they are different in the specifics of what they use once
4 they've gotten beyond the currently validated and
5 accepted methods. I mean, those are basically on the
6 table for everyone and there's a very limited number of
7 them.
8 But once you get beyond that, what are used
9 internally by different organizations are the things that
10 they're comfortable with, most of them or many of them
11 are published because they want people to buy into them.
12 But they're not -- certainly not validated in the sense
13 of what we've talked about here as a process by which
14 anybody would go through and say, yeah, these are methods
15 that everybody can and should be using.
16 MS. SASS: Do you think that it's more valid to
17 jump from these kinds of in vitro -- more synthetic and
18 controlled and defined tests to a human skin test. And
19 I'm not saying I'm averse to what you're doing, I'm just
20 saying it seems to me that scientifically we've always
21 had an in between stage and that has been an animal, and
22 it wouldn't take a lot of animals and it's not a painful

1 test, it's not painful on the humans, and I'm certainly
2 not talking about the Draize test, but I'm talking about
3 the skin patch test that you were talking about where you
4 get a red patch that you're claiming you almost can't see
5 if it's a low level.
6 Why go right to the human? Why not go to --
7 DR. ROBINSON: It's a fair question.
8 MS. SASS: -- you know, the hind limb of a rat?
9 DR. ROBINSON: Yeah, it's a fair question.
10 Number one is I don't believe the rat is going to tell me
11 any more or the rabbit is going to tell me any more from
12 a predictive standpoint than the culture does.
13 MS. SASS: Maybe that they'll volunteer quicker
14 for the experiment probably.
15 DR. ROBINSON: And it's -- you know, again, we
16 have to be real careful because, you know, volunteers are
17 paid for their participation, but they can only be paid
18 for their inconvenience not as an inducement. So, the
19 ethics of this -- I wrote a review article with the
20 Unilever group about a year ago that really went through
21 20 pages of ethics on this methodology, and it really did
22 hit hard on all these kinds of questions.

1 And part of it is the experience. I mean, you
2 know, we relied on what they had done when we got into
3 it, between the two organizations, and now a number of
4 other groups have gotten into it in formulation testing.
5 The SDA Task Force that I mentioned has representatives
6 from over a dozen U.S. companies. We've approached this,
7 we've approached it very carefully and I think the track
8 record has been that it's both safe to do, and we would
9 believe, ethical to do, and if I took a piece of
10 cellophane tape and went around the room and took one
11 swipe off of everybody's forearm, I would get more
12 reactions than what we typically see with these patch
13 tests. That's just the facts. And more accurate
14 representation.
15 Again, you know, the human -- by definition,
16 humans are variable, but the human response is, by
17 definition, the correct one. No one is going to validate
18 a new rabbit test based upon the human response.
19 MS. SASS: Right. But all those same arguments
20 that apply to why it's important to take that test to
21 that level of human, that you get the response in a
22 complex whole and verbal articulate organism that can

1 respond, are all the same deficiencies -- I don't want to
2 use deficiencies, but the limitations of the in vitro
3 testing. So, I mean, I think they're all really key and
4 really important, and I think they all could be used to
5 be red flags or indicators or begin to hone and be more
6 specific about those final tests. But --
7 DR. ROBINSON: No, I don't know if I agree. I
8 think the human testing in practice has proven to be
9 very, very reliable. It's been reliable across and
10 between laboratories. It's been reliable between
11 studies. It's being used as the benchmark for human data
12 for developing the in vitro tests in Europe through the
13 ECVAM process. So, there's a lot going on it in terms of
14 its reliability at this point. Again, that's all I can
15 really say about it.
16 MS. SASS: Thank you.
17 MR. HOUSENGER: Okay. I think we have one last
18 question from Alan.
19 DR. LOCKWOOD: Just to set the record -- one
20 item to set the item straight. Yesterday, on my way to
21 the Buffalo airport, I didn't see any terrorists, I
22 didn't see any snow.

1 **(Laughter.)**

2 UNIDENTIFIED MALE: They're hiding.

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

6 UNIDENTIFIED MALE: Give it another week.

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

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

22 MS. MULKEY: Let me observe that one reason you

1 may not be hearing this is because of the decision of
2 this group to focus on this really quite small subset of
3 overall testing, that is the acute testing of the end use
4 products and there's no questions that these larger
5 issues arise when you look across the broad range of
6 testing, and we could definitely have had a multi-day
7 dialogue on some of that. I think that's the primary
8 reason.
9 MR. HOUSENGER: Okay. Our last presenter from
10 Procter and Gamble is Rosemarie Osborne, who's a
11 Principal Scientist there. She received her
12 undergraduate degree in biochemistry from Skidmore
13 College and her Ph.D. in pharmacology from Harvard
14 University. Her expertise is in cell culture, and her
15 work at P&G is focused on non-animal alternatives for eye
16 and skin irritation testing.
17 DR. OSBORNE: Thank you. I'd like to start by
18 thanking the committee for the invitation to come here
19 today and tell you a little bit about what we're doing to
20 develop non-animal methods for eye irritation testing.
21 What I'd like to do is to overview the general process
22 that's used by consumer product companies to determine

1 the eye irritancy of our products and ingredients; then
2 talk a little bit about the specific test methods and how
3 they work; and then end up by showing you an example of a
4 risk assessment using a bridging approach that
5 incorporates both historical data as well as in vitro
6 data. Next slide, please.
7 A lot of what I'll be discussing today is based
8 on a workshop that was held at the Institute for In Vitro
9 Sciences close by here in Gaithersburg, Maryland.
10 Participants in this workshop included Procter and
11 Gamble, Colgate-Palmolive, Gillette, J&J, L'Oreal, S.C.
12 Johnson and Unilever.
13 At this workshop, we discussed some of the
14 common approaches that we use for eye irritation
15 assessments, as well as specific differences in test
16 methodologies. Nonetheless, a lot of the examples that
17 I'll be discussing today are based on ones that were
18 presented at this workshop that we're currently in the
19 process of writing up as a manuscript for a submission
20 later this year. Next slide, please.
21 This is the basic approach that we are all using
22 for our eye irritation assessments. It's very similar to

1 the one that Mike was just showing for skin irritation.
2 First of all, starting with human exposure estimates,
3 then getting into a review of historical data. After
4 that, taking all of this information into account, it
5 might be possible to go into an eye safety assessment if
6 it's a minor change in a formulation relative to
7 currently marketed product. If there's new traditional
8 information, then it goes into an in vitro testing mode
9 and then all of this information is taken into account in
10 the overall eye safety assessment process.
11 As Kathy indicated, there's also post-market
12 surveillance that's conducted via our 1-800 contact
13 number or e-mails or faxes, letters, whatever we're able
14 to gather. We use that both as a check on the pre-market
15 assessment that was made, as well as to gain information
16 on the sorts of scenarios in which people accidentally
17 splash our products into their eyes. This is the basic
18 process.
19 What I'd like to do is talk about the review of
20 historical data and then get into the in vitro
21 methodologies. Next slide, please.
22 Again, similar to what we saw for skin

1 irritation, the eye exposure estimates are based on the
2 intended use and foreseeable use or misuse of the
3 product, and known habits and practices. So, the types
4 of ways that our consumers use the product and scenarios
5 in which they might actually get product in their eye.
6 That allows us to assess whether certain types of
7 products might have the potential for accidental
8 exposures and also to estimate the amount that folks
9 might get in their ideas.
10 We have a large database in-house of existing
11 either rabbit or human exposure information and
12 irritation information based on assessments that have
13 been done over the last 50 years or so. That's a very
14 rich source of information for a toxicologist in making
15 these sorts of assessments. In addition, we have links
16 into government and trade associations and other types of
17 online databases that we use as a source of information
18 for the ingredients and analyze. Next, please.
19 The standard eye irritation test that's been
20 used for the last 50 years in industry and is the basis
21 for regulations around the world is the Draize Rabbit Eye
22 Irritation Test that was developed at the Food and Drug

1 Administration back in the 1940s. The procedure
2 incorporates placement of a 0.1 ml of test material into
3 the lower eyelid of albino rabbits. The eye is held shut
4 for a fix period of time, generally about one second, and
5 then the responses are scored using a subjective scoring
6 scale. The observations are made on the cornea, which is
7 the transparent tissue in the front of the eye,
8 inflamation of the iris, which is the pigmented part of
9 the eye, the blue or brown, as well as the conjunctiva,
10 which is the membrane that lies overtop of the square,
11 which is the white part of the eye.
12 From an EPA FIFRA standpoint, classifications
13 are based not so much on individual tissue scores
14 acutely, but how rapidly those heal. So, for example,
15 Category I, which would be the most aggressive materials,
16 would be those that take greater than 21 days to heal
17 when the material is instilled once into a rabbit's eye.
18 Category II, 8 to 21 days to heal; Category III, as we're
19 getting into milder materials, less than seven days; and
20 Category IV materials are those that would clear within
21 24 hours. Next, please.
22 Now, we tried to develop alternatives to using

1 rabbits for assessing eye irritation. There's been a
2 number of different approaches. First of all, reducing
3 the numbers of animals per test. I use as an example
4 there the change in the FIFRA guidelines 870 that now
5 requires three rabbits instead of the original six as a
6 part of the standard protocol.
7 There have been refinements to the in vivo test.
8 Those include modified procedures, such as the low volume
9 eye test, which was a modified procedure to try to more
10 closely model the types of exposures and responses as
11 they occur in human eyes as opposed to rabbit eyes, and
12 also objective measurement of responses in rabbit eye
13 tests.
14 And then also, replacement of the rabbit eye
15 irritation tests with either ex vivo or in vitro
16 alternative tests. And I'd like to tell you a little bit
17 about those types of methodologies.
18 I inserted here -- what you'll see in your
19 packet -- a couple of slides I brought from Roger Curran
20 and Joe Harvell from Institute for In Vitro Sciences that
21 I thought gave a really nice picture of the types of
22 systems that are used as alternative methods.

1 If you think about the eye, the tissues of
2 greatest concern from an accidental splash standpoint are
3 the tissues that are right in the front of the eye, that
4 are accessible to the test chemical or the product, and
5 of particular concern is the cornea, which is right in
6 the front, it's the transparent tissue that acts as a
7 barrier and also acts to transmit light back through the
8 lens and back on to the retina.
9 If a chemical is splashed onto the cornea and
10 causes it to become damaged, such that it swells, it
11 becomes opaque. So, then it's not possible for light to
12 be transmitted through there and there's a decrease in
13 visual acuity. So, a lot of the alternative tests have
14 focused on trying to understand what might happen to the
15 cornea if there is an exposure to a test chemical.
16 So, methods that involve -- if I could go to the
17 next slide, please. Methods have involved either use of
18 an intact eye, such as nucleated rabbit eyes or chicken
19 eyes, these are eyes that are derived from slaughterhouse
20 animals that are part of the human food chain. In
21 addition, there are methodologies that use excised
22 corneas, such as the bovine cornea method. Bovine cornea

1 opacity and permeability method, the BCOP, that's a
2 widely used method. Or an emerging method is the human
3 corneal model, and the goal there is to try to model just
4 the isolated cornea to see if it's possible to measure
5 changes in the isolated tissue that would be similar to
6 what we would see either in rabbits or humans.
7 Now, on the surface of the cornea -- you see
8 over on the right there is the epithelium. That's a
9 protective barrier right on the surface that's exposed to
10 -- potentially exposed to test chemicals if they were to
11 test chemicals, if they were to be splashed into the eye.
12 So, there's been a lot of work trying to develop three
13 dimensional tissue constructs or monolayer culture
14 systems that would model the changes as they might occur
15 in the epithelium.
16 And if we look at these test systems, they try
17 to model the sort of range of responses as they might
18 occur to a whole range of test chemicals. So, for
19 example, over here on the left, if we're looking at very
20 corrosive materials, severely irritating materials, it's
21 been found that methods that have intact eyes or intact
22 corneas, such as the isolated rabbit eye test, the

1 isolated chicken eye test or the bovine cornea test, have
2 the greatest degree of sensitivity for these severe
3 materials. In fact, these tests have been accepted
4 within the EU as screening tests for eye corrosives.
5 Now, on contrast, if you have very mild
6 materials, such as some of our cosmetic products, they
7 wouldn't be detected or distinguished by using these
8 intact eyes or cornea tests. However, the tissue
9 constructs or some of the cell culture systems are very
10 sensitive to differences in these types of materials.
11 So, what we found in our workshop is that
12 companies tend to use a combination of tests. So,
13 depending on what types of products they're interested
14 in, be they severe materials or mild materials, they
15 would either use a tissue construct for the mild
16 materials and then some sort of isolated eye test or
17 excised cornea test for the more severe materials. So,
18 usually these types of tests are used in combination.
19 Next, please.
20 I'd like to go through some examples of a
21 nucleated eye test, an isolated cornea test and then get
22 into cell culture methodology. What we're looking at

1 here is an isolated rabbit eye. In this case, you can
2 see an opacity that's formed on the surface of the
3 cornea. What we're looking at here is actually a plastic
4 Petri dish. Here's a Teflon dosing ring that's lying on
5 top of an actual rabbit eye. Again, these were
6 slaughterhouse derived tissues.
7 The tissue becomes opaque, but it's possible to
8 examine the eye more closely by using microscopic
9 techniques, such as confocal microscopy. What we're
10 looking at here is the eye essentially looking down at us
11 through the bottom of a confocal plate and you can see
12 the opening of the iris here. There's the surrounding
13 tissue. Next please.
14 Now, if we look at these tissues under confocal
15 microscopy using fluorescent stains that indicate either
16 live or dead cells, we can look at responses to various
17 different types of test materials. And for example, on
18 the left here is a 5 percent solution of sodium laurel
19 (phonetic) sulfate. This is a surfactant that's commonly
20 been used in liquid dishwashing detergents or shampoos.
21 And what we're looking at here is actual
22 individual cells. You can see, for the most part, these

1 are green. This is actually looking at the surface of a
2 rabbit cornea. This is the epithelial cells, and you can
3 see that there's just a very slight damage. Most of the
4 cells that are there are alive, but you'll see areas
5 where it seems that cells might actually be missing, and
6 that's what this very mild treatment does. It causes
7 cells to actually slough off the surface of the
8 epithelium. So, if you shampooed this morning and got a
9 little bit of the shampoo solution in your eye, this is
10 what your cornea looked like earlier this morning. By
11 now, since we're after lunch, it's had time to renew
12 itself, it's now, again, an intact epithelium. It's a
13 very mild response.
14 But in contrast, if an eye were exposed to a
15 severe material, such as a cationic (phonetic)
16 surfactant, you can see here that the barrier has a lot
17 of red cells in it. These are a lot of damaged cells.
18 And not only that, but there's this almost like a crater
19 that's formed where the epithelium is completely denuded
20 off the surface of the cornea. This would be the sort of
21 response that you'd see to a much more severe material
22 such as (inaudible).

1 Even inside the damaged area here, you can see
2 some small red areas. Those are actually the connective
3 tissue cells within the stroma of the cornea, and it
4 turns out that if you have very deep injuries to the
5 cornea, it doesn't heal. There's too much of a crater,
6 if you will, for the epithelium to renew itself over the
7 surface of the lesion. So, this would be a non-healing
8 injury that would result in a permanent opacity in the
9 cornea, which is an irreversible or Category I type of a
10 response.
11 Now, there's been a lot of work using this basic
12 approach of confocal microscopy to understand the
13 fundamental mechanisms by which eyes become irritated.
14 It turns out that this damage, this cytotoxicity, is a
15 primary step in the response, things like an increase in
16 opacity or swelling or the cornea are secondary to this
17 cellular damage. Next, please.
18 You can see here, too, in the black bars, we're
19 looking at the depth of damage into the stroma of the
20 cornea that's on the Y-axis versus a range of different
21 test materials, going from mild on the left here to very
22 severe materials. And one of the things I'd like you to

1 appreciate here is that if you have severe materials and
2 you're using an intact eye test such as this, there's a
3 lot of sensitivity to extinguishing the severe materials
4 versus less severe materials. I want you to kind of
5 remember that because later on we'll be looking at a
6 different type of test that has much more sensitivity for
7 distinguishing very mild materials. But this is an
8 important basis for an ex vivo test, looking at depth of
9 injury and cytotoxicity as the primary mechanism of
10 response. Next slide, please.
11 This is a different type of approach, but very
12 complimentary. It's looking at bovine corneas, and you
13 can see here a response to a corrosive test material
14 causes an opacity on the isolated cornea. This is the
15 exact same lesion as is evaluated in rabbit eye tests.
16 Next, please.
17 Now, instead of using animal derived tissues, an
18 emerging area is the use of reconstructed human corneas,
19 and this is growing out of the medical community where
20 these types of corneas are being developed for
21 transplantation to patients who have corneal injuries.
22 And on the left here is shown a backlighted human cornea

1 that's an eye bank tissue, and it's backlighted so the
2 square here appears black, and there's a letter E put
3 behind it to try to mimic an eye chart type of approach.
4 What you can appreciate here is actually the eye bank
5 cornea is more opaque than what you see over here, which
6 is the reconstructed cornea, which is much more
7 transparent. If I could have the next slide.
8 This shows the two tissues in cross section. On
9 the left here is the eye bank cornea. It has the
10 outermost epithelium, which is the protective barrier on
11 the front of the cornea, a large stromal element, and
12 then a single layer of endothelial cells. So, there are
13 three different cells types to the cornea.
14 Over here is the reconstructed cornea that
15 contains immortalized epithelial cells that are co-
16 cultured with stromal keratinocytes (phonetic) which are
17 the connective tissue cells, and again, there's an inner
18 layer of endothelial cells. This is a fully
19 reconstructed cornea that's based on immortalized, but
20 not transformed, cells that are grown together. Next,
21 please.
22 In the upper left here, you can see an excised

1 human cornea, this is the control cornea and this is a
2 cornea that was treated with a cationic surfactant
3 solution. You can see that the area by the pointer here
4 has become opaque. And similarly, in the reconstructive
5 cornea, there's a control cornea, it's transparent;
6 however, areas of opacity develop upon exposure to these
7 severe types of materials.
8 Over on the right here it shows -- if you can
9 appreciate the reddened area here, that the area of
10 opacity contains damaged cells. The non-opaque area, the
11 transparent area, has living cells.
12 In the bottom here, we're looking at changes in
13 light transmission through the cornea as it becomes
14 opaque, and the point of all these is -- over on the
15 right here is human corneas from eye bank tissues that
16 are relatively insensitive to these types of materials,
17 ranging from mild materials to those that are more severe
18 and drastically decrease the amount of light that's
19 transmitted through the cornea and to opacity.
20 Over on the left here, you can see that rabbit
21 corneas are much more sensitive to these types of
22 materials, and the reconstructed corneas provide a sort

1 of happy medium that provide a safety factor relative to
2 human corneas but are still not quite as sensitive or
3 (inaudible) predictive as what's been seen with the
4 rabbit corneas.
5 So, that's the newly emerging human corneal
6 cultures. A surrogate that's been used for the past
7 couple of years for actual ocular cells is skin-derived
8 cells that are grown on filter membranes, such as on the
9 right here, and this is very similar what Mike was
10 showing for reconstructed skin cultures. This is
11 actually sort of a reconstructed mucosal epithelium. It
12 has several layers of epithelial cells, but without a
13 stratam-corneum. This is a model system that, again, has
14 an epithelium and a stroma, so it's two cells types in
15 co-cultures. These systems have been used for topical
16 application types of assessments, looking at cytotoxicity
17 as an endpoint. Yes?
18 UNIDENTIFIED MALE: Those of us who are drifting
19 off here, can you explain -- I mean, not drifting off
20 asleep, but like not catching on.
21 **(Laughter.)**
22 UNIDENTIFIED MALE: What is a reconstructed --

1 UNIDENTIFIED MALE: We drift for a lot of
2 things.
3 UNIDENTIFIED MALE: What -- can you define two
4 terms for those of us who don't know what they mean.
5 DR. OSBORNE: Okay.
6 UNIDENTIFIED MALE: Reconstructed tissue and
7 immortalized. I'm especially interested in immortalized.
8 DR. OSBORNE: Okay.
9 **(Laughter.)**
10 DR. OSBORNE: (Inaudible) immortalized part on
11 behalf of our tissue culture expert over here. I'll
12 start with reconstructed, and what that means is as
13 you're trying to develop a tissue that you might want to
14 transplant back into a person's body, what you do is you
15 take the isolated cells, and in isolation, you put them
16 back together.
17 So, for example, I'll just use the cornea as an
18 example. It has three different cell types, and if you
19 were wanting to cure that person's problem with their
20 cornea, you need to put all three cell types back in
21 there. But you have to put them back in the right
22 confirmation so that they mimic the actual tissue, so

1 they mimic cornea. Now, it turns out the way the cornea
2 is constructed is that it has like endothelium on one
3 side, it has a stroma in the middle and then epithelium
4 on the surface. So, in cell culture and isolation, you
5 can put all those back together in that right
6 confirmation and then take that construct and put it back
7 in a person's eye. That's called a reconstruction or
8 reconstruct or construct. That's that kind of
9 terminology.
10 Now as far as immortalization, that has to do
11 with how you treat the cells when you're growing them to
12 make sure that you can maintain them in cultures so you
13 have a big enough supply, so when you start to put these
14 tissues back together, you have enough to actually do the
15 work. And so, what -- if we could, right now, take part
16 of your skin and put it in a nutrient culture medium,
17 which is kind of a nutrient broth, grow it up on Petri
18 dishes, and expand it out so we'd have many millions of
19 cells, we could freeze those down and for years to come
20 we could be using your cells with your skin construct.
21 UNIDENTIFIED MALE: (Inaudible) skin cancer,
22 right.

1 UNIDENTIFIED FEMALE: (Inaudible).

2 **(Laughter.)**

3 DR. OSBORNE: But those would be primary

4 cultures. If we take them right off the body and put

5 them into cultures, those are primary cultures. We can

6 treat those with protease and expand those out, and those

7 would be like secondary or tertiary cultures.

8 But what if we wanted them to go on forever? We

9 want to use them today, but we want to develop a test

10 method that's useful in 10 years. We want to have a

11 stable cell life. So, what we do -- what we could do is

12 to treat those cells with a virus that causes them to

13 immortalize. So, it's almost like a step in the cancer

14 process, but it allows us to maintain those cells in

15 culture for a longer period of time, still with a

16 differentiated -- you know, they will still be like skin

17 cells and still like corneal cells, but we'll be able to

18 maintain them for a longer period of time.

19 Did that explain --

20 UNIDENTIFIED MALE: Yeah, that's great.

21 DR. OSBORNE: Okay. So, that's reconstruction

22 and immortalization. If you have any questions like

1 that, please ask. I'm sorry (inaudible) jargon.
2 Here's a reconstructed mucosal epithelium, which
3 taking actual human skin cells and growing them on the
4 inserts, they're stratified. We put test materials on
5 the surface and then look at cytotoxicity endpoints and
6 relate those to eye irritation. If I could have the next
7 slide, please.
8 This shows a comparative -- a comparison of in
9 vitro responses on the X-axis here relative to historical
10 rabbit data on the Y-axis. This is very typical for the
11 relationship between a non-animal test and it's data set
12 relative to the animal test. It's a sort of bi-phasic
13 relationship as you can see here. This is what we would
14 refer to as a validation data set, and this is from some
15 of our in-house work. (Inaudible) roughly 100, 120 or so
16 materials that have been tested in historical rabbit eye
17 irritation tests and we took those very same materials
18 and evaluated those in a non-animal method and then we're
19 able to develop this sort of plot.
20 What this allows us to do is to take new test
21 materials and put them into the context of our historical
22 database. So, for example, if we have a new shampoo, we

1 would expect it to fall in the same range of other
2 shampoos that have been tested previously, such as those
3 that are shown here in the black spot. If we have
4 strongly irritating materials, they would fall up in this
5 range and have very low in vitro values. They'd be very
6 potent. In contrast, things like cosmetic products or
7 liquid hand soaps or that sort of thing are very mild and
8 so they'd end up on the far right of the curve.
9 What I wanted to focus on in this next example
10 is some of our anti-microbial hard surface cleaners that
11 are shown here in the black triangles, and those would be
12 on kind of the high of this innocuous to slight
13 categorization.
14 This is a case study looking to predict the
15 human eye safety of a new liquid household cleaning
16 product, HSCL is that (inaudible) designated. The
17 strategy was to use the in vitro tests that we just
18 looked at, as well as three marketed hard surface
19 cleaning products that we used as internal benchmarks for
20 comparison. These historical benchmarks had low eye
21 irritation in the historical rabbit (inaudible) eye test,
22 as well as in consumer accidental exposures based on the

1 marketplace experience.
2 So, we're taking the new product and we're going
3 to compare it to three marketed products in in vitro
4 methodology. Next, please.
5 You can see here the responses to the three
6 benchmarks based on the historical rabbit data. These
7 are all really quite low. MAS on this scale is measure
8 of eye irritation and (inaudible) 110 scale. So, you can
9 see the responses here are really quite low. And also,
10 the days to clear are really quite fast. So, these would
11 be either a Category IV or a Category III, I guess based
12 on the FIFRA classifications.
13 Also, in the in vitro method, you can see that
14 the response is really quite high, indicating that these
15 are mild materials, and our new hard surface cleaner
16 would fall in the mid-range of these. So, based on the
17 similarity of formulation of this new material relative
18 to the marketed standards, as well as the historical data
19 that we're using for bridging and the in vitro data, our
20 assessment is that this new formulation has innocuous to
21 slight irritancy and that's similar to the previously
22 marketed products.

1 In fact, this product was marketed and the low
2 irritancy was later confirmed by the marketplace
3 experience, which showed that had very low irritation,
4 that any exposures healed very rapidly in consumers.
5 Next, please.
6 So, the lessons from what we've learned from use
7 of alternative methods for eye assessments is that the
8 alternatives can be used in the assessments as long as
9 validation has occurred. So, we have this range of
10 historical data that we can use for perspective. That
11 any new test materials are similar to those that have
12 been evaluated previously and for which we have
13 validation data, that we use benchmark controls in our in
14 vitro tests so that we can bridge new data to existing
15 historical, be it rabbit or marketplace, experience data,
16 and that we use this overall weight of evidence approach
17 in taking into account historical data, SAR, all of the
18 arguments that we've heard, in addition to any new in
19 vitro data.
20 So, the state of the art is that within
21 industry, in vitro tests are used to assess small, well
22 defined classes of chemicals and formulations, such as

1 the anti-microbial hard surface cleaners. This approach
2 has allowed consumer product companies to end finished
3 product testing in vivo in rabbits.
4 The weight-of-evidence assessment process is the
5 same across companies. That's what we found in our
6 workshop, although specific in vitro methodologies used
7 might be different between companies. Nonetheless, the
8 way that we use those tests for benchmarking and for
9 bridging is the same across companies.
10 And also, I just wanted to reiterate the point
11 that some of these methods have been accepted within the
12 EU for screening for corrosive chemicals. Next slide,
13 please.
14 So, the recommendation coming out of all this
15 work is that the weight-of-evidence assessment process,
16 as we've described it, be accepted for the anti-microbial
17 cleaning products, such as hard surface cleaners. Thank
18 you.
19 DR. STITZEL: I just have two or three things I
20 wanted to summarize on behalf of P&G. I know we're
21 running late, so I'll be real brief. I don't know
22 (inaudible).

1 We have five issues that we saw are core issues
2 that we think are core issues that we think are
3 important, specifically for anti-microbial regulations.
4 One is that we think there should be more support for
5 development of new test methods, and particularly both
6 internationally and nationally to have direction setting.
7 Because as you have seen, every company is going out and
8 doing their own kind of test development. We really need
9 to have better coordination.
10 We need to have a multiplicity of endpoints,
11 tests for each endpoint, and we need to have the
12 regulatory agency understand that there's a multiplicity
13 of tests and be able to deal with that.
14 More importantly, we need to have the agency
15 personnel aware of what's going outside and involve not
16 doing a development, but understand what's going in
17 development and have some consultation input into how
18 these tests are developed and what kind of test methods
19 and endpoints are used.
20 Our second issue has to do with validation.
21 Validation still needs continuous improvement. I think
22 that's partly -- the example of the corrosion test is a

1 good example because those tests were validated against a
2 prediction model which did not fit the United States,
3 which is why they're not being accepted in the United
4 States as final tests, and that's just a learning that we
5 need to change and not do that again.
6 Validation is extremely resource intensive the
7 way it's set up right now and we need to work on trying
8 to save that, and we need a process to allow the agencies
9 to understand about these internal tests that companies
10 are using. If they validate it internally, then they
11 have a lot of faith in it. Somehow, the agencies have to
12 be able to also judge this data and say, is this really a
13 good test, does this company -- does this internal
14 validation set -- is this the right data, did they do
15 this right, and so they can also have some faith in these
16 tests, because we're not going to be able to take all
17 these many, many tests through ICCVAM or ECVAM. ICCVAM
18 and ECVAM do not have enough resources to look at all
19 these different kinds of tests.
20 Finally, there's also the issue of acceptance.
21 We think the process is still too slow. We realize that
22 the agency is working rapidly on it and just learning how

1 to do this because they've only had a few tests that have
2 gone through ICCVAM, but we're hoping the process will
3 speed up. We think that the use of the SAP is
4 duplicative and increases our work. We're hoping that we
5 can reduce that as much as possible. We're particularly
6 concerned that the use of new methods should increase the
7 time that it takes for approval of new processes. For
8 industry, times means money. We need to get these
9 products out on the market as soon as possible. And if
10 it seems like it's going to slow down the process to use
11 alternative tests, then industry is likely to say, well,
12 we just won't use them because it's faster to use animal
13 tests.
14 So, we really need the agency to not make it
15 slower if you submit alternative data, and we also need
16 them to not say, okay, we'll accept your alternative
17 data, but we will increase -- we'll just knock it up one
18 labeling classification. That, also, won't help us
19 because we want to have the lowest labeling that we can.
20 So, we need to have these tests accepted for what they
21 are, as replacement tests.
22 And we definitely need a way to prework the use

1 of bridging data, alternative data and waivers, so we
2 know before we turn in -- this is for anti-microbial
3 registration, I'm talking about, particularly before we
4 go and turn in our packet of materials that these things
5 -- not that they're going to accept the data necessarily,
6 but the test method would be acceptable. So, we'd like
7 to have a way of coming in and preworking some of this so
8 it would go as fast as possible once it's accepted.
9 Issue number four is the data requirements. We
10 really think the agency needs to rethink the six-pack.
11 Do we really need to do all these tests every time? Our
12 two examples that I'm sure all of you are -- I would be
13 surprised if some of you at least haven't used Tide with
14 Bleach and Mr. Clean, and understandably, we went to put
15 anti-microbial labels on those products, even though they
16 had been on the market, we had to do the six-pack of
17 tests. We were allowed to get by without doing the eye
18 test, but otherwise, we had to go back and test for acute
19 dermal toxicity for those tests, even though those
20 products had been on the market and you and I had been
21 using it all this time.
22 So, we really need to rethink this. We need to

1 be able to validate alternative methods. We need to be
2 able to use historical data. We need to be use structure
3 activity approaches and we need to be able to use
4 exposure considerations.
5 And, finally, we realize that facilitating
6 change is difficult. The primary thing is there must be
7 a reason for people to change and we understand that
8 that's difficult. We need training that is -- we realize
9 that agency people need training on new methods. We need
10 -- in order to have faith in these new methods, people
11 really need to understand learnings in toxicology and
12 that means continuing education. We understand that
13 that's a problem for agency people, and however we can
14 help to provide not just us, but the industry in general,
15 provide continuing education, we really need that, and we
16 need to understand better each other. We're constantly
17 learning reasons why the agency needs different kinds of
18 data than we think they do, and I'm sure you're
19 constantly learning what we're doing. So, the more that
20 we can talk to each other and learn each other's needs,
21 the better we can develop new test methods.
22 My final is, toxicology is changing and we all

1 must change with it, and I think the genomics is -- it
2 will be a few years before it ever gets (inaudible) but
3 we're all going to have to learn to live with these new
4 approaches and so we've got to learn how to change.
5 Thank you very much.
6 MR. HOUSENGER: Very good.
7 **(Applause.)**
8 MR. HOUSENGER: All right. We have a little
9 time for questions. We won't be taking on how to
10 immortalize Larry's skin, though.
11 **(Laughter.)**
12 MR. HOUSENGER: If not, let's move on to our
13 final presenter. Since graduating with Honors Health
14 Sciences Degree, Troy Seidle has served as the director
15 and consultant to numerous animal protection
16 organizations in Canada and internationally. He is a
17 former member of the Canadian Council on Animal Care, the
18 national peer review body that sets monitors and
19 establishes standards for the care and use of animals in
20 Canadian laboratories. He currently serves as Science
21 Policy Advisor to the People for the Ethical Treatment of
22 Animals, and is active in the development of non-animal

1 chemical testing strategies in North America, Europe and
2 OECD.
3 MR. SEIDLE: Thank you very much. Give that
4 we've had some excellent technical presentations, I'm
5 going to shift gears here and focus more on a policy-
6 oriented talk and take a step backwards to where we've
7 been and make some projections as to where we can go.
8 The process began back in 1959, as Marcia said,
9 with the publication of the Principles of Human
10 Experimental Technique, and the first major progress we
11 saw was in 1969 in the UK with the formation of the Fund
12 for the Replacement of Animals in Medical Experiments, or
13 FRAME. Twenty years later, Germany followed suit with
14 the formation of ZEBET, and the first major progress we
15 saw in the United States from Federal agencies was in
16 1993 with the NIH Revitalization Act and specific
17 language calling for the development of three Rs methods
18 or alternatives.
19 1994 saw the formation of ECVAM, the sister
20 organization to ICCVAM in the U.S., and the Netherlands
21 Centre for Alternatives, and that's when we really
22 started to see some concerted development of non-animal

1 test methods. And then in 1996, the OECD, Organization
2 for Economic Cooperation and Development, organized a
3 workshop --
4 **(END OF SIDE B, TAPE 3)**
5 MR. SEIDLE: -- non-animal test methods. The
6 following year, ICCVAM was created as a standing
7 committee and in the year 2000, ICCVAM, under the ICCVAM
8 Authorization Act, became a Congressionally mandated
9 entity as has been discussed. In 2001, we saw the first
10 Congressional appropriation of $4 million in support of
11 the development of non-animal test methods by the EPA,
12 and in 2002, some of the best activity we've seen so far,
13 a second OECD validation conference was held in
14 Stockholm, OECD National Coordinators endorsed three non-
15 animal test guidelines for phototoxicity, skin corrosion
16 and percutaneous absorption, and the OECD Task Force on
17 Endocrine Disruptor Testing and Assessment established a
18 dedicated Validation Management Group for non-animal test
19 methods, which was quite a precedent. Next, please.
20 To date, we have seen some non-animal methods
21 that have achieved validation. Most of these, as
22 previous speakers have said, have come from Europe. We

1 have phototoxicity, four methods for skin corrosion,
2 several options for vaccine testing. But what does this
3 mean in the context of pesticide tests? Unfortunately,
4 not a lot.
5 40 CFR 158 prescribes numerous animal tests
6 protocols, very few of which are addressed by current
7 validated non-animal test methods. So, we have an
8 enormous challenge ahead of us if EPA is fully implement
9 reductions, refinements, and ultimately replacements of
10 animal use in its pesticide programs. Next, please.
11 So, today, as we've heard, we're dealing with
12 the six-pack, and if you hit it three more times, for
13 visual aides of exactly which tests we're talking about,
14 skin irritation, eye irritation, and lethal poisoning.
15 So, the effects, I think, should be pretty clear at this
16 point. Next.
17 I'll just skim over these, as they've been dealt
18 with in a great deal of detail. Acute systemic toxicity
19 in the U.S. is still involving mortality or moribundity
20 as an endpoint, and this is almost universally condemned,
21 and it's something that really needs to -- we need to
22 move beyond as a matter of urgency. In addition, the

1 reliability and the relevance to humans of acute systemic
2 toxicity tests have not been established, and two
3 factoids, to come from a multi-center evaluation of in
4 vitro cytotoxicity study, published in 1999, demonstrate
5 that rat and most LD50 are not necessarily self-
6 predictive, much less predictive of human lethal doses.
7 Next.
8 As replacement methods that have been
9 (inaudible) two of the more promising ones are normal
10 human keratinocytes and mouse fibroblast cell lines. The
11 battery that was examined in the MAEK (phonetic) study of
12 three of these assays found them to be highly predictive
13 of human lethal blood concentrations. The R squared was
14 0.79. When a blood brain barrier biokinetic was added to
15 the equation, the predictivity increased to 0.83. This
16 isn't quite -- well, they're significantly better than
17 the LD50 predictions, and given additional R&D, we are
18 quite hopeful. In addition, the MAEK study recommended
19 the addition of ADME parameters looking at absorption,
20 distribution and metabolism, and these are also under
21 development.
22 In October 2000, NIH asked that ICCVAM organize

1 an international workshop in acute toxicity testing and
2 the use of alternative methods for this purpose. They
3 concluded that it in vitro cytotoxicity assays are ready
4 for us now as a starting dose prediction for acute
5 toxicity studies. Researchers at ZEBET in Germany
6 predicted that animal use could be reduced by up to 40
7 percent by using this methodology, and earlier this year,
8 OPPTS issued a guidance to participants in the HPD
9 program for the use of in vitro methods for starting dose
10 calculation.
11 Participants in this workshop also concluded, as
12 Dick had pointed out earlier, that if the political will
13 was there, within two to three years, we could
14 potentially have a validated replacement on our hands.
15 However, two years have already passed and we're already
16 -- we're just at the point where a joint U.S. and EU
17 validation study is beginning. So, clearly, there are
18 political, among other forces, that are perhaps going to
19 extend these timelines.
20 Eye irritation, largely the same issues
21 ethically speaking. Three bullets, I'll let you look at
22 on the slides in your handouts, but the predictivity of

1 the Draize eye irritation test is nothing to write home
2 about. The inter-laboratory variability back in 1971 was
3 found to range from 42 percent to 117 percent. Now,
4 bearing in mind that this was prior to the establishment
5 of good laboratory practice, previous -- or subsequent
6 research, rather, has found that these numbers haven't
7 changed substantially. So, these are certainly, by no
8 means, a gold standard by which to validate non-animal
9 methods or even a reliable basis for human health risk
10 assessment.
11 Many of the non-animal methods that have been
12 invented to date have already been identified by
13 Rosemarie. This is just another iteration, including
14 below each of the major bullets the jurisdictions in
15 Europe that have accepted these as screening methods for
16 severe irritation. Next.
17 Skin irritation, same issues, we can skip over
18 this.
19 Actually, let's just skip over all of these.
20 We've already covered these. Let's move onto factors
21 affecting progress, and there are five. Not to go into
22 too much detail because Kathy's raised many of these.

