MEETING

BEFORE THE

CALIFORNIA AIR RESOURCES BOARD

SCIENTIFIC REVIEW PANEL ON TOXIC AIR CONTAMINANTS

THE GROSVENOR HOTEL

380 SOUTH AIRPORT BOULEVARD

SOUTH SAN FRANCISCO, CALIFORNIA

WEDNESDAY, MARCH 19, 1997

9:40 A.M.

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MEMBERS PRESENT

James Pitts, Chairman
Craig Byus
Gary Friedman
John Froines
Stanton Glantz
James N. Seiber
Hanspeter Witschi

DPR Staff Participating:

Jean-Mari Peltier
Chief Deputy Director

Paul H. Gosselin
Assistant Director

Thomas Thongsinthusak, Ph.D.
Staff Toxicologist

Carolyn M. Lewis, MS, DABT
Associate Toxicologist

Kevin Kelley, Ph.D.
Associate Environmental Research Scientist

Tareq A. Formoli
Associate Environmental Research Scientist

ARB Staff Participating:

Mike Scheible
Deputy Executive Officer

Peter Venturini
Chief, Stationary Source Division

Genevieve Shiroma
Dr. Joan Denton
Robert Krieger

APPEARANCES, continued. . .

OEHHA Staff Participating:

Bill Vance, Ph.D.
George Alexeeff, Ph.D.
Melanie Marty, Ph.D.

I N D E X

P R O C E E D I N G S

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CHAIRMAN PITTS: Let's get this public meeting on the road. Let me just start by introducing myself. I'm Jim Pitts, Chair of this Panel, and I want to welcome all of you here today in the audience from very perspectives, various interests in the activities of the SRP and how they relate to OEHHA and the ARB, and the general problem of airborne toxics.

One of the interesting points that I might mention at the beginning just prior to our first speaker, who we'll get to shortly, is -- see if I can find it amidst all of this. I have, just for fun -- questions have been raised: Who, or what, or why do we have an SRP? It's been around for 12 years or so.

And just let me take a minute or two at the outset to sort of say some of our background, sort of briefly, to refresh some of us as to what our function is and how our Panel members are chosen, sort of where we come from, because we certainly ask questions of the people who testify and provide information to us.

Just for fun, I went back and -- just for fun -- picked up a copy of the bill 2728, AB 2728, and this is a bill on toxic air contaminants by Sally Tanner. And it essentially supersedes 1807, which is the original Tanner

bill.

And in the bill, they have an interesting set of comments here on how, in fact, the Panel is composed. The SRP, how is it made up? How did you derive a Scientific Review Panel? And if you look at this Section -- I'm going to read it here just so we get the ground rules of where we're at, where we come from. And it's useful, as I said, to do this once in a while.

It's Section 39670 of the bill, and it says that members of the Panel shall be highly qualified and professionally active or engaged in the conduct of scientific research. That's sort of step one, so we are all either in or have been, or are and in currently in scientific research. That's criterion one; that we're researchers in the field.

Secondly, they shall be appointed as follows, subject to Section 39671, for a term of three years. And then, it does into how we are -- who will appoint us. We are appointed -- five members are appointed by the Secretary for EPA, CalEPA; one of whom shall be qualified as a pathologist, one of whom shall be qualified as an oncologist, one an epidemiologist, one atmospheric scientist, and one who's had relevant scientific experience and shall be experienced in the operation of scientific review or advisory boards.

Two members shall be appointed by the Senate Committee on Rules -- on a biostatistician, and one a physician or scientist specializing in occupational medicine.

Three, two members shall be appointed by the Speaker of the Assembly, one of whom shall be qualified as a toxicologist and one of whom shall be qualified as a biochemist or molecular biologist.

Then, it's interesting. How are we appointed? It's rather a clearly defined and fairly detailed process. Members of the Panel -- and it's interesting, as I say, to see this in law, statutory law.

Members of the Panel shall be appointed from a pool of nominees submitted to each appointing body by the President of the University of California. The pool shall include at a minimum three nominees for each discipline represented on the Panel. So, there's a major pool, or at least three candidates.

Now, why they would want to be candidates is a different question. And there are certain days when I'm sure the audience or some of you wonder we were -- wanted to be a candidate and some days when we wondered why we were candidates.

But, at any rate, there's three nominees for each discipline represented on the Panel, and shall include only

individuals whole hold or have held academic or equivalent appointments at universities and their affiliates in California. That'd be U.C. campuses. And the late Tom Davis was a great guy, a member of the Panel, was from Stanford.

Okay. Now, the Secretary of the EPA shall appoint a member of the Panel to serve as chairperson. At this point in time, I happen to be the Chairperson.

The Panel may utilize special consultants -- this is interesting -- or establish ad hoc committees, which may include other scientists, to assist it in performing its functions.

Now, we operate under certain rules, too. And I think, in terms -- if you know, many of you are familiar with panels appointed by the National Academy of Sciences, by the EPA, by various bodies of that sort. And many of us, of course, on this Panel -- and many of you have served on these panels, I'm sure. Many of us who are on this Panel served for the EPA, the Academy panels, and so forth. And it's very interesting to see sort of what qualifications or what are the ground rules under which we operate as members of this specific Panel.

And I can tell you, if you read this, I can assure you, having been familiar with the others, that it's a very interesting set of ground rules that we operate under by

law.

Members of the Panel and any ad hoc committee -- in other words, not just Panel members, but any ad hoc committee that we appoint, established by the Panel shall submit annually a financial disclosure statements -- that's interesting -- that includes a listing of income received within the preceding three years, including investments, grants, and consulting fees -- which is interesting -- derived from individuals or businesses which might be affected by regulatory actions undertaken by the State Board or districts pursuant to this Chapter.

These financial disclosure statements submitted are public information. Members shall be subject to disqualification and so forth.

And then, it says what we get for this -- or if somebody wonders how well paid we are -- we shall receive $100 per day for attending Panel meetings. That's only when you attend a Panel meeting, not for the days that you B.S. on the phone back and forth and that sort of thing, and for what you probably shouldn't be paid because it's kind of fun, in any case.

So, basically, I think it's important to know that those are the ground rules that we operate under. And we are, in fact, familiar with a variety of other -- IARC, the International Agency for Research on Cancer, the Academy,

and we've served on these. And these are very, very tight rules. And, as I say, the Panel members have never complained about them. These are the rules and it's how we play the game.

So, that gives you a little story there. And there's also a very clear statement, which I don't think I need to read right now, but it is here, in terms of what -- well, here. I will read this point. This is a report. Now, this comes down to the basis for reports, a basis for involvement.

Okay. It says, this report -- this is 39661. Upon receipt of the evaluation and recommendations prepared pursuant to da-da-dah, the State Board shall prepare a report. This is what we'll be talking about today. So, I'm giving you background. We're not necessarily talking about a final report today, but this is the background, legislative background, statutory background to reports, which inform, may serve as the basis for regulatory action regarding a particular substance pursuant to subdivisions da-dah-da-dah.

The report, together with the scientific data upon which the report is based, shall -- with the exception of trade secrets -- be made available to the public and shall be formally reviewed by the Scientific Review Panel established pursuant to Section 39670, which I just read to

you.

The Panel shall review the scientific procedures and methods used to support the data, the data itself -- which I might say we might make a comment to the legislative person who wrote this, data is plural, remember that.

(Laughter.)

CHAIRMAN PITTS: It's always nice to throw out even if you flunked Subject A, as I did, when I went to UCLA back in the old days.

(Laughter.)

CHAIRMAN PITTS: And actually learned a hell of a lot more of grammar and writing skills than I had been exposed to before.

At any rate, the data "itself" and the conclusions and assessment upon which the report is based. And it says another point in here, which I'll read, and is a subject of interest in a lot of quarters and it's fairly -- and we have thought about this -- any person may submit any information for consideration by the Panel, which may -- at its discretion -- receive oral testimony.

The Panel shall submit its written findings to the State Board within 45 days and so on.

So, basically, that is the framework and their wish. Basically, we were operating under 1807 from about, what, 1984 until this 2728 came out in 1993.

And with that, then, with that little background, I'm prepared now to open the formal presentations, which we have noted -- it can be formal, but somewhat informal and interactive. And I would like to introduce the first topic, which will be the DPR's presentation report on the evaluation of S,S,S,-Tributyl Phosphorotrithioate, which we will call DEF -- for obvious reasons -- as a toxic air contaminant.

And it's my pleasure and the Panel's pleasure to meet for the first time and to introduce us to her and she to us, Ms. Jean-Mari Peltier, who is the Chief Deputy Director of the DPR, and the staff who will be assisting her. And we welcome you here and look forward to your comments and testimony.

MS. PELTIER: Thank you, Dr. Pitts. I appreciate this opportunity. Can everyone hear me all right?

I appreciate this opportunity of making a presentation before the panel. This is my first time, as you know, to come before you, and actually my first time to ever make a presentation before a scientific panel. I've testified before Congress, and I've been involved in international trade issues. I'm been involved in marketing kinds of things. But this is the first time I've had a presentation of this sort. And I'm kind of reminded of my son who, yesterday, had to do his first recitation of a poem

in his fourth-grade class. And he pointed out that he had a real hard time doing it, because there was one kid who was making facing at him the whole time.

So, as long as I don't have anyone making faces at me here today, hopefully, I'll get through this like my son did yesterday.

What I'd like to do today is try to give you a new perspective on the way that the Department of Pesticide Regulation is approaching its responsibilities under the 1807 requirements and what I hope will start a new cooperative relationship between the Department of Pesticide Regulation and the SRP as we go through and evaluate pesticides under the program.

As we have reviewed the historic relationship and, as I was preparing to make this presentation here today, I have to say that I share your concern that has been a dearth of information shared between DPR and the SRP over the last several years. And I think, as we talk through today's presentation, you'll see that the stage is set for that to be quite a bit different as we approach this year, starting with our presentation to you today on DEF.

And I'd like to take a minute, if I could, to introduce the staff that's going to formally presenting the papers to you, starting first with Kevin Kelley. Kevin, you want to come up? He's an Associate Environmental Research

Scientist with our Environmental Monitoring and Pest Management, and Kevin is going to be leading off with a discussion of the environmental fate report on DEF.

Joining him is going to be Tareq Formoli, who is an Associate Environmental Research Scientist, and he is with our Worker Health and Safety Branch, and he'll be walking through the exposure assessment on DEF.

And then, finally, Carolyn Lewis, who is an Associate Toxicologist out of our Medical Toxicology Branch, will be reviewing for you the health effects assessment for DEF.

And, if you could, if you could just flip on the switch there for a minute -- let me stand up so you can sit down.

(Thereupon, Ms. Peltier approached the overhead screen.)

MS. PELTIER: We have outlined here what our proposal is for the schedule for reviewing not only DEF but the other materials that we plan to bring before the Panel this year.

But starting first with DEF, let me kind of walk through where we are here. We completed this report, which you'll be getting copies of today, in February of this year. The draft report we're releasing to you is also going to OEHHA and to U.S. EPA.

We're hoping to get comments back from you and the other agencies by May. We'll be revising the report and going to public workshop in July and August. And then, finally, we'll be getting back to you with a formal report for SRP review in October of this year.

Now, let me say that what we're hoping to get comment on during this first review -- actually, what we're doing, in a sense, is prereleasing this to you, and we'd like comments from you on format and the scope of what we're presenting in these documents.

So, let me turn it over to Kevin Kelley to walk through the report, then I'll come back up and try to handle any questions you have, and then also walk through some other ongoing activities at DPR that are going to be affected here.

DR. FROINES: I have a question.

MS. PELTIER: Yes.

DR. FROINES: Does that mean that there's going to be a presentation today about what's in the draft document?

MS. PELTIER: Yes.

DR. FROINES: But you're not expecting us to give you detailed scientific comments about the report today? This is really a briefing, and you're going to want input from us in June or whatever that date was.

MS. PELTIER: Yeah, the workshops. Actually, the

formal period for comments will be in October. And we've presented it this way to try to give you advanced input into it, and try to give us an opportunity to make revisions even before it gets to the workshop process.

We had talked about the possibility of exploring with you making this a one-step process, where we do this release at this point and not come back with a revised report. But at least, as we're planning to -- as we're contemplating walking through it now, we're actually -- this is a prerelease to you at this point.

Yes?

DR. SEIBER: Just a quick comment on that. I like this process, because one of the questions we had a year or so ago was, just as a matter of format, how do we want to receive the information, so if we want to pay close attention to the format, which I personally feel is quite good; and, secondly, just to get scientific issues surfaced on this compound and others as early as possible. I think it's really good.

DR. FROINES: So, what happens is there'll be a subsequent presentation in October?

MS. PELTIER: Yes.

DR. FROINES: And then, depending upon -- let's assume we find minor problems, and then it goes back to you. And then, will it come forward a third time?

MS. PELTIER: The process, as it's outlined in the laws and regulations, is that we get your formal comments. If you have things that we need to respond to, we're supposed to get back to you within a 30-day -- no, excuse me, 60-day period. So, after we have your formal report, I believe it's incumbent on DPR to respond to you within 60 days; so, hopefully, if everything goes right, sometime right after the first of the year, in 1998.

DR. FROINES: So, procedurally, will we then write a report which has, as we've done in the past, which includes our findings to go the Director?

CHAIRMAN PITTS: That's a good question. That is one of the key questions. Will it be treated as an 1807, the 1807 process; when, in fact, the requirement is that, after formal approval of the document -- or whatever it may be -- then the SRP is required to prepare a set of findings, legal findings, which then accompany that document. And then they go forward, for example, to the Air Resources Board.

MS. PELTIER: I believe it comes back to the Director of the Department of Pesticide Regulation to make the determination as to whether or not this material should be listed as a toxic air contaminant.

CHAIRMAN PITTS: And, yes. And the Panel may say, yes, we vote that it should be a TAC, but that's our

recommendation. That's our evaluation of it, and then it goes to the ARB for the ultimate, in the case of the toxic air contaminant. So, that would be a parallel process, would it not?

MS. PELTIER: Actually, I believe it goes to the Department of Pesticide Regulation for the determination of whether this particular material is a toxic air contaminant.

CHAIRMAN PITTS: Right.

MS. PELTIER: Okay?

CHAIRMAN PITTS: Are there -- yes, Stan. Dr. Glantz.

DR. GLANTZ: I spent, some years ago, a lot of energy working with the predecessor department of DPR, and just hit a brick wall on these issues. And I'm pleased to see that you're starting to move forward on this. And I also think that the process, as you've outlined, is pretty reasonable.

I just have two comments. First of all, I think that we should just assume that we will be issuing findings, because we always issue findings. I mean, that's never been controversial in the past. But I think that should be an anticipated part of the process.

The second thing, which is kind of a minor point on what you said, is the way that we have functioned in the past is to have designated lead people on the different

compounds, which I don't know if someone's designated on this one or not yet.

Is there someone designated?

CHAIRMAN PITTS: Peter on health effects and Dr. Seiber on the exposure aspects.

DR. GLANTZ: Okay. And I think your desire to have the report reviewed or looked at by the SRP sort of informally during the public comment period is a good idea and something that we've done on other things in the past.

There's also been a tradition of kind of open informal communication as even that first draft is being written, and a lot of back and forth, with the idea of heading off problems. And that's actually become something of an issue recently regarding OEHHA.

And I would hope that you guys would maintain that kind of open relationship with the SRP, and not just when the thing goes out for public comment, but even before that to the extent that the lead people are interested.

And I think, in the past, this Panel has also been a resource to OEHHA and the ARB in terms of preparing the initial public review draft.

So, I would hope that, in addition to the formal process which you've outlined here, which I think is fine, you would also have informal involvement of the interested SRP people even before it goes out for public comment.

MS. PELTIER: Let me say we would really welcome that.

CHAIRMAN PITTS: Excuse me. Would you mind speaking into the microphone?

MS. PELTIER: Actually, we'd welcome that opportunity. And really, to follow up even further when we get into it later in the discussion, to continue some discussions that we've had informally, including the review of this Panel a year ago in informal discussions on methyl bromide. And, you know, I'd like to open the door to continue that dialogue, because we really don't want to do this in a vacuum.

DR. FROINES: I don't want to prolong it either, because the people who are going to make presentations are sitting there wondering when they're going to get to their material.

As far as I'm concerned, for example, I have some significant interest in issues of chronic neurologic toxicity. And I read that section of the document rather closely.

And how do you want to do it, Peter? Do you want us to make comments to go back through you, as the leadperson of the Panel, or should we go directly to people at DPR? How do you want to do that?

DR. WITSCHI: No, I think you could go directly.

I mean, there's no point in going through me. But, yeah, I would agree, there are a few things which do not belong in the official public meeting, but which should be straightened out before.

DR. FROINES: Okay.

MS. PELTIER: All right. Then, Dr. Kelley, you're up.

DR. KELLEY: Hopefully, my presentation and my overheads will at least elicit a glance or two.

My name is Kevin Kelley, and I'm presenting an overview of the environmental fate section of the report. The report is called "Evaluation of S,S,S,-Tributyl Phosphorotrithioate," which is referred to as "DEF" -- and I'll be using DEF to refer to this mainly out of pity for the reporter, who would need to write down the long chemical name each time it's said -- as a toxic air contaminant.

What I'm going about today is what is DEF, its physical and chemical properties, the use of DEF in California, the seasonality of DEF use. I'll also talk about the environmental fate of DEF and DEF concentrations in the air.

Next.

The common names for DEF are tribuphos and butyphos (phonetic). Trade names are DEF 6 and Folex 6EC. Each formulation contains 70.5 percent of the active

ingredient, and it's formulated as the most viable concentrate.

DEF is a colorless to pale amber liquid with a melting point of less than negative 25 degrees celsius, a boiling point of 150 degrees celsius, and a vapor pressure of 10 to the minus 6 millimeters of mercury at 20 degrees celsius.

DEF is readily soluble in most organic solvents, and is practically insoluble in water, which is why it's formulated as an emulsifiable concentrate.

DEF is designated a toxicity Category II restricted use pesticide.

DR. GLANTZ: Could I just ask one question? What's it used on?

DR. KELLEY: I'll be getting into that.

CHAIRMAN PITTS: That's the cotton.

DR. KELLEY: Yes.

CHAIRMAN PITTS: You said Category II of --

DR. KELLEY: It's a Category II -- excuse me. It's a toxicity Category II.

CHAIRMAN PITTS: Would you, in one minute, define for all of us -- or at least for me -- the categories, toxicity categories. What's I, what's II, what's III, what's IV? Just briefly, so we know the ball park we're playing in with DEF relative to say methyl bromide. Is

methyl bromide I? Or ethyl parathion?

DR. KELLEY: Ethyl parathion is a Category I, yes.

CHAIRMAN PITTS: Well, I have your 1988 report, which I want to point out here, which is a landmark report that was put out by you people, and went through the Panel, and was the first report going through 1807. And I find it very interesting. In this report, I might add as an example of interactions with the Panel, that this report not only describes the atmospheric transformations, the toxicology in detail, but is the first report that I've seen or one of the first that paid specific attention to children, and particularly infants. You remember, some of us who were on that Panel in 1988, this is ethyl parathion.

And that's the one where it was pointed out by -- in fact, Dr. Becker pointed out, in terms of the responses of infants, how serious this was for infants, zero to six months, in their systems.

I just wanted to point out that this is the report. And three years later, it was banned in the U.S., totally. So, that's an interesting example of where interactions between the groups, and came out with a report that was a key factor in actually the total banning of this compound, and it specifically addressed children in terms -- and I notice you've done that in your report.

I'm jumping ahead a bit. But in your report, just

to set the framework, that the impact of this particular pesticide, not only on healthy adults in terms of milligrams per kilogram, or microgram per kilogram of body weight and so forth -- what units that you use -- but that it's significantly different. You've looked at the impacts on children.

And that's very important to establish, that this was looked at nine years ago and introduced, and it's important to see that the EPA recognized this a couple of months ago when they came out finally and said that children have very different reactions to and sensitivities to -- to these various toxic air contaminants.

So, as a framework, that's part of the history that I've been trying to get through a bit this morning. So, that's neat. So, it's Category II.

DR. KELLEY: Right.

CHAIRMAN PITTS: Fine. Thank you.

DR. KELLEY: Okay. It's defined in FIFRA. I don't have a copy of it, but I can sort of muddle through it.

DR. GLANTZ: What's FIFRA?

DR. KELLEY: FIFRA is the Federal Insecticide, Rodenticide, and Fungicide --

DR. SEIBER: Federal Insecticide, Fungicide, and Rodenticide Act.

DR. KELLEY: The toxicity categories are set up based on LD-50s, LC-50s, and also some ocular effects. I know -- I can't give you the actual ranges, but generally on a pesticide label, pesticides that are in Category I would have "Danger," or "Danger Poison" on the label.

Pesticides in Category II would have "Warning" on the label. And pesticides in Category III or IV would have "Caution" on the label as just a single word.

Now, depending on what actually happens with eye effects, you can move pesticides that would normally only be a warning, they would move into the Category I. I can't give you anything much better than that.

DR. FROINES: The categories he's referring to are categories associated with acute toxicity. They do not include carcinogenicity and other end points. It's one of the multiple categories that they have in their prioritization.

DR. SEIBER: Let me just make a comment. California has a fairly extensive regulatory system at the county level. And the other important categorization is whether it's a restricted use, or can be used by anyone, or whether it needs to be reported to the County Commissioner when it's applied, or a permit needs to be obtained.

So, in this case, it does require a permit, and everything is controlled at the county level. Is that

correct?

DR. KELLEY: Right. That's correct.

DR. SEIBER: So, there's checks and balances on its use.

DR. GLANTZ: You'll find that, as you work with this Panel, that we pursue not in the engineering view of things, which is linear, we tend to do a random walk process.

(Laughter.)

DR. GLANTZ: I just wanted to get stochastic.

(Laughter.)

DR. KELLEY: That's the reason why I wrote down what I was going to say today, so I know what's next.

DR. FROINES: The trouble is you may never get to the "what next."

(Laughter.)

DR. FROINES: Anyway, the only thing I want to say, and this is directed to you. The Panel still has some questions about the prioritization process, and that we raised some of those questions in -- I forget -- two meetings ago or one meeting ago. And at some point, we'd like to pursue that subject. Because I think that, at least in terms of oncogenicity or carcinogenicity, we still think that, for example, the designations that you use are too limited. But I just want to point that out, and we can come

back to that at some time.

We'd just like to talk further about it. It's all in good spirit.

DR. GLANTZ: Sort of like a Ph.D. qualifying --

CHAIRMAN PITTS: That's just dodging it right there.

DR. KELLEY: Okay. I'll talk about DEF use now. In the San Joaquin Valley, growers defoliate cotton in autumn to meet State-mandated early plowdown dates. These plowdown dates are intended to reduce infestations of pink bollworm and the cotton boll weevil.

Winds and storm fronts transport the pink bollworm up from the Coachella Valley into the San Joaquin Valley, and overwintering adults will be destroyed by crop debris when it's disked under.

In Fresno County, Kern, Kings, Madera, Merced, San Benito, and Tulare Counties, all cotton plants must be destroyed during December, and then cotton may not be replanted until March the following year.

DEF is used as a cotton defoliant, and solely used on cotton. It's generally applied to the cotton plant one to two weeks before harvest. DEF accelerates the desiccation of green cotton leves, leading to leaf drop four to seven days following application.

Plants dry thoroughly and mature bolls open

faster. Less green foliage means less jamming of picking machines and also less staining of cotton bolls linked to a higher quality of cotton.

DEF is applied at a rate of three-quarters to two pounds per acre, and approximately 80 percent of those applications are made by aircraft.

Next slide.

DR. FROINES: Does anyone know how many acres in California are used for cotton?

DR. KELLEY: Approximately 900,000 to a million, maybe a little more, little less. About that.

DR. FROINES: Because your document says that 374,000 acres are covered with DEF; so that would leave out 600,000 where DEF is not used?

MS. PELTIER: It's not the only means of defoliating cotton.

DR. FROINES: At some time, I'd just like to know what else do people use, that's all.

DR. KELLEY: Okay. DEF use has fluctuated over the past decade or so, with a low of 56,000 pounds (sic) applied in 1986 to a high of 1,006,000 pounds in 1990. The yearly average of DEF use from 1983 through 1985, was approximately 825,000 pounds of the active ingredient.

DEF applications for 1993, were 980,000 pounds; in '94, 915,000 pounds; and in 1995, 885,000 pounds.

Next slide.

DEF use also varies by county, yet remains very steady within counties over time. Fresno County accounted for 49 percent of all DEF applications in 1993, 1994, and '95. Kings County accounted for an average of 21 percent; Kern County, 12 percent; and Merced County, 9 percent. I apologize. I don't have a pointer for this to make it a little easier for your viewing.

The final 9 to 11 percent of use was spread throughout the remaining counties. And to put this in perspective, in 1993, 475,000 pounds of DEF were applied in Fresno County versus 7600 pounds applied in Imperial County versus, in San Bernardino County -- which is over there, the second to the last -- 500 pounds.

In '94, it's 450,000 pounds in Fresno County, 9,000 pounds in Imperial, and 600 pounds in San Bernardino.

Applications of DEF in other counties, such as Glenn, Stanislaus, or Yolo, average less than 200 pounds a year.

DR. GLANTZ: Now, is that because they grow more cotton in Fresno, or is it because of some other reason?

DR. KELLEY: More cotton's grown in Fresno.

Next slide.

My next set of several figures will show the seasonality of DEF applications. Aside from a few spurious

applications which occur before August -- and that's generally applications to cotton on a research basis -- in the San Joaquin Valley, DEF is applied during September and October, with occasional applications in early November.

This is the seasonality of DEF applications in Fresno County. As you can see, applications begin in September on through October, with occasional small applications in November.

Next?

Same basic application pattern in Kern County, with the majority of applications in September, a few less in October, and some in November.

Next.

This is Tulare County. You can see applications beginning in September, ending in October.

Next?

Once again, in Merced County, which is a little further north, the majority of the applications are in October, yet they begin again in September.

Next?

DR. SEIBER: Just a quick comment, Kevin. You might -- this is really unusual; very few pesticides have such a --

DR. KELLEY: Right.

DR. SEIBER: -- restricted use area, crop, and

time of the year, right?

DR. KELLEY: Right. That's correct. In fact, the reason that I did these graphs in this manner was simply to show that it is applied in September and October in the San Joaquin Valley, and that is it, except for some -- like I said -- spurious applications at other times.

However, in Imperial County, we find that applications begin in October -- excuse me -- August and continue on through September. But again, it's the same 60-day, plus or minus 60-day window of application.

Okay. This is concentrations of DEF in air, which is briefly mentioned. The monitoring from this is Seiber, et al., 1988. And air concentrations were measured from August 31st through November 4th of 1986. I've presented the values just for September and October here.

The highest concentration of DEF measured was 375 nanograms per cubic meter, and that was recorded at Five Points during the peak of the application season.

