MEETING

STATE OF CALIFORNIA

AIR RESOURCES BOARD

SCIENTIFIC REVIEW PANEL

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Mr. Andrew Salmon, Ph.D, Chief, Air Toxicology and Risk Assessment Unit

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PROCEEDINGS

CHAIRPERSON FROINES: I would like to call to order the Scientific Review Panel on Toxic Air Contaminants for the meeting dated January 11th, 2007. And the entire Panel is here. All members are in attendance.

And the first topic on the agenda is the review of the draft report on Methidathion, the Risk Characterization Document that was revised on November 2006.

And I think to get started -- first, Peter, have you circulated the findings, draft findings?

MR. MATTHEWS: Not yet.

CHAIRPERSON FROINES: Would you please do that?

No, in writeing, to avoid people bringing their computers up and...

We've received comments from -- I've received -- I've seen comments from Dr. Friedman. I understand Roger had some comments as well. But there mail be others.

So to get us started I think the first person to speak will be Carolyn Lewis from Department of Pesticide Regulation, who's going to tell us about changes -- correct me if I'm wrong, Carolyn -- changes that have occurred since the last meeting basically.

(Thereupon an overhead presentation was Presented as follows.)

DPR ASSOCIATE TOXICOLOGIST LEWIS: Yes. I'm only going to cover the changes to the health risk assessment --

CHAIRPERSON FROINES: Put your mike closer.

DPR ASSOCIATE TOXICOLOGIST LEWIS: Is that better?

CHAIRPERSON FROINES: Yes.

DPR ASSOCIATE TOXICOLOGIST LEWIS: Okay. My presentation today, I'm just going to cover the revisions to the health risk assessment that were made since the last presentation. And I'm going to go through these in the order that they appear in the document.

Okay. Next slide.

--o0o--

DPR ASSOCIATE TOXICOLOGIST LEWIS: In the toxicology profile, an older metabolism study was added. In this study they labeled Methidathion with P32 as well as C14. The findings from this study supported the findings of the more recent metabolism studies as far as the fate of the leaving group. It also provided additional information regarding the fate of the phosphate moiety. So the proposed metabolic pathway for Methidathion was changed to include the metabolism of the

phosphate moiety, which you can see here on the right here now in the metabolic pathway.

Next slide.

CHAIRPERSON FROINES: I just wanted to mention that Gary Friedman, his comment asked about my putting the word electrophilic chemistry in. And if you go back to that slide.

--o0o--

CHAIRPERSON FROINES: There are compounds there that will readily react with macro molecules, namely, thio groups on proteins. And so that's the -- and form irreversible covalent bonds. And so this is a very interesting and important addition because it suggests that there's a complex metabolism that is still under investigation.

Is that fair, Carolyn?

DPR ASSOCIATE TOXICOLOGIST LEWIS: Yes.

--o0o--

DPR ASSOCIATE TOXICOLOGIST LEWIS: As requested by the Panel, a table was added to the toxicology profile showing the incidents of the liver tumors in the mouse carcinogenicity study, which was not acceptible by FIFRA guidelines.

In addition to the incidents of the liver tumors I added the incidents of non-neoplastic lesions in the

liver that were also elevated. And as you can see, that most of these lesions involved the bile duct.

The incidents of both the neoplastic and the non-neoplastic lesions was lower in this study than in the mouse carcinogenicity study that was found acceptable.

CHAIRPERSON FROINES: Did they report data on pancreatic cancers as well?

DPR ASSOCIATE TOXICOLOGIST LEWIS: I don't recall that they were elevated in this study.

CHAIRPERSON FROINES: It's just that there's a possibility when you go from the bile duct and the liver to the pancreas that it would be worth --

DPR ASSOCIATE TOXICOLOGIST LEWIS: I could look at that again --

CHAIRPERSON FROINES: It's not important.

DPR ASSOCIATE TOXICOLOGIST LEWIS: -- but I didn't.

CHAIRPERSON FROINES: It's not important. It's just a curiosity.

--o0o--

DPR ASSOCIATE TOXICOLOGIST LEWIS: If you recall from the last draft, the acute neurotoxicity study in rats was selected as the definitive study for evaluating acute exposure to Methidathion. The problem with the study was a NOEL was not observed in this study due to statistically

significant inhibition in the cerebral cortex of males at the lowest dose level.

I estimated a NOEL by dividing by an uncertainty factor of 3 rather than 10, because the inhibition was only seen in one sex and one region and the females appeared to be more sensitive at higher dose levels.

Also, if I had estimated the NOEL by dividing by 10, it would result in an acute NOEL that was lower than the subchronic NOEL for the same endpoint.

The Panel suggested that I do a benchmark dose analysis instead to estimate acute NOEL.

--o0o--

DPR ASSOCIATE TOXICOLOGIST LEWIS: Now, one of the problems with doing a benchmark dose analysis on continuous data is you need to set a threshold for toxicological significance. The U.S. EPA used a benchmark response level of 10 percent inhibition when it did its cumulative risk assessment for OPs. However, this was applied to whole brain data.

This graph shows the coefficient of variation for a cholinesterase activity in the whole brain of control rats in various acute and subchronic neurotoxicity studies that have been submitted to DPR.

And on the left-hand side you'll see the acute studies with the time of measurement indicated in days.

And on the right-hand side are the subchronic studies with the time of measurement indicated in weeks.

And as you -- oh, and for those who are not familiar with a coefficient of variation, that is the standard deviation divided by the mean times 100, and is often a measure of normal variation.

As you can see, most of the the CVs are below 10 percent, suggesting that a level of 10 percent inhibition is a reasonable threshold for whole brain data.

--o0o--

DPR ASSOCIATE TOXICOLOGIST LEWIS: This is a graph of the CVs for the cholinesterase activity in the cortex of control rats. And as before, the acute studies are on the left and the subchronics are on the right.

And I should point out that Methidathion acute study is here and the subchronic study is over here.

And you'll notice that there are more data points with the cortex. And the reason for that is usually when they measured regional brain cholinesterase activity, they measured it at more than one time point. So most of these studies had at least two to four time points in which they looked at the activity in the cortex.

As you can see from this graph, there were a number of incidences when the CVs were greater than 10 percent. So 10 percent seems like it may be too low of a

threshold when looking at the cortex. And I've only shown this graph of the cortex. I have similar ones for other regions. And the type of variation they saw in the other regions is very similar to what you see here.

--o0o--

DPR ASSOCIATE TOXICOLOGIST LEWIS: So when I did the benchmark dose analysis for Methidathion, I looked not only at the 10 percent response level but also the 15 and 20 percent response level. And I also looked not just at the cortex in the acute study but also at the various regions that were measured in the subchronic study.

One of the requests of the Panel was that DPR work with OEHHA to come to some agreement on the acute NOEL. And so we met and discussed this benchmark dose analysis. Unfortunately we weren't able to agree on a threshold to use. I then suggested as an alternative was to use the observed NOEL at two weeks in the 90-day study, which was based on statistically significant inhibition in the cortex of males.

And, by the way, this NOEL corresponded to a benchmark response of 15 percent.

Next slide.

--o0o--

PANEL MEMBER GLANTZ: Can I ask a question?

DPR ASSOCIATE TOXICOLOGIST LEWIS: Yes.

PANEL MEMBER BLANC: Use the microphone.

PANEL MEMBER GLANTZ: Is that okay?

CHAIRPERSON FROINES: No, please interrupt. This is the most important.

PANEL MEMBER GLANTZ: Yeah, this is one point I was -- I missed the previous meeting where this was discussed. But this was the one thing I was confused about in the report. And there are two related questions.

One is, when you -- you say you use a coefficient of variation of 10 percent as the threshold for the effect. I don't quite understand if you -- does that mean that you're saying if you're 10 percent below the mean -- pardon me -- if you're one standard -- that would mean you were like one standard deviation away from the mean. So you're saying that if you had an effect that was one standard deviation from the mean response, that's what you would consider to be a threshold? I don't quite understand how the 10 percent coefficient of variation then relates to a dose.

DPR ASSOCIATE TOXICOLOGIST LEWIS: Well, I mean when you measure inhibition in these studies, it's all -- it's activity relative to the controls. So it's just another way of looking at deviation from control activity. And so I -- to me it was just trying to put a handle on how much normal variation you see in the

activity and trying to use it as some way of setting the threshold. I'm not saying there's --

PANEL MEMBER GLANTZ: No, I'm not criticizing the use of it. I'm asking about precisely how you used it. Because it seems -- and I mean I may be completely wrong here. But just listening to you, it seems to me that if the -- if the coefficient of variation is 10 percent, that means the standard deviation is 10 percent of the mean.

DPR ASSOCIATE TOXICOLOGIST LEWIS: Yes.

PANEL MEMBER GLANTZ: Okay. So what you're saying then is if you get a change from the controls of 10 percent, then you're one standard deviation below the mean -- or above -- I guess it would be above the mean, and that's where you're putting your -- you're saying, okay, that's the -- is that what your doing?

DPR ASSOCIATE TOXICOLOGIST LEWIS: Yeah, I think -- yeah, yeah, yeah.

PANEL MEMBER GLANTZ: Okay. Well, then is that far enough? Or why would you -- what's magic about one standard deviation?

DPR ASSOCIATE TOXICOLOGIST LEWIS: There's nothing magic. I mean it's just -- you know, that's the problem with this trying to set a threshold. You know, one's comfort level varies from one person to the next. So it's just how do decide when you've gone high enough

for --

PANEL MEMBER GLANTZ: Right. But what -- I mean in practical terms, if you --

DPR ASSOCIATE TOXICOLOGIST LEWIS: Or low enough or --

PANEL MEMBER GLANTZ: Well, but no. Let's assume that you're 10 percent number is the right number. Could you explain to me why it would make sense to set the threshold one standard deviation above the mean response in the controls? I mean What would that mean in practical -- what fraction of the people who are exposed are going to be above that? Is that a sensible question to ask?

DPR ASSOCIATE TOXICOLOGIST LEWIS: Well, in this case we were actually looking at people whose activity would be below --

PANEL MEMBER GLANTZ: I'm sorry, below -- I'm sorry. Yeah, below that.

DPR ASSOCIATE TOXICOLOGIST LEWIS: -- or animals in this case.

PANEL MEMBER GLANTZ: Right, right.

What is -- I mean I couldn't figure out what that meant in real biological terms.

DPR ASSOCIATE TOXICOLOGIST LEWIS: Well, I guess I -- it was more if -- you know, if it's one standard

deviation, what's that, like 65 percent or something, of the population, you know, should be, you know, have activity that's greater than that threshold. And so if you're down below there, then you're starting to get outside of what someone might consider normal activity.

PANEL MEMBER GLANTZ: All right. So that -- and then I have -- did you want to say something, Kathy? I have another related question.

PANEL MEMBER HAMMOND: This is related to that.

And, again, I apologize, because I missed the last meeting too. So I'm trying to interpret what you've said.

Let's just say the mean was 150. And if there's a 10 percent CV, that means the standard deviation was 15, right?

DPR ASSOCIATE TOXICOLOGIST LEWIS: Um-hmm.

PANEL MEMBER HAMMOND: So are you saying -- you're not saying you set the benchmark dose at 135. It must be you're -- this is the mean of the response, right, of the ACE levels, right?

PANEL MEMBER GLANTZ: Isn't that the mean of the controls?

PANEL MEMBER HAMMOND: The mean of the controls -- but the ACE level in the controls, is that right? We're talking --

DPR ASSOCIATE TOXICOLOGIST LEWIS: Yeah, that's --

PANEL MEMBER HAMMOND: So are we saying -- are you saying the benchmark dose is the dose which will give you 135 if you make a linear plot of the values that were there?

DPR ASSOCIATE TOXICOLOGIST LEWIS: Well, actually where you take that 10 percent or 15 percent, whatever you use, is you just plug that into the software, as this is the response --

PANEL MEMBER HAMMOND: Yeah, but what is the software doing with that number?

DPR ASSOCIATE TOXICOLOGIST LEWIS: It's then drawing a line from the curve that it's -- it's drawing the same curve, you know, no matter what response level. It's just where it draws a line down to the lower limit on the benchmark response is where that response number comes in.

PANEL MEMBER HAMMOND: Are we saying that you're taking the dose response curve -- you have a dose response curve?

DPR ASSOCIATE TOXICOLOGIST LEWIS: Yeah.

PANEL MEMBER HAMMOND: And you were going to say that in order for there to be a detectable effect, the suppression has to be 135 or less, the response, right,

the AC --

DPR ASSOCIATE TOXICOLOGIST LEWIS: Yes.

PANEL MEMBER HAMMOND: It's in my example --

DPR ASSOCIATE TOXICOLOGIST LEWIS: Yes.

PANEL MEMBER HAMMOND: -- of 150 with a 15 -- you're saying 10 percent you take. So it's got to be 135 or less to be detectible as a response. And then are you saying I go to the response part of that curve and come down and say what dose gives me that? Is that why you're doing that?

DPR ASSOCIATE TOXICOLOGIST LEWIS: Yes, we look at the lower --

PANEL MEMBER HAMMOND: And that becomes your benchmark dose?

DPR ASSOCIATE TOXICOLOGIST LEWIS: Yeah.

PANEL MEMBER HAMMOND: That's what wasn't clear.

DPR ASSOCIATE TOXICOLOGIST LEWIS: Yeah. And it's the lower limit on that response curve. It's not -- which takes into account some of the variation in the response.

PANEL MEMBER HAMMOND: Okay.

PANEL MEMBER GLANTZ: So would it be -- just not to beat a dead horse, but --

CHAIRPERSON FROINES: Did Paul have a question that --

PANEL MEMBER GLANTZ: Oh, okay.

PANEL MEMBER HAMMOND: Oh.

PANEL MEMBER BLANC: No, I'll wait till you're done.

PANEL MEMBER GLANTZ: Okay. So basically by taking the coefficient of variation the way you are, what you're saying is that "I want to make sure the effect is pretty much below" -- at least one -- you know, within one standard deviation of the uncertainty of what the mean response is?