1 But provision of adequate resources for test method
2 development and validation -- actually if you want to
3 skip -- there are a few regulatory bodies in North
4 America that have committed resources to develop,
5 validate and utilize non-animal test methods for risk
6 assessment. As I mentioned, the $4 million appropriation
7 Congressionally mandated for EPA for non-animal methods,
8 has been (inaudible) to genomics which one could consider
9 a good or a bad thing. It certainly isn't focused on
10 endpoint-specific non-animal method development, which is
11 a concern. Next.
12 International coordination of R&D efforts. We
13 have substantial cultural differences that we've
14 encountered. On one hand, Europe and Japan are
15 definitely the leaders when it comes to in vitro method
16 development, whereas North America is the stronger
17 proponent of in silico, or QSAR, methods.
18 ECVAM, in May of this year, published a very
19 comprehensive report on the status of alternative
20 methods. However, until that time, there was no
21 internationally recognized review document that covered
22 all of the major endpoints in pesticide and other

1 chemical risk assessment and there really wasn't a
2 roadmap from which to proceed. This has been a major
3 deficiency. And although international coordination
4 through ECVAM tends to focus on Europe only, efforts
5 coordinated through the OECD have always focused on
6 animal tests, and we really don't have a mechanism
7 between government agencies, between industries and other
8 stakeholders in North America, much less worldwide, to
9 coordinate these efforts. As Kathy pointed out, there's
10 a lot of money going into it, but it's very fragmented
11 and it is stunted progress. Next.
12 Availability of trained personnel and
13 experienced laboratories, another problem. We found that
14 many laboratories like to tweak protocols rather than
15 following a standardized methodology, and this is a major
16 problem for validation. Next.
17 Availability of high quality human reference
18 data. This has come up again and again in reference to
19 validation studies, where animal data has been used as
20 the default, but given that no animal test has been
21 validated for its relevance to humans, much less its
22 reproducibility between laboratories, one example being

1 the Draize test, the results have been across the board
2 and it's been almost impossible, largely for this reason,
3 to validate a replacement method for this test.
4 Likewise, at the OECD Stockholm conference
5 earlier this year, it was recognized and recommended
6 quite clearly that an expert meeting be organized to
7 either create a human health effects database or some
8 opportunity or some mechanism to gather reliable human
9 data for validation purposes, recognizing in many cases
10 animal tests have unknown validity or none. Next,
11 please.
12 And finally, as Kathy pointed out, regulatory
13 acceptance of scientifically valid non-animal methods and
14 testing strategies. There are definitely political
15 undertones to this process moreso than the validation
16 process itself. Non-animal methods are quite
17 consistently held to a higher standard of scientific
18 excellence than animal tests. We believe OECD admits
19 this in numerous of its discussion documents.
20 And even in some cases, non-animal methods that
21 have undergone successful validation in one jurisdiction
22 are not accepted in another, and the most recent examples

1 are the skin corrosivity assays which were validated by
2 ECVAM in the late 1990s. The ECVAM Scientific Advisory
3 Committee issued a statement of their validation in 2000.
4 They were accepted by the EU in the same year, accepted
5 by the OECD earlier this year, and still ICCVAM in the
6 U.S. is requiring that negative results be followed up by
7 an animal test as part of an in vivo weight-of-evidence
8 (inaudible). So, we still have a ways to go politically.
9 Next.
10 So, returning to the current challenges, we’ve
11 got, already, a laundry list of animal tests that need to
12 be revisited. Next.
13 In addition to these, we have a number of
14 emerging challenges, among them a disruption in pesticide
15 reevaluation for aggregate and cumulative effects, a
16 trend towards perpetual new animal testing. New
17 endpoints are being raised all the time. Reference was
18 made to the EPA reference dose, reference concentration
19 document, which outlines a number of proposed
20 methodologies, none of them validated, some having the
21 potential to reduce animal use, some proposing new
22 endpoints, which could substantially increase it.

1 And unfortunately, the current trends we're
2 seeing tend to be more focused on the increase in animal
3 tests as opposed to the reduction or replacement, and
4 this, in the grand scheme of things, undermines the 3Rs.
5 Next.
6 So, some of the action items that we would like
7 to see are the establishment of a subgroup of the PPDC to
8 continue to monitor the progress of non-animal method
9 development, formulate recommendations and report back to
10 this body on a regular basis. Some of the issues for
11 discussion have already been raised. I won't spend much
12 time on them, but they deal with the percutaneous
13 absorption test, in vitro that has been accepted by the
14 OECD, the use of the (inaudible) embryonic stem cell test
15 to screen for development toxicity, the use of in vitro
16 genotoxicity tests as a stand-alone when combined with
17 metabolism studies, and the potential to use genotoxic
18 data as the screen for carcinogenicity in lieu of the
19 rodent bioassay. Next.
20 And finally, back to the funding. There needs
21 to be far more coordination and far more human and
22 financial resources dedicated not only by EPA's ORD but

1 also by industry in a coordinated manner to start looking
2 at some of the longer term endpoints. It's taken us 20
3 years to look at acute and local toxicities. It's going
4 to take us a whole lot longer to look at these. So,
5 there's no time like the present. Thank you.
6 **(Applause.)**
7 MR. HOUSENGER: Okay, thank you, Troy. Are
8 there any questions for Troy?
9 UNIDENTIFIED FEMALE: Larry has one.
10 MR. HOUSENGER: Oh, I'm sorry.
11 MR. ELWORTH: This isn't my issue, so what are
12 the political -- you mentioned that the political issues
13 were in play on this. What are the political issues that
14 are involved in either -- in preventing people or
15 institutions from moving to non-animal testing?
16 MR. SEIDLE: Some of them in the regulatory
17 community are just the fact that when you have animal
18 tests that are prescribed under regulations. It's
19 difficult, at the best of times, to get those changed.
20 But the flexibility that Kathy alluded to that toxicology
21 is always evolving and the methodologies have to evolve
22 along with it, and this -- what we found to be an

1 inherent mistrust in non-animal test methods and also a
2 belief that just in the terminology that's used that they
3 are simple methods, that, you know, by implication they
4 are less robust, less relevant, and even in the presence
5 of a successful validation study, some of those attitudes
6 persist. So, it really is that cultural belief that
7 animal tests are inherently more relevant than the non-
8 animal tests and that sees to be politically or
9 philosophically based as opposed to scientific.
10 MR. HOUSENGER: Are there any general comments,
11 questions that people want to raise?
12 UNIDENTIFIED MALE: I was wondering just if you
13 would address something, Troy. It seems like all the
14 discussion today has been in the sense of animals being
15 used in order to protect humans, but you could also argue
16 to protect animals, we actually need to do more animal
17 testing because many of these species and other high
18 order groups are not even being tested at all. And if
19 you wanted to know what the effect of a compound is,
20 pesticides are a good example, you would have to say
21 there would have to be a lot more animal testing just
22 those species groups and also different types of

1 endpoints, toxicological and others that are now totally
2 neglected.
3 MR. SEIDLE: I'll respond to your question
4 first. From an ethical point of view, we don't draw a
5 line ethically between if you put an animal in a
6 laboratory, the animal's interests somehow matter less
7 than a wild animal. As far as we're concerned, from a
8 pain and suffering point of view, it's complete
9 equivalence, that killing one animal to protect another
10 is not an ethical position to take whether we're looking
11 at non-human or human animals as part of the equation.
12 So, we're looking at specifically non-animal test methods
13 across the board for that reason.
14 In terms of the ecotoxicity studies, to which I
15 guess you're referring, it is a different animal in some
16 cases from the human health risk assessment where you're
17 looking at extrapolating to a population, and there are
18 limitations there as well in terms of the validity. We
19 went around and around in Stockholm on how you validate
20 the data for one species to -- say one avian species to
21 all others. Is that -- can you generalize -- can you
22 make valid generalizations in so doing? And even though

1 there's a belief that within one taxonomic group there
2 may be the same or similar ADME, that's not necessarily
3 the case. And in the absence of proper validation, I
4 think the scientific question is -- you know, it's a mute
5 point and, you know, none of these methods have been
6 validated to date.
7 MR. HOUSENGER: Jay.
8 MR. McALLISTER: I'm Jay for an afternoon. I'm
9 Ray McAllister filling in for Jay. Earlier -- late this
10 morning, Deborah McCall described to us the progress that
11 has been made in validating methods by OPP, by OPPTS,
12 using the ICCVAM procedure and I commend the agency for
13 that progress that's been made there. If I understood
14 right, you're describing primarily the validation of new
15 methods, the new alternatives to animal testing, but from
16 time to time the agency promulgates new guidelines for
17 animal testing and makes revisions to the current
18 guidelines for animal testing, whether it's on a
19 permanent basis, from now on you're going to do this test
20 differently, or perhaps on an ad hoc basis, for this
21 circumstance, you need to do this test differently.
22 I wanted to ask, to what extent EPA does now or

1 plans to validate such changes in the animal testing, and
2 would those changes in the animal tests go through the
3 same involvement of ICCVAM or meeting the ICCVAM criteria
4 before they are required of registrants?
5 MS. MULKEY: Well, I think the answer to that is
6 essentially -- at least the primary answer to that is
7 essentially case-by-case. Before we establish new
8 guidelines for animal testing, there is always robust
9 peer review engagement of some sort. The most frequent
10 would probably be the scientific advisory panel. But
11 many of these are not new, they are modifications. Now,
12 I don't know if Margaret or somebody is here that would
13 feel comfortable speaking at the level of detail that you
14 raised the issue, but the short answer is that while the
15 formal ICCVAM process is not typical for the additional
16 animal testing or modified animal testing, peer review
17 certainly is.
18 Can you think of anything beyond that?
19 MR. HOUSENGER: Julie?
20 MS. SPAGNOLI: I think, you know, looking at --
21 if we're focused on acute toxicity testing, which I think
22 was the -- where this was really supposed to be looking

1 at and how the agency classifies products. They are
2 categorized. And what you're really trying to do in this
3 testing is determine a category and a lot of these
4 categories are fairly broad. I think in the area of like
5 acute oral toxicity, a Category III is anywhere from 500
6 to 5,000 milligrams per kilogram.
7 So, you know, the point of the acute six-pack is
8 really just to categorize a product, and I think we've
9 seen in a number of experiences that there's a lot of way
10 that you can probably categorize these products based on
11 available data. And I think we've heard -- I've heard
12 over and over again about looking at weight-of-evidence,
13 and some of the actions that the agency's already taking
14 in the area of batching and bridging, and I think we can
15 do more there. And a couple of personal experiences that
16 I've been involved with, where we took batching even to a
17 further standpoint of doing sub-batching where we'd say,
18 okay, for certain types -- for like, acute oral, dermal
19 inhalation, we can even combine some of these batches and
20 do one set of tests for four or five batches and then
21 only do fewer tests on the individual batches.
22 We also -- and Debbie's group was very much

1 involved with this and it resulted in the issuance of --
2 I think it was PR Notice 20012 where -- actually, where
3 looking at criteria for formulations, what the active
4 ingredient toxicity was, what level it was at in the
5 formula, what the, you know, components were, that you
6 could make a very clear determination of what category --
7 again, we're not looking for the exact LD50, but I think
8 in most cases, a judgment could be made that, okay, if
9 it's a fraction of a percent of a Category III active
10 ingredient on fertilizer, we know what it's going to be.
11 We don't need to look at the toxicity of fertilizer over
12 and over again.
13 And I guess I would think that there's probably
14 opportunities to look at other types of product
15 categories and other types of formulations to see if we
16 can't make those similar kind of judgments. I know what
17 we did in the case of the granular fertilizer and
18 granular pesticide products, we looked at all of the
19 existing products and tried to make correlations between
20 active ingredient toxicity and end-use product toxicity,
21 and after you look at about 100 or so formulations, it
22 starts to become fairly clear.

1 I'm just wondering if there might not be other
2 opportunities for other types of formulations that are --
3 you know, outside of just the substantial are similar.
4 Do we know enough about certain types of formulations
5 that based on the formulation type and the active
6 ingredient that we can probably make a pretty clear, you
7 know, indication of what category, not an exact LD50, but
8 what category it would fit into.
9 MR. HOUSENGER: Erik?
10 MR. NICHOLSON: I just had more of a general
11 comment I'd like to share. Representing the farmworker
12 community, I guess in terms of context, our membership
13 and our constituency are regularly exposed to pesticides
14 on almost a daily basis, and then often are the subjects
15 of studies to look at what are the impacts of those
16 pesticides on their physical well-being.
17 So, in that context, I'm very much concerned
18 that while we strongly agree with the move towards
19 getting away from animal testing, that this not be a back
20 door to increase human testing. In fact, I would use the
21 phrase I've often heard before that, humans are animals,
22 too, and that we indeed keep humans within the scope of

1 the three Rs and not expose more humans to pesticides as
2 part of the toxicological data.
3 MR. HOUSENGER: Bill?
4 BILL: Yeah, I have a couple of questions for
5 Troy and then some for Procter. Troy, forgive me for
6 these. I'm not trying to ply you on this, but I really
7 do want to know this.
8 When -- what's PETA's position in terms of --
9 when we're looking at this idea of animal replacements?
10 Like where would you focus more on? Is it on tests that
11 are -- sort of like the eye irritation tests, which seem
12 pretty cruel, or the idea of number reduction? Do you
13 guys make a -- do you divvy it that way?
14 MR. SEIDLE: We do and we don't. How's that for
15 a non-answer?
16 BILL: Well, I'm just thinking about if we're
17 going after something for a reason, you know, and you had
18 to make choices.
19 MR. SEIDLE: Well, as far as our priority
20 targets, then, we do -- we're most concerned, I would
21 say, about the heavy duty tests, if you're looking at
22 repro, development, carcinogenistic, chronic, they are

1 long-term, involve large numbers.
2 The reason that we chose to focus on acute today
3 is because the methods are more developed and, you know,
4 they provide, we thought, very tangible case studies for
5 which there's a ton of data to document the readiness of
6 some methods and the near readiness of others to be used
7 as total replacements. But as far as our priorities for
8 R&D and agency attention and industry attention, we would
9 focus on the longer term, larger number aspects.
10 BILL: And would you draw a distinction in a
11 sort of -- I don't mean this necessarily either, but a
12 hierarchy of animal-like, you know, a bacteria to a fish
13 or a daphnia to a fish to a rat to a dog to a chimp kind
14 of thing?
15 MR. SEIDLE: We generalize within the vertebrate
16 kingdom, that if they've got a backbone, they're of very
17 high concern. Certainly, if we look at -- some of the
18 nastiest tests are conducted on the smallest animals.
19 So, our concern is no less for a rat than it is for a
20 dog.
21 BILL: Okay, thanks. I was really impressed
22 with the whole day's presentation. There was a lot of

1 deep science in this and I want to commend everybody,
2 particularly from Procter, for being willing to share all
3 of their work, which is pretty incredible.
4 One of the things that concerns me, though, is
5 the idea of broad applicability of the philosophies of
6 how Procter does risk assessment to every registrant.
7 Have you thought about -- I think Kathy you gave a pretty
8 impassioned advocacy of a position and a new way of
9 thinking. Have you thought about it for companies or ma
10 and pa registrants who may not have the resources that
11 Procter has at its disposal to doing alternatives?
12 DR. STITZEL: There's several parts of that, and
13 it doesn't have to do with anti-microbial testing, but
14 let me just tell you that for cosmetic testing and
15 cosmetic companies, that has been an issue and there has
16 been an attempt by all the bigger companies, particularly
17 in Europe, to try and provide training for the smaller
18 companies and to get this information out.
19 What I was trying to say for -- that I think is
20 important for EPA for right now is to understand and be
21 able to evaluate data that's come in to them so they can
22 somehow judge what information has been generated by one

1 of these companies that does have a good database.
2 I mean, as Rosemarie said, there's a whole group
3 of companies that have been doing this sort of thing for
4 a long time and most of them have a lot of data, and the
5 trick is to be able to understand and look at that data
6 and say, yes, this is the data we mean, here's what a
7 validation study should look like, here's some positives,
8 here's some negatives, and here's importantly some in
9 between, because if you just have positives and
10 negatives, you can make a nice straight line, and that
11 sort of data and we just need to, as an industry
12 probably, help train people -- IVS is good resource for
13 that -- into how to look at this data and say, this is
14 good data or not. Providing training for smaller
15 companies is something we probably need to do on an
16 industry-wide basis.
17 BILL: Thanks.
18 DR. STITZEL: And we have been doing -- I mean,
19 this stuff has all been presented many times, but I
20 understand about the mom and pop stuff is harder.
21 UNIDENTIFIED MALE: Right. And I think the
22 publications are also a part of that. Mike's publication

1 that he presented on the skin is very comprehensive on
2 how to do this and Rosemarie and all of her friends are
3 putting together a similar paper on eye.
4 UNIDENTIFIED MALE: Yeah, I think we try to --
5 one that does is it levels the playing field in terms of
6 -- a lot of the resources at P&G and at Unilever and a
7 number of these other companies can put against these
8 programs is because we do have those resources and we can
9 develop the methods. But once the methods are developed,
10 we don't view toxicology as proprietary information. So
11 we really have promoted our own effort to get this stuff
12 out. And then people can pick and choose. Like I said,
13 there are many methods in the reviews that other
14 companies, small companies can look at and say, this is
15 the way I would like to approach it.
16 UNIDENTIFIED MALE: Thanks. I think my last
17 comment on this is that probably there may be a way to do
18 this if we just look at the problem differently, and I
19 think Julie was trying to get at that a little bit, too.
20 I mean, when you boil down the why are we doing the six-
21 pack and what does it translate to, and it translates
22 into labeling decisions and presumably those labeling

1 decisions are for people who read the label and
2 understand that they're being warned. You know, there's
3 a lot of assumptions about what a label is and the CLI
4 tried to get into that a little bit.
5 But I think if we examined the why are we doing
6 this and what its value is and what decisions get made on
7 a practical basis, which is, I think, a labeling
8 decision, you know, we may not have to do a six-pack. We
9 may not have to study to study replace all six. I mean,
10 there could be some new evaluation scheme that gets at
11 good warning and is sort of formulaically based but
12 doesn't have to do all this testing.
13 MR. HOUSENGER: Win?
14 DR. HOCK: This is kind of directed to everyone
15 really. I need some enlightenment about MSDSs. The
16 question I have -- or at least the statement -- I'll make
17 the statement first. To the best of my knowledge, every
18 chemical that's used in the United States or marketed in
19 the United States, in one way or another, I understand
20 there has to be an MSDS prepared. And I'll give you an
21 example. White-Out, I understand there's an MSDS for
22 White-Out. In fact, I've given it to my secretary so she

1 can hold me responsible.

2 But at any rate, on an MSDS, you generally see

3 things like toxicity information, corrosiveness, skin and

4 eye irritation and other information like that, and I

5 guess the question I have simply is that in developing an

6 MSDS, are animals used in every case to develop the

7 database? Does the six-pack come into play in every one

8 of these products? I don't know, that's why I'm asking.

9 And then I guess the other thing is what Federal agencies

10 requires MSDSs? I'm guess it's not entirely or maybe

11 it's not EPA. But what Federal agencies require MSDSs to

12 be prepared --

13 UNIDENTIFIED MALE: OSHA.

14 DR. HOCK: I thought it was OSHA or NIOSH

15 (phonetic) or one of those, right. But it's that kind of

16 thing. What is the role or where do we come in with all

17 this toxicological testing in an MSDS? How does that all

18 blend together? Don't all answer at once.

19 UNIDENTIFIED MALE: It's an OSHA form and OSHA's

20 put out -- there are regulations on how to fill out an

21 MSDS and what you're supposed to consider and what data

22 is required to be on there. Recently -- or not so

1 recently, but there's a pretty full requirement now that
2 if you don't have tox on the formula, if you have tox on
3 the components, then that's got to be on there. So, some
4 MSDSs, there's no tox on the formula that you're looking
5 at, but there's tox on all the ingredients there. So,
6 you'll get a whole mixture of approaches to that.
7 Some people, there are software programs that
8 will write an MSDS, other ones are handcrafted. So,
9 there's a wide variety on how they're authored and the
10 approaches taken by folks. But if you want how that's
11 done or what's supposed to be included, that's in the
12 OSHA regs.
13 UNIDENTIFIED FEMALE: And just your first
14 question, I think, about -- MSDSs are generally required
15 for, I think, almost all commercial products. In fact, I
16 wrote the MSDS for SOS Soap Pads, which, I guess, now is
17 one of Bill's products.
18 UNIDENTIFIED MALE: And my first MSDS I wrote
19 was for a tape dispenser for 3M.
20 **(Laughter.)**
21 UNIDENTIFIED FEMALE: And as -- if you didn't --
22 what you have to identify in an MSDS are any hazardous

1 components by OSHA's hazard classification and any
2 hazardous components in that formulation have to be
3 identified.
4 DR. HOCK: Okay. Is the identification, though,
5 done through animal testing? I guess that's the
6 question.
7 UNIDENTIFIED MALE: Sometimes.
8 UNIDENTIFIED FEMALE: Probably of the individual
9 components, yeah.
10 DR. HOCK: Of the individual components, yeah,
11 yeah. Thank you.
12 MR. HOUSENGER: Beth?
13 UNIDENTIFIED FEMALE: I don't think that's
14 necessarily true. I mean, I think there are companies
15 who (inaudible) that will develop an MSDS based on what
16 they are and if they are a technology. So, they don't do
17 any testing at all. They say that the safety is based on
18 historical data and if they don't know (inaudible)
19 classification. But (inaudible).
20 MR. HOUSENGER: Okay, Beth?
21 DR. CARROLL: I was prompted by Ray's question,
22 and there may not be an answer for this yet, but as I

1 look back over the morning's presentation, ICCVAM
2 agencies are quite diverse from Consumer Product Safety
3 to Department of Ag to Department of Interior, Department
4 of Transportation, EPA, Food and Drug and OSHA. Has
5 anybody thought a lot about whose data quality guidelines
6 ICCVAM is going to use? Because it seems to me when I
7 read through those, they're all different.
8 UNIDENTIFIED FEMALE: Can I answer that?
9 DR. CARROLL: Um-hum.
10 UNIDENTIFIED FEMALE: The data quality
11 guidelines that ICCVAM is using were set up -- are based
12 on some data quality guidelines that were developed by
13 what was called IREG, which was Interagency Group of
14 Regulatory Agencies back in the late '80s, right? And
15 they're pretty strict.
16 Data is supposed to have been done under GLPs.
17 Because we're using a lot of historical data, some of it
18 will get by, you know, in the spirit of GLPs. But you
19 have to be able to find the data and look at the data.
20 When we sent the Local Lymph Node Assay in, they went
21 back and they asked us to give us the original data for
22 these tests just randomly and we had to go find the lab

1 notebooks and copy the data. So, they're pretty strict
2 on quality, and that's really was set up by a group of --
3 the predecessor to ICCVAM, which was IREG.
4 DR. CARROLL: And are those available like on
5 the web, the guidelines?
6 UNIDENTIFIED FEMALE: They're on the NIEHS
7 website, the ICCVAM website.
8 DR. CARROLL: Okay, great, thank you.
9 UNIDENTIFIED FEMALE: They were adopted by OECD
10 as well, so they're pretty well universal guidelines.
11 MR. HOUSENGER: Ray again?
12 MR. McALLISTER: If those data quality
13 guidelines you're talking about date from the 1980s, how
14 do they compare to the now developing data quality
15 guidelines under the OMB regulations?
16 UNIDENTIFIED FEMALE: I have no idea. I don't
17 know anything about OMB regulations. Are you talking
18 about (inaudible)?
19 MR. McALLISTER: Well, that's data quality
20 across the board.
21 MS. MULKEY: I don't think any of us know the
22 instrument.

1 MR. McALLISTER: Okay.
2 MR. HOUSENGER: I guess considering all the
3 presentations that everyone's heard, we have heard some
4 general comments regarding guidance at the agency, how we
5 could do a better job. Does the panel have any further
6 guidance, recommendations based on what you heard today?
7 (No response.)
8 MS. MULKEY: Are we ready for a -- oh, excuse
9 me.
10 UNIDENTIFIED MALE: I'd just say that, you know,
11 there's been some discussion here of a more systematic
12 approach by the agency, by OPP in particular, with the
13 assistance and input from stakeholder groups to look at
14 how alternative methods can be used and developed. I
15 would support that. I think we need that approach,
16 whether it is this group in particular that forms a
17 subgroup, I'm not sure that's the best one because our
18 toxicology experts on the panel today are invited.
19 They're not permanent members of the group. So, I don't
20 know that we have expertise to address those questions.
21 But perhaps there's another forum within the agency to
22 address that.

1 MS. MULKEY: (Inaudible) in the corner.
2 MR. HOUSENGER: Okay.
3 UNIDENTIFIED MALE: Yeah, I'd like to echo that.
4 It's interesting. Marcia, you said earlier that it's a
5 case-by-case basis, and I think really in a lot of these
6 cases from our stakeholders, from a registrant
7 perspective, it is case-by-case. I think it exemplifies
8 how important preregistration meetings are. Because in
9 point of fact, during preregistration meetings, you can
10 talk about what toxicology data you'd like to generate,
11 what you'd like to use from the literature, what you'd
12 like to use as an alternate kind of thing. I mean, we've
13 done things as simple as reduce fly testing by doing HPLC
14 analysis. Well, that's reducing an animal test, I guess,
15 in some small way.
16 So, it is a case-by-case basis really, and I
17 still think the preregistration meetings become key
18 because of that.
19 MR. HOUSENGER: Anyone else?
20 (No response.)
21 MS. MULKEY: All right. Well, it works quite
22 well for us to take a 15-minute break at this point. To

1 induce your return, let me remind you that in addition to
2 the follow-up issues that you were planning, that you
3 will hear about this year's registration activity and
4 that is a topic which ought to be keenly interesting to
5 everybody. We also have public comment and I think we
6 all want to be sure that this advisory committee complies
7 with the meaningful public input portion of our charter.
8 So, while I'm sure everybody will enjoy this
9 break and be back right at 4:00, I'm equally sure
10 everybody will be back, and as I tell some of you, the
11 cocktail hour at this hotel on Tuesday nights features
12 the -- anyone who chooses to bring his or her pet dog.
13 And I gather it's quite charming and a pleasant
14 atmosphere to hang out with some very much beloved
15 animals, citizens of Alexandria. So, I think we can all
16 make it till then. We can have that little uniqueness.
17 See you at 4:00.
18 **(A brief recess was taken.)**
19 MS. MULKEY: -- to our timetable.
20 **(Brief pause.)**
21 MS. MULKEY: It's not entirely consistent who
22 can be counted on to be back at the end of the moment.

1 But we very much appreciate those who are consistently
2 back in the moment. This was, I know, a long hard
3 afternoon's work, not hard in the unpleasant sense, but
4 in the -- I don't know what time they arrive, about 5:30,
5 I think.
6 **(Brief pause.)**
7 MS. MULKEY: I'm ready for cocktail hour, I'll
8 give you that, with or without dogs.
9 **(Brief pause.)**
10 MS. MULKEY: We really appreciate all the work
11 and effort that has brought you this far today. We are
12 mindful that we have not called upon the full committee
13 to be as actively advisory as we have in some other
14 sessions. But it's certainly a key subpart of the
15 committee, which invested heavily in our ability to have
16 the kind of input that we have gone through on this
17 topic.
18 Several of you said to me in sidebars on the
19 brief break that you're very mindful that in order to
20 offer any kind of perspective on a topic like we just
21 have heard about, you have to invest a fair amount in the
22 learning curve, if you will, if you're not already

1 engaged in a topic like that. And we're mindful that not
2 everybody is prepared to do that on every topic. But
3 we're really grateful for those of you who understand the
4 context in which we operate to take the opportunity to
5 give this level of investment in order to share with us a
6 topic like this, which definitely is relevant to us and
7 can have, at least, a marginal impact on the more
8 particularized interests that some of you have with
9 regard to our work.
10 As you can tell, I'm trying to fill time with
11 something other than merely sitting or whining. What we
12 have left to do is actually quite a lot and I want to be
13 sure that we maximize people's return because I think
14 there's going to be an interest in all the pieces of it.
15 Let me have you take out your agendas and let me sort of
16 frame the remainder of the day.
17 We had planned follow-up from two other of major
18 topics from May, the Section 18 revisions, reforms on
19 which you got a report in May, and we have an update, and
20 you will remember the examples of the non-isolated misuse
21 that we were experiencing in last year's season and we
22 were going to give you sort of an update around that --

1 those particular problems and that kind of problem.
2 At the request of an active one of the members
3 who is interested in being present for that discussion
4 and in light of our need to triage time, we're actually
5 going to move that to the updates in a minute tomorrow,
6 but you will remember that we retained from this
7 morning's updates in a minute the registration activity.
8 That is important in and of itself and it also gives you
9 some information that I think you will find relevant in
10 tomorrow's discussion of the way we spend our money and
11 allocate our resources in OPP, not directly, but not that
12 indirectly either. So, that should be of value.
13 And I also wanted to take -- we have public
14 commenters, we have at least two -- more than that,
15 Margie?
16 MS. FEHRENBACH: (Inaudible).
17 MS. MULKEY: And finally, I wanted -- because so
18 many special guests were here for our presentations, but
19 who don't seem to have made it back, probably because
20 they are -- maybe they rushed to the cocktail hour after
21 their ordeal but --
22 **(Laughter.)**

1 MS. MULKEY: Okay.

2 UNIDENTIFIED MALE: Dogs to test.

3 MS. MULKEY: If I learn that they're likely to
4 be around -- but I wanted to give a little feedback about
5 next steps around this issue today because I thought
6 there might be attendees today who would not be here
7 tomorrow. Normally, tomorrow would be the more obvious
8 time to do that. So, we'll do a little bit of that.

9 All right, then I suggest that we go to this
10 follow-up issues by turning to Debbie Edwards'
11 presentation on behalf of all of our registering
12 division, the Registration Division, the Anti-Microbials
13 Division and the Biopesticides and Pollution Prevention
14 Division, and get a report on this year. For us, that
15 means October 1 to September 30 activities.

16 MS. EDWARDS: Thanks, Marcia. As Marcia pointed
17 out, this is a -- normally you would report the
18 Registration Division the registration program outputs
19 for the entire office for the fiscal year, which ends on
20 September the 30th. It is today September 17th and we're
21 all working very hard to continue to meet the goals and
22 hope to get a lot done in the next two weeks.

1 But anyway, I will -- you should each have in
2 your package a piece of paper that starts with
3 registration division outputs, it actually says. You
4 might want to follow along there because I don't think I
5 should be spending your time and my time reading through
6 each and every chemical that we've registered this year,
7 but rather, I'll kind of try to make a summary of what
8 we've achieved.
9 And also, as Marcia pointed out, I'll be
10 covering the outputs for conventional chemicals,
11 biochemicals, microbial pesticides and plant-incorporated
12 protectants and anti-microbials.
13 So, on the first page there, you'll see that,
14 just for context, in FY 2001, the new active ingredient
15 registration total that we registered this last year was
16 12. The goal for the current year, 2002, was again 12.
17 To date, we have registered six new active ingredient
18 chemicals in the registration --
19 **(END OF SIDE A, TAPE 4)**
20 MS. EDWARDS: And two additional ones to total -
21 - the two additional ones are signed but not yet
22 registered. That means it's a sure thing and it will

1 happen by September 30th.
2 Of these eight chemicals that are essentially
3 registered, four of them are reduced risk chemicals.
4 They achieved a reduced risk status, one of them as well
5 is an OP alternative chemical. In addition to that, we
6 have established some import tolerances, two of which
7 actually are for new chemicals, one being Iprovalicarb on
8 grapes, and the other Tolyfluanid, which is a new active
9 ingredient for several commodities listed there.
10 Finally, I would say that we are still working
11 on five active ingredients, working through issues,
12 trying to get these looked at, and I'm hopeful that we
13 will get four of them registered by the end of the fiscal
14 year, which would allow us to achieve our goal of 12.
15 If you move to new uses, which should be on the
16 next page, for convention chemicals, last year in FY
17 2001, 204 new uses were registered. The goal for fiscal
18 year 2002 was 230 new uses, and as of September 13th, we
19 had registered 124 new uses, of which 62 are reduced
20 risk, 30 were OP alternatives and 59 were IR-4 or minor
21 uses. You can see there's some overlap there. Often,
22 IR-4, in particular uses, are reduced risk uses.

1 We also have signed, which again that means it's
2 a done deal for the year, 61 additional new uses. That
3 takes us pretty close to our goal, and we're working on
4 and we're pretty certain we're going to get an additional
5 45 new uses by the end of the fiscal year, which will
6 allow us to achieve our goal of 230.
7 In addition to new chemicals and new uses, we
8 have cleared nine new food use inerts, as well as five
9 food use polymers through the polymer exemption, and as
10 well, 69 new non-food use inerts this year. We're not
11 anticipating doing any more in the next two weeks, but we
12 did achieve those this year. And you'll see, also, a
13 table that shows our progress over the years in Section
14 18s. I think the numbers are looking pretty similar
15 throughout the years, but as you can see there, the
16 average response time is continuing to go down. This
17 year, the average response time for Section 18s is 33
18 days.
19 And then you'll see there in the footnotes that
20 many of these exemptions and several of the crises
21 exemptions this year were related to the anthrax
22 incidents that occurred in buildings here in D.C. and

1 other areas.

2 Moving on now to the Biopesticides and Pollution

3 Prevention Division, last year, they had two new

4 active -- I'm sorry, seven new active ingredient

5 registrations and this year the goal was to register nine

6 additional ones. To date, they have registered four

7 biochemicals listed there, three microbial pesticides,

8 and one plant-incorporated protectant, which takes you to

9 a total of eight, and they are anticipating completing

10 three more which will exceed their goal by two. So,

11 they'll have a total of 11 probably for the year.

12 As far as new uses go, last year they registered

13 in the Biopesticide Pollution Prevention Division a total

14 of 90 new uses. This year, they are registering a total

15 of 80, 61 microbials and 19 biochemicals.

16 And finally, the Anti-Microbial Division

17 outputs, FY 2001, the Anti-Microbial Division measured

18 one new active ingredient, new chemical. The goal for FY

19 2002 was two new active ingredients, and this year

20 they've actually exceeded their goal by one. They've

21 registered three new active ingredients.

22 Also, in the new use area, last year a total of

1 nine new uses were registered in the Anti-Microbial
2 Division. The goal for this year was 13, and again, that
3 goal has been exceeded. They registered 17 new uses in
4 the Anti-Microbial Division. And as always, Frank
5 Standers and his management, with Jack Housenger on his
6 team now, continues to meet all FQPA timelines for all
7 anti-microbial registration actions. So, that's a
8 summary of outputs for this year.
9 Any questions?
10 UNIDENTIFIED MALE: Marcia, what drives the
11 number of the goal, 230? Why not 240 or 220?
12 MS. MULKEY: Those goals are part of the budget
13 process and they're worked out as part of the --
14 originally the President's budget that's submitted to the
15 Congress and then I guess they're revised. When the
16 agency gets its budget and establishes its operating
17 plan, it's tracked under the Government Performance and
18 Results Act. It's reported on to Congress, in the
19 agency's public documents. I think there's a colloquy
20 with OMB around those goals.
21 UNIDENTIFIED MALE: We also try to -- when
22 resources are stable, to always have a goal that's equal

1 or better than the previous year's goal because we have
2 an expectation that we're enhancing our efficiency and
3 productivity as a general expectation. And so, that goal
4 -- that number has actually crept up rather dramatically
5 over the last six years because we've been enhancing our
6 efficiencies around how we do new uses.
7 UNIDENTIFIED MALE: Debbie, how does this relate
8 to any backlog within those divisions as a percent? Do
9 you have any idea?
10 MS. EDWARDS: I can't really speak, I don't
11 think, right now for the -- maybe Janet can from BPPD,
12 she's here. But for the Registration Division, I would
13 say that an equal number of new chemicals, maybe 18 to
14 20, are in the cue, next year's -- candidates for next
15 year, but the goal will probably be 12 again. We always
16 have to have more candidates, you know, than we issue.
17 And then I would say another between 16 and 20 are in
18 backlog over and above that candidate list.
19 MS. MULKEY: Janet, do you (inaudible)?
20 MS. ANDERSEN: We have 32 pending active
21 ingredients right now in the Biopesticides and Pollution
22 Prevention Division. We know that some of those will not

1 actually make it next year. Our goal is 12. And there's
2 a couple of them that are sort of (inaudible) that we
3 might exceed that depending on how the data goes when we
4 actually see it. So, 32 new active ingredients are
5 pending.
6 STEVE: Who's next?
7 MS. EDWARDS: Steve?
8 STEVE: Debbie, I couldn't help but wonder about
9 sucrose as a wood preservative. It seems like it might
10 attract ants or something, huh?
11 But Carolyn actually had a good solution, if you
12 used chlordane as an inert, it would probably work for --
13 **(Laughter.)**
14 UNIDENTIFIED FEMALE: (Inaudible) animal testing
15 (inaudible).
16 STEVE: No, no. Yeah, but the Clordane is fine.
17 And I was also wondering about the -- when you consider
18 12 new AIs in the Registration Division, when two of them
19 are import tolerances, I wouldn't announce that
20 necessarily to the American farming public. That almost
21 flies in our face as promoting your efforts when, in
22 fact, it's what they use overseas and we don't get to use

1 it here.
2 MS. EDWARDS: Actually, the goal of 12 does not
3 include the imports.
4 STEVE: Okay.
5 MS. EDWARDS: So, you'll notice here I'm listing
6 eight -- in total, I'm listing 11 as done, if you include
7 the -- I guess 10 as done if you include the imports.
8 But our goal is actually to register 12 new chemicals,
9 and that means register, not establish tolerances.
10 STEVE: You still have a couple more you're
11 trying to get through.
12 MS. EDWARDS: Those are over and above that
13 goal.
14 STEVE: Okay.
15 MS. MULKEY: Debbie, do you want to talk a
16 little bit about how it happens that we work on those
17 import tolerances and sort of a little bit about what the
18 dynamic is?
19 MS. EDWARDS: Sure. Well, I mean, for the most
20 part, the reason that we're working on import tolerance
21 registrations, it would be two different reasons. One,
22 they may need the active ingredient there and they don't

1 -- in another country and it's not needed here, in which
2 case the company just has no interest in pursuing the
3 registration here. And so, to prevent any trade barriers
4 from developing, we would go ahead and review those
5 applications.
6 I know a recent case actually where a company
7 came to us with a -- wanting us to participate in a NAFTA
8 project where the -- there would be an import tolerance
9 for the United States, but the product would be actually
10 registered in Mexico, and it's just simply not needed
11 here and the company is claiming that. And I think that
12 the growers are in agreement. We had a meeting where
13 many of the growers came along to substantiate.
14 So, that's one of the main reasons why we do end
15 up working in import tolerances.
16 MS. MULKEY: Would these typically be registrant
17 priorities? Is that how they got to --
18 MS. EDWARDS: Right. I'm sorry, that's true as
19 well.
20 STEVE: So, they've established that as a
21 priority?
22 MS. MULKEY: Right.