CHAIRMAN PITTS: Excuse me. Was that averaged over two hours, four hours, what was the sampling time over which you took those?

DR. KELLEY: I think 24 hours.

DR. SEIBER: I'm trying to remember, but I think it was 24 hours.

CHAIRMAN PITTS: Okay. 24 hours. As a point of

reference now, in terms of the documents, that raises questions. Be sure that you specifically state the sampling times, and these are averages. Because we're all interested in averages and interested in peaks. And it will verify all the way through, if you would.

DR. KELLEY: Right. Okay.

CHAIRMAN PITTS: And another point that we made through the years, just as a possible helpful point to us who can't convert from micrograms per cubic meter to parts per billion -- actually, though, we have. I have something helpful here that tells me how to do it.

But we found it would be useful in the regular 1807 documents, when you put micrograms per cubic meter -- of a given gas obviously -- it'd be kind of nice to put "ppbs." Because I think in ppbs, and I think a toxicologist thinks in micrograms per cubic meter. We're coming from different perspectives. Just as a sort of a general idea, as you do these documents, and that would just be helpful.

It's a thought. You have it somewhere in there. But as you would put these numbers down --

DR. SEIBER: In other words, put them both down.

CHAIRMAN PITTS: Put them both. Put a paren, and put micrograms and then, paren, ppb.

DR. KELLEY: Okay.

CHAIRMAN PITTS: With me?

DR. KELLEY: Yeah.

CHAIRMAN PITTS: That'd be great.

DR. SEIBER: And, Jim, I hate to jump in so often, but if you wonder why Seiber, et al. did that monitoring, it's all part of the process. This group at U.C. Davis was under contract with the Air Resources Board to go out to do this. Essentially, we worked on a protocol together. So, that was all part of this process.

It wasn't just a group going out and taking samples.

CHAIRMAN PITTS: Good. That's the kind of background that's important to know. Good.

DR. KELLEY: We do present both nanograms per cubic meter and parts per trillion in the document.

CHAIRMAN PITTS: Yeah, sure.

DR. KELLEY: That 375 nanograms per cubic meter corresponds to 29.2 parts per trillion.

CHAIRMAN PITTS: See, that's kind of neat to know. Because you're talking about factors of a lot. Okay. Go ahead.

DR. KELLEY: Thank you. The average concentration over the sampling period at Tranquility was 68 nanograms per cubic meter, which translates to 5.4 parts per trillion; at San Joaquin, was 37 nanograms per cubic meter, or 2.9 parts per trillion; at Five Points, the average 102.4 nanograms

per cubic meter, or 8.1 parts per trillion; and at Huron, it was 28.4 nanograms per cubic meter, or 2.2 parts per trillion.

Okay. Possible fate of DEF in the environment; this is Kilgore, et al., 1984.

The presence of DEF in air is the result of its application to cotton fields and its volatilization from foliar and soil surfaces. In the presence of light, DEF is converted to n-butyl mercaptan, which is the second chemical formula --

DR. SEIBER: The structure's wrong. As you probably know, Kevin, there shouldn't be "po" at the end of that n-butyl mercaptan. It's already gone. I think it's just a typo or something.

DR. KELLEY: Oh, yeah, you're right.

CHAIRMAN PITTS: You don't want to get "P.O.'d" on this.

(Laughter.)

DR. KELLEY: That's what happens when you do a search and replace the night before a presentation.

CHAIRMAN PITTS: That's just a Freudian slip, right?

DR. KELLEY: Okay. It's converted to n-butyl mercaptan, which is the second and incorrectly represented structure up there, and also n-butyl disulfide, which is the

third.

These reactions generally occur within 24 hours; but, under certain conditions, may take longer.

After n-butyl disulfide is formed, you then get the sulfone, and then it finally breaks down into sulfate and alkyl chains.

DR. FROINES: There's no other pathway from mercaptan directly to those sulfurs?

DR. KELLEY: I do not know.

In conclusion, DEF is an organophosphate pesticide used for preharvest defoliation of cotton. Second, DEF applications range from 550,000 to 1,006,000 pounds of the active ingredient in the years represented in this document.

Use occurs over a 60-days, plus or minus, application window, and air concentrations ranged in the study presented here from zero to 375 nanograms per cubic meter, or 8.1 parts per trillion.

DR. FROINES: Jim, when you did the study, what was the time frame and the distance from spraying? In other words, there are temporal/spatial characteristics that we don't get from just seeing the numbers.

DR. SEIBER: We did two types of monitoring. And again, this has only been ten years ago; so, I'm trying to remember. But we do what we call application monitoring, where we'd actually place the samplers right around where

they were spraying the chemical. And then we did what we call ambient monitoring, which I think is the results that you've shown.

DR. KELLEY: Right.

DR. SEIBER: And those were mainly -- the sampler locations were picked in relationship more to where there were a few, of course, people -- like schools and public buildings.

So, the answer is that they all varied. And that probably explains why the samplers picked up different levels. They could have been several miles away from the closest field, and others may be half a mile or something like that. I honestly don't remember.

DR. KELLEY: Well, actually, the field in San Joaquin, the west side field station, was within 25 meters of the cotton field. So, it's fairly close.

DR. SEIBER: So, it's pretty close.

DR. KELLEY: At Huron, it was approximately 402 meters from the nearest cotton fields.

DR. FROINES: Well, I think that in developing the document, it would be nice to have some kind of map that shows where the samplers -- sampling was done, and give us some sense of the time -- to the degree that you know it -- vis-a-vis the actual use of the pesticide. Otherwise, you can't make a judgment, because -- well, that's obvious.

DR. KELLEY: Yeah. We do not know whether DEF was applied during this sampling period to those cotton fields.

DR. SEIBER: You know, that's one of the really hard things to do, is to figure out what field was sprayed when. Even though the applicators take out a permit, and you should theoretically know that, trying to distill that out of these handwritten application records turns out to be a major, major chore.

It's easier now. I think a lot of it's computerized. But in those days, it was all handwork.

DR. FROINES: I realize it's a problem you get into, because the way you approach this will come to this, because there are some problems, I think, associated with the approach.

When you actually make determinations of dividing NOELs by exposure characteristics, then the numbers you use become quite important. And so, the numbers you use may be a worst case, it may be a best case. It may be a mean or a median. And so, a lot of your interpretation of toxicity is dependent upon your exposure measurements.

So that, if your exposure measurements are not properly characterized, then your whole toxicity -- you have a whole toxicity problem.

DR. KELLEY: Right. Which is one reason we do both ambient air monitoring, where monitors are set up away

from cotton fields, and we do monitoring of an application site. At that point in time, we were doing application site monitoring. Monitors are generally placed within 20 meters of the field, and we begin a background application -- a background monitoring before application. And then, at application time, we start the monitoring. Or actually, the Air Resources Board does that for us.

DR. FROINES: Well, I think there are two sort of criteria we want to use, one of which is what's the best science to do. And the second is, what's the best way to prepare a document for the Panel to review.

And those are hopefully somewhat related to each other. But I think that, in some respects, in your document, addressing this issue of the -- how do you say, not the adequacy, but the relevance of the sampling to the subsequent determination seems to me to be an important thing, so that the Panel has a sense of -- I mean, I've been in coal mines where they've put samplers in places where nobody ever is, and there's no exposure.

And they essentially -- and I'm not suggesting for a minute that you do this -- but I'm saying that some people play fast and loose with exposure characterization as we all know. And so, we want to know that, you know, where samplers are placed has some relevance to the potential exposure.

DR. SEIBER: John's got a really good point, and it actually goes beyond DEF and beyond pesticides, because we're still doing our sampling in fixed stations that were set up 20 years ago, you know. In the South Coast Basin, I think that's the case. And what you really want to know is what people are exposed to. And those may or may not have any relevance.

So, we've got the same problem. This is not a unique problem for pesticides, but it's a good point.

DR. KELLEY: That's basically all I had to say.

CHAIRMAN PITTS: Are there questions from the Panel? Dr. Byus? John, all set? Dr. Froines? Okay.

DR. SEIBER: So, Kevin, are you going to talk about the other chemicals that are used? I think Dr. Froines raised the question. I think it's an important question, because people aren't just exposed to one compound at a time, as we know, there are multiple chemicals.

DR. KELLEY: Well, paraquat is also used to defoliate cotton, and perchlorite also. Other than that, I don't know.

DR. FROINES: Well, it just seems to me that by your numbers of a million versus 300,000 plus, that means that there's about 600,000 acres that somebody is using something else to defoliate. And so, that's more -- that's at least equal or greater to the amount of DEF that's being

used.

DR. KELLEY: Are you asking the total number of cotton acreage?

DR. FROINES: Yes.

DR. KELLEY: Okay. The figure I gave you was the total approximate acreage off the top of my head that DEF was used on in '93, '94, and '95, applied at approximately one pound per acre, maybe a little more, so it's going to be about 900,000 acres.

DR. FROINES: Your document says that DEF was applied to 574,000 acres. It's on page 1. It shows you the depth of my knowledge here.

(Laughter.)

DR. FROINES: All I was asking was, how many acres of cotton is there in California to get a sense of what proportion that 574,000 represented.

And then the next question was going to be: Well, what else happens in those other acres? That's all I was getting at.

DR. KELLEY: Well, I don't know the extent of cotton acreage in California, but I do know that they use paraquat and perchlorite as defoliants.

MS. PELTIER: If it would be helpful, we could add that to the documentation to be able to put in perspective how much is used on cotton acreage.

CHAIRMAN PITTS: It would be, sure.

DR. KELLEY: Okay.

CHAIRMAN PITTS: Any comments? Gary? Dr. Witschi, any comments?

DR. SEIBER: I had just a couple of questions. As we noted the structures -- and I think we need to address a little bit better the butyl mercaptan and butyl disulfide. We don't have a very extensive database of air concentrations, as you note in the document. Yet, there are some. And I suppose at some point we might want to discuss whether we need to do more with those particular chemicals, because that's kind of a weakness in the database.

But I think you've adequately covered it in here; you mentioned what you had and said there weren't enough measurements. So, we can kind of leave it go for now. But we don't want to lose that point completely.

CHAIRMAN PITTS: Maybe I'll ask a question. Now, the material you presented was basically the material under environmental fate; is that correct?

DR. KELLEY: Yes.

CHAIRMAN PITTS: So, that would be Part A. And then Part B will be the exposure assessment.

DR. KELLEY: Right.

CHAIRMAN PITTS: Okay. I'm looking forward to that. One question that I had -- and I'm trying to remember

whether it was in the -- and maybe Jim or you could answer this. You mentioned also the use of a phosphorite as against a phosphorate. You've got a different bond in there somewhere, which is presumably activated on exposure to the atmosphere.

And I think that's an important point to bring in, because they may have very different toxicologies. It was hard to get rid of the order I think was one of the reasons that -- to minimize the butyl mercaptan odor.

I'd like to see the structure of that in the body of the document.

DR. SEIBER: Well, can I get in on that?

CHAIRMAN PITTS: Yes.

DR. SEIBER: The situation's really kind of complicated. There used to be two, there was the phosphorothioite, and phosphorothioate, DEF and Merphos. The manufacturers of Merphos could never meet the butyl mercaptan limit. They just couldn't keep it out of their formulation. So, they stopped making it.

And they made a deal with the other company, if I remember right, that they would each market the same compound, but under two different names. And I don't know why they reached that deal. There was obviously some financial considerations. The thioite is not used at all anymore.

CHAIRMAN PITTS: That's the point I want to see made, because then you won't have toxicologists wondering what that structure --

DR. SEIBER: There's just a trivalent instead of pentavalent.

CHAIRMAN PITTS: And was the mechanism, just out of curiosity, the mechanism of toxicity of that thioite and oxidation, and the environmental oxidation to a thioate, the P double bond -- the oxone nails the end section and us?

DR. SEIBER: Well, it nails the plant. It's a defoliant.

CHAIRMAN PITTS: Plants, insects, or us, right?

DR. KELLEY: The thioite, when it was exposed to the air, rapidly was converted into the thioate.

CHAIRMAN PITTS: That's called environmental or atmospheric activation.

DR. KELLEY: Right.

CHAIRMAN PITTS: And that's an important -- that's a very important concept, as you know, throughout all of these various questions of atmospheric activation.

DR. SEIBER: I'm glad you brought that up for another reason, because it shows that our system is working. There was a compound that was a real problem, this Merphos, and the State basically told the manufacturer he couldn't use it anymore. He couldn't meet our specifications. So,

they stopped selling it.

DR. FROINES: May I ask a question? I was out of the room, but I wanted to ask you -- this compound and this compound (indicating on screen), do they last very long in the soil? In other words, I assume this has -- this mercaptan has some volatility; it's not going to hang around too long.

These two are more likely to be persist a little longer, depending upon their chemical reactivity. Let me ask -- let me make a point here that I want to make.

I don't know how long those persist, but if they do persist and if they have toxicity, then, as you regenerate dust into the air, you create another source of exposure for those compounds, which is a re -- what am I trying to say --

DR. KELLEY: Reentraining.

DR. FROINES: -- reentraining dust. So, when you start to look at exposure from a particular compound, we tend to look at it from inhalation, for example, in terms of application, but we seldom go back and look and say, how much ends up back in the air because of coming out of the soil where it ends up in?

And so, one of the questions I think is to what -- when we start to look at toxicity and when we look at exposure in relationship to toxicity, we have to be able to

say, to what degree is recirculating dust containing compounds like this that are more likely to persist, and do they become a problem or are they, in fact, negligible?

And I think lots of times with most pesticides we often don't know the answer to those kinds of questions.

DR. KELLEY: I would agree.

DR. FROINES: That's an editorial; unless you know an answer.

DR. KELLEY: Oh, it's a great editorial. And in the creation of this document, we did many literature searches. And also in the creation and working on other documents in the 1807 process, there is a dearth of information out there as to what happens to these breakdown components.

DR. FROINES: Well, it really gets to a very important point when we get into the 189 HAPs. Which is, when you deal with pesticides, we have such limited information, that it's not clear on what action constitutes the most significant ambient exposures. That's different than the occupational exposures, which are going to be pretty much directly -- except in this case, where you also have skin absorption possibilities. So, you have skin absorption possibilities over a long period of time if it's in the soil.

So, there's a question of -- the total exposure

matrix becomes more of an issue where, in fact, you have these open fields with dust and where you regenerate that dust as you work in those fields. And so, it becomes an issue, which I think is important for us to think about, not so much in terms of any particular document, but in terms of our long-term exposure characterization analysis.

DR. SEIBER: It's an excellent point, particularly with cotton. Because right after you defoliate, you go in and harvest. And all this dust -- at least for paraquat, the study has been done. They've measured it in the reentrained dust, and that is a significant route of exposure.

Now, DEF is probably not as significant, because it's already -- in the two or three weeks, it's mostly gone from the plant by the time they've harvested. The paraquat's a lot more residual. And I think you did mention that. If I remember right, you mentioned something about entrained dust during harvesting containing some residues. I don't think there's much data, but they did mention it.

DR. FROINES: It's a very good research issue.

CHAIRMAN PITTS: Fine. Well, thanks.

DR. KELLEY: Thank you.

MR. FORMOLI: My name is Tareq Formoli. I am the author of the exposure assessment part of the DEF toxic air contaminant document.

Kevin Kelley already talked about the products and the usage. I just want to mention that we have some restrictions on the use of DEF in California. We have a half a mile buffer zone from residential areas and schools that are in session or due to be in session.

We have a one-eighth mile buffer zone from any school regardless if they're in session or not. You also have a limit on the n-butyl mercaptan level, which is .1 percent in formulated product.

We looked at several studies in regard with DEF concentration in the ambient air. The first three or four studies that I listed, the level of DEF in the air was nondetectable to very low amount.

Next, please.

Starting from Kilgore, et al., this was a more detailed study that was done. They looked at several locations in rural areas, and one location in a city, Bakersfield city. That's in Kern County.

And highest level, as you say, is about 82 nanograms per cubic meter in the rural areas. And in urban areas, it's about 37 nanograms per cubic meter.

The way this study was done was they monitored the air just at the start of the season. Then again, they monitored during the peak season, then a week after the peak season and, finally, at the end of the season, or several

weeks after the peak season.

Next one, please.

This is the Seiber, et al. study that looked at four areas in Fresno County, and also at Fresno and Bakersfield cities. The figures show the pattern of exposure at these four locations. Five Points had the highest level of DEF in the air, followed by Tranquility in San Joaquin.

This study is more in detail, because the monitoring was done during the entire season. As we can see, it started on August 31st and it goes to the 3rd of November.

And, as we can see, the peak concentration is about mid-September to mid-October. And the highest level of 548 nanograms per cubic meter. That is after the correction we made for trapping efficiency. That was at Five Points.

The seasonal average was 182 nanograms per cubic meter. And the lowest level we found was -- in Huron, the highest level was 177 nanograms per cubic meter. The seasonal average was about 44 nanograms per cubic meter.

Next, please.

In order for us to estimate exposure to the public, we divided the exposed individuals in three subgroups of children, adult male, and adult female.

Children of six years old were chosen because they have the highest ratio of inhalation rate per unit of body weight.

We also divided the types of exposure in three groups -- absorbed daily dosage, which represents the acute exposure or daily exposure; we have seasonal average daily dosage, or SADD, which represents seasonal exposure; and we have annual average daily dosage, which represents chronic exposure or annual exposure.

DR. GLANTZ: Can I just ask a question here? This is sort of in the context of having read part of this stochastic document we're going to talk about later.

When you a child is six years old, are you saying we're taking a six year old child as sort of typical of children, or is that like an average of all people who can't vote or something? What do you mean when you talk about a child

MR. FORMOLI: A child of six years old was picked up as the representative for all children up to age 18.

DR. GLANTZ: Okay.

MR. FORMOLI: Yes.

DR. GLANTZ: And then by adult male, you mean all that are over 18?

MR. FORMOLI: That's correct.

DR. GLANTZ: Are you worried at all about infants?

MR. FORMOLI: The infants are included in the

child category as we picked the six year old as having the highest level of inhalation rates per body weight, even when you do compare them to infants.

DR. GLANTZ: Okay. I know that in some of the other compounds we've looked at, there were neurotoxicity differences and physiological differences among infants. I don't know anything about this chemical. Is that an issue here that you need to worry about?

MR. FORMOLI: The reason I picked up six years old is because that would be the worst-case scenario; first, because of their inhalation rate and, second, because of their daily activity, which we were going to talk about later, which is a factor in exposure.

DR. GLANTZ: Okay.

DR. SEIBER: Do you mean, Stan, that even though their breathing rate to body weight is not as high or low, whichever the case is, as a six year old, on a nanogram per kilogram per day, they still might have a higher exposure?

DR. GLANTZ: Yeah, that's one issue. And the other issue is, if there's neurotoxicity effects here, the infants might be more susceptible to the effects of the compound, you know, to the same dose.

I'm not saying that's the case. I'm just asking the question. Because that's something that has come up in some of the other compounds that we've looked at. In

addition to just the exposure, there may be a higher susceptibility to adverse consequences.

CHAIRMAN PITTS: Stan, yeah, that's what we were referring to in the ethyl parathion in the '88 risk assessment. It's what Chuck Becker pointed out. There's a huge difference in susceptibility and impact on infants.

DR. GLANTZ: Yeah. I mean I don't want to sidetrack your presentation. I think your selection of six years olds seems reasonable and your definition of adults seems reasonable.

I just think this is another point that you might want to at least look at as you move the process forward.

MR. FORMOLI: Okay. The way we calculated exposure, we basically used the air concentration and inhalation rate at different activities.

For acute exposure, which is the ADD, we used the 95th percentile of the data. For seasonal average daily dosage, we used the seasonal average concentration. And for annual or chronic exposure, we used the seasonal average during the season and a 365 day year.

We use some factors to estimate our exposure, and we divided the daily activity pattern in four categories. And for adults, these factors were picked up from the Exposure Factors Handbook of EPA; for children we chose the ARB study.

For inhalation rates, we used the Exposure Factors Handbook; and also, for body weight, we used the Exposure Factors Handbook.

Next one, please.

These are our estimates based on the factors that I mentioned.

In Fresno County, which was based on the Seiber, et al. study, the range of exposure was 94 nanograms per kilogram per day for an adult female to 304 nanograms per kilogram per day for a child.

And that pattern follows in the seasonal exposure and also in annual exposure, which children have the highest exposure, followed by male adults, and then female adults were the last.

That shows the Five Points measurement, which was the highest level found.

Next, please.

These estimates are based on the data in Kern County. Again, the levels were 16 nanograms per kilogram per day for an adult female to 52 nanograms per kilogram per day for a child in the rural areas. In urban Bakersfield, it was about 9 nanograms per kilogram per day for an adult female to 28 nanograms per kilogram per day for a child.

There are a couple of items that I want to mention that I thought was a conservative assumption was inhalation

-- uptake and absorption -- of 100 percent we assumed in estimating our exposure.

The other item was that we assumed that DEF indoor concentration would be as much as outdoor concentration..

That's my presentation.

CHAIRMAN PITTS: Thank you. Okay. Questions, comments from the Panel?

DR. SEIBER: I had a question about units. When I went into the executive summary, I saw micrograms per kilogram per day. And then in back of the text, where the numbers are actually derived, I saw nanograms per kilogram pr day.

And I didn't actually try to read enough detail to see if these are in different phases or it's a clerical error. But it's fairly glaring. If it's supposed to be nanograms in the executive summary, then we want to look at those very carefully.

MR. FORMOLI: It's supposed to be nanograms.

DR. SEIBER: Okay.

CHAIRMAN PITTS: On page iii, it's nay, nay, nay.

(Laughter.)

CHAIRMAN PITTS: Because the first page is a synopsis. Any further comments?

DR. SEIBER: Only that it's a fairly glaring -- it's only three orders down.

And the other question -- I don't think you have an answer, none of us do -- this is only airborne exposure. And we assume, since it's used on a nonfood crop, there's no ingestion. But maybe there is in water. Or is there any other source of exposure besides airborne inhalation?

MR. FORMOLI: Airborne inhalation probably is the major source. But, as you said, there might be some exposure through skin, which we think would be negligible. First of all, the exposure would be negligible; second, the absorption through the skin -- the dermal absorption would be not more than 10 percent or so.

DR. FROINES: Are you saying -- based on what?

MR. FORMOLI: We don't have any data to show how much is the exposure to the skin. But we assume it is negligible, because for inhalation, we assume 100 percent absorption; for dermal, the absorption is much, much lower.

DR. SEIBER: There's two issues. First, we don't know people are exposed to dermally; and, secondly, we don't know what the absorption rate is, right? They're two separate -- they're related, but separate issues. And we simply don't have any data?

I mean, I shouldn't say that as a matter of fact. Do we have any data?

MR. FORMOLI: No, we don't have any data.

DR. FROINES: Well, it's an interesting, you know.

When you look at your priority setting scheme, DEF turns out to be IV. And, as you've shown, DEF is only applied basically two months a year.

But it gets an acute toxicity rating of IV in your priority setting, and it's based on dermal absorption. So, if it ends up with a high ranking based on dermal absorption and then you tell me it has no significance in terms of dermal absorption, then your priority setting scheme has to be questionable.

You can't use it both ways. You can't give it a high ranking based on dermal absorption, and then tell me that it doesn't constitute a significant problem based on dermal absorption.

Secondly, as I said a few minutes ago, you have no idea how much dust contains breakdown products of parent. So, your ongoing exposure -- your exposure estimates are still quite unclear whether those defulsides represent any kind of significant exposure.

So, I think that the danger in what we've got is you've got data from '84 and data from '87 that represent a certain number of measurements. But by today's standards, I think we would argue that that's really very limited data.

MR. FORMOLI: I agree on the limited amount of data regarding dermal exposure and dietary exposure. But the dietary exposure, which is --

DR. FROINES: I didn't say anything about dietary exposure. I was talking about reentrainment of breakdown products into the air and breathing them as they are absorbed onto a particulate.

This issue of exposure assessment for environmental chemicals is very complicated and we tend to oversimplify it. We go out and measure, and monitor, and think about it in ways that I think are not sufficient, or don't give us a complete picture of what may be occurring.

DR. GLANTZ: Do you think that the net effect of the simplifications underestimate or overestimate the exposure?

DR. FROINES: Well, I think one of the primary issues about underestimating exposures is based primarily upon what we talked about earlier. We don't really know where these chemicals, where the actual monitoring was done. And so, that's a problem.

And then we also then have to realize that there's two kinds of issues. There's an ambient issue, where the exposures are likely to be relatively low, although there are these other factors about reentrainment of dust. And there's the occupational exposures, which are a different issue, and which this Panel doesn't really address.

And I think, yes, there is an underestimation of exposure, and I think there are a number of reasons why

there may be an underestimation. But I think that a lot of that is based on the fact that we don't have sufficient data to -- he hasn't done biological monitoring. He doesn't have any idea of how much dermal absorption exists. He hasn't looked at reentrainment of dust. They don't know that.

They know what Wendell Kilgore and Jim Seiber did ten years ago and fifteen years ago. And that's what they know. And one would have to argue that they need to develop better ambient and occupational exposure monitoring so we get a better sense of what the dimensions of the problem really are.

MS. LEWIS: I would just like to say that we have and are currently working on another document addressing occupational and dietary exposure to DEF. So, those issues are being addressed.

And in that document, we are combining the ambient air exposure from this document to the dietary exposure for the general public. So, we're at least addressing those exposure scenarios, maybe not all of them.

DR. FROINES: Well, I would really think that you have to go out and look at how much dust people are breathing when they work those fields. Because, if there's a lot of breakdown products in those fields that are toxic, that could account for a very high level of exposure to people in that surrounding area.

I don't know what the numbers are. I don't know if people have even studied it. But I know it's something that needs to be given some attention to.

DR. SEIBER: They've done a little bit. It's interesting, they require what they call a closed cab, certainly in the application, and I think in the harvesting, too.

DR. FROINES: Does anybody know?

MR. FORMOLI: Yes, we have data on the exposure of harvesters of cotton during the -- after DEF application. So, we have data for the harvesters. And that includes exposure to dermal and inhalation both.

DR. FROINES: I'll bet you have multiple chemicals you have to worry about at that point, too.

So, you've got to worry about multiple exposure, and then you've got to worry about toxicokinetic interaction. So, it escalates on you pretty fast.

DR. SEIBER: But one thing that occurred to me is that we're still stuck with single numbers and point estimates here, and you haven't really shown -- I think what we're all bothered by is what is the worst -- the 95 percentile of exposure? And I don't know whether we can really get at it from the database. We may not have enough data, but still someone ought to make an estimate of what the worst-case exposure might be for people who live in that

area.

And I'm not sure we've done that adequately in this document.

CHAIRMAN PITTS: I agree. I'd like to get back to the point you raised, Dr. Froines. On relative ranking, it's listed as a toxicity route IV for dermal. How are you going to change that? That has to be somehow reconciled with the statement that -- the data that are basically inhalation data.