DPR ASSOCIATE TOXICOLOGIST LEWIS: Um-hmm.

PANEL MEMBER GLANTZ: But then I mean usually people will go two. Why didn't you go two standard deviations?

DPR ASSOCIATE TOXICOLOGIST LEWIS: Well, now that's actually kind of a mixed bag, because if you actually say, well, it has to exceed that, that actually raises -- it requires that you have more inhibition before you say this is significant. So you're actually being more cautious in some ways by setting it one standard deviation than at two.

PANEL MEMBER GLANTZ: Okay. And then the last question I have is the -- and you were just talking about it here and I also didn't understand it here. When you did the experiments where you got the NOEL and the LOEL,

they didn't actually observe a no-effect level, right?

DPR ASSOCIATE TOXICOLOGIST LEWIS: Right. That's why we --

PANEL MEMBER GLANTZ: So you took the lowest effect -- the lowest level that in effect -- basically you took the lowest level they studied?

DPR ASSOCIATE TOXICOLOGIST LEWIS: Yes.

PANEL MEMBER GLANTZ: And then you divided that by three --

DPR ASSOCIATE TOXICOLOGIST LEWIS: -- three, yeah.

PANEL MEMBER GLANTZ: -- for the reasons that you specified?

DPR ASSOCIATE TOXICOLOGIST LEWIS: Yeah, I did, yeah.

PANEL MEMBER GLANTZ: Okay. I think that that could be more clearly stated in the text. I got very confused by that.

DPR ASSOCIATE TOXICOLOGIST LEWIS: Okay.

PANEL MEMBER GLANTZ: I don't think it's an unreasonable thing to do. But you might just want to go back and be just a -- add another sentence there.

DPR ASSOCIATE TOXICOLOGIST LEWIS: Well, I was no longer doing that, because I -- if I could go on, I'm using this other study now. So I'm not --

PANEL MEMBER GLANTZ: Oh. Well, no, I'm talking about for the one you used.

DPR ASSOCIATE TOXICOLOGIST LEWIS: Oh, the one I -- okay.

PANEL MEMBER GLANTZ: Because it wasn't clear what -- the one that you used -- and I read this a little bit ago -- but it was the one where you're looking at total brain activity or something, right?

No?

DPR ASSOCIATE TOXICOLOGIST LEWIS: No, I didn't --

PANEL MEMBER GLANTZ: What was the one you used?

DPR ASSOCIATE TOXICOLOGIST LEWIS: I used the 90-day study. I ended up going to the two-week time point in the 90-day study. It had the same effect and same region in males, was the most sensitive effect. But there was an observed NOEL for that study.

PANEL MEMBER GLANTZ: Okay. Well, at least when I read it that --

DPR ASSOCIATE TOXICOLOGIST LEWIS: -- wasn't clear?

PANEL MEMBER GLANTZ: -- wasn't clear. Because I couldn't figure out if you were taking a LOEL and then extrapolating a NOEL, or if there was an actual direct going through.

DPR ASSOCIATE TOXICOLOGIST LEWIS: Yeah, there was an actual. So that was the advantage.

And while I'm on this slide, because I'll make this point later, is I thought that study was a good surrogate for the NOEL in the acute study, because if you look at the benchmark responses at the two-week time point and then at the time of peak effect in the acute study, the BML values are identical, which I thought was very interesting.

PANEL MEMBER GLANTZ: Okay. Well, the one thing I would just suggest -- because I read it about three or four times. The thing you just said about the direct leaves are of NOEL I couldn't find. Maybe it's there, but maybe you need like bigger print or something. But I --

DPR ASSOCIATE TOXICOLOGIST LEWIS: I'm going to have to make a point of saying "observed" or something.

PANEL MEMBER GLANTZ: Yeah, because that's such a central point in the whole report, I think you just want to be very -- because I mean it's obviously much stronger if you actually observe a NOEL rather than if you're taking a LOEL and then just dividing it by some number that then you can argue about.

So that's basically everything I had about the report.

PANEL MEMBER BLANC: Paul Blanc.

Can you clarify for us, because this is an important -- potentially important precedent, what was the nature of the gap in consensus between the Department of Pesticide Regulation and the Health Department?

DPR ASSOCIATE TOXICOLOGIST LEWIS: Oh, why we couldn't come to an agreement on the response level?

PANEL MEMBER BLANC: That's correct. I mean I'm assuming that there was agreement that it was appropriate to do a benchmark calculation and that the entire difference in opinion had to do with the best measure of variation to apply --

DPR ASSOCIATE TOXICOLOGIST LEWIS: Yeah, well --

PANEL MEMBER BLANC: -- is that correct?

DPR ASSOCIATE TOXICOLOGIST LEWIS: Well, they had a problem with using CVs to set the threshold, because they didn't think that it was equivalent to when you compare to means, you know, do a statistical comparison. And I mean it's true, it's not the same. But they didn't come up with an alternative way to set the threshold, you know, so that was the problem that we got down to, and what's high enough and --

PANEL MEMBER BLANC: So fundamentally the Health Department disagreed with the EPA's approach to organophosphates? Because you made --

DPR ASSOCIATE TOXICOLOGIST LEWIS: No, they --

yeah, they didn't have a problem with using 10 percent. But, you know, I still had concerns about using 10 percent for the regional data. I didn't have a problem with whole brain data, which is what U.S. EPA did. It was only whole brain data. So it was just the regional brain data I had reservations about.

PANEL MEMBER BLANC: I understand that that was your question and your rationale for using 15 percent instead of 10 percent. And I think that you make a reasonable argument in that regard. And that's why I'm trying to understand the Health Department's difference of opinion. And if I understand what you're saying --

CHAIRPERSON FROINES: You mean OEHHA.

PANEL MEMBER BLANC: OEHHA, I'm sorry.

If I understand what you're saying, in fact OEHHA's trepidation was not 15 percent versus 10 percent; oEHHA's trepidation was using any coefficient of variation as a driving force in a benchmark calculation.

DPR ASSOCIATE TOXICOLOGIST LEWIS: That's my understanding.

PANEL MEMBER BLANC: And If I also understand what you said, in fact your use of a coefficient of variation in this approach was based on the EPA's overall approach to organophosphates, taking into account that they were using whole brain variation.

Did I understand that correctly?

DPR ASSOCIATE TOXICOLOGIST LEWIS: Yeah.

Now, I should point out that U.S. EPA, how they came up with 10 percent was there was just this feeling that generally this level was statistically significant, you know, in brain, and that's how they came up with it.

I started using the CVs -- when we've been working on our cholinesterase policies, we used CVs to try to come up with thresholds. And so it was just an extension of that. We had had trouble initially when we looked at the regional brain data coming up with thresholds because of the variability compared to the whole brain data. I looked at it again and looked at more of the individual time points and started to get a stronger feel that, well, maybe, you know, something a little bit higher, you know, maybe like 15 percent instead of 10 would be better, yeah.

PANEL MEMBER BLANC: Okay. So the reason I'm taking so much time with this particular issue is because -- not because I think that it would change fundamentally something about the report that you've done and the way that you've done it. And I think it was very responsive to go back and do the benchmark. But I think it raises issues for us as a panel going forward and echoes I think something that Dr. Froines has brought up

on more than one occasion in terms of a consistent approach to organophosphates and the need to address state-of-the-art questions. And I think this clearly will come up in the future.

And I would certainly like to see going forward further work by OEHHA and the DPR looking at the issue of variation in organophosphate responses and the EPA's approach and whether or not OEHHA does or does not endorse this sort of basic component of the EPA approach. Because if they don't -- and I'm not saying whether 10 percent versus 15 percent. It's a more fundamental question, is is it appropriate to be using the variation in the controls in manner in which EPA has done? And I think there needs to be some more definitive comment from OEHHA which isn't simply "we're not happy with that but we don't have any alternative approach."

CHAIRPERSON FROINES: Andy -- I think I'm calling Andy instead of Melanie, but either one is appropriate.

The question that Paul's raising I think is really quite important because it has long-term policy implications for anything we do in the feature. And if we're not sanguine about the current approach, then this will come up repeatedly in the future I think to the degree that we do organophosphates.

OEHHA AIR TOXICOLOGY AND EPIDEMIOLOGY SECTION

MANAGER MARTY: Yeah, I think I can only speak to what I know. And, that is, we have had discussions in the past with DPR about --

CHAIRPERSON FROINES: Could you put the mike closer.

OEHHA AIR TOXICOLOGY AND EPIDEMIOLOGY SECTION MANAGER MARTY: I'm sorry.

We've had discussions in the past between our two groups about how to use cholinesterase inhibition data. And the ball got dropped at some point. We never really came out with a final document. So I can take that back to George and say we really ought to get that work group up and going again and talk these things through.

I think in the end we ended up agreeing with how DPR generated their NOELs. We may have gotten there in a different way. So I don't think there's any basic disagreement right now with how they've done this assessment in the end.

CHAIRPERSON FROINES: Well, just for people who -- for example, Charlie who wasn't around. We held a workshop on how to address organophosphates. It was a daylong workshop. And that was an extensive discussion on the science associated with OP pesticides and how we were going to approach them, because there was different policy decisions that EPA was making.

And then there was a work group that was established to develop a concerted policy on this issue. And then the then director, Mr. Helliker, basically as far as I remember killed that group that were working together, and though the issue from this Panel's standpoint was dead. And nothing came forward as a culmination of that process.

And so now we're now back into that issue through the back door with Methidathion. And so I think Paul's entirely correct that the OP issue is one that we need a consistent California policy on if we're going to -- if we're going to have -- because we don't want to set DPR and OEHHA at odds with one another, and so it seems to me that we need to proceed to come to clarity about this issue, which is what I think you're saying.

Kathy.

PANEL MEMBER HAMMOND: Yeah, the reason I asked my question earlier actually relates to this. And I think -- I agree with what John is saying. I think it's very important that the methodology be agreed upon and thought through so that we don't fight the battle over a particular chemical but rather, you know, think it through.

And so my understanding, a benchmark dose and that whole benchmark dose idea was a way to get around the

question of what -- how to look at the shape of the curve below the lowest observable value --

CHAIRPERSON FROINES: Right.

PANEL MEMBER HAMMOND: -- and how the different equations will give you different shapes and therefore different dose response -- you know, and different extrapolated LOELs and NOELs and things.

And so my understanding was the benchmark dose starts out being a dose at which everybody who looks at the data would agree there's an effect that's happening here. Now, I totally agree with -- I mean you have a reasonable way to approach how to determine what that -- recognizing that something has happened, has occurred, that there's an effect; in other words taking a response that's less than one standard deviation from the norm of the controls. And that just defines at what point --

PANEL MEMBER GLANTZ: -- more than one standard deviation.

PANEL MEMBER HAMMOND: No, no, no. Just hold this for a minute. Just don't -- go there, elsewhere later.

But one has to decide when you've got a continuous variable, it's not a dichotomous variable, when is there an effect? You know, is this like -- is this like a very small little blip, you know, part of diurnal

variation and, you know, you see a need to pick that number, however it's picked.

All right. But at that point that's when you can say you've observed an effect. But if you had done an experiment -- let's just take my example from before where we -- for whatever reason, we've all agreed that going below 135 units -- I have no idea what the real units are -- but 135 units is a real effect, a real suppression. Then if in your experiments, you know, the very first dose, the lowest dose you have has a suppression so that you're down to 85 units, you can't extrapolate to look at that dose because then you've totally undermined the benchmark dose. You're into another realm of risk assessment at that point.

So I think the standard approach with benchmark is if the lowest dose has an effect that you agree is an effect -- you know, if your lowest dose group has an effect, then I think that's your benchmark dose. You wished that you'd done an experiment lower. And you need to then divide that dose by 10 or 100 or something and not by 3. I mean I think you -- there's some standard things that people could talk about what you divide it by.

CHAIRPERSON FROINES: Well, Kathy --

PANEL MEMBER HAMMOND: But I think it's conflating two different issues, you know. But you don't

want to be now trying to describe the shape of the curve below your lowest point and call it benchmark, because then you've lost the whole advantage of benchmark dosing.

CHAIRPERSON FROINES: But the benchmark is a level at which there is an observed effect.

PANEL MEMBER HAMMOND: An actual experimentally observed effect, yes.

CHAIRPERSON FROINES: Yeah. And then one uses uncertainty and safety factors to get down --

PANEL MEMBER HAMMOND: Right. But, see, that is what I was hearing described when I asked earlier about what happened. It sounded to me like you take the 135 response and then you go down to the dose that would do that. And if that dose were below the lowest dose where you did your experiment, then you're back not into the benchmark realm but you're into another risk assessment. Not a wrong one but just a different one.

OEHHA AIR TOXICOLOGY AND EPIDEMIOLOGY SECTION MANAGER MARTY: Can I jump in here, and maybe I'll have Andy jump in too.

We're using the term "benchmark dose" differently. I think it's part of the semantics. Because in risk assessment, when you do a benchmark dose methodology, you're actually modeling that dose response curve to a specified response rate, either 5 percent --

that might be below your observable dose range.

PANEL MEMBER HAMMOND: That's different than a --

OEHHA AIR TOXICOLOGY AND EPIDEMIOLOGY SECTION MANAGER MARTY: And then that's the departure point that risk accessors use to then divide through by uncertainty factors. So we're using the term a little bit differently.

CHAIRPERSON FROINES: Yeah, the -- my understanding of the benchmark dose is that the percent that you go down to is not necessarily an observed value. It's a selected value. And you can select 5, 10, 1, 100, whatever you choose. But it's a selected value that presumably gives you some confidence in the shape of your dose response curve. and what you're then doing is using uncertainty factors to get you down to what you would consider an acceptable level of protection.

And so, Kathy, it's not -- the 10 percent is not a -- like a LOEL. It's not an observed dose -- it's not an observed effect. It's a defined point in the dose response curve. And correct me if I'm wrong.

OEHHA AIR TOXICOLOGY AND EPIDEMIOLOGY SECTION MANAGER MARTY: No, that's right.