1 MS. EDWARDS: Right.
2 STEVE: Still, it's not something to brag to
3 American growers about.
4 MS. MULKEY: But we're transparent.
5 MS. EDWARDS: Yes.
6 STEVE: Good for you.
7 **(Laughter.)**
8 MS. EDWARDS: Julie?
9 MS. SPAGNOLI: Yeah, two questions. One, is the
10 agency still on track for issuing their 2003 work plan in
11 the October time frame? I think that was kind of the
12 goal.
13 MS. EDWARDS: I would say that it's likely to be
14 around the first week in November.
15 MS. SPAGNOLI: Okay.
16 MS. EDWARDS: More likely. It's been delayed
17 slightly.
18 MS. SPAGNOLI: And then the second question is,
19 you know, you indicated that the review times for the
20 Section 18s have continued to (inaudible). How are the
21 review times for both conventional and reduced risk AIs
22 and new uses, are they -- what's the trend there? Are

1 they staying stable? Are they increasing, decreasing?
2 Is there any trend or is it -- that you can see?
3 MS. EDWARDS: I would say that they're staying
4 stable. I mean, particularly for reduced risk, we're
5 trying to meet the shortened time frame. As far as I
6 know, they're staying stable. Actually, I don't have it
7 at my fingertips now, but a lot of -- I don't know if
8 Anne Lindsay has them with her, but we've just put
9 together a whole lot of statistics about that, which I
10 actually intend to present at the CLA Registration
11 Committee meeting in about a month.
12 But, Anne, do you have any of that information
13 with you?
14 MS. LINDSAY: (Inaudible).
15 MS. EDWARDS: Great. No, okay. This is for new
16 conventional chemicals, so I'm strictly talking about
17 Registration Division actions right now. For reduced
18 risk or OP alternatives, we're averaging 23 and a half
19 months. For work shares, reduced risk, OP alternatives,
20 20 months. For reduced risk, OP alternatives that are
21 not joint reviews or work shares, 22 months. And for new
22 chemicals which are not reduced risk or OP alternatives,

1 39 months.

2 MS. MULKEY: Is that actual review times?

3 MS. EDWARDS: Now, that is over -- no. It's

4 actual review time -- probably it's close to average

5 review time possibly for many of the ones that are joint

6 reviews and things like that. But the 39 months date, it

7 represents probably at least as year of Q time. They

8 don't get as high a priority typically.

9 MS. SPAGNOLI: Thanks.

10 MS. MULKEY: Any other -- (inaudible)?

11 UNIDENTIFIED MALE: Debbie, I wanted to ask a

12 question dealing with the expedited review portion.

13 You've given a very good, detailed summary of the new

14 active ingredients and new registrations. I wondered

15 where we were on the expedited review, the ME-2

16 (phonetic) labels, the ME-2 products and the label

17 changes, and as to where we are, perhaps, in meeting the

18 90-day deadline, which the agency has been meeting, I

19 guess, over the last couple of years. I wondered if you

20 could simply update some of those numbers.

21 MS. EDWARDS: I don't actually have the specific

22 numbers with me. It's my understanding that we're -- at

1 the end of this fiscal year, we will have a zero backlog
2 on fast-tracks. So, that is good news, I hope.
3 UNIDENTIFIED MALE: Where's --
4 MS. EDWARDS: On the non-fast-tracks, it
5 probably doesn't look as good.
6 UNIDENTIFIED MALE: Are we still under the 90
7 days? I would assume that we are, but --
8 MS. EDWARDS: Yeah.
9 UNIDENTIFIED MALE: Okay. In the past, you've
10 done anywhere from 1,000 to 1,500 ME-2s and between 3,500
11 and 4,000 simple label changes. Are those ballpark
12 numbers or are they up or down?
13 MS. EDWARDS: The last time I looked at the
14 numbers, they were continuing to kind of trend along, not
15 really going up, but not going down.
16 UNIDENTIFIED MALE: Okay.
17 MS. EDWARDS: Anyone else?
18 MS. MULKEY: Anything else on this?
19 (No response.)
20 MS. MULKEY: Thank you, Debbie. And now Dan
21 Rosenblatt is going to provide us a continuation of our
22 earlier discussion about some issues around Section 18.

1 If you'll remember, we talked through some areas for
2 reform and revision at the last PPDC meeting, and this is
3 an update on that.
4 MR. ROSENBLATT: Hi. This is just a brief recap
5 and sort of progress report on where we are on a project
6 that the PPDC heard about in May. This will sort of
7 summarize what we're calling the Section 18 Process
8 Revision Project, and we're moving at least forward with
9 an upcoming Federal Registry notice, which the policy
10 shop is busy drafting and is here in the back, taking a
11 short break from drafting that. I'll put a schedule
12 around what's ahead and for the Section 18 season in
13 2003, how we will be integrating, at least in part, the
14 new ideas that we developed for you in May.
15 Okay. This slide, sort of in a qualitative
16 fashion, summarizes what this project is about. We are
17 putting these proposals forward in sort of a good
18 government spirit. Can we get to a decision point on a
19 Section 18 faster and with less paperwork while still
20 maintaining the standards of FQPA and the standards of
21 the regulations for health and safety protection.
22 For folks who are involved in the Section 18

1 process, I'm sure you're familiar with sort of the very
2 high degree of time pressure connected to each and every
3 application. So, I think we're very proud of the numbers
4 and our average turn-around time, but at the same time,
5 we know that with each application, there really is a
6 high degree of time sensitivity. So, we're looking to
7 integrate efficiencies where we can.
8 As I said, the way we're moving this forward is
9 bringing -- sorry about that -- a Federal Register notice
10 and we've got three areas where the notice will be
11 specifically covering. One will be in terms of a
12 streamline application for repeat Section 18s and
13 specifically dealing with second and third year requests.
14 We're proposing a manner for the applicant, in most all
15 cases, a state lead agency, to provide a certification
16 about the continuing nature of the emergency in the
17 new -- sort of the battery of data that would be required
18 under the regs, Part 166.
19 Concerning this first bullet, the streamline
20 application process, I want to make clear that although
21 the applicant will be providing less data, the
22 information that EPA is in control of will continue to

1 re-reviewed and reassessed each year. So, specifically
2 concerning risk alternatives and progress towards
3 registration, those areas will be reevaluated each year
4 in the second and third year cycle where we're offering
5 sort of this abbreviated opportunity to submit an
6 abbreviated Section 18 package.
7 Further on this point, the exemptions that are
8 eligible for this streamline treatment are selected by
9 EPA. The criteria are going to be laid out in the
10 Federal Register notice that we'll be publishing soon.
11 But in a nutshell, we are going to be asking ourselves,
12 and the State needs to ask themselves, whether this sort
13 of emergency that we're facing is one that is likely to
14 be ongoing. A classic example would be sort of the
15 identification of a new pest and as a problem for a
16 certain group and we would sort of anticipate that
17 retrenching and gaining sort of pest management tools, or
18 something along those lines, would be an ongoing
19 emergency.
20 Concerning the second point, the tiering pilot
21 for the assessment of significant economic loss, the
22 established sort of precedent here is for EPA to look at

1 historical data, usually five years' worth of information
2 and to evaluate whether the request and the pest problems
3 in this year fall outside the baseline that has been
4 generated by the five-year track record.
5 In the spirit, sort of, again of getting to the
6 decision point quicker, we were looking at putting
7 forward a tiered process whereby it's very likely that
8 many exemptions would not need to travel through sort of
9 this historical net revenue approach, but rather, we
10 could do an assessment, as a first try, yield
11 information, next try would be revenues and then finally
12 would be profit. So, as an application would work its
13 way through the process, more and more data would be
14 needed until you get to tier three, which approximates
15 the existing procedures. Our economists have done an
16 evaluation of past 18s under the old paradigm, and in an
17 analytical sense, rolled out the tiered processes, and
18 the important bottom line finding was that there were not
19 likely to be any difference in the likelihood of EPA
20 finding in support of an emergency using the historic and
21 established net revenue method versus the tier method,
22 and the up-side, of course, is that we could get there

1 with a lot less paperwork and a lot less analytical time.
2 In terms of the economic analysis and the tiered
3 approach, that's a feature that the states, themselves,
4 are going to opt into when they see that it may be to
5 their advantage. There will be plenty more on that in
6 the Federal Register notice, and I think we'll be
7 available to sort of clarify that if there remain
8 questions.
9 This third area, a proposal for potential
10 resistance management exemptions, it's a policy notion
11 that we are wrestling with, and in the notice that's
12 coming out shortly, we are at least tentatively stepping
13 into the arena of more aggressively facilitating
14 resistance strategies, and at the moment, the Section 18
15 program takes sort of a passive posture in connection to
16 resistance management in that you can sort of backdoor
17 your way into an emergency if the registered pesticide
18 lacks efficacy to the degree that you are facing a
19 significant economic loss, whereas the proposal that
20 we'll be putting forward sort of moves the bar to a
21 different spot and puts the emergency exemption process
22 sort of in as a tool for resistance management.

1 There's an implementation section in the Federal
2 Register notice and that's going to describe what we're
3 open for business for in the 2003 Section 18 season. We
4 do want to take a narrow -- begin a narrow pilot project
5 for Section 18s in the 2003 season, and at this time,
6 we're limiting the universe to reduce risk pesticides.
7 The first process, the emergency exemptions eligible for
8 the streamline application process, that's -- we will, as
9 part of the Federal Register itself, have some companion
10 documents that are in the docket, and we'll I.D. the 18s
11 that we saw this year, in 2002, that we think are
12 candidates for this steamlined application process.
13 The second point, if you're a state lead and
14 you're in the audience, it's one. If you want to opt in
15 and try for the -- making a significant (inaudible)
16 finding based on the new tiered process, that's for you
17 to raise your hand and send your application forward in
18 that fashion.
19 Regarding resistance, again, it's presented here
20 as a parenthetical. Resistance management is not in the
21 pilot for 2003. For this upcoming season, the status quo
22 policies for resistance management connected to Section

1 18s will be in place. There's some pretty substantive
2 policy ideas that we'll be putting forward on resistance
3 management, and for that reason, we thought we need to
4 take comments on the program that we've got in the FRN.
5 Federal Registry notice is well drafted and in
6 the final stages. We're expecting the Assistant
7 Administrator to sign it shortly in the upcoming weeks,
8 and it will likely publish in October of 2002. It's
9 going to have a 60-day comment period on it, so please,
10 if you're interested in this topic, give us your
11 feedback. We will also launch this limited pilot for the
12 '03 Section 18 season and give us some sense of whether
13 we are on track with the ideas for the streamlined
14 application for repeats and a tiered process for the
15 significance of (inaudible). That's it.
16 MS. MULKEY: Thank you. Any feedback,
17 reactions?
18 UNIDENTIFIED MALE: I have a question.
19 MS. MULKEY: Okay.
20 UNIDENTIFIED MALE: Will that FR notice be in
21 the form of a proposed regulation?
22 MS. MULKEY: It's not set up as a rule. It's

1 set up as a -- I don't know that the styling is a PR
2 notice, but an approach. One of the issues that we may
3 ask for comment on with regard to, especially the
4 resistance management piece, is whether people believe
5 that it requires a rule or would be better done by rule.
6 I think the other two, I think, we feel pretty
7 comfortable are just guidance-like, if you will.
8 Julie?
9 MS. SPAGNOLI: Just a couple of questions for
10 clarification. I guess the pilot program, the streamline
11 application, that would be for repeat Section 18s, so
12 this is just for repeat Section 18s. As far as the
13 reduced risk, I'm not -- does the agency make a reduced
14 risk for a Section 18 so that it would be a repeat -- so
15 it would have to be a chemical for which there's an
16 existing Section 3 registration, that was considered
17 reduced risk? Because sometimes they actually will make
18 a -- that a use will be considered reduced risk even
19 though the chemical might not have previously. So, this
20 would be for chemicals that were considered reduced risk
21 for some Section 3 registration, and then this would be
22 for a repeat Section 18?

1 MR. ROSENBLATT: Right, that's right. It is
2 intentionally (inaudible) --
3 MS. SPAGNOLI: I just want to make sure I
4 understand the criteria.
5 MR. ROSENBLATT: -- criteria to get us some
6 traction and some degree of record with the 2003 season.
7 MS. SPAGNOLI: Okay. I just wanted to make sure
8 I understood that right. Okay, thanks.
9 MS. MULKEY: Erik?
10 ERIK: Yeah, unfortunately, I missed the last
11 PPDC meeting at which this was originally presented.
12 But, frankly, we're deeply troubled by this proposal for
13 several reasons. One, it seems like it's a solution
14 without a problem. In my 12 years of monitoring
15 pesticides in the State of Oregon, which is a major
16 Section 18 requester, I'm not aware of any crop loss
17 whatsoever due to the current Section 18 program.
18 And, also, we just heard the report from the
19 folks in the Section 18 -- turnaround time has been
20 reduced this fiscal year. So, the first part of my
21 question is, I'm not sure what the problem is we're
22 trying to fix.

1 Second, if a review of the current Section 18
2 program -- it's ripe with abuse. We've tracked a 14-
3 years consecutive Section 18 approval in the State of
4 Oregon with no evidence ever submitted showing movement
5 towards a full Section 3 registration and we're in the
6 tens of pesticides right now over the five-year bar
7 without similar documentation.
8 So, we're concerned about the streamlining
9 process simply expediting a Section 18 process when the
10 current program is, in our opinion, not adequately
11 policed.
12 And then, finally, I think the Environmental
13 Working Group did a good job in their report several
14 years ago of really asking the question, what is an
15 emergency. So, again, if we're streamlining this, in our
16 perspective, this is going to make a bad situation only
17 worse.
18 So, my question, specifically, what is the
19 problem we're trying to fix in terms of concrete crop
20 loss data as a result of a Section 18 program not meeting
21 current needs?
22 MR. ROSENBLATT: Those are some strong points

1 and I think we -- it is sort of a double-edged sword in
2 the sense that we have -- we are very proud of the
3 turnaround time, and it is low. I think at the same
4 time, we do acknowledge and I think we foresee that some
5 of these streamlinings will be non-trivial for the State
6 lead agencies and they'll facilitate a diversion, to a
7 small degree, of EPA resources. I think the other thing
8 that is motivating the agency here is we're responding
9 explicitly to some (inaudible) recommendations about the
10 Section 18 process.
11 MS. MULKEY: But, of course, your comments are
12 wholly appropriate for the comment period, among other
13 places. That's why we propose these kinds of things, to
14 be sure that all these points of view do get heard.
15 Well, thank you -- yes, Steve?
16 STEVE: One quick question. Relative to the
17 shortening of the time period that you get or that you --
18 the turnaround time, I guess it is, have you had a chance
19 to analyze the number of repeat Section 18s relative to
20 previous times? In other words, one would assume that if
21 it's the same Section 18 application as last year, you
22 don't require the same amount of work to review it, which

1 would shorten your overall time. Where the problem
2 occurs, particularly, from an emergency standpoint, is
3 the first year. After that, presumably, the commodity
4 knows their problem and can generate sufficient and
5 proper data in an effort to get it to you in a timely
6 manner. So, it's that first year.
7 So, (inaudible) just take the first year data
8 and say what's your turnaround time on that and have you
9 been able to decrease that and does this streamlining
10 help that.
11 MR. ROSENBLATT: Right. That is an astute way
12 of looking at it. There's often -- with first time
13 Section 18s, since FQPA, we need to do the tolerance to
14 cover that. There is, you know, an awkward weeks
15 potentially or hopefully there's a convergence of use in
16 the field with no tolerance established just yet.
17 STEVE: Trust me, I know that all too well. We
18 were the first.
19 MR. ROSENBLATT: In terms of volume, the number
20 of 18s that we've gotten over the past years has been
21 about 550, plus or minus, and in general, 70 percent or
22 so are repeat uses.

1 MS. MULKEY: We've done some analysis of this
2 issue you've described and I think we are achieving
3 significantly shorter time between registration and
4 tolerance setting, and I suspect we're seeing fewer
5 first-time -- well, maybe not, maybe not. Lori?
6 DR. BERGER: There were seven other reforms that
7 were proposed, I believe, and several of those actually
8 were -- seemed to make the process more prohibitive in
9 how you could request a Section 18 or how you could use
10 it, and I'm just curious to know what happened to those.
11 MR. ROSENBLATT: The short answer is that we've
12 been in ongoing dialogue with APCO (phonetic). This
13 project, the reforms, actually came up as an idea and
14 something that people were working on prior to FQPA. In
15 March of 2002, APCO actually shortened their list of
16 priority policy areas, and these are the three that are
17 there.
18 DR. BERGER: There were several members amongst
19 this committee that actually expressed interest in some
20 of those other reforms at the last meeting. So, will
21 that be maybe looked at again or --
22 MS. MULKEY: Anne, do you want to --

1 MS. LINDSAY: Just real briefly. I think that
2 when the Federal Register notice comes out, there will be
3 a brief sort of report about all seven of the original
4 recommendations so you can see what happened. One that
5 comes to mind, there was a request, could state lead
6 agencies do an effective regional 18, and I think that
7 that's an approach the Registration Division has been
8 able to incorporate into its existing process. So, it,
9 in effect, got done several years ago.
10 I've certainly been to State lead agency
11 meetings where states have talked about working together
12 to develop the basis for a Section 18 request. But all
13 of them, there will be some, at least, brief discussion
14 on sort of what happened to them.
15 MS. MULKEY: Thank you. Well, we --
16 UNIDENTIFIED FEMALE: There's one more here,
17 Marcia.
18 MS. MULKEY: Oh, I'm sorry.
19 DR. HOCK: Just a real quick one.
20 MS. MULKEY: Win.
21 DR. HOCK: What happened to the multi-year
22 possibility of a Section 18? I think that was one of the

1 ones that was discussed. Wasn't there one that we had a
2 multi-year -- am I wrong about that?
3 MS. MULKEY: That's what this first one is.
4 Repeat is --
5 DR. HOCK: Repeat is -- that will be --
6 MS. MULKEY: Multi-year is, I guess, in the eye
7 of the beholder. But this first one is -- that's the
8 evolution of the multi-year idea was that the applying
9 agency could certify the continuation of the -- as you
10 heard it described.
11 DR. HOCK: Okay, I think I understand. In other
12 words, what's happening is you'll still approve it every
13 year. You wouldn't give, for instance, a -- I'm just
14 going to use an example. You wouldn't give a Section 18
15 for 2003 through 2005 carte blanche?
16 MS. MULKEY: Right. That's not what this
17 (inaudible). And I think there are issues relating to
18 the regulations, among other things on that issue.
19 DR. HOCK: Okay, thank you.
20 MS. MULKEY: Well, we do have two public
21 commenters. I did want to take a moment before we call
22 on them to do two things. One is to thank you all and

1 invite you to provide any feedback that you think would
2 make a difference between today and tomorrow about how
3 the meeting has gone, is going, and our approach to the
4 meeting. But in particular to think about an opportunity
5 to provide that feedback tomorrow, as you spend the
6 evening.
7 In light of the fact that we do appear to have
8 most of the folks who participated in the panel -- the
9 big panel today have already left, except for those who
10 are PPDC members, and I assume will be present again
11 tomorrow, we will take an opportunity again tomorrow to
12 talk a little bit about our feedback to that group and
13 some next steps so that you don't feel like we're letting
14 that fall through the cracks.
15 We are, to some I think pretty modest extent,
16 the victim of our collective ambition about the scope of
17 what we would cover, bearing in mind that much of what's
18 included here came from you. And we have deferred, I
19 think it's two topics, from today until tomorrow. So, it
20 will require us to exercise continued self-discipline
21 tomorrow.
22 Let me just take an opportunity, before we hear

1 the public comment, to see if any of you want to react to
2 issues relating to trying to enhance the quality of the
3 remainder of this meeting. I don't mean today, I mean
4 today and tomorrow.
5 Yes, Win?
6 DR. HOCK: Is there any chance you could give
7 about a 30-second update tomorrow on the DRIFT PR notice
8 and what the status of the DRIFT -- I think it was
9 probably a Federal Register notice, actually a Federal
10 Register notice, where it stands and when it might be
11 reissued?
12 MS. MULKEY: I think we could probably say
13 something on That tomorrow.
14 UNIDENTIFIED FEMALE: Um-hum.
15 DR. HOCK: I mean, just a quick overview.
16 UNIDENTIFIED FEMALE: Uh-huh.
17 MS. MULKEY: All right. We have two commenters
18 who, at least I can guess from the organization of one of
19 them, have appeared particularly because of interest in
20 the topics that we have tackled today. We look forward
21 to hearing from both of them. Roger Curran from the
22 Institute for In Vitro Sciences.

1 MR. CURRAN: Thank you. I'd like to compliment
2 the OPP in beginning to look at a subject that's very
3 dear to my heart and close to my heart that we've worked
4 at in our organization for quite a while, and I'd also
5 like to compliment the audience for making a number of
6 cogent comments about in vitro and the alternative
7 testing that is going on.
8 I'll try and make the presentation short once it
9 brings it up here.
10 **(Brief pause.)**
11 MS. MULKEY: Yeah, why don't we do that? Why
12 don't we ask Fred Smith --
13 MR. CURRAN: (Inaudible) start.
14 MS. MULKEY: It's really part of a joint
15 presentation, in effect. Technology, it's wonderful and
16 occasionally frustrating.
17 MR. CURRAN: Okay. I represent the Institute
18 for In Vitro Sciences. We were founded in 1997 although
19 it didn't make it on the (inaudible) chart. We're a not-
20 for-profit 501C(3) organization dedicated to the
21 advancement of in vitro methods for safety evaluation and
22 determination of biological activity.

1 We have two sections to what we do in our
2 company, one is an actual hands-no conduct of in vitro
3 tests for companies throughout the United States, Europe,
4 Japan, throughout the world. That means a lot of what we
5 talk about and what we do is a science-based activity.
6 Essentially, we test in our laboratories well over 1,000
7 chemicals, products per year in in vitro tests. So, we
8 have a reasonable knowledge of how these tests work, how
9 they can be applied, how you would use them in day-to-day
10 working. That's the hands-on technical side.
11 We also have -- conduct an educational program
12 and an interaction program with organizations throughout
13 the world, including regulatory agencies here in the
14 United States, NIEHS, EPA, FDA and so forth. And I'm on
15 slide two right now.
16 The last (inaudible). We provide general
17 information and actual hands-on instruction to people, to
18 groups who want to learn about in vitro methods, and this
19 includes industry, government, academia, animal welfare.
20 We've had hands-on presentations -- we've had one major
21 one every year and actual EPA representatives have taken
22 advantage of our programs, come to our laboratories to

1 see how some of the in vitro methods work, and how the
2 data can be applied to some of their questions.
3 We also work closely with the animal welfare
4 groups, and what we try and do is promote situations
5 where we can have dialogue between animal welfare groups,
6 industry and government, and that's occurred several
7 times within our facilities where sometimes these
8 disparate groups have been able to sit down in a neutral
9 territory and be able to discuss issues that are very
10 substantive and very important to them. Next slide.
11 We commonly work with about 100 clients, more or
12 less, per year, and the reason I put that up is to say
13 that I'm speaking not just for myself, but for a lot of
14 companies within the United States. When I do that, I'm
15 saying that industry routinely is using in vitro tests.
16 This isn't something that's a bit obscure that Procter
17 and Gamble and Syngenta were talking about today. It's a
18 process that hundreds of companies use around the world.
19 These companies range -- and to address a question that
20 came up earlier, these companies range from a P&G, a
21 L'Oreal, multi-billion dollar companies, to single person
22 cosmetic companies who are churning something up in their

1 backyard or smaller companies of 10 and 20 people.
2 So, we're able to utilize non-proprietary
3 information that we gain from some of the larger
4 companies to help out the smaller companies in the
5 process. They use these methods for a lot of things.
6 It's not just screening methods for early safety, but
7 it's all the way from early product development to final
8 safety decisions.
9 Why do they do it? Why do they use these
10 methods? As Kathy said earlier, time and money savings
11 is one thing. The tests are often much more sensitive.
12 They're able to determine biological activity at much
13 lower levels than some of the animal tests. Ethical
14 considerations and mechanistic information. So, it's not
15 entirely let's replace animals. That is a very important
16 component of it. It's also, let's get better scientific
17 information. Luckily, the tests are able to do both.
18 How can we use these tests? Well, also spoken
19 of by Procter and Gamble, private internal evaluations of
20 products, constructino and uses of databases,
21 benchmarking, there are a number of ways. You don't use
22 any -- you shouldn't use any toxicological test by itself

1 and you don't use in vitro tests by itself. It's a
2 combination of information. Next slide, please.
3 One of the things we do is to develop tests not
4 just to replace animals again, but to facilitate getting
5 information. One example is an ocular irritation. We
6 use, very often, a test that Rosemarie talked about for a
7 minute, called the bovine cornea test where we use
8 discarded cow corneas. But we found out that although
9 this test didn't work perfectly in some of the earlier
10 validations of it, there were some reasons why, and so
11 we've, along with others, modified the protocol so that
12 it can give more mechanistic information.
13 One of the things is to be able to actually look
14 at histopathology, something that animal toxicologists
15 always like. Next slide, please.
16 And in this situation, I'm just quickly showing
17 that you can now do cross sections and look at a mild
18 material. You can see that cells are damaged by a
19 slightly more aggressive material and that a highly
20 aggressive material completely tears up the epithelial
21 level of this cornea. So, not only do you have some
22 biochemical measures, but you can also see some of the

1 damage. And this gives us a little more comfortable
2 feeling with how to apply some of these tests. Next
3 slide, please.
4 And one of the reasons I put this up is because
5 a very important thing is ingredient interaction, one of
6 the important questions that I think a lot of
7 manufacturers ask themselves, and that's applications
8 certainly to pesticides. I used the -- we used the same
9 example here of the bovine cornea in cross section and
10 what I'm showing is a series of studies conducted by John
11 Harvell in our label and S.C. Johnson as one of our
12 clients, and there's nothing proprietary here. This is
13 already published information.
14 But they were able to show, to investigate two
15 ingredients of a formulation, a base material and then
16 sodium hydrochloride -- yes, we do know a lot about
17 sodium hydrochloride. We see some just superficial
18 damage of epithelium. We look at the base plus a sodium
19 hydroxide concentration and, again, see just a
20 superficial denudation of the upper layer of the cornea.
21 But the combination of the ingredients is much more than
22 either one can be seen together.

1 Here you combine this into the final formulation
2 and you see some very deep tissue injury, you see the
3 epithelium completely separated from the stroma down
4 here, and you begin to see dead cells.
5 **(END OF SIDE B, TAPE 4)**
6 MR. CURRAN: -- important to both regulators and
7 companies, mechanistic information and interactions can
8 be seen with in vitro tests. Next slide.
9 But from our point of view, do we think there
10 are things that could be done to help facilitate the
11 speeding up of acceptance of in vitro methods? Within
12 the regulatory community, it would be nice to see more
13 proactive situations so that regulators and management
14 can build familiarity on the scientific basis of the
15 assays and the performance of the products and
16 ingredients that are of special interest, those things,
17 how the assays work with chemicals and formulation of
18 your interest.
19 The validation process can be accelerated by
20 adding a key that we're often missing, and that's good,
21 reliable reference data. And if agencies, FDA, EPA can
22 provide historical animal data in situations where we're

1 going to have to use animal data, this will enable us to
2 have a little better idea of setting the target, and that
3 includes both knowing how the animal test works with
4 individual materials, but what the reproducibility of the
5 animal test is, which has been one of the criticisms,
6 certainly, in some of the acute areas.
7 If the agencies could express a positive
8 attitude towards the use of alternative methods, by
9 perhaps providing a means to capture and review parallel
10 data submissions, this is part of a learning process
11 where in vitro information comes in in parallel with
12 animal information (inaudible). And at the same time, to
13 begin the dialogue with test developers regarding what
14 specific toxicological needs of the agency exist.
15 Sort of a combination of these two, it would be
16 nice if there was some type of preregistration,
17 presubmission situation or a company who had suggested
18 the types of in vitro testing that they might want to
19 use, and then determine if it's even feasible that this
20 could be reviewed by the agencies. I have one more
21 slide.
22 That's what I think some of the agencies can do.

1 What can we do? Our organization -- and we have a good
2 background in in vitro testing, we can help -- we agree
3 to commit resources to interact directly with the U.S.
4 EPA in any way (inaudible) with U.S. EPA and its clients
5 or directly with ICCVAM as we do right now, so that
6 technical details of these in vitro assays can be
7 communicated and understood in the context of the EPA's
8 regulatory needs.
9 MS. MULKEY: Thank you very much. Fred Smith
10 from Cyrad (phonetic), Inc. Is Fred Smith still here?
11 (No response.)
12 MS. MULKEY: Well, how about that? Thanks to
13 Fred's bailing out, we are right on time.
14 **(Laughter.)**
15 MS. MULKEY: Well, thank you all. I know it's
16 been a long day. It's been a very dense -- in the good
17 sense of that term -- rich, information dense.
18 UNIDENTIFIED MALE: Robust.
19 MS. MULKEY: Yeah, robust -- I've always loved
20 that adjective, that sort of personalizes it -- day. So,
21 I think tomorrow will be, too. So, we appreciate the
22 work that went into it and we look forward to tomorrow.

1 Bye.

2 **(The meeting was adjourned.)**

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22 **Day Two - September 18, 2002**

1 MS. MULKEY: Greetings. It's nice to see so
2 many of you so close to your seats. It's another
3 beautiful day in the neighborhood. I'm personally very
4 fond of this part of the D.C. Metro area, so I hope those
5 of you who have had a chance to hang out in Alexandria
6 have been enjoying it.
7 Well, as I said, thank you all for returning.
8 Thank you, Adam and Burleson, for being with us again
9 today. I think we all collectively appreciate that very
10 much. I don't want to distract any more from our
11 ambitious agenda. I promise you that you will find a lot
12 of today interesting.
13 I want to ask all of you to bear with us, to be
14 with us in the early afternoon. This is the phase where
15 we begin to look forward to issues that we want to tackle
16 together, and while I understand the temptation to allow
17 lunch to be the natural breaking point, it's really
18 important to us to get your feedback and reaction as we
19 talk through the next steps. So, a special plea to see
20 you after lunch.
21 Okay, Jim is again going to march us through
22 another raft of updates in a minute, including -- I

1 think it's two issues left from yesterday -- three --
2 three issues left from -- two from last and one added at
3 request.
4 MR. JONES: Well, we will finish with the last
5 three and start with the first one on the printed agenda,
6 which is the NAFTA TWG five-year plan.
7 Okay, one of the documents that you should have
8 received, I think ahead of time, was the draft NAFTA
9 Technical Working Group five-year plan, and I just want
10 to walk people through a few of the highlights.
11 Probably the most important take-home message is
12 it's a draft document at this point. It's been developed
13 by all three countries, Mexico, Canada, U.S. We actually
14 have Janice Hopkins from Canada with us for the whole
15 meeting, so it represents a collective perspective by the
16 governments of the three countries. It was built both on
17 the previous five-year plan, which is drawing to a close
18 this year, as well as significant input from the last
19 full NAFTA Technical Working Group meeting, which was
20 held in Mexico about a year ago or nine months ago now.
21 It's a very high-level document. It does not go
22 into all of the detail of everything that is either

1 ongoing right now or might start in the next five years.
2 It's that way by design. It's meant to be a kind of
3 high-level guidance, but to allow flexibility over time
4 for either the governments themselves or for our many
5 stakeholders to come forward and propose some
6 redirections, new activities, time to finish off, wrap
7 something up. So, it's built with a fair amount of
8 flexibility in it.
9 It maintains the two basic goals of the original
10 plan, which is to make work sharing the routine way of
11 business between the governments of the three countries,
12 and I guess work sharing is a term we may have coined in
13 the NAFTA context, but it means just literally what it
14 sounds like, which is to share the work of regulation in
15 all the many ways that it may be appropriate to do so.
16 The second is to develop and maintain and
17 broaden a North American market for pesticides that also
18 maintains and, where possible, improves the high levels
19 of protection of public health and the environment and in
20 a way that supports the principles of sustainable
21 development. So, I think we're trying to have our cake
22 and eat it, too, with the goals, but those are the same

1 basic goals that we have had for the first five years.
2 They seem appropriate for the next five.
3 One of the things I'd mention, though, is we
4 spent -- the Government spent some time doing a little
5 visionary brainstorming, and so it actually articulates a
6 vision which I don't think we did in our previous plan,
7 and the vision is that the North American region could
8 come to serve as a model for excellence for the whole
9 world in the realm of safe food, safe pesticides,
10 training and protection of the pesticide labor force, and
11 that to the extent that we're able to do it, we really
12 want to integrate all of our activities, both
13 governmental and non-governmental, into a life cycle
14 approach to pesticide management that would actually help
15 us achieve this high standard of excellence.
16 So, we've deliberately set ourselves a vision
17 that we think is very high, but we also feel like at the
18 governmental level that it's attainable and that it's the
19 sort of vision that all of us are likely to be able to
20 subscribe to, though in any individual case and with
21 regard to any individual activity, we may have a
22 difference of perspective as to its relative priority and

1 importance in achieving that standard. So, I want you to
2 keep that vision in mind.
3 It tries to hit in all the sort of areas that
4 we've heard so far that were important to people. We're
5 talking about broadening Mexican participation within the
6 NAFTA Technical Working Group for the first five years.
7 To a very large extent, a lot of the actual work was done
8 between the U.S. and Canada, with Mexico in what I would
9 call more of an observer capacity, and so in this next
10 five years, we're trying to develop what I would call a
11 full trilateral partnership.
12 We're actually in the process of embarking on a
13 trilateral review of a new active ingredient with Mexico.
14 It's been sort of specially designed and crafted so that
15 it will take advantage of Mexican strengths, not over-tax
16 them in areas where they don't have the same capacity
17 that the U.S. and Canada does. A registrant was actually
18 very critical in helping select a viable candidate for
19 this trilateral review. So, we actually have very high
20 hopes for that.
21 We'll be working on minor use issues in the
22 North American venue. It's already been started, IR-4

1 showing a lot of leadership in that arena. Canada has
2 some new developments that I think will enhance their
3 capabilities pretty significantly, so I think minor use
4 will be a clear focus of the NAFTA TWG.
5 As always, there's the harmonization of MRLs,
6 and here we're counting on growers and others to actually
7 help us identify where real trade irritants and problems
8 are occurring because of differences in MRLs, and we're
9 also going to be doing our own analysis of the situation.
10 So, that is underway, and I think later on, from a
11 government perspective, we'll be able to present a better
12 picture of progress in that arena.
13 The last thing I might mention is the NAFTA
14 label. We've talked about that for a number of years in
15 various different venues. The good news I have to report
16 is there actually is one approved NAFTA label. It's
17 approved only for use in Canada. That was the
18 registrant's choice, so that for the U.S. they have stuck
19 with a U.S. ePA only label, but in Canada, they've got a
20 NAFTA label. So, U.S. growers can go up to Canada,
21 purchase the product there if they so choose and bring it
22 back into the U.S., and they'll be fully in compliance

1 with U.S. requirements. The label doesn't need to
2 change.
3 We also have another proposed NAFTA label
4 pending with one of the new active ingredients that is
5 part of Registration Division's workload for the coming
6 year, 2003. So, I'm hopeful by the time the Registration
7 Division makes a decision on this new active ingredient,
8 it will actually become the second and in this case I
9 hope fully utilized NAFTA label between the U.S. and
10 Canada.
11 In addition, Mexico, who originally felt a
12 little hesitant about the concept of a NAFTA label, has
13 decided that the time is right for them to begin to
14 entertain that idea. We've been going through an
15 analysis with Mexico of differences between the labels.
16 We don't think that they're so substantial that it would
17 prevent actually having a NAFTA label with Mexico.
18 And I think the other piece of good news is we
19 have a new industry group, the Non-agricultural --
20 Warren, help me -- Working Group, thank you, NAWG is its
21 acronym, and they're at least exploring the concept of
22 using NAFTA labels for different kinds of

1 non-agricultural products and I think may, during the
2 course of the year, have some interesting proposals to
3 present to the NAFTA TWG.
4 So, I'm going to stop talking about the
5 specifics of the plan, but what I'd like to encourage all
6 of you to do is to take a look at it in a little more
7 depth, think about what you want this Technical Working
8 Group to be focusing on. Have we hit the right mix of
9 things? Are there some things that are really missing,
10 some things that from your perspective maybe need to get
11 a heightened priority or a lessened priority, because
12 we're not going to be able to do everything that
13 everybody wants. Give us comments. We're asking
14 comments to come to us by the 15th of October.
15 If you're a U.S. citizen, you can send them to
16 U.S. ePA, to Verace Altero and Tyler Wayne (phonetic) who
17 are our NAFTA secretariat. If you're Canadian, send them
18 to PMRA, and if you're Mexican, send them to Sequa
19 Plafest (phonetic), to Salude (phonetic). We need them
20 by around the 15th of October so that the document can be
21 revised, translated in our three respective official
22 languages and to be ready for the next full NAFTA

1 Technical Working Group meeting, which will be the 5th of
2 December in New Orleans.
3 The U.S. is the host this year. We have chosen
4 New Orleans not only because it's a fun place to be, but
5 because we actually thought it did a good job of
6 representing our North American cultural heritage in a
7 way that no other U.S. city probably did quite so well.
8 So, that's it for NAFTA.
9 SPEAKER: And I may have missed the nuances
10 here. Are you saying that the NAFTA label would actually
11 be accepted by the Sequa Plafest now in Mexico?
12 MR. JONES: What the Mexican Government has said
13 is that they are willing to entertain the idea of a NAFTA
14 label. I think that there's a lot of specifics that need
15 to be worked through for any individual case, but they
16 now want to pursue that.
17 SPEAKER: So, that one particular label you're
18 talking about, they would not recognize it right now,
19 then.
20 MR. JONES: No, that one label that's been
21 approved was done between the U.S. and Canada, so it
22 doesn't reflect work that -- and I, in fact, do not even

1 know if that particular product is approved for use in
2 Mexico or would have a use in Mexico.
3 SPEAKER: Okay. Well, I think this is great
4 stuff. I'm very encouraged by the whole concept, and
5 congratulations. A couple questions.
6 One, has anyone entertained the idea of bringing
7 in the independent republic of California into this
8 harmonization process? Too bad Toby Jones isn't here to
9 help represent -- and actually, that really is a
10 problem. I know you've been working a lot on
11 harmonization with California, but I truly hope that
12 California is involved at least peripherally in these
13 discussions so that they understand the issue.
14 What's the time frame? I realize there are
15 probably multiple time frames depending on the issue. Is
16 it going to be within anyone's lifetime here at the table
17 that some of these things can be accomplished, because
18 this is a huge undertaking it seems to me.
19 MR. JONES: Well, from my perspective, there are
20 a lot of things that have already been accomplished, and
21 when this five-year initiative is finalized, we will
22 attach to it a list of the specific things that the three