DR. FROINES: You also include the Henry's Law constant as your basis. And so, the question is, if we get a lot of dust exposure from products, then your Henry's Law constant doesn't -- in other words, your priority setting is based on one assumption, and that assumption is that vapor pressure is the key element -- vapor pressure, which you measure twice, one by Henry's Law constant and one by vapor pressure, so you double-count a little bit.

But the assumption is that the primary exposure to pesticides derives from inhalation as a result of application, which may be true. But science is based on finding, you know, exceptions to the rule, and sometimes the exceptions to the rule change our hypotheses dramatically. And so, we have to be aware that sometimes all ravens aren't black, as it were.

DR. KELLEY: I'd like to point out that in the

candidate document, the acute toxicity, the rating of IV at dermal at that point is -- comes from the information that we have which shows that the dermal LD-50 of DEF was less than 200 milligrams per kilogram. That where that four points come from. It had nothing to do with whether -- with the rate of absorption or anything else as far as absorption goes. It was just the fact that this is where it came out as far as straight toxicity.

DR. FROINES: That also implies that if you take the algorithm of toxicity and exposure, and if toxicity is enhanced by dermal absorption, then that affects your overall view of that chemical. Understand?

DR. KELLEY: Yes. Yeah I see that. I don't know if we have information on inhalation and that sort --

DR. WITSCHI: I have --

CHAIRMAN PITTS: Yes?

DR. WITSCHI: I have a small comment. You mention on page 4 or page 3, you mention the TLV, for mercaptan --

DR. KELLEY: Right.

DR. WITSCHI: Now, when you do this, are you going to the TLV booklet, or are you going back to the original documentation of this value that was arrived at by the ACGIH?

The reason I'm asking this is because very few people know that every number that is in the booklet is

backed up by extensive documentation on how they came at this number. And sometimes it might be worthwhile to go and look it up.

MR. FORMOLI: We just go to the TLV booklet.

DR. WITSCHI: Yes. I'm on the TLV Committee, and this information is available on how this number was derived, and it might be worth looking at.

CHAIRMAN PITTS: I have a question, too. I ran across this in the environmental fate, the actual atmospheric fate of DEF. Somewhere in here, I read the atmospheric lifetime, or half-life, was 24 hours. Where was that?

It was sort of stated that it was 24 hours, and it sort of implied that the sunshine and the 24 hours -- that half of it had gone to the butyl-mercaptan, which is a lot and very important if you're talking environmental fate. Because 24 hours later, 50 percent of what you were breathing as DEF is now the butyl-mercaptan, presuming there was a unit quantum yield -- in other words, that each photon absorbing -- each molecule absorbing photon gives you one, two? One and a half? What's the efficiency of the process? Because that's a critical factor in the atmospheric science aspect, of the exposure aspect. You see?

I also went back to look at this table here, which is in your Part A, environmental fate -- going back to that

basic table that gives all the physical and chemical characteristics. But you've got to be careful. You're dealing with a guy who's a geriatric photochemist that took his degree in chemical reactions caused by light.

(Laughter.)

CHAIRMAN PITTS: Boy! What does it do with sunlight, and what's a quantum yield, and what's the mechanism?

It turns out that after '52, sunlight did do things. Well, in that table, for example, in Table 1, it says the half-life, T one-half equals "blank" weeks. I think it would have been better if you had said, "Damned if we know."

(Laughter.)

CHAIRMAN PITTS: That isn't consistent, first of all, with 24 hours. And (b) you should have a section -- I would suggest, for example, you should consult the risk assessment 1807 document on formaldehyde or on acetaldehyde.

As a matter of fact, for particulate matter, the document that was approved on benzo(a)pyrene in 1994. And by the way, these are all HAPs. These are our HAPs.

And in there, there's a full section written on the atmospheric transformation and fates of these molecules. And that's a very critical section. What is the fate? How much is due to sunlight? How much of the conversion is due

to hydroxyl radicals?

What if you do that in September? Man, that's ozone month in the Valley. How much of it goes with respect to ozone? What are the lifetimes and what are the products? Because what's you're breathing is not a drop of vapor of DEF, certainly not after 24 hours in the atmosphere. And then you talk weekly averages, weekly exposures. You're dealing with a wholly different ball game.

And I'd like to make a formal recommendation now that you give real consideration, go back and look carefully how they handled formaldehyde and acetaldehyde. For example, it turns out that when you looked at the atmospheric levels of formaldehyde, if I have this correctly, 90 percent of the formaldehyde is formed in the atmosphere. Do I have that right? 90 percent, isn't it? And acetaldehyde is 50 percent.

That means that, when you start beating the heck out of industry for formaldehyde, the problem is that 90 percent was formed up in the air in the smog. And that's a very different question when you start talking about application of risk assessment to risk management, and applications to health. You have to be very careful to know what are the atmospheric transformation products.

You know, as you well know, you spray malathion in droplets over the people -- the good people of Orange

County, Garden Grove, and 24 hours later -- by a very good study, an excellent study by Brown, et al., published -- 48 hours later, more than half the malathion is malaxone, which, by your own numbers, is 70 times more toxic than malathion, which is still not that toxic perhaps.

So, we must look at -- there's a great book by somebody you may be familiar with, a big chapter. I think his name is Seiber, Seibers, Jim, somebody --

(Laughter.)

CHAIRMAN PITTS: -- Seiber wrote a great chapter on atmospheric activation. These compounds are activated or deactivated, so it's gone in a matter of a few hours and converted into other products, which aren't very nice, but they decompose rapidly. So, you have a deactivation. You don't think about a weekly average of what the impacts are going to be. Hell, it's gone. And that's been addressed in these 1807 documents.

So, before we come back with any final draft of this -- and this is why I think today is so important, and it's so important that we what we're doing here, applying these interchanges, which are great. This must be done with the scientific staffs so we can discuss this and get some really valuable input back and forth. We're both learning a great deal, both sides.

So, I'd be happy to talk to you. And correct me

if I am wrong, but the ARB -- I see some back there -- they actually went so far in the initial stages of 1807 -- essentially, I was sort of writing as an atmospheric chemist what the fates of these compounds were, because the staff -- because we're researchers, we work with the staff.

And I believe Professors Atkinson and Arey (phonetic), professors at UCR were brought in to develop and to write, as the leaders in the field, the atmospheric transformation section.

Now, whether or not you'd want to do that or put them under contract, as I understand it -- and I heard yesterday from very good sources that, you know, important areas of better science, peer review, state of the art, there should be funds available. So, I would think that that might be useful, and I think you'd find the support of the Panel in any measures that you wanted to take, as the professional scientific staff and with the Deputy Director here -- that's a hint, right?

MS. PELTIER: I'm taking it down.

CHAIRMAN PITTS: -- that this would be an area that would be very useful to develop a new information base. So, that's kind of a general thought.

DR. SEIBER: Could I make just a comment?

CHAIRMAN PITTS: Sure.

DR. SEIBER: It's directly on the point. I don't

want to defend the state of the science, but I think Dr. Pitts will be appalled when the finds out how little vapor phase photochemistry has been done with these pesticides. It's going to be a short section in your report, because I doubt of you'll find much on DEF or most of the other chemicals on this list. There just isn't much done.

CHAIRMAN PITTS: That's right. Then, what's the next step? Do you say three years from now that there isn't much to read, or do you say that we ought to get going on this, and we ought to be supporting -- because I heard ideals of supporting research -- that this is a positive thing that could go forth, not necessarily from your existing budget, but request in very clear-cut terms that we need additional funds to launch research and support in-house and out-house --

(Laughter.)

CHAIRMAN PITTS: -- to support research. And I don't have any grants anymore, so I have no conflicts of interest, but to support research in these areas that can be directly applied to human health effects of hazardous air pollutants, including economic poisons, as they're defined in this law.

That will get real public support, as we read this stuff, as well as support I think from both sides of the aisle of the Legislature and from the Governor's Office.

But you have to define it, get a target, and then ask for it.

Another thing is that I would say, when you write the report, and there is this dearth of DEF, as it were, material -- dearth of DEF -- it sounds like "Star Wars," doesn't it? "Dearth Vader." "Death Vader."

No, seriously, it would be useful as you prepare this atmospheric persistence and fate, which I think must be there -- it may only be six lines that say, "The literature on this is scant. The only material that is of any use is the work of so and so. This is not directly relevant to so and so, but here it is."

And then it will say something in there that would indicate why you would need to have additional information, and what additional information you would want as a toxicologist, what do you want as an environmentalist? What would you want to have, what sort of data is needed?

You see, these documents are read worldwide. I can guarantee that the risk assessments, the 1807 documents, are known throughout the world by the scientific and medical, community and public health communities, and atmospheric chemists. And so, that would help others who are in the field who will have access. It would be very useful.

Okay. I've sort of said my say, but that's done.

Dr. Glantz.

DR. GLANTZ: Yeah. I think that's all fine, but I would hate to see --

CHAIRMAN PITTS: That's like a put-down. "That's all fine, but. . ."

(Laughter.)

DR. GLANTZ: Well, I've been trying to behave.

CHAIRMAN PITTS: Well, what's wrong with what I just said?

DR. GLANTZ: Well, nothing.

CHAIRMAN PITTS: You agree with it?

DR. GLANTZ: It's wonderful. Yes.

CHAIRMAN PITTS: Thank you. Do we have that down in the transcript? Thank you.

DR. GLANTZ: The one concern that I just want to put on the record, though, having watched the DPR and its predecessor agency take forever to move anything through this process, it looks like you've got something moving now. And I would remind you that 1807 specifically says that not knowing everything is not a reason to not make a decision.

CHAIRMAN PITTS: That's right.

DR. GLANTZ: So, I think that in highlighting the issues that have been discussed -- which I think are very reasonable issues -- that should not become a reason to spend five years before this report comes back to us. And I

just wanted to say that.

CHAIRMAN PITTS: But we're in agreement on that.

DR. GLANTZ: I don't have to say that.

CHAIRMAN PITTS: That's accepted.

DR. FROINES: I want to ask one question, and I think we should go on.

Do you know how many pesticides that are on your priority list, including DEF, are on the 189 HAPs list?

DR. KELLEY: Yes. The ones that are on our priority list and the ones on the 189 HAPs list would be zero.

MR. GOSSELIN: The ones on the HAPs list were already listed administratively -- oh, this is Paul Gosselin -- are already administratively listed as TACs. And when that 189 list came out, we immediately went in and administratively listed all the pesticides as TACs.

DR. KELLEY: And so, since we listed them as toxic air contaminants, they're not in the list to generate reports to decide whether they should be listed toxic air contaminants.

DR. FROINES: So, that's these essentially.

DR. KELLEY: The ones in here in Appendix A are SB 950 chemicals that we used to create the candidate list that were declared toxic air contaminants.

There are a number of other pesticides that are

not on the SB 950 list that were in the 189 HAPs EPA designation that were subsequently also declared to be toxic air contaminants.

CHAIRMAN PITTS: Yes, sir.

DR. THONGSINTHUSAK: May I make a comment related to Tareq's presentation?

Tom Thongsinthusak, DPR. I'll spell it for you later. There's some concern about the overestimation of the exposure estimates. There was a study by U.C. Davis, by Robie, et al., in 1988. He used several chemicals and estimates for measuring inhalation uptake and absorption.

For example, for chloroform, formaldehyde, and also small molecules, the inhalation uptake and absorption is about 50 percent. For DEF, DEF has a higher molecular weight. And we used 100 percent. So, we assume that there's a 50 percent overestimation of exposure.

So, the way we use the 100 percent is very conservative. I just wanted to point it out.

CHAIRMAN PITTS: Thank you.

DR. THONGSINTHUSAK: You're welcome.

CHAIRMAN PITTS: Thank you very much. Are there other comments on the gentleman's comment? That's fine. Thank you.

MS. LEWIS: First slide, Tom? I'd just like to introduce myself. I'm Carolyn Lewis. I'm the author of

Part C, the Health Effects Assessment.

Next slide.

The adverse effects observed in laboratory animals after acute exposure to DEF are primarily cholinergic signs and delays neuropathy. Other effects seen include hypothermia and hematological changes.

The hematological changes were attributed to n-butyl mercaptan, which is formed in the gut from the hydrolysis of DEF. However, the neurological effects appear to be the most sensitive end point for acute exposure.

An acute inhalation study in rats was selected as the definitive study for evaluating acute exposure to DEF in ambient air. The critical no-observed-effect level, or NOEL, was 159 milligrams per cubic meter, or 25.4 milligrams per kilogram day based on death, cholinergic signs, red and nasal turbinates, and firm zones in the lungs.

The neurological effects were also the predominant effects observed with subchronic exposure to DEF. In addition a reduction in electroretinographic responses, pale retinal fundus, and fatty droplets in the adrenal glands were observed in one rat inhalation study.

Also, in a rat reproductive toxicity study, there was a reduction in the fertility, birth, and viability indices, and increased gestation length, a reduction of pup weights, cannibalism of pups, and discoloration of pup

livers.

However, the neurological effects appear to be -- the neurological effects, and the ocular effects, and the lesions in the adrenal glands appear to be the more sensitive end points.

As a result, the definitive study selected for evaluating seasonal exposure to DEF was a 13-week inhalation study in rats. The critical NOEL in this study was 12.2 milligrams per cubic meter or 2.9 milligrams per kilogram day based on cholinergic signs, brain cholinesterase inhibition, hematological changes, reduced electroretinographic responses, pale retinal fundus, and fatty droplets in the adrenal glands.

No chronic inhalation studies were available for DEF; however, in several chronic feeding studies with rats, mice, and dogs, hematological changes and brain cholinesterase inhibition were observed in all three species.

In addition, several lesions in the small intestine and the adrenal glands were observed in both mice and rats. Numerous ocular lesions were also observed in rats. These included bilateral retinal degeneration, optical nerve atrophy, cataracts, and corneal opacities.

However, year-round exposure to DEF is not expected in the general public; therefore, a chronic NOEL

was not selected.

The oncogenic potential of DEF was used to evaluate lifetime exposure to DEF in ambient air. All the genotoxicity data for DEF were negative. In addition, no -- oh, next slide, please.

All the genotoxicity for DEF were negative. In addition, no tumors were observed in a two-year rat study. However, in a 90-week mouse study, there was an increase in adenocarcinomas of the small intestine of both sexes, in liver hemangiosarcomas in males, and in alveolar/bronchiolar adenomas in females.

An oncogenic potency was estimated for DEF using linear low-dose extrapolation, because multiple tumors were observed in -- tumors were observed in multiple sites, and the adenocarcinomas were extremely rare.

The incidence of the liver hemangiosarcomas in males was used to calculate the oncogenic potency, because there was a significant increase in the tumors at both the mid- and high-dose levels.

The estimated oncogenic potency for DEF ranged from 4.7 times 10 to the minus 2 per milligram/kilogram day for the maximum likelihood estimate to 8.4 times 10 to the minus 2 per milligram/kilogram day for the 95th percent upper bound.

As mentioned earlier, n-butyl mercaptan is a

volatile degradation product of DEF in the environment and may be responsible for many of the complaints in communities near cotton fields due to its strong skunk-like odor. Therefore, the toxicity data for n-butyl mercaptan were also evaluated.

Unfortunately, the data available in-house and in the open literature was very -- very limited. The effects observed in the standard battery of acute toxicity tests included CNS depression and lesions in the liver and kidneys.

With inhalation exposure, there was also evidence of respiratory irritation. This included sneezing, hyperemia of the trachea and lungs, capillary engorgement, edema, and hemorrhage in the lungs.

A NOEL could not be established from any of these studies because the incidence of clinical signs and pathological lesions was not summarized by dose level. The only other toxicity study available for n-butyl mercaptan was an inhalation developmental toxicity study in rats and mice.

A NOEL of 10 ppms, or 17 milligrams per kilogram day was observed in mice based on maternal toxicity, increased postimplantation losses, and fetal malformations.

The risk estimates were initially calculated for locations with the highest offsite and ambient air

concentrations. In the study by Seiber, et al., four monitoring sites near Fresno were less than 400 meters from cotton fields. These sites would be within the buffer zone if those fields had been treated, which was unknown. However, the assumption was made that if the exposure levels were acceptable at these sites, they would also be acceptable just outside the buffer zone.

Among these four sites near Fresno, the Five Points location was selected because it had the highest air concentration for a single day and on average over the 60-day cotton defoliation season.

Ambient air concentrations were considered air concentrations that were more typical of township exposure. The estimates for ambient air were based on the data collected by Kilgore, et al. from six rural communities in Kern County.

Next slide, please.

The risk for adverse health effects from acute or seasonal exposure to DEF is expressed as a margin of safety, or MOS. The MOS is the ratio of the critical NOEL and the human exposure dosage. Generally, an MOS of at least 100 is desirable to account for intraspecies and interspecies variation in susceptibility.

When the critical end point -- when the critical NOEL is based on a severe end point such as DEF, a larger

margin of safety, such as 300, may be appropriate. The acute margins of safety for DEF in offsite and ambient air were all greater than 80,000. The seasonal margins of safety for offsite and ambient air were all greater than 20,000.

No margins of safety could be calculated for n-butyl mercaptan due to the lack of reliable toxicity and air monitoring data. However, the highest daily average air concentration for n-butyl mercaptan, 28.6 micrograms per cubic meter, or 7.75 parts per billion, was greater than the odor threshold for humans, which is between .1 and .01 parts per billion.

Offensive odors can trigger symptoms in humans, such as headache and nausea, through the indirect physiological mechanisms, such as innate odor aversion, stress-induced illness, and aggravating underlying medical conditions.

The oncogenic risk is the product of the oncogenic potency and the lifetime exposure dosage. An oncogenic risk level of less than 10 to the minus 6, or one in a million, is generally considered negligible. In this risk assessment, the annual average daily dosage, or AADD, for adults was used for the lifetime exposure dosage with the assumption that people would be exposed every year for a lifetime at the AADD.

The estimated oncogenic risk levels for offsite air range from 3.9 times 10 to the minus 7 for the maximum likelihood estimate to 7.1 times 10 to the minus 7 for the 95th percent upper bound. The oncogenic risk for ambient air ranged from 7.5 times 10 to the minus 8 for the maximum likelihood estimate to 1.3 times 10 to the minus 7 for the 95th percent upper bound.

Reference concentrations were calculated for acute and seasonal exposure to DEF using the critical NOEL and an uncertainty factor of 100 for intraspecies and interspecies variation in susceptibility.

The acute 24-hour exposure reference dose is 374 micrograms per cubic meter, or 29.1 parts per billion. The seasonal reference dose for DEF is 43 micrograms per cubic meter, or 3.3 parts per billion.

The lifetime exposure reference dose corresponds to a negligible risk level of 10 to the minus 6. The lifetime exposure reference dose was 42 nanograms per cubic meter, or 3.3 parts per trillion.

Are there any questions?

DR. FRIEDMAN: That dose, is that figured on the basis of ambient air or offsite air? And when you say offsite, how far from the --

MS. LEWIS: (Interjecting) It's not taking any exposure levels into account. This is just based on the

critical NOELs or oncogenic potency, and then assuming standard uncertain factors or a negligible risk level of 2 to the minus 6.

DR. FRIEDMAN: When you say offsite air, how far away from the site?

MS. LEWIS: Oh, you're talking up on the lifetime exposure?

DR. FRIEDMAN: Right.

MS. LEWIS: Yeah. That's actually uncertain, because in the -- what I considered offsite air were the monitoring sites that were used in the study by Seiber, et al. It's unknown if these were actually within the buffer zone or outside, because of the structures that were located at those buffer zones. Hopefully they're outside the buffer zone. But it was unknown.

As far as ambient air -- to me, the definition of ambient air is not real clear. I considered it a typical township exposure. I didn't know whether the sites in the Seiber study would be considered typical township exposure since they appear to be so close to cotton fields.

And so, that's why I had selected the Kilgore study for estimating ambient exposure.

DR. WITSCHI: I have a few comments. I found it very well written. And I was also pleased to see that quite a few people are DABTs, of which I was a member of the

Board, so we did something good.

I have, however, a few questions. The first one is that I liked your classifications of the studies. How do you deal with the ones which are not acceptable by FIFRA standards? And when do they go back? I don't know at the moment.

MS. LEWIS: What was that last one?

DR. WITSCHI: The FIFRA standards go back to when?

MS. LEWIS: Oh, around 1976, I believe. I'm not sure of the exact date, but about that time. When we look at these studies, we usually give preference to the ones that meet the FIFRA guidelines. However, that doesn't mean we don't use one that is unacceptable. It really depends on the deficiencies in the studies, whether they come into, you know, question, you know, what the animals were actually exposed to and whether or not there was enough information to characterize the effects that were seen.

DR. WITSCHI: The next question I have, there are quite a few -- this is the nature of the beast, but many of your references are company reports.

Now, there are two questions. Is this public information? And are they available? In others, if I'm wondering about something and would like to look up and use information you quote, can I do this?

MS. LEWIS: I think you can put a request into our

Registration Branch, and then they will review whatever it is you request, and determine if it actually is considered confidential business information.

DR. WITSCHI: Well then, if it's confidential, I don't think you should use it.

MS. LEWIS: My understanding --

DR. WITSCHI: I mean, we have the same problem which --

MS. LEWIS: (Interjecting) Yeah. This, I --

DR. WITSCHI: And it's not so much its confidentiality, but the other one; it's also accessibility. You know, there are some things in there one would like to go and look up, and have access to them immediately. And I was wondering whether there was a mechanism for this available?

MS. LEWIS: I think --

DR. WITSCHI: And the other one, as I said, if it's confidential, I do not think it can be used in a public document. I may be wrong. I don't know. But I would hate to draw any conclusions on something I do not have full access to the original data.

MS. LEWIS: I don't know. We can double-check on this, but my understanding is that for releasing this information, even if it is classified as confidential business information, we can do that as long as it's to

other official entities like yours. But we can double-check on that.

DR. FROINES: But that raises the other problem of nonpeer-reviewed reports are nonpeer-reviewed reports.

DR. SEIBER: It's as little different in this case, though, isn't it? Because the data was submitted to a State agency in support of registration or maybe to the federal agency. So, it's not like a company generated it in an internal report and it didn't go anywhere from there.

In this case, these were submitted data. I hope we can use it somehow, because that's the data that's available. That is the data.

DR. WITSCHI: Yeah. Actually, this is not quite trivial either, because in many of the inhalation studies, you go by having the exposure concentrations and then you assume 100 percent retention. But that also would depend on the particle size as to how much of those concentrations are inhalable.

I do not know with the dose studies, most of them from Bayer, whether they have characterized particle size.

MS. LEWIS: Under FIFRA, they have to characterize the particle size.

DR. WITSCHI: Well, then, aren't they respirable?

MS. LEWIS: Well, I can't recall off the top of my head.

DR. WITSCHI: Let's say half of it is not respirable, then you underestimate the risk from inhalation. And some of those concentrations are horrendous. In dust storms, that can be a horrendous concentration. But if it never gets into the air, then it might take much less to produce those -- and that was my biggest concern in all those inhalation studies, to what extent those estimates of dose are really correct. Of course, we don't have any information or it was not discussed about the respirability of those aerosols.

MS. LEWIS: Yeah, and I can add, when it's available, the information about the particle size and whether or not it would be considered respirable. It is not in there now.

DR. WITSCHI: Well, I have no problem with some of the Bayer studies, because I know who did them. But other ones, I did not know who did them, and that's why I was wondering whether this might be something that might be looked at in a more critical way.

The other one was also the calculation of the 60 days. How realistic is it to come to those estimates just for the defoliating season as exposed year-round? These are trivial details, you know, but the red zones in the lungs don't mean anything.

MS. LEWIS: Pardon?

DR. WITSCHI: The red zones, firm red zones in the lungs, that doesn't mean anything.

MS. LEWIS: Oh. I just took that out of the pathology report. I don't know what they meant. I'm not a pathologist. And so, when I'm given information like that, I just take it as it is and --

DR. WITSCHI: Well, I don't think you should do this to some extent, because you might want to talk to somebody who might know what that means. But, you know, just red turbinates and firm zones in the lung is kind of meaningless. And yet it's in here as something that sounds terrible, but doesn't mean anything.

MS. LEWIS: Well, when I see a dose-related trend in the incidence and effect, I assume that it's a treatment-related effect. How important it is, I think is, you know, always questionable. But I make the conservative assumption that it is adverse.

DR. WITSCHI: Well then, the pathologist was lousy in this regard, because he didn't specify what it meant.

MS. LEWIS: Yeah.

DR. WITSCHI: Yes. Why did the human health effects go into the exposure document and not into the health effects document?

MS. LEWIS: Because the Worker Health and Safety Branch has traditionally monitored the illness reports and

summarized the illness reports in our documents. And so, we just have carried that over --

DR. WITSCHI: Okay.

MS. LEWIS: -- from the previous documents.

DR. WITSCHI: That's all I have.

CHAIRMAN PITTS: Stan? Dr. Byus?

DR. BYUS: No. It's fine.

CHAIRMAN PITTS: Dr. Froines??

DR. FROINES: I think that this is perhaps not the place to go into great detail of problems, and that I can communicate with staff, because I think that we have a long agenda, and this is going to come back to us later.

I should say that I have serious problems with this document, and could go on for quite some time. I think there's a fundamental problem that we have to talk about, and I don't think we need to do it necessarily today. But everything that's in this document is tied to the estimation of exposure.

In the 1807 process, we have never tied anything to exposure. We evaluate toxicity as a separate category entirely. Here, what happens is, you take a carcinogenic potency and you then connect that with an expected exposure. If that exposure ranking is wrong, or if it underestimates exposure, or if exposure changes over time, then that number is wrong, fundamentally wrong.

So, to the degree that you tie your toxicity evaluation to anticipated or existing exposure characterization, your numbers can change radically and fundamentally change. And I think that's a problem. Because I think toxicity should be evaluated on its own in great depth, and one should look at the toxicity within that particular context, the way we do, for example, in other 1807 documents.

We've never had MOSs, for example, in lead, or diesel, or anything else we've ever done. And this is a very peculiar way of doing things. I know of no other place that does things like this. And so, there's both a scientific issue and a policy issue. And that is, is this an acceptable approach to the characterization of toxicity according to this SRP? And I think that's a very fundamental question that we have to deal with.

All right. That's the forest. That's the forest. Now, the trees get you into some, I think, problems that are more specific. For example, one of the best neurotoxicologists in the United States, Abou-Donia, who's at Duke University -- who I have Ph.D. student who did a post-grad with him -- I know him very well. We tried to recruit him to UCLA. His work is excellent. In this document, there are a number of references to Abou-Donia's work.

Abou-Donia's work comes up with a NOEL of about .5 or .1, I don't remember which. .1. That NOEL done by one of the best scientists in the United States is dismissed. It's a factor of more than 10 times lower than the number they picked.