PANEL MEMBER BLANC: I just want to also clarify that the reason why I think this has been well handled in the report as you've done it is that you're using the

benchmark extrapolation as the secondary analysis approach, but your actual recommendations are based on the no-effect level in a study in which you had a no-effect level rather than an extrapolation from a low-effect level. And I think that's an important point, because basically what we're saying here is that in this report and in our findings related to this report, it's not that we are making a precedent of using a 15 percent acetylcholinesterase when regional brain suppression level endpoints are available rather than whole brain. But we've used it here as a secondary approach, much in the way that we used the meta-analysis of the diesel exhaust data as a secondary confirmatory approach to the data, say, are we -- if we use an alternative approach, are we still on the same -- more or less the same conclusion, which in fact we are in this case.

And I think that is important. Because I think it would be less comfort if we were really doing something which was potentially establishing a precedent. Which I don't believe we are, but I think it does highlight the need to come to a clearer consensus going forward, because in fact the next organophosphate that we view, we may have to or prefer to use a benchmark approach as our key study endpoint.

Does that make sense?

CHAIRPERSON FROINES: Yeah.

Two things: I want to give Carolyn a chance to say something, before -- because we are going around our table here. But I think Paul -- I want to reemphasize Paul's point.

There was much more tension between ourselves and DPR at one point in history. That's changed dramatically. And so I think this would be a very good time for OEHHA and DPR to look at that OP issue again in a much better environment, and at some point in the future come back and say, "Here's what we think," if that would be acceptable to you guys.

Stan.

PANEL MEMBER GLANTZ: Just one quick -- I think the point that Paul made about the use of the benchmark as the backup and those things, those are the kind of things I didn't get when we reading the report. And I would urge you to just integrate -- you know, that's sort of getting to the point of clarification I made earlier. So I think the kind of way he presented it you might be able to get out of the transcript to make the changes in the report. And I think the -- the use of the thing in a confirmatory way, that was another thing I was confused by. And I think that really strengthens the number you came up with.

CHAIRPERSON FROINES: I just wanted -- I say that

we're going to give it to Carolyn and then I go back and talk some more.

PANEL MEMBER BLANC: At least you're consistent.

PANEL MEMBER GLANTZ: What's new? Yes, you're consistent.

(Laughter.)

PANEL MEMBER BLANC: Your coefficient of variation is much less than 10 percent.

PANEL MEMBER GLANTZ: It's vanishingly small.

CHAIRPERSON FROINES: The meanness is with the Panel, not with the agency relationship.

(Laughter.)

CHAIRPERSON FROINES: I forgot what I was going to say.

PANEL MEMBER GLANTZ: I think Craig wanted to say something.

CHAIRPERSON FROINES: Oh, I know. I did want to say that we -- without going through the long litany of the weaknesses, particularly statistic, about the NOEL approach, obviously it seems to me that if we can use benchmarks, that that is the better way to go in the long term. So that would be like a charge I think we would all agree with, that the benchmark gives you a much better sense of the dose response relationship. And the NOEL is what we've been doing since FDA looked at these issues

with how much crud can we allow in food in the fifties. And so that -- enough said.

Carolyn.

DPR ASSOCIATE TOXICOLOGIST LEWIS: Okay.

CHAIRPERSON FROINES: I'm sorry.

PANEL MEMBER BYUS: I just want to make one comment. And that was a -- as I recall from the workshop, which I recall an cholinesterase inhibition in organophosphates, it was very illuminating. And there were a lot of issues in there. One of them, as I'm recalling now, wasn't how you do the assays for cholinesterase. But there's various ways to do it and that had less variation.

And so that is a factor that you really would want to apply in deciding which data to include in these calculations. And I don't think that was ever -- I mean that would be something really worthwhile to factor in in some standardized way, that certain assays had inherently less variation and were more accurate, as I recall, than others, certain ways of doing the assays based on the individual data that was provided.

And the other factor is the end. I mean you can have more variation and have a lot of significance depending on how many values are there. So I mean you don't want to ignore that fact.

DPR ASSOCIATE TOXICOLOGIST LEWIS: Yeah.

PANEL MEMBER BYUS: Just because it this you're -- this approach of the variance doesn't get to the end in a study, does it?

DPR ASSOCIATE TOXICOLOGIST LEWIS: No. I mean the standard deviation sort of takes care --

PANEL MEMBER BYUS: Right. So I mean, you know, the end is another thing. So I mean I think there's a lot -- I'm just -- let's say what Dr. Froines said, that I think it would be a good idea to revisit that issue -- those issues in a standardized way.

DPR ASSOCIATE TOXICOLOGIST LEWIS: The --

PANEL MEMBER BYUS: Because there are still a fair number of organophosates out there and this would be of value.

DPR ASSOCIATE TOXICOLOGIST LEWIS: Yeah, yeah.

The variation -- or the -- and the methodology actually came up when we were working on the cholinesterase policy before. And you look at plasma data and you look at RVC data, and you see a lot of variation in those, some of which I think with the plasma is due to physiological factors. With the RBC more methodological factors come into play because the hemoglobin can interfere with a chromatic assay because they read it at a wavelength where it can interfere. So, you know, a lot of

that -- and then it turns out the brain usually has the least variation -- the whole brain has the least variation.

CHAIRPERSON FROINES: But it's still true that we never did resolve the RBC plasma issue. That's still sitting out there. And if the criteria was only brain cholinesterase, I think you'd find this Panel would be in disagreement with that as the only endpoint that would be appropriate. And I think that's a fair statement.

DPR ASSOCIATE TOXICOLOGIST LEWIS: Yeah. I think we are now including the plasma in RBC as an endpoint in our risk assessments.

CHAIRPERSON FROINES: Good. This is a very good discussion.

OEHHA AIR TOXICOLOGY AND EPIDEMIOLOGY SECTION MANAGER MARTY: One other little point to partially address Craig. If you use the benchmark dose approach, you can account somewhat for sample size, because you're doing that -- like the hood estimate, if you use that lower bound on the slope of that dose response, you are implicitly accounting for our difference in sample size a little bit. But you're right though, that it's a little -- you get nervous when you look at the sample size of some of these studies.

PANEL MEMBER BYUS: That's right, exactly. I

mean the sample size --

OEHHA AIR TOXICOLOGY AND RISK ASSESSMENT UNIT

CHIEF SALMON: It's one thing to have a statistical remedy for the problem and another to feel comfortable about it actually.

(Laughter.)

CHAIRPERSON FROINES: Shall we move on.

Were you going to say something?

PANEL MEMBER BLANC: No, let's move on.

CHAIRPERSON FROINES: Thanks, Melanie and Andy.

That's the way we should have these discussions.

--o0o--

DPR ASSOCIATE TOXICOLOGIST LEWIS: Okay. So both DPR and OEHHA agreed to use the two-week NOEL from the 90-day study for an acute NOEL. And I just had this table here just as a refresher to show the magnitude of inhibition that was seen in the 90-day study. The most severe inhibition was seen usually at the 13-week terminal sacrifice. I also have included in this table though the inhibition in the cortex at two weeks as a point of comparison.

There was some concern about using the NOEL from this study, the lowest dose level, because there appear to be some reduction in activity at this dose level. However, I should point out that these reductions were

within the normal variation for regional brain cholinesterase.

--o0o--

DPR ASSOCIATE TOXICOLOGIST LEWIS: Okay. So the evidence supporting the use of the two-week NOEL of .18 milligrams per kilogram from the 90-day study for the acute NOEL was that the BMD responses were the same for the cholinesterase inhibition in the cortex at 1.5 hours in the acute study, which was the time of peak effect, and at two weeks in the 90-day study.

Also, the CV for the cholinesterase activity in the cortex in the controls at two weeks was low. It was 9 percent. And so the statistical analysis at this time point should be very sensitive -- or fairly sensitive, I should say.

The NOEL at two weeks is also similar to the BMDL at 10 percent that U.S. EPA calculated for Methidathion, which was based on whole brain cholinesterase data from the two-year rat study. And this was done as part of the cumulative risk assessment for OPs.

And, finally, the two-week NOEL is fairly similar to the lowest chronic NOEL that was seen in the one-year dog study. Now, that NOEL was actually based on liver toxicity. There was a slightly higher NOEL in the two-year rat study of .17 that was based on cholinesterase

inhibition.

--o0o--

DPR ASSOCIATE TOXICOLOGIST LEWIS: Okay. Well, that's interesting.

Those are supposed to be microgram -- those little computers symbols.

Anyway, this is a summary of the revised exposure assessment -- or revised exposure estimates for Methidathion. Most of the changes are in the application site estimates because of a surrogate study now being used for estimating exposure. The surrogate study was used because the study for Methidathion had samplers that were not downwind at the time of the study. And this study had samplers. It was a methyl parathion study in a walnut grove done in 2000 -- in the summer of 2003. And the samplers were all around the field, and the exposure estimates were based on the downwind samplers.

PANEL MEMBER BLANC: Can you point out to us in the draft document what page that piece was on -- I mean you've got it here, but --

DPR ASSOCIATE TOXICOLOGIST LEWIS: Oh, where you'd find that in my document?

PANEL MEMBER BLANC: Yeah, in the big document.

DPR ASSOCIATE TOXICOLOGIST LEWIS: Okay. Let me see. Give me a minute.

CHAIRPERSON FROINES: While they're looking for that, do you anticipate -- Randy will give my answer -- that this dramatic drop in Methidathion use is going to continue and that it's going to slowly but surely be not a pesticide of choice over time?

DPR SENIOR ENVIRONMENTAL RESEARCH SCIENTIST SEGAWA: Yes. Randy Segawa with the DPR.

Yes, the use for Methidathion should continue to decline because, in addition to the health effects, we also have environmental concerns with that particular pesticide as well as all other organophosphates particularly on orchards.

CHAIRPERSON FROINES: And does that relate to the water issues?

DPR SENIOR ENVIRONMENTAL RESEARCH SCIENTIST SEGAWA: Correct.

DPR ASSOCIATE TOXICOLOGIST LEWIS: Okay. This discussion is on page 91 in the health risk assessment. And the table is basically Table 31 in the the document. It's on page 92.

PANEL MEMBER BLANC: So I have a couple reactions to this. One is that I thought it was a much better approach certainly to try to find a surrogate exposure sampling data event rather than simply saying, "Well, we only have these data for this specific chemical when there

were no downwind samplers." So I think that's great.

DPR ASSOCIATE TOXICOLOGIST LEWIS: Um-hmm.

PANEL MEMBER BLANC: And there is another organophosphate. I'm assuming -- and you adjusted for the usage level --

DPR ASSOCIATE TOXICOLOGIST LEWIS: Yeah, application.

PANEL MEMBER BLANC: -- one would to an active ingredient.

I'm assuming also that you had reason to believe that the physical properties of the two organophosphates were similar enough that the application of the alternative organophosphate should be a reasonable model for application of this organophosphate in terms of this sort of general physical properties of the material?

DPR ASSOCIATE TOXICOLOGIST LEWIS: Yeah. Now, Cheryl was the one who evaluated that study. But my understanding was she took the physical properties of methyl parathion into account and compared them with Methidathion and thought they were reasonably similar, that it made a good surrogate.

PANEL MEMBER BLANC: I think -- and the reason why I asked you to point out the page where this is, I don't think that is stated either implicitly or explicitly.

DPR ASSOCIATE TOXICOLOGIST LEWIS: Not in my -- I think it's in her document. I can -- I can add it to mine.

PANEL MEMBER BLANC: I think it needs to be there. And I think that it needs to be in our findings in so far as they touch upon the -- you know, we talk about the substitution, but -- we say that it's a reasonable model because the physical -- the physical properties were similar?

We certainly talk about the rationale because we didn't have decent data for the other.

DPR ASSOCIATE TOXICOLOGIST LEWIS: Yeah. Okay.

Yeah, I'll make sure that gets in --

PANEL MEMBER BLANC: Right, because if the -- what was it that you -- you did use methyl parathion? No.

CHAIRPERSON FROINES: Yes.

PANEL MEMBER BLANC: Is that right?

DPR ASSOCIATE TOXICOLOGIST LEWIS: Yes.

PANEL MEMBER BLANC: Yeah. I mean if methyl parathion, for example, were five times more volatile then the material in question, then it wouldn't -- you'd have to have a factor of 5 or something to adjust for it, right?

DPR ASSOCIATE TOXICOLOGIST LEWIS: Yeah, yeah.

PANEL MEMBER BLANC: You wouldn't know whether it

was at the edge of the field or -- whatever.

DPR ASSOCIATE TOXICOLOGIST LEWIS: Yeah. You know, unfortunately I don't have sheryl's document to confirm that it's in hers. But I was fairly sure I remembered her talking about the similarities in the physical properties between the two chemicals.

Okay. So anymore --

PANEL MEMBER BLANC: No, I just -- in principle I'm very pleased that you did this, because the other approach really didn't sit well, just saying, "Well, we actually don't have good data, but we'll use the data that we have," which is where we were at before. So this is a much more reasonable approach. And I would just like to see those dots connected with the other.

DPR ASSOCIATE TOXICOLOGIST LEWIS: Yes.

Okay. So, mainly the values that the application --

CHAIRPERSON FROINES: Would you just as a practical note, when you put that sentence or two or three in to your document, would you send it to me by e-mail, and I'll incorporate it into the findings --

DPR ASSOCIATE TOXICOLOGIST LEWIS: Oh, for your findings.

CHAIRPERSON FROINES: -- and that way we don't have to -- I don't have to try and be as creative as a

writer.

(Laughter.)

CHAIRPERSON FROINES: Because then I'll get comments back from the Panel.

DPR ASSOCIATE TOXICOLOGIST LEWIS: I may borrow it from Cheryl too.

(Laughter.)

CHAIRPERSON FROINES: Thanks.

DPR ASSOCIATE TOXICOLOGIST LEWIS: Okay. So the exposure values estimates at the application site were revised, mainly due to this surrogate study. But also seasonal and chronic exposure estimates were added for the application site, which was requested by the Panel.