1 countries believe we've accomplished. There are a lot of
2 actual joint reviews that have been done between the U.S.
3 and Canada. They're complete. They're done with --
4 Debbie Edwards yesterday actually sort of made reference
5 to a time frame.
6 There are MRLs that were identified as causing
7 real trade problems, and they have been harmonized. We
8 have not had a lot actually identified as causing active
9 trade problems, but where we have had those identified,
10 we feel like we've largely been able to move forward and
11 adjust things so that it works.
12 SPEAKER: Right. Well, I would suggest that the
13 MRLs are clearly the most important in this whole
14 process, trying to ease trade restrictions. This is by
15 far the most important. Labels are great, to have
16 similar labels, but you're still going to -- that's less
17 important to trade and simple movement across borders,
18 so --
19 MR. JONES: I think the joint review and the
20 work sharing that's gone on, particularly between the
21 U.S. and Canada, has done a lot to what I would call sort
22 of equalize access for growers to products so that you're

1 having -- getting access to the same product at
2 basically the same time.
3 SPEAKER: Right.
4 MR. JONES: And so whether or not it's got a
5 NAFTA label, the product becomes available, and we've
6 chosen to focus on reduced risk products, alternatives to
7 OPs, methyl bromide in that program, so not only are you
8 giving equal access, but it's got kind of a safer
9 component to it.
10 SPEAKER: Yeah, that's great, great.
11 SPEAKER: Steve, there's quite an active
12 stakeholder involvement in those processes, including
13 grower involvement, so you may want to --
14 STEVE: And we ought to.
15 SPEAKER: Yeah.
16 SPEAKER: Just another meeting to go to.
17 Erik?
18 MR. OLSON: Thanks for your presentation. I
19 would caution the agency not to look past issues of
20 enforcement. Our Mexican counterparts have filed a
21 complaint under NAFTA alleging failure of the state and
22 Federal Government, specifically in Washington, not

1 enforcing health and safety regulations, and that
2 complaint has been upheld after its initial hearing. So,
3 I think the issue of enforcement is critical here in the
4 United States and also in our -- in the counterpart
5 countries of NAFTA.
6 SPEAKER: Okay, good.
7 SPEAKER: A couple questions. One is, will the
8 NAFTA labels be trilingual, will they be bilingual? How
9 will you handle the language issue? I know Canadian
10 labels currently are both in -- I believe in English and
11 French, and I'm just wondering how that's going to be
12 handled. If you get all three languages on there, it's
13 going to be a rather voluminous document.
14 The other issue or the other question I have is
15 how are you going to handle -- and I'll call it rogue
16 states or rogue provinces -- and Steve, I'm not talking
17 about California now, don't -- but just an example, I
18 read recently that Quebec is going to ban all
19 non-agricultural pesticides by the year 2005. That means
20 all, if you want to call it, cosmetic materials. How do
21 you integrate that kind of situation into a "NAFTA
22 label," which is supposed to be kind of broad and

1 covering, you know, all three countries.
2 MS. LINDSAY: I don't know if you're suggesting
3 we have a special program for California, Quebec and, I
4 don't know, for Mexico, which state it would be, and
5 Janice, I don't know if you have any perspectives you
6 want to share on the particular situation.
7 When -- I think each -- three countries always
8 has to pay attention to what its individual states or
9 provinces are doing, and that will remain sort of a
10 national responsibility and prerogative.
11 If we've got insights to sort of offer each
12 other as to how to handle those issues, we do that, and
13 we will continue to do that. I actually think that to
14 the extent that people see that their federal governments
15 are working together and that they're working together
16 with this sort of sustainable development reduced risk
17 focus, it actually can help deal with the more particular
18 issues that might surface in a state or a province,
19 because they have greater confidence in what their
20 federal governments are doing.
21 You also asked the language question about the
22 labels, and yeah, we have a requirement that English is

1 the language, although we can also have Spanish labels
2 already in the U.S. So, for a NAFTA label, you will be
3 looking at either bilingual or trilingual, depending on
4 the market range of the product. I think we think it
5 obviously adds a layer of complexity, but it's not
6 something that's insoluble.
7 SPEAKER: Folks, we are 15 minutes into our
8 allotted 45 minutes on this one topic with three more
9 cards up. If there's this much interest in the issue,
10 you all may want to think about this in your feedback to
11 us this afternoon, but we'll roll through these last
12 cards and move on.
13 Larry?
14 MR. ELWORTH: I'll just raise the issues,
15 because one of them actually could take a fair amount of
16 time.
17 Number one, can you tell us a little bit more
18 about this chemical for joint review, what it is, what
19 it's used -- what crops it's used on?
20 MS. LINDSAY: The trilateral one?
21 MR. ELWORTH: Yeah, yeah.
22 MS. LINDSAY: Actually, literally, I can't. My

1 brain cells have aged, Larry, to the point that I can't
2 remember its name.
3 MR. ELWORTH: Okay. Do you remember the --
4 well --
5 SPEAKER: We can get that to you.
6 MR. ELWORTH: Yeah, that --
7 MS. LINDSAY: It's possible to tell you more
8 about it.
9 MR. ELWORTH: Right, right.
10 Second, and this may be to Jim's point, that it
11 -- are you dealing with inerts in this trilateral issue
12 as well?
13 MS. LINDSAY: There -- yes, and there is
14 discussion about just exactly what form and shape that
15 would be. There's been a lot of I think informal work
16 that actually Kerry Leifer has done with PMRA over the
17 years. They have got an inerts or formulants policy very
18 similar to ours, so...
19 MR. ELWORTH: Okay. I think maybe Jim's right,
20 this is something we probably want to look at a little
21 bit more.
22 The last thing is I hope that's a canola

1 registration that you've got that NAFTA label for.
2 MS. LINDSAY: I don't think that it was,
3 actually, unfortunately.
4 SPEAKER: Okay, the draft five-year plan was
5 appended or supposed to be appended to Margie's e-mail
6 Friday, and I'm just looking at my printout, and I
7 realize I don't have it here. I don't know whether my
8 printer ran out of paper or maybe all of us didn't get
9 that, but I would just make sure that we all do have a
10 copy of it.
11 MS. LINDSAY: It's also on our website, on the
12 NAFTA homepage, so...
13 SPEAKER: Jose?
14 DR. AMADOR: Are you familiar with the work the
15 Texas Department of Agriculture is doing with Mexico on
16 pesticides and Mr. Rojas?
17 MS. LINDSAY: Um-hum, yeah, we actually work
18 with TDA on some of the activities, especially activities
19 relating to enforcement and inspector training, also
20 safety training for applicators and farm workers. So, a
21 number of U.S. states, and Texas is probably the premier
22 one, are very active participants.

1 DR. AMADOR: Good, I'm glad that you know,
2 because they are doing a lot of work, particularly in the
3 pesticide safety area.
4 MS. LINDSAY: Yes.
5 DR. AMADOR: They have done a lot of work there.
6 SPEAKER: Okay, next -- Denise, you have the
7 next two.
8 SPEAKER: In a minute.
9 MS. KEEHNER: I'll try to stay with my script so
10 that we get done in a minute.
11 I'm sure that most of you are familiar with the
12 fact that the Montreal Protocol provides for the
13 phase-out of methyl bromide by 2005. My guess is that
14 you're also familiar with the provision of the Protocol
15 that allows for the granting of exceptions through a
16 critical use exemption process to that phase-out
17 requirement of 2005.
18 What I'd like to do is quickly update people
19 here today on where we are in terms of designing and
20 implementing the critical use exemption program for
21 methyl bromide, because the Office of Pesticide Programs
22 is working very closely with the Office of Air and also

1 with USDA to design a critical use exemption program for
2 those uses that are believed to be critical needs in
3 terms of continuing to have methyl bromide available
4 beyond 2005.
5 We have been working within the Biological and
6 Economic Analysis Division with the Department of
7 Agriculture and the Office of Air to set up this process,
8 and USDA has been very forthcoming in identifying
9 technical experts in the field to work with us in the
10 technical review of the incoming applications. You have
11 in front of you a summary table that lists out all 54
12 applications that we have received as of 9/11 or so, I
13 think actually it might be up to the 13th of September.
14 Our first order of business in looking at these
15 applications that have come in is to see if there are any
16 data gaps that need to be filled. Our objective early in
17 the process is to see what we can do jointly working with
18 USDA to fill in any gaps that might exist in terms of
19 information or data on the biological or economic
20 feasibility of alternative compounds or practices for
21 methyl bromide for each of these uses, because that
22 technical review is a critical part of the

1 decision-making process ultimately on what the United
2 States is going to send forward to the international
3 petite panel, which is ultimately where these critical
4 use exemptions have to be reviewed and accepted.
5 We've seen quite an amount of variability in the
6 depth to which individual applicants have addressed the
7 issues of biological or economic feasibility of
8 alternatives. So, there's some applications that have
9 come in that are quite thorough. There are others that
10 are going to require a little bit more effort on the part
11 of both USDA and BEAD to fill in those gaps.
12 We expect to be fully into the application
13 review process after having filled in and taken whatever
14 reasonable steps we can take to fill in gaps by the mid
15 to late November time frame, and it will be at that point
16 that our review panels that will be made up of BEAD
17 people as well as USDA technical experts will forward the
18 results of the evaluation to the Office of Air.
19 Subsequent to the forwarding of the technical
20 review results, there will be the convening -- there
21 will be the formulation of an EPA position and then a
22 formulation of a U.S. government position that will be

1 brokered by the State Department with full participation
2 of Department of Agriculture and also EPA in basically
3 deciding what is going to go forward into the
4 international arena.
5 So far, in terms of establishing the process,
6 it's been a very good and collaborative relationship with
7 the Office of Air, and also we've been working very well
8 with the Department of Agriculture, and so we're very
9 optimistic that we'll be able to meet basically the next
10 four-month deadline of getting ready for the submission
11 of the packages to the international panel.
12 I'll stop there on methyl bromide. That's sort
13 of the one-minute update on where we are, if anybody has
14 any questions.
15 SPEAKER: I have a quick question. Is there any
16 internal agency effort to identify gaps in applications,
17 more or less, is the agency trying to determine if
18 there's a commodity, for instance, that probably needs an
19 exemption but for which no exemption was applied for?
20 MS. KEEHNER: One of the positive aspects of how
21 we're approaching this is that there is a second bite at
22 the apple. So, we do know that there are some commodity

1 groups that -- like particularly during the last week or
2 so, you know, September 2nd to around the 9th, we're
3 saying, gee, we just found out that we need to do this.
4 There is a second bite at the apple which will start in
5 mid-2003.
6 So, it's not too late to apply, and that's kind
7 of the direction that we've been giving people, is that
8 with what we have right now, we feel like we've got a
9 pretty full plate to get through what we have. In
10 addition to working through these applications, we remain
11 available to work with other commodity groups and other
12 user groups who have -- didn't make this first round of
13 applications, to help them prepare for the next round,
14 which will be, as I say, around -- in mid-2003.
15 SPEAKER: Gabrielle?
16 GABRIELLE: Denise, I just want to make sure I
17 understood this correctly. What you're saying is that
18 BEAD and USDA take a first cut and review and summarize
19 their assessment of the applications, and then that gets
20 handed over to the Office of Air for them to review?
21 MS. KEEHNER: Correct. We're doing the
22 technical review. The Office of Air doesn't have a lot

1 of experience in agriculture, and the Office of Pesticide
2 Programs, particularly BEAD, as well as USDA obviously
3 has a lot of technical expertise in biology as well as
4 agricultural economics, and so the concept is that we try
5 to conduct an objective technical scientific review of
6 what's come in, and then those -- the results of that
7 evaluation are then forwarded to the Office of Air and
8 Radiation, and clearly there will be a continuing need
9 for dialogue between Air and OPP so that we're sure that
10 there's a good understanding of what it is that we're
11 sending over to them in terms of the technical review.
12 GABRIELLE: Thank you.
13 SPEAKER: All right.
14 MS. KEEHNER: Okay, my next topic is to just
15 quickly update and alert you to the fact that there is a
16 scientific advisory panel meeting coming up October 1st
17 involving the Biological and Economic Analysis Division.
18 We are going to be presenting to the scientific advisory
19 panel a proposed new statistical methodology for
20 projecting percent crop treated for tolerance
21 re-assessment purposes for use in the dietary risk
22 assessment.

1 We have used a process in the past that has
2 taken sort of a weighting of historic percent crop
3 treated for particular commodity chemical combinations,
4 where we would weight more recent statistics on what the
5 percent crop treated was more heavily than historic use
6 rates, and what we have found in looking at the various
7 statistical approaches that one might use to doing trend
8 analysis is that there are what look to be some better
9 statistical approaches that provide a more accurate
10 representation of what those future percent crop treated
11 might be for particular commodities and chemical
12 combinations.
13 So, this is sort of a program -- it started as
14 sort of a programmatic review kind of thing, where we
15 said let's see how accurate we have been in the past in
16 projecting percent crop treated, and then what are the
17 other statistical methods that might be able to be used
18 and how accurate are they in projecting percent crop
19 treated, and does it look like there's a better method
20 than the method that -- the statistical approach that
21 we've used historically?
22 It turns out that a method called exponential

1 smoothing seems to give us a better and more accurate
2 projections of percent crop treated, particularly in
3 cases where there has either been a downward or upward
4 trend in use or if things have been bumping around a
5 little bit.
6 What we plan to present to the SAP is the
7 statistical methodology. Of course, there are always
8 follow-up issues of, you know, how do you introduce the
9 new methodology into the process and what kind of
10 approaches you are going to take to -- from a policy
11 standpoint to introduce that, but this particular
12 scientific advisory panel meeting is really on the
13 statistical issue of given the kind of data that we have
14 available and the length of time that we have data
15 available for particular commodities and crops, does this
16 process, the statistical technique of exponential
17 smoothing, is that the appropriate statistical technique?
18 Is that a better statistical technique to use?
19 We will talk a little bit about what we've done
20 in the past. We'll talk a lot about what the
21 alternatives are from a statistical standpoint to better
22 project, present crop treated, and we will be presenting

1 some case studies of what difference it makes in the
2 projections of percent crop treated using this particular
3 method versus the method that we have historically used,
4 and that will give people I think a pretty good feel at
5 least at the initial level for, you know, how much of a
6 difference might this make.
7 It is on October 1st. It's from 9:00 to 5:00,
8 and it's at the Sheraton Crystal City hotel, and you
9 should have copies of the FR notice in your packages on
10 your tabletops here that includes a description of what's
11 going to be presented.
12 SPEAKER: Beth?
13 DR. CARROLL: Yeah, Denise, I just wondered if
14 you're going to draw or if you're even going to discuss
15 the sources of data. You remember the old Leonard Seepud
16 (phonetic) days when we --
17 MS. KEEHNER: Right.
18 DR. CARROLL: -- discussed this ad nauseam, and
19 it seemed like every database that was used, there was
20 something that wasn't quite what you needed.
21 MS. KEEHNER: Right. We're going to -- as part
22 of the presentation, there's going to be a background on

1 DONE (phonetic) and also on NASS (phonetic), and the data
2 that we're using is -- are from those statistical
3 databases.
4 DR. CARROLL: And is this going to cover water
5 as well? You said dietary --
6 MS. KEEHNER: Well, I should say food.
7 DR. CARROLL: Okay.
8 SPEAKER: Larry?
9 MR. ELWORTH: Is the agency going to make those
10 case studies available so that we can look at them? I
11 mean, I don't need to see them before the --
12 MS. KEEHNER: Yes, actually, the analysis is
13 part of the paper that's in the docket for the SAP, and I
14 can certainly get you a copy of that if you would like.
15 MR. ELWORTH: Yes, I would like to see it.
16 MS. KEEHNER: Sure.
17 MR. ELWORTH: The other -- can I just follow up
18 on Beth's question a little bit, and not in any depth.
19 It's not just the source of the data but the accuracy of
20 the data that matters a great deal, and I would hope that
21 whatever statistical approach you take accounts for the
22 fact that the time series may or may not be

1 representative and may or may not be really --
2 representative of what actually happens, nor --
3 MS. KEEHNER: Right.
4 MR. ELWORTH: -- and that you actually talk
5 about the bounds of confidence and accuracy around the
6 data.
7 MS. KEEHNER: Right, and we have looked at that.
8 MR. ELWORTH: Okay.
9 MS. KEEHNER: And we've looked at -- I mean,
10 what we're dealing with really is -- this is the current
11 approach, which has all its warts and pimples and things
12 associated with it because of the nature of the data, and
13 then is there an approach that, in fact, seems to provide
14 a more accurate -- and it's -- the interesting thing,
15 when you look at the case studies, is that it's not --
16 you know, it's not the case that out of the 17 cases that
17 we looked at that, you know, 16 out of 17 result in
18 higher and, you know, only one results in lower. It
19 really does -- it's fairly even as to how it comes out
20 based on the use of this particular method.
21 The other thing that I would like to add is that
22 regardless of what statistical approach that you use,

1 analysts and the agency have to take a look at what's in
2 front of them at the end of it and ask other questions,
3 like is there something going on otherwise that we
4 anticipate is going to have some impact on the percent
5 crop treated for this particular chemical/commodity
6 combination? For example, if you happen to know that,
7 you know, some phase-out is going to come in place, you
8 know, in two or three years, looking at historical trends
9 in percent crop treated, that's not the full story, and
10 you need to use some judgment and build that into your
11 sort of post-statistical analysis determinations.
12 MR. ELWORTH: Yeah, that's important,
13 especially -- because that may not be abundantly obvious
14 to someone who basically has a statistical background.
15 MS. KEEHNER: Right. We can't -- you just
16 can't flip a program switch and then have it spit it out
17 and use it without thinking about what you're looking at.
18 SPEAKER: Jay?
19 SPEAKER: Yeah, and Larry, we looked at this ad
20 nauseam in SEEPUD, and Denise was in on that. You know,
21 there's a lot of them. One database will be accurate,
22 one will be precise, one won't be available until

1 whatever, so that we discussed a lot of that, and I hope
2 that that historical information is available either from
3 Leonard or somebody else, because there was a lot of
4 discussion on that.
5 SPEAKER: Jay?
6 MR. VROOM: Thanks.
7 Denise, three questions kind of in sequence.
8 Number one, how many and what percent approximately of
9 the risk assessments that have been done since you've
10 been having access to this kind of percent of crop
11 treated data have been employed, in other words? And
12 then, what impact does that have, as I recall, in
13 triggering the FQPA requirement that when you have that
14 kind of data, that it kicks in the five-year registration
15 and renewal requirement?
16 Secondly, you issued an information collection
17 request a few years ago for public comment and input on
18 percent of crop treated, and I'm wondering sort of where
19 that input will be examined by the SAP when they meet.
20 And then thirdly, do you think there will be any
21 new data requirements or guidelines that might be
22 published for public comment following -- I'm not asking

1 you to anticipate or tell us what you think the SAP will
2 say, but do you think it might result in that kind of an
3 action step?
4 MS. KEEHNER: Let me start by -- preface my
5 remarks with saying that our focus right now has been
6 much on sort of the technical, scientific, statistical
7 issue of what methodologies, the physical methodologies,
8 might be more or less appropriate given what the question
9 is that's being asked and given the nature of the data
10 that we have.
11 So, there are issues that have to be dealt with
12 in terms of the policy implications of whatever comes out
13 of the SAP. If the scientific advisory panel, that's
14 basically a group of statisticians and agricultural
15 economists that are going to be looking at this and
16 saying, you know, here's what we think about it from a
17 standpoint of the appropriateness of that particular
18 methodology for what it is that you're trying to do.
19 So, I do envision a period after the SAP where
20 we have to engage with the policy and risk management
21 sort of side of the program within OPP about, okay, where
22 do we move with this methodology? What are all the other

1 issues that we need to address, and maybe some policy
2 paper or something like that might have to be looked at.
3 In terms of the relevance of percent crop
4 treated and how it's used in dietary risk assessments, as
5 we have gotten more and more PDP data and market basket
6 kind of data, the importance for tolerance re-assessment
7 purposes has gone down somewhat, but there are still
8 issues where it does play a role in projecting, for
9 example, for detections or levels of pesticide below the
10 limit of detection. There still is a need for that sort
11 of extrapolation to percent crop treated.
12 So, our customers in the Health Effects Division
13 as well as in the Registration Division are very
14 interested in moving percent crop treated methodology
15 forward, and incidently, not just for tolerance
16 re-assessment purposes but also in the context of
17 registration decisions, sort of the projections of,
18 without any historical data, what do we expect a
19 particular crop and pesticide combination to ultimately
20 result in in terms of the percentage of the market that
21 it might fill?
22 So, what I would say is that there is -- it

1 seems to be meaningful enough and it's playing enough of
2 a role that there is a lot of interest in seeing what we
3 can do to improve the methodology for tolerance
4 re-assessments purposes, and also there is interest for
5 new registration-related decisions and improving that
6 approach as well.
7 MR. VROOM: Okay, and maybe the question then
8 about triggering the five-year registration/renewal
9 question may not be appropriate for you, but I don't know
10 if, Jim or Marcia, you know. Is that a driver or is
11 that sort of an afterthought factor in terms of
12 initiating, you know, that five-year registration/renewal
13 process?
14 MS. MULKEY: Well, maybe I'm -- I think that
15 the five-year revisiting of the percent crop treated is a
16 little different from the 15-year registration review
17 process, although obviously you can and should integrate
18 them.
19 MR. VROOM: Yeah.
20 MS. MULKEY: We have begun to do some work to
21 figure out the five-year issue, and we also have, by a
22 notice of proposed rulemaking and some other things,

1 involving the 15-year registration review. I don't know
2 that either of those has crosswalked to the other yet.
3 MR. VROOM: Okay.
4 SPEAKER: Erik?
5 MR. OLSON: Actually, Jay asked part of my
6 question, but my -- I wonder, I guess we're now six
7 years past the enactment of FQPA, and I would -- if I
8 went back in my memory, if memory serves, there were
9 several pesticides for which percent of crop treated
10 started to be used not that much after the Act was
11 passed. Have you started doing the five-year reviews
12 yet? Are you going to be using this new methodology to
13 do the percent of crop treated? And also, you know,
14 we've continually raised the issue about --
15 congressional concerns about using this for acute as
16 opposed to chronic. Is this new methodology going to
17 continue to apply to acute, pesticides with acute
18 effects, where that's the effect of concern?
19 SPEAKER: Erik, we have identified the use of
20 percent crop treated as well as the other one that's
21 relevant is the use of anticipated residues, both have
22 the five-year clock on them, and actually, we -- the

1 number of -- affected in the year -- between '96 and
2 '97 is very small. There was actually very little
3 activity that first year after FQPA.
4 So, we have done the identification work and
5 have begun to work at what information we need for the
6 verification and the recertification on both anticipated
7 residues and percent crop treated.
8 On the second question, we do continue to expect
9 to be using percent crop treated for acute as well as
10 chronic effects in the --
11 MS. MULKEY: Probabilistic.
12 SPEAKER: Probabilistic, yes.
13 MR. OLSON: Pardon?
14 SPEAKER: Probabilistic, percent crop treated
15 and our probabilistic acute risk assessments.
16 SPEAKER: All right, Al.
17 MR. JENNINGS: All right, IPM symposium, and I
18 will keep within the minute.
19 As mentioned several times yesterday, there is
20 an IPM symposium coming up April 8, 9 and 10 in the year
21 2003 to be held in Indianapolis. There is a website that
22 has a lot of information on it, and I did not bring that

1 with me, but what I will do is give that to Margie and
2 ask her to get it out to all of you electronically.
3 Again, it's going to cover a full range of
4 typical pest management topics, and in my mind, IPM and
5 pest management are becoming one and the same, and there
6 is really no difference between the two. It's been a
7 while. This is advertised as the fourth national IPM
8 symposium. I remember one other, so I'm not sure how
9 long ago that was. Steve probably remembers since he's
10 reacting, but --
11 STEVE: You're so young.
12 MR. JENNINGS: Yes, I know.
13 But this is just a good opportunity. We haven't
14 met and talked for a while, so it's getting the IPM
15 practitioners and interested folks together for three
16 days. Certainly part of this will be a follow-up to the
17 GAO report of somewhat over a year ago in which the
18 Department did acknowledge that we needed to get together
19 and sit down and talk about goals and priorities and
20 those sorts of things.
21 Some of you will recall that a number of years
22 ago, a USDA employee set a goal saying it was a good idea

1 that we achieve 75 percent IPM acreage by the year 2000
2 --
3 SPEAKER: That would have been the Secretary of
4 Agriculture.
5 MR. JENNINGS: Oh, excuse me. That employee is
6 no longer with us, but his spirit lingers.
7 No, we are past the year 2000, and of course, we
8 met that goal, but anyhow, it is time to sit down and try
9 to figure out --
10 SPEAKER: Depending on how you define it.
11 MR. JENNINGS: Yes. Well, anyhow, where are our
12 IPM programs, and more importantly, where are we going
13 with them? So, that will be an important part of that
14 symposium, or at least if we don't solve it all there, it
15 will be a start of that process of discussing goals and
16 measures and where are we headed. So, anyhow, certainly
17 I hope those of you who are interested will be able to
18 join us, and as I said, I will get the website
19 information to Margie, who will hopefully then transfer
20 it on out to you folks.
21 Questions? Great.
22 SPEAKER: Kathleen?

1 DR. CARROLL: I was going to say if anybody
2 wants it today, I've got it.
3 MR. JENNINGS: Oh, okay. If you want the
4 information today, Beth has it. Yes, there is a very
5 active planning committee going on right now, so...
6 SPEAKER: Kathleen?
7 MS. KNOX: Okay, IPM in schools, just a brief
8 update. At your places, there's a brochure which we
9 published I believe -- I think we got it out in June.
10 We are on our second printing. The first printing was
11 sent to school districts and all of our mailing lists.
12 The second printing was done recently. It's got a lot of
13 information, web addresses, things like that.
14 The second thing is that in 2001, we funded two
15 pilot technical resource centers for IPM in schools to
16 investigate whether a center -- a virtual center that
17 could provide tools, training and technical support to
18 the states would be effective in providing the kind of
19 support needed to folks who were interested.
20 We funded these competitively through grants.
21 The intention was that the program would become
22 sustainable when our grant funding ran out. We are

1 rapidly approaching the time when that funding is running
2 out. So, we're in the process of starting to do an
3 evaluation of the effectiveness of the two centers.
4 They're both mentioned in here, and the states they cover
5 are mentioned in here. They both have websites, so we
6 will be evaluating whether there is an effective tool to
7 basically facilitate the implementation of IPM in
8 schools.
9 The third thing is something that we are not
10 sponsoring, but the National Foundation for IPM Education
11 is having a very focused facilitative workshop
12 predominantly with a relatively small group of IPM in
13 schools practitioners, many of whom are PESP partners,
14 our Pesticide Environmental Stewardship Program,
15 partners. That's on October 3rd, and the hopes, at least
16 the intention of the Foundation when they planned this,
17 was to try to bring together the folks who are doing the
18 work and talk about what will it take to move it forward
19 or to further implement, lots of discussion of tool
20 development. There are manuals, there are technique,
21 there are things that work. There are a variety of
22 things. Many people feel that you don't need to start

1 from the basics and develop a whole new manual to do
2 this, so these folks who have been doing this for some
3 time are going to sit in a room and talk about what kinds
4 of things could improve implementation in the future.
5 So, that's my update in maybe two minutes or three
6 minutes, so...
7 SPEAKER: One question, the October 3rd National
8 Foundation facilitative meeting, is there a list of
9 invitees that's available to the committee?
10 MS. KNOX: I don't have it. Steve --
11 STEVE: I'm sorry?
12 MS. KNOX: Bob asked if there's a list of
13 invitees available for the workshop, and I know schools
14 isn't your issue, but --
15 STEVE: I can get it to you, yeah.
16 Allen?
17 MR. JAMES: That was basically my question as
18 well.
19 MS. KNOX: Okay.
20 MR. JAMES: How we get more information.
21 MS. KNOX: You'd contact the National Foundation
22 for IPM Education.

1 MR. JONES: Kerry?
2 MR. LEIFER: Back in May, a presentation --
3 MR. JONES: I'm sorry, Kerry.
4 John, did you have a question for Kathleen?
5 MR. VICKERY: Yes.
6 MR. JONES: I'm sorry.
7 MR. VICKERY: You mentioned there was a meeting
8 coming up to identify some of the things for the next --
9 I was wondering if you could share some of your own ideas
10 based on what you know about maybe offering two or three
11 examples of things that you think are critical needs or
12 next steps.
13 MS. KNOX: Well, I think one of the things that
14 we will do is see what the outcome from the workshop is
15 and try and see how that -- how we could facilitate
16 that. I mean, we don't have a large program supporting
17 this. In fact, our internal work group is
18 cross-divisional, but we don't have anybody working
19 full-time on this. So, the idea is how can we build the
20 kind of -- how can we facilitate the kinds of networks
21 out there to provide the support that the states need to
22 do this.

1 So, I think we're looking forward to the
2 outcomes from the workshop, and in terms of our internal
3 work, we're really going to evaluate whether these pilots
4 have provided significant support.
5 (End tape 1-A.)
6 They were fairly small, each grant was $100,000,
7 and again, they were competitively granted with the idea
8 -- part of the proposal had to be a plan for
9 sustainability, so that the center could continue after
10 our grant funding ran out, so --
11 MR. JONES: Yeah, if I could add, there have
12 been lots of independent efforts in California, in Monroe
13 Schools in Indiana, in Las Vegas School District area --
14 MS. KNOX: New York City.
15 STEVE: -- New York City, the tribes have shown
16 great interest in IPM in schools, and so the thought was
17 let's bring together the leaders in all these different
18 areas and see if we can begin to develop some
19 coordination and some interaction and reduce the
20 redundancy and the -- where everyone has the same
21 learning curve, get everyone up along the same curve, and
22 then discussion -- further discussions about some sort

1 of -- does it make any sense to have some centralization
2 of information so that -- so that everyone can use a
3 central location as a resource, so that all school
4 systems can go to that location, get all the materials
5 they need to develop an IPM-in-schools system.
6 Monroe County and Mark Lane who's at Purdue --
7 no, University of Indiana -- Indiana University --
8 MS. KNOX: That's right.
9 MR. JONES: -- have been very progressive in
10 this whole issue and have really driven a lot of this,
11 and I think for those of us at the IPM Foundation and in
12 IPM in general feel like this is not only the obvious
13 advantage of less exposure and better use of pest
14 management systems in the school system, it also helps
15 the public understand what integrated pest management is
16 and helps draw IPM -- there will be a pull from the
17 consumer side for IPM in agriculture, as well. So, it
18 also helps just get the word out about what integrated
19 pest management is all about.
20 DR. HOCK: Yeah, just to follow up on what Steve
21 said, a little different wrinkle, in Pennsylvania, our
22 State Department of Education actually passed a basic

1 curriculum requirement -- in other words, in addition to
2 the three Rs, teachers are now required to actually teach
3 or have a segment of their curriculum in IPM. It's a
4 totally different wrinkle from the standpoint that it
5 will be taught in schools as part of the basic core
6 curriculum.
7 MR. JONES: Okay, Kerry.
8 MR. LEIFER: Back in May, a presentation was
9 made to the PPDC that was essentially kind of a
10 pre-release overview of a new risk assessment
11 methodology, primarily to be used for pesticide inert
12 ingredients, really to deal with many of the issues that
13 we were faced with under FQPA. That methodology, the
14 proposed guidance documents, was released on June 7th and
15 is posted to OPP's website. The Federal Register notice
16 of availability was published on June 13th. That's also
17 available on EPA's website. That notice pointed to the
18 methodology and basically asked -- solicited comments on
19 four questions that included was this methodology a
20 workable, logical approach; would it produce an
21 efficient, productive process. The methodology talked
22 about a number of sources of information for evaluating

1 these substances, and we asked if we had missed anything,
2 were there other sources that we should be considering in
3 evaluating these types of materials. And lastly, the
4 document provided guidance to the regulated community,
5 and we wanted to know if there were any additional
6 information that would be helpful to the regulated
7 community.
8 Now, the comment period was to be September
9 11th, that's been extended now to October the 11th. So,
10 the comment period for this guidance document is October
11 the 11th. OPP will, of course, review and consider these
12 comments that we receive after the close of the comment
13 period.
14 As we stated at the PPDC meeting and as noted in
15 the Federal Register Notice of Availability. OPP has
16 been piloting this new methodology, and in fact, we have
17 been looking and using this in various iterations for
18 about a -- almost a year now, and some of the things
19 that we have done have included the re-assessment of
20 about 442 substances using this new methodology,
21 including 152 lower toxicity active ingredient tolerance
22 exemptions, as well as about 290 inert ingredient

1 tolerance exemptions.
2 We are also utilizing, again on a pilot basis,
3 this process, and it has resulted in the establishment of
4 tolerance exemptions for four new inert ingredients.
5 MR. JONES: Troy?
6 MR. SEIDLE: Thank you. My question is more
7 procedural. We are very pleased with the pre-release of
8 the strategy, and my question relates to the proposed
9 revisions to Part 158 and whether those will go through a
10 similar process and opportunities for public comment.
11 MR. LEIFER: Yes.
12 MS. MULKEY: Absolutely. That's actually a
13 rulemaking, so it's a full-blown Administrative Procedure
14 Act notice and comment.
15 MR. JONES: Bill?
16 MR. TRACY: Yeah, Kerry, what I found in the
17 guidance is that it gets a little vague about the tier
18 approach and how one -- do you want submitters to select
19 the tier if they're going in to propose, let's say, a new
20 inert? Are they -- I would appreciate I guess greater
21 guidance on the tiering process, and are you planning to
22 do something like that? Are you finding that an outage

1 so far?

2 MR. LEIFER: Well, we have been mostly utilizing

3 this for the existing chemicals, existing inert

4 ingredients for tolerance re-assessment purposes, and

5 essentially it's been predominantly an agency process

6 where we've been putting the information together. These

7 tiers are basically just pathways to -- for risk

8 assessment purposes. I mean, I think we certainly would

9 appreciate as part of the comments to get any comments

10 about where you think that is, if that's not really clear

11 to the regulated community.

12 Yeah, I mean, in essence we are or we would be

13 expecting that in the case of new submissions or

14 submissions on the re-assessment that the submitter would

15 be essentially identifying where they fell into this

16 process and essentially identifying substances

17 particularly that are of particularly low toxicity.

18 MR. JONES: Warren?

19 DR. STICKLE: One of the things that is

20 something that I think needs to be addressed very rapidly

21 is really an updating of the inert list. As you may very

22 well know, it was -- initially came out in May of 1995,

1 and since 1995, a lot of actions have taken place. About
2 250 inerts have been removed from the list. I think 87
3 were done for the first trimester for re-assessment, and
4 then for the second trimester, there were I think 287 or
5 something like that, and of course, during the period
6 from 1995 to today, there have been a number of products
7 that have been added to that list, they are polymers, et
8 cetera.
9 The question ultimately is that right now, the
10 regulated community, the general public and perhaps even
11 people and product managers at EPA, are somewhat lacking
12 in a definitive list, and I know the agency has been
13 working very hard on it. In fact, I know Kerry's been
14 working very hard on it, but I wondered if you might be
15 able to give us a -- perhaps an update and a timetable
16 by which that updated list might be made publicly
17 available.
18 MR. LEIFER: Well, we're actually -- we've just
19 been in the process -- as you know, we have been working
20 quite hard on the tolerance re-assessment front to meet
21 the August 3rd mandate. We have now begun to kind of go
22 back and account for the actions that we've made and what

1 they mean in terms of reclassification for many of the
2 inerts that were re-assessed, be it to List 4-B or 4-A.
3 That's predominantly where they moved to.
4 So, we have now pretty much completed that
5 process, and we are beginning to put that all together.
6 We have already -- have internally captured all of the,
7 quote unquote, the "new" inert ingredients that have been
8 added since '95. So, I think we are very, very close,
9 hopefully within a matter of weeks, of having an updated
10 listing of all the inert ingredients with their
11 corresponding list classification on the website.
12 And on a related matter, I guess we're going to
13 be looking into making publicly available in some form
14 the substances that have been re-assessed under this
15 process as well.
16 MR. LEIFER: Do you want to handle the next
17 three of yours, the drift issues -- I'm sorry, the
18 nonisolated --
19 MS. LINDSAY: Which one do you want me to do
20 next? I was going to do inerts disclosure.
21 MR. LEIFER: Start with inerts disclosure, and
22 then take the two carryover issues.

1 MS. LINDSAY: Okay. This group a number of
2 years ago commissioned a work group, the Inerts
3 Disclosure Stakeholder Work Group, which labored long and
4 hard to look at ways of making information on inert
5 ingredients more available to the public while still
6 being mindful of the FIFRA requirements and the CBI
7 concerns that are relevant.
8 The group actually submitted its report to the
9 full committee in April this year, and we also opened a
10 public comment period on that report which closed at the
11 end of July. We did not get a lot of comments, I'd say
12 in the neighborhood of a dozen or so, most of which were
13 of the sort of postcard variety, but there were two that
14 actually were substantive, one from the Minnesota
15 Department of Agriculture that was quite I think soundly
16 in support of improved disclosure of information while
17 being mindful of a number of the issues that are
18 surrounding doing that. It went on to describe actually
19 some very concrete and different sorts of situations than
20 the group itself had looked at, of difficulties they
21 actually have in doing their pesticide regulatory job
22 because of the current state of affairs.

1 The other letter was from the American Pet
2 Producers -- no, American Pet Product Manufacturers
3 Association that, again, went through some of the issues
4 that were developed by the work group.
5 The actual report ended up not, of course, with
6 a single set of recommendations but with three different
7 proposals. One discussed the creation of a voluntary
8 program to create releasable non-CBI summaries. Another
9 proposal recommended rulemaking to modify labeling
10 requirements to require the name of each inert ingredient
11 be included on pesticide products. And a third proposal
12 also proposed a rulemaking to modify labeling
13 requirements to require the name of each inert ingredient
14 to be on pesticide product labels, but also this third
15 proposal directed EPA to determine up front or to
16 substantiate up front any CBI claims that were made for a
17 particular formulation.
18 Then the report actually also had a number of
19 other suggestions kind of embedded in it beyond the three
20 specific proposals. One concerned strengthening
21 databases that contain information for health care
22 providers. The current systems are voluntary, and they

1 don't necessarily include all information. It talked
2 about disclosure of inerts on labels using general
3 descriptors, such as surfactants or fragrances rather
4 than very specific chemical names, standardizing
5 nomenclature of inert ingredients, and then finally,
6 develop ways to provide recognition to those registrants
7 who actually voluntarily disclose all inert ingredients.
8 So, build a kind of incentive program.
9 We're now in the mode of actually looking at all
10 three of the proposals, the comments that we got through
11 the comment process, these other suggested initiatives
12 that are embedded in the report, and would expect over
13 the next several months to be able to elaborate some
14 directions forward in this arena, and when we do that, we
15 will have public process around those ideas as part of
16 our roll-out of them. We're being a little bit
17 deliberately vague at this point about what that public
18 process might be, because there are a number of different
19 directions we could take that. So, that's it.
20 MR. JONES: Bill?
21 MR. TRACY: Anne, I think you have a yeoman's
22 task on this one, and you know it.