We have all of these industry documents, which are not peer-reviewed, which we don't have access to, but we take Abou-Donia's work, which looks at chronic effects, not just acute effects or subchronic effects. It looks at the potential for chronic effects, and then we dismiss that NOEL on the basis of metabolism, and there is no data on metabolism in this entire document.

MS. LEWIS: I disagree.

DR. FROINES: Now, let me finish, because I'm not entirely happy about this level of productivity.

We have a NOEL of .1. And over here, it says that we're not going to use that, because there may be metabolic differences that affect that. We have carcinogenicity studies in which there are potency values determined, although I'd like to know why you didn't use the lung tumors to do the risk assessment, because I think you'd get slightly different answers.

And then again, the potency -- the dismissing of the oncogenicity data is done because you assume an exposure, and you get down to 10 to the minus 7, and you

say, oh, we weren't at 10 to the minus 6; so, therefore, this is irrelevant.

All the way through, what we basically have is the dismissing of potential effects. It's as though you wanted to dismiss them. And so, you found ways to do that. And I think that's inappropriate. I think that when you have serious neurotoxicologic data by a nationally known investigator, you don't just say, based on some notion of metabolism, that we can dismiss this finding.

I think it's inappropriate. It's unconscionable, in fact. And the problem we have here is we have a lot of data, a lot of data, which shows very different results.

And by the way, excluding -- not determining the chronic NOEL because there's not chronic exposure is a misstatement of the science. You produce chronic NOELs because you have chronic effects. Let's get that clear. We're not talking about the fact that this stuff is only used for two months of the year.

So, I think that here are some really fundamental problems with this document. Ad I think we have to clear them up in this document, because I think this is the beginning of a long process and we don't want to have arguments about that.

But I think that the Abou-Donia work is particularly bothersome for me. So, you have subchronic

data on -- see, we're dealing with neurologic effects that are not just acute reversible effects. They are potentially long-term effects. And then the children's issue becomes very important. Because in the developing brain in the early infant, that could affect that infant throughout the course of their entire lifetime. It's not just what happens in the acute context when they're six months old. It happens when they -- what irreversible neurologic effects occur that may affect their growth and even into early senescence. And there is data in the neurotoxicology literature that shows that effects in children can affect the person throughout their entire lifetime.

And so, to simply say we're not going to look at those kinds of issues is really not appropriate.

Well, that's enough. But I think that these aren't trivial. And I think we can work through this over the next few months. But I think that the treatment of Abou-Donia's work is really quite bad.

MS. LEWIS: Can I just respond to that? We did not use that study because it stood out in terms of the NOEL that it identified of .1. All the others -- we had nine subchronic neurotoxicity studies available to us, and it was an order of magnitude lower. All we had available to us was the published report, which doesn't have the same level of detail in it as some of the FIFRA guideline studies that we

had.

DR. FROINES: But the problem I have with this is that you have a mindset, and the entire mindset is to find a NOEL. It's absolutely simplistic in the context of toxicologic mechanism to only go looking for the NOEL. You have to look at the science of those studies and try and make some determinations based on what you perceive to be mechanistic consideration.

And what we have here is delayed neuropathies. In the first place, somebody in there wrote something about neurotoxicesterase. I would have to tell you that the concept of the neurotoxicesterase is about 15 years out of date. So, one ought do a little bit of updating of one's knowledge.

The second matter is that long-delayed neuropathies are serious problems, because they have clearly long-term, potentially irreversible effect. And there is no discussion of that in here.

MS. LEWIS: I'm not trying to dismiss the delayed neuropathy. What I saw when I examined all the subchronic studies, and I looked in particular at the one study that we had that met FIFRA guidelines, the NOEL for the delayed neuropathy was not any lower than the cholinergic signs. And I gave preference to an inhalation study because of not having to do route to route extrapolation.

DR. FROINES: But the problem is -- what I'm saying is that you're so wed to the NOEL look that you're losing the science for the NOEL. The delayed neuropathy is different than cholinesterase inhibition. You know that as well as I do.

And only looking for a NOEL as your guideline -- the cholinesterase toxicity has very different implications than the delayed neuropathy, because it has long-term versus short-term effects. And so, one has to be looking at these things, not so much just in terms of finding NOELs, but in terms of what does the data tell us about this chemical? And that's the concern I'm expressing. It's the approach to the problem.

MS. LEWIS: Well, I may not be getting your point, but my -- I'm not -- I tried to look at all the end points, and I -- I felt, in selecting the study that I did, that I was also protecting for delayed neuropathy based on, in particular, the one study that we had that met FIFRA guidelines. It did not obviously protect for it if you used the study by Abou-Donia. But --

DR. FROINES: I don't know what the FIFRA guidelines are. But if they're peer-reviewed scientific studies of high quality, I don't know -- EPA's strength is not in health effects evaluations. So, I don't know what the FIFRA guidelines are. And I think it's very dangerous

to be locked into some guidelines that may or may not be scientifically current.

And I think that one has to look at the data themselves rather than being tied into a guideline which I don't know anything about the guidelines for adequacy of studies. But I do know that I keep hearing you say that, but I'm not convinced that that's necessarily the way to go looking at these studies.

When you have a table here where you have NOELs of .1 and .3, and you also mention .5, how you come up with 12.

MS. LEWIS: The NOEL I used was 2.9. 12 was the milligrams per cubic meter.

CHAIRMAN PITTS: Dr. Gosselin?

DR. GOSSELIN: Thanks. Looking at the clock, and really what we wanted to present today was just really a snapshot of this draft that came out -- because I think all of these issues do a couple things. One is that it really points out why we really need to engage the public process, and the peer review process, and the science. Because I think a lot of these issues are legitimate and really need to be followed up in greater detail.

And I think, just to keep things going, we need to probably maybe transition into, you know, that this process is going to go forward on this document, and then start talking about -- you know, at least bring closure to what

we're planning on doing for the rest of the 1807 process.

CHAIRMAN PITTS: Jim?

DR. SEIBER: Yeah. What occurred to me was the involvement of OEHHA in it. At what point did they look at the document? I know that eventually they will receive the same set of documents for a closer review, let's say, and to address some of the questions about consistency that maybe were brought up here.

So, I have a question to Paul or to Jean-Mari about the process. And when does this set of documents go to George or whoever at OEHHA?

DR. GOSSELIN: I believe they've already gone to OEHHA and ARB.

DR. FROINES: Is George here? Because I had asked George this morning if he had seen the documents, and he said no.

Melanie, have you seen the documents yet?

DR. MARTY: We haven't seen them yet.

DR. KELLEY: They've been sent to OEHHA twice. I'm Kevin Kelley. We sent them twice to the Director's office. And the second time they were sent over approximately two weeks ago. So, where they are from there, I don't know.

DR. SEIBER: So, they just haven't filtered down in the system. But that is part of the intent is to have

them --

DR. KELLEY: Definitely.

DR. SEIBER: -- go over them.

MS. PELTIER: That's where we are in the process right now, releasing this to OEHHA.

CHAIRMAN PITTS: Is there some way we can send -- why don't we make a point of sending copies right to the staff who are going to be involved in this?

DR. GLANTZ: George just walked in.

CHAIRMAN PITTS: Just a moment. I'd like to respond to the comment that maybe we ought to move along. But I think it's very important that we focus on this document. We should focus on it and go into the details. Because I'd much rather have these issues explored and examined in detail, so we're not left with having to do ten more documents and raise certain issues that don't need to be raised, because they will have been resolved by -- that there will be a format in which we will address these issues; there will be a prescribed approach; that these will be in concert with the OEHHA perspectives on 1807.

So, my theory is that once in a while it's a good idea when you've got all this floating around, take a specific example, and just go in detail on that. Now, go ahead. I want to hear your comments, because I think they're important, whatever they will be, in the context

that -- let's not move off of this. We've got time. We will take our time and go through it, and then we'll go on, in the context of what we've been discussing on this specific item and look at the broader scope of what will be coming down the pike.

Go ahead, John.

DR. FROINES: I think that part of the problem -- I want to separate what is the problem of the draft document from what you had used to do the draft document. I think the problem isn't so much yours as what you're working with.

We deal with pesticides with extremely limited databases. And Hans I think is entirely correct. Many of those databases are privileged industry documents. So, don't misunderstand. When I'm being critical, I'm not being critical of you. I think that there are some critical issues that I think we need to work on, though.

I think that one of the things we know in the last ten years is that toxicokinetics is really quite crucial, and I think that we need to do more work on the metabolism section of this document to try and look to see to what degree are toxic metabolites being produced or to what degree are there competing detoxification pathways that may reduce the toxicity. It cuts both ways.

For example, with butadiene, people have now identified about metabolites, all of which are likely to be

carcinogenic. And as people look, they find more. And this is a very simple compound, so that one may not find very complex metabolism.

But I think that the metabolism issue and pharmacokinetics is really important. And I think we need to try and tease out whether we're getting bioactivation and what data are maybe missing or not more available. And I think it falls into the same category of what I raised earlier on exposure, in terms of reentrainment of materials that are in the soil. These are important areas that may lend themselves primarily to research. But we should try to do the best we can with them.

MS. LEWIS: I just wanted to say a little bit on the metabolism. There is a section in Part C on metabolism.

DR. FROINES: I read it.

MS. LEWIS: And there is a rat study, fairly recent rat study, that was done. Unfortunately, they weren't able to identify many metabolites. They had speculated that was because it was so quickly incorporated into natural constituents within -- within the body.

DR. FROINES: That's the kind of statement that potentially -- if that ends up bound with proteins or whatever happens, it doesn't mean that its toxicity goes away. It means that its AUC has changed.

MS. LEWIS: Well, I think what they had speculated

is that it's broken down to phosphoric acid and other normal metabolites within the body. And the only metabolite that looks like it might be there, but we didn't have a lot of evidence of this, was that it looks like in the gut, based on Abou-Donia's data, it's broken down to -- DEF is broken down to n-butyl mercaptan, and that may be responsible for the effects that you see with the -- by the oral route; n-butyl mercaptan is also probably a normal metabolite of DEF in tissues, but that's speculative.

DR. FROINES: I'm done.

DR. GLANTZ: I just realized. Nobody gave me this document. Bill Lockett, you're fired. That's why I have not so many opinions. But I've got some on the other ones.

The one thing, though, that came up is this point that I just want to reiterate what John said. I think in your assessment of these compounds as toxic air contaminants, it should be based on the toxicity, not the exposure.

And sort of bad experiences I had with your predecessors were coming back to me where they were saying like -- I think it was ethyl parathion, where we had listed that and recommended it as a toxic air contaminant, and went through the whole process at the ARB. And the pesticide people came forward with essentially the identical same report and a new executive summary saying it wasn't a toxic

air contaminant.

And that met a fairly hostile response from the committee, because it was like the evidence hadn't changed. And the pesticide department -- whatever it used to be called; I can't remember -- well, there isn't that much of it out there, so it isn't toxic. And I think it's very important, as you move forward, that those two issues be decoupled; that the toxicity is one question, and then the body count is another question. And that does depend on the current exposures.

So, I would hope that the decision of whether it's toxic or not is independent of the exposures. And then the question of what is the public health impact of that toxicity does depend on the current exposure patterns. And that's the way we've done it in the past, and I would hope that's the way you will do it as you start moving forward and dealing with these pesticides.

MS. PELTIER: As a point of clarification, Dr. Glantz, you're not suggesting that the report shouldn't include a portion that is dedicated to the issue of amount of exposure, but --

DR. GLANTZ: No.

MS. PELTIER: -- rather that the issue be decoupled.

DR. GLANTZ: Right. That's right. If you look

back at the 1807 documents we've done, there's the Part A, which was the exposure assessment, and then the Part B was the health effects. And then at the end of the Part B, there was a section where they said, okay, given what we know about the toxicity and what we know about the exposures, what's the body count? And that's in there.

But the decision as to whether something is a toxic air contaminant or not depends on the toxicity.

(Thereupon, Dr. Froines and Dr. Glantz engaged in a sidebar discussion.)

DR. FROINES: There are statistical issues associated with the definition of NOEL. And in this document, there isn't any discussion of that kind of question.

And so, I think you ought to read it from the standpoint of what are we meaning when we talk about a NOEL in the context of this.

DR. GLANTZ: Well, yeah, that's true. It's just that that was a point we went round and round back when we were talking to people about pesticides years ago. We went round, and round, and round about this issue. I just think, since we're having this sort of a new start, you ought to do it where the compound is or isn't a toxic. And then the question is how much of it is out there. That's a second question.

That should be in the report, and I'm not saying it shouldn't. But in terms of determining whether something is a toxic air contaminant, as I recall the definition, is it toxic, not how much. That's a second question.

DR. GOSSELIN: And I think since, you know, my take -- at least the initial discussion on this document really covers a lot of the issues that we've been thinking about as we reengage this process in a more active way is, you know, what really and how should we prioritize the monitoring aspects and risk assessment aspects.

Besides this going into a document, we need to enter into some discussion and consultation on that. Then, when we do get all that information, how is it put together? How are the issues laid out? And we need to continue the consultation on that.

And the end point, what's the triggering mechanism and what's the relevance of listing pesticides as TACs? And going into that, we need to resolve that. We need to spend more time, you know, on the science, you know, talking about this and coming to at least some understanding as to where we're coming from, and hopefully coming together. So, when we do the documents, that mostly they're geared towards the science aspect, making sure that we hit everything and it's complete, and we're not jockeying around some of these policy issues and coming together on it.

DR. GLANTZ: I think that you're right. I mean there's two different questions here. One of them is how should these documents be put together and how should you deal with the toxicity question.

I think in the priority setting, there you want to get at least a back-of-the-envelope estimate of the public health impact, which I think you tried to do here.

And then you should deal with things, the ones with the greater impact going first. Back years ago, when I was -- I mean I was the person who started pushing the priority issue on this committee, longer ago than I care to remember. And one of the compounds at one point that OEHHA, or its predecessor, and ARB were going to look at coke oven emissions, because they're highly toxic, except there's no coke ovens in California.

So, we had suggested to them that maybe they might not want to put a lot of resources into coke oven emissions. And I think you've got the same issue here.

So, I think in the priority setting, you definitely want to consider exposure and toxicity both. But in terms of determining if something's toxic, that specifically should be based on the toxicity.

MS. PELTIER: Dr. Glantz, let me just add, if I could, though, the regulations, as they're currently worded, say specifically that a pesticide would be identified as a

toxic air contaminant if its concentrations in ambient air are greater than the following levels, including a tenfold safety factor.

I know that in the Wall Street Journal, Director Wells was quoted as saying you might as well designate everything as a toxic air contaminant, because pesticides are, by their very nature, toxic. But the regulations -- and they may need to be changed. But the way the regulations were put together, with direct input from the Legislature, when we came back and said, really, by their nature, we could just virtually put everything through the process, they wanted us to revise that to reflect the issue of exposure as well.

DR. GLANTZ: What does that regulation say? I don't have a copy.

MS. PELTIER: I can make a copy of it available to you, but it's under Subchapter 2, Air, Article 1, Toxic Air Contaminants. And it's Section 6890, Criteria for Identifying Pesticides as Toxic Air Contaminants.

DR. GLANTZ: What's the definition?

MS. PELTIER: (Reading) "A pesticide shall be identified as a toxic air contaminant if its concentrations in ambient air are greater than the following levels (for the purposes of this section, a threshold is defined as the dose of a chemical below which no adverse effect occurs):

"(a) For pesticides which have thresholds for adverse health effects, this level shall be tenfold below the air concentration which has been determined by the Director to be adequately protective of human health; or

"(b) For pesticides which did not have thresholds for adverse health effects, this level shall be equivalent to the air concentrations which would result in a tenfold lower risk than that which has been determined by the Director to be a negligible risk."

So, within our regulations specifically, the designation of a toxic air contaminant is based on toxicity but also on the amount of exposure in the ambient air.

DR. GLANTZ: I think I'd want to go back and read AB 1807, because that may not be consistent with what AB 1807 says. We don't need to get into that whole discussion right now. But that may be inconsistent with the law as I recall it.

DR. FROINES: I just want to say that I think this is a very exciting process we're engaged in. I don't mean to come on too harshly, especially with Carolyn, who I respect her work. And I don't want to make her feel that that was directed at per personally or anything of that nature.

I feel that we are dealing with a situation where we lack data. We have very little data to draw conclusions

from when it comes to pesticides. And most of our problems derive from our lack of information. But I think the process we're started out on is a very good one, a very, very good one. I can't -- this is one of the best -- the last two meetings we've had have been very positive. And I think we should take that even in the context of nyah, nyah, nyah, nuh on various issues. But it's designed to improve public health protection, and it's not meant in any other way than that.

And I think we really do have a lot of obstacles, but I think the process is really good.

DR. GLANTZ: The reporter needs you to spell nyah, nyah, nuh.

(Laughter.)

DR. SEIBER: I've got a question for our Chairman. Personally, I'd like to get back to the ranking scheme, and I'm not sure whether DPR had a presentation to make on it. I hope we can, because what we've been talking about directly relates to how we're prioritizing our future workload.

And I also know that my watch is stopped, so I have no idea what time it is. And I want to make sure we have time for a good discussion on the prioritization.

As I recall Halloween Eve of last year, the real concern was whether we were going to get lunch, if ever. It

arrived about 3:00, didn't it?

CHAIRMAN PITTS: I recognize what you're saying. Well, for your information, it's about 12:16. We answered that question. That's easy.

What was the other?

DR. SEIBER: The question is, do we talk about this before or should we do this after lunch?

CHAIRMAN PITTS: As far as I'm concerned, I see no problem. That could be after lunch. Do you have a problem with that?

MS. PELTIER: No. I was just going to suggest we anticipated that portion of the presentation to be relatively short, you know, probably no more than 15 minutes.

(Laughter.)

CHAIRMAN PITTS: For someone who comes in here fresh and optimistic, we want you back here every time.

I suspect that it might be a good idea to break for lunch now. But first, one last comment that we'll bring up that was raised by a gentleman who is absent at the moment.

Here he is! I think I counted roughly 40 references to technical reports mostly from the industry. And getting back to your point, Peter, as a quick check, I think there's roughly 100 or something references in there.

DR. WITSCHI: Yes.

CHAIRMAN PITTS: Don't hold me to my statistics, but it's roughly in that ball park. That's a hell of a lot of references. Now, that's a matter of great concern that we need to discuss after lunch as to how that's going to be handled. And we need to discuss in detail, because it's not something we can brush aside.

It may be that you'll have to decide to take them with a big caveat written after every statement in there, caveat -- supplied by -- just so you know where it came from.

Now, I would also point out for some of you that might not be aware, the EPA years ago, when they made their draft criteria documents, they took reports coming in from here or there. They wouldn't take anything but peer-reviewed articles from peer-reviewed literature.

Now, if you did that, it's a very critical decision that has to be made. And I've been hearing from the Director, hearing from Mr. Dunlap, and Tuttle, and up above, that you want the best peer-reviewed science. Now, we heard that at length.

Now, the best peer-reviewed science is not confidential or even public, necessarily, reports of the type that Professor Witschi referred to. If there is a dearth, as we have indicated -- right, there isn't that much

in the literature -- I would like to recommend also something that's really important.

There are areas where we need to get definitive research; a statement that we can't give you this number because there's no peer-reviewed research of quality in the literature. We should begin these reports that way so the world can know. It could be followed by, "the best we could do is something from so and so," but that's the way it is. That's just like asking what your qualifications are, what your conflicts of interest are to even serve on the Panel.

Yes, sir, Jim.

DR. SEIBER: Jim, I agree with you up to a certain point. But I'm a little bit confused, because these are economic poisons. The database is what the companies generate. They're probably isn't a whole lot.

So, it's going to be different from say benzene or butadiene. I think we've got to deal with this head-on. If a company submits data according to FIFRA guidelines to the State of California to register the pesticide, can we use it or not? We'd better deal with it.

CHAIRMAN PITTS: And one way to deal with it is by specifically stating these data are from this nonpeer-reviewed source. In other words, you don't mix the data. You do not mix data and conclusions from A and B.

So, if you stipulate the conflict of interest with

the public knowledge, fine. What I'm getting at is that it's in the documents, and it's agreed that it's being used. That way you have a clear understanding with the public and the scientific community worldwide -- have a clear understanding of that fact. I'm not suggesting they won't be inaccurate. They will be inaccurate. You just want to be sure everybody knows where they come from.

MS. PELTIER: I was just going to respond and say that Dr. Seiber raises a good point. Our regulatory program is based upon requiring registrants to bring to us, the same as they do under the Federal Insecticide, Fungicide, and Rodenticide Act, to bring to U.S. EPA the data on which we make our decisions whether or not to register a material.

So, the system by its very nature, we are within our program required to follow FIFRA guidelines. And maybe it would be helpful at some point to review for this Panel exactly what kinds of data we go through, whatever, you know, the kinds of guidelines in place for determining whether or not a study's adequate or not.

CHAIRMAN PITTS: We understand about that. We've gone through that with ethyl parathion. But I think it's a good point.

My point would be that, as long as we stipulate and make clear what these -- they're called disclaimers.

DR. GLANTZ: And then I think we should like eat

lunch.

CHAIRMAN PITTS: I agree.

DR. GLANTZ: I think that basically the way you need to handle this -- this is just reiterating what Jim said. You need to be clear. And I think when you are presenting industry unsupported, unpeer-reviewed data, you should clearly so state. And I think that the bias, whether it's a conflict, is the one that John was talking about. You should go with the peer-reviewed information, unless there's a very good reason not to and it's made very, very explicit. And you have to recognize that industry is going to come at this from one perspective.

And I think as long as you're very clear about that and don't mix the apples and the oranges; don't mix the peer-reviewed and unpeer-reviewed data in your presentations, then I think -- as Jim said, I think that's the best you're going to be able to do.

I think it would be silly to ignore all of this stuff which industry has submitted. I mean, I think it would be irresponsible to ignore it. But I think you also have to consider the source and recognize that, if something has been done by and outside group and has been peer-reviewed, it would have a stronger data point than the stuff which is being submitted here as part of the registration process.

But I think it would be a mistake to avoid it, because the industry could come in and say, oh, this is the most toxic stuff ever on the face of the earth. And then we'd say, we're going to ignore that, well. . .

I think she's right about coming in at some point and making a brief presentation on FIFRA, because I don't really know the guidelines. And I think making a presentation like that, we can then have a discussion about how do we evaluate science irrespective of regulatory guidelines, which I think is very important to not only see things in terms of -- the reason for separating risk assessment and risk management is to separate in a sense the regulatory management issues from, quote, the "science."

And so, it seems to me that it would be very helpful for me personally to have a little discussion on that.

DR. WITSCHI: I might be not correct, but I think the FIFRA guidelines must be very much in line with the GLPs of the FDA.

DR. FROINES: I also think there should be a specific section on the calculation of NOEL that is separated out so it's very visible in the document, so you're not picking through where things are at.

There is a risk assessment section -- and there is one in here. But the one that specifically has the

formatting and structure so you can find it very easily.

CHAIRMAN PITTS: Time out. I have the signal. The time out is called. That's it.

It's 12:30. We will come back at 1:30.

(Thereupon a luncheon recess was taken.)

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AFTERNOON SESSION

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CHAIRMAN PITTS: We'll start the afternoon session. And we're going to conclude Item 1 on the agenda. My thought is that it might be a useful idea to just continue briefly along the lines that we were discussing with Ms. Peltier, Paul, and the crew, interacting again with the Panel regarding some of the contrasts between the manner in which 1807 might be handled on a particular toxic air contaminant; e.g., benzene versus a regulated chemical we have as a pesticide.

So, I've asked if they wouldn't mind spending 15 more minutes and interrupting some very busy schedules, changing a couple actually, if they would sort of wrap this up -- (a) wrap up this session as where we are now, and (b) as a springboard looking ahead to future sessions where we can explore and expand on these issues.

I'll turn the floor over to both of you. Please give us your input.

MS. PELTIER: All right. I think the way we'll handle this is I'll get started and try to put it in a framework. And then any specific questions you have about the way we've prioritized materials for review, I'll defer Paul Gosselin, who is our Assistant Director.

CHAIRMAN PITTS: Sounds good.

MS. PELTIER: Let me say first, and without being redundant, the nature of the way the Department of Pesticide Regulation interacts with the SRP is somewhat different, because the kinds of products that we're regulating are different.

Pesticides are by their nature toxic. They are, unlike other Boards and Departments that are trying to regulate or keep products from getting into the environment, we're dealing with a situation where these materials are purposely introduced into the environment to have an effect, which is to control pests.

It's the role of the Department of Pesticide Regulation to mitigate those impacts and to minimize those impacts. We have, as a portion of our charge to regularly evaluate materials before they're allowed to be used, we have a fully integrated program, which is to say that the Department of Pesticide Regulation regulates pesticides whether they're in the water, whether they're on land, whether they're in the air. And so, ours goes across multimedia.

And the pesticides that come into California, unlike other States in the country, in addition to undergoing review by the U.S. EPA -- through their Office of Pesticide Programs, OPP -- those pesticides then, when they come into the State of California, have to again be

evaluated before they're registered or licensed to be able to be used in this State.

The Department of Pesticide Regulation has a staff of 450 people, including a number of toxicologists, a couple you heard from earlier this morning. And we're involved in both reviewing data submitted to us by pesticide registrants before we allow those materials to be used in California.

And then, in addition to that, we have a number of processes that are in place to continue that evaluation of pesticides once they are registered for use in the State.

One of the difficulties that we've had in the implementation of AB 1807 is the fact that we have conflicting that are put on the Department that are -- that have resource considerations. In addition to dealing with the Toxic Air Contaminants Act, we also have to deal with the Birth Defect Prevention Act, or so-called SB 950 requirements.

In addition to that, we have the AB 2021 requirements, which set up a set of criteria for data that we have to look at in the area of water.

One of the things we've tried to do initially was deal with the independent process under AB 1807 and conducting risk assessments in a separate track for those materials that we had as candidate toxic air candidates, and to handle that as a separate discrete process from the

ongoing risk assessment that we have under 950.

What ended up happening under that scenario was that very few materials were coming through the pipe for you, because when we take a look at the overall review of materials, those which are viewed to be the most toxic are the ones that drive the risk assessment process and hence the generation of materials for you to review.

And so, what we've tried to do, particularly over the last two years, is reevaluate the way we're handling those processes and try to integrate them together, so that materials that are coming up for risk assessment under 950 are materials that we are doing monitoring for -- assuming the material has a chemical constituency that would require us to monitor. And conversely, those materials that we have done monitoring for are then merged into the 950 risk assessment process.

And that in a nutshell is what I think you see before you in that gray document that was put out in October.

With that having been said, let me just say that we do have two additional documents that are going to be coming forth for the Panel to review. If someone will flip on the slight over there.

(Thereupon, Dr. Glantz turned the overhead light on for the overhead screen.)