The ambient exposure values basically didn't change.

--o0o--

DPR ASSOCIATE TOXICOLOGIST LEWIS: So these are the revised MOEs for the application site and the ambient air. I also added a percent RfC calculation here as another way to look at the -- or interpret the acceptability of the exposures.

The MOEs again mainly changed at the application site primarily because of the surrogate data, but also because the acute NOEL had changed. And then, again, there were now seasonal, chronic MOE calculations.

There is concern about the acute exposure at the application site, because the MOEs are less than 100 or the exposures were greater than 100 percent of the RfC. The MOEs at the application site for seasonal chronic exposure were greater than 100. However, they still represented less -- or more than 10 percent of the RfC, prompting its consideration as a toxic air contaminant.

CHAIRPERSON FROINES: Carolyn, can I make -- this is a little bit off topic, but it's not entirely.

When I was writing the -- working on the findings, I went looking for a table of the RfCs. And I had one from OEHHA. But I found, if I'm -- unless I missed something, and I may have missed it -- I found the RfCs as a footnote in a larger table. But there was no RfC table.

DPR ASSOCIATE TOXICOLOGIST LEWIS: Oh, there is one. There's a section called the reference dosed concentration section at the end.

CHAIRPERSON FROINES: Could you tell me where that is, because I clearly then missed it.

DPR ASSOCIATE TOXICOLOGIST LEWIS: Yeah. Well, it's also in the summary too. If you look in the summary, there's a table.

CHAIRPERSON FROINES: I didn't look at summaries.

DPR ASSOCIATE TOXICOLOGIST LEWIS: Okay. Page

124, 125 is a calculation of reference doses and concentrations. And there's Table 46.

CHAIRPERSON FROINES: Well, then okay. Forget it. It's my fault. I used the OEHHA one. So unless you have an objection, just for the sake of argument, I'll just leave it the way it is unless there's something wrong with your view of their table.

PANEL MEMBER BLANC: Are you talking about in the findings?

CHAIRPERSON FROINES: Yes.

PANEL MEMBER BLANC: As the appendix to the findings?

CHAIRPERSON FROINES: Yes.

DPR ASSOCIATE TOXICOLOGIST LEWIS: All right. So there's less concern about the ambient air exposure because the MOEs were greater than a thousand and -- or an exposure represented less than 10 percent of the RfC.

--o0o--

DPR ASSOCIATE TOXICOLOGIST LEWIS: Since chronic exposure estimates were now calculated for the application site, cancer risk estimates were then calculated for the application site. The cancer risk estimates range from 2.5 times 10 to the minus 5th to 3.9 times 10 to the minus 5th. These are an order of magnitude higher than those that were calculated for the ambient air. Those values

for ambient air did not change from the previous draft.

However, the cancer risk for both the application site and ambient air are of concern because they're greater than the negligible risk level.

--o0o--

CHAIRPERSON FROINES: This is a good example of a tension that we had two, three, four, five years ago where there was debate about ambient versus application site monitoring. So this was an issue, and this is dealt with well I think.

DPR ASSOCIATE TOXICOLOGIST LEWIS: Okay. There was no toxicity data for the oxon of Methidathion. We contacted the registrant to see if they had any a data they just had not submitted to us. They said they'd never conducted any studies because the oxon had not been included in the tolerance for Methidathion. Apparently U.S. EPA considered the oxon of Methidathion a minor plant metabolite, therefore did not include it in the tolerance.

However, U.S. EPA has become concerned about the contribution of Methidathion to drinking water exposure when they did their cumulative risk assessment. And they assumed that the oxon was 10 times -- or 100 times as toxic as the parent. And I thought this was an interesting exercise. So I decided to see what would happen to the MOEs if I made similar assumptions about the

oxon. And so these are what the exposure estimates would be if the oxon was 10 times or 100 times as toxic.

And the biggest effect is on the ambient air exposure, because the oxon contributed more to the total exposure in ambient air compared to the application site.

PANEL MEMBER BLANC: And this is the -- I'm sorry. Paul Blanc here.

The numbers that you're providing here in this table are the MC -- I'm sorry, I've got the initials wrong, but the --

DPR ASSOCIATE TOXICOLOGIST LEWIS: -- MOEs?

PANEL MEMBER BLANC: -- the MOEs?

DPR ASSOCIATE TOXICOLOGIST LEWIS: Yes, yes.

PANEL MEMBER BLANC: These are the MOEs.

So therefore the MOE for infants of 93 is less than 100?

DPR ASSOCIATE TOXICOLOGIST LEWIS: Yes, yes.

PANEL MEMBER BLANC: And the other is right at 100 for infants?

DPR ASSOCIATE TOXICOLOGIST LEWIS: Yes.

PANEL MEMBER BLANC: And, in fact, if you looked at as a percentage of the RCD -- RCD?

DPR ASSOCIATE TOXICOLOGIST LEWIS: Yes.

PANEL MEMBER BLANC: -- for adults, although the MOE is 200, it would be 20 percent of the MCD, would it

not?

DPR ASSOCIATE TOXICOLOGIST LEWIS: Sounds about -- yeah.

PANEL MEMBER BLANC: Something like that?

DPR ASSOCIATE TOXICOLOGIST LEWIS: Yeah.

PANEL MEMBER BLANC: But that was a good relationship that you were doing.

So I think this is extremely important. And although I think the findings -- well, first of all, you said you did this. Is this in the document?

DPR ASSOCIATE TOXICOLOGIST LEWIS: This is in the risk appraisal section. I didn't put it up front further because it is very hypothetical.

PANEL MEMBER BLANC: But it's in the document, is it?

DPR ASSOCIATE TOXICOLOGIST LEWIS: It's in the risk appraisal section, sort of a what-if, you know.

PANEL MEMBER BLANC: Right.

I would suggest, John, in terms of the findings, because I know that our findings talk about there really aren't data for the ox -- this is all -- may not be conservative enough because the oxon doesn't have good data. I'd actually like to see the findings explicitly say that if one assumes 100 times greater potency of the oxon, then the ambient extrapolations would indeed fall to

MOE of a hundred or less for infants.

CHAIRPERSON FROINES: This table is in the document?

DPR ASSOCIATE TOXICOLOGIST LEWIS: Yes, in the risk appraisal section. I can -- if you want to know, I can tell you what the table number --

CHAIRPERSON FROINES: No, I can do it.

PANEL MEMBER GLANTZ: You don't need to go to a 100. And in some cases even with a 10 times assumption you get below an MOE of 100.

DPR ASSOCIATE TOXICOLOGIST LEWIS: Yeah. Well, as it -- we were already below 100 without even assuming, I mean 10x for the acute exposures. But it does push some of the ambient airs down below a thousand, you know, which is I think maybe more.

CHAIRPERSON FROINES: This is maybe a question for Roger.

But do you have any sense of how rapidly the Methidathion is transformed atmospherically to the oxon? In other words, when we actually talk about Methidathion, are we making an error in judgment that that's the chemical that people are being exposed to?

PANEL MEMBER ATKINSON: If the Methidathion is totally in the gas phase, its lifetime will be on the order of a couple of hours at most. And a certain

fraction of it will be transformed to the oxon.

CHAIRPERSON FROINES: So what --

PANEL MEMBER ATKINSON: Over a time period of something -- depending on the time of day, it could be -- noon time presumably could be an hour or so.

PANEL MEMBER BLANC: Well, that just relates to .6 in the findings.

PANEL MEMBER ATKINSON: Yeah, which needs -- well, 6 needs to be moved. But, yeah, that's right.

CHAIRPERSON FROINES: Point 6 --

PANEL MEMBER BLANC: And I think that John --

PANEL MEMBER ATKINSON: Six needs to be amalgamated with 8 in the final end spot.

PANEL MEMBER BLANC: So it's somewhere between .8 hours and two days?

PANEL MEMBER ATKINSON: Well, I didn't put the two days, but --

CHAIRPERSON FROINES: The point about -- you see, the problem with finding 6 -- and I'm sorry, Carolyn, for back and forth here. The problem with 6 is that it doesn't draw the conclusion that Paul is raising with this other point, which is that it's entirely possible -- well, we do say it in the findings that we may be underestimating toxicity because of this. But I wonder

if -- do we need something in 6 that's more specific to the fact that we -- well, we do say it later, so maybe it's fine.

PANEL MEMBER BLANC: Well, I mean I think what we should do is logically come back after we complete this to the findings and sort of go through more systematically.

CHAIRPERSON FROINES: Right, right, right.

Let's go ahead, Carolyn.

DPR ASSOCIATE TOXICOLOGIST LEWIS: Okay. There's just one other point I wanted to make.

In U.S. EPA's cumulative risk assessment they noted that they only had toxicity data for two -- for the oxons of two OPs. That was chlorpyrifos and methyl parathion. And in both cases the OPs were less -- the oxons, excuse me -- were less than 10 times as toxic as the parent. So that perhaps the 100x assumption is maybe excessive but not the 10x.

CHAIRPERSON FROINES: This is a rhetorical statement, and I apologize for it. But it does seem slightly absurd that EPA doesn't spend more time looking at the toxicity of these oxons. I mean here we have -- this comes up repeatedly where you have a sulfur going to an oxygen and nobody's studying the right compound, perhaps.

DPR ASSOCIATE TOXICOLOGIST LEWIS: They

apparently have requested data on the oxon of Methidathion now as a result of that cumulative risk assessment, from what I understand. But we haven't seen any of the data for it yet.

CHAIRPERSON FROINES: It's crazy, isn't it?

--o0o--

DPR ASSOCIATE TOXICOLOGIST LEWIS: Okay. This is the table with the critical NOELs, the endpoints, and the corresponding reference doses and concentrations that were used in the risk assessment. That was that table, I think it was 46, in the back of the document. And it's also been in the summary too. And that was just to summarize it in a clear fashion.

--o0o--

DPR ASSOCIATE TOXICOLOGIST LEWIS: And then I just want to briefly mention some other minor changes to the document that were requested by the Panel.

One was a discussion was added to the weight of evidence for carcinogenicity regarding the potential genotoxic metabolisms.

The term "oncogenicity" was changed to carcinogenicity since more people were familiar with that term.

The environmental fate section was reduced to a few paragraphs since much of this information was

redundant since there's a environmental fate document.

And, finally, although not requested by the Panel, a summary of U.S. EPA's 2006 update to the cumulative risk assessment for OPs was added to the risk appraisal section.

And that concludes my presentation.

CHAIRPERSON FROINES: Thank you.

Roger Atkinson and Charles Plopper were the leads on this compound. So I guess what I'll ask them is: Do you have anything more to add at this point?

PANEL MEMBER ATKINSON: I had a fair number of comments which I sent up to Cheryl before Christmas. I Fed Ex'd the whole thing with red ink over it. I haven't heard anything more. So I have no idea what happened.

DPR ASSOCIATE TOXICOLOGIST LEWIS: I think she did receive them. I think she just hasn't had time to start working on them. So she had higher priorities. I assume she'll address them and --

CHAIRPERSON FROINES: Well, let me ask a question. Since obviously we're going to be discussing findings and yet we've already had discussion about some relatively minor changes that we'd like you to make, the question for Roger is: Can we go ahead with tentative approval of the document recognizing that his comments have not been incorporated?

PANEL MEMBER ATKINSON: Yeah, they're all -- they were relatively minor. I called -- I also talked with Cheryl over a couple of things where there was some, let's call them, typographical errors, which we resolved the problem on that.

But then I added this bunch of -- some were mainly editorial, but they don't -- they're fairly minor. So I could go ahead, with the understanding that these changes will get made.

CHAIRPERSON FROINES: Tobi.

DPR ASSISTANT DIRECTOR JONES: This is Tobi Jones.

Roger, I understand from Cheryl that she had received your comments and had no problem with those. And so we will be making changes to those sections of the document.

CHAIRPERSON FROINES: So if you're comfortable and Roger's comfortable, then I think we're okay.

Charlie.

PANEL MEMBER PLOPPER: Yeah, there was -- I think that discussion earlier about how the benchmark was established, that needs to be clearly in there. But I didn't have any other comments.

I did -- one thing that was of concern was in the exposure document. It really doesn't explain, well, to

me, why -- unless I didn't find it. I've looked for that earlier, methyl parathion, why this was a comparable study, because it only has one sentence in there on page 23 of her document. And I think some -- it needs to be in both documents, it needs to be explained

CHAIRPERSON FROINES: So one point that -- one major point is that there needs to be a discussion of the methyl parathion vis-a-vis Methidathion -- the chemical -- and in the health effects document as well as the exposure document.

And, again, I would ask Paul and you the same question: Is that change something that the Panel wants to have come back to it prior to approval or is it something that could be made without hindering the approval process?

PANEL MEMBER BLANC: No, no. My point would rather be that I want the findings to also say that clearly in the appropriate section. So I don't want that to be an ellipse in the findings. That's okay with me if we haven't seen their exact wording. Although I think you had the commitment that it would be sent to you so that we corresponded. I don't need to see a revised document. But I do want the findings to reflect the content, which is that the physical properties of the -- the surrogate marker were appropriate to use it in that manner.

CHAIRPERSON FROINES: Well, I agree. What I'm trying to do is to create a record so that everybody is in agreement on the record. And that I believe that in fact you can't have it in the findings unless it's in the document --

PANEL MEMBER BLANC: Well, I think we've been assured that it will be put in to the document, so that satisfies me.

CHAIRPERSON FROINES: All right. I'm just double checking to bring to closure.

PANEL MEMBER GLANTZ: Say yes.

DPR ASSOCIATE TOXICOLOGIST LEWIS: Oh, yes. I didn't know.

Okay. Yes.

CHAIRPERSON FROINES: No, I wanted Paul to say yes. And he's niggly-wiggling here. And so I -- we're fine.

So in terms of other Panel members.

Stan?

PANEL MEMBER GLANTZ: I'm fine.

CHAIRPERSON FROINES: You're fine.