1 I guess my question is a little bit about EPA's
2 process on this and who is it that's working on it, not
3 individuals but what entities, and do you have ODC or
4 some sort of legal folks or what's your team look like
5 and who are you going to vet process with?
6 MS. LINDSAY: Unless the team who supported the
7 Inerts Disclosure Stakeholder Work Group refuses to do
8 this anymore, because they have done yeoman's work, I
9 would expect that to be the core team. So, for instance,
10 Kerry Leifer from Registration Division was a critical
11 member. I've got some staff. Our General Counsel's
12 Office was always a main player. And I think they will
13 be the core group that moves things forward.
14 MR. JONES: I'm sorry, Bill, were you --
15 MS. LINDSAY: I may need to create an incentive
16 program for them.
17 SPEAKER: That was a tough job. I was part of
18 that. Thanks.
19 I just want to make sure -- and I think Bill
20 asked the question, but just to emphasize that any
21 program, any project that we move forward with take into
22 consideration the statutory authority in FIFRA and FOIA.

1 I thought the letter that Marcia sent to the petitioners
2 was particularly good, because it did lay out the legal
3 authority. Without getting into that here, I think
4 that's really critical and important.
5 We had some problems laying that on the table
6 during the proceedings, because I think the leaders and
7 everyone wanted to move forward to see what we could
8 agree on, if anything, but I think it is critical that
9 the Office of general Counsel be very involved in
10 anything that finally comes out as a proposal.
11 MR. JONES: Julie?
12 MS. SPAGNOLI: A number of registrants have, you
13 know, initiated their own kind of voluntary activities in
14 this area, and I think one of the problems that we've run
15 into is, you know, a number of stumbling blocks with some
16 of the states and just trying to I guess have some
17 guidance on -- and this would, of course, all be
18 voluntary at this point, and I guess I would be asking,
19 what is -- does the agency have any kind of more
20 immediate plans maybe to facilitate some type of guidance
21 to registrants who are looking for ways to, you know, to
22 -- maybe to voluntarily provide this kind of information,

1 particularly on consumer labels I think is where the main
2 focus has been, and maybe to try to eliminate some of the
3 stumbling blocks that we've encountered in voluntary
4 disclosure.
5 MS. LINDSAY: Okay, that's an interesting
6 suggestion. We'll look at that.
7 MR. JONES: Did you want to go ahead and --
8 MS. LINDSAY: Yeah, I was going to talk about
9 misuse next. At the last of the PPDC meetings, we had a
10 panel discussion. Phil Benedict was part of that, Jay
11 Vroom, and a number of other people who I think are not
12 in the room today.
13 What I want to do is just a very brief update.
14 The misuse cases that we were discussing then were pretty
15 significant, pretty -- not focused in any one specific
16 region of the country. Most of them seemed to involve
17 use of a product registered for one crop on a crop for
18 which it was not registered, though in at least one case
19 I think there was a pending registration.
20 I'm happy to say, after having done sort of an
21 informal poll of our regional offices, Registration
22 Division, our state lead agencies and others, that we're

1 not seeing reported to us these kind of significant
2 patterns of misuse that we saw in the past couple of
3 years, so I think that's actually very good news, that
4 the sort of egregious kinds of situations that we were
5 looking at don't seem to be occurring.
6 I will say that in doing this little poll in
7 preparation for the meeting, I did get what I would call
8 some anecdotal information in some areas that we might
9 think about. The first is actually the use of pesticide
10 products in a manner in which they were not intended to
11 be used, as bait for nuisance animal control, and then
12 the second area is the sort of -- I'm not quite sure
13 what to call it, sort of like a copycat 24-C situation.
14 If, for instance, Phil Benedict had issued a 24-C in
15 Vermont and in a neighboring state they didn't have the
16 24-C but the grower knew about it, the grower in the
17 state without the 24-C may just go ahead and do what
18 Phil's growers are quite legally doing.
19 So, both of those are anecdotal. I don't have
20 what I would call hard, concrete information about the
21 extent of those kinds of problems, but to me what it
22 suggests is that there's a reason to keep a bit of a

1 focus on the issue of proper use and misuse, because the
2 temptations are always out there, without maintaining
3 some level of focus.
4 I think Jay actually has a little bit to add.
5 MR. VROOM: Yeah, thanks, Anne.
6 At the May PPDC meeting in that panel
7 discussion, I think we talked a bit about the fact that
8 there was some legal hurdle to get over at that point in
9 time to get published what turned out to be two sort of
10 parallel editorial pieces that Steve Johnson and I
11 separately authored, and those have now been cleared by
12 the -- all the lawyers and have been published fairly
13 widely in the ag trade media, probably a little later
14 than we would have preferred in the growing cycle for
15 this particular crop year, but nonetheless, I think they
16 have gotten good attention.
17 I have actually been quite surprised with the
18 amount of e-mail response that I've gotten from growers,
19 extension agents, university folks around the country. I
20 think there have been five major ag farm media that have
21 picked both of those editorials up, and a number of them
22 have republished them, and others have put them on their

1 websites. That's led to requests from I think the Oregon
2 Extension Service Newsletter asked to republish these
3 articles. So, I think all that's been very positive.
4 It also has probably contributed to the
5 anecdotal survey that you referred to, which does seem to
6 indicate that people have been reminded through, you
7 know, these articles and other communication from the
8 agency and the industry that the label is the law, and
9 that's something that you need to follow.
10 Lastly, I think it's elevated a few problems
11 that need to be addressed. One of them is the definition
12 of hay, for instance, and I think this is still a
13 continuing problem, Phil, in your state and some other
14 parts of the Northeast, and it probably relates more
15 directly to milk-producing areas where people are more
16 critically concerned about residues in milk than in meat
17 animals that would be consuming hay, but it is an area
18 that we have raised informally now, this definition of
19 hay crop and residue concern.
20 I think that the agency staff are addressing it,
21 but I wanted to make sure, Marcia, you and Jim were aware
22 of that, because it is something that while it is a

1 fairly minor use category, it is one that apparently has
2 been a persistent problem. Phil has talked about it, and
3 I don't know, Phil, if you want to speak to it again, but
4 if it hasn't received your attention at the highest
5 levels in the program, we would like to ask that you look
6 into it.
7 MR. BENEDICT: I still think it's a Northeast
8 problem and probably broader than that. I really think
9 it's not just hay, though, it's forages, it's mixed
10 stands is what it really is.
11 MR. VROOM: I stand corrected, sorry.
12 MR. BENEDICT: That's fine. It took us a long
13 time to figure out what it was, actually, according to
14 the rules.
15 MS. LINDSAY: If I could just add, I actually do
16 think that Jim anyway, I know that Jim and I have talked
17 about this issue and sort of our internal plan of attack,
18 so it's had high-level attention and continues to have.
19 MR. JONES: Okay, next topic, Anne?
20 MS. LINDSAY: Spray drift, and here I'm doing my
21 imitation of my associate, Jay Ellenberger, and he was
22 kind enough to actually give me his official Power Point

1 presentation to crib from, so I may actually get things
2 correct.
3 Win, you had asked for sort of an update on the
4 spray drift issue --
5 MR. HOCK: Yes, thank you.
6 MS. LINDSAY: -- we put out -- this is just
7 background -- draft guidance in the form of a draft PR
8 notice in August 2001. We had what amounted to a very
9 long comment period. It ran from August to end of March
10 2002. Ultimately, after a couple of extensions, we got a
11 very significant number of comments, 5249, with a total
12 of individual comments, which I think this is
13 significant, 1771. These are not campaign letters.
14 They're really, you know, letters that people sat down
15 and wrote to us about the issue. So, obviously the topic
16 of spray drift has -- really touches a lot of different
17 nerves and I think in a lot of different ways.
18 Just a run-down, 56 percent of these were
19 individual grower comments; 17 from ag retail business; 6
20 percent from private citizens. Although that's a very
21 small percentage, I again find that very significant,
22 because we almost never, at least in my experience, get

1 comments from just like real people, not that you're all
2 not real people, but it's pretty amazing when just an
3 ordinary person takes the time to actually file a comment
4 in a Federal Government comment sort of process. 4
5 percent from associations; 1.4 percent from environmental
6 groups; 1 percent from applicators; and 0.3 percent
7 registrants.
8 The one missing category, Phil, in the official
9 comments were states, and that actually surprised me
10 since APCO had been a significant partner in developing
11 the ideas. That were ensconced in that draft.
12 Anyway, primary issues. Recommended application
13 within the range of the three to ten miles per hour wind
14 speed was viewed as being unrealistic by a number of the
15 commenters. The height of the application is a concern.
16 I think we talked about ten feet above whatever it is,
17 and a lot of the aerial applicators gave us very specific
18 examples of why that was totally loony and wouldn't work.
19 Orchard growers -- like telephone poles and
20 rolling countryside and that sort of stuff.
21 Orchard growers were concerned that the orchard
22 blast spray technology that seemed to be sort of

1 ensconced in the PR notice was unrealistic. Concerns
2 about economic hardship to small farmers due to new
3 equipment costs, so that even though there might be
4 equipment out there that was really good and would help
5 with drift control, it wasn't necessarily accessible to
6 everybody.
7 Then, enforcement concerns, and those would be
8 really from the -- I think the state agency perspective.
9 There were some of what we're calling special issues
10 around forestry applications and also adult and larvaside
11 applications for mosquito control. And my favorite one
12 of all, the beekeepers and protection of bees during
13 aerial spray programs.
14 But the vast majority of programs did come from
15 farmers and the ag community broadly and were quite
16 unfavorable I think is a fair way to characterize it.
17 Those who favored the revisions tended to include the
18 private citizens, that 6 percent that wrote to us,
19 especially those that have actually experienced spray
20 drift personally in their life and believe that they
21 suffered adverse effects from those, because they live
22 near the treated fields, and environmental groups and

1 organic farmers. So, it's kind of I think a classic
2 split.
3 What we're doing right now and what we have been
4 doing all through the comment period and since the
5 comment period closed is doing a lot of I would say very
6 informal getting out there, listening and talking with
7 people in all different directions. I know that, Adam,
8 you and Steve and Jay made a trip to.
9 DR. LEWIS: In the height of the summer, ideal
10 vacation time in.
11 DR. LEWIS: . Jay will actually be going shortly
12 to a very large conference in Texas about vegetation
13 management with lots and lots of folks there who care
14 about the ag drift issues.
15 But we're also in the midst of planning some
16 more specific workshops, and our current thoughts are
17 that we would have probably three workshops, one on the
18 East Coast, probably most likely in Washington, one in
19 the middle and one on the West. Actual time frames,
20 specific dates and locations aren't crystallized enough
21 yet to sort of give you a better feel for it than that,
22 but we're really looking forward to the workshops. We

1 actually think we have got enough interest in the issue
2 that we're going to get some very constructive input, and
3 I think eventually we'll find a way forward that is
4 reasonable, practical and also protective.
5 Assuming that I'm right about my expectations of
6 our success in the dialogue, and I see Adam is looking at
7 me a little -- he's smiling at me now, this is better
8 -- the expectation would be that we would probably do
9 another draft PR notice -- or not probably, but that we
10 would do another draft PR notice, and that would go out
11 for comment, and then obviously, depending on what that
12 comment showed us, we would decide what our next steps
13 are. So, that's it.
14 MR. JONES: Julie?
15 MS. SPAGNOLI: Just for clarification, kind of
16 what is the scope of these workshops? Is it going to be
17 to solicit stakeholder input or to discuss the various
18 issues, I guess just kind of what is the agenda idea for
19 these workshops?
20 MS. LINDSAY: Well, broadly obviously we want to
21 discuss with stakeholders, and I think we want to make
22 sure that we actually get a full range of stakeholders at

1 the workshops. I think we're going to have to look at
2 the issues that have come out of the public comment
3 period and use those issues to properly frame discussion
4 at those workshops. I think also we're open to
5 suggestions from all of you as to, you know, what might
6 make those workshops be good and useful.
7 MR. JONES: Win?
8 MR. HOCK: First of all, thank Jay Ellenberger
9 and Anne, I appreciate that very much. The expectation
10 of another PR notice, that's probably going to be after
11 the workshops, am I --
12 MS. LINDSAY: Oh, definitely.
13 MR. HOCK: Definitely?
14 SPEAKER: Well after the workshops.
15 MR. HOCK: Because I thought, yeah, you know,
16 you'll go through this whole thing again, you know, so
17 you'll incorporate those comments and suggestions and so
18 forth into the new PR notice.
19 I guess you're really looking about, what, nine
20 months away, something like that, an expectation?
21 MS. LINDSAY: I would say that that's a very
22 aggressive estimate on your part.

1 MR. HOCK: All right, we will look for the
2 workshops.
3 MR. JONES: Erik?
4 MR. NICHOLSON: For what it's worth, I had to
5 evacuate my family from our house, which borders a
6 strawberry field, this summer. I have a two-year-old
7 daughter. When the grower applied unknown chemical,
8 preharvest application, to strawberries in a field that
9 sits about 30 feet behind our house, we just had to get
10 out of the house as quickly as possible.
11 In terms of enforcement, we have had such a bad
12 experience with the Oregon Department of Ag, I didn't
13 even bother filing a complaint. My concern was the
14 safety of my family.
15 MS. LINDSAY: Thanks.
16 MR. JONES: Adam, did you want to --
17 MR. GOLDBERG: Yeah, actually, I just wanted to
18 chime in a little bit on spray drift. It really has been
19 a lot of varied comment, I think very constructive
20 comment that we've received over the last six months from
21 folks, and it's really been informative. I just wanted
22 to back up kind of what Anne was saying. I think we're

1 going to have some very constructive workshops aiming at
2 the level of interest that we've had in this, and it has
3 been a lot more than possibly expected I think and from a
4 lot wider range of folks. So, I think it's going to be a
5 good discussion. I think we are going to have good
6 workshops on those, and we look forward to your continued
7 comment and input from everybody. Thank you.
8 MR. JONES: Next I am going to introduce Don
9 Wood, who I don't think most of you have met previously.
10 He is with the Senior Budget Office in the assistant
11 administrator's office, and Don is going to give us an
12 update on EPA's strategic plan revision.
13 MR. WOOD: Thanks, Jim.
14 Good morning, everybody, nice to see you. This
15 is our current strategic plan, the EPA strategic plan
16 dated September 2000. This is not a document, I can
17 guarantee you from personal experience, that sits on the
18 shelf. We use this document a lot in the budget office,
19 and in fact, it is sort of the brooding omnipresence of
20 our budget work, because every time we gin up a budget
21 for the next fiscal year, we need to go back and show
22 Congress and show the public and show you all how we're

1 doing against our explicitly stated goals in the
2 strategic plan.
3 This is our second strategic plan. Each one is
4 to last five years, and we're now starting the cycle to
5 begin a new strategic plan that is to be in effect from
6 FY 2003 through the end of FY 2007, five years. We have
7 in the past and will continue to very strongly encourage
8 public participation in the formation of the strategic
9 plan.
10 What we'll be doing in OPPTS and OPP in
11 particular is to seek public input over the next year in
12 three ways. The first thing will be coming up very
13 quickly, and that will be a letter from Steve Johnson
14 which is now in gestation and we hope to have finished by
15 next week that will lay out a series of questions that
16 we'll be asking the public and our stakeholders about the
17 strategic plan and providing input, asking input into our
18 next plan, and that letter will be out next week and will
19 direct folks to the EPA e-docket, and the e-docket will
20 be the way that we and OPPTS will be seeking your input
21 on the strategic plan.
22 The major portion of the strategic plan and the

1 thing that really drives our budget are the objectives
2 and sub-objectives, and I would like to read a couple of
3 sample objectives and sub-objectives to you to show you
4 how specific the strategic plan is and also show you
5 what -- ask you how you can help us with our next round
6 of objectives and sub-objectives.
7 For example, in the current plan, one of our
8 sub-objectives is by 2006, residues of carcinogenic and
9 cholinesterase-inhibiting neuro-toxic pesticides on the
10 foods most frequently eaten by children will be reduced
11 by 50 percent from baseline levels in 1994. That's in
12 our current plan, and every year we need to demonstrate
13 how we're doing against that particular sub-objective.
14 Another one is by 2005, reduce by 50 percent
15 from 1995 levels the number of incidents and amounts of
16 mortality to terrestrial and aquatic wildlife caused by
17 15 pesticides currently responsible for the greatest
18 mortality of such wildlife.
19 Those are the kinds of specific drivers that we
20 have in the budget, and those are just two of several
21 that we will be asking folks to help us update and
22 provide new objectives and sub-objectives as we face the

1 next five years.
2 We'll also be asking what are the organizational
3 difficulties that our stakeholders and you are facing
4 that we can help through planning over the next five
5 years. So, look for the letter from Steve Johnson next
6 week. We'll be sending it out through our very
7 comprehensive mailing lists, and we'll make sure to give
8 Margie that letter. That letter should point you to the
9 e-docket where we will have the specific questions that
10 we really would appreciate your help on.
11 Then, two other opportunities to take a bite out
12 of the apple will be in the beginning of December when we
13 will have draft objectives and sub-objectives out for
14 public comment, and then in the beginning of March of
15 2003, we'll have an entire revised strategic plan
16 available for comment, and that will not only include the
17 work in the pesticides program but, in fact, throughout
18 the entire agency. That will be early March of 2003.
19 Then our final plan is due to be finished and sent to
20 Congress at the end of fiscal year 2003, which is
21 September 2003.
22 So, again, I very much encourage you to continue

1 your help, as you did in the last strategic plan, by
2 providing us input in the next revision. Thank you.
3 MR. JONES: Larry?
4 MR. ELWORTH: Is the -- is OPPTS or the agency
5 or both doing an evaluation and publishing that of
6 performance at -- from -- to a certain point on
7 performance in meeting those objectives, because I think
8 it would be a little difficult to comment on a strategic
9 plan without having some sense of what had happened to
10 date in achieving whatever objectives you had.
11 MR. WOOD: That's a very good question. Every
12 year we are required by GPRA and would be by good
13 management practices anyway to report how we've done on
14 our strategic plan, and in fact, we have annual reports
15 that come out every year, and right now we're starting
16 the 2002 annual report, and those are all available on
17 the EPA Office of Chief Financial Officer website,
18 epa.gov/ocfo I believe is the address, and those reports
19 will indicate how we've been doing against the goals and
20 measures that are in the strategic plan.
21 MR. ELWORTH: So, when is the 2002 report on the
22 website?

1 MR. WOOD: The 2002 report we're starting now,
2 and I'm not exactly sure when the release date is, but
3 it's earlier than it has been in recent years.
4 MR. ELWORTH: Okay.
5 MR. WOOD: It will be out I would imagine --
6 probably not in time for Steve's letter, but certainly in
7 time -- in late December or early January to use to
8 comment when we come out with the draft objectives and
9 sub-objectives.
10 MR. ELWORTH: Well, I would encourage you --
11 and maybe this is one of the forums to do it -- is some
12 opportunity for discussion as well and not -- in
13 addition to whatever response, to letters or e-mail,
14 maybe if this is worth bringing up later as something we
15 could discuss as part of this group's discussions, that
16 would be helpful.
17 MR. JONES: Would you give that website again,
18 please, the addition to the epa.gov?
19 MR. WOOD: The website for the annual
20 performance reports -- and I'm doing this from memory
21 -- is epa.gov/ocfo, and another way to do it is just go
22 to the epa.gov and look for the Office of Chief Financial

1 Officer link, and they are very good about putting up all
2 of the annual performance reports, the strategic plans
3 and the yearly budgets. The yearly budgets, by the way,
4 also have our annual performance measures and progress
5 toward the -- annual performance goals and progress
6 towards those goals every year.
7 MR. JONES: Okay, Marcia, you have the last
8 update.
9 MS. MULKEY: And responsible as I am for the
10 entire agenda, I am motivated to make this very quick.
11 As you know, there's been a lot of interest in
12 worker risks and worker risk assessment -- oh, I'm
13 sorry, Phil.
14 MR. BENEDICT: I'd like to talk from a state
15 perspective now. We have the Office of Pesticide
16 Programs, and we also have the other branch or another of
17 the agency that funds a major component of the pesticide
18 program, that's the enforcement grants, and to me somehow
19 there's a disconnect in the way the agency does its
20 planning if you don't look at both what's going on in
21 OPPTS and OECA for talking about the pesticide program,
22 you're only painting part of the picture, and I think the

1 agency has historically done that.
2 So, I would hope this time around that you would
3 take a more holistic look at the pesticide program and
4 deal with both sides of the agency, because it's -- what
5 you're putting out in reality is really an agency plan,
6 of which OPPTS is part of, but if you don't combine
7 what's going on in OECA, you don't really paint a very
8 good picture. The pesticide program in my opinion is
9 unique. It's the only one where Congress delegated use
10 to the states, and in all of the other programs, the
11 delegation has been by the agency, but in doing that, it
12 has really created a program that is really a true
13 partnership, and I think the strategic plan ought to
14 better reflect that personally.
15 MR. WOOD: Well, you're right, and of course,
16 the Office of Research & Development, not so much from a
17 state perspective but in other ways, it's also critical
18 to understanding the entire pesticide program.
19 MS. MULKEY: With regard to our update in a
20 minute, more or less, on worker risk and worker risk
21 assessment, there has been in this forum and in the CARAT
22 quite a lot of very strong stakeholder interest in more

1 attention, more detailed attention and more specific
2 attention to issues relating to estimates of worker risk,
3 the actuality of worker risk, means of worker risk
4 management issues, the whole range of those kinds of
5 things, and out of those requests -- actually, the
6 Deputy Administrator made a commitment that there would
7 be some increased stakeholder engagement around this
8 issue, and out of that commitment, along with your and
9 your counterparts' keen interest, we developed an idea to
10 try to do some kind of forum that would meet those
11 criteria.
12 We were mindful that our efforts in the past to
13 be more transparent and more comprehensive in our
14 dialogue had not met all the hopes and expectations, and
15 so we embarked this time first on a planning activity.
16 We invited a group that is drawn primarily from this but
17 also from CARAT, Cindy Baker, Melody Kawamoto, Richard
18 Finsky (phonetic), who's actually on neither but
19 specializes in research in this area, Lori Berger, Dan
20 Botts, Larry Ellworth, Sherry Davis and Al Jennings
21 convened with us. We spent a full -- almost a full day
22 and a subsequent conference call in an attempt to plan

1 this kind of thing.
2 What came out of it was the fact that we had
3 more than two days needed for such a forum and that the
4 topics were both -- were wide-ranging -- they had both
5 depth and breadth elements, and so we have basically
6 attempted to plan two such what we're calling workshops,
7 for lack of a better word, each about two days, the first
8 of which is dominated by but not exclusively focused on
9 OPP's approach to estimating worker risk, both handlers
10 and post-application exposure in fields, along with some
11 other topics that are related directly to measurement of
12 the risk of workers, including some portions of Dr.
13 Finsky's work and some new data development that's going
14 on in the industry and a new study that has been
15 sponsored over the last 10 or 12 years, so it's not very
16 new, but some newly emerging information from studies by
17 the National Cancer Institute.
18 There's a copy of that agenda in your folder.
19 The planning group is continuing to work toward the
20 second session, and so its agenda is not as refined, but
21 it's likely to include such things as what kind of
22 technological improvements can we identify and pursue

1 regarding worker protection; what kind of information can
2 we derive from epidemiological data, measurements of
3 worker body burden, all the -- sort of the science --
4 the medical/occupational health science of worker --
5 pesticide -- workers exposed to pesticides in fields;
6 and a range of other topics of keen importance, the
7 omission of which shouldn't signal anything in this
8 remark.
9 So, that group, the planning group, which has
10 worked very hard, is going to continue to work so that we
11 hopefully hit the mark with these two sessions. The
12 first one is October 29 and 30 in the D.C. area, so mark
13 your calendars. We hope to did I say gorge all the
14 information about how we do risk assessments that you
15 ever wanted to know, along with some other really
16 important and valuable information.
17 Erik?
18 MR. NICHOLSON: I appreciate the agency's
19 interest in pursuing these issues further, and I'm
20 heartened to hear about the second seminar. Frankly, the
21 second agenda is not as -- representing someone who
22 represents the most farm workers in the United States,

1 this agenda really doesn't get at very many of the issues
2 at all that we have in terms of worker risk, so I would
3 really encourage the agency to please not forget in
4 particular the issue of farm worker children.
5 I think the General Accounting Office study came
6 out several years ago, was very critical to the agency,
7 especially the pesticide program, obtain their oversight
8 of farmer worker children, specifically referring to
9 children who incur occupational exposure who are under 12
10 years old who are continuing to work in the fields.
11 That, among other issues, I think are critical to be
12 raised in this forum. I look forward to seeing the
13 agenda for the second meeting.
14 MS. MULKEY: And we welcome any input you have
15 to the planning for it. Thank you. Anybody else?
16 All right, let's -- Jim, do you have any
17 wrap-up of your segment?
18 MR. JONES: No, I don't.
19 MS. MULKEY: Well, we have a time challenge, but
20 it's not an insurmountable one, I think. You've probably
21 noticed that the agenda never planned a break for this
22 morning's session. Some of you are probably mildly

1 uncomfortable, literally, with that. I think we need to
2 do one, but equally, we really need not to have a full
3 break or we can't keep going. So, what I suggest is that
4 people take care only of the necessities, which I
5 understand to include coffee, and that we return
6 literally in ten minutes, 15 'til, to our seats so we can
7 cover these important issues.
8 **(A brief recess was taken.)**
9 MS. MULKEY: Thank you again for returning to
10 your seats. If you will model that behavior ahead of
11 your colleagues, we will actually succeed. Thank you,
12 Beth and Phil. We very much appreciate everybody's
13 attention to this.
14 This next segment I think many of you will find
15 extremely interesting. You do have a handout at your
16 seats. Don't spend too much energy reading forward. You
17 really do need to hear the verbal context setting.
18 This next topic is one that we have had a
19 request for and actually attempted to respond to pretty
20 much every other PPDC meeting, some version of we would
21 like to know how you're spending your money at EPA on
22 pesticides. We have attempted to answer it. We have

1 brought in the budget people. We have revealed the
2 budget numbers. And for whatever reason, we have managed
3 to choose a language and a format and a level of detail
4 for those presentations such that nobody ever went away
5 feeling they got the question answered, and it was -- I
6 assure you, it was never for any lack of intention on our
7 part to be as utterly transparent as we could be, but we
8 did sort of get it that we were not being able to convey
9 information about our resources in a way that was meeting
10 people's needs, and so we attempted two things that in
11 some ways were fundamentally different this time.
12 One is we attempted to get some feedback from
13 some of you and others who were interested in our program
14 at what I would call the macro level but whose needs were
15 not being met by our previous attempts and who could help
16 us understand what kind of information it was that was
17 desired and that would be in an accessible way. So, that
18 was one thing we did, and I very much appreciate the
19 folks, including Wesley Warren, who I believe is
20 president of NRDC -- I'm not sure of his title, but I
21 know he's the big gun, Jay Vroom, who is also a big gun,
22 Phil Klein and Allen James and Carolyn Brickney, who was

1 there by phone and Adam Goldberg. So, we had an
2 excellent group to help us figure out whether we've
3 gotten this right or right enough that it's a meaningful
4 exchange with you. So, I wanted to give you that
5 context.
6 The other thing -- and for this, I am hopeful
7 that everybody who is going to hear this session will
8 join us, so is there anybody out there -- outside we
9 need to push in here?
10 SPEAKER: (Inaudible.)
11 MS. MULKEY: Yeah, I noticed that, because this
12 next few remarks that I want to do for stage setting are
13 pretty critical to your understanding what this is and
14 isn't, so the last thing we need is for somebody to hear
15 the rest, not having heard this part.
16 Yeah, I can't whistle personally, so I need to
17 get one of those piercing types. Good line. You win the
18 prize for the best line of the day.
19 As you've picked up some hints from the colloquy
20 we've just had, EPA gets from Congress certain monies
21 that are in certain categories of the larger EPA budget,
22 and into those categories come monies for pesticides.

1 That, for those of you who are budget gurus, are in goal
2 three and -- all of goal three almost and a portion of
3 goal four, but EPA's pesticide program consists of
4 entities and work outside of Crystal City and the two
5 laboratories that we in OPP manage. The pesticide
6 program's budget includes monies that go to the -- that
7 is, the pesticide budget, pesticide work budget, includes
8 monies that go to the Office of Research & Development,
9 monies that go to the Office of General Counsel, monies
10 that are retained by the infrastructure of the agency to
11 pay our approximate pro rata share of the overhead and
12 operations of the agency, our administrator's office and
13 our budget office and all of the infrastructure that
14 supports not only the pesticide program but other parts
15 of the agency. There are enforcement monies which are
16 not in those two goals but which are dedicated to work
17 on, among many other things, the pesticide program and so
18 forth.
19 At the end of the day, there is -- and then it
20 comes to the -- our assistant administratorship, Steve
21 Johnson, and he then allocates it within that
22 organization. In that case, it's actually a very small

1 fraction that is taken for the operation of his office,
2 sort of our pro rata share, if you will, of Steve and
3 Adam and Susie and their immediate staff, and then the
4 remainder goes through to the Office of Pesticide
5 Programs.
6 The information we're going to supply today is
7 about the money that makes it across the river, if you
8 will, makes it to the Office of Pesticide Programs.
9 You'll get some indication of the fraction that does not
10 make it there, it's somewhere around 12 to 15 percent,
11 and that doesn't include a lot of the ORD money, but
12 that's sort of the money that is operational,
13 programmatic money. So, this information is about the
14 money that we have.
15 The money comes in certain colors, if you will,
16 as you will learn, basically three in our case. One is
17 called S&T, science and technology. It is money that can
18 only be used for certain narrow functions. In our case,
19 it's almost entirely the operation of our laboratories.
20 We have two laboratories.
21 There is the FIFRA fee money, and that money is
22 designated -- it's the maintenance fee money I guess is

1 what it was, and it sort of has a new name in the last
2 two appropriations, but it's money that is designed to
3 pay for certain things, and as you will learn, it goes to
4 pay for those things. It's essentially the salaries or
5 the -- to the extent it can cover them -- of about 200
6 people who work on re-registration.
7 Then finally, there is everything else. The
8 everything else money is the general appropriated funds,
9 and it is divided, as you will see, primarily between
10 money to pay the salaries of our people, and relative to
11 many EPA programs, we are a people-expensive program.
12 So, the overwhelming majority of the money we receive
13 goes to pay the salary, the over -- the benefits and
14 everything that goes with fully funding our people.
15 Then there is a final amount, and as you will
16 see, depending on which way you look at it, $30 or $40
17 million which is available to spend on things other than
18 merely salaries, and that's sort of the context of what
19 you're going to see and hear today.
20 Doug Weik is our budget person responsible for
21 what we call budget execution, I've always found that
22 sort of an amusing term, and he is very, very good at it,

1 and he assures that we not only spend our money in the,
2 you know, legally correct and proper way but that we're
3 smart, that we're not wasteful, that we monitor it, that
4 we know at all times where we are, that we spend it all,
5 which is very important, but that we not overspend, which
6 is also important. So, he is just I think the optimal
7 person to provide you with this information.
8 The slides he's using are numbered. They will
9 prompt questions in your minds. Please make notes on the
10 slides as you go along. If we -- we really need to go
11 through the whole thing in order to both make our
12 timetable and make the dialogue meaningful, but we will
13 have comment time.
14 We're going to run at least until noon and maybe
15 until 12:15 before our lunch break, and I think that will
16 make this session sufficiently comprehensive.
17 Doug?
18 MR. WEIK: Thank you, Marcia.
19 Okay, the first slide is just kind of laying out
20 what we'll be talking about. We're going to start with
21 just a very brief definition of some of the sorts of
22 funds. We'll move on to some of the historical trends.

1 Then, as you can see, we're going to delve into the 2001
2 year specifically, that's the last complete year that we
3 have, starting with major programs and working our way
4 down into some more specific views of some of the
5 registration, re-registration issues that may be of
6 interest.
7 Flipping to page 1, I won't spend much time on
8 the definitions. Authorizations just allow us to legally
9 receive funds. The key one here is the appropriation.
10 Without the appropriation, you are not allowed to spend
11 whatever money you may be authorized to spend. Jumping
12 down, you probably may find of interest the fact we have
13 a mixture of administrative funds that support other
14 areas of the program, not specifically directly science
15 reviews and things, such as training, supplies,
16 equipment, relatively small part of the budget, and then
17 the programmatic funds are the ones that support the
18 program activities, such as the risk assessments,
19 processing of registration applications.
20 Before we move on to looking at the resources, I
21 just wanted to make a note of what a full-time equivalent
22 or FTE, you are going to see this term, and what it

1 represents is 2088 hours. So, it doesn't always equate
2 to an on-board person. There's an example here showing
3 that if you had a work team of five people that worked
4 four hours a week all year long, that would only use a
5 little less than half of an FTE worth of the 2088 hours.
6 So, that's just to set the context.
7 Flipping over to page 2, Marcia's pretty well
8 covered this section. This kind of gives you a breakout
9 of our four major pots of money, if you will.
10 Environmental program management is by far the largest.
11 That's the one that Marcia referred to as covering about
12 everything else. It's a two-year appropriation. We can
13 use it for contracts, grants, salary, travel, just about
14 everything.
15 The S&T, science and technology appropriation,
16 is only $4 and a half million out of the total of $130.7.
17 Again, a two-year appropriation primarily dedicated to
18 the laboratories.
19 Marcia didn't really mention the STAG, the State
20 and Tribal Assistance Grants Program. This is a regional
21 program. We do have $13 million. Of that, virtually
22 everything goes right out to the states. We have about

1 $1.3 million that is sent out a little bit later out of
2 the headquarters operating plan, but through the year,
3 all this money goes straight out to the states and
4 regions.
5 The last thing is the FIFRA Revolving Fund,
6 which in 2001, we spent $16.8 million, all on salaries
7 and -- yes?
8 SPEAKER: Would it be appropriate just to ask a
9 couple of clarifying question?
10 The two-year appropriation reference for the
11 first two categories is -- can you explain that a little
12 bit more --
13 MR. WEIK: Sure, sure.
14 SPEAKER: -- and the -- for instance, the
15 $96.3 million for the EPM amount is an annualized amount
16 as opposed to whatever the two-year appropriation
17 designation is.
18 MR. WEIK: Correct, correct, that's correct.
19 Let's take EPM as an example, and since we're talking --
20 and that was another reason for using the 2001 year,
21 because the 2001 appropriation, this $96.3 million, was
22 actually available to us to spend throughout 2001 and

1 throughout 2002, and frequently we will refer to it in
2 the budget world as '01-'02 money, and that's the two
3 years that it's alive and we are allowed to use that
4 money.
5 The 2001 money will expire in about two weeks,
6 September 30th of this year, and we will no longer be
7 able to commit those funds for 2001. So, we're
8 virtually -- that's another reason we used this, because
9 we had virtually completed spending of the 2001-2002
10 dollars, and each year we get an annual appropriation
11 that will be, you know, roughly that same amount, so in
12 2002, we got another additional $96 or $97 million, and
13 that's available for expenditure during 2002 and 2003.
14 So, in any given year, you usually have two
15 years of EPM dollars that are available for spending, but
16 quite honestly, the first year they're available,
17 virtually all of them are committed. It's a very small
18 -- you know, less than 10 percent remain uncommitted
19 after the end of a fiscal year.
20 SPEAKER: So, a two-year appropriation
21 designation means that you just have more expenditure
22 flexibility over the use of that money and --

1 MR. WEIK: Right.
2 SPEAKER: -- you don't have the same kind of
3 pressure to have to sort of spend it or lose it at the
4 end of a given fiscal year. You've got more like two
5 years to do that.
6 MR. WEIK: Right, and it gives you a little
7 better planning horizon, and sometimes there are
8 circumstances that will prevent you from getting
9 something committed in a given time frame. Some of these
10 monies arrive with earmarks, they are designated for
11 certain things, and they will have to go through certain
12 vehicles to get committed and funded. So, it allows you
13 that flexibility to get all the money spent properly.
14 Now, and the other two, the no-year
15 appropriations, those monies do not expire. They are
16 usually re-issued -- you know, they go back and get
17 re-issued each year. It's not like we can just go and
18 roll them over and respend them. We will be given a
19 target that we use to spend at certain levels each year,
20 but the money does not expire.
21 For the FIFRA Revolving Fund, for example, for a
22 number of years when we first started, we would carry

1 balances over. We have now gotten to a point where we
2 are no longer carrying balances over, we're really on a
3 cash-and-carry basis, but if there is any money left
4 over, it just rolls over to the next year and is
5 available for spending.
6 Okay, we'll move on to number 3, and this is
7 just trying to break out the $130.7 million into some
8 general categories. As Marcia mentioned, nearly 60
9 percent of the headquarters funds go into salaries and
10 benefits. The next largest category are the (inaudible)
11 contracts and grants, and the $13 million, 10 percent
12 that goes right out is the state grant money. Then
13 smaller percentages go into our working capital fund, the
14 administrative expenses I mentioned earlier, and then
15 less than 1 percent for travel.
16 We will move on to the next slide, slide 4.
17 This just tries to present an historical picture of our
18 FTEs since 1980, and the shading represents the beginning
19 of the FIFRA Revolving Fund, 1989 and beyond, and it
20 shows you the breakdown between the appropriated funds
21 and the fee-supported FTEs.
22 Oh, I might -- yeah, move on to the next one.