MS. PELTIER: Today, you received the first document, which was the DEF document. In June of this year, we're going to be submitting to you the risk characterization document on metam-sodium, and giving you the draft final report in December. And so, that will walk through the metam-sodium process much the same as we did today starting in June.

And then finally, we're also going to be presenting a risk characterization document on azinphos-methyl. We're actually going to complete that volume -- that three-volume report in December of this year. You should be getting it in January of 1998.

But to give you an idea, we're hopeful then that this is the first in a series of steps that we'll be going through with you in presenting these formalized reports to you as well.

As a side point, let me just get back to something that we talked about briefly this morning, and clarify it. We have two other documents that we'd be glad to continue to work with this Panel on, and those are the review documents that we're preparing on methyl bromide and also on 1, 3-dichloropropene. Notwithstanding the fact that those two materials have already been listed as toxic air contaminants, and notwithstanding the fact that we don't, as we see it, don't have a legislative or regulatory directive

to now run documents through the Panel.

We would like very much to continue to consult with you, and continue the dialogue that was started I believe last year with Dr. Pitts, Dr. Seiber, and Dr. Froines, in working with our staff as we develop those documents.

And I might say that the telone document -- that risk characterization document is completed. And so, we can share it with you informally and then see where we go from there.

The methyl bromide document, we have a preliminary risk characterization document put together, which I'm not sure if that's been shared with you yet or not. We'd be glad to share that. As you know, methyl bromide was the subject of a special legislative session, because not all of the data was completed by the registrant within the statutory time frames that they were supposed to meet. And so, the registrant was given a two-year extension to develop that data.

The data is scheduled to be back to DPR by December of 1997. And so, we'll commence work on the final risk characterization after all the data are complete.

DR. SEIBER: Just a quick comment on certainly the methyl bromide I think. I can only speak for myself, but I expect some of the others on the 5

Panel would be interested in helping, as we did a year ago when we had a meeting that I think was very useful. And we'd like to propose that we do that again in the near future.

But secondly, on the issue of when a pesticide is already been declared a TAC under the reconciliation with Federal law, we still need to look at the risk assessment. Isn't that right, Jim?

CHAIRMAN PITTS: I believe so.

DR. SEIBER: And this is a basic question that goes beyond pesticides. Things that are on the list of 189 that have been grandfathered or brought in as TACs, we still need to look at the risk assessment documents.

CHAIRMAN PITTS: We have asked the lawyer, the ARB lawyer, I'd asked the question again to clarify exactly what the legal status is.

MS. PELTIER: And let me just say that we need to do that as well, because I think there's some question in our mind. But notwithstanding whether or not we have a legal requirement to do it, we'd like to --

CHAIRMAN PITTS: Do it anyway, huh?

MS. PELTIER: -- we'd like to seek your input.

CHAIRMAN PITTS: Let's get the two lawyers together. Let's just be sure we know where we stand. I think we're particularly interested in methyl bromide.

That's one of the problems when you look through the priority, list of priority chemicals, and methyl bromide's not on there. And that's because --

MS. PELTIER: (Interjecting) It's already listed as a TAC.

CHAIRMAN PITTS: -- it's already listed.

MS. PELTIER: Well, these are materials for which they have not yet had the determination of whether or not they're a TAC. It doesn't mean we're not continuing to conduct monitoring on them.

And, in fact, we just completed some winter monitoring on methyl bromide.

CHAIRMAN PITTS: Okay.

DR. GOSSELIN: The way our end of the law works on TACs, there are two ways they get listed. One is the way this process is going through now, where DEF's at, and also administratively when they're automatically -- if they're a HAP, they're automatically listed. And we immediately took that listing and administratively listed them as TACs.

And that's why it's not on that sort of list. But the next phase of that is, how do we confer on follow-up monitoring on the ones we've administratively listed to see if we need to mitigate the exposure to them.

Secondly, the ones like methyl bromide and telone that were administratively listed, the steps were taken to

control the use and exposure to that. How we're doing that, we need to also confer with the SRP.

And I think that, you know, is something in hindsight that I think we should have been doing earlier on and continuously. So, this is probably another starting point.

Back to the meeting and the discussion we had last spring hopefully can serve as a model on some of the consultation that we can have so you could provide us with some good thoughts and considerations on how we carry out this program to make sure we do the best job possible.

CHAIRMAN PITTS: Thank you. Any more comments or questions from the Panel members?

DR. GOSSELIN: Systematically, it all starts with how we choose and make recommendations over to ARB to go out and monitor. And you said at the last meeting, in an ideal world, we'd be able to have all the monitoring data on all these compounds done right now. But we do have to make some choices and some value choices. And even internally we have different perspectives about some people were looking at the toxicology, the toxic end of things. And some are more interested in the fate issues. And a lot of that goes into your own perspective or where your discipline may come out of.

You know, personally, I'm more interested in the

environmental fate from an exposure standpoint, but also the toxicity has a major effect on that. So, all I'm saying is that the document we put together on prioritization is a relative document that's a snapshot in time. That also does need some more consultation on, you know, when we do have the two to three compounds monitored a year by ARB, we do need to maybe sit down, go over the considerations, some of the toxicology background, and really decide what things do we want to have come out on the next round.

And we also want to bridge with that what we also have in line for risk characterization documents coming out, so we don't have monitoring data that's sitting around for ten years waiting for a risk assessment to get done, so we'll have both projects merged together so they can come out on a timely basis.

DR. SEIBER: Is this a good time to talk and ask some detailed questions about the priority? Should we be doing this now or is this -- I don't want to get started.

I'm not so worried about the individual countdowns, it's more the do we have the right categories, are we giving the right weight to the right chemical? Should we be doing that now?

Is that a subject for a later discussion?

CHAIRMAN PITTS: Well, while we're in the framework of what you want to see, I think it's very

important. Let's take 15 minutes.

DR. SEIBER: Let's go back to what he brought up this morning about double-counting the vapor pressure. And that's a fairly simplistic way of putting it. But it's true. So, vapor pressure gets kind of counted twice. It's important. There's no question about it. But is it that important that it be double-counted in the priority scheme?

DR. GOSSELIN: And to some extent, I think, in taking a look at this document, it did take a couple years to put together, and we spent a considerable amount of time with getting comments from agencies, the Panel, and outside people.

To some extent, you have a horse designed by a committee. So, it's definitely not a perfect prioritization scheme, and it's not something I would -- not just for this process or any process -- want to have to totally walk into without making some judgments and some common sense, going down this list, what we really should have at least for here and now the immediate monitoring data in on.

The other side of that, too, that's also just as important for keeping the process going, we need to also bridge what we have coming out for risk assessments to make sure that the data is coupled with that risk assessment in a timely way to get that. And that's primarily based upon the health end.

So, that is a balance back when we start going down this priority list, you know, going from the top down, and then also taking a look at where is something in the risk assessment which is primarily based upon the toxicity of the compounds.

DR. FROINES: P-dichlorobenzene has a ranking of 17. So, it's just below metam-sodium and DEF. But it has a 4 on sales and use, so it's widely sold. It has a IV on oncogenicity, so it's a carcinogen perhaps, probable. But it's lower on Henry's Constant and vapor pressure.

Well, p-dichlorobenzene, as we all know, probably isn't very volatile. But again, it is persistent in soil. And again, we don't have data on reentrainment of p-dichlorobenzene in those fields where you have people working. But this stuff is going to stay around for a while.

And so, I'm not convinced that this priority system adequately addresses that particular compound. And I think this problem with the Henry's Law Constant is that it assumes -- well, I'm just repeating what Jim said as an example. So, I'll stop.

DR. GOSSELIN: Right.

MS. PELTIER: Just as a point of clarification on that particular material, it's my understanding that within California, p-dichlorobenzene is used primarily indoors.

It's primarily not ag usage. But be that as it may.

DR. SEIBER: I think it's actually used in latrines as a purifier? Isn't that one of the main uses of p-dichlorobenzene?

MS. PELTIER: But it does get into this issue.

DR. FROINES: Well, let me make my point then. You heard me say this before, so I'm just repeating what I've said in the past. I think that is oncogenicity classification is much, much too limited. And that is, we all know how limited Federal EPA's carcinogen identification process is.

The NTP reports, which you talk about here I think is less than 200 chemicals that have been identified. How many are in the NTP list?

Prop 65, you have over 400 chemicals, and on IARC you have a certain number of chemicals. But there are data on oncogenicity for probably at least a thousand chemicals and maybe as much as two thousand. And so, what happens with the 1807 process is Alexeeff and people go look at the carcinogenicity data on a particular compound.

Here, you define whether a substance gets a ranking based on what EPA's done. But there's hundreds more chemicals than that with oncogenicity data. So, this is a totally inadequate way of evaluating carcinogenicity.

DR. GOSSELIN: Right. And this is not intended to

evaluate or be the definitive ranking for carcinogenicity or, you know, essentially any of these other factors. What it is, you know, is a seat of the pants approach to at least a ball park -- you know, relative to one another, which compounds should we actually go out and collect monitoring data on and start the process.

Again, when we go back and initiate our risk assessment, it's based primarily on the toxicity, which I heard the Panel saying earlier should be the driving factor on getting documents out.

And if we do merge the two, you're going to see that, I think, be fixed. But if you're raising the point that there are a lot of other, you know, just taking a look at these factors, there are a lot of other considerations that need to be made beyond just that ranking, I absolutely agree. But this was just sort one shot when presented -- the Panel asked us to come up with sort of some methodology on how to pick and choose which compounds we're actually going to have ARB go monitor. We came up with this one.

And it's not perfect, but it's a start.

DR. SEIBER: I have one other comment. I don't want to bash the document. It's better than no document, that's for sure. At least it's a starting point.

But the highest score that you got for propargite was 21. And I just picked an example, No. 33, down there.

I have nothing against this chemical. But for vapor pressure you list 2, and yet it's a gas. It really ought to be 4 according to what I read. I think it's either a mistake or something.

And if it was 4 instead of 2, it would have jumped all the way up about 10 or so slots on this ranking. And so, I guess my bottom line comment or question would be, has this been sent out for people to look at, and make sure we got the right numbers in each category?

DR. GOSSELIN: Before we finalized this, we went through two rounds of public comments on this. And I think in one pretty in-depth panel discussion here and a lot of good comments on pointing out problems we had and inappropriate -- or additional criteria we should use. You know, that might be another error that we have to add back in that might, you know, put this up in the queue for monitoring for next year.

But I think it really gets back to the point of having some continuous dialogue and consultation about is the list we have -- is this document, which is one piece of the decision that we need to consider as to what actually gets monitored for, and then have some dialogue on the choices we have to make just on priority.

It doesn't mean that we're not going to ever get to all of these compounds. It's what can we get to for this

next year.

DR. FROINES: Well, you looked at this list of 70 compounds that NRDC raised that I'm reading in all these newspaper things that we got here.

I just went through yours, and I compared it with these, and there seems to me -- you can see from where you are sitting a very large number of these compounds are not in here. So, this would make me think that EPA has some lists of chemicals that you don't have or perhaps are not used in California.

So, I don't know whether these represent a problem or not, but they are, as far as I know, the most recent ones that have been raised.

MS. PELTIER: I haven't seen the NRDC list, but I'd be glad to take it back with me to look at it. We can take a look at which ones are still available in California.

DR. GOSSELIN: The list we have represents all the pesticides registered in California that are subject to the Birth Defects Prevention Act. So, that in itself prioritized the ones that have the highest toxicity.

DR. FROINES: I can't promote this list, because I don't know anything about where it came from.

DR. GOSSELIN: People come up with things that were missed, you know --

DR. FROINES: Reproductive toxics.

DR. GOSSELIN: Right. We'd like to know that. Actually, you know, one thing that's interesting in this process, like the monitoring on metam, the need for that principally came from county health officers who had some odor complaints and some other complaints. And part of this process is, you know, should be even more interactive with people, not just local agencies, dealing with these issues, so that all of us here are making sure what choices we make are the right ones.

DR. SEIBER: Just one last comment. When the AB 2021, the Groundwater Protection Act, was passed, it had a kind of numerical system associated with it. And the Department, CDFA, at that time did a good thing. They hired a couple of outside consultants to look over the specific numerical values to make sure they were right. And actually, I was one of the consultants.

I'm not looking for work here, it's just a recommendation. You might want to get somebody outside DPR to look at your listing to make sure your numbers are the best they can be.

CHAIRMAN PITTS: Yeah, that's a good point. I just glanced down the list again and saw our old friend methyl parathion. Now, somewhere in the dim recesses of my memory, which the recesses are getting bigger and my memory's getting dimmer, I recall that methyl parathion was

coming through our process three, four, five, or some -- has that become a virtual TAC as it were?

We made some progress on that, and we actually -- there was nothing really in our hands. And we got talking about it. So, I'd like to know, hey, whatever happened to methyl parathion?

MS. PELTIER: Dr. Pitts, we're going to have that one to you as well. We don't have it on the list. This is one of those -- I can't explain to you where methyl parathion went, though it fell through the cracks as we were working out prioritization schedules.

You will have that this year. It's not going to be a virtual TAC. We will have that report to you this year.

CHAIRMAN PITTS: Well, I noticed also in that line, and I understand it is available, but it's highly regulated. But it's down in No. 38 on this list. And sometimes I look at these things and wonder if I'm looking at -- I think methyl parathion would kind of make me nervous, particularly if there were infants and small children. I think 38 -- this wouldn't be around 38. It'd be up with methyl bromide, which would be about 1 or 2. And that's just a gut feeling, or a brain feeling, or whatever the feeling is.

Our concern about this is that this can fall into

the hands of wide groups of individuals and professionals. And if they look at this and sort of take it like it comes, they play the numbers game. And thinking only in terms of toxicity first, as John was pointing out, separate them. Toxicity is one number, and then exposure.

If you were to look at this, it would be very, very useful to have it in what constitutes the real threats. You almost could sit down here with Jim and others and say, look, what are really the bad operators? And think of the scale in terms of what would go into this sort of scale which would be -- which would be important to public health.

Now, let me just briefly say that there was one great big article that I saw somewhere -- I think it almost sounded like Newsweek, but it wasn't -- oh, CNE News on ethyl parathion. And it's going to cost more money, $50 million, to clean up homes down in Georgia down South, where illegally -- these homes were illegally sprayed with methyl parathion, and a lot of very sick people occurred. They're talking abou worse than Superfund sites.

And so, the idea that something isn't -- that's a registered illegal chemical. But the fact that it's registered and illegal versus the public exposure -- particularly the public who will walk into a home. So, it's a baddy regardless. Methyl bromide is a son of a gun indoors.

Six hours after a building -- six days it was after a building was declared safe for methyl bromide. They got 30 parts per million, 30 parts per million. Now, these are numbers and these are exposures that are related to real people, to the real public, in realtime.

So, I will just say that we would really spend some time to think about the uses to which this might -- the confusion that might result that we wouldn't want to see.

MS. PELTIER: Well, you've really captured well the dilemma that DPR goes through when it has the requirement to conduct monitoring, and yet some of the materials that are the most toxic are not necessarily the materials that make a lot of sense to monitor for in the air, because they basically aren't very volatile.

And so, we do have within DPR a risk assessment process that is driven by the toxicity, into which we're trying to merge the requirement for monitoring the materials that we believe will show up in the ambient air. And those two aren't always the same process.

I agree that what we have with this document we need to take a look at. I think you raised an excellent point about double-counting for vapor pressure. It sounds like a good argument to me.

With regard to the issue specifically of methyl parathion, that document will be coming to you hopefully --

I can't commit time. It will come to you this year.

With regard to methyl parathion -- and I don't know fully why it ended up at this particular classification, but let me say that this document in a sense becomes obsolete before it finally gets printed.

With methyl parathion, it may well have been that the reason it got down here is that we were talking about a different kind formulation in California. Most of the methyl parathion at least that I'm familiar with that's used in California is an encapsulated version.

And so, in terms of exposure through ambient air, problems with methyl parathion, the issue about monitoring, because it's illegal in California -- I don't know whether it's illegal elsewhere in the country -- but it is definitely illegal to use methyl parathion indoors. So that kind of application --

CHAIRMAN PITTS: It's illegal in Georgia, too, but they just used it. That's why you do want to separate exposure from a thing that might be used illegally. Because it's illegal to use methyl bromide in California to fumigate, isn't it?

MS. PELTIER: No, it's not.

CHAIRMAN PITTS: Oh, I thought it was.

MS. PELTIER: No, it's not. It's subject to --

CHAIRMAN PITTS: Then you really want to look at

those data, because I have the data in my hand generated by your laboratory people in which they have -- in this paper, it's commented that after so many hours, days, that these methyl bromide -- in 15 minutes, this is critical for acute exposures.

And they found up to 30 ppm in the open window, and it drops down. It just sticks to everything.

Now, they made a comment that -- something to the effect that after so many days, that it dropped below the something standard --

DR. GOSSELIN: I think it was NIOSH.

(Thereupon, several persons spoke simultaneously.)

CHAIRMAN PITTS: And the standard, as I read this, was 3 ppm. Now, I don't know --

UNIDENTIFIED SPEAKER: For one hour.

CHAIRMAN PITTS: Yeah, that's just one hour. It can be that way for days. Let's find out for sure whether methyl bromide, for example -- let's find out soon if it's still allowed.

DR. GOSSELIN: I can tell you right now that it is allowed. It's used in about 10 percent of the fumigation uses in structural. The levels are extreme high, and it triggered us to do was to immediately notify EPA that there was a problem. It was a nationally allowed use. And we

immediately issued emergency regulations to deal with that.

During that emergency hearing, EPA changed the label to prescribe specific procedures for locking up structures, for aeration and time periods, and levels before people could reenter.

CHAIRMAN PITTS: Okay.

DR. GOSSELIN: But they said they were safe at the 3 ppm level.

CHAIRMAN PITTS: Which I find astonishing.

DR. GOSSELIN: Well, it's frightening.

CHAIRMAN PITTS: To assume you can go into a home with your six-month old baby and sit there where she spends 80 or 90 percent of her time, which the indoor studies show, at a level of 3 ppm, or a half a ppm. . . I don't know why we're worried about benzene at 2 ppb at a State average, when you're talking about --

DR. GOSSELIN: Our standard isn't 3 ppm for indoor. Actually, we put more monitoring in place. This goes back about a couple years ago. It's sticking to the 210 24-hour exposure level, and also monitored the homes to make sure that, you know, to track the dissipation, you know. Because you're absolutely right. It is dealing with a constant indoor exposure, and it needs to be regulated a heck of a lot differently than outdoors where it dissipates.

But that's where we have to make sure that the

right aeration procedures are in place to make sure the levels get down to below any level that poses any risk in children and adults.

MS. PELTIER: Let me just clarify. You were saying 3 ppm, and you said 210.

(Thereupon, several persons spoke simultaneously.)

CHAIRMAN PITTS: This does illustrate the point that you want to be sure what constitutes -- what factors really go into what are the highest priorities for protecting the public health of California.

DR. BYUS: I've been quiet all day, and I'd like to say something.

CHAIRMAN PITTS: Say hello first.

(Laughter.)

DR. BYUS: Hello. I'd just like to say that I've been on the Panel for quite a few years now, and I'm actually thrilled by this document. Because I don't really know much about pesticides, and I think this document answered much of our questions we had about what pesticides are there, what you're thinking about doing.

And I think it's a great effort to start with. You can always criticize the shortcuts with prioritizing. There's almost no way to do it really effectively. I mean you can argue that no matter what is you come up with, you

can argue. And I think, as a first attempt, it's tremendous. I do agree with the double-counting of vapor pressure, and I also agree that the oncogenicity should be looked into considerably more.

But to start considering where we were a year ago, I think this is an enormous step forward. Now at least we have something to look at and something to think about, something to talk about, which before we had nothing. It's infinitely better than before.

CHAIRMAN PITTS: How do you like that for a wrap-up?

(Laughter.)

DR. GOSSELIN: May I ask a question? Does all the Panel feel that the prioritization should be solely based or principally based on -- initially on the toxicity? I'm talking about deciding what you're going out and monitor for.

DR. GLANTZ: I think that your prioritization should be based on toxicity and your best guess on the would be exposure.

Because I think your prioritization activities should be based on your best estimate of the public health impact, recognizing you may be wrong. And that's why you've got to go do your monitoring.

DR. FROINES: Did you say it should be based

solely on toxicity?

DR. GLANTZ: No. I said it shouldn't be based just on toxicity. I said it should be based on toxicity and exposure. You want to find the things which you think are going to be having to do with public health impacts. But both the toxicity and exposure have to be considered.

CHAIRMAN PITTS: And you should also use the old hot spot approach, too. You're looking at populations: (a) an assessment which says this is a priority relative to the overall population -- 20-some-odd million. Put some numbers in.

But then, (b) you consider if you're living next to that particular field that was just sprayed by methyl bromide. So, you can actually have two categories in terms of exposure. And remember the indoor, remember indoor. Be very sure that when you talk about exposure, you consider situations in which exposures are indoors.

You have to have a couple of columns. And the very first column is the toxicity, that's the number. Then you indicate that number and relate it to hot spots, humans, several environments. And then you can use it, saying, I'm really worried about -- what's the impact of methyl bromide on children indoors, in homes that have been fumigated with methyl bromide for termites.

So, if you could do that, that would achieve the

objectives. And it would be subject to revisions as you got new ambient data or new toxicity data.

We should wrap this up. This will be the last question.

DR. FROINES: I think the danger with matrices, as you well know, is they become mechanical if you're not careful. And one of the problems with the Federal EPA is that they have historically been very weak in the health area. They're not so bad at modeling. But they don't look at receptors very much. They look at big transport models and so on.

So, there's one other element of all this that I think is worth at least thinking about, which is health. And in that context, I think it would be useful if you had developed another side perhaps in connection with Department of Health Services and OEHHA, if it's relevant, and that is to what degree are you finding people who are becoming sick from pesticides?

And I think that illness and disease are end points that should be factored into this, because it may be that you find a lot of acute toxicity. But the more and more we look at acute toxicity, we tend to think that over time there may be chronic toxicity associated with acute toxicity. And so, we also have to be aware of those kinds of potentials.

So, I would simply have you say that let's build health into this as well as the more mechanical aspects of it.

MS. PELTIER: I think that's a really good point. And it's not reflected this document because, once again, this was put forth to say, of those that we know are toxic, let's take a look at which ones should we monitor.

But we do feed into our Worker Health and Safety Branch an analysis of the data. We prepare an annual illness data report. And that is factored in in determining exposures when we do the formalized risk assessment.

DR. FROINES: In that regard, when you do your monitoring schedules, I would also start to answer some questions like, is there skin absorption; that is, do we need to do some biological monitoring and not just monitoring air. And do we want to look at receptors; that is, people who are being exposed to relative and ambient -- in other words, to get away from the sort of more mechanical monitoring and to find out more about whether or not a chemical really does have an impact to human beings.

CHAIRMAN PITTS: With those comments, I think we will conclude. This will conclude Item 2 at 2:00 or so.

And thank you and your team who presented the discussion. We appreciate the interaction. We appreciation not only the facts of the presentation, but the philosophy

behind your approach and the way you're approaching and -- producing interacting with the Panel on a scientific basis. It's great.

And I was amused and appreciated Professor Byus' enthusiastic response, because it does reflect the fact that progress is being made in a very complex area. And if you want to know how complex it is, I will for the record put something I think you all should have maybe tucked away. And I use it all the time. This is (reading document) master notes, save for Chapter 16 of book, et cetera. Seminar, UCI. It's called Concentrations and Transformations of Hazardous Air Pollutants. And it's in the Environmental Science and Technology. It's Volume XXVI, 1994, and it's pages something like 380 on.

And it's a superb compilation, as of 1994, all the EPA field study data on 189 HAPs, including your pesticides. And it just goes down the list here.

And it tells me particularly about atmospheric transformations at ambient levels. And it cites the original efforts. Here's one, 1, 1, -- there's just 189 of these things here. They give you case number, class, oxyorganic, ambient concentration measurements in the U.S., 50 locations, 1100 samples, median ranges, lifetime, then atmospheric transformations, lifetime, and known products. Are they known or not known?

And then the references are here, so you can go back and actually see something that's very important that you noted today. It backs up exactly what we've all said here. There's a very interesting statement in here about the dearth of data, because there's a last column I would suggest you read, and use this as a reference when you go to the Legislature.

And when you go, it's not just you speaking. And it's not just those academic who-whos on the SRP that are saying we got to have more data, so we need more research. But it's here in a peer-reviewed journal. And they point out that ambient data sufficient for health risk assessments exist for only about one-third of the 189 HAPs. Thus, quantification of existing health risk, much less confirmation, of mandated reductions in health risk will be difficult.

I might say, though, that California's air toxic program is so far superior -- this is EPA national data. And the national data sure can't be applied to California in either the quality or the quantity of data. But it is a handy reference.

And with that, let's move on. Thanks very much.

MS. PELTIER: Thank you.

CHAIRMAN PITTS: The next item on the agenda is the overview of the exposure assessment and stochastic

analysis technical support document, OEHHA. And George Alexeeff and Melanie Marty are going to make the presentations.

Now, before you do, George, I don't know beans about stochastic modeling. Modeling, shwadling, I don't. It's not that I don't know the details of what they're talking about, I don't even know the subject.

So, I asked Bill Lockett. And Bill isn't here, but I called Bill, and said, "Bill, what the hell is stochastic modeling?"

And Bill Lockett, who just walked into the room, Bill Lockett said, quote, "I don't know what stochastic means either. But I have a Funk & Wagnalls Dictionary here, and he reached up and called me, and said, "Well, I have the definition of stochastic," which I'm now reading to you, and I made an overhead, which I show to seminar audiences and so forth. Students get a big kick out of it.

They say, "When someone tries to give you this jazz, you know, just read 'em the old -- the Greeks have a word for it."

It says here, "Stochastic. Adjective 1: Of, pretending to, or characterized by conjecture. 2: Denoting the process of selecting from among a group of theoretically possible alternatives those elements or factors whose combination will most closely approximate a desired result."

Then, finally it says in brackets: "[Greek for the Greek stokhiastikos]," and then, "stokhazesthai, meaning to guess at."

(Laughter.)

CHAIRMAN PITTS: So, I leave this for the record. I did warn you I might do this, right? So, blame it on Bill's Funk & Wagnalls.

But anyway, with that, this is a very complex and important subject, and we very much appreciate -- and we understand it's important and very timely these days. And we appreciate very much the opportunity to hear from you experts in the field.

We appreciate you're being here.

DR. ALEXEEFF: Okay. I'm George Alexeeff, Chief of the Air Toxicology and Epidemiology Section in the Office of Environmental Health Hazard Assessment. And with me is Dr. Melanie Marty, who is Chief of the Air Toxic Risk Assessment Unit.

And the purpose of today's presentation is to give an overview of a project we've been working on for several years.

In 1993, we came before the committee -- that is, Genevieve and I -- to discuss implementation of 1731, SB 1731, which was part of the Hot Spots Act, and it was an amendment to the Hot Spots Act.