You raised a number of questions earlier.

PANEL MEMBER GLANTZ: Yeah, they've answered them.

CHAIRPERSON FROINES: Kathy?

PANEL MEMBER HAMMOND: Okay.

CHAIRPERSON FROINES: Craig?

PANEL MEMBER BYUS: Fine.

CHAIRPERSON FROINES: Joe?

PANEL MEMBER LANDOLPH: Yeah, I sent my comments June 23rd, 2006 --

UNIDENTIFIED SPEAKER: I can't hear you.

PANEL MEMBER LANDOLPH: Yeah, I sent my comments back in June. They've all been answered.

CHAIRPERSON FROINES: Gary?

PANEL MEMBER FRIEDMAN: I have no major scientific concerns. I did send out some editorial things for readability for the findings, but --

CHAIRPERSON FROINES: We haven't got to the findings yet. So we will --

PANEL MEMBER FRIEDMAN: No problem with the report.

CHAIRPERSON FROINES: So at this stage then, we need a motion to approve the document pending the changes that we've just finished discussing.

PANEL MEMBER BLANC: Is that correct, John? I thought usually we approved the findings. We don't approve the document.

PANEL MEMBER GLANTZ: So moved.

CHAIRPERSON FROINES: No, we approve the

document.

PANEL MEMBER GLANTZ: So moved.

CHAIRPERSON FROINES: We have to approve the document. That's the whole point.

PANEL MEMBER BLANC: I thought that -- Okay, that's fine. Just a clarification.

CHAIRPERSON FROINES: The findings are just what we communicate to the agency.

PANEL MEMBER BLANC: I see.

CHAIRPERSON FROINES: The document is what --

PANEL MEMBER BLANC: Well, then I'll second the motion.

CHAIRPERSON FROINES: The document is what we have to approve. That's our legislatively mandated responsibility.

PANEL MEMBER BLANC: Fine. Then I was confused. I'm sorry.

I second the motion.

CHAIRPERSON FROINES: Any discussion?

All those in favor of approval?

(Hands raised.)

CHAIRPERSON FROINES: The approval is unanimous.

And shall we take a ten-minute break? And then we'll come back and we'll discuss the findings.

(Thereupon a recess was taken.)

CHAIRPERSON FROINES: We'll call the meeting formally back to order.

I don't know whether it's useful to go to the leads to start the discussion on the findings or whether just to go around the room.

PANEL MEMBER GLANTZ: The leads.

CHAIRPERSON FROINES: All right. Let's do that.

Roger.

PANEL MEMBER ATKINSON: Okay. The only ones I've looked at have to do with the atmospheric stuff. So I would like to amalgamate 6 -- or propose to amalgamate 6 and 8. And add some stuff to the first -- at the end of the first sentence in 6 put in ", with an estimated lifetime of a few hours during daylight." And then move all of 6 after the first sentence of 8. Delete the second -- what is presently the second --

CHAIRPERSON FROINES: Wait, wait, wait. So go -- do that a little slower.

PANEL MEMBER ATKINSON: Oh, okay. So move all of 6 after the first sentence of 8.

CHAIRPERSON FROINES: After the hydroxyl radical --

PANEL MEMBER ATKINSON: -- "little is known about the atmospheric fate of" whatever this compound is. And then "in the atmosphere," bring in 6, delete what was

originally the second sentence of 8, and then delete the last three sentences of 8. I don't see any point in all this stuff about travel significant distance.

CHAIRPERSON FROINES: Can I ask you a question?

PANEL MEMBER ATKINSON: Yeah.

CHAIRPERSON FROINES: Are you going to -- two questions: One, are you going to send me some language for 6?

PANEL MEMBER ATKINSON: Yeah, I'll send you a revised 6 amalgamated with 8 now. I'll send you an e-mail.

CHAIRPERSON FROINES: Okay. Now, I have a substantive question. That's procedural.

"Given the" -- the sentence reads, "Given the complexity of the metabolism of Methidathion, further work on the atmospheric products and toxicity is clearly warranted."

PANEL MEMBER ATKINSON: It shouldn't be metabolism. It should be -- well, given complexity of Melathion's

CHAIRPERSON FROINES: Methidathion's --

PANEL MEMBER ATKINSON: Or Methidathion. I'm sorry.

-- further work on --

CHAIRPERSON FROINES: Methidations's what?

PANEL MEMBER BLANC: Breakdown, isn't it?

PANEL MEMBER ATKINSON: Yeah, degradation.

"Given the potential complexity of the degradation" -- "environmental degradation of Methidathion" -- or "atmospheric degradation of Methidathion" --

CHAIRPERSON FROINES: Okay. You'll send --

PANEL MEMBER ATKINSON: I'll send that --

CHAIRPERSON FROINES: You'll send that to me?

PANEL MEMBER ATKINSON: I will indeed, yes.

CHAIRPERSON FROINES: Because I do want to say that further research on the products is necessary.

PANEL MEMBER ATKINSON: Yeah. Never be done. But, yeah, sure.

CHAIRPERSON FROINES: But I think that we need to call attention to where there may be other toxic products of concern.

PANEL MEMBER ATKINSON: Sure.

CHAIRPERSON FROINES: Okay?

PANEL MEMBER ATKINSON: That's all I have, because those are the only two I looked at.

CHAIRPERSON FROINES: Good.

PANEL MEMBER ATKINSON: Since I got one whole -- sure.

CHAIRPERSON FROINES: Charlie.

PANEL MEMBER PLOPPER: Well, I think on 9 and 10 there need -- we need to address that issue of why the exposure to methyl parathion was used as a substitute in terms of what we discussed earlier. But it's not in the other document either. So --

CHAIRPERSON FROINES: So she's going to fix that and send it to us. And I'll edit it.

What would you like to do? Would you like me to send the revised findings to the Panel for final approval, and then I'll send them off from there?

PANEL MEMBER BLANC: Yes.

PANEL MEMBER ATKINSON: Yes.

CHAIRPERSON FROINES: So that's our plan of action.

So we're going to get material from DPR on the 9 and 10 issue that you just raised. And then you'll see it again before the document goes out.

PANEL MEMBER BLANC: And I would actually suggest that 9 and 10 be one point. It will avoid some confusion.

CHAIRPERSON FROINES: Yeah, that's what he said.

PANEL MEMBER PLOPPER: Yeah, that's -- I agree.

CHAIRPERSON FROINES: And would you remember to send an e-mail to me saying combine them?

PANEL MEMBER PLOPPER: Yes.

PANEL MEMBER ATKINSON: Oh, I had one more

actually.

I think number 5 should be moved after the present number 7. Then all the environmental -- it will be together. Five will become 7, and 6 and 8 would be combined into what is presently 8.

CHAIRPERSON FROINES: Well, then I would move 7 down to where we're starting to talk about health effects down at 11, because 7 is really about health effects and it doesn't belong where there -- so I'm going to move 7 to the previous -- 7 before 11.

PANEL MEMBER ATKINSON: Okay. That solves that problem then.

CHAIRPERSON FROINES: And what did you want to do?

PANEL MEMBER ATKINSON: No. In that case, having done that, that's okay. If you moved 7, that's fine.

CHAIRPERSON FROINES: Okay. Charlie.

PANEL MEMBER PLOPPER: I was pretty happy with the rest of it. I think it questions how much detail to put in there. But I think if we have that -- we might want to add a section in here when it gets into the document about the approach to the benchmark and selecting the doses. But otherwise I don't have too much more to comment on this.

CHAIRPERSON FROINES: How do people feel about

that? Do you want to add a section on the benchmark methodology?

PANEL MEMBER PLOPPER: I was trying to figure out where to put it in here, just because it's such a confusing issue.

PANEL MEMBER BLANC: I thought it was in there where --

PANEL MEMBER PLOPPER: Well, I didn't -- well, maybe, but -- it talks about MOE and MLE and --

CHAIRPERSON FROINES: I would almost suggest that we wait on the OEHHA DPR document that's going to come a little bit later -- not too much later hopefully -- that will clarify that as a statement of policy.

Is that reasonable, Tobi, rather than put it in these findings?

PANEL MEMBER GLANTZ: I think that's --

PANEL MEMBER PLOPPER: That's a better idea. Yeah, that's a much better idea.

PANEL MEMBER GLANTZ: Yeah, it's really a separate issue. So I don't think it should go in these findings.

PANEL MEMBER BLANC: Well, I think I would argue that there should be a statement here that although it did not drive the findings, a very similar value was arrived at using a modified benchmark approach.

PANEL MEMBER GLANTZ: I agree with that. I thought you were saying something different.

CHAIRPERSON FROINES: Do you want to draft that?

PANEL MEMBER GLANTZ: I thought you were raising the issue generally. I think putting in what Paul said is a good idea.

CHAIRPERSON FROINES: Go ahead. What were you saying?

PANEL MEMBER BLANC: I thought it was in here. So...

CHAIRPERSON FROINES: I don't think it is.

PANEL MEMBER PLOPPER: No, I didn't see it in here.

Maybe just a statement that -- because they match. We could probably do that.

CHAIRPERSON FROINES: A statement that what?

PANEL MEMBER PLOPPER: Just what Paul said, I think would be to put it in somewhere maybe at the end of the discussion of MOEs, like 18.

CHAIRPERSON FROINES: Carolyn, would you send me a sentence or two that says that the basis of the -- the ultimate basis was the -- what am I trying to say?

PANEL MEMBER GLANTZ: -- was the LOEL?

CHAIRPERSON FROINES: -- was the benchmark.

PANEL MEMBER GLANTZ: No, it wasn't the ultimate

basis.

CHAIRPERSON FROINES: It wasn't. You're right. Was the --

PANEL MEMBER BLANC: Where it needs to be, John, is --

CHAIRPERSON FROINES: -- is a conclusory sentence.

PANEL MEMBER BLANC: It's in point 14 where we say, "The no-effect level" -- this is where it should be -- "selected for evaluating acute exposure was .18 milligrams based on the reduction of acetylcholinesterase in the cerebral cortex of male rats."

CHAIRPERSON FROINES: Well --

PANEL MEMBER BLANC: There should be a sentence that follows that says, "However, a similar value was obtained using" --

PANEL MEMBER GLANTZ: -- benchmark methodology.

PANEL MEMBER BLANC: -- "a modified benchmark methodology."

CHAIRPERSON FROINES: However, a --

PANEL MEMBER GLANTZ: Well, I wouldn't say, "However." I would just say, "A similar value is obtained using benchmark methodology."

CHAIRPERSON FROINES: Is that okay with you?

DPR ASSOCIATE TOXICOLOGIST LEWIS: You would say

something, that this corresponds to the benchmark dose response at 15 percent if you want to --

CHAIRPERSON FROINES: Well, wait a second. No, I'm writing down what I'm going to put in. And you're talking faster than my brain can function.

So I'm saying, "A similar value was obtained" --

PANEL MEMBER BLANC: -- using benchmark methodology. And I think that's enough.

CHAIRPERSON FROINES: You're too close to it. You wanted to add the complexity.

DPR ASSOCIATE TOXICOLOGIST LEWIS: Be specific, yeah.

CHAIRPERSON FROINES: Thanks.

So far I'm expecting material from you and from Roger. So that's -- I just need to remember that.

All right. Randy.

DPR SENIOR ENVIRONMENTAL RESEARCH SCIENTIST SEGAWA: Excuse me, yeah.

Lyn Baker just pointed out that Finding No. 9 is factually incorrect.

Finding No. 9 is referring to ambient air monitoring. But it should be referring to the application site monitoring at the walnut orchard as in Finding No. 10.

CHAIRPERSON FROINES: Should I take out 9?

DPR SENIOR ENVIRONMENTAL RESEARCH SCIENTIST SEGAWA: You could take out 9 or combine it with 10.

CHAIRPERSON FROINES: What?

DPR SENIOR ENVIRONMENTAL RESEARCH SCIENTIST SEGAWA: You could either take out 9 or combine 9 and 10.

CHAIRPERSON FROINES: We already did that.

PANEL MEMBER BLANC: You're just saying it's not ambient. You mean its application site monitoring, not ambient air monitoring?

DPR SENIOR ENVIRONMENTAL RESEARCH SCIENTIST SEGAWA: Yeah. Actually that first sentence in number 9 after the comma where it says, "but unanticipated changes in meteorology," that part is the part that's incorrect.

CHAIRPERSON FROINES: So take out "but unanticipated... made it likely that the monitoring did not capture the highest concentrations"?

DPR SENIOR ENVIRONMENTAL RESEARCH SCIENTIST SEGAWA: Correct.

CHAIRPERSON FROINES: But it's --

PANEL MEMBER PLOPPER: No, it's ambient --

DPR SENIOR ENVIRONMENTAL RESEARCH SCIENTIST SEGAWA: That's the part that's true about --

CHAIRPERSON FROINES: But is it the meteorology that is the issue or is it --

PANEL MEMBER PLOPPER: No, it's the type of

monitoring.

PANEL MEMBER BLANC: Randy, are you trying to say that in fact there are two separate things: One is that there is ambient monitoring, which we did use which is based on four sites in June and July; and in addition to that there's a sentence missing which says, "Site monitoring which had been done in 1993" -- or something, I don't know what it was -- "was unacceptible because of the meteorology"?

DPR SENIOR ENVIRONMENTAL RESEARCH SCIENTIST SEGAWA: Correct.

PANEL MEMBER BLANC: So actually I think that -- do you follow that?

Well, there is ambient data that is used that's based actually on the actual product. And then there was -- in addition to that there was site monitoring which we couldn't use because of the meteorologic. And that's from a different date and a different site.

CHAIRPERSON FROINES: Well, let me just say, application -- is it application --

PANEL MEMBER BLANC: No, that was ambient --

CHAIRPERSON FROINES: -- air monitoring -- excuse me.

What's the word? Is it ambient or is it application site?

ARB AIR POLLUTION SPECIALIST BAKER: Lyn Baker from the Air Resources Board.