1 This is really what has contributed to the fact that we
2 can only support the payroll out of the FIFRA Revolving
3 Fund. Since 1982, the average cost of salaries and
4 benefits have increased from less than $40,000 up to
5 nearly $100,000 this year, and these basically just
6 reflect the annual 3 to 4 percent increases in the GS
7 schedule.
8 On to the next. And a breakdown of a typical
9 FTE in 2002, base salary of $76,800 and then your
10 retirement and other benefits on top of that get the
11 subtotal for salary and benefits up to about the $100,000
12 level, and that's what's actually in the payroll account.
13 We have added another line here showing the working
14 capital fund. This is a significant amount of money that
15 we put into communications, computers, mainframe,
16 infrastructure support that's handled centrally by the
17 agency, and it amounts to about $6,300 per FTE for us in
18 2002.
19 The next one. Okay, this is starting to get
20 into how we have split out our FTEs into the major
21 program areas, and how we derived this data, we have a
22 time accounting information system, and our Science

1 Divisions and our Special Review and Registration
2 Divisions report into the system, so it gives us an idea
3 of how the hours are spent and the different categories.
4 We'll get into more detail on how the registration and
5 the re-registration break out, but it shows you roughly
6 an equal split between re-registration and registration,
7 with about 10 and 11 percent for field programs and
8 information and program management.
9 Slide number 8. Now we're going to look a
10 little more specifically at the registration FTEs: 326
11 of the FTEs were devoted to registration in 2001; 75
12 percent of those went to conventional pesticides, with 14
13 percent-plus to biopesticides, which includes microbials,
14 biochemicals, transgenics and pesticides in plants, and
15 10 percent to anti-microbials.
16 Slide number 4 -- I'm sorry, 9, yes, my number
17 is a little sketchy here. Looking at the conventional
18 pesticide part of registration, we estimate about 245 of
19 the FTEs went into support conventional pesticides, and
20 as you can see, about 25 percent of that went into either
21 fast track or nonfast track me-toos, and that would be
22 the registration of new or amending existing products,

1 and then another 25 percent to new AI and almost 20
2 percent into tolerances, with lesser percentages for the
3 other registration categories.
4 SPEAKER: Can I ask a clarifying question?
5 MR. WEIK: Sure.
6 SPEAKER: Does this also include, then, this is
7 the FTEs for the scientific review of data associated
8 with these various actions?
9 MR. WEIK: Yes.
10 SPEAKER: So, that 24.8 percent also includes
11 all the science reviews? Okay.
12 MR. WEIK: The science reviews going for new AI,
13 right, and there will be science reviews for some of the
14 other categories also.
15 SPEAKER: Okay.
16 MS. MULKEY: One thing that -- new AI overlap
17 some with tolerances and things -- and so does new uses,
18 so if you really look at -- if you distribute the
19 tolerance work between new AIs and new uses, you get a
20 sense of the total going to new registration activity for
21 the most part.
22 MR. WEIK: Right, right.

1 MS. MULKEY: I mean, that oversimplifies it,
2 but --
3 SPEAKER: Can you clarify that -- Marcia --
4 MS. MULKEY: Remember, this is registration of
5 conventionals.
6 SPEAKER: Right.
7 MS. MULKEY: So, the tolerance piece of the pie
8 is mostly about either new AIs or new uses.
9 SPEAKER: Okay, okay, that's what I thought --
10 MS. MULKEY: So, if you want to think about how
11 much is going to new AI and new uses, you really need all
12 three of those pieces of pie.
13 SPEAKER: Okay.
14 SPEAKER: So, if a science reviewer, if they
15 account it to a tolerance, then it goes to a tolerance.
16 If they're accounting it just to a new AI, then it goes
17 to a new AI.
18 MS. MULKEY: Right.
19 SPEAKER: So, it's just really how it's
20 accounting for it.
21 MS. MULKEY: Right.
22 MR. WEIK: It's really a reflection of how they

1 actually report it, the people that are doing the work,
2 yeah.
3 Moving on to slide number 10, this is just
4 looking at the biopesticides portion of the
5 registrations, and again, the new AIs and the two me-too
6 categories make up a significant portion. We do have a
7 fairly large other category, and in that we've -- that
8 includes such things as pre-application meetings, work
9 planning, policy development related to registration, PR
10 notices, efficacy, guidelines, such things as managing
11 joint reviews with Canada, California, NAFTA work, also
12 managing the public docket, maintaining the website,
13 addressing data compensation issues, just as some
14 examples, since it's a fairly large category, of what's
15 in the "other" application review category.
16 MS. MULKEY: There's a clarifying question.
17 MR. WEIK: I'm sorry.
18 SPEAKER: Is there a breakout or are you going
19 to discuss a breakout of how this -- within the
20 biopesticides, how it breaks out, like the transgenics or
21 the PIPs or the microbials or biochemicals? It would be
22 kind of interesting to know how much of that budget is

1 actually on the plan-incorporated pesticides, for
2 example.
3 MS. MULKEY: We don't have the data broken out
4 that way, and I don't think it's available to break out
5 that way using this methodology, which is deriving it
6 from the reporting -- the worker reporting. So, what
7 you have to do is get a -- sort of an informed judgment
8 estimate by the management team or something to -- to
9 get a handle on that.
10 MR. WEIK: I don't know if Kathleen has a sense
11 of that. I don't know, it seems like it's probably a
12 disproportionate amount, perhaps, on the
13 plan-incorporated pesticides.
14 MS. KNOX: We do think that probably in that
15 other application review category, particularly because
16 this was 2001, that a lot of those hours that were
17 reported did relate to the plan-incorporated protectants,
18 and that, again, is because we had several SAP meetings.
19 There were a lot of the activities that fall into that
20 other category going on with your biotech products that
21 year, but we really don't track that. We would have to
22 go back and do an individual-by-individual summation of

1 the year's worth of records, and I'm not sure that that
2 would be very useful.
3 MS. MULKEY: But there is no question that a
4 significant portion --
5 MS. KNOX: They are costly.
6 MS. MULKEY: -- of the work under biopesticides
7 is attributable to PIPs. I don't know --
8 disproportionate is in the eye of the consumer, if you
9 will, but a significant portion. I don't think there's
10 any question about that.
11 SPEAKER: Can I ask a quick question, and this
12 may -- it may be a dumb one, but why is other
13 application review for biopesticides so high versus --
14 SPEAKER: Yeah, good question.
15 SPEAKER: -- versus conventional?
16 MS. KNOX: Well, again, particularly for the
17 year 2001, where there were a whole lot of things going
18 on in the biotechnology arena, we did hold I think at
19 least three SAPs that year. They would be counted in
20 here and all the preparation for them. We do a lot more
21 pre-registration meetings with our registrants, a lot
22 more data requirement, particularly in the microbial

1 area, defining what the testing will be. The nature of
2 our pesticides is different from conventionals, so we do
3 a lot of -- a lot more of the kinds of things that fall
4 under this category.
5 SPEAKER: So, do you expect this or do you
6 believe that this may be an abnormally high number as you
7 get more comfortable with --
8 MS. KNOX: I'd really have to go back and look
9 at the year 2000 to find out whether 2001 was abnormally
10 high. Again, it could have been just because of the
11 biotech issues that we were dealing with in 2001.
12 MS. MULKEY: It's just a guess, but it's
13 entirely possible that the people filling out their
14 forms, working on these pesticides, sort of resorted to
15 the other category more readily than the people filling
16 out their forms working on the other pesticides. It
17 could be as simple as that, or it could be that they had
18 a disproportionate share of work that just wasn't easy to
19 categorize.
20 Remember, when you're talking about a fraction
21 of a 48 doing SAPs is a much bigger fraction of the total
22 than it is of the 245 or on the re-registration side.

1 MS. KNOX: John just reminded me, the reporting
2 form was designed for accounting reasons, and it was
3 designed for conventional chemicals. So, when the
4 Biopesticide Division was created, we sort of split off
5 some categories, but I think using the data for this
6 exercise, we need to go back and revisit that and make
7 sure that if we're going to use those data for this kind
8 of thing, we need to probably refine the form a little
9 bit more and make sure that we know a little bit better
10 that the people are putting down the categories that
11 really apply.
12 SPEAKER: I have a clarifying question about the
13 me-too designation. Are these just fast track and
14 non-fast track amendments as opposed to me-toos?
15 MR. WEIK: No, both, it's both amendments and
16 --
17 MS. KNOX: New products.
18 MR. WEIK: -- and new products.
19 SPEAKER: Right, so the idea that it's me-toos
20 is a bit of a misnomer as a category, correct?
21 MR. WEIK: It's adding the two together.
22 SPEAKER: Right.

1 MS. MULKEY: He's talking about amendment --
2 yeah.
3 MR. WEIK: I don't think it's misleading,
4 because they are me-toos in the sense that when they are
5 new products, they are identical to something that's
6 already out there. They are identical or substantially
7 similar in their formal construction. So, the point is
8 that they are thoroughly precedented decisions, and
9 whether they happen to be a new product or an amendment
10 to a previously registered product, the most important
11 thing that -- we thought, for purposes of these pie
12 charts -- was to distinguish the ones that did require
13 science review, in other words, the non-fast tracks, from
14 the ones that didn't, which were perfect matches for
15 something that didn't require any science review.
16 MS. MULKEY: But you're right, it's wholly new
17 products or amendments of products that might be added
18 use or a formulation or something.
19 SPEAKER: I just -- to me, "me-too" means
20 you're doing a new registration, getting a new
21 registration number for a me-too product, but I'm
22 assuming and you're confirming that in that fast track

1 and non-fast track, me-too slices -- that's also
2 amendments with data or without data.
3 MR. WEIK: That's correct.
4 SPEAKER: That's all.
5 MR. WEIK: That's correct.
6 Now to slide 11, this is the split-out of the
7 anti-microbial slice, and as you can see, the me-too
8 categories we were just talking about combined make up
9 nearly 80 percent of these, with the rest of it falling
10 out into the new AIs, new uses and other applications,
11 but very much so on the existing.
12 Number 12, now we're moving over to the
13 re-registration FTEs, approximately 320 of them, and it's
14 kind of a Pacman chart with the conventionals virtually
15 eating up the whole pie and 7 percent going to
16 anti-microbials and less than 1 percent to the
17 biopesticides.
18 Slide 13 gets into a little more detail on the
19 re-registration FTE distribution. Now, these are
20 categories that on our time accounting reporting, the
21 largest one is the current red production. This includes
22 such things as issuance of the re-registration

1 eligibility documents, the reds, information updates,
2 data reviews for the current fiscal year, reds, public
3 docket development. The next largest slice, product
4 re-registration, is a very busy part of it now that we're
5 in the waning years of re-registration. Then the DCIs in
6 red pipeline makes up the other significant portion of
7 the breakdown of the red re-registration FTE
8 distributions.
9 Okay, we are going to move over to the
10 non-payroll side now. Slide 14 is an historical trend
11 chart showing the non-payroll dollars. The big spike in
12 1989 is an influx of storage and disposal money we got
13 that was specifically earmarked, primarily I believe for
14 Dyna 7 (phonetic), 2-4-T Sovex (phonetic) works, so that
15 was not something that had an impact on the rest of the
16 program at all, but if you look at it, there really are
17 roughly three trends here.
18 You have got the pre-FIFRA 88 at lower levels,
19 and there was a bump-up with the passage of FIFRA 88, and
20 then another bump-up with the passage of FTPA in '96, and
21 then it's, you know, reasonably stable around those three
22 tiers.

1 Slide 15 is a breakout by major program activity
2 of those -- of just the headquarters and contract --
3 contracting grant funds, that's about $30 million. The
4 re-registration makes up about a third. The field
5 programs and communications, about a third.
6 Registration, a little less than a fourth of that, and
7 the rest is the information/program management slice.
8 Slide 16 -- yeah? Oh, I'm sorry.
9 SPEAKER: I actually want to ask a clarifying
10 question. When we say headquarters contract and grant,
11 we mean for within OPP.
12 MR. WEIK: Right.
13 SPEAKER: We are not including enforcement.
14 MR. WEIK: That's correct. This is OPP only, as
15 Marcia made clear earlier.
16 SPEAKER: Because there is a separate allocation
17 of money that runs through our Office of Enforcement.
18 MR. WEIK: This is only what we spend through
19 OPP, right. Thank you again.
20 Slide 16 splits out the large field program
21 slice into the general areas just to give you a better
22 flavor of where this money goes. Communications

1 outreach, certification and training, PSP has been
2 included here also, we have got a tribal program,
3 groundwater, worker protection, endangered species, and
4 this kind of gives you a feel for the field program slice
5 and communications.
6 SPEAKER: So, this is only over a couple of
7 divisions, then?
8 MR. WEIK: This -- right. It's primarily the
9 field enforcement --
10 SPEAKER: It's the field --
11 SPEAKER: Field PPD.
12 SPEAKER: -- field PPD and IRSD. You see the
13 FOIA dockets and --
14 SPEAKER: Okay, okay.
15 MR. WEIK: So, it's pulling in from some of
16 those, but it's --
17 SPEAKER: Primarily just this.
18 MR. WEIK: Right, right.
19 Slide 17 shows the breakout of the registration
20 contracting grant dollars. As you can see, nearly --
21 almost 60 percent goes to data review. Information
22 management's about a fifth, and guidelines and methods,

1 less than 10 percent. Data acquisition, a couple of
2 percentage points, and other is 11 percent. In the other
3 category here, we've got some intern programs. They've
4 got a senior environmental employee program, and we tried
5 to attribute those to registration and re-registration,
6 but we weren't comfortable splitting that below that
7 category, so that's what makes up a large part of that
8 other.
9 SPEAKER: Do you have a --
10 MS. MULKEY: So you understand that, those are
11 essentially people who come and work in our midst,
12 through a grant program, senior employees or interns.
13 So, in effect, they are more like salary dollars than
14 they are like grants and contracts dollars.
15 SPEAKER: So, these aren't contract reviewers?
16 MS. MULKEY: No, not the 11 --
17 MR. WEIK: Not the other. I was talking about
18 the other. No, the reviewers are in data review.
19 SPEAKER: Would you have this -- and I don't
20 need it right now, but can you break this out in terms of
21 HED reviews, registration reviews?
22 MR. WEIK: We have it by division.

1 MS. MULKEY: You mean HED versus EFED?
2 SPEAKER: Right, right, right.
3 SPEAKER: Right.
4 MR. WEIK: Right, I mean, it can be broken out
5 by contracts, by division, right.
6 Slide 18 is the re-registration portion of the
7 contract grants, about $10 million, and data review makes
8 up more than half of all the re-registration contract
9 dollars. A significant portion goes to information
10 management. A lot of the tracking of the data and things
11 is supported by our information management, and again,
12 the data acquisition guidelines and other fall out about
13 the same percentages as they did in registration.
14 Right, right, as John pointed out, data
15 acquisition is a little bit larger, because we purchased
16 usage data more for the re-registration.
17 That's the formal slides, and we have allowed
18 some time for further discussion.
19 MS. MULKEY: Yeah, all right. Okay, Larry?
20 MR. ELWORTH: Well, first of all, thank you very
21 much for doing this. I mean, we have been talking about
22 this a lot. This is nicely done, and I appreciate the

1 information.

2 Two quick questions. One is, how do you use

3 this in budgeting, or does this have any -- does this

4 kind of information have a use in budgeting or what other

5 ways do you use it in management?

6 MS. MULKEY: Well, we have an operating plan

7 each year in which we make decisions about sort of large

8 categories, registration, re-registration and so forth,

9 and so obviously we plan so that this is what comes out

10 at the end.

11 Our planning process is a combination of the

12 agency operating plan and internal decision-making that

13 is at a somewhat more particularized level, which is --

14 on FTE doesn't tend to involve major movement. On

15 dollars, a little bit more from year to year,

16 decision-making about where the dollars need to go, but

17 we do quite a detailed amount of planning that sort of

18 leads to having this kind of result, and actually at a

19 higher resolution than this.

20 MR. ELWORTH: Also, I would be interested in

21 looking at slide 11 on anti-microbials for 2002, given

22 what you folks were doing with the anthrax stuff, it

1 probably is -- is another one of those Pacman pie
2 charts --
3 MS. MULKEY: Well, on 2002, you would have seen
4 a big Section 18 section there.
5 MR. ELWORTH: Oh, really? Right, right.
6 MS. MULKEY: Which you didn't see in 2001 at
7 all, you did on registration. So, that would be an
8 example of a very significant change, but that's unusual.
9 MR. ELWORTH: Right, right.
10 MS. MULKEY: These things are pretty -- the
11 macro is very stable from year to year, the division
12 between registration and re-registration, for example.
13 Even at this level of resolution, it's pretty stable from
14 year to year. You'll see trends. You heard some
15 regarding product re-registration growing and -- but
16 that is an example of one where you would have seen a
17 pretty meaningful shift.
18 MR. ELWORTH: Would it be possible at some point
19 to see the data review on contracts broken out, I mean
20 -- by HED versus -- on 17 and 18? Right.
21 MS. MULKEY: You're talking about within
22 registration and/or re-registration, broken out --

1 MR. ELWORTH: On slides 17 and 18 where you had
2 the contract for data review --
3 MS. MULKEY: And you want it broken basically by
4 support of the HED work versus EFED work?
5 MR. ELWORTH: Yeah, and I don't want to give you
6 a whole lot -- I'm just generally interested, if it's
7 --
8 MS. MULKEY: That's probably doable.
9 MR. ELWORTH: I'd be interested. Thanks.
10 MS. MULKEY: Yeah. You would want to look at
11 the split for re-registration and registration, because
12 they may be making different choices about FTE versus
13 contract approach.
14 MR. ELWORTH: That's a good point.
15 MS. MULKEY: Jose?
16 DR. AMADOR: My question is related to, you
17 know, his question on budgeting, how you use this
18 information. The way I see it, in budgeting, in how much
19 money you actually get, there's four forces that come
20 into play here, right? One is the OPP, what you plan and
21 you decide you're going to need. Then that has to mesh
22 with the agency, with what the agency thinks, you know,

1 you're going to have. Then the administration I guess
2 decides, you know, how much they're going to go forward.
3 Then Congress decides.
4 How do you work all those four things into --
5 what is the play there?
6 MS. MULKEY: Whoa.
7 DR. AMADOR: And which one is --
8 MS. MULKEY: I mean, at the risk of seeming to
9 be unresponsive, we really did want to sort of keep the
10 scope of this dialogue today to the expenditure side and
11 OPP specifically. Now, I'll try to make at least a broad
12 brush answer to your question, but this issue -- you
13 know, there is budget planning. There's everything that
14 wraps up to the President's budget, and that's -- your
15 questions seem to go to that issue, which is how does the
16 Executive Branch develop the Government that the
17 President reports to the Congress? And you're right,
18 there's initially an internal to the AAship, which we
19 include our regions and we involve the states and some of
20 our sort of customers and partners like OECA and ORD, and
21 we develop an approach for the internal dialogue.
22 Then there's the agency-wide dialogue, in which

1 the administrator makes some choices about priorities,
2 basically what kind of things are going to grow, what
3 kind of things are going to shrink and what the total --
4 they're given a mark by OMB. So, she's not allowed to
5 just pick an amount of money and ask for it. So, within
6 that mark, she then makes agency-wide decisions. That
7 then goes to OMB. The Executive Branch -- OMB on behalf
8 of the President and the Executive Branch develops a
9 package for the entire federal budget. So, there are
10 trade-offs made at that level.
11 Then the budget is submitted to the Congress,
12 it's the President's budget, and the Congress just passes
13 it. No, the Congress obviously makes decisions about
14 what to actually appropriate, and I mean, how do we do
15 all that? By a series of annual exercises that involve
16 all of the key players, the green eye shade types and the
17 macro programmatic types.
18 (End tape 2-A.)
19 MS. MULKEY: And everybody in between.
20 DR. AMADOR: Yeah.
21 MS. MULKEY: Okay? I mean, that's really the
22 best I can do with the question for this forum.

1 DR. AMADOR: And that really goes on year-round,
2 right?
3 MS. MULKEY: Every year there's a cycle and a
4 season by which it goes on, and of course, it builds on
5 previous years. I mean, things don't just sort of start
6 in a vacuum.
7 DR. AMADOR: The slide that you showed with the
8 three different areas, that's very illustrative of what
9 -- you know, what goes on, you know, the FIFRA time, then
10 what happened after FIFRA, then what happened after FQPA.
11 You can really see the levels there and how --
12 MS. MULKEY: If you look at the slide on number
13 of FTEs and the slide on dollars, that really gives you a
14 sense of what scale of program we have, what kind of
15 change-over time, degree of stability.
16 DR. AMADOR: Are these real dollars or are these
17 dollars for every year, right?
18 MS. MULKEY: These are -- they are --
19 MR. WEIK: They're not adjusted.
20 DR. AMADOR: They are not adjusted for
21 inflation.
22 MS. MULKEY: They are not adjusted. They are

1 absolute dollars.
2 MR. WEIK: Right.
3 DR. AMADOR: The fact that from '97 to 2000
4 higher in real dollars compared to pre-FIFRA, there may
5 not be that much difference.
6 MR. WEIK: That's true.
7 MS. MULKEY: Well, especially when you have some
8 big inflation years in there.
9 MR. WEIK: That's true.
10 DR. AMADOR: Thanks.
11 MS. MULKEY: I believe Stephanie had her card
12 up, and then I will come back over here. I'm really --
13 let me get my classes on. Lori I was looking at and
14 seeing S T E P and trying to put -- Steve had his card
15 up. My apologies.
16 STEVE: Could you go back to I think it's slide
17 7?
18 MR. WEIK: Which is --
19 STEVE: We talked about the working capital fund
20 of $6,300 per FTE. Could you explain that again?
21 Shouldn't that be in a capital account or -- that's 6,
22 sorry.

1 MS. MULKEY: It's a term of art that EPA uses.
2 Doug, why don't you explain the working capital fund.
3 MR. WEIK: Yeah, I think it was about three or
4 four years ago, they established the working capital
5 fund. I think EPA is one of several agencies that was an
6 initial pilot, and it's like a revolving fund. It's to
7 try to support all of our communications, postage, such
8 things as desktops for all our computer desktops, the
9 LAN, our local area network, all of these kind of
10 infrastructure communications, computer type of things,
11 and it -- in 2001, I think it was about $5.2 or $5.3
12 million that OPP had to put in as our share to support
13 that, and that's what made up that $6,300 per FTE.
14 MS. MULKEY: Let me try and add a little bit to
15 that. There's overhead, as I explained, the agency takes
16 some things off for overhead. A portion of what used to
17 be treated as overhead is now being managed by the agency
18 by setting up that function but funding it by the
19 purchase, buying into it, of the various customers for
20 that subset of overhead. So, we in effect have to either
21 go out on our own with our own money and buy these
22 functions, some of which are not really -- you can't.

1 MR. WEIK: We can't, right.
2 MS. MULKEY: Or we have to pay the price that
3 the agency is charging us to get those functions
4 performed. So, we, and I expect the entire rest of the
5 agency, pays the per capita cost to the suppliers of that
6 subset of overhead in order to get it. It's just a
7 different way of keeping the overhead books.
8 SPEAKER: Okay, thank you.
9 MS. MULKEY: Now we will come back over here to
10 Erik, now that I've got my glasses on.
11 MR. NICHOLSON: I was wondering if you've --
12 have you done a careful analysis of roughly what
13 percentage of the cost of reviews and re-registration
14 reviews is paid for by the registrant fees as opposed to
15 comes out of, you know, general revenue?
16 MS. MULKEY: Yeah, why don't you put the chart
17 --
18 MR. NICHOLSON: I saw the general overview
19 numbers, but do you have that on --
20 MS. MULKEY: Well, those fees are assigned to
21 people working on fast track and re-registration, and for
22 a while they paid the salaries and benefits --

1 associated benefits for 200 people. Now they pay it for
2 --
3 MR. WEIK: It's probably closer to about 170
4 we're able to support.
5 MS. MULKEY: 170.
6 MR. WEIK: Just because of the cost.
7 MS. MULKEY: Because of the cost, and those
8 people are all working on re-registration and/or fast
9 track.
10 MR. NICHOLSON: But you have other people
11 working on that as well, presumably.
12 MS. MULKEY: Well, if you look at the numbers on
13 FTE -- put up the one on re-registration, for example.
14 MR. WEIK: Yeah, where is that?
15 SPEAKER: (Inaudible) where we have got 38
16 percent of 833 --
17 MS. MULKEY: Well, you have got one that
18 actually has the number on it.
19 SPEAKER: (Inaudible.)
20 MS. MULKEY: If you look at the chart, 320 FTEs
21 --
22 MR. NICHOLSON: I was kind of doing the mental

1 math, but it seems like it's a -- what's the ballpark,
2 20 percent, 25 percent?
3 MS. MULKEY: Well, it looks like it's closer to
4 maybe -- but not all 170 are working on re-registration,
5 because some are working on fast track, so that's about
6 --
7 MR. WEIK: Traditionally, when FIFRA 88 passed,
8 it was set up so it was supposed to be roughly split
9 between the two appropriated versus fees, and for some
10 years it ran about 50/50, would waiver between 51/49,
11 either way. Now, because we don't have enough fees to
12 cover, I think the appropriated portion has, you know,
13 moved up into the 55, you know, 56 range, and --
14 MS. MULKEY: Probably higher than that.
15 MR. WEIK: And it's getting higher each year.
16 MR. NICHOLSON: I was trying to do the mental
17 math, and I don't think you can do it from the stuff
18 that's here.
19 MR. WEIK: Right, right.
20 MS. MULKEY: Well, a very crude estimate would
21 be subtracting 17 -- I mean, what portion is 170 of 320?
22 MR. WEIK: Right, right, but since the funds are

1 interchangeable, I mean, we can use appropriated or FIFRA
2 funds, we don't even really look at the color of the
3 money other than we -- the FIFRA funds we always make
4 sure that we are looking at folks who have reported
5 they're working on re-registration. We have to make sure
6 that they -- the fee monies support that, but other than
7 that, I mean, it doesn't really matter and we don't try
8 to send fee monies to one division versus another or
9 anything like that. We just try to --
10 MR. NICHOLSON: I just think it would be useful
11 for this committee and others to see EPA's actual numbers
12 on that, what percentage over time has gone, you know, of
13 the fee has been paid for by fees as opposed to by
14 general revenue.
15 MS. MULKEY: Contracts and grants just -- I
16 think we can do that calculation. Doug can do it, just
17 add up the cost of the FTE and the cost of the contracts
18 and grants, but because of fast track, that confuses it a
19 little bit.
20 MR. NICHOLSON: There are a lot of
21 complications. I don't think it's -- you can't just sit
22 and look at this, I don't think, and answer the question.

1 MS. MULKEY: Right, right.

2 MR. NICHOLSON: My other question is, I thought
3 this was really useful. I'm wondering if perhaps we
4 could get something -- Burleson, whether there might be
5 an opportunity to get something like this from USDA, in
6 particular looking at what percentage of USDA's funds go
7 to SARA (phonetic) and to various pesticide-related
8 activities, just because I think it would be really
9 interesting for us in viewing how the money is being
10 spent over at USDA. I don't know if you guys have ever
11 done that kind of presentation.

12 SPEAKER: There are various cuts that are given
13 looking at some of the program-related areas. The
14 problem is is that as you start getting into the details,
15 as with most of the accounting systems, they're set up
16 primarily for management of either program areas but not
17 necessarily subsets of the program areas, and so it's
18 difficult to cut out some of the details, to split them
19 out rather, but there are aspects of that that are
20 ongoing.

21 MR. NICHOLSON: Well, do you have, for example,
22 estimates of how much of the USDA funding is going

1 towards AIPM/SARA/those -- whatever we're calling it
2 these days versus other expenditures? I'm assuming
3 you've already done this. I --
4 SPEAKER: Personally, I do not. Yes, there are
5 estimates of those within each of the mission areas, and
6 part of it would be a matter of collecting it and pulling
7 it in, so...
8 MR. NICHOLSON: I at least think it would be
9 very interesting for this committee to at some point hear
10 about that, because I know a lot of the dialogue between
11 EPA and USDA is specifically on these issues, and it
12 would be really interesting to see some kind of
13 information about that. Maybe it is a CARAT issue, I
14 just heard somebody say that over there, but it does seem
15 like it would be very useful information.
16 MS. MULKEY: You know, most parts of EPA would
17 have difficulty providing these kind of pie charts,
18 because they don't have time accounting systems for their
19 workers. Now, the dollar ones, grants and contracts, you
20 can -- everybody in EPA could do with very good
21 precision, but the ones that -- the FTE part, time and
22 accounting systems are -- we're sort of unusual at EPA

1 in having it. Now, the Super Fund program has them.
2 Warren?
3 DR. STICKLE: I really had two questions. If
4 you go back to chart number 2, it breaks out the amount
5 of dollars that were put into the revolving fund,
6 realizing that the monies come from two different sources
7 there, maintenance fees on one hand and also the
8 tolerance fees on the other, also realizing that some
9 years you raise more money than you're allocated and
10 sometimes you raise less, that it goes up and down over
11 the years. It would be interesting to see a breakout of
12 how much money's been collected in maintenance fees and
13 how much money has been collected in tolerance fees over
14 the years.
15 MR. WEIK: Over the -- I don't have it for over
16 the years, but in 2001, we collected $15.4 million in
17 maintenance fees and $1.4 million in tolerance fees, and
18 you'll notice we actually spent more or about -- I'm
19 sorry, that was the -- that was just about right on,
20 okay. So, basically we were in a cash-and-carry
21 situation. That's virtually what we spent.
22 DR. STICKLE: Well, and the number of

1 maintenance fees has gone up and down over the years, and
2 in 2001, for example, it was $14 million. So, really you
3 were able to collect $15.4 million of that --
4 MR. WEIK: I'm sorry, I'm sorry, we collected
5 -- yeah, I misread my note here. We collected $15.4
6 million in total, $14 million maintenance fees, $1.4
7 million tolerance. I was misreading my note here.
8 DR. STICKLE: That doesn't get to 16.8.
9 MR. WEIK: That's right. So, we had a little
10 bit of a carryover going into 2001.
11 MS. MULKEY: We were spending previously
12 collected --
13 DR. STICKLE: I don't understand that. See,
14 that's the point I was trying to get to.
15 MR. WEIK: Yeah, 2001 was probably the last year
16 we were able to carry any kind of substantial amount from
17 a previous year.
18 DR. STICKLE: It would be worthwhile if it was
19 actually broken out on a year basis just to see the ebb
20 and flow of how those finance fees are collected.
21 MS. MULKEY: I think it's all ebbed.
22 DR. STICKLE: But it is -- but in the very

1 beginning, it was -- you were collecting less than you
2 were supposed to, so...
3 The second question I have deals with chart
4 number 9, and on the conventional pesticides, you break
5 out the amount of inert clearances and work done on
6 inerts, but on the next two charts, for biopesticides and
7 for anti-microbials, there is in breakout on costs for
8 inerts, and I was just trying to get a better handle on
9 the total amount of monies spent on inerts, and that was
10 not reflected -- it's probably buried in there
11 someplace, but I wondered if we could clarify that.
12 MS. MULKEY: Well, remember that what drives
13 this is what people reported on their time sheets.
14 DR. STICKLE: Right.
15 MS. MULKEY: For starters, but most of the inert
16 work is done in the Registration Division.
17 DR. STICKLE: Right, I understand.
18 MS. MULKEY: So, in all likelihood, if they were
19 doing inert work on a chemical that was an anti-microbial
20 chemical, it was showing up in this conventional category
21 under inerts, would be my guess.
22 MR. WEIK: Or those two divisions just were not

1 reporting work on --
2 MS. MULKEY: Right, that they were reporting it
3 some other way. It's either a difference in reporting
4 --
5 DR. STICKLE: Right, right, I understand.
6 SPEAKER: (Inaudible.)
7 MS. MULKEY: But a lot of the inerts cut across
8 chemical classes, and most of that work is done in RD, so
9 it's probably most of the work done on inerts anywhere is
10 showing up on this one pie chart.
11 Julie?
12 MS. SPAGNOLI: A lot of work has been done over
13 the years on trying to -- like the rejection rate
14 analysis and streamlining efforts and different things to
15 try to I guess reduce cycles and increase efficiency.
16 Has there been any analysis done to look at, you know,
17 like kind of the numbers of actions versus the FTE
18 equivalents put to that, are we seeing a reduction in,
19 let's say, the amount of hours or FTEs that go into, you
20 know, any -- like per fast track action or per new
21 registration, just to see, are we seeing a trend in some
22 kind of increase maybe in efficiency due to some of

1 these -- I guess like trying to reduce cycles and reduce
2 rejections?
3 MR. WEIK: It's been a number of years since
4 we've done a real systematic analysis along those lines,
5 probably -- actually, it was pre-FQPA for certain --
6 SPEAKER: '94.
7 MR. WEIK: -- and a lot of that work was done
8 specifically around the beginning of the creation of the
9 Anti-Microbials Division, because you're trying to figure
10 out how large the division ought to be, but it's been
11 pre-FQPA since we have done something along those lines.
12 MS. MULKEY: If you had enough confidence in
13 these data and you produced them year to year -- and
14 remember, these data are derived by the time and
15 accounting system, and that is the FTE data as opposed to
16 the other dollars. Then you obviously could overlay them
17 with production.
18 The problem is that a year's outputs are not
19 necessarily the same as that year's input. This measures
20 inputs in that year. Now, for fast tracks, probably
21 matching it with the same year would work very well.
22 MS. SPAGNOLI: Or if you were going to look for

1 trends.

2 MS. MULKEY: Even for me-toos, but I think you

3 probably could derive, at sort of a crude level, some

4 sense of how much you're spending for how many outputs.

5 MS. SPAGNOLI: I think just to see are we seeing

6 some positive impacts or --

7 MS. MULKEY: I will tell you this, new use

8 outputs are up dramatically, and new use inputs are

9 pretty stable, so there's one where I think there's not

10 much question.

11 SPEAKER: (Inaudible) Section 18s are very

12 clearly the efficiency gains have been dramatic in the

13 last five years.

14 MS. MULKEY: I mean, you can sort of see that

15 without much further analysis.

16 Jay?

17 MR. VROOM: I'd like to echo the comments that

18 several people like Erik have made, that I think this is

19 -- represents a lot of forward progress and is serving

20 the needs of -- kind of the larger interests that many

21 of us are engaged in forward looking on, you know, how to

22 advocate that the Congress continue appropriations as

1 well as wrestling these various difficult fee issues.
2 One of the things that occurs to me is that the
3 best detail here that feels to me like it's new and
4 comprehensive is embedded in these pie charts, and what
5 seems to be lacking to me, though, is any kind of
6 historic perspective, in other words, they are one-year
7 snapshots in a vacuum, and I would ask that you get us
8 comparative prior year and '03 budget projection parallel
9 pie charts for each one of these.
10 I don't know when you're going to close FY '02,
11 I mean the fiscal year ends September 30, so when do you
12 think reasonably you could give at least a reasonable
13 forecast, comparative detail, for each of these pie
14 charts for FY '02 do you think?
15 MS. MULKEY: Doug, do you have a sense of that?
16 MR. WEIK: Well, they close what they call the
17 13th month or whatever around the 4th of -- no, it would
18 be about the 4th of November, it's about 30 days
19 afterwards. So, I mean, we would have some figures at
20 that point. Obviously, since the 2002 appropriation will
21 still be alive all through 2003, there will be further
22 spending going on, and those numbers would change

1 somewhat, but probably we'd have 9 -- at least 90-plus
2 percent spent, probably higher this year, because we seem
3 to be more strapped.
4 MS. MULKEY: Well, the FTE part would be very
5 -- the FTE -- how about just the FTE piece of it, the
6 piece that's dependent on the TIAAs?
7 MR. WEIK: That would probably be about four
8 weeks also, because --
9 MR. VROOM: Because the sooner we have that for,
10 you know, our fees working group, whether or not it's '02
11 accurate or just the '99 and '00 so that we have some
12 kind of perspective just to get a sense of the
13 comparative trend lines in some of these accounts I think
14 will help us get a better feel for driving down detail
15 around advocating both resource appropriations and fee
16 decisions the Congress will be looking at hopefully very
17 soon.
18 MS. MULKEY: You are putting us slightly -- so,
19 we will be happy to do this in the interest of
20 transparency.
21 MR. VROOM: Right. On the working capital fund
22 issue, Doug, you mentioned that EPA is one of several

1 federal government departments that have switched to this
2 or been either told by OMB to switch to this kind of cost
3 accounting.
4 MR. WEIK: The capital funds?
5 MR. VROOM: Yeah.
6 MR. WEIK: I don't know if we were necessarily
7 told. I think we were -- officially we volunteered, but
8 we probably were told.
9 MR. VROOM: What are the other agencies, and
10 have you done any comparison in terms of, you know, the
11 benefit or --
12 MR. WEIK: See, I have -- we really have not.
13 It's centrally run through EPA. They may have some
14 things -- it's actually its own enterprise really,
15 supposedly a self-supporting group, the working capital
16 fund.
17 MR. VROOM: So, do you serve on an agency-wide
18 committee that oversights this or is this a black hole in
19 the administration.
20 MR. WEIK: I believe there is a representative
21 on my staff that participates and there is an executive
22 committee that oversees it.

1 MR. VROOM: So, 4 percent or $6,300 per FTE for
2 the FY '01 that we're looking at here, how does that
3 compare to FY '00 or '02? Do you have any --
4 MR. WEIK: It's staying pretty steady. The
5 dollar amount itself has been growing slightly, so if
6 anything, it may be inching up a little bit, and I think
7 that's just -- you know, it's supporting staff down
8 there as well as the systems themselves. So, I mean,
9 it's probably a reflection just of their costs kind of
10 inching up a little bit. I think it was 5.2 or 3 million
11 in '01. We are looking at probably $5 and a half million
12 for '02.
13 MR. VROOM: Yeah. So, it's only $5 million, but
14 I would think, Erik, you, Wesley, Carolyn and I and
15 others that are working on this fee initiative with Steve
16 probably would be interested in a lot more comparative
17 kind of detail, because that's, you know, $5 million is
18 real money in the context of what we're trying to get at
19 here.
20 MS. MULKEY: But remember, Jay, it's just a
21 portion of what is overhead, and the rest of it doesn't
22 show up in our budget at all, because it never gets

1 there.

2 MR. VROOM: The $5 million does, though.

3 MS. MULKEY: The $5 million does, but I'm saying

4 it's just a portion of the total agency overhead.

5 MR. VROOM: Yes, but then there's another 2 and

6 a half percent for administrative expenses, right, if I'm

7 understanding --

8 MR. WEIK: That's correct.

9 MR. VROOM: -- that slice on slide number 3.

10 MR. WEIK: That's correct.

11 MR. VROOM: So I mean there's another piece that

12 agency overhead, you know, is carving out.

13 MS. MULKEY: That's our overhead, though.

14 That's our overhead.

15 MR. VROOM: That's yours.

16 MR. WEIK: That's our training, our furniture,

17 supplies.

18 MS. MULKEY: Everything else except --

19 MR. VROOM: So, the only money going to the

20 administrator's office is the 4 percent.