In that amendment, it required OEHHA to develop guidelines on how to do these hot spot risk assessments. One of the key aspects of the requirement was to prepare what is called supplemental information. And there were some criteria listed in the statute saying what the supplemental information is.

And the purpose of the supplemental information was to allow additional -- either local information or other known information that could be added to a risk assessment to make it more comprehensive.

CHAIRMAN PITTS: That's a very important point. That's a bullet in one of your bullet paragraphs. That's a bullet. Say that again. The purpose is to enhance, to expend --

DR. ALEXEEFF: The purpose is to enhance the risk assessment by allowing additional -- either local information or other information that might be known about the chemical or that sort of thing that could be added to the risk assessment to make it more comprehensive.

And then we were supposed to provide guidelines on how to do it. And in the statute, it also stated the need to provide it in a likelihood type of distribution. So, that's where we came to this terminology "stochastic." Some people might refer to it as uncertainty, but uncertainty, as we've talked to statisticians, tell us that that is actually

something different from a statistical point of view.

So, we called it stochastic modeling. That's what we'll be talking about.

DR. MARTY: I guess that I could add in here that my dictionary had a little bit different definition. Actually, in terms of mathematics, a stochastic calculation is one that involves a random variable, and that is conjectural I suppose in a sense. And that's the definition that we are really going by.

DR. ALEXEEFF: Probably in the early nineties or late eighties, we also came before the committee -- ARB and us -- to discuss this CAPCOA multipathway risk analysis document. You might remember that.

And so, one of the things we were looking at is building upon that exposure analysis that was in that document and adding a stochastic component. That was one of the things we considered and that's the alternative that we basically decided to go with after considering other alternatives.

So, what we've compiled at this point is an explanation of how one would do an exposure analysis from a facility, and then how one could add supplemental information in this stochastic mode.

The document has been sent out for public comment. It's still actually out for public comment right now. And

we've had some input from the liaison, the committee's liaisons, Dr. Seiber and Dr. Glantz.

Now, the information that we're dealing with here is different from the normal health documents we've provided in the past, where we've looked at a chemical and gone through stepwise the acute chronic and carcinogenic effects. It's sort of a whole new area.

And it was very much an education for me and my staff on what this was, how to do it, and we thought, after talking with Dr. Seiber and Dr. Glantz, that it might be good to at least give an informational update now before the document comes before the committee just in case there's aspects of this we want to discuss, to explain, that sort of thing.

So, there was another aspect of this whole process that we added in to the development of this document. Since it was an area that our Department did not have a lot of resident experts, we created what was called this external advisory group. And it was also, along with the current philosophy of adding multiple stakeholders when you're dealing with a complex issue and you can often get a better answer that way.

So, I'll put this one slide up. So, we created this external advisory group, where we had representatives from industry, environmental groups, the air districts, the

other Cal-EPA boards and departments -- and that included the Department of Pesticide Regulation, Air Resources Board, Department of Toxics, and also we had to include a number of academic folks that were experts in statistics just to help us understand.

And over a period of a little over a year, we had kind of an educational process when the people brought the information together, and that's what led to this report. So, it was a different sort of process that was very helpful actually. In the end, it speeded up the whole document delivery. I think that's our conclusion.

DR. FROINES: George, can I ask you a question about that?

DR. ALEXEEFF: Yes.

DR. FROINES: If I had to put together an external advisory committee on stochastic modeling, this is not the committee I'd put together.

DR. ALEXEEFF: Okay.

DR. FROINES: I'd have Duncan Thomas. I'd have Dale Haddis. And I'd have others like Duncan who have both statistical skills, but also have thought about exposure assessment.

This looks like a lowest common denominator committee of interested affected groups, but not scientists. And the number of scientists on here -- I would have put Tom

McKone on it, for example. I think McKone would be great.

But I'd have McKone and Thomas -- Duncan Thomas, and Dale Haddis is three.

How does this committee function to give you the best scientific information as opposed to serving what is essentially a nontechnical advisory process. Because these are representing affected parties of risk assessment, but they do not reflect scientists associated with risk assessment.

DR. ALEXEEFF: Well, actually, I guess I have to differ a little bit with you. I think most of the -- do you have the list?

Okay. This group was strictly not just -- I was going to say like an academic sort of think tank of the experts in stochastic modeling in the country. That's for sure.

The purpose of this group was twofold. I think we did have talented folks at he table; but at the same time, it was also parties that had been interested in this in the State, that'd constantly be asking us questions about this; that they could both educated about it, and supply other kinds of things.

So, the actual technical -- Tom McKone and Michael Tarter (phonetic) were really, I would say, the most technical experts on the committee, the two academicians.

And they provided us a lot of analysis and additional information.

The other members of the group sort of reviewed it, brought in other studies that they might have heard of, and sort of discussed how one could kind of put this together so that everyone could understand how it might work. So, in that sense, we -- Duncan Thomas, whom we would have liked, but he was in France. And we'd been trying to get him on a number of activities.

But I think we were also concerned about enlarging the group too much. But these were folks that are fluent with the risk assessment process. In other words, they've been working on the hot spots program for years and are familiar with the risk assessment process, and wanted to know how this was going to go forward.

So, I don't know if I can explain it better than that.

DR. FROINES: I think that stochastic modeling has become very popular, as you well know, across the United States. But the ultimate question is: At some point, when you've done the Monte Carlo simulation, and you've done other modeling, people still have to make decisions, and decisions are based both on science and policy. And we want to be sure, I think, that our advisory committees that we use to develop these kinds of approaches stay as -- how do

we want to say it -- as methodologically oriented and scientifically oriented, and don't become the kind of lowest common denominator approach to a problem which --

DR. ALEXEEFF: Okay. I think it's a point well taken. We were also were expecting the Panel to provide its input as well.

DR. GLANTZ: We will.

DR. ALEXEEFF: We weren't trying to create an alternate panel.

Okay. So, as I mentioned, the document's out for public comment still, and we wanted just to discuss it briefly with you here. And I think you have copies of -- I'll do the status of the whole guideline process at the end.

But I think you have copies of the presentation that we can give to you that Melanie can present. But with regards to the time, I'm not sure how you want to proceed on this. If you would like us to go through our presentation or if you want to ask certain questions about some of the slides or some of the issues, however you would like us to do it. I think the presentation, sort of the mini-presentation would take at least 15 minutes, and it's probably optimistic. I mean that's 15 minutes without any questions.

(Laughter.)

DR. ALEXEEFF: So, you can see how long it could take, probably an hour or two.

DR. SEIBER: Let me just say it's 15 minutes well spent. Your alternative is to read this big document. And this is basically a pathway through the document. I've heard it. I think I heard something like this in one of the workshops. So, I thought it was quite valuable. That's my own opinion.

DR. ALEXEEFF: Okay. Then we'll proceed.

DR. GLANTZ: I think, given the fact that our esteemed Chair didn't know what stochastic really meant underlines the need for the presentation. But he's not here. He still won't know.

Just for the record I don't think it would be fair to say that the Panel thinks stochastic means pulled out of the air or whatever definition that Dr. Pitts read.

DR. MARTY: Conjecture.

DR. GLANTZ: Yes. Conjecture, yes.

DR. MARTY: The first slide is essentially a schematic of what we do when we do a health risk assessment document, not the typical documents that you folks review on a chemical, but rather a health risk assessment for a facility in the air toxics hot spots program.

And currently there's a PC model available. The inputs consist of the air dispersion modeling results, which

gives you concentrations in air of chemicals that are emitted by these facilities, the exposure parameter values; for example, the breathing rates, body weight, and so forth.

Reference exposure levels for acute and chronic toxicity, and unit risk factor, and you end up running all this information through the model, and you get out what we call a point estimate output of risk, which is the risk from this facility is 5 x 10 to the -6, or whatever the number is.

In terms of the stochastic process, what we needed to do is to develop a model whose output is actually a range of risks rather than a single number. So, the part that's shaded in gray is the stuff we've been working on in the last year or so. That is the other types of input that need to go into the model to give you a range.

Next slide.

The document is entitled the Technical Support Document for Exposure Assessment and Stochastic Analysis. We just call it Part IV. And it consists -- the type of information in there is the algorithms or exposure formulas, the point estimates of the algorithm variates -- that's, for example, breathing rate or body weight -- the descriptions for the key exposure variates that we treated stochastically, including the mean of the distribution, standard deviation, percentiles, and shape of the

distribution, and also discussion on the data that were used to characterize the distribution for those variates that we actually chose to do so.

Next slide, please.

This is a listing essentially of the exposure variates that we identified as key, and for which we attempted to develop distributions from data that were available in the open literature.

Next slide, please.

We ended up using the statistical software package, SAS, to characterize the distributions, and they're all presented in the technical support document for use in stochastic models. And they're all in that document that Dr. Seiber was waving around just a moment ago.

Next slide, please.

I just wanted to go through with you a characterization of a distribution, just so that you kind of get an idea of the type of stuff that we were looking at and the type of data, and sort of the -- all the different issues that come up when you try to characterize a distribution variant in an exposure model.

So, we're going to look through daily breathing rates, which is important if you're looking at chronic, for example, cancer risk estimates, you need an estimate of the daily breathing rate in order to get a risk number.

So, we took the CARB sponsored study of breathing rates that was done at U.C. Davis by Adams in kids and adults. They looked at breathing rates. They actually measured them and heart rates using various lab and field protocols. Minute ventilation was measured, heart rate, and breathing frequency.

Next slide.

The laboratory protocols included lying down, sitting, standing, walking, running. And the field protocols varied for adults and adolescents actually, including car driving or riding in a car, maintenance on a car which was done with the men, housework in the women, yardwork, and mowing.

(Laughter and cat calls.)

DR. MARTY: I didn't design the study protocol.

DR. GLANTZ: Will the court reporter please get the tone of voice.

(Laughter.)

DR. MARTY: And then the children participated in spontaneous play protocols. They just let the kids run around and be kids.

And the sample sizes in the different protocols by age and gender and protocol ranged from about 12 to 40. And there were actually a total of 200 subjects in the Adams study.

Next slide, please.

We took the minute ventilation rates measured in the Adams study and normalized them to body weight. So, we had the data from the Adams study on each individual's body weight. We took their measurements of ventilation rate in liters per minute and divided by the body weight to get liters per minute kilogram body weight.

Then using the SAS program and the unit variate load, we developed distributions of liters per minute kilogram by activity, age, and gender.

We were able to combine some of the distributions when analysis of variates indicated that there really were no statistically significant difference. And actually, it's pretty interesting, when you do normalize the minute ventilation rates per unit of body weight, you get rid of a lot of the variates in the data.

So, we were able to increase our sample sizes for specific protocols by combining, for example, men and women or adolescents and adults.

Then we ended up choosing activities from the CARB breathing rate study to represent breathing rates at resting, light activity, moderate activity, moderately heavy and heavy activity.

Next slide, please.

We also had from ARB some CARB-sponsored activity

pattern studies in both adults and children. These were done at U.C. Berkeley using a retrospective time diary survey. They had over 1700 Californians age 12 and older, and 1200 kids under age 12. And the time diary, essentially in chronological fashion, recorded what these individuals had done in the previous 24 hours. It was taken in a telephone interview. For the kids, the parents or the adult in charge answered the questions.

So, we ended up with a total of almost 2,000 subjects.

Next slide, please.

The activities from the activity pattern study was then grouped -- and this is, of course, a little bit subjective -- into resting activities, light activities, moderate and so forth. And from the activity patterns, it's pretty clear that a lot of us are sedentary. So, the large majority of activities ended up in the light category.

We then for each individual summed the product of the liters per minute kilogram body weight times minutes per day at that given activity for a 24-hour period. And then a distribution was developed for each one of those almost 2,000 humans for each individual in the activity pattern study. We then turned all that data into a distribution of daily breathing rates. And we did it separately for adults, and actually we threw in adolescents into there, because

there was not a statistically significant difference in their breathing rates. And we did it separately for kids under 12.

Next slide.

This is just an example of what the distribution looks like -- it's not really what it looks like, but we've selected specific percentiles. You can see the mean for children's breathing rates is about 540 liters per kilogram day, which translates for a 15 kilogram into about 7 cubic meters per day, just under 7.

And the distributions are lab normal, according to the procedure for normality. The 50th percentile then you see is a little bit different than the mean.

Next slide.

This is just the adults' breathing rate. The mean is the first line, which is equivalent for a 70 kilogram person to 16 cubic meters per day. You have the 5th, 50th, and 90th, and 95th percentiles for that distribution.

Next slide.

The question arises, well, that's fine. Now you have this distribution. What does that have to do with calculating risk for a specific facility?

So, what we did was just -- to give an example of how you might use this, this is an example of calculating risk from a facility that emits dioxin using the inhalation

pathway, 70-year exposures, and then we're going to compare the point estimate for the stochastic estimate.

Next slide.

What we need really is the dose. So, we're concentrating on calculating a range of doses for a single dose for the concentration in air, which was in this case was about 10 to the minus 7 micrograms per cubic meter dioxin. So, the key parameter that we ended up treating as a random variable is described as BR/BW in this equation, which is the breathing rate in liters per kilogram day. And we either entered a point estimate and then derived a risk based on a point estimate, or we actually used the entire distribution in a Monte Carlo type simulation.

And then there are other considerations in that equation, absorption fraction, if that's ever applicable -- I've never used it. But if you're going to use an exposure frequency less than 365 days per year, you can do that with that information. You can change your exposure durations around, too, but not inhalation.

Okay. Next slide.

This is the range of risks or what we call the stochastic estimate for a concentration of 10-7 micrograms dioxin in the air. The mean is the top line. That would be a risk of 3.4 times 10 to the minus 7. Standard deviation, 5th, 50th, 90th, and 95th percentile.

Next slide.

This is kind of what it looks lie visually. It is truncated on the right. That's just the way it printed out. The calculations were not truncated. It just gives you an idea of the spread using -- this is the information you get out when you use a range instead a single point somewhere in that curve.

Next slide, please.

And this is a slide to compare the point estimate with the stochastic results. On the left, we used a mean of 16 cubic meters per day and a high end of 20 cubic meters per day. And 20 cubic meters is what's typically been done, and that would be the result of a risk assessment if it were done the usual way today. And that is the risk would be 3.7 times 10 to the minus 6, and in the right column you can see the mean and the various percentiles from the distribution.

Next slide.

DR. ALEXEEFF: Okay. We've now finished the example for breathing. We have another example for produce.

DR. GLANTZ: Is it going to tell us -- when we talked about this on the phone, the idea was to let people see sort of how you do it. Is doing produce going to show you anything different than breathing did in terms of --

DR. ALEXEEFF: It shows, you know, like with the breathing rate, there were various factors that we had to

use in order to come up with the distribution.

In this situation, the information is totally different. But so, on the specific, yes; on the general, no. It's very data intensive to derive these things. And it's pretty much what it shows.

DR. GLANTZ: I don't think we need to go through that, unless you think. If we want to go into details, we have your phone number.

DR. FROINES: Can we go back to the last overhead? Now what?

DR. MARTY: Now what do we do with this information?

DR. ALEXEEFF: Well, I think that the key is that the -- the stochastic information is supplemental. I mean the whole purpose of this is to provide a supplement to the additional information.

And in the document we actually provide what's called a tiered risk assessment approach. We haven't discussed it here because it's not really a technical -- it's more of how one could do it, where you would start with the simple point estimate approach and then, if you get more and more complicated -- because if you're bringing in more information, it's more expensive and you may not have it.

So, in terms of -- if your question has to do with, you know, how does one make decisions based upon a

whole bunch of numbers instead of one number, I think the idea is that one can still come up with point estimates. And a stochastic estimate can be used to provide a sense as to how does it compare with the point estimates.

So, there's been concern that a number of the point estimates might be ultraconservative. In this case, it doesn't look that way. But when we have multiple pathways of a chemical and we're combining all these different pathways, it could end up being that the point estimate is different from the stochastic estimate. We don't know. We haven't done a lot of examples.

So one thing would be to provide guidance to the point estimate in the stochastic mode. The other thing is just, as with the lead document that we did, where we have a distribution information of blood lead, it can also give you a sense as to who's in the different percentiles.

I think like on this example, you an see that the 5th to the 95th is pretty tight, in my opinion. And it's twofold. But if you had another example where the distribution was very broad, it might -- it would help the decision-makers in terms of making decisions.

For this slide, there's not -- it's not as big of a breaking point. But it could be used also for communication of the risk. This is actually one of the things that I know the air districts have asked us to

provide guidance on how we will implement this. And that's one of our future tasks to explain how this can actually be used to the Air Resources Board and the air districts, because it's no longer a simple cut off.

DR. SEIBER: Well, in a way, doesn't it complicate life for the risk managers, because now instead of -- well, they have several numbers to choose from it seems like. And, in effect, they have a whole range of numbers to choose from.

DR. ALEXEEFF: Well, it either complicates or simplifies. In one sense, it gives them more choice. So, it all depends on the individual. If a person feels that they only want one number to deal with, and that's how they want to run their analysis, then, yeah, this is much more complicated.

But if a risk manager -- and most of the ones I know are trying to weigh lots of things, of which this is one. And this gives them a sense as to how much movement is in the health data, for example. So, if you had an assessment that came out like this, you would see that from the 50th to the 95th, it's not, you know, orders of magnitude movement. Other risk assessments, there's likely to be orders of magnitude.

But in this example, there isn't. I think that would give them a sense of how confident they feel about,

you know, the number that they're using and how much play there might be.

DR. FROINES: I don't want to sound like a Neanderthal that says we were fine with point estimates, because I think this -- about a month ago, Duncan Thomas and I had a discussion about some work that he had done, epidemiologic work that he had done three years ago. And we went through a series of looking at uncertainty in exposure assessments. And one of the things that was clear when you're all finished is it looked like where you have a lot of uncertainty within a number of parameters.

And the area where you have the largest uncertainty ultimately drives the whole process. And where you have a little bit of uncertainty and a lot of parameters, you know, it's kind of equal. And then, on an intermediate situation where you have varying uncertainty, it gets more complicated.

So, once you start to have a number of parameters and a lot of spread in uncertainty, it's going to be very difficult for AQMDs, for example, to sort of make use of that in terms of any decision matrix.

I think it's extremely useful to see where the uncertainty is in the various estimates as you go through them. How you then go to the level of policy and decision-making I think then becomes extremely difficult,

because it's no panacea in the long run. I think it's very useful. I think it's particularly useful in epidemiology, especially where you're linking health and exposure.

When you're in risk assessment, it has the potential of being to some extent a benefit, but to some extent confusing.

So, I think it's kind of a mixed bag.

DR. GLANTZ: Well, I've read about half of it. And I think that the general approach you're taking in here is quite good. And I think that elucidating these distributions is informative and helpful.

But I had a similar reaction to parts of this document that I did to the lead document. And there are a few numbers that sort of stood out to me like sore thumbs. And I'd like to discuss those briefly. And I realize this will come back to us more formally later. But just as we spent a long time with the pesticide people this morning, kind of telling them what we didn't want to see, and I think this slide with the breathing rates is a good place to start.

I read through the report, and you went through a great deal of effort to describe these distributions of breathing rates. And then historically what I've been used to you guys coming in and talking about is sort of the high end or the health protective numbers within the 95th

percentile.

And there's nothing magical about that. But that's what I've been used to seeing all these years in these reports. And, you know, when I look -- well, these are the breathing rates as a result of the calculations. But after going through this whole big drill of the breathing rates, you picked the 87th percentile. Now, the reason you did it was this harmonization because that's what the EPA used. Except you got better data here than the EPA has.

And, you know, I think that, to me -- and you've done that throughout as much of this document as I've read. And there's tremendous inconsistencies. For adults, you pick 87 percentile. And where the EPA didn't have a number, you picked the 95th percentile. For water intake or something -- I was reading the part -- it was a 75th percentile. I mean this makes no sense to me.

And I'd like you to justify for me why you go to all this trouble to get these distributions, making good case for them, and then are so inconsistent in your treatment of the results in terms of what you're taking as your high end numbers. The mean numbers don't seem to be all that much affected.

But can you justify using all these different cutoff points for the different outcomes that you're using

it. Or would you rather I just simply say, "Don't do it"?

DR. ALEXEEFF: Yeah. Well, I think the stochastic information represents all the data processing that we've been doing, all the data accumulation, what we found, and how we put it together.

The point estimates basically reflect, like in this case, past practice or existing practice.

DR. GLANTZ: Right. And what I'm saying to you, George, is that you just did all this work and, having done all of this work, you shouldn't say, well, we used to do it this way based on less information and weaker science. And I don't know how long you spent doing this. And after going through this whole effort, we're going to keep doing what we used to do.

It's crazy. You know, for kids you use a 95th percentile, which I think is a completely defensible thing to do. You should be using it for the adults, and you should be doing that consistently throughout the report for your high-end estimate.

Now, if you don't like the 95th percentile, if you want to use the 75th percentile like you did for drinking water, which I think you'd have a very hard time selling, but if you want to go through and say, "We're going to consider the high end number the 75th percentile," then you need to say that upfront and be consistent throughout the

document. You know, you can't just say -- I mean, I read this. It was like why did you bother doing all of this if you're going to ignore your own results?

I'm sorry.

DR. ALEXEEFF: Well, all I can say is that it has been a topic of great discussion among our EAG group, among our staff, and it's something that -- it's a weighing from moving from an existing practice to a new practice. And it's easy when you have a stochastic situation where we don't have to worry about other people. We're going to a new area showing something that is new compared to what we have done in the past.

So, there's things to weigh, for example, all the risk assessments that we've done in the TAC program, which is using the 20 cubic meters. There's a lot of things I think that has to weigh as opposed to simply, you know, the science. The point estimates are sort of reflecting kind of a historical or, you know, past practice approach. And we haven't -- that is to say, not just we, but I would say U.S. EPA is also aware of this type of information coming out of stochastic analysis.

I think they are also trying to figure out how to move from past practice to new practice.

So, one could say, oh, be consistent, just pick one. But then there's all the other things that you have to

think about. Like, for example, U.S. EPA is changing the way the extrapolate among species from two-thirds to three-quarters, this is not a big number difference. But now there's a question, okay, everytime they go to a meeting, the question comes up, when are you going to make all the adjustments.

So, part of it has to do is how to figure ut what the hole picture -- how to balance to all. I think that from a scientific view point, staff would probably have felt more -- much happier just choosing the 95th percentile off the board and just say forget the past, we're going to go on with the new. But you have to kind of weigh everything else that's been done and how we're going to handle all those things.

DR. GLANTZ: Well, I think I understand that, George. But I think the purpose of this report is to move things forward. The fact that in the past we used the 20 cubic meters per day -- I mean that was the best number that was available at the time, and I think that people felt that was giving you a, quote, "high end" estimate. So, I'm not saying you should go back and redo every document that we've seen in the last however many years it's been.

But what you've put together in this document iis a very compelling case that the high end estimate, using the common definition of the 95th percentile, which is what most

people would call the high end, is 26. Okay. And to me, to come in, having gone through this whole drill, and then to say, well, we're going to use -- having showed and made a very compelling case that 26 is the number you ought to be using without coming out and saying it, and then to have a table there that says we're going to use 20, because that's what we used to use, I think -- I can tell you, when this comes back to the committee, I will have a cow if it is still done that way.

You still have a public comment period, and I'm offering you this as friendly advice.

(Laughter.)

DR. GLANTZ: And the point is this -- I mean, if you want to say in this document that we used to use 20, because that's what the EPA used, because that's what God said, or something, I mean I don't mind if you say that's what you used to use. But, you know, you can't put a document in front of at least me that I actually understand without all the chemistry stuff, and build a good case of what the distribution is, and then essentially ignore it -- I mean you've just done it over and over and over again.

My suggestion to you would be to take the 95th percentile, the mean of the distribution or the median, whatever you view as more appropriate as your mean estimate, and then the upper 95th percentile as your high-end estimate

and apply that and say that -- that's what you're doing right up front, and then apply that consistently throughout the document when you come up with these recommended numbers.

And then, if you guys decide that you'd rather use the 75th percentile, which is what you used for water, I think, then fine. Say we're going to use the 75th percentile throughout, then I will have a good time at the meeting. But at least you're being explicit about it. Because right now it frankly looks silly.

DR. ALEXEEFF: Anyway, I really appreciate your comments, an I think that, you know, please submit them, and I think we're going to get other comments.

DR. GLANTZ: I just did.

DR. ALEXEEFF: I don't know how they're going to, you know --

DR. GLANTZ: Consider them submitted.

DR. SEIBER: The way I heard your question is, did you choose a number strictly to harmonize with the EPA number, or did you have a better reason?

DR. ALEXEEFF: I think what we tried to do was to choose on the point estimates numbers that similar programs were using. So, it is a harmonization. The point estimate sort of reflects -- it's a harmonization kind of decision-making process. It reflects either past practice by 20

cubic meters Almost everyone uses 20 cubic meters.

So, and we looked across similar types of programs to try to figure out what people are using so that we know that the process will move. I think the question is how to move this process. And it's a question of -- there's been a couple of documents that we took before the TAC committee -- I mean before your committee on TAC, and I don't recall if I was -- if we had any of those documents where we had 18 cubic meters. And we used 60 kilogram body weight. And that was because we were trying -- the female would have ended up being a little bit higher dose than the male.

And although may be technically correct, it ends up getting very complicated when you start doing further analysis. So, with the comments that were made about making small changes based upon new information, there are some other factors you have to weigh.

Now, in this case, for breathing rate, the change, it depends on what we're comparing in terms of small changes. Are we comparing the 20 cubic meters to 21. which is the 90th percentile? Or are we comparing it with 95th.

It almost goes back a little bit to John's question, which I tried to avoid a little bit, on how are we going to use these analyses, in the sense that I didn't say, well, everything's going to be regulated on a 95th percentile or something like that.

It's no clear exactly which percentile is going to end up being the definitive percentile.

U.S. EPA divides it into median and high end, and high end is 90 and above. So, U.S. EPA is inconsistent in choosing a percentile.

DR. GLANTZ: But you see, the point is, George -- and this has been the way this has been the whole time I've been on this committee, we've always done better work than the U.S. EPA.

DR. ALEXEEFF: I agree.

DR. GLANTZ: And this is, to me, kind of an abuse of the harmonization concept, where you're taking a very nicely done job in terms of the science, and then -- it's a little bit like what I was complaining about in the lead document, where you're basically laying out a good case and then ignoring it.

And I think if you want to point out that the 95th percentile on breathing rates is 26 and then put a comment in there saying the number that the EPA uses, which is based on older, less up to date, less wonderful scientific data, was 20, I mean I think that's fine. But I think that we're being asked to or will be asked when this comes before us is to say that this represents the best possible science.

And I think it looks silly to not be consistent in what you're recommending as your so-called high-end numbers,

and also your central tendency numbers need to be consistently, too.