Dr. Froines, if I could suggest. The phrase that Randy mentioned that's after the comma in 9, that phrase to the period belongs down in point 10. So the rest of 9, "Ambient air monitoring was done at four sites in June and July of '91 for the parent and the oxon," and then the second sentence, "These monitoring data were used to estimate seasonal and chronic human exposure," that's all accurate. But then the part about the --

CHAIRPERSON FROINES: Wait a minute. So it's ambient air monitoring?

ARB AIR POLLUTION SPECIALIST BAKER: Yeah. There's nothing wrong with that. It's the part that says that unanticipated changes in meteorology -- that wasn't about the ambient. That was about the application.

PANEL MEMBER BLANC: And what were the dates of that application monitoring --

ARB AIR POLLUTION SPECIALIST BAKER: In 1992, I believe.

PANEL MEMBER BLANC: And how many -- was that a single application?

ARB AIR POLLUTION SPECIALIST BAKER: This was a single study, yes.

PANEL MEMBER BLANC: A single application --

ARB AIR POLLUTION SPECIALIST BAKER: -- monitoring, which was attempted to be upwind and downwind of a single application.

CHAIRPERSON FROINES: Wait.

(Laughter.)

PANEL MEMBER BLANC: I understand it, John. Let me try to explain it to you again.

CHAIRPERSON FROINES: No, it's not explaining it. I'm trying to write the language that he's giving me. And he's saying it too fast for my pen. We'll assume it's my pen, not my brain.

(Laughter.

CHAIRPERSON FROINES: Go ahead.

ARB AIR POLLUTION SPECIALIST BAKER: So I would just remove that phrase from "but unanticipated," remove that. And then that could go -- well, actually you don't really even need it.

PANEL MEMBER BLANC: Yes, you do, because you have to explain why you had to go to this alternative thing.

ARB AIR POLLUTION SPECIALIST BAKER: That's true. Intent.

PANEL MEMBER ATKINSON: Yeah, you could just move that little section down after "used as surrogates to estimate at bone levels of Methidathion."

PANEL MEMBER BLANC: No, you can't put it there either. You have to have a sentence that says they did the site monitoring which couldn't be used.

ARB AIR POLLUTION SPECIALIST BAKER: Yeah. So you could start --

PANEL MEMBER BLANC: And you have to -- and this is --

CHAIRPERSON FROINES: Okay. Who is going to write this section?

ARB AIR POLLUTION SPECIALIST BAKER: Well, I could --

CHAIRPERSON FROINES: You will write it and you'll send it to me on an e-mail?

ARB AIR POLLUTION SPECIALIST BAKER: Well, I could tell one sentence I think that would just capture it.

CHAIRPERSON FROINES: Well, I don't want to hear any more one sentence telling me. Write it in after -- when you leave the podium here, write it and give it to me and that will be fine.

ARB AIR POLLUTION SPECIALIST BAKER: Will do. Okay.

DPR ASSOCIATE TOXICOLOGIST LEWIS: And of course you still want the sentence in there about the physical properties?

PANEL MEMBER BLANC: Yes, we do.

DPR ASSOCIATE TOXICOLOGIST LEWIS: Because it looks like that's where -- and 10 is where you want the --

PANEL MEMBER BLANC: Yes.

CHAIRPERSON FROINES: Yes. The idea was to combine 9 and 10 and to correct it. That's all.

PANEL MEMBER BLANC: So you want to go around the table, right?

CHAIRPERSON FROINES: That's right. And we left off with whom? I'm sorry.

PANEL MEMBER BLANC: You've done the two leads. And now you're going --

CHAIRPERSON FROINES: We finished the leads. And so why don't we go to Gary, since --

PANEL MEMBER FRIEDMAN: Well, my suggestions were mainly minor changes in wording. And I leave it to you to look at them and evaluate them. For example, if we take -- you know, if we take out -- have the changes that Roger suggested, removing part of 8, then my question about Sequoia National Park no longer applies.

So would you just take these and see in your final draft whether any of them would still apply?

CHAIRPERSON FROINES: Okay. But just for the sake of question, I -- I wrote in the sentence about chromosomal aberrations, because there is a section on

genotoxicity and the data in that section is mixed. But there is -- there was this finding in actual human beings of chromosomal aberrations, so that I thought that it was relevant to have that because it means that there is some human evidence for chromosomal changes.

PANEL MEMBER FRIEDMAN: Oh, but it said men working in fields. You know, exposed to this chemical or -- what fields?

CHAIRPERSON FROINES: I see what your problem is. Your problem isn't conceptual. It's --

PANEL MEMBER FRIEDMAN: Yeah, it's just men working in fields. I mean, yeah, I work in the field sometime, you know. It's just too vague.

CHAIRPERSON FROINES: Yeah, I took it right out of the document. And I'll rewrite it. That's fine.

PANEL MEMBER BLANC: Gary, working field epidemiology, isn't that where you --

(Laughter.)

PANEL MEMBER FRIEDMAN: I've actually sawed off branches and -- you know, on a trail.

(Laughter.)

CHAIRPERSON FROINES: And I'll deal with -- I can deal with all of these.

I do want to add -- this is another epidemiologist. The metabolites -- some of the

metabolites are likely to have electrophilic chemistry where they bind with sulfhydrol groups. And so I'll add the sulfhydrol group and I'll say it's irreversible.

So the implication of the toxicity -- of the potential toxicity is electrophilic chemistry may occur through binding with thiol groups, or DNA for that matter, and with potential irreversible toxicity.

PANEL MEMBER FRIEDMAN: Yeah, I mean that makes it very specific. To me as a non-chemist, just reading "potential electrophilic chemistry" made no sense. But now that's very clear.

CHAIRPERSON FROINES: Yeah. You notice that Charlie was nodding his head when I said that. So this is one of these disciplinary problems of why we need -- why the world needs more chemists.

Okay, Joe.

PANEL MEMBER LANDOLPH: You know, I think it's pretty good. I don't want to add too much to it.

I was kind of intrigued that this is about -- I was kind of intrigued that this chemical is about -- it's about a tenth as carcinogenic as benzopyrene. I don't know whether you want to work that in there or not. They have a beautiful table on page 78. And maybe a comment about the applicators and their risk of oncogenicity might be useful. Very concise.

CHAIRPERSON FROINES: The what?

PANEL MEMBER LANDOLPH: The potential carcinogenic risk to the applicators, which was mentioned in the document.

CHAIRPERSON FROINES: We're not -- we don't deal with occupation.

PANEL MEMBER LANDOLPH: Okay.

CHAIRPERSON FROINES: And I wouldn't want to connect it to benzopyrene, frankly. I think the science on Benzopyrene's a mess. And so that --

PANEL MEMBER BLANC: No one said anything about the Spanish Inquisition. You don't want to mention all these things.

(Laughter.)

CHAIRPERSON FROINES: Every textbook on the carcinogenicity of benzopyrene's wrong.

PANEL MEMBER BLANC: Okay.

(Laughter.)

CHAIRPERSON FROINES: Paul.

I think Joe's done.

PANEL MEMBER BLANC: I have a generic question in terms of the findings that -- and, that is, that it seemed seemed to me these were more wordy than often. And I wanted to know -- you know, longer. They were longer, more detailed comments on various parts. And was

that -- was there a reason for that? Was there a particular reason it was felt in this instance that it needed to be as extensive as it is?

That's a generic question, because it does flavor -- it would flavor my comments a little bit. Because a lot of what -- I have a few specific things I'm going to raise. But my general take on it was that it was very lengthy and sometimes more narrative than it needed to be. And let me -- and that can cause problems.

For example, if you look at point 12.

CHAIRPERSON FROINES: I think the answer to your question is, it's better if we try and deal with it specifically rather than generally, because it makes it impossible to --

PANEL MEMBER BLANC: Let me give you an example then.

CHAIRPERSON FROINES: Let's shorten it. I, for example -- I'll tell you this, I put in number 3, which is sort of a general statement about how exposures were ascertained. I don't think that's necessarily germane. I think that could go. But it was an attempt for clarity.

PANEL MEMBER BLANC: Okay. Well, point 12: Acute, subacute, and chronic toxicity of Methidathion has been evaluated on a variety of species -- stop. I don't need to know that it was chickens and ducks and geese and,

you know, marmots and -- and although you do mention that there were rhesus monkeys, I don't think otherwise there's a point being made that there was another primate -- that it included another nonhuman primate. And unless you think that's important, I would just say a variety of animal species.

And similarly, similar -- "signs of acute intoxication are cholinergic in nature and should be predominantly cholinergic in nature." The problem with listing all those various signs is that some of them aren't particularly in fact cholinergic in nature. And, therefore, it's confusing to me when I read it.

CHAIRPERSON FROINES: Okay.

PANEL MEMBER BLANC: And I think it's sufficient to say similar cholinergic signs occurred following subchronic exposure." Without going...

CHAIRPERSON FROINES: Okay.

PANEL MEMBER BLANC: And then the whole thing on pathological --

CHAIRPERSON FROINES: Wait a second.

Okay. You're pathological.

PANEL MEMBER BLANC: Yeah. So "similar cholinergic signs occurred following subchronic exposure."

And then there's this whole list of various pathological findings. Well, the one we really care --

the only two that we really care about is that pathological observations included reduced brain cholinesterase activity, period.

And I was completely confused by the statement, "With the exception of increased prevalence of hepatotoxicity" -- first of all, you just said in a previous sentence that there were lesions to the liver. I don't know what increased prevalence -- my understanding was it was only in the chronic studies that hepatotoxi -- that the liver appeared to be a target organ. I mean that was the point, right?

CHAIRPERSON FROINES: Right.

PANEL MEMBER BLANC: That was where target organ toxicity --

CHAIRPERSON FROINES: Right.

PANEL MEMBER BLANC: -- was seen.

DPR ASSOCIATE TOXICOLOGIST LEWIS: I think we've seen some evidence in the subchronic studies. But --

PANEL MEMBER BLANC: But it wasn't the most sensitive, it wasn't the target organ. The target organ -- everything else was acetylcholinesterase. In the chronic studies the target organ for toxicity was the liver.

DPR ASSOCIATE TOXICOLOGIST LEWIS: Yeah. And that varied from species to species. Like the rats were

more sensitive to the neurotoxicity and the dogs seemed to be more sensitive to the liver --

PANEL MEMBER BLANC: But the lowest --

DPR ASSOCIATE TOXICOLOGIST LEWIS: Yeah, the lowest.

And the dogs were more sensitive to the liver toxicities.

PANEL MEMBER BLANC: I mean that needs to be -- I think it needs to be said simpler without bringing in all this other stuff that I don't really -- so, for example, what does it mean lesions of the stomach and heart? Why do I care about that? We never deal with it as being a substantive --

CHAIRPERSON FROINES: Good.

PANEL MEMBER BLANC: On 14, when you say Methidathion and its oxygen analog, do you mean its oxon derivitive? Is that what that's supposed to mean?

CHAIRPERSON FROINES: That's what's -- yeah.

PANEL MEMBER BLANC: Okay.

CHAIRPERSON FROINES: Shall we say oxon derivitive?

PANEL MEMBER BLANC: Yeah, I think so if that's what you mean.

And later in that paragraph where it says a significant reduction, I think in a document like this, if

you ever use the word "significant," if what you mean is statistically significant, then you should say statistically significant. Otherwise I don't know whether you mean important or --

CHAIRPERSON FROINES: Where are you at? You lost me.

PANEL MEMBER BLANC: Later in that same point 14, the no-observed effect level was selected for evaluation. It was based on significant -- on a significant reduction in acetylcholinesterase activity in the cerebral cortex. I assume that means a statistically significant reduction. I think that was where that came from.

PANEL MEMBER GLANTZ: No, actually I would just delete the word "significant."

PANEL MEMBER BLANC: One way or the other.

PANEL MEMBER GLANTZ: I mean I agree with you. But I think rather than getting into -- because this is -- this is a common complaint I have about the use of the word "significant" in this kind of context. So I think you could just delete the word and you made the point.

PANEL MEMBER BLANC: Right.

CHAIRPERSON FROINES: Paul, would you delete the sentence that -- it goes, "The cholinergic signs observed in laboratory animals after acute exposure included lack

of muscle" blah, blah, blah, blah, blah. Because those are still more cholinergic.

PANEL MEMBER BLANC: Yeah, everywhere you see that I would just say there were, you know -- or just get rid of the line altogether.

And also, by the way, in a similar vein, on point 7, where -- the end of point 7 and going on to page 3 where it says, "This is an important area for research given evidence for chronic health outcomes including liver toxicity in the dog on a chronic basis as well as ulceration and inflammation of macrophages in the alveoli in a chronic feeding study." First of all, it's not inflammation of the macrophages. That doesn't make any sense at all. You could say -- I mean it could be inflammation because there were macrophages. I don't know what it means.

But since I don't understand what this means and since we don't anywhere else talk about a pulmonary effect from chronic -- the chronic feeding study, which I assume was not the target organ in any event, I mean I don't know -- it just seems it comes right out of blue, unless it's --

DPR ASSOCIATE TOXICOLOGIST LEWIS: Yeah, that caught our attention. We were trying to figure out where that came from too. So I haven't had time to look up

which study that was in. I think it was probably the chronic dog study, but I'll have to look it up.

CHAIRPERSON FROINES: That's why I put it in. What I'm -- the point I was trying to make is that we focused on organo -- on cholinergic effects. But there are apparently other effects of Methidathion that are of more systemic importance.

PANEL MEMBER BLANC: So what I would say is this is an important research area given evidence for chronic health outcomes unrelated to acetylcholinesterase inhibition. That's what you truly seem to be implying, right?

CHAIRPERSON FROINES: Yes.

PANEL MEMBER BLANC: And just leave it at that.

And I have other little word changes, so I'll just give you copies of my own notes on the document and you can see them. Because I don't think -- some of them we've already talked about verbally and the others are just, you know, editorial things that aren't -- I don't want to take up the time of the Panel.