21 MS. MULKEY: Well, going back to some other

22 fraction of the agency. The administrator's -- the

1 operation of the administrator's office is not included
2 in the working capital fund.
3 MR. VROOM: Okay.
4 MS. MULKEY: It -- that's why I'm cautioning
5 you. It has certain functions in it --
6 SPEAKER: Telecommunications, we would have to
7 pay for our own phone system if we were not paying into
8 this, which would not be cheap. We would have to pay for
9 our own LAN system if we were not paying into this, those
10 kinds of things.
11 MS. MULKEY: But it's a subset of agency-paid
12 overhead, and whatever's in it is in it, and even
13 comparing the other agencies, you would have to first
14 find out what did they put into that function?
15 MR. VROOM: True.
16 MS. MULKEY: So, that's just the caution. I
17 mean, it's relevant, but you want to be sure that -- if
18 what you're thinking about is overhead -- agency
19 overhead, then that's a piece of it, and so is the piece
20 that never gets to us.
21 MR. VROOM: Yeah, okay.
22 SPEAKER: (Inaudible.)

1 MS. MULKEY: Right.
2 SPEAKER: The working capital fund, $6,300,
3 comes to us and then we get it back.
4 SPEAKER: That's logical.
5 MR. VROOM: On the slides, I think it's 12 and
6 13 -- no, 11 and 12, the pie charts that talk about
7 re-registration -- 12 and 13, re-registration, FTE
8 distribution. Anyway, the reference to 320 FTEs, most of
9 what we've been operating off of was the assumptions that
10 200 FTEs are paid for out of -- by the maintenance fees,
11 so of the other 120 FTEs, are they funded, then going
12 back to slide 2, out of EPM or science and technology
13 account or both? How do you make those allocations?
14 MS. MULKEY: First of all, as we said earlier
15 when talking to Erik, it's closer to 170 whose salaries
16 can be paid. The rest are EPM --
17 MR. WEIK: And there are some S&T where the labs
18 report that they're --
19 MS. MULKEY: A few, but not much.
20 MR. WEIK: -- that they're supporting
21 re-registration. Again, it's based on how they report
22 their --

1 MS. MULKEY: Right.
2 MR. VROOM: So, you are going to work at trying
3 to give us more of that kind of detail then, right?
4 Okay.
5 MS. MULKEY: The specific question of the
6 fraction of re-registration and fast track --
7 MR. VROOM: Right.
8 MS. MULKEY: -- that are paid with fees and the
9 fraction that are paid with appropriated funds, I mean
10 that's essentially the question.
11 MR. VROOM: Yeah, right.
12 Another issue that's come up as we're looking at
13 the maintenance fee question for the new fiscal year is
14 the oversight of some amount of charge for rent that
15 hadn't been accommodated in FY '02, I forget how much it
16 was, but it's some millions of dollars --
17 MS. MULKEY: For the labs, is that --
18 MR. WEIK: No, no, that's the OARM piece that is
19 taken off. That's the agency overhead equivalent coming
20 out of the FIFRA fund.
21 MS. MULKEY: Oh.
22 MR. WEIK: About $1.9 million a year.

1 MS. MULKEY: Doug can explain that.
2 MR. WEIK: That would never come to us. It was
3 like, you know, you'd collect so many fees, and then
4 there would be about $1.8, $1.9 million would go toward
5 supporting those FTEs. Again, this would be the
6 equivalent of the agency overhead we don't see in the EPM
7 side.
8 MR. VROOM: And this attributed to rent?
9 MR. WEIK: Largely to rent, goes into the office
10 of OARM, I think it's the administrative resources
11 management group that handles the leasing of the
12 buildings and that type of thing.
13 MR. VROOM: So, can you get us a slide that
14 would sort of capture that, then? That's something new
15 for FY '02.
16 MR. WEIK: No.
17 MR. VROOM: No?
18 MR. WEIK: No, it's been going on ever since the
19 fund was initiated.
20 MR. VROOM: Okay. So, where is that -- in the
21 slides that we've got here --
22 MR. WEIK: It's not money that we see. It never

1 comes to us, and I don't even know how -- it goes -- I
2 know the amount after the fact. We will get a report
3 from the Comptroller's Office, how much was spent, but
4 there's no way that I see it during the year or anything
5 like that.
6 MS. MULKEY: Just in the interest of keeping
7 this within the scope of what we brought, for things that
8 don't come through to OPP, let us take it back to Steve's
9 budget office and express your interest in a better
10 understanding of that, okay?
11 MR. VROOM: Okay, but it is material here to the
12 issue.
13 MS. MULKEY: To your issue, absolutely.
14 MR. VROOM: Let's see, my last question, just as
15 an example, we talked yesterday about cumulative risk
16 assessment and the Life Line cumulative risk software
17 development, which was done pretty much with -- by
18 outside contractors. Where will that money be? How much
19 is it over the string of years that it's been in process?
20 And have you spent the last contract dollars on Life
21 Line, or is it continuing, et cetera?
22 MR. WEIK: I believe it falls under the

1 guidelines and methods slice is where that is picked up.
2 The -- and I'm not sure what the status of --
3 MS. MULKEY: On any particular investment, we
4 can give you very precise accounting. So, if Life Line
5 is what you're interested in --
6 MR. VROOM: Yeah, specifically I am, but I'm
7 also interested in sort of as an example context here, so
8 that's great.
9 MS. MULKEY: If you are interested in what
10 fraction is going for that kind of thing, in '01 it was
11 this 6 percent here, and it was a comparable number in
12 registration, and some of that's because some of this
13 work is for both.
14 MR. VROOM: How do you make that decision?
15 MS. MULKEY: Well, we -- this is -- was our
16 attempt, remember, to be transparent about what we
17 actually spent. When we go and buy a Life Line, we don't
18 see, all right, what fraction of this are we buying for
19 re-registration, and what fraction are we buying for
20 registration?
21 MR. VROOM: Um-hum.
22 MS. MULKEY: So, you don't buy it --

1 MR. VROOM: You say you don't do that?
2 MS. MULKEY: No, you don't buy it asking
3 yourself that question. You buy it because you have a
4 need to have a capacity which will be used initially in a
5 re-registration context in that example, and over time in
6 both.
7 MR. VROOM: But then subsequent --
8 MS. MULKEY: What we did was sort of an
9 after-the-fact effort --
10 MR. VROOM: Right.
11 MS. MULKEY: -- to attribute guidelines work to
12 the appropriate piece of the pie, and we did some of it
13 pro rata, we did some of it where we thought it was
14 primarily one or the other, but --
15 MR. VROOM: And those kinds of contract
16 expenditures for a capital good, whether it's computer
17 software or bricks and mortar, whatever it is, but that
18 is strictly attributable to OPP are expensed every year.
19 They are not like in a private sector business
20 capitalized and depreciated over time or anything.
21 MS. MULKEY: They are expensed when you pay for
22 them.

1 MR. VROOM: Right.
2 MR. WEIK: Right.
3 MR. VROOM: So, some of that -- those kinds of
4 decisions may end up being incorrect in terms of the
5 arbitrary decisions you might make between allocation
6 against registration and re-registration?
7 MS. MULKEY: Remember that, you know, we keep
8 careful books, but we don't necessarily keep them around
9 these pie charts.
10 MR. VROOM: Yeah.
11 MS. MULKEY: And this was designed for your
12 needs, and so we did some things around some issues like
13 that in order to work in the pie chart.
14 MR. VROOM: Sure. Yeah, great. Thanks.
15 MS. MULKEY: Bill?
16 MR. TRACY: Yeah, on the FTE distribution pie
17 charts, these are look-backs based on reporting based on
18 time charts and all that. To what extent -- I assume
19 -- did you collect this just for the purposes of this
20 group and reporting out, or -- and were there any
21 "ah-has" in looking at those distributions, and will you
22 use that information to guide or re-allocate people to

1 different efforts? I mean --
2 MS. MULKEY: Let's back up.
3 MR. TRACY: Or is this just a report out, yeah,
4 this is what we did --
5 MS. MULKEY: The accounting information is
6 collected for a lot of purposes, so it wasn't obviously
7 collected just so we could do this presentation. This
8 particular, exact template for looking at the information
9 we did do for this presentation. We had not done exactly
10 this template before.
11 MR. TRACY: And were there any "ah-has" for you
12 on that?
13 MS. MULKEY: Were there any "ah-has"?
14 SPEAKER: Well, I mean, we had --
15 MS. MULKEY: Mostly it was just what I thought,
16 thank God.
17 MR. WEIK: We have done this type of analysis
18 over the last ten years multiple times.
19 MS. MULKEY: Right.
20 MR. WEIK: So, I think most of us on the senior
21 team have looked at various versions of this over the
22 last ten years, and as Marcia said, it sort of comported

1 with our last recollection.

2 MS. MULKEY: Yes. I mean, we hadn't done

3 exactly this exercise using exactly these input data, but

4 we pay very close attention to such issues as a basic

5 split between registration and re-registration, and you

6 know, you know where you're spending your dollars and you

7 know where your FTEs are sitting and you know what

8 they're working on, and this was largely -- I would say

9 that there were a few -- I don't know that there were

10 "ah-has." There were a few subtleties that some of you

11 have keyed on, that you sort of said, well, that's

12 interesting, what do we think is going on here?

13 I found, for example, the first time I saw the

14 pie chart, they had communications and outreach or

15 information, had a pretty big chunk, and I thought, wow,

16 what is that all about? Then when I learned that

17 included FOIA, it included the grant that we give to the

18 National -- the 1-800 number, NBTN, then, oh, yeah, all

19 right. So, there was a little of that kind of thing, but

20 I didn't -- did you experience any "ah-has"? Did you

21 guys when you saw this?

22 SPEAKER: We are, though.

1 MS. MULKEY: Actually, I have picked up some
2 conventional wisdom on the outside that there had been
3 some major torque, for example, away from registration
4 toward re-registration, and I was quite confident there
5 had not, but, you know, this kind of thing helps you sort
6 of be transparent about that, and you can pick up that
7 perception if some -- you know, if three people who work
8 on X start working on Y, that can become conventional
9 wisdom that we've redirected all the resources from X to
10 Y, and so I think it's been really useful in that regard,
11 and I agree with Jay, that you want to look at more than
12 one year just in case you didn't pick some sort of oddly
13 anomalous year, but we're also quite confident we didn't
14 do that.
15 MR. TRACY: Right. And I guess my only other
16 question, on some -- I'm sort of confused on the
17 accounting of -- when you have like BPPD -- the
18 self-contained units, like anti-microbials and BPPD, how
19 you look at things like re-registration and fast track
20 and allocation when you go to some of these
21 re-registration -- like the pie chart on 13, is that a
22 cumulative, all-division kind of breakout, or is that

1 just R&D?
2 MS. MULKEY: All of them are cumulative, all
3 division. So, it's at least theoretically possible that
4 you'll get some work done outside of BPPD and AD for the
5 anti-microbial pie chart and the biopesticide pie chart.
6 MR. TRACY: Right.
7 MS. MULKEY: And in fact, we're pretty sure you
8 may be getting a little RD work on biopesticides that are
9 not managed -- not -- that's a term of art -- on
10 biological, we're pretty sure we're not --
11 MR. WEIK: What we do is the product
12 re-registration happens in Registration Division AD, BPPD
13 and SRD. I mean, everyone who does work in the program
14 has the same form. It doesn't matter where they are,
15 they're all looking at the same form, and they're --
16 every other week, they fill out what they did.
17 MR. TRACY: Got it, okay.
18 MR. WEIK: So, it doesn't really matter where
19 you sit. It matters what you actually were working on.
20 MS. MULKEY: And yes, they are all cumulative.
21 BEAD is showing up everywhere, but the self-contained
22 divisions I would guess is very high percent comes from

1 within them.

2 John, did you --

3 JOHN: With respect to this particular chart,

4 which is numbered 13, because the sliver for

5 re-registration (inaudible) was so small, we didn't break

6 them out. This is everybody. This is the

7 undifferentiated --

8 MS. MULKEY: Oh, I see.

9 JOHN: -- (inaudible) for re-registration by

10 (inaudible). If you take that 9 -- (inaudible) break it

11 down like this (inaudible). BPPD and AD presumably did

12 not conduct any special reviews (inaudible), but for the

13 three big sites, it's almost certainly about the same.

14 MR. TRACY: Okay, thanks.

15 MS. MULKEY: Okay, Steve.

16 MR. BALLING: Okay, this is exhausting.

17 MS. MULKEY: But you're interested.

18 MR. BALLING: Of course. We're always

19 interested in budgets.

20 SPEAKER: (Inaudible.)

21 MR. BALLING: Tell me about it, with an E on it.

22 Slide 3, 24 percent of total OPP funds go to

1 contracts and grants, and if you look back at one of
2 these other slides, 60 percent of that is data review.
3 I'm curious, have you had any -- and I think your answer
4 to Julie probably suggested you don't have this
5 information -- but have you had any opportunity to look
6 at sort of productivity on a cost or on -- cost on a per
7 unit productivity basis, so you have some sense whether
8 going out to contracted reviewers is more or less
9 efficient on a cost basis?
10 MS. MULKEY: Well, we don't use our contract
11 reviewers, for the most part, the same way we use our
12 internal reviewers, so there's a difficulty in comparing
13 apples to oranges. We did do an exercise this year about
14 what kind of our work was susceptible -- that's being
15 done by employees now is readily susceptible to being
16 done by contract, and there were some analyses conducted
17 in connection with thinking that through.
18 There are -- over time, there have been a
19 number of analyses done about what it costs to have a
20 government worker do something versus what it costs to
21 have a contractor do something. The real truth is it
22 depends on how immediately useful the contractor-produced

1 work is, and the higher order the work goes, the more
2 complex it goes, the more it requires an understanding of
3 how it fits with the rest of it, the less immediately
4 useful it is. So, it's -- you have to find some way to
5 compare apples to apples.
6 We might have the capacity to do that, where we
7 have pockets of doing the same exact sort of sit at the
8 desk, review work that we're contracting out that we are
9 still doing internally, but even that, because it's
10 pockets, it might be being done by our more inefficient
11 people, and that's -- I mean, there are -- you know, I
12 think it would be very hard to --
13 MR. BALLING: And there is always intangibles, I
14 understand that.
15 MS. MULKEY: Right.
16 MR. BALLING: But I --
17 MS. MULKEY: But there is no question that we
18 need to pay attention whether what we're contracting for
19 is being done smart, in a smart way.
20 MR. BALLING: Yeah. Well, the reason I asked is
21 that if you look two slides over, page 5, and you look at
22 the average cost of salary per FTE over time --

1 MS. MULKEY: Right.
2 MR. BALLING: -- I don't know, Doug, you
3 mentioned that was just cost of living raises, but it
4 sure seems faster than we would expect at Del Monte. We
5 wouldn't want to see something like that. It -- I think
6 it reflects an age structure issue, that you have a lot
7 of senior people.
8 MR. WEIK: Yeah, I think that certainly is a
9 factor.
10 MS. MULKEY: That's part of it. Part of it is
11 we've been hiring pretty -- part of it's this function
12 of contracting. The more routine work you contract out,
13 the more it becomes important that you fill your work
14 force with --
15 MR. BALLING: Senior people who are --
16 MS. MULKEY: -- senior -- or, you know,
17 pricier people. Part of it's what's happening with
18 regard to support staff, and this must be happening in
19 the private sector, too. We don't have typists and
20 keyboarders and data inputters. I mean, we have very,
21 very few people in the grade 5, 7, 9, even 11 range, and
22 that used to be a very high percentage of the federal

1 work force, because the -- you know, the functions that
2 were associated to that are now done by the higher graded
3 people and/or by machines. So, there's a lot of factors
4 that drive this.
5 What might give you a handle on how pricey is
6 OPP is how do we compare per capita with other parts of
7 EPA headquarters, and we're on the high end. We're not
8 through the roof, the top. We're above the 50th
9 percentile.
10 MR. WEIK: We're in the top third, I think.
11 MS. MULKEY: Yeah, so that helps you get at it.
12 MR. BALLING: Well, that's not really what I'm
13 getting at necessarily. What I'm thinking is with that
14 age structure, that age distribution you have, you're
15 probably going to be seeing a fair number of retirements
16 in the next decade.
17 MS. MULKEY: We are watching that very closely.
18 MR. BALLING: And do you go to contracted
19 outside work or do you try to bring it internal? That
20 thing will probably flatten out a little bit in the next
21 decade, I presume, because of the retirement --
22 MS. MULKEY: I don't know, benefits are going up

1 11 percent.
2 MR. BALLING: That's true.
3 MS. MULKEY: The private side is going up 11 --
4 what I pay is going up 11 percent next year. I assume
5 the Government side is going up at least comparable, so I
6 don't know about that, but --
7 MR. BALLING: Okay, but if that was just a
8 salary distribution --
9 MS. MULKEY: Okay, well, you're assuming a
10 rational model about the way people --
11 MR. BALLING: I know, assuming rationality is
12 foolish, but --
13 MS. MULKEY: -- but as you know, there are FTE
14 caps in government, and ours have been declining; that
15 is, EPA-wide and OPP. So, while you can go below your
16 cap, you can't go above it. So, you can never make the
17 decision to hire more people no matter how much more
18 efficient it is to hire people than it is to contract,
19 and you can never make the decision to hire two cheap
20 people instead of one expensive person.
21 MR. BALLING: Right, right.
22 MS. MULKEY: So, you have those constraints in

1 the system which make it harder for you to think through
2 those things. We're in a declining FTE mode, so we are
3 by definition not replacing everybody who leaves and
4 making choices about how to get the work done that
5 include more aggressive use of contracting where we have
6 dollars available.
7 Within that, we have made -- and we did it
8 thinkingly -- the choice that we should maintain a full
9 work force and pay the salary costs associated with that,
10 and we made that based upon some of these analyses about
11 whether we have viable functions that are readily
12 shiftable away from the federal work force and decided
13 that as a practical matter we did not.
14 But other than that, there's not a lot of choice
15 in that system, between those two kinds of expenditures.
16 MR. BALLING: Actually, I am not a big proponent
17 of contracted services. It hasn't worked real well for
18 us necessarily, but I know those kinds of pressures are
19 going to come to bear.
20 With re-registration, you know, presumably
21 winding down over the next three-plus years, will you
22 find the need for FTEs declining?

1 MS. MULKEY: Well, registration review is built
2 into FQPA, that contemplates a 15-year cycle, and the
3 first pesticides that would -- have not gone through
4 re-registration date from 1984 --
5 MR. BALLING: About 15 years from --
6 MS. MULKEY: -- which is, what, 17 years and
7 counting, and the complexity, the science, the issues for
8 reworking pesticides doesn't seem to me to be likely to
9 be cheaper for the next 15-year cycle than it was the
10 re-registration cycle, although it's possible. It's
11 possible to have some kind of major breakthrough where
12 you have a lot less data, because you have genomics or,
13 you know, it's possible you will get to some place where
14 the level of effort necessary to revisit the database and
15 the risk of a pesticide changes, but that certainly
16 doesn't seem to be true in the sort of first wave of the
17 post-'84s.
18 MR. BALLING: Of course, we're also seeing new
19 targets, end points that we have to keep looking at,
20 which also --
21 MS. MULKEY: But that's part of the -- it's the
22 science changing complexity and all that goes with it,

1 you know, what kind of data you look at, what issues they
2 present, not to mention a few little things like
3 aggregating exposures and accumulating common mechanism
4 groups and so forth.
5 MR. BALLING: Okay, thank you.
6 MS. MULKEY: Oh, I'm sorry, Pat.
7 MR. QUINN: I think I was also interested in the
8 break between contract dollars and FTEs, and I guess I
9 was surprised, looking at chart number 17, I just want to
10 make sure I'm understanding that, that data review,
11 contract data review, according to that chart, is only
12 about $4 million a year. Is that right?
13 MS. MULKEY: That's for registration.
14 MR. WEIK: This is only registration.
15 MR. QUINN: Just registration.
16 MS. MULKEY: And then the --
17 SPEAKER: (Inaudible.)
18 MR. QUINN: Right. I guess still I'm a little
19 surprised by that and sort of wondered if you could
20 comment, looking out, which you just have to some degree,
21 you know, whether or not you see that trending --
22 MS. MULKEY: Shifting to --

1 MR. QUINN: -- and I mean, I know that the
2 Anti-Microbial Division's re-registration strategy is
3 heavily premised upon contract dollars.
4 MS. MULKEY: Right, and in Biopesticides and
5 Pollution Prevention Division, we shifted what in
6 absolute dollar terms was a very modest sum, less than a
7 million dollars, but in fact, we'll make a fairly
8 material shift in their balance between FTE and contract
9 use, so yes, it -- the margins, you see there is a
10 trend.
11 But the other limiting factor is that we don't
12 have an infusion of contracting grant dollars either, so
13 if you were to go dramatically into data review, that
14 either has to come from salary or it has to come from
15 other expenditures of contracting grant dollars.
16 MR. QUINN: Right.
17 MS. MULKEY: And those are basically your
18 choices. So, you would have to decide that contracted
19 data reviews were a higher priority than either what else
20 you're spending your contracting grant money on or what
21 you're spending -- or your work force.
22 MR. QUINN: Generally, I mean, Jay is trying to

1 look ahead at, you know, the 2002 kind of data. Are you
2 able to give us back years as well? Is it --
3 MS. MULKEY: Yes.
4 MR. QUINN: Is that available in this kind of
5 format with this template?
6 MS. MULKEY: Yes.
7 MR. QUINN: Is it? Okay.
8 MS. MULKEY: I mean, I think the request to at
9 least look one year back and one year forward --
10 MR. QUINN: I guess one thing --
11 MS. MULKEY: -- is not a terribly burdensome
12 thing that I can contemplate doing. I don't know if I
13 want to commit to a 15-year --
14 MR. QUINN: Right, no. I guess one thing that
15 does surprise me, again, you know, just looking at the
16 anti-microbial side of things is chart number 12, which
17 would indicate that you've got 24 FTEs, roughly, working
18 on re-registration, which just -- I don't know, it
19 doesn't feel right, you know, doesn't --
20 MS. MULKEY: Well, the wood preservatives are
21 all in that, and we did some -- that was one where we
22 actually did ask ourselves, what does this mean?

1 MR. QUINN: Right.
2 MS. MULKEY: The wood preservatives are all in
3 that. All the methods development we have been engaged
4 in, and that started in 2001, to wrap up to do a
5 re-registration program is included in that, and we had
6 some other thoughts about what might explain that, but I
7 actually think that looked a little high to me, too.
8 MR. QUINN: Unusual, yeah.
9 MS. MULKEY: Not extraordinarily, because it may
10 include some work that's not being done in the
11 Anti-Microbials Division, it's being done in labs or in
12 BEAD. I mean, we had a whole team that went beyond that
13 organization to sort of think through the anti-microbials
14 re-registration program.
15 MR. QUINN: I guess I just want to echo some
16 things that others have said, that it's really a nice
17 piece of work, and thank Doug and John and everybody who
18 were involved in it.
19 MS. MULKEY: Win, is your card up from before
20 or --
21 MS. MULKEY: Wow, we got around, and not a whole
22 lot worse than I promised you for your lunch. Now, of

1 course, you have to be back right at 1:00 -- no, not
2 quite, but if we could reconvene at 1:15 and make it
3 real, we can still make our end-of-day schedule, and we
4 look forward to it.
5 Thank you for all your interaction with us on
6 this topic.
7 **(Whereupon, a lunch recess was taken.)**

1 **AFTERNOON SESSION**

2 . MS. MULKEY: All right, thank you very much for
3 returning. We look forward to finishing up what I hope
4 you think has been a very productive session.
5 We have -- do we have any public commenters --
6 is Margie here yet?
7 SPEAKER: She's outside.
8 MS. MULKEY: Margie, do we have any public
9 commenters signed up?
10 MARGIE: No.
11 MS. MULKEY: Okay, well, that's good news. We
12 recognize that there's going to be an interest in as
13 early a wrap-up as possible. We also recognize that
14 there are relatively few of you left, and while I expect
15 at least a handful of you aren't here yet, we are mindful
16 that there would be some loss.
17 We did manage to complete the agenda that we
18 were planning to complete by noon, but we have learned a
19 lesson, which is that we have been overly ambitious about
20 our capacity to cover this many updates in the kind of
21 time that we've allocated to it. So, one of the things
22 I'll be asking for feedback is are there updates you're

1 getting you can live without, or are we going to have to
2 consciously devote more of the total to updates?
3 And in connection with that question, as you
4 know, updates come at the expense of real dialogue. So,
5 there are real issues around whether you want to turn
6 this into the periodic update meeting or not. So, I
7 don't think it's an easy question, so yeah, if you want
8 to speak to that now, that would be good.
9 Go ahead, Allen.
10 ALLEN: Well, my question is -- it's a question
11 that will lead to the comment. Were most of the updates
12 on topics requested by the members or were they a
13 combination or were they strictly updates that the agency
14 decided we ought to do?
15 MS. MULKEY: They were a combination, but I
16 think most -- and in fact, I think the overwhelming
17 majority were requested. Margie would be able to --
18 ALLEN: Then that makes it not as simple. I
19 mean, if it had all been agency decision, we could have
20 said, let us tell you what we want to hear, but if that's
21 what you went by --
22 MS. MULKEY: Right. In one or two instances,

1 the request may have come from only one person and not
2 been -- but in fact, if we thought a request was too
3 esoteric, we didn't include it, and IPM, for example, was
4 something that several people wanted a vastly more robust
5 range of updates, and we specifically chose to focus on
6 just two little pieces of it, the symposium and the
7 development in schools, and I would say the NAFTA piece
8 was probably one we put on, the strategic plan was one we
9 put on. I'm not sure anything else was other than
10 requested. The endangered species workshop we probably
11 put on, but the endangered species issues were almost
12 certainly included in the requests, so it's a real
13 dilemma.
14 So, as we wrap up and those of you who are
15 hearty enough to stay around and give us our last advice
16 if you have further thoughts on this.
17 Steve?
18 MR. BALLING: Well, I was just thinking, I know
19 the threshold of regulation issue was my request, and I
20 probably was the only one who requested it.
21 MS. MULKEY: Um-hum, I think that's probably
22 right.

1 MR. BALLING: But it also seemed like something
2 that should come to light for everyone as well. I mean,
3 people should know that there is this mechanism --
4 MS. MULKEY: And that's one reason why we --
5 MR. BALLING: -- here that isn't being used.
6 MS. MULKEY: Exactly.
7 MR. BALLING: And some understanding of why it
8 isn't being used might be of some value, particularly --
9 and maybe it's better for CARAT relative to the
10 transition issues at CARAT, I don't know, but --
11 MS. MULKEY: Well, I thought the best thing that
12 came out of not that topic but the -- I guess it was the
13 biotech topic, one of the best things was this is a topic
14 that deserves some attention in the CARAT transition work
15 group, and so unless you do surface issues -- I think
16 you were right, that you were the only one who requested
17 it, but we certainly thought it was appropriate for
18 inclusion, and --
19 MR. BALLING: But then again, you might just
20 make the argument, push back and say, hey, listen, Steve
21 --
22 MS. MULKEY: Right, nobody else is asking.

1 MR. BALLING: -- you're the only one who's
2 interested, go call Anne, and she'll tell you -- fill
3 you in on the latest and leave it at that.
4 MS. MULKEY: Well, the other thing that -- I
5 believe our chat room, our dialogue room -- Jim calls it
6 our forum, which gives it a nice elevated sound -- but
7 is also creating a dynamic in which people actually do
8 push back on each other a little bit, you know, I really
9 don't think we need to do that. So, I think that if you
10 use that as a discussion, there is an opportunity to use
11 that to sort of manage down, but it's not like it had
12 been that long since we had a meeting. We had one in
13 May. So, there's going to be demand for something
14 similar to this volume. Well, I wanted to put that issue
15 out there while we gathered the critical mass. Now that
16 we have the critical mass -- yes, Steve?
17 MR. KELLNER: I think it really does -- I'm
18 sorry, I think it does serve a good function to have a
19 -- just a couple minute review. I know sometimes we go
20 beyond it, but you have such a diverse group here that I
21 think it's a help just to jag your mind that, oh, yeah,
22 this is coming up or this is important, et cetera. So, I

1 do think it serves a good function, and I think it's very
2 worthwhile.
3 MS. MULKEY: Okay, well, the feedback last
4 meeting was that you really liked -- I know that they're
5 not in a minute. Maybe we'll start calling them -- I
6 think it was Burleson who said call it in a moment, that
7 will help us to be other than literally inaccurate
8 anyway. Quick updates might be another way.
9 We could introduce some more discipline on
10 ourselves to cut down the time, but the truth is you have
11 multiple presenters, you have people with different
12 presentation styles. There's only just so much of that
13 that you can do, and we do practice and try to manage it.
14 Okay, well, as we come to the end, I'll look for that.
15 This afternoon, there are on your agenda five
16 topics, four of which have been requested in most
17 instances by more than one or we know that there's
18 broader interest. With the exception of the one that
19 wasn't requested, which is the data quality guidelines,
20 and I'll go into a little bit about why that's there,
21 none of these are topics, frankly, that there's some
22 agency thrust or new agenda or special reason for

1 encouraging as a topic at PPDC. I don't mean to imply we
2 don't want to do them, but they're not really driven by
3 any agency sort of need to have a forum and a discussion
4 that we identified independent of your requests.
5 The strategic plan discussion in a minute
6 prompted a level of interest and even a suggestion, so
7 I'm adding that, so if you will mentally add that as your
8 sixth bullet for this discussion, we can work through
9 each of these one by one a little bit.
10 I also noticed quite a bit of energy around the
11 NAFTA -- I'm not sure whether it was around the NAFTA
12 five-year strategic plan or whether it was around some
13 sub-issues on that, like maybe the NAFTA label or
14 movement of products across borders or tolerance, MRL,
15 harmonization, but some interest around at least one of
16 those issues that I was picking up as maybe people
17 wanting to engage in a dialogue. So, we can add that.
18 Then I'll say one other thing, and then we will
19 open it up to general discussion on this whole list, and
20 then if that doesn't prompt enough attention to
21 individual ones, we will find a way to do that.
22 One of the issues for us is not whether these

1 things are worth talking about but whether this is the
2 right forum, and I -- and an example of that is the
3 various issues surrounding plant-incorporated
4 protectants, and frankly, one of the reasons why we did
5 the update in a minute around opportunities for public
6 participation on that set of issues was that there are so
7 many other fora that are very sort of stakeholder-rich,
8 many of which are much broader than just the pesticidal
9 biotech, but many of the issues people want to talk about
10 are broader than pesticide biotech. They are, for
11 example, allergenicity, which has to do with any
12 agricultural or food-related biotechnology and maybe even
13 non-food-related for all I know.
14 So, you know, depending on people's interest --
15 now, so, what I think I would say is that if we embark on
16 a use of this forum to talk about PIPs, it really ought
17 to be something that's about PIPs, some issue that really
18 is focused on BT, for example, or something involving --
19 that is not more generic by owetech, because there are
20 all these other forums, and the NAFTA TWG has -- that
21 whole process has an enormous amount of stakeholder
22 mechanism around it, which frankly is underutilized by

1 many types of stakeholders.
2 Environmental groups are practically never
3 engaged in that fora in the U.S. There's a little bit
4 more engagement in Canada and actually more in Mexico
5 than here. The non-ag industry wasn't but now is. The
6 ag users are engaged, but it tends to be a different set
7 of players than we see in this forum and in CARAT, not
8 entirely different but some -- a little bit more grass
9 rootsy version I would say of the ag users are involved
10 there, and academia is -- I mean, the -- you know, like
11 people interested in children's health issues are
12 generally not engaged here -- there, and the farm worker
13 advocacy community has not been very evident there,
14 although you would think that would be just a real
15 obvious place because of the Mexico-U.S., you know, the
16 labor flow and so forth. So, there's sort of an
17 under-participation of stakeholders.
18 I would say that the ag chemical industry is the
19 exception to that. They've been very engaged, although
20 as you know, Jay, it tends sometimes to be a different
21 subset, and there even is a disconnect between the way in
22 which the ag chemical industry engages there and the way

1 you do with us in other contexts.
2 So, one of the things on my mind there is not so
3 much do we talk about it -- maybe it would be a good
4 thing to bring it into this -- but how do we vitalize
5 that? So, having made those opening comments, and I
6 don't think any of these other topics sort of scream out
7 for the "why don't you go to another place to talk about
8 them" issue -- actually, the strategic plan sort of
9 does, because there are going to be all these stakeholder
10 processes around the strategic plan, although I don't
11 think they're nearly at robust as the ones around biotech
12 or NAFTA.
13 Okay, well, then let's open up this whole
14 subject matter and see if that works, and if not, we'll
15 identify some of the particular ones.
16 Steve?
17 MR. BALLING: Well, it struck home when you
18 mentioned that many of the points that you have on this
19 list are not issues that are of particularly great
20 impending importance to OPP, and that's something I've
21 struggled with all along in this whole process, is we're
22 supposed to be an advisory committee to the Office of

1 Pesticide Programs, yet you're always asking us what we
2 want to talk about, and I always thought it should be the
3 opposite, you know, we're advising you, what are your
4 problems, what are your issues, what can we provide
5 advice on, and when you ask us, we end up with a lot of
6 somewhat arcane, very generic issues that may not be
7 appropriate for the PPDC, and I think some thought needs
8 to be given about how to bring those back within the
9 confines of what you guys need out of this group.
10 MS. MULKEY: Well, how important do you think it
11 is for stakeholders like this to help set our agenda?
12 Because I mean the flip side of that is that because you
13 raise the profile of issues, it may become important to
14 us in ways that wouldn't have but for your attention to
15 it.
16 MR. BALLING: Well, one would presume that as
17 the discussions proceed, they'd become important, and
18 that's part of the give and take in P -- and you would
19 realize that this is an important issue and in turn make
20 it important internally, internalize it in some fashion,
21 but I just think sometimes we really kind of get offline
22 with this whole process, not unlike the CARAT group as

1 well, where I think we get offline fairly frequently on
2 what, in fact, the role of that group is. So, just a
3 thought.
4 MS. MULKEY: That's helpful.
5 Larry?
6 MR. ELWORTH: Well, the other thing that we tend
7 to do is when you ask us about issues, all of us tend to
8 respond based on the issue that we find most either
9 immediate or important or vexing at the moment, and I
10 think it's hard to pull together an agenda for 25
11 people's vexing issues or pressing issues, but I think a
12 mixture of those issues is probably a good idea. I think
13 the update -- you identified the update issue, probably
14 a little more -- either fewer or more time or both,
15 maybe not try to do it in a minute.
16 I think it's -- and I did not anticipate that I
17 would ever say this -- but the stuff on non-animal
18 testing was really interesting. The presentations were
19 really good, and from an educational point of view, like
20 reading a magazine article you wouldn't have looked at
21 ordinarily, it was really interesting and well done, and
22 I like the idea of this -- I mean, it's useful to me to

1 learn about things I don't know about. So, everything
2 doesn't have to be immediately relevant to something that
3 I have to deal with every day.
4 But I think it's also real important to have
5 topical issues, and when you look at some of the updates
6 that I think are important that aren't necessarily
7 transparently obvious where you folks end up six months
8 from now on ESA I think would be both topical and
9 interesting, and interesting not just because of its
10 effect on pesticides but the way that there's interaction
11 on both different statutes and different agencies and how
12 they resolve those kind of problems.
13 At least in agriculture, we keep running into
14 situations where we're dealing with multiple agencies now
15 who don't always look at us the same way. So, I think
16 that kind of issue would be a useful issue.
17 I also -- and maybe everybody here already
18 knows about it -- but I think it would be helpful if on
19 a semi-regular basis, as new members come on, for the
20 agency to talk about what FIFRA is. I mean, I happen to
21 think it's a great statute, you know, found it very
22 interesting, but maybe everybody here knows what the

1 difference between Section 6-C and Section 6-F and when
2 somebody -- when you were talking about Section 28.
3 It's a really interesting statute, and I think it would
4 be useful to -- maybe a one-hour primer on part of FIFRA
5 would be a useful thing. I mean, maybe not.
6 Well, I just think it's a fun law. I just love
7 it.
8 MS. MULKEY: Well, you know, Larry, I would do
9 that, but --
10 MR. ELWORTH: I know you would, but -- so,
11 that's why it's easy for me to say this, but I think
12 everybody here is being asked to look at pesticide issues
13 and the level of background information and knowledge may
14 be really variable --
15 MS. MULKEY: Maybe we need a series of breakfast
16 seminars -- I'm only half joking -- before PPDC
17 meetings, and people could attend or not.
18 SPEAKER: Yeah, that's a good idea.
19 MS. MULKEY: You actually sort of like that,
20 huh?
21 MR. ELWORTH: Yeah, yeah.
22 SPEAKER: I mean, I think it's a great law, too,

1 but I don't necessarily need a primer on it.
2 MR. ELWORTH: Well, I know. Well, I don't -- I
3 don't think everybody does, but I think it would be
4 helpful to the discussion here if people at least had the
5 same kind of basic information. It's a service that the
6 agency can provide through this outreach group that
7 really informs the public.
8 The other thing that I'd be real interested in
9 seeing from the agency is how OPP is dealing with the
10 methyl bromide issue, and it's not just critical use
11 exemptions. It's how you're working with the Air Office,
12 where it surfaces as a priority in the agency's
13 registration priorities, and how the agency interacts
14 with USDA. I think it would be a good issue.
15 I would also at some point like to hear about
16 the agency's international programs, maybe not where
17 there's a NAFTA thing, and as you said, there's a
18 well-developed stakeholder group, but the agency's
19 involved in a lot of international issues. I mean, we
20 were talking in the hallway, POPs, I mean, there's a lot
21 of things you folks have been doing, prior informed
22 consent. Again, maybe you don't have to do an afternoon

1 on prior informed consent, but there's a lot of
2 leadership this country has taken in international
3 pesticide regulation, international pesticide safety,
4 some of the Latin American projects you all have had,
5 which I think people would be really interested in.
6 MS. MULKEY: Well, as usual, pretty rich mix of
7 things.
8 Bob?
9 MR. ROSENBERG: Mine is like actually specific,
10 and actually Julie understands the issue so much better
11 than I do. Can I defer to her first? Am I allowed to do
12 that?
13 MS. MULKEY: Of course.
14 MS. SPAGNOLI: Well, first, just in general, I
15 think that as far as topics to be taken on, I think it's
16 a mixture of -- the agency could -- we're not the only
17 group of stakeholders that's going to give input to the
18 agency on what they have issues with, and I think a lot
19 of different groups bring issues to the agency, and I
20 think it's somewhat -- if the agency sees an opportunity
21 because of an issue that's been brought to them by anyone
22 and saying this would be a good thing to take to the

1 PPDC, then I think that's probably that they bring --
2 that the agency brings that issue to the PPDC, and then
3 vice versa, as we see issues we believe might be
4 appropriate for the group, then we can bring them. So, I
5 think you could have both. I think it doesn't all have
6 to come from one group or the other.
7 The particular issue that I had brought up and
8 wanted to I guess have for consideration in this group
9 has to do with product claims, especially for alternative
10 claims or -- and I'm going to say reduced risk claims,
11 but it might not necessarily be reduced risk, but more
12 and more we're seeing that the agency has a lot of
13 initiatives and a lot of encouraging the use of, you
14 know, lower risk products, reduced risk products.
15 As a marketer of these products, though, we're
16 very, very limited in how we can present them, and I know
17 it's -- there's -- it's a Pandora's box to -- you
18 know, to completely open up and not allow people to say
19 products are environmentally friendly or environmentally
20 safe, but I think it could be something that -- to look
21 at, are there good factual ways that we could present
22 information on label and label claims that would help --

1 especially I think to consumers to help them make, you
2 know, informed decisions? You know, if a product has
3 been shown to not be toxic to bees, you know, shouldn't
4 we be able to say on our label, "Will not harm bees," you
5 know, something along that line.
6 Then I think with alternatives, especially as
7 new alternatives to some of the older chemistries become
8 available, one of the difficulties we've faced is trying
9 to communicate to the public that these alternatives are
10 available, and I know I had a personal experience of
11 registering a new insect repellant product, and one of
12 the difficulties we had bringing it to market was how to
13 convince the retailers to put this -- you know, or the
14 marketers to put this product out when they could not
15 call it an alternative to D, they could not make that
16 claim, yet you are going to have a higher-priced product
17 that you couldn't really distinguish in any way, and I
18 think that there's -- like I said, without misleading
19 the public or providing, you know, I want to say trying
20 to do scare tactics or any other way, I think there must
21 be a way that we should be able to try to better
22 communicate, you know, the attributes of these preferable

1 products to the public.
2 MS. MULKEY: Well, I think you've done a good
3 job of framing that issue. I'll add just a couple of
4 tidbits to the context.
5 We have a regulation that is pretty
6 prescriptive -- as you know, FIFRA doesn't have many
7 regulations. That's another one of the arcania of people
8 who operate in this law, but we do have labeling
9 regulations, been on the books a very long time, labeling
10 regulations on the issue of claims, safety claims or
11 claims that are really quite strictly drawn. Now, that
12 doesn't mean there's no room without regulation changes
13 for some rethinking, but that sort of context, and it's
14 not just that the regs say this, but sort of the history
15 of the thinking about pesticide labeling, which predates
16 actually almost all of us, despite the long in the tooth
17 crowd that has gathered here, has been very -- rigid I
18 think would not be an overstated word in terms of
19 labeling.
20 So, you are talking about opening a dialogue
21 that would revisit that long-standing and pretty dug-in
22 mind set. I don't mean by that in people, I mean just in

1 the infrastructure, you know, in the existing labels and
2 so forth.
3 Having said that, we are in a very different era
4 where we know a lot more about products, we have had
5 these reduced risk initiatives, and there is -- there is
6 definitely an argument that the past should not be
7 prologue in this area and that there should be sort of a
8 completely fresh opportunity.
9 Then there's the incrementalist who could say,
10 well, let's be careful here and not rush all the way, but
11 what if we open up this door? And then actually, we did
12 open up one very small door recently, which has to do
13 with the labeling of products that are -- that contain
14 only the substances that the Organic Standards Board had
15 certified as appropriate for organic gardening. So, now
16 -- not gardening -- well, farming, organic growing. So,
17 there will be now a pesticide label opportunity, as we
18 finish that exercise, that was proposed and so forth that
19 does that. So, very narrow, as you said, very factual.
20 So, we sort of opened one little door.
21 So, I just wanted to add a little bit so when
22 people react to your idea, they have a little sense of

1 this context, and this is one where it's not like
2 somebody is sitting in OPP right now and saying, boy,
3 this is the year we're going to embark on the initiative,
4 because it's frankly a pretty high cost subject to try to
5 figure out. Maybe if you did a little tiny piece, that
6 wouldn't be too high cost, but to figure it out and to
7 engage all the people who matter. I think we would have
8 to understand the FTC's thinking on an issue like this,
9 we would have to certainly understand our enforcement
10 office's issue on -- you know, because -- and there
11 would be all kinds of questions about just how much the
12 agency should manage it, how much it should be left to
13 industry to manage.
14 So, it's just even a difficult topic, but I
15 think if there's a general sense, especially from a
16 multitude of perspectives, that this is a topic that
17 warrants the agency sort of dusting off that historic
18 approach and putting some energy into rethinking, that
19 you can make the case that sort of the time has come for
20 an opportunity for the consumer to obtain some of this
21 kind of information which may be driven by market
22 positioning but may also have benefits beyond the market

1 --

2 MS. SPAGNOLI: Yeah, and we have also seen I

3 guess from the retail side that the retailers, you know,

4 kind of -- they want this, because even how they make

5 their decisions on offerings to the public, and so I

6 think there's a multitude of levels. I think from also

7 -- and I think that Bob is going to reflect on it --

8 from his industry's perspective, too, because they have

9 to make product choices for their uses, too.