Now, I think if you go back and look at the way things have been done, we've traditionally used an upper 95 percent confidence interval when we have been doing upper bound risk estimates. And my advice to you, based on past practices and conventional wisdom among statisticians, is to use the 95th percentile with upper end estimates consistently.

Now, if you think there's a good scientific reason to use a different percentile, then, you know, bring it forward and make your case. But then apply that consistently throughout.

To me, the way to harmonize this with the EPA and those other people is to simply know what they said and make the point that this is based on a more complete and a more up-to-date analysis.

(Thereupon, there was a sidebar conversation not heard by the reporter.)

DR. GLANTZ: I know. I didn't say enough this morning, so I have to make up for lost time.

DR. FROINES: I'll make one comment and then I'll stop.

DR. GLANTZ: No you won't. You're worse than I am.

DR. FROINES: On water intake, one of the issues that I in a research context is having to deal with is in arsenic risk assessment in drinking water. And one of the questions is, what do we use doing the risk assessment for the daily intake of water?

And you go through that in some detail. I haven't had a chance to read it in detail, but I skimmed it. And what EPA is doing now, they are arguing that the Taiwanese data, they are assuming a daily intake somewhere around three to four liters a day, because they say that people in Taiwan live in very hot climate, often a hundred degrees, and so people drink a lot more.

Well, if you drink a lot more water, you know what that does to the risk estimates. It drives the risk estimates down.

So, people are now arguing that one should assume three to four liters of water a day in a hot climate.

Okay. So, that's a Taiwanese issue. But now the California issue, when we're looking at assessment, and we start to say, well, what do people in California drink, and what do people do out there in the desert as opposed to San Francisco? Are there significant differences in the amount of water intake?

And you don't have temperature as a variable in the way you look at this. And so, the part of the problem

is that one can do lots of modeling to look at uncertainty, but in fact it may be that here are real parameters that actually do vary and that aren't addressed by the stochastic process or at least should be incorporated into the stochastic process.

So, I think that the use of data that does have some California specificity has relevance. And arsenic in drinking water intake I think is one example of that. So, it's something to be kept in mind.

DR. ALEXEEFF: Let me just make a general comment. I think in the water document, I think we have both national and western data in there. And it doesn't -- unfortunately, it's like one of those things where we don't have -- the best studies aren't just California based studies. I think, though, in the western study, that water consumption rate is at least visibly higher than the national rates on that.

DR. ALEXEEFF: You had some comments about the temperature or --

DR. MARTY: The only comment I had was essentially that the population of California sort of dominates the western region. So, in a sense, California is overrepresented. And that might help to take that into account. But there are problems trying to figure out how much people actually intake in a given day.

DR. FROINES: But then it seems to me the number

you come up with is consistent with that kind of knowledge where your actual, quote, local situation may dominate over the national situation.

And I think that's -- what I mean is that where you have information on uncertainty, that that should help guide your decision-making.

DR. ALEXEEFF: I think you have a good point. Let me see if I understand it. Let's say, in addition to this information there, one could come up with a way of doing local adjustments based upon temperature. And I don't know if the information is there. But I think it's something that I can take back to the staff that worked on this to see what information's there.

DR. FROINES: The question also becomes, is that somebody who wants to show arsenic at a lower risk, arguing for a four liter a day argument. And so, I'm just saying that there's a lot of uncertainty based on different circumstances. We've got so much uncertainty that we have to be careful to not let things like this necessarily drive the way you view a decision.

DR. GLANTZ: Well, but having just given them a very hard time, you know, I think what they're getting at here, though, it's better than what we had before.

DR. FROINES: It's not necessarily better. If you miss the fact that people in California with high arsenic

exposure are drinking four liters of water a day, and you've messed around with small differences like this, you haven't improved things. You have added a mathematical tool, but your evaluation is still flawed by the nature of the analysis.

DR. ALEXEEFF: We've tried to cover those things. And Melanie was just talking about the fact that there might be some data for us to look at as a temperature adjustment, some Army data. But again, it may not have the full picture of, you know, children as well as adults. It's going to be kind of limited in its population.

So, I think we can go back and look and see if there is some other information that could be added if one wanted to sort of bring it to bear.

But I think another example, one that we haven't discussed, is on our fish consumption chapter. It's based upon results from a study in Santa Monica Bay. And in that case, we looked not only at the general consumption, but also people who fish for a livelihood or fish for subsistence, and included that in -- included a separate distribution on that to try to pick up exactly the kind of thing you're talking about.

So, it is our desire in this report to try to find those subpopulations that either are being exposed greatly either through, like you say, drinking a lot of water, or

eating a lot of fish, or eating a lot of some particular type of fruit or vegetable, and have that in there.

So, when the situation comes up, we can do it. So, I think that's something -- that's one of the intents of this report.

DR. GLANTZ: Again, I haven't finished going through the document. But I think they were trying to take into account those kind of variations. And we can always make it better, but I think that the effort here tried to account for those variations.

And again, my concern is having done this, you're not really going to where the data's taking you in a consistent and logical manner.

But if there are other variables, like temperature and drinking water, then I think to the extent that data is available to consider that, I mean that's a good idea.

DR. ALEXEEFF: And we don't actually consider this uncertainty in that sense. We tried our best to characterize the variability in the population.

DR. SEIBER: I like the document. I think it's a very useful piece of information, in that it tells people like me and Jim Pitts what stochastic modeling is. Because it really has a lot of concrete examples.

Earlier, I had made a comment that I hoped there'd be more examples. I think examples really will illustrate

what you're doing. And I think food consumption is going to show you a lot bigger range than maybe airborne, because breathing rates are pretty much the same for everybody. So, I would think you'll see some differences in some cases.

I think the real value of this document -- and I want to make sure I've got this right -- is that it gives a way for people, kind of a pathway for default values. It gives them guidelines on how to deviate and to build their argument.

And before we had this document, I don't think -- you know, people would try and they'd gather some data, but we didn't have much to go on.

DR. FROINES: Yeah, what it does is to give you a basis to establish some ways of addressing default values. But I don't think the reason George and Melanie have been hesitant is that the step that you're looking for is the hard step that people haven't really developed yet.

I still think it's the question of what do you do once you've done this.

DR. ALEXEEFF: Yeah, I think in the fish example, if my recollection's correct, I think the distribution is almost 50-fold different in comparison to breathing rate, which is 8 or something. It's much smaller.

People have to breathe a certain amount and they can only breathe so much, and the same thing with water

consumption. But certain things like food and things like that, or even, you know --

DR. SEIBER: Although water's a little tricky. Because you talk about drinking water, but also the water that's used to make up Kool-Aid and all that, that's water, too. And we want to make sure that we don't neglect that water.

DR. MARTY: In this document, water is actually tap water. So, it does include food preparation.

DR. SEIBER: It wouldn't include things you bought, like soda pop.

DR. MARTY: No, it wouldn't. No.

CHAIRMAN PITTS: Bill wanted to say something, too.

DR. VANCE: I'm just sitting to the right of Melanie.

Good afternoon, I am Dr. Bill Vance. I'm the Acting Deputy Director for the Office of Environmental Health Hazard Assessment. And I'm very pleased by the presentation that was made this morning by Dr. Alexeeff and Dr. Melanie Marty.

It is a good start for what stochastic risk assessment is all about. I'm also very pleased and want to thank Dr. John Froines for two ideas. And he mentioned three names. It's incumbent on me to make sure that maybe I

get this document to Dr. Duncan Thomas and to Dr. Dale Haddis. And I'm not sure I've done that yet.

But I do have until April 9th to do it. So, I'll Fed Ex it off. But I think Dr. McKone may have a copy of this document and maybe providing us comments.

So, I thought those names, while they didn't participate in on our external advisory group, I will make every effort to get the document into their hands to see if they will furnish us with some comments.

Just a reminder that we did extend the public comment period so that we could get more comments. We had one group in particular, the Sierra Club, had not had an opportunity to look at it. They could not download it from our web page. And then I also had the South Coast AQMD ask for a short extension, because they, too, have a large bureaucracy, and it was going to take time to get their comments mailed to us.

I especially look forward to your comments, and you know that, Dr. Glantz, because you give us lots of good comments. They've always been very, very helpful and getting us a very good document out.

If you will provide them, I will make it a point to look at this transcript and look at those, and we'll try to do what we can.

DR. GLANTZ: Well, I think I've given you the

substance of them. I think -- I mean I'll look through the thing a bit more, but the -- I think you've heard my primary comments so far. I think that the general presentation -- I mean I'm not an expert on every detail in here, but I think that the general presentation and development of the distributions look reasonable.

The question to me is applying it to the system standard of which you're calling this so-called high-end value, and to a lesser extent what you're calling the mean. I don't know whether you would do better with the mean or the median, for example. I don't know if it makes much difference. But that's just something that stood out. And I think you absolutely have to fix that. And it applies throughout the document.

If I have any other specifics -- there was one other thing, and that was you were counting anybody over six as an adult, I think.

DR. MARTY: That comes again from the U.S. EPA methodology, where six and under is a kid and seven and up is an adult.

DR. GLANTZ: Well, I think that's stupid. I think you ought to harmonize with what the Department of Pesticide Regulation. They call 12 and up an adult. And I think that's more defensible than six.

DR. MARTY: That's what we've got under the

stochastic --

DR. GLANTZ: Yeah. But again, I think you need to make your point estimates and your high-end estimates consistent with that.

And then just say this is different from what EPA had done, and here's why. Anybody with kids knows that a six year old isn't an adult. You don't even have to have kids to know that.

CHAIRMAN PITTS: Are you about finished?

DR. GLANTZ: This is so I won't have to write anything. One other thing that struck me as a bit strange was the breast feeding analysis. I think you took the denominator as the whole population rather than the people who are breast feeding. And I would suggest you limit those numbers to people who are actually breast feeding. You know, what fraction of the population is breast feeding. That's it.

CHAIRMAN PITTS: Fine. Is that basically the presentation?

DR. ALEXEEFF: Yes.

DR. MARTY: That's it.

CHAIRMAN PITTS: Fine. Are there any other comments? I'm not trying to hurry them, but I definitely want to get through 4 and 5, and it's a quarter of four.

DR. SEIBER: I do, too, but I want to know what's

going to happen from this point on with this particular document.

DR. ALEXEEFF: Okay. As I mentioned, when we came before the committee in '93, we divided our guideline project into five parts. And the one that we've just been talking about was the exposure assessment stochastic analysis. And this is an update of the slide that I gave in December, where we had planned on releasing the document in December, and we actually did.

And the next document is the determination of acute toxicity levels, and that one is still -- we're still revising that. We're scheduled at this point I believe for releasing it in June. And Dr. Glantz and Seiber are the liaisons for that. And they've given us comments on that.

I'll elaborate a little more on that one, the acute toxicity levels. At the last SRP meeting, there was a discussion on how are we going to bring a document to the committee which talks about 20, 30, 50, 60 chemicals? How are we going to do that as a process?

So, we had a couple of conference calls with Drs. Glantz and Seiber to try to brainstorm that, because we thought the first one might be this acute document. So, we thought we would try to see what would be the logic in bringing that document forward. It has around 50 chemicals in it.

So, the plan that we have come up with -- and I think we're still working on the plan -- we were given some homework that we haven't completed yet from Drs. Seiber and Glantz. But the plan is basically -- it will probably take at least two meetings to go through the document. And the first meeting would be to discuss the methodology with lots of examples. And then the second meeting would be to kind of go through the compounds in groups. And we've come up with some information on how to group them. And we'll be grouping them more along toxicity lines as opposed to chemical lines.

The third document, the chronic document, is still being prepared for final review. And at this point, internally, we're scheduled on releasing it in May.

The next one, the cancer potency -- and, oh, for the chronic reference document, Dr. Friedman is the lead on that.

For the cancer potency factor document, that one is scheduled to be released in April, and Dr. Byus is the lead on that.

And then this last one, the last document is kind of -- how will people use this stochastic modeling document? So, it's sort of what we call either the cook book or the step-by-step document. How will all this information be incorporated? And that one is scheduled for July to come

out.

So, you see, pretty much every month we have kind of another different document coming out along these lines. And then, that's just for the public release part.

And then there will be the comments, workshops. So, each one, we have to do two workshops and comments, and then depending upon the extensiveness of those comments, we're hoping to start bringing these documents to the Panel in about July, to start feeding them to the Panel July and August, whenever the Panel meetings are.

DR. GLANTZ: So, the stochastic document that we've just been talking about, if things go well, will come to us in July?

DR. ALEXEEFF: Right. July or August. Originally we planned July, but since we extended the comment period 30 days, I would say we plan to shoot for August. But whenever the meeting might be, around that. That's our hope at this point. But we also have the more likely one, which is this acute document. So, it depends on when we're planning that acute document.

The summer meeting, you'll be getting one of these documents.

DR. SEIBER: And then one a couple months later?

DR. ALEXEEFF: Yeah. Based upon this, you'll be probably getting one almost every Panel meeting for the next

five meetings.

CHAIRMAN PITTS: How often are we going to be meeting relative to the frequency of them coming in?

DR. ALEXEEFF: It depends upon the open comments. So, it's a little bit hard for us to know. I would say between two to four months.

CHAIRMAN PITTS: Two to four, somewhere in that range. Okay. We don't want to schedule just to schedule. But we don't want to go for four or five months without a meeting. That's fine. That's good.

Okay. Well, thank you very much on that score.

DR. GLANTZ: The acute toxicity one, there are some things we had talked about, depending on when the next meeting is, I think it might be useful for you to come in with a briefing for the Panel sort of like the one you did on the stochastic document, just to get --

CHAIRMAN PITTS: That's helpful. Good idea.

DR. GLANTZ: To get some input even as you're drafting the document. This was discussed on the conference call. There's a lot of issues here. And I think it would benefit -- the Panel would benefit and I think you would benefit from a little bit of a presentation to just generate some informal feedback before you actually finish writing the document.

DR. ALEXEEFF: It would be helpful for us, because

all these documents are structured differently from the previous type of document.

CHAIRMAN PITTS: We'll have to work this out, but probably within two months, we're going to have an excellent meeting probably in mid-June.

DR. ALEXEEFF: The acute document we sent to Drs. Glantz and Seiber I think a year or two ago. And every once in a while, we've asked them for some comment.

CHAIRMAN PITTS: What will we be looking at specifically in the next two months from now, say?

DR. ALEXEEFF: Well, okay. The documents we're providing to the Liaisons; that's what I was thinking of. So, we've provided copies of various documents to the liaisons and we're providing them --

CHAIRMAN PITTS: Over the next --

DR. ALEXEEFF: Well, the acute one went out early, and the other ones are going out as they're getting close to being prepared.

DR. GLANTZ: When I suggested you come back for a briefing, I wasn't thinking so much -- maybe I was referring to the wrong document. I wasn't so much thinking about the document as the procedures that you're going to use for handling all these compounds.

DR. ALEXEEFF: That's right. You meant the methodology of bringing that document to the Panel.

DR. GLANTZ: Yeah, with some examples maybe. We talked about this a month or two ago, so you will have had three or four months to further refine it, and to come and present how you're approaching the methodology, just as you did here, with some examples, to get input from the Panel about, you know, is this a good idea? What do you need to change? Because I think there's a lot of complicated issues there, and I felt like there's a lot they need to know that I didn't know.

Is it clear about what I'm looking for here?

DR. ALEXEEFF: I think so.

CHAIRMAN PITTS: Okay. Fine. Let's move ahead now.

We'll take a break right now.

(Thereupon, there was a recess taken.)

CHAIRMAN PITTS: We'll reconvene. Genevieve, talk to me.

MS. SHIROMA: All right. Well, nice to see you folks. Good afternoon. I'm going to give yo a short presentation on the prioritization of the 189 hazardous air pollutants, how they fit into the 1807 program, and how we envision working with you on moving forward with those substances.

So, I'll begin by saying, "In the beginning," we had 1807 in 1983, and we started the process of looking at

comprehensive risk assessments. And through that, we processed 21 substances. And we also developed prioritization criteria that we presented to the Panel in 1990, and the Panel approved. And it was a 28 point scoring system.

Then in 1992, Tanner introduced 2728, which passed into law and became effective 1/1/93. And it was geared for streamlining the 1807 process by, in one fell swoop, identifying all 189 HAPs as toxic air contaminants.

Now, what we did in early 1993, was to discuss with the Panel how we would handle those substances and we also formed a subcommittee of Drs. Seiber and Glantz to work with us on how we would handle those substances. We updated the prioritization criteria to account for, in more specific terms, cancer and lung cancer data and the available exposure information, including the AB 2588 hot spots emissions data and risk data.

Then we proceeded to take a look at the 189. What we envisioned was, on the one hand, a process whereby we'd incorporate the OEHHA guidelines, the acute chronic and cancer numbers out of the 1731 program, and then we, ARB, would compile the available emissions information, persistence, ambient concentrations, monitoring data, and so forth.

And then the idea was that we would take that

information --

DR. FROINES: What is that thing you're holding up?

MS. SHIROMA: This is the toxic air contaminant identification list of compound summaries. What we put together in 1993, albeit a number of years ago, working with you, Dr. Glantz, and also with Dr. Seiber, we put together the criteria, essentially looking at the physical properties, sources of emissions, ambient concentrations, indoor sources and concentrations, atmospheric persistence, risk assessment, and health effects, all towards being able to prioritize those identified hazard air pollutants as toxic air contaminants towards the idea of looking at which one of those could be handled through the 1731 process with available data and which ones needed to go through the more comprehensive AB 1807 type of process.

And these are substances that have already been identified as toxic air contaminants. But we realize that to provide the information needed to do risk management, either for statewide control measures or for the 2588 hot spots program, that the health data was needed and the exposure data.

And so, between '93 and today, OEHHA has been working on these guidelines which George just discussed with you. And then we have been working on this report, which

was issued for comment. And we're in the process of revising the report and finalizing it.

Once it's finalized, we'll also make it available on the Internet.

So, the next step is to do the prioritization. Now, what we do know is that 79 of the hazardous air pollutants are not emitted in California, not emitted. 21 have already gone through the 1807 risk assessment process.

One substance was removed by U.S. EPA, and that's caprolactam, a pesticide. Another pesticide, methyl bromide, which you heard about earlier today, is being handled by DPR. So, that leaves us with 87 hazardous air pollutants to prioritize.

Now, on our list we also have nonhazardous air pollutants. We have about 40 additional substances that re not on the Federal list, but are on our list. Those also will be prioritized and are also in this document.

So, what we intend to do is to proceed with the criteria that we devised with Drs. Glantz and Seiber, go through the calculation/prioritization of the substances.

Also, when OEHHA has issued the next two for the acute and chronic -- chronic and cancer, we're going to fold in those new draft values to see what happens to the prioritization score as well.

Then we will consult with the air districts and

with OEHHA on looking at the substances as far as which ones are in the top 30 or so, which ones for other types of reasons need to be moved forward, whether it's because of a U.S. EPA program, or whether there is a special circumstance surrounding a particular pollutant, towards the goal of determining which substances we would come back and recommend to you that we do with a comprehensive 1807 type of risk assessment.

Now, we envision doing this around the June to July time frame.

CHAIRMAN PITTS: Completing it roughly at that time?

MS. SHIROMA: Right. The prioritization will be back to you in the June to July time frame. We need to sit down with the subcommittee, we need to sit down with OEHHA, also consult with the districts. That would provide us sufficient time then to come back and give you a recommendation on the compounds that we feel we ought to go ahead and initiate an 1807 type of process, and the time frames involved.

CHAIRMAN PITTS: If it wouldn't be too much of a burden, July is kind of a tough month for many of us. It's sort of like August in Europe. Would it be possible to tie this into a June meeting then or a late June meeting?

You'd have to ask your consultants here and your

staff. I don't want to overload. If not, I would not worry about July; we would go to August.

DR. FROINES: August might be worse.

CHAIRMAN PITTS: Certainly, if you have the continental approach.

DR. FROINES: Well, Peter Venturini is shaking his head yes.

CHAIRMAN PITTS: What does Peter say? Give us a number.

MR. VENTURINI: Well, we'll do our best, if you're going to have a meeting in June, to get back to you in June with where we are.

CHAIRMAN PITTS: Okay. Put that on the June agenda. We may have a May agenda, also. That would be a good reason for having a May/June, and then skipping July/August, and then coming back in September. That makes some sense.

Does that sound reasonable as sort of a working agenda for all of us?

MS. SHIROMA: Yes.

CHAIRMAN PITTS: Good. You noted it, right? Okay. I didn't mean to interrupt, but that'll be helpful for all of us.

DR. SEIBER: I have just a question for Stan and I. Are you going to wait some input from us before that

June meeting?

MS. SHIROMA: Yes. That's right. We're going to provide you with some materials and whether it's a conference call or a sit-down meeting, we'll go through the results of the prioritization and look through which substances are rising to the top, and also whether it's satisfactory to go with the 1731 process in your view of those documents and health values, or whether there may be a substance that needs further investigation.

DR. SEIBER: I'm asking that because I kind of lose track when things get strung out. I know I did something a year or two ago, but I don't remember what it was.

MS. SHIROMA: Okay. That's it. Then we'll be reporting back to you at your June meeting, and we'll meet with Stan and Jim soon. Okay?

CHAIRMAN PITTS: Fine. Are there any other comments? George?

DR. ALEXEEFF: We're just going to go to the next agenda item when you're ready.

DR. FROINES: I have a question. I've been through that document, and one of the things that hits you square in the face is how limited the monitoring data in the State is for almost all of the chemicals in that document. So, I'd like to get an update at the next meeting

from maybe Peter or whoever as to here is the list of 189 chemicals, and here is the monitoring that we are doing in the State of California for those 189, and here is what we are learning and what we are developing in terms of emission factors for those compounds.

In other words, how are we addressing the exposure side of the 189.

MS. SHIROMA: That's fine. We'll get the latest information from our Monitoring Laboratory Division. We have sat down with them, gone through the 189, looked at a plan for them to add compounds to the monitoring network. A lot of it was dependent upon certainly resources, but also the availability of test methods. They have to go through a process of deriving new test methods for some of these.

DR. FROINES: In this huge committee that we currently have here, does this committee know what the State is doing with respect to monitoring for toxic air contaminants?

CHAIRMAN PITTS: You're looking at the two people who know, Joan and --

DR. FROINES: I know they know.

(Thereupon, there was a simultaneous conversation.)

MS. SHIROMA: In fact, our Monitoring Laboratory Division has put together a really nice program on -- I

believe it's Voyager software, where they can show you with computer graphics visually the concentrations at the various points on the network. And it just gives you a frame of test seeing this visually.

CHAIRMAN PITTS: Would you furnish the committee with how we get on it and where it is? That's exciting.

MR. VENTURINI: It's still kind of a beta version. We'll be glad to see -- I was playing around with the CD Rom version. I can certainly provide you with that. And it's kind of cutting edge technology, and it tries to take the data and kind of apply it to the given areas and kind of see the distribution. It's in beta version, and it takes some understanding to get through, but we can certainly provide you with that.

DR. FROINES: Does that include the data that the local air districts are going?

MR. VENTURINI: I'm not certain. I'd have to check on that.

What I'm hearing is that you'd like a presentation at the next meeting of kind of an update on our monitoring activities?

DR. FROINES: I think it's a strange situation. I some respects, I think that we, as a Panel -- and I'm not speaking for everybody -- others may know much more than me. But I don't really know the level of monitoring that's going

on in the State on air toxics.

MR. VENTURINI: We'd be more than happy to have folks that do that, if you'd like, to give you an overview of the network, the compounds that are being monitored.

In the meantime, we'll see what documents we have available that we can share with you on that.

(Thereupon, Dr. Pitts began reading from a document, and the reporter remarked she did not capture what he said.)

CHAIRMAN PITTS: I was just summarizing. Overall range of concentrations for these areas are from .5 to 11 milligrams, to so and so -- just add so and so.

(Laughter.)

CHAIRMAN PITTS: With an overall median range of 2.6 micrograms per cubic meter, U.S. EPA, 1993. Well, that's nice to know, but it's really nice to know exactly what are much better data. And they cover indoor.

DR. GLANTZ: In fact, I think the committee should be reconvened to recommend that the EPA harmonize itself with California.

CHAIRMAN PITTS: California has the top, right back where we started from.

MS. SHIROMA: I wanted to bring out one more thing on this, and Dr. Froines' point is well taken. The other thing this document is very useful for is pointing out where

there are data needs, and we'll be able to take a look at prioritizing were we to generate new data.

CHAIRMAN PITTS: Okay. Are there any other questions? If not, thank you very much. And we'll move on to the next item, which -- we basically have gone through this, and we have a meeting in May and one in June?

MR. LOCKETT: Right. And we're going to work out the dates that will best fit the Panel.

CHAIRMAN PITTS: Absolutely. We may not be able to get everybody on the Panel, but we need to keep the momentum going. Okay. Good.

All right. This is the diesel exhaust as a TAC. Item 5, update on the status of schedule for reviewing diesel exhaust as a toxic air contaminant, also update on the ETS report.

MR. KRIEGER: Good afternoon, Dr. Pitts and members of the Panel. My name is Robert Krieger. And I'll give you a byline now that we have with our release of the draft diesel exhaust report.

In early April, we plan to send out a letter to the public announcing the draft report release. Then, in late April, we plan to have outreach and a public briefing to release the revised draft, public comment, SRP version for a 90-day comment period.

DR. GLANTZ: Can I ask? It used to be 45 days.

And then it sort of got pushed up to -- like for the ETS report, it was 60 days. And now it's 90 days. And I mean, this report is like -- how many years has this report been out there kicking around?

MS. SHIROMA: Here's our dilemma. So, it's been out there kicking around for a few years. In the process, we have added whole new chapters that have not been unveiled to the public yet.

For example, on exposure we have an assessment of a near source, a hot spot assessment near the Long Beach Freeway. And we have the including of indoor/outdoor source apportioning. We've also updated the inventory. So, there are a whole portions of the report that have not been reviewed before.

We felt that, also given the public workshop, we needed to provide a sufficient amount of time for people to take a look at this material.

DR. GLANTZ: I mean, they're all going to like write their comments the night before they're due, you know. They're going to like wait till Day 87, and hysterically call you up and demand more time.

CHAIRMAN PITTS: I do the same thing.

We have the schedule up here then, so we'll have the revised draft 90 days, and the key item right here is the public workshop. Before we get to that announcement, I

would like to discuss with you and give a little thought maybe upstairs as to what -- the public comments, the hearings. I want to be very sure that those public comments, will they involve written statements, and people will come in with written statements, or will they just stand up and say, "I'm for this," or "I'm for that"?

Is there any reason why at a public workshop -- let me ask you, why can't we ask that they come in -- you got 90 days to figure out. That's plenty of time to come in with a written statement that can be presented to the Panel. Here it is, with their name, rank, and serial number, and whatever organization they're involved with, and where they come from, and here's our comment.

MS. SHIROMA: Ordinarily, we don't require that they come with written materials at the public workshop.

CHAIRMAN PITTS: Why not?

MS. SHIROMA: To allow for a back-and-forth discussion. I mean certainly we always ask who they're representing, who they are, and so forth. And then we ask them to follow up their verbal comments in writing to us.

CHAIRMAN PITTS: I've been to several workshops. But it just strikes me that -- well, certainly, if we come to this question, which is constantly raised, why can't we have public comment at the SRP meetings? That's another issue.

DR. GLANTZ: I think the workshop is a much more informal thing than the formal part of the comments. I hate to sound like a broken record, but it just seems like this is taking too long. What is an outreach event? I think it's like a party or something.

MR. KRIEGER: Basically, it's a public briefing.

MS. SHIROMA: What we will be doing is providing copies of documents -- we have a mailing list as well -- we'll also describe for whoever comes to the meeting what the contents of the report are and what are the new areas for review.

So that would be the public briefing, outreach event. We did that when we first provided a copy of the risk assessment.

The other thing about the 90 days is some of the interested parties and other stakeholders will want to comment on both the Part A and Part B. Part B also will have whole new portions. And I know in the past that they've argued that they have to hire their consultants. They need to divide the report, so forth, and so on.

And also, we've been presented with the argument that we've been allowed to work on the report for the time we have.

DR. GLANTZ: Oh, Genevieve, I don't know how long I've been on this committee, but we've been hearing this for

however long. I mean it's all just a bunch of malarkey. You're giving plenty of warning that this is giving. You know, they can go hire their consultants today, you know? They know what's in this report more or less. It's been out for public comment before.

I mean, if you want to have another workshop, if that makes you feel good, then it's okay. But I -- the concern I have is that we're getting back into this protracted process. When we used to do these 1807 compounds, when it got to this point, there was a 45-day public comment period before it came to us. And there were always changes in the document before it went out for the final review before it came to us. And sometimes, there were big changes in the document.

It just seems to me that this is just taking too long. And plus, we thought it was to be out by March. And now you're talking about late April. Well, who's going to argue over two months.

But, you know, I really think this is too drawn out a schedule.

CHAIRMAN PITTS: Jim?

DR. SEIBER: Yeah. I have a couple of questions. First of all, I've got a Part A that says June of 1994. Can I throw that away? Is there a more recent document? Do I have the most recent document?

MS. SHIROMA: That is the most recent document. That is the only version.

DR. SEIBER: So, this is still good, right?

MS. SHIROMA: Yes. That is the version that we --

DR. GLANTZ: What I'm reviewing is --

MS. SHIROMA: As leadperson, we have provided you with --

CHAIRMAN PITTS: Well, I have a suggestion. Provide those documents to the rest of the Panel.

MS. SHIROMA: Dr. Pitts, we have given you -- see, the process, and I think Dr. Froines is going to mention this, is that, as we work on these documents, we have, as a matter of policy, given our leadpersons our working draft. We gave you our Part A. That's the document that we're looking at then releasing to the entire public.

CHAIRMAN PITTS: I misunderstood.

MS. SHIROMA: The public version is that June --

(Thereupon, several persons spoke simultaneously.)

MS. SHIROMA: The most recent one is the working draft.

DR. FROINES: I think the very important point here, and we talked about this yesterday with the Chair and Mr. Tuttle. And I want to go on the record and say that that document should only be given to the leadperson for the

SRP at this point. It should not go to the other Panel members. It should also only be used in the context of raising issues which facilitate your process. And any comments back from us to you, a note should be made -- as far as I'm concerned -- for the record, so that the public is aware that the comments back to the Panel are within the context of raising issues that may ultimately improve the document.

We have the role of quality control with respect to the documents you prepare. We are not participants in their production. We simply raise questions to improve the process, but I am not working on this document as a member of the staff.

And I think that separation of quality control versus participant is ann extremely important separation of responsibility. Otherwise, the stakeholders can legitimately, as far as I'm concerned, raise questions about the role a Panel -- can we maintain our role as oversight, if you will.

And so I think, one, the only people who should have a document are the lead people. And the way that document is handled is only within the context, as I described it, to ensure the integrity of the process.

And then I have one more question that relates to this. Has the document that I have been changed since I

received it?

MR. KRIEGER: Well, it's on my LAN and we're constantly adding a little bit here and a little bit there. It's probably changed from yesterday to today.

DR. FROINES: We'll talk about that later.

DR. SEIBER: Before we get into that, do we have two lead people or one leadperson? Usually we have dual, you know, one on the exposure and one on the health effects.

CHAIRMAN PITTS: I'm the exposure guy anyway.

DR. SEIBER: So, you two are the leads, and you both have -- that's why you're getting these documents.

CHAIRMAN PITTS: Yeah.

DR. SEIBER: Okay.

CHAIRMAN PITTS: But I see no reason why if you wanted to come in and explore at this stage of the game, and interact --

DR. SEIBER: Well, I'd kind of like to interact, because in September, I'm going to be sitting there not knowing enough to make any decision. One question, of course, would be this public workshop. Wouldn't it be good if the SRP members, all of them, not just the lead people, went to this workshop? Would it or not?

DR. FROINES: We shouldn't talk among ourselves here, because you get the document -- I don't agree with Jim Pitts on this. The workshop is in mid-June. Theoretically,

you would have had a chance to read it over that two month period. And at the SRP meetings in which you then discuss the document would be as late as September. So, you would have the document from April, May, June, July, August, and perhaps even part of September.

Now, if the Panel starts to get copies of the document while the document is in process, then I'm afraid it compromises our role as having a specific time frame around which this process occurs. I don't think it's just up for everybody to sort of get a copy and read it.

There is a timetable that begins when the Panel officially receives the document. That's when our quality control oversight process begins. And we have to maintain that; otherwise, somebody's going to come in and sue our asses.

DR. SEIBER: Yeah. Now that I understand, now that you've explained it the whole thing, I'm not against this. I just didn't understand where we were in the process.

CHAIRMAN PITTS: I didn't understand it either.

But there have been huge changes in emissions. And the old PM10 question, and the ultrafine particle, 10 nanometer particles.

UNIDENTIFIED VOICE: They don't deal with that.

CHAIRMAN PITTS: They'd better deal with it. It's

in there. The whole PM10 issue is the biggest issue today. It's as big as the rest of the diesel issue.

(Thereupon, several members spoke simultaneously.)

DR. GLANTZ: We got it two or three months ago, and we discussed the diesel report. And the consensus among our two esteemed lead people was that you had a document that could have been released that day. And here we are in March, and you're now talking about the end of April. Why is this taking so long?

DR. ALEXEEFF: At least from the Part B standpoint, also, Dr. Vance indicated that he had -- we sent the document to get some additional internal type peer review -- internal/external. These are with other governmental agencies.

CHAIRMAN PITTS: There's another simple reason, Stan. Documents are prepared by highly professional, highly overworked staff people, and their administrators, who are under one hell of a lot of pressure to do a lot of things, and these things take time.

DR. GLANTZ: I understand.

CHAIRMAN PITTS: I just want to make that clear for the record. We appreciate the efforts and the hours that have been put in by the staff on both sides, OEHHA and the ARB.

And they're highly professional. And sometimes -- and we also appreciate the fact that there are stakeholders out there with billions of dollars riding on this, huge amounts. So, there's a lot of interest in this.

One month is one month out of 72 on this document.

DR. GLANTZ: Okay! Okay!

I don't disagree about the quality of the staff. But the point is -- I mean of the concerns I've had in watching this process is this sort of endless peer review, and just this constant review of re-review, or re-re-re-re-review.

And, you know, we've got a public comment period, we've got the panel here, and it just seems like this should have been done by now and out to public comment.

And I will now give up.

DR. FROINES: I really hesitate, George, to get into this, but --

CHAIRMAN PITTS: But you will.

DR. FROINES: You did it.

(Thereupon, there was a sidebar conversation between Drs. Glantz and Froines, which was not decipherable by the reporter.)

DR. FROINES: Let me just go to George. I haven't read every word in that document that I have, but unless I,m mistaken, the issues that Jim Pitts raised are not included

in the Part B. The noncancer effects associated with diesel particulate PM10, PM2.5, et cetera, et cetera.

DR. ALEXEEFF: There is a section on the noncancer effects of diesel exhaust. There is also a discussion in the appendix about how it fits in with particulate matter. But there is not a separate -- and it reviews the health effects that have been reported in the recent U.S. EPA staff report that came out in '96. So, it summarizes that.

I think the previous appendix that we had was maybe two pages or something. This current one has been lengthened up a little bit more, so it has more of a complete summary of what the health effects are of particulate matter.

But it simply is to put it in perspective the diesel exhaust health effects. There's more than enough specific information on diesel exhaust that we don't have to go to particulate matter to find out what kind of health effects it has.

But we did include a section just to put it in perspective because of those recent health studies having to do with particulate matter in total. That information is summarized in the appendix, but it's not the focus of the document.

DR. FROINES: But the point is there is not a full blown risk assessment based on noncancer health effects.

DR. ALEXEEFF: Correct. WE have a separate program with the Air Resources Board, the Research Division that deals with the criteria air pollutants. And we actually have a separate advisory committee called the Air Quality Advisory Committee that reviews those health risk assessments.

We haven't brought particulate matter to them recently, because we've been waiting for EPA to finish, mostly because it's so resource intensive. We wanted them to do the work first and see where they came up. Because the current California standard is already more health protective than the current Federal standard.

So, there's some issues. So, we haven't worked on adopting a particulate matter report, but it would come under a different part of my program and a different part of the Air Resources Board's program, and a different peer review panel.

CHAIRMAN PITTS: Okay. Are there any other questions or comments on this?

DR. GLANTZ: If you're doing a risk assessment on diesel, shouldn't it include all the end points? I mean with lead you did the noncancer end points on lead.

DR. ALEXEEFF: Yeah. There is a noncancer health assessment on diesel exhaust. There just is not a full blown assessment of particulate matter.

DR. GLANTZ: Okay.

CHAIRMAN PITTS: Fair enough. How about ETS?

DR. VANCE: Good afternoon. Once again, I'm Dr. Bill Vance, the Acting Deputy Director for the Office of Environmental Health Hazard Assessment, and I am pleased to tell you that each of you should have now the ETS document in hand. We put that on the Internet about the last week of February. And we started the official public comment period on March 7th that will run through May 5th.

And we have to do by law a 60-day comment period, and that was in the statute itself of Calderon's 1082, 57003. We're also obliged to hold a workshop in that period. So, we have scheduled a public workshop in Berkeley at the Department of Health Services in their auditorium on April 17th. You all come, please.

Assuming we don't get any requests for extensions, the public comment period would close on May 5th. And then, depending on how many comments we get on this document, which may be in the order of magnitude we might get on diesel, we will look at those comments. And I think people understand from a briefing that I gave to Dr. Pitts, that e only intend to address new issues, not previously addressed, in the ETS document to try to speed up this response to comment period.

So, if that turns out to be very short, we might

be able to make your June workshop for the version that you would like to review. We will take the public's comments and summarize a response to those in what would become Appendix B. Appendix A is the previous comments on this document. And we know that you would like to look at more of a finished product.

If by chance we get carloads of comments and we have to sort through those then at the outside, we would be ready at your September workshop. I'm sorry, your September "meeting."

And I will call the meeting at Berkeley, Dr. Glantz, a public forum, or was it you, Dr. Froines? We're going to call it a public forum. It's truly not a workshop in the sense that we had these nice diesel workshops.

DR. SEIBER: Again, for clarification here, where are we headed with this document? Are we going to be asked to declare ETS a toxic air contaminant? What was the answer to that?

DR. VANCE: I believe it's on the inside cover page, but I would defer to the Air Board for that response.

MR. SCHEIBLE: I'm Mike Scheible, Deputy Executive Officer. The current course we're on would not take ETS to the Air Resources Board for a regulatory action on ETS and identification of it as a toxic air contaminant. And the reason why we chose to go that way is, when we look at the

risk management side of ETS, we are not risk managers in terms of decisions we make the way environmental tobacco smoke and its source are not a source that we control at the Air Resources Board. That's the responsibility of other arms of the State Government in terms of influencing public habits and restricting smoking.

In terms of the way the law is situated, it's very clear that our identification of something as a toxic air contaminant under 1807 is, one, a regulatory decision and, two, is a prelude to regulatory action on our part. It triggers an obligation for us to go ahead and do reports on what the compound is and what we're going to do about it.

Since we don't have that option with ETS, we did not put into the formal 1807 identification process.

DR. GLANTZ: Well, I don't appreciate that. I think that we have said all along -- and I think we've said it today -- that the risk management and risk assessment parts of the process should be separate. This has become the mantra in certain quarters.

And if you read the document, it's clear that -- in fact, the document says ETS is a toxic air contaminant. And it just seems to me, having come this far, it's important to just finish the job. I think that the process that Dr. Vance talked about is going to take care of all the work that would be involved between here and there, and it

would just simply be a matter of the SRP issuing findings and taking those to the ARB as we've done with other chemicals, other compounds.

And the ARB has considered in the past indoor exposures and indoor health effects in many of the reports that we've done. Even though it doesn't have any specific regulatory authority, it just seems to me that the logical culmination of all this work is to take the thing to the Board.

I think everyone understands that you aren't going to issue regulations, per se, but if you look at the effects of the U.S. EPA's report on passive smoking and lung cancer, the issuance of that report from the U.S. EPA had a tremendously positive public health impact. And I think a similar thing would happen if the ARB were to do that here.

Again, it seems to me you're mixing up risk management issues and risk assessment issues.

DR. VANCE: I will offer that our current plan is when you have finished your comments and we've responded to those, is that we would give this document to the Department of Health Services and their tobacco control section.

MR. SCHEIBLE: And, Dr. Glantz, I will surely take back that point of view, and we'll have a discussion in terms of what our role might be. But this is clearly quite different from the other compounds we have identified by the

1807 process. And the law doesn't see this -- at least in our reading of it -- it is principally arranged so that we'll do things for which we have a risk management role and will do subsequent control in terms of the formal identification under the regulatory authority.

DR. SEIBER: Okay. There's a step in between. I guess I skipped something when I asked my question. Will there be a risk assessment done on ETS by the State?

DR. GLANTZ: I think that's in the document already. We have to wait to see what the public comment is, but I think that's been done quite credibly.

DR. SEIBER: That's one part we need to look over. But then the next step logically would be whether it's classified as a TAC, and that's a question that we need to get clarified.

DR. GLANTZ: I don't want to make any statements that are prejudicial one way or the other about the document, because it's out for public comment. But I think I can fairly say it's up to the high standards that we've come to expect from OEHHA and the Air Resources Board.

And having gone all this way and you're almost there, and I think if the -- if the ARB -- if this committee and the ARB were to complete the process of identification of a toxic air contaminant, the tobacco control section at DHS will still have access to the document. We're not

saying identify it and then burn it.

And I think if you would consult with them, that it would be given a much stronger standing from the scientific point of view to have that imprimatur on it. And I have been encouraging a lot of people to take a look a look at it and download it off of your website and to comment on it, because this document represents the first comprehensive review of second-hand smoke since 1986, when the Surgeon General did it, and the National Academy of Sciences did it.

And what you have in this report is far more complete and more comprehensive than anything the Federal Government has done in the last ten years, or that anybody in the world has done.

And it seems to me, having gone this far, presuming we will get public comments, which hopefully will lead to further improvements of policy with the document, you've got a tremendous resource here that will be valuable for a lot of people. And you need to do just the last little bit of it.

And I know the concern has been expressed that the tobacco industry will come in with their usual dump truck full of comments. Dr. Vance alluded to them.

But that's their prerogative, you know? And I think in the process of putting the parts of this Appendix B

together that Dr. Vance has talked about, they're going to respond to those comments. And I don't see between when that happens and if this were to go to the ARB -- unless there's some radical breakthroughs, I don't know what they're going to say that OEHHA wouldn't have already addressed.

So, it seems to me a fairly pro forma action to go to the -- finish the job of identifying it. It's a little bit like I was saying about the stochastic document. When you read the document, there's some logical conclusions that you saw from them. And my criticism of the stochastic document was that they weren't going to where their own document had gone.

And it seems to me the same thing is true with finishing the process up under 1807 on the ETS document.

The document, if you read it, it leads you to a logical conclusion. And that is that it should be listed as a toxic air contaminant. I want to hear what other people think. Am I all by myself in thinking this way?

DR. SEIBER: I'm personally in favor of finishing the job and doing it as timely as possible. So, there's a dual edge to my statement. And if you feel the risk assessment is in there, then we as a full committee need to probably spend some part of the meeting on that, and then take it to the next step, which is to draft out a

declaration and circulate it and see if everybody agrees with it.

CHAIRMAN PITTS: I agree.

If you look at environmental tobacco smoke, look at the already identified TACs that we have in there. Good Heavens! You've got benzo(a)pyrene, you've got formaldehyde. It's automatic. So, you're not going anything that's particularly revolutionary. It's a very reasonable thing to do. And I think quite frankly, I think that this would be an important step for the ARB to declare it, with the full understanding -- it's not risk management. That's clear, stipulated, stated. We'll cut it in bold letters. But this is an important -- we talk about stakeholders. A lot of stakeholders and they're concerned.

And this would bring the state of the art once again, CalEPA once again has created a state of the art document on one really toxic air contaminant. And so, it would seem to me almost a shame or a waste of -- a partial waste for not utilizing the enormous efforts that all of you have put into this.

And the other thing is that it's going to come out from a body of scientists that are internationally recognized. And it's going to mean something to a lot of people, not just in California, not just the U.S., but around the world.

So, as far as I'm concerned, the Panel will be more than interested in convening and having a session, in fact, to declare -- it's a recommendation we could make that it be declared a -- findings that it be declared a toxic air contaminant.

MR. SCHEIBLE: I will surely take the sense of the Panel back with me.

CHAIRMAN PITTS: It's a friendly sense. It's a sense of recognition of what all of you have done.

MR. SCHEIBLE: And I don't take, from our perspective, any -- the decision on its formal identification, which is a regulatory action by our Board, it's not a policy finding. It is, under the law, very clearly triggered to further steps by our direct risk management of a compound. We would be dealing with this differently. And the course we're on now in no way takes away from the scientific effort or the need for the Panel to review it and ensure that we have the highest quality and meets normal standards in terms of risk assessment and the science in the document, nor in any way takes away from the fact that once done, the work should be used in great influence by those folks inside the State that do risk management with regard to environmental tobacco smoke.

CHAIRMAN PITTS: The Panel's not trying in any way influence regulatory decisions. Totally out of it. We

fully understand, and we understand the pressures.

DR. FROINES: I have a different way of looking at it. The report will at some point officially come to this Panel, and so this Panel will officially review it. And this Panel will then officially write a letter to the Board.

CHAIRMAN PITTS: That's the findings.

DR. FROINES: Well, it seems to me that there is no question before us then. Because it's up to the Board to decide how they want to deal with it once we've sent the letter officially?

DR. VANCE: I nodded my head when you said official, and I'm thinking I'm not sure what is meant by an official, when we had a memo of an agreement and an understanding between the Chairs of our Department and -- it's not a chair, but our former director and Chairwoman Jan Sharpless. This particular document was deserving of an 1807-like health evaluation, that would then include exposure.

In that memorandum, it was agreed that the SRP would, in fact, review this document. You, in fact, had agreed to review it.

MR. SCHEIBLE: But it is not under its current course being brought to you through the process that triggers the 1807 review.

DR. FROINES: I understand that. That's the

reason I'm raising this question. Because it seems to me that Bill's point is very clearly stated, and it's exactly what the Panel needs insofar as the document will come to the Panel based on the agreement, and the Panel will review it, and then we can write findings that suggest, if we decide to do that, that it be declared a toxic air contaminant, and the Board can then, if they could take it up as such, they can do that. If they think it's not within their jurisdiction, they can decline.

But it seems to me that we have -- that we're just fulfilling our responsibility within a process that was started some years ago.

DR. GLANTZ: I think that is fine. I'll tell you my one concern. We could just allow the thing to move forward on its current trajectory, and I think -- given the discussion here and what I perceive to be the quality of the document, I think there's a high probability that come June, or September, or whenever it finally comes to us, that there's a high probability that this Panel will write a letter to the ARB recommending it be listed as a toxic air contaminant.

The preface in the current document states what was said at the outset; that this is not being done as part of the 1807 process.

What I'm concerned about is that if that is left

to stand as the current stated position of the CalEPA, and the committee then recommends that differently, then the tobacco industry could come in and claim that, hey, guys, you said this wasn't 1807, and now it is, yell and scream and jump up and down, and raise a bunch of procedural objections.

And I think it would be much cleaner if this issue were resolved in a way to bring an end to 1807 now, and any necessary amendments to the public notice -- it just went out a couple weeks ago anyway -- could be made in a prompt manner to make sure that everything was done in a way where there's no procedural issues left hanging. That's not going to affect the scientific content of the document. I just want to raise this as a procedural matter, because I think that it would be perhaps more expeditious to deal with this now rather than wait until September.

It would seem to me that it would be the same situation as when we have dealt with indoor air pollutants, where it did not trigger a regulatory action, but was more advisory. And it seems to me that this would be the same situation.

MR. SCHEIBLE: It's different.

DR. GLANTZ: Okay.

DR. FROINES: I think it's' not quite correct to say this is an indoor air pollutant. Because that assumes

something that we've never worried about. DPR takes into consideration exposure levels in their determinations. In the 1807 process, we've never dealt with exposure levels as a criterion for defining a toxic air contaminant. ETS exists outside and it exists inside. And so, therefore, within the context of our history, we are not necessarily addressing it as an indoor air pollutant. It is a toxic air contaminant and, in fact, there's a lot of chemicals that have already been declared within that context.

And so, to say that this is not -- should not be considered a toxic air contaminant because it's an indoor air pollutant is a change in policy.

MR. SCHEIBLE: I don't think that's our position. Our position is we do not have regulatory authority and we will not be taking regulatory action on this particular substance that happens to be airborne. And we do not bring compounds through this process for which there is no risk management in the end consequences for the Air Resources Board.

If it's a pesticide, we don't do it; DPR does it. If it's a compound that's airborne, but for which we are not in some ways the risk management agency, it doesn't go through the process.

DR. SEIBER: I'm getting lost in semantics here, because I think we were talking about bringing the best

science to bear on issues like this. And if a person is exposed maybe a little bit to ETS outside, and quite a bit more indoors, it's still total exposure.

And if you sit behind a guy at a baseball stadium like I used to do when I was a kid and breathe cigar smoke for nine innings, yeah, that was ETS.

We've got to look at total exposure. And that's what the DPR is going. That's what I really liked about their presentation. They're required to do it by law, but they're doing it and I think very well.

CHAIRMAN PITTS: Let me inject a bit of history here. But I have a letter here written by my formerly nicotine, cigar-stained fingers. It says, Dear Ms. So and So and Dr. So and So.

At its February 13th, 1991 meeting, the SRP passed a motion to send a letter recommending that environment tobacco smoke, ETS, be entered into the AB 1807 process for identification as a toxic air contaminant. The reasons for this recommendation include -- I'll indicate now it was to Jan Sharpless, Chairwoman, ARB, and Ken Kaiser, Director, March 8th, 1991.

Reasons include, the evidence that ETS causes death and disease is very strong, predominately based on realistic field exposures to high exposure animal studies, which require significant extrapolation.

IARC has identified tobacco smoke as a human carcinogen. This is March 8th, 1991.

And the EPA Science Advisory Board has recommended that ETS be listed as a Class A carcinogen. California has identified tobacco smoke as a substance known to cause cancer in the State of California under Prop. 65.

(Thereupon, the reporter requested Dr. Pitts to speak up.)

CHAIRMAN PITTS: It's in the file. Noncancer effects of ETS are present in exposures commonly experienced particularly among children. Finally, ETS is in the air in California and exposure is widespread. We believe the identification process could continue with reasonable staff effort because of the availability of recent scientific consensus documents on the subject of ETS.

These include the 1986 Surgeon General's report, the Health Consequences of Involuntary Smoking, 1986 National Academy of Sciences Report, Environmental Tobacco Smoke, and the 1990 EPA risk assessment, health effects of passive smoking, assessment of lung cancer in adults. . .and disorders in children.

We look forward to continuing to work with the ARB and the Department of Health Services in advancing this risk assessment process for ETS.

So, we're not just Johnny Come Latelies in the

Game. This is some six years when a very formal request went in.

I'll give you copies of this letter to take to your bosses if you care to take them up. It's a public document that this Panel made the recommendation.

MR. SCHEIBLE: And I believe we responded back saying what we would do, and we have done and are bringing you the health assessment. And in our view, given how we see the law and how it works, referring you to the appropriate risk managers in a formal process. That's where we're not having a not quite meeting of the minds here.

DR. GLANTZ: I think we've sort of beaten this into the ground. I think you understand where we're coming from. I think, based on the conversation we had in the hall, there was a little bit of a misunderstanding between at least me and you guys. Because before, when people talked about the ARB would not want to take regulatory actions, I interpreted that to mean issuing rules about where you could and couldn't smoke.

I had always understood or probably misunderstood that the decision would still leave you the ability to make the identification. And now you've explained that is also reviewed as a regulatory action.

But I think the sense of the Panel is pretty clear. I think that the people at OEHHA have done a very

good job in producing a document which is going to stand up to public scrutiny. But I think it is a world class document. And I would hope, based on this discussion, that you guys will reconsider how you're going to handle when we finish with it and make whatever necessary adjustments to the process.

CHAIRMAN PITTS: Recognizing the fact that it will come through the process, and we'll issue findings.

MR. SCHEIBLE: I think that's perfectly appropriate.

CHAIRMAN PITTS: Okay. That's great. So, the cards are all on the table.

All right. Are there any other items for discussion?

DR. GLANTZ: I, as I mentioned, encouraged several friends of mine around the country and around the world to download it off your website. And I've heard back from a couple of friends that U.S. EPA will find the document quite intimidating.

And they were very impressed with the job your staff did, Bill, and I think you should carry that back to them.

DR. VANCE: We have a corps of very dedicated scientists, and there were people who came from outside the department who were willing to work on it on their own.

CHAIRMAN PITTS: We appreciate that. Thank you very much.

(A motion to adjourn was heard.)

CHAIRMAN PITTS: Is there a second?

All in favor?

(Ayes.)

(Thereupon, the meeting was adjourned at 5:20 p.m.)

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CERTIFICATE OF SHORTHAND REPORTER

I, Nadine J. Parks, a shorthand reporter of the State of California, do hereby certify that I am a disinterested person herein; that the foregoing meeting was reported by me in shorthand writing, and thereafter transcribed into typewriting.

I further certify that I am not of counsel or attorney for any of the parties to said meeting, nor am I interested in the outcome of said meeting.

In witness whereof, I have hereunto set my hand this 2nd day of April , 1997.

Nadine J. Parks

Shorthand Reporter