CHAIRPERSON FROINES: I wanted to just make a generic comment about that. I feel that one of the greatest weaknesses in this whole field of pesticides is that -- especially organ -- I mean with organophosphates and others, is that people pay attention to cholinergic

effects, for example, but they don't do research on other systemic effects that may be occurring. And so I wanted to make a point in here that it's -- we have to look beyond simply the cholinergic effects, because that's an oversimplification of the toxicity of these compounds. That was my point.

PANEL MEMBER LANDOLPH: Yes. And following up on your point, at number 16, I wonder if -- I still would like to make a small modification in the last sentence where it says, "As a result the cancer potency was derived and discussed below." Would you consider, "As a result an intermediate cancer potency of 1.5 times 10 to the minus 4," with the units? It just nicely communicates that this compound is in the middle of the range of carcinogenicity; i.e., it's not innocuous. It was a significant carcinogenic potential.

CHAIRPERSON FROINES: You're talking about having in 16 --

PANEL MEMBER LANDOLPH: In 16, the very last sentence, where it says, "As a result a" -- instead of "a" make it "an intermediate" then "cancer potency" like you have, and then just put in parentheses 1.5 times 10 to the minus 4. And --

CHAIRPERSON FROINES: Where's the 4 come from?

PANEL MEMBER LANDOLPH: 1.5 times 10 to the minus

4, that's the unit risk from Table 24 on page 78.

Oh, unless you want to use the 5.3 --

PANEL MEMBER GLANTZ: 16 and 20 should really be combined.

PANEL MEMBER LANDOLPH: Unless you want to use the --

CHAIRPERSON FROINES: No, the risk assessment -- the --

PANEL MEMBER GLANTZ: Okay.

CHAIRPERSON FROINES: -- the hazard characterization is one category and risk characterization's another. And we generally keep them separate.

PANEL MEMBER GLANTZ: Oh, okay.

CHAIRPERSON FROINES: And, Joe, you want me to say, "As a result an intermediate cancer" --

PANEL MEMBER LANDOLPH: That's it, intermediate --

CHAIRPERSON FROINES: -- "and discussed below." But that's not where you would put the unit risk value, because that's -- because the cancer potency is not the unit risk value. Those are apples and oranges.

PANEL MEMBER LANDOLPH: You want the potency factor -- potency it says in Table 24?

CHAIRPERSON FROINES: You can put, "The

carcinogenic risk from exposure of bystanders range from" blah, blah, blah, blah, in 20, and then add a sentence about the unit risk value.

Carolyn, would you -- is that okay with you?

DPR ASSOCIATE TOXICOLOGIST LEWIS: Yeah.

CHAIRPERSON FROINES: You're okay with that?

PANEL MEMBER LANDOLPH: I thought it made more sense to put it in 16.

CHAIRPERSON FROINES: Well, but, see, in 16 you're talking about -- you're talking about the evidence of carcinogenicity. You're not talking about -- that's why we have 20, which is the risk characterization. See, the hazard identification is 16; risk characterization is 20.

PANEL MEMBER LANDOLPH: Oh, okay. I mean -- it could go either place. I don't care. Just so it gets in there somewhere.

CHAIRPERSON FROINES: Well, just following the traditional kind of approach to these things.

In fact, that's an interesting debate. Our findings -- if you took hazard identification, exposure, dose response, and risk characterization and we did all our findings based on that sort of simplistic model, that would be following the traditional risk assessment paradigm. We don't do that, but one could. We generally

start off with exposure, go to health, go to risk. And that's not the way people describe it in the red book.

PANEL MEMBER LANDOLPH: Yeah, my point was just a fairly simple one, that it does have a significant carcinogenicity and it falls in the middle quantitatively on --

CHAIRPERSON FROINES: But that should be down when we're talking about the risk assessment.

PANEL MEMBER LANDOLPH: That's fine.

DPR ASSOCIATE TOXICOLOGIST LEWIS: Going back to 7, if you -- I'm not sure if you're still going to include those non-cholinergic effects there at that last sentence that was confusing about ulceration and inflammation macrophages. I've found the study, and actually there's some words missing. There was -- it was a rat study and there was ulceration and inflammation of the skin, and then there was focal accumulation of foamy macrophages in the alveoli. So it just needs a couple of words inserted there to --

PANEL MEMBER BLANC: Well, I think we've decided we weren't going to use --

DPR ASSOCIATE TOXICOLOGIST LEWIS: You could delete it all? Yeah, I wasn't sure if that was the final decision, was to delete that.

CHAIRPERSON FROINES: Right. We're not going to

leave in -- we're not going to get into the endpoints themselves.

DPR ASSOCIATE TOXICOLOGIST LEWIS: Okay.

CHAIRPERSON FROINES: The important point is, from my standpoint, is I want people to not just think of OPs as only causing cholinergic effects, because it's simply not true. You know, we put emphasis -- we go looking for delayed neurotoxicity, but that's only one other endpoint.

Compound that -- never mind. Never mind.

Craig, you're on.

I think Paul's finished.

PANEL MEMBER BYUS: I just have -- I think it's very good. I was particularly pleased, under 19, this here and also in the document, that you did a very nice job trying to assess aggregate exposure. And I think we should say that. You really tried -- well, you did. I mean you didn't just try. You did a very nice job looking at all kinds of potential exposures, diet and water, and tried to add it all up and see if it -- for aggregate exposures. It was a very nice extensive analysis of it, which I was very pleased to see. And we really should say that the aggregate is -- something about the aggregate exposure from all these sources is unlikely to be much greater than, et cetera.

CHAIRPERSON FROINES: Wait a second.

PANEL MEMBER BYUS: The aggregate exposure. Now, that's from a single -- from -- if I could say it -- Methidathion. And that's in. -- but that's different than all the organophosphates.

CHAIRPERSON FROINES: Yes.

PANEL MEMBER BYUS: Okay. And so I think we need to make that distinction and to make that statement. So I mean I think you did a very nice --

CHAIRPERSON FROINES: All due respect to Carolyn and all the good work she's done. I wrote 19.

(Laughter.)

PANEL MEMBER BYUS: No, I mean in the -- I'm talking in the document, 19 doesn't say about aggregate exposure. But we should make -- I think we should make two points here.

CHAIRPERSON FROINES: Send me an e-mail that says, "Here's what I want you to add."

PANEL MEMBER BYUS: And then if I must criticize 19, and now I must --

CHAIRPERSON FROINES: Please do.

(Laughter.)

PANEL MEMBER BYUS: The last sentence --

CHAIRPERSON FROINES: At your own risk.

(Laughter.)

PANEL MEMBER BYUS: At your own risk, I know.

The last sentence, "Clearly a wide range of pesticides and the issue of cumulative exposure to a range of pesticide is a matter of great importance." I'm not sure exactly what you mean by "clearly a wide range of pesticides." There seems to be something missing here. You mean -- I mean I know what you mean. But you mean that there are --

CHAIRPERSON FROINES: I'll fix that. It's --

PANEL MEMBER BYUS: Is that valid, John?

CHAIRPERSON FROINES: Absolutely. It's a poorly crafted sentence.

PANEL MEMBER BYUS: Okay. But I do think in there -- and I will send you a few sentences about that, because it would then be aggregate exposure versus exposure to all of the different organophosphates, which you didn't deal with, although you actually did mention the EPA's attempt to deal with it in there. It is a nice --

CHAIRPERSON FROINES: You're talking about aggregate exposure?

PANEL MEMBER BYUS: Well, it was they tried -- which is what I asked them to do with sulfuryl fluoride and fluoride, which they didn't do and they did, where does was Fluoride can come? It can come from the water

and not just --

PANEL MEMBER BLANC: -- then get exposed by various --

PANEL MEMBER BYUS: -- by various roots.

PANEL MEMBER BLANC: -- of this single pesticide.

PANEL MEMBER BYUS: -- of this single --

CHAIRPERSON FROINES: Right.

PANEL MEMBER BYUS: In other words just because -- and we don't -- as I said, just because -- they did see -- try to ask the question quantitatively that, okay, ambient air may in and of itself might not be bad. But if you added it on to all the other roots that you may be exposed, it could be significant. That was the question. And you did an excellent job trying to ask that question.

CHAIRPERSON FROINES: No, me, me. She --

PANEL MEMBER BYUS: No, I mean in a document it was --

CHAIRPERSON FROINES: We're talking about the findings.

PANEL MEMBER BYUS: I know, I know. But I'm saying -- but that's part of the -- part of the finding is what is in the document.

CHAIRPERSON FROINES: I want you to write a section that will provide your point.

PANEL MEMBER BYUS: Okay. Will do.

CHAIRPERSON FROINES: And whether or not they had it in their document --

PANEL MEMBER BYUS: Dr. Froines did an excellent job.

(Laughter.)

CHAIRPERSON FROINES: The point I'm trying to make here is I think that an aggregate -- going back to what Paul just said -- the issue of the aggregate exposure is a finding separate from "people are exposed to multiple pesticides."

PANEL MEMBER BYUS: That's correct. That's absolutely correct.

DPR ASSOCIATE TOXICOLOGIST LEWIS: Even though these aren't my findings, I was going to suggest maybe a separate item there on your findings to aggregate as opposed to cumulative.

CHAIRPERSON FROINES: He will. And that will be great.

DPR ASSOCIATE TOXICOLOGIST LEWIS: Yeah.

CHAIRPERSON FROINES: And I'm glad everybody's having such a good time.

PANEL MEMBER GLANTZ: At your expense.

(Laughter.)

CHAIRPERSON FROINES: At my expense.

And we didn't need that.

(Laughter.)

CHAIRPERSON FROINES: Roger we've been through.

Kathy.

PANEL MEMBER HAMMOND: (Shakes head.)

CHAIRPERSON FROINES: Stan we've been through.

PANEL MEMBER GLANTZ: I don't have anything yet to add.

CHAIRPERSON FROINES: So with that in mind, can we -- recognizing that all these are really wordsmithing changes, there was not really a single conceptual issue raised, everything is about how it was said rather than what was said -- I think that's a fair statement.

So given that --

PANEL MEMBER BLANC: I would make the following motion, that taking into account the anticipated editorial changes in the document, the Panel approves the draft findings as presented for Methidathion.

PANEL MEMBER GLANTZ: Second.

PANEL MEMBER HAMMOND: How long did you practice saying that?

(Laughter.)

PANEL MEMBER GLANTZ: I second it.

CHAIRPERSON FROINES: Discussion?

All in favor?

(Hands raised.)

CHAIRPERSON FROINES: A Unanimous vote.

It's 10 minutes to 12.

We have two options. One is to break for lunch. Second is to go ahead and -- I think, from talking to Janette yesterday, it looks like the two next items on the agenda are going to take about an hour -- about a half hour each, I would guess.

And so the choice is: Do we want to break and come back at 1 o'clock, or do we want to continue and basically finish around 1 o'clock?

PANEL MEMBER BLANC: I personally think it would be better to break since Stan has to go to a meeting now anyway. And if he -- I assume that that meant you could come back after your meeting. So why not have the full Panel here if we can.

PANEL MEMBER FRIEDMAN: If we break, could it be a short time like a half hour?

CHAIRPERSON FROINES: Stan, how soon can you be back?

PANEL MEMBER GLANTZ: I don't know. The thing starts at 12:15. I'm sure it won't go more than an hour. It might go less.

CHAIRPERSON FROINES: Well, see, that's the problem with Paul's suggestion, because that would mean

you're not going to be back till 1:15 and it's 10 to 12. So we're not going to take an hour and a half lunch.

PANEL MEMBER GLANTZ: Right. Well, I suggest -- personally, I don't know that I'll have a lot about item 2, but I might have something about 3. And maybe could we just do 3? That's going to be pretty short, isn't it? And maybe we could get through 3 --

PANEL MEMBER BLANC: -- through 3 before we break for lunch?

CHAIRPERSON FROINES: Somehow I'm --

PANEL MEMBER GLANTZ: Do three and then you can decide what you want to do. Because I think I might get volunteered for something on 3, so I would like to be here when it's discussed.

(Laughter.)

PANEL MEMBER BLANC: And your meeting is -- you don't have to really leave here until 12 after the hour?

PANEL MEMBER GLANTZ: I have to leave about ten after.

CHAIRPERSON FROINES: So 3 is OEHHA and ARB.

PANEL MEMBER BLANC: Why don't we start that then, John, and see what happens.

CHAIRPERSON FROINES: All right. Let's start 3. I believe that 3 could --

PANEL MEMBER BLANC: Well, if we see that it's

going on and on, then we'll have to break.

CHAIRPERSON FROINES: I want to say one thing about 3 at the outset. Janette, come up. And, that is, that I would like to have the Panel at a future meeting have a discussion about future toxic air contaminants, and even bring in some expertise from outside this Panel and have an intellectual discussion about future potential TACs.

We're going to hear something from the two agencies today. But I think this is an issue that has broader implications, and it would be useful to have kind of a mini-workshop on the topic if you'd all be willing to do that.

Because it has been since 1998, with the exception of ETS -- no disrespect intended -- but we haven't had sort of a toxic air contaminant in an air pollution sense since '98.

PANEL MEMBER LANDOLPH: Yeah. And particularly that discussion we had over a cup of coffee, perhaps some discussion about the potential linkage of pesticides with neurodegenerative diseases should be worked in there.

CHAIRPERSON FROINES: And so we'll plan something at some future meeting. So this is -- but why don't we just see this as a kickoff for coming up with a list that the Panel will know what our workload is going to be over

a period of five years and -- but, more importantly, to have an in-depth -- I don't know what's funny -- but an in-depth discussion of what do we -- what do we mean when we're talking about toxic air contaminants? Remembering that when even though there are 189 HAPs which have been declared toxic air contaminants, that doesn't mean that they've had risk assessments in the context of the 1807 process. Which you may have 2588 or Prop 65 risk assessments, but the -- but the 1807 process, once it's brought before this Panel, even if it's been grandfathered as a TAC, if we approve it and it goes before the Board, then that theoretically begins a regulatory process.

So the difference between what -- the 200 chemicals that Melanie's brought before us is they use those risk assessments in the context of other legislation, not in the context of 1807.

So that the acrolein risk assessment that we did is not being now regulated as a TAC, based on a risk assessment that Melanie's group has done. Is that an accurate statement?

OEHHA AIR TOXICOLOGY AND EPIDEMIOLOGY SECTION MANAGER MARTY: I think it's close. I would say it's a little murkier than that, because some of the numbers we have derived under the SB 1731/AB 2588 have gone into considerations of airborne toxic control measures. So

it's a little bit squishy. But for the most part, they generally just get funneled right into stationary source risk assessments rather than used generally or regionally for ARB by ARB to look at regional issues.

CHAIRPERSON FROINES: But then I would -- this question has come up before. Then if a chemical comes before us as a risk assessment and the Panel's operating under the assumption that this is a 2588 chemical, for your purposes, I want -- I really do think it's incumbent upon you to explicitly state this is also coming forward for the purposes of 1807. So that we're not saying we're doing 2588 risk assessments and this has nothing to do with the regulatory framework that's been established under 1807 which creates this -- in other words if it's going to be used for 1807 regulatory processes, then we shouldn't be bypassed.

ARB AIR QUALITY MEASURES BRANCH CHIEF BROOKS:

John, and the Panel wouldn't be on any -- and this is going to happen with the hazardous air pollutants that we had to add as tox -- that per legislation became toxic air contaminants in 1992, 1993 timeframe. So some of those won't have for the cancer effects unit risk numbers.

If Melanie develops those under the guise of 2588 and brings them before you, all she'll have to say is

"Well, the ARB is going to be working on control measures and they're going to be using this number for this 2588 compound, which is also a toxic air contaminant."

CHAIRPERSON FROINES: Yeah. I just want that to be made clear to --

ARB AIR QUALITY MEASURES BRANCH CHIEF BROOKS:

And I think that can be done.

CHAIRPERSON FROINES: -- be made clear to us. And, for example, this issue -- one major issue here -- I objected to doing benzopyrene. And I was told that if we regulate benzopyrene, we will be affecting all the PAHs. If we control BAP, we'll be controlling all these other particulate bound PAHs. And that was the rationale for doing one PAH.

There has been no control strategy developed for BAP. So not only did we not do it for BAP and all the PAHs, but that has lain fallow since whenever we did BAP, which was the early nineties I think.

So nobody -- so we all recognize that PAHs are important toxic air contaminants. And nothing has happened in terms of control strategies since the early nineties when those were adopted.

And so there are issues of chemicals that are -- that have either been identified by the committee or chemicals that have been identified under 2588. And

all I'm asking for is -- not to put pressure on you -- but really to have clarity in the process, so that we know when a chemical comes before us, that if it's going to be just 2588 or -- what's the other law? I forget the name.

OEHHA AIR TOXICOLOGY AND EPIDEMIOLOGY SECTION MANAGER MARTY: 1731. But that just modified 2588.

CHAIRPERSON FROINES: So if it's going to be a 2588, that's fine, we'd take it up. But if it's going to also end up in her shop for control strategies, the Panel should know that as well, I think. And --

OEHHA AIR TOXICOLOGY AND EPIDEMIOLOGY SECTION MANAGER MARTY: I think we can put it directly into some of the toxicity summary, whether or not it's been identified as a TAC under the Tanner process.

CHAIRPERSON FROINES: And so we might at some point -- you bring a chemical under 2588, and the Panel -- you know, Stan may have had a bad day and he says, "Well, why the hell don't we take this up as an 1807 chemical." So we can come back on you and say, "Why isn't this coming forward in an 1807 context?"

Am I clear?

ARB AIR QUALITY MEASURES BRANCH CHIEF BROOKS: Well --

PANEL MEMBER GLANTZ: Kathy wants to know what 2588 is.

CHAIRPERSON FROINES: It's a Hot Spots legislation.

OEHHA AIR TOXICOLOGY AND EPIDEMIOLOGY SECTION MANAGER MARTY: I think part of the consideration is under 1807 if you're bringing a new chemical forward as a TAC, there's -- what you guys are doing is looking at the identification documents, that part of the process. So the chemicals that got put in because they were HAPs are -- you don't need to identify them. They're already TACs. So it's kind of created this funny --

CHAIRPERSON FROINES: But we also --

OEHHA AIR TOXICOLOGY AND EPIDEMIOLOGY SECTION MANAGER MARTY: -- meshing of the two programs.

CHAIRPERSON FROINES: Well, if I can remind you, we were sued by a whole bunch of companies under diesel, and they went after the risk assessment. They didn't give a damn about all the hazard identification. They didn't like the fact that Stan and I were joking at the damn meeting about this is all irrelevant.

PANEL MEMBER GLANTZ: Which is also a joke, for the record.

(Laughter.)

PANEL MEMBER GLANTZ: We don't get sued again

CHAIRPERSON FROINES: For the next lawsuit we are --

PANEL MEMBER BYUS: Still joking.

PANEL MEMBER GLANTZ: It's still a joke.

CHAIRPERSON FROINES: So the point is that the risk assessment actually is what you guys end up in court on. And so that needs -- the fact that something's coming before us may end up in a court case and -- and it's going to be an 1807 process because there are regulatory implications as opposed to identification implications -- that really needs to be made clear to this Panel, I think.

OEHHA AIR TOXICOLOGY AND EPIDEMIOLOGY SECTION MANAGER MARTY: Okay. That's easy.

(Thereupon an overhead presentation was Presented as follows.)

OEHHA AIR TOXICOLOGY AND EPIDEMIOLOGY SECTION MANAGER MARTY: I'm going to provide a brief overview of the documents that OEHHA is producing that are coming down the pike to this Panel. And at the present time they're all being done under the Senate Bill 25 amendments to the Toxic Air Contaminant Program.

And just a reminder, that OEHHA's major roles under SB 25 include identifying toxic air contaminants which may differentially impact children. And that's the list that you all saw four or five years ago now.

And also we have to explicitly consider infants and children when we're doing quantitative risk assessment

where data are available to do so.

--o0o--

OEHHA AIR TOXICOLOGY AND EPIDEMIOLOGY SECTION MANAGER MARTY: So the actual requirement of SB 25 is:

In evaluating health effects of toxic air contaminants, OEHHA shall assess to the extent data are available:

Exposure patterns of infants and children and how they are different from that of adults.

Special susceptibility of infants and children. And we have in turn interpreted that to mean toxicological susceptibility.

Effects of co-exposure to other substances with common mechanisms of toxicity. And they frequently are not dated to do this.

As well as interaction of multiple air pollutants. Again, frequently we have little data to work on.

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OEHHA AIR TOXICOLOGY AND EPIDEMIOLOGY SECTION MANAGER MARTY: Just to remind you that the -- this had actually been updated. I'm sorry. There are 6 TACs previously identified as differentially impacted children. The first go-around we added diesel, dioxins, lead, acrolein, and PAHs to the list. And then when ETS was

identified as a toxic air contaminant, in that process we also added that to the list of TACs that differentially impact kids.

--o0o--

CHAIRPERSON FROINES: Which one?

OEHHA AIR TOXICOLOGY AND EPIDEMIOLOGY SECTION MANAGER MARTY: ETS was added through the 1807 process.

--o0o--

OEHHA AIR TOXICOLOGY AND EPIDEMIOLOGY SECTION MANAGER MARTY: The law actually requires us to evaluate annually 15 toxic air contaminants in order to ensure that the risk assessments done for those adequately protect infants and children.

This requirement triggered us to reevaluate our risk assessment methodologies to ensure that the methods we are using are child protective.

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OEHHA AIR TOXICOLOGY AND EPIDEMIOLOGY SECTION MANAGER MARTY: Following evaluations of these additional toxic air contaminants and after review by the Scientific Review Panel, we can update that list of toxic air contaminants that may disproportionately impact children.

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OEHHA AIR TOXICOLOGY AND EPIDEMIOLOGY SECTION MANAGER MARTY: So in terms of the SRP, SB 25 is asking

you to update -- to review our updates to the list of the TACs, to review our risk assessment methodologies and any new or revised reference exposure levels or unit risk factors.

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OEHHA AIR TOXICOLOGY AND EPIDEMIOLOGY SECTION MANAGER MARTY: Currently we are working on our risk assessment methodology, and we have been for some time, to incorporate more specifically additional considerations for infants and children.

The closest to the gate is the noncancer risk assessment methods. And that's the methods we use to derive our reference exposure levels.

Then the next document after that, which is a little bit -- about six to eight weeks behind, is the cancer risk assessment methodology. In that methodology we are talking about weighting by age at exposure.

And then a ways away is our exposure parameters update. We do have some exposure parameters in our risk assessment methods that are based on data in children. But we're updating that, because there's a lot more data now since the last time we did that document, which was in 2000.

CHAIRPERSON FROINES: When do you anticipate -- do you anticipate the three documents coming

to us at one time, separately, and what's the timeframe?

OEHHA AIR TOXICOLOGY AND EPIDEMIOLOGY SECTION MANAGER MARTY:

Separately. And the timeframe I think is the next slide.

--o0o--

OEHHA AIR TOXICOLOGY AND EPIDEMIOLOGY SECTION MANAGER MARTY: The update -- we are updating the list of TACs that may disproportionately impact infants and children. We're using our revised methods, and sample reference exposure levels using those revised methods, as the way to get at that. And we started with the Tier 2 chemicals from the 2001 prioritization.

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OEHHA AIR TOXICOLOGY AND EPIDEMIOLOGY SECTION MANAGER MARTY: We think that the noncancer risk assessment methodology and the accompanying half dozen or so reference exposure levels will undergo public review starting in March. And we anticipate that the Panel will get the document some time in the summer. It really depends on the extent of public comment and the extent of response and revision that we have to do.

The cancer risk assessment methodology, which essentially is the weighting by age at exposure, we hope the public review will start in May. And so SRP review

would be in the fall.

I don't want to surmize on the exposure parameters because we really are pretty -- in the pretty early stages of revising that document. But I'm guessing at sometime in 2008, hopefully the first half of 2008.

--o0o--

OEHHA AIR TOXICOLOGY AND EPIDEMIOLOGY SECTION MANAGER MARTY: I did want to mention there's one other item that may come to the Panel from OEHHA and, that is, a unit risk factor for ethyl benzene. We have the document now squared away, and are awaiting management review. And hopefully we will get public review in the March to April timeframe. Again, depending on the extent of public comment and revision, we should get that to the Panel this summer.

So that's a brief picture of what you folks will see.

PANEL MEMBER GLANTZ: Melanie, just a minute, because I've got to run off now.

But I talked to Melanie before. I believe I was one of the leads on the methods for the original -- the current methods. And I'm willing -- if the Committee wants me to do that for this, I'll volunteer for that, for the methods part.

What time do you want me to come back?

CHAIRPERSON FROINES: As soon as possible.

PANEL MEMBER GLANTZ: Okay.

PANEL MEMBER BLANC: Melanie, just for our clarification and edification, can you remind us as to the identities of the Tier 2 chemicals left over from last time?

OEHHA AIR TOXICOLOGY AND EPIDEMIOLOGY SECTION MANAGER MARTY: Yeah, I should have brought that with me.

A couple ones off the top of my head. We have -- mercury was one of them, manganese is another, arsenic, formaldehyde. There were I think 17. We're bringing 6 or 7 of those forward.

PANEL MEMBER BLANC: And can you -- you haven't finalized which 6 or 7 you're bringing forward, or you have finalized --

OEHHA AIR TOXICOLOGY AND EPIDEMIOLOGY SECTION MANAGER MARTY: We're in the process of finalizing that. We're trying to work out some methods issues on one or two of those.

PANEL MEMBER BLANC: So there are some that no matter what the methods do, they're going to be coming to us?

OEHHA AIR TOXICOLOGY AND EPIDEMIOLOGY SECTION MANAGER MARTY: Yeah. I think I can safely say that will be arsenic, manganese, and mercury.

Andy, you got to help me out.

OEHHA AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: I think we may be likely to see -- acrolein is of course is a Tier 1 --

OEHHA AIR TOXICOLOGY AND EPIDEMIOLOGY SECTION MANAGER MARTY: Right.

PANEL MEMBER BLANC: I can't hear that at all.

OEHHA AIR TOXICOLOGY AND EPIDEMIOLOGY SECTION MANAGER MARTY: Okay. So acrolein is one that's coming forward.

PANEL MEMBER BLANC: Acrolein was already on the list.

OEHHA AIR TOXICOLOGY AND EPIDEMIOLOGY SECTION MANAGER MARTY: It's actually a Tier 1. It's already on the list. But we're using it to apply our new methodologies. You can see the difference between the old and the new methodologies.

And also we were asked by the Air Board to relook at that compound, because it's an important compound to them. It's emitted in a whole lot of combustion processes. And they repeatedly are asked by the air districts for help looking at acrolein sources. So that's one reason that one's also coming forward.

CHAIRPERSON FROINES: You've read the Bay Area Management District document on airports and the acrolein

associated with it?

OEHHA AIR TOXICOLOGY AND EPIDEMIOLOGY SECTION MANAGER MARTY: Yes. That's --

PANEL MEMBER BLANC: Can I ask, as part of your methodology have you come at the question completely from the opposite point of view, which is what are compounds for which we could anticipate there being a marked difference between infants and children and adults? Rather than starting at the point of, you know, what do we think are -- are we already looking at for other reasons?

OEHHA AIR TOXICOLOGY AND EPIDEMIOLOGY SECTION MANAGER MARTY: It's a combination of both. I think the metals -- we believe that there's going to be a marked difference between --

PANEL MEMBER BLANC: Right.

OEHHA AIR TOXICOLOGY AND EPIDEMIOLOGY SECTION MANAGER MARTY:

-- developing organisms and material organisms.

For the aldehydes, we've asked aldehyde and formaldehyde, there's just a lot of exposure. And we are repeatedly asked by the air districts and the Air Board for help on those compounds. So we wanted to get, you know, a good handle on the reference exposure level