10 MS. MULKEY: Well, this would seem to be a good

11 time to call on Bob.

12 MR. ROSENBERG: About as good as any, and I

13 think FIFRA's fun also, just for the record. This is I

14 guess a corollary to what Julie's talking about and

15 probably even less directly within the domain of the

16 agency, but the long in the tooth crowd will remember

17 that back in the early nineties, there were congressional

18 hearings about the lawn care industry, and as a result of

19 those, the agency convened a lawn care advisory committee

20 which produced a set of draft lawn care advertising

21 guidelines which were, to the best of my knowledge, never

22 adopted but have become a de facto standard throughout

1 the United States upon which state attorneys general and
2 state lead agencies rely and often make regulatory
3 decisions.
4 The upshot of that is that they are actually
5 pretty good. I mean, I'd have to go back and take a hard
6 look to say that I love them, but they were actually
7 pretty well done, but what they didn't allow for was the
8 making of any kind of health, safety or environmental
9 claim. So, if there are pest control operators or lawn
10 care operators who do, in fact, use reduced risk products
11 or do provide IPM or do embrace reduced risk strategies,
12 there isn't any way for them to differentiate their
13 product from someone who sprays baseboards, for instance.
14 If it's the agency's goal to try to move the
15 applicator community in the direction of embracing those
16 reduced risk strategies, I think revisiting that set of
17 advertising guidelines would be a worthwhile endeavor.
18 MS. MULKEY: I know -- people may have had
19 their card up for a while, but if people want to talk to
20 this specific topic, it would probably be a good idea for
21 them to call on them before, so -- I'm pointing to
22 Carol.

1 SPEAKER: I thought you put it down. I'm sorry.
2 MS. BRICKEY: I think this is a good idea, and
3 I'm very interested in it. I think it would be a good
4 -- it is a good time for the agency to explore it, so I
5 agree with Julie.
6 MS. MULKEY: Bill, you were on this topic, too?
7 They have had their cards up for a while.
8 MR. TRACY: Well, I actually had something else,
9 but a tie-in may be, and looping back to the presentation
10 we had yesterday, you know, on a lot of shampoo products
11 or, you know, cosmetic products, you see no animals were
12 killed for this product kind of deal, and then, you know,
13 I can envision the day where, you know, if people are
14 embracing alternatives and we have a new structure for
15 that, that would be a claim that people would like to
16 have on their products as well.
17 MS. MULKEY: You can leave it up if you have
18 something else you want to talk about later, but while
19 we're on this topic, Larry?
20 MR. ELWORTH: Well, I just thought your initial
21 analysis of why this is the way it is with labeling was
22 really important. I mean, the whole -- one of the

1 primary foundations of FIFRA was a label -- a quality
2 assurance for growers that they were actually getting X
3 percent of X -- of Y chemical in the bag when they
4 bought the pesticide. So, it's not coincidental that it
5 started out -- that it's this prescriptive, this strict
6 from the beginning. So, it -- I would be interested in
7 hearing how the attorneys look at this, as well.
8 MS. MULKEY: Win, are you on this topic, on this
9 sub-topic? Okay, because I wanted to get back to those
10 who -- but Erik is, okay.
11 ERIK: It strikes me that it's probably worth
12 having that conversation. I think it needs to be had
13 very carefully, and the doors should not be swung wide
14 open, but there are probably opportunities to make some
15 reasonable changes that are probably worth discussing.
16 It makes me nervous just because I know some of that
17 history, and I know about some of the enforcement actions
18 that have been taken by state attorneys general and so
19 on. So, I think it would be key to bring in state AGs as
20 well as enforcement folks and others, but I -- you know,
21 I think if a legitimate and scientifically credible
22 argument can be made that there may be reason to

1 authorize some fairly narrow provisions like that.
2 MS. MULKEY: Anything else on this topic?
3 Okay, Jose, you've been very patient.
4 DR. AMADOR: I let the other guys talk.
5 I've got a couple of things. The first one is
6 the remark that Larry made on the international programs.
7 I don't know if we've done enough of that in the past,
8 and I'd be very interested in learning more about what
9 the agency is doing, because, you know, living two or
10 three miles from the border, because that's important to
11 us, and I know that the Texas Department of Agriculture
12 had a program on that, and I kind of would like to
13 explore that a little more.
14 Then, in talking about the state programs, I
15 think the assumption that Phil referred to in the
16 morning, I don't know if this is the same disconnect that
17 he was talking about or not, but we had a lot of
18 activities from OPP, and I think that OPP has done a
19 tremendous job on worker protection standards, but I
20 don't hear much about what the states are doing or how
21 the states are carrying on the programs, and it would be
22 interesting for me to find out, you know, what is it

1 they're doing.
2 In talking to Anne earlier on this morning, the
3 enforcement part of it is not part of your group here,
4 and I wonder if it might not be good sometime to have
5 somebody from enforcement to come to us and bring us up
6 to date, you know, how are they doing and follow up on
7 the things that OPP say needs to be done.
8 I've been thinking back, and I've been one of
9 the guys who have been around for quite a while, I'm not
10 as ancient as Larry is, and I don't want myself to go and
11 crowd you or anything like that, I mean, one Larry is
12 enough, but I can't think back to when we had that kind
13 of conversation with somebody from enforcement. Maybe we
14 had, I don't know, I can't remember, but I think it might
15 be good to visit that and see how they're carrying on
16 the -- and I'm not talking only about my state but I'm
17 talking about all the states.
18 I know the level of activities in this area
19 varies a lot, you know, from the heavy agricultural
20 states, Florida. California and Texas, but I would like
21 to see what the picture is for the whole United States.
22 I would like to see how this is being enforced.

1 MS. MULKEY: Well, this planning group that's
2 been working on these two worker risk workshops, there's
3 been some discussion in that group about whether
4 enforcement-related or state implementation-related
5 issues fit in that dialogue. So, that -- we can take
6 that as input to that as well.
7 DR. AMADOR: But I think it fits in it, because,
8 you know, what good does it do to do all of that if it
9 doesn't get out to the end of it?
10 MS. MULKEY: Well, certainly the issue of
11 whether there's compliance with labeling or the
12 standards, I think that the planning group definitely
13 felt there was a need for some focus on that, which is
14 not to say it's not sort of for this forum, too.
15 Beth?
16 DR. CARROLL: Well, first I'd like to say this
17 is the third meeting I've been to, because I started with
18 this new round, and you know, we go to so many meetings,
19 this is a meeting I would not miss, because we do
20 communicate and talk about so many different topics, and
21 a lot of them may not be for everybody on that day, and
22 we kind of had that discussion yesterday, but, you know,

1 a lot of it is really enlightening, and I do like the
2 breakfast idea. I mean, maybe some of the animal
3 testing -- because it did get a little long -- could
4 have been accomplished, you know, early, and then the
5 discussion could have ensued during the meeting.
6 But having said that, I don't know about all of
7 these that have been put forth for the next meeting, but
8 it may be that some of them could be taken care of in a
9 shorter time frame than -- it seems like we have one
10 main thing that comes on board, like the animal testing,
11 electronic submissions, whatever --
12 MS. MULKEY: One or two, maybe three.
13 DR. CARROLL: -- but maybe there could be some
14 that in your updates in a minute session, maybe you kind
15 of already know it's going to take five minutes, and
16 those are set up a little differently. I don't know, I'm
17 just thinking out loud there.
18 Then I would like to echo Larry's suggestion
19 about a discussion on ESA. The data quality guidelines,
20 I'm wondering if since it's come up recently if we
21 shouldn't think about during that discussion, or doing it
22 separately, have IRIS and ORD come in and talk about the

1 IRIS database. It would be nice to know what their
2 future plans are for updating it, how it -- you know,
3 how they work with you guys in OPP to get this done, and
4 I think probably some of the members would like to
5 present some of the problems they've had with the
6 database, and I think that database certainly is going to
7 pay into the Data Quality Act guidelines. So, that's
8 another one I'd like to suggest.
9 And I don't want to blindside Charlene Matten
10 (phonetic), because she and I have talked a lot about
11 this voluntary resistance management labeling, which with
12 the exception of maybe one product that's in a category
13 by its own I don't think has happened. We at Syngenta
14 have some problems with it from -- that I think it might
15 be helpful to air with this group, because some of them
16 represent the grower community, and this is going to be
17 -- I mean, the problems we have it are not that we can't
18 put it on our label, but what it translates to when it
19 gets out into the field is an issue, and what happens if
20 my -- if the Syngenta labels have it, and our sales
21 force is put out there, and the other guy's label doesn't
22 have it. I know that pushes towards mandatory, but it

1 would be nice if we could all kind of agree that this is
2 a good idea, and we need to get this information on our
3 labels.
4 MS. MULKEY: But it has been interesting. We
5 were lobbied pretty heavily at one point by some of the
6 big grower -- I mean, I don't remember whether it was
7 corn or wheat, but, you know, some of the big ones to
8 move this issue, and we moved -- you know, we did what
9 we did. We haven't heard much from them either. So, I'd
10 also like to know, you know, what is the energy behind
11 this, because, it's -- I think it's mandatory in Canada,
12 isn't it?
13 DR. CARROLL: It is mandatory -- well, I'm not
14 sure the date's kicked in yet, but we have had some
15 meetings on it, but we all kind of keep talking around
16 the same points, and we don't resolve them.
17 MS. MULKEY: Okay, well, that's helpful, um-hum.
18 DR. CARROLL: And I'd like to see it happen. I
19 mean, it's critical for the longevity of a lot of these
20 products and, you know, we keep -- we've been sticking
21 it out there for glyphosate but haven't seen much more on
22 other labels, so -- and then last, I just had a

1 question. I don't understand what the decision process
2 and time line for how companies manage R&D pipelines --
3 what does that topic mean?
4 MS. MULKEY: Well, that topic came -- I can't
5 remember from whom, it might have been Larry, but --
6 SPEAKER: Probably was.
7 SPEAKER: Bob Holm.
8 MS. MULKEY: Was it Bob Holm?
9 SPEAKER: Yeah. So, this is sort of a
10 mischaracterization.
11 MS. MULKEY: Fair enough. The interest was in
12 understanding what's going -- having a better
13 understanding of how R&D decisions are being made.
14 SPEAKER: Actually, it was -- I think it was
15 bigger than that. It was, you know, the consolidation of
16 the industry, the shrinking investment in discovery
17 research, both by the industry and also all research,
18 which really could involve the National Coalition for Ag
19 Research, which is active, and USDA has got a stake in
20 that, so you can make this however large or small you --
21 MS. MULKEY: Fair enough. I mean, I heard
22 several different things. One is just sort of what's in

1 the pipeline and is it shrinking or growing.
2 SPEAKER: Right.
3 MS. MULKEY: Then I thought there was some
4 interest and a little bit more in how are decisions made,
5 what kind of products are pursued, and the interests
6 seemed to be more around what's driving it in the
7 marketplace and economically than what's driving it with
8 regard to environmental impact, and those things --
9 SPEAKER: It both ties to the resource question
10 and a looking forward through OPP so that you know what
11 to expect in terms of workload.
12 MS. MULKEY: Right, that's -- I mean, it's
13 inartfully worded for sure, but that was the topic.
14 DR. CARROLL: That helps.
15 MS. MULKEY: Win?
16 MR. HOCK: Before I go into my dissertation,
17 which will be brief, I have a suggestion. I think that
18 the agency should produce a button, "I love FIFRA."
19 After all, you go to New York or you go to any other
20 place, there's always an "I love whatever," so I think
21 --
22 MS. MULKEY: How about "I love FQPA," do you

1 think everybody would wear that?
2 MR. HOCK: We have a mutual admiration --
3 SPEAKER: All you guys would.
4 MS. MULKEY: Bring back Delaney.
5 DR. HOCK: No, wait a minute, let's not go too
6 far about Delaney.
7 You know, we talk about a lot of EPA regulatory
8 activities, and you know, I look at EPA as much more than
9 just a regulatory/enforcement agency. I really look at
10 EPA as doing a lot of outreach, and in fact, something
11 -- it was Larry's comment, and boy, Larry, you have made
12 an historic comment about this, when he said about
13 international safety programs. The bottom line is, you
14 know, international safety programs, but we have a lot of
15 domestic safety programs, and I guess I just wonder if it
16 would help the group to get a feel for what kind of
17 "outreach programs" you people do have.
18 I mean, you know, I'm familiar with most of them
19 because that's the area I work in, but thinking in terms
20 of the support that EPA gives to USDA, to the EPA
21 regional offices, the state lead agencies, cooperative
22 extension, we all work very closely with the state lead

1 agencies. I think Phil and Jose, they would confirm
2 that. We work closely with them but not strictly in an
3 enforcement/regulatory capacity. Often it is an
4 educational capacity in some way or form.
5 I think of the support for the SLAs, cooperative
6 extension. You have a very strong CNT program here. The
7 CNT program encompasses worker protections. That's
8 largely I look at as a lot of outreach. The Endangered
9 Species Act is really an educational program. It's not
10 strictly an enforcement program, but it's to educate
11 people, educate people on changes to the label or these
12 endangered species bulletins.
13 I'm just wondering if it would help the group
14 -- and I think most of the group here probably has not
15 been engaged in, if you will, outreach type of education
16 -- if it would help them to realize the magnitude of the
17 programs that you really do sponsor, if you will, that
18 you support, that you aid in promoting pesticide safety
19 education.
20 So, I'm just throwing that out as a thought,
21 because you know, even our industry people here, they
22 take a major role in many cases in pesticide outreach

1 education, to their growers, to the general public. We
2 have a lot of that going on, and I guess I would like to
3 see -- you know, I want to say -- think a little
4 outside the box, that yes, you're considered a regulatory
5 agency, yes, you do enforcement, but yes, you also do a
6 lot of outreach education either directly or indirectly,
7 and we support that.
8 MS. MULKEY: Okay, Erik?
9 ERIK: I wanted to support what Jose had
10 suggested actually, and in particular, I think it's --
11 we spend so much time debating what goes on labels and
12 what the PHIs are, et cetera, and re-entry intervals and
13 so on, and one thing, I think some of it is a worker
14 issue, but I think there's sort of a broader compliance
15 with label issue that I would certainly be interested in
16 hearing what hard data the agency has, what data there
17 are generally on compliance with labels and compliance
18 generally with the agency's regulatory requirements.
19 You know, I'm not -- I think part of that might
20 have to come not from OPP but from your enforcement and
21 from state folks, but I think it would be a really
22 interesting exercise to hear about what data you have on

1 that issue and whether a lot of the sound and fury over
2 label changes and so on really ends up making it out into
3 the field.
4 MS. MULKEY: All right, Lori?
5 MS. HARDER: I'm not sure if this is the right
6 forum for this, but I think it would be interesting to
7 discuss cross-media issues with the Office of Water,
8 Office of Air and how they may challenge or uphold the
9 registration -- pesticide registration process and label
10 and those kind of issues.
11 MS. MULKEY: There certainly have been some
12 obvious ones, like the methyl bromide exemption process
13 and the NPDS permitting intersection with HOLSAD
14 (phonetic) application.
15 I believe Warren and then Jay.
16 DR. STICKLE: I would like to make three quick
17 comments. The implementation of the Data Quality Act on
18 October 1st I think is going to have a significant set of
19 ramifications for a whole variety of issues and programs
20 in a lot of federal agencies, including EPA and including
21 OPP. So, it might be worth taking some time at the next
22 meeting to sort of focus on the impact that the Data

1 Quality Act might have on various programs and what its
2 real impact is going to be.
3 Secondly, you know, I think Larry's really
4 touched on an interesting concept of dealing with the
5 various international efforts that the agency is making.
6 I think a lot of us are cognizant of some of those, but
7 no one's really put together a whole package of where EPA
8 is taking the leadership in the international arena, and
9 that would be good to just look at and review.
10 And thirdly, over the next six months or so,
11 there's going to be a number of decision points on
12 inerts, and whether that includes the new risk assessment
13 model and the comments that are due on October 11th or
14 the development of a data compensation scheme where
15 there's going to be a meeting in late September or
16 whether there's an impact on international harmonization
17 with NAFTA or, for that matter, work on the 450
18 tolerances that are going to be worked on over the next
19 four years, plus the update of the inert list. So, there
20 are a lot of things happening in the next six months, and
21 that might be a viable topic for the next meeting as
22 well.

1 MS. MULKEY: Okay, Jay?

2 MR. VROOM: I have three suggestions for our
3 next meeting, two of which would be continuations of
4 things that we've done, and the third will be I think a
5 relatively new idea topic-wise.

6 Number one is Endangered Species Act and its
7 many implications or ramifications --

8 (End tape 3-A.)

9 MR. VROOM: -- with particularly interest in
10 getting someone here from both Fish and Wildlife and
11 NIMPS. I think that kind of dialogue opportunity for
12 senior representatives of those two groups and perhaps
13 even someone higher from Interior, in the Secretary's
14 office, that we might be able to illustrate, you know,
15 the level of expertise and outside advice that OPP gets
16 as is embodied around this table ought to give some
17 benefit to those programs, to understand the magnitude of
18 the involvement plus USDA's involvement at this table as
19 well.

20 Secondly, I think we will continue to have fees
21 and resources and performance and strategic plan as kind
22 of an integrated topic. I think it ought to be a

1 permanent agenda item for this committee, and in
2 particular, I -- new subcategory opportunities to
3 explore. Ray just informed me that he's a member of
4 something called the Chemicals and Pesticides Results
5 Measures Advisory Stakeholder Group to OPP. I didn't
6 even know he was doing this, so I come here and learn
7 something from my staff colleagues, but obviously there's
8 a lot more detail around your strategic plan as it
9 relates to GPRA goals and accomplishments and all of that
10 that I think would be very rich further topic opportunity
11 for this committee.
12 Lastly, I'd suggest that it be considered to put
13 a topic on the next agenda strictly focused on benefits.
14 Almost everything we've discussed has related to risks
15 except for the conversation yesterday around efficacy
16 data. USDA's got a lot of information that could be
17 composited under this kind of a topic for future PPDC
18 meeting. Certainly BEAD does, and I think the industry
19 is bringing together, along with university sources, a
20 lot of new information, and I think it would be an
21 opportunity for us to put some focus on that, and also
22 dialogue and give advice to the agency about how you are

1 pursuing that part of the statutory authority under FIFRA
2 for benefits consideration.
3 MS. MULKEY: Bill?
4 MR. TRACY: I'd like to second and third the
5 concept that's talking about the field programs along
6 with the registration program and how they benefit each
7 other, and in the field programs, I guess I'm talking
8 about CNT, there's disposal programs going on out there,
9 there's the groundwater issue, there's the surface water
10 issue, and there's enforcement I think, and we used to
11 talk, at least at SFIREG (phonetic) about the field data
12 plan, which was supposed to support the registration
13 process as kind of a check on the system. I honestly
14 think some dialogue about all of those kinds of programs
15 around this table and how they work with or don't work
16 with the registration process is important. I really
17 view the program as being a national registration program
18 and then kind of a disperse program on implementation out
19 in the field, and I think just focusing a little about
20 where we connect well and where we don't would be real
21 beneficial, and I think this group could give some input
22 into that.

1 MS. MULKEY: In addition to or in the absence of
2 a complete sort of integrated tackling of that topic, do
3 you think some subparts of that lend themselves to this
4 update approach so that at least they get, you know --
5 MR. TRACY: Well, I think endangered species has
6 been talked about a number of times. That's kind of come
7 back up on -- it looks to me on the plate, and that's
8 part of that whole performance, but, you know, we have
9 dealt with groundwater issues for a long time, we have
10 skirted the surface water issue for a long time, and
11 there is this whole -- this linkage between what's going
12 on in the field found through enforcement.
13 Even more important than enforcement, where do
14 you have troubles in the field when you're following the
15 label? Where do you have environmental concerns or
16 health-related concerns when you're actually following
17 the label directions? That's probably even a bigger
18 issue, because that's legally used with consequences,
19 which we're not supposed to probably talk about or have,
20 but it does seem to happen occasionally, so...
21 MS. MULKEY: Okay, thank you.
22 Well, all of this -- oh, excuse me, I'm sorry.

1 Nancy, I'm sorry.
2 DR. LEWIS: That's okay.
3 On future topics --
4 MS. MULKEY: I don't know, I think it's the
5 light or something, I've got to --
6 MR. LEWIS: -- I consider myself very much a
7 beginner in the whole pesticide area, and because of
8 that, the primer idea does appeal to me a lot, and also
9 maybe even a primer on your office and structure and to
10 give me some sort of an umbrella of where to put these
11 different topics as they come up. I think that would
12 have helped with the language, too. A lot of new terms
13 every meeting for me. I'm sort of getting there, but I
14 could still use a lot more help on that.
15 MS. MULKEY: Well, let me make an offer -- that
16 I hope I don't live to regret -- that for any of you who
17 really feel that you would like some specialized help on
18 sort of getting up to speed in a fairly basic area, like
19 structure or -- if you just ask, through Margie, we will
20 actually do some one-on-one tutoring here for some
21 people's needs, and that's not to say in lieu of some
22 kind of, if you like, breakfast session, but we obviously

1 do have a range, and what happens is that there will be
2 somebody who sits among us -- Troy might be an example,
3 he's not here -- who has a very keen interest in one
4 area but who wouldn't have had any reason to have sort of
5 developed mastery in other areas, but who if he's going
6 to sit around the table with us might really add value in
7 some of these other areas if there was an opportunity to
8 do so.
9 So, I imagine there's a handful of you like that
10 who are here because of a pretty narrow role, but who
11 might welcome -- and we might do some one-on-one for
12 that kind of thing if that would be helpful.
13 Well, we're doing great on time, because I
14 assume we still have no public commenters, and we have 15
15 minutes left under our schedule. So, I would like to use
16 that by asking for -- back up.
17 We heard you on all this. What's interesting is
18 that the activity-based REIs, which I know Lori Berger
19 has brought up and I thought several others of you had,
20 and so while we don't have to know now, it's sort of
21 interesting there was no mention of that in this
22 discussion, but we are going to continue to use our chat

1 room. We have heard you. We actually -- the fact that
2 I'm not taking notes doesn't mean we're not hearing you.
3 We actually have very careful notes prepared and
4 presented to us very shortly, and there is a transcript
5 of this proceeding, so we'll actually be able to use this
6 input that you just gave us.
7 We may frame it up for you a little bit so that
8 on the -- in the chat -- in the e-dialogue, you can
9 refine your thinking. Some of you may want to -- and,
10 in fact, vote for topics that you didn't say something
11 about this time or not. So, there will be an opportunity
12 for some of that. I think this was actually very rich
13 input, an opportunity to plan both some of the more
14 comprehensive kinds of things and some more targeted
15 kinds of approaches for our meetings or other -- even
16 other forums.
17 Having said that, the one thing that we are
18 really doing differently than what we had done until
19 maybe two meetings ago is put together these, for lack of
20 a better word, panels, this group of people who sometimes
21 fairly loosely, sometimes in a quite integrated way, who
22 invest in preparations and then have the opportunity to

1 have a sustaining involvement on that issue with us. The
2 biopesticides industry and marketing issue is an example
3 of that, and as you can see, although it's not a highly
4 structured work group with a lot of meetings, there is a
5 certain continuing cohesiveness of that group.
6 The group that was working on alternative
7 testing seems to have a strong self-generated desire to
8 maintain and continue to invest in that issue and engage
9 with us. We are finding it helpful. It would be even
10 more helpful if there were a couple of other
11 perspectives. We sort of drafted Syngenta into that
12 group, and they clearly have added something a little
13 different from the consumer products industry perspective
14 that was already there.
15 So, that's sort of going to take -- and I don't
16 know whether we'll dub it a work group or keep it
17 somewhat less formalized, but it does appear to have the
18 desire, works for us, a potential to sort of -- so,
19 there are some of these kind of topics which lend
20 themselves to that kind of approach, and we're finding
21 that useful, because it takes some of the work off of us
22 for one thing. It gives you a multitude of perspectives

1 instead of just agency talking heads.
2 It can be other parts of the agency, you know,
3 or other parts of the Government. It wouldn't have to
4 always involve the private sector or participants from
5 this -- from among you. So, we will think about that as
6 we think about these topics, and we'll ask you to, too,
7 which kind of topics lend themselves to that approach,
8 because we find that richer for us in terms of having a
9 topic be more than just our preparing and then hearing
10 your reactions.
11 So, I think that in choosing among topics, the
12 fitness of some -- of an issue like that -- I mean, of
13 an issue for that kind of approach will help inform our
14 thinking about what issues to engage in. So, having
15 offered that, having asked you the questions I asked you
16 throughout the day yesterday as well as now, what I would
17 like to do is to get your general reactions to what's
18 working, what's not, what you want to see. If you want
19 to give feedback on this meeting now, fine; if not, you
20 can do it in the electronic forum, and just sort of your
21 last word kind of thing.
22 In particular, I encourage any of you and all of

1 you who haven't been saying a whole lot in particular to
2 be sure that we hear your perspective if you have
3 something you feel you want to offer.
4 Bill?
5 MR. TRACY: I want to talk a little bit about
6 meeting format. I really like the in-depth, you know,
7 four-hour examination of an issue. It gives an
8 opportunity to really go deep and think that should be
9 maintained for each meeting, have one of those, because
10 they're very educational, and probably in contrast to a
11 lot of people, I loved yesterday, but I come in from a
12 tox background. So, I knew what all those words meant,
13 so it was fun for me.
14 The minute updates seem a little -- they are
15 not poorly managed, but they're not a minute update, and
16 I -- and one of the things I think we need to do about
17 -- I think they're great. I like getting, you know, a
18 rapid sort of update on everything. I think a little bit
19 about -- I don't know if we need to establish some game
20 rules about that, but, you know, I'm sort of struggling
21 about commenting when they're minute updates, and they
22 can easily turn into half hour, and I know we don't want

1 to do that.
2 So, I don't know if we need to think about what
3 they are exactly and are we just supposed to sit here,
4 you know, or are you asking for a reaction, and so those
5 -- we need -- I think we need to do something about how
6 we do that, and maybe they need to be a little longer. I
7 don't know. So, those are my only two comments.
8 MS. MULKEY: Okay. Beth?
9 DR. CARROLL: Well, I love the minute updates.
10 I don't disagree that sometimes when we're -- we get
11 into something and there's other comments, you kind of
12 feel like, well, maybe I should just wait and put it on
13 the web, but maybe there's a way to figure out which ones
14 are going to generate most discussion and have a little
15 more -- which ones are just informational, because some
16 of them are, they're -- this is going to be published on
17 this day in the Federal Register and we're working on
18 this or whatever, and others that might be more to the
19 group with we would want to make some comments, but I
20 think we cover a lot of territory with those things, and
21 I think they're great.
22 MS. MULKEY: Maybe we could parking lot the ones

1 that seem to want discussion and come back to them later.
2 I'm not sure we can predict. We wouldn't have batted a
3 thousand I'm predicting for this one, I'll tell you that.
4 We might have gotten over 300 or whatever is a good
5 average in baseball.
6 Warren?
7 DR. STICKLE: I think the updates are really
8 excellent, because they give you a broad range of issues
9 and a snapshot of what's happened on a particular issue.
10 I'd like to suggest two things you might want to
11 consider. One, the House of Representatives sort of
12 works under a five-minute rule, and you might want to
13 consider not one minute but perhaps five minutes as a way
14 of giving a little bit of an in-depth analysis on a short
15 topic.
16 Then secondly, if there's any way to one week
17 ahead of this meeting put together sort of a discussion
18 or an outline on these topics so people can digest that
19 information and then come prepared with a question or
20 two, that might create more of a dialogue on these
21 issues, but again, do it very, very quickly.
22 MS. MULKEY: We are trying to get relevant

1 information out. I know we've had mixed success. So,
2 any feedback on both the up and the downside of what
3 we've achieved would be welcome.
4 Julie?
5 MS. SPAGNOLI: I likewise share I think the
6 comments that I think the updates are very, very helpful.
7 I think maybe there might be some ways to organize them
8 into ones that are just -- that are just informational,
9 such as, you know, if there's a group of upcoming
10 workshops, maybe just present all those as, you know,
11 here's some upcoming activities that we're doing and kind
12 of present them all together, and that's more
13 informational.
14 I think when you -- as we know from yesterday,
15 you know, with the topic of the objections to the
16 tolerances that had been filed where the agency was
17 actually looking for input, there obviously that wasn't
18 an update in a minute type topic, and so again, I think
19 if we kind of look at them and say -- maybe how we
20 organize them, and what are we trying -- are we trying
21 to look for feedback versus just provide information, and
22 then we might be able to manage them a little better.

1 MS. MULKEY: Yeah, we definitely drafted on our
2 solicitation at the 11th hour, and that was probably a
3 mistake.
4 Nancy?
5 MR. LEWIS: I agree, I like the one-minute
6 updates, too, and I did like the in-depth science as
7 well, but some of it got a little long, so that the time
8 limit there might be useful, too, 15 to 20 minutes might
9 be enough for each topic.
10 I had a couple other general comments, thinking
11 last night about what did I get out of this meeting. One
12 thing that struck me yesterday was the comment on
13 attitude, a couple of different times people mentioned
14 attitude, and I'm not sure what the real message was, but
15 I think for myself it is really critical to maintain an
16 open attitude, and I don't know if that was the message
17 that was trying to be conveyed or not, but I just
18 remember hearing that more than once. So, I think there
19 was a message there.
20 The other thing, since being on this group, I've
21 noticed media more on pesticides, and it seems that every
22 time I read it, it's negative, and it makes me think I

1 know there's a lot of good things, and is there any way
2 of capitalizing on that and trying to put forward more of
3 what it's really doing for us that's good?
4 MS. MULKEY: You're talking about negative about
5 the products themselves?
6 MR. LEWIS: Well, like the pictures of the frogs
7 with three legs, the kind of thing that gets the fear up
8 in consumers.
9 MS. MULKEY: Okay, yeah. I thought you were
10 talking about coverage of government's role.
11 MR. LEWIS: No, no. No, negative as to
12 pesticides.
13 MS. MULKEY: You're talking about products, I
14 understand, exactly.
15 All right, others? We have a public comment
16 process, so we'll just allow you to participate in that
17 if you will go to the mike and identify yourself.
18 SPEAKER: My name is Larry Hammond, I'm with --
19 a consultant to the 240 task force, and I just want to
20 make a couple of comments perhaps for the itinerary. One
21 is to echo what was said earlier about IRIS. I think
22 that IRIS is woefully behind; however, we do know that

1 there's some interaction going on at this time between
2 crop life and industry to try to update that, but that
3 should be something that perhaps is discussed.
4 A second one, I don't think I heard it here, was
5 about (inaudible) disruption. NSAX (phonetic) is kind of
6 behind us, but the son of NSAX is very current, and where
7 are they on the validation of the methodology and what
8 can we expect on that, because it's a soft issue, but it
9 keeps coming up about different compounds, and we need to
10 know kind of where the agency is at at this point in
11 time.
12 MS. MULKEY: Thank you very much.
13 Any other public comment that didn't sign up but
14 we wanted to hear? Very good.
15 Well, we're in good shape. You've been
16 terrific. You've worked hard. So have we. It's -- we
17 really appreciate all the positive feedback, and there
18 has been a lot of positive feedback, but we equally
19 appreciate your suggestions about how to not only get
20 this meeting better but to get all our work better, and
21 we hear a lot of that in this context, and we welcome
22 that, too.

1 SPEAKER: Are we going to talk about a next date
2 kind of thing?
3 MS. MULKEY: A date? I think that's a good
4 idea. I was contemplating taking a deep breath, but it's
5 probably better to do that -- to start that here. We
6 were going to do that on the list.Serve obviously, but do
7 we have some perspectives on that at the table?
8 SPEAKER: The question is --
9 MS. MULKEY: The next meeting time frame.
10 SPEAKER: Are we looking at January possibly?
11 MS. MULKEY: My own thinking is probably January
12 is the earliest to be looking at. There are some issues
13 around January, travel and weather issues. There's also
14 the CARAT -- at least the CARAT transition work group
15 which, you know, has issues around scheduling that
16 intersect with this.
17 On the other hand, if you go much beyond
18 February, you've sort of created too long a gap.
19 SPEAKER: Yeah.
20 MS. MULKEY: Do you -- are you eager enough
21 that if we could pull it off, you'd want to see December
22 or January?

1 SPEAKER: Not December.
2 MS. MULKEY: Not December.
3 SPEAKER: January.
4 MS. MULKEY: Good.
5 SPEAKER: Not December.
6 MS. MULKEY: Yeah, so the other thing is the
7 second of these worker risk workshops needs to be
8 scheduled, and one of the -- I mean, it would be four
9 days, because this is probably likely to be two days, but
10 one of the opportunities is co-scheduling -- how do
11 people feel about that? Is co-scheduling basically more
12 a good thing than a bad thing or more a bad thing than a
13 good thing, because you wind up with too many days?
14 SPEAKER: Good thing.
15 MS. MULKEY: More a good thing.
16 SPEAKER: It's a long way from California.
17 MS. MULKEY: We consciously scheduled the
18 endangered species workshop for tomorrow, and I take it
19 you're saying that's a good thing.
20 SPEAKER: Yes.
21 SPEAKER: Yes.
22 MS. MULKEY: Any contrary point of view? So,

1 what you're saying is relatively sooner rather than
2 later, you're liking January, and if it were co-scheduled
3 with something like the transition work group or the
4 worker risk, you'd welcome that. Is that what we're
5 hearing?
6 Great, we'll see what the story is on hotels and
7 such -- like -- well, thank you. Thanks for --
8 SPEAKER: It's too bad we can't have one on
9 Halloween, because that's the last dog day downstairs,
10 and they bring them in costume they tell me.
11 MS. MULKEY: Oh, wow. Well, I had great fun
12 with the dogs, and I never would have gotten over here if
13 it hadn't been for this meeting, so that's great. Well,
14 thank you all. It's been fun.
15 **(The meeting was concluded.)**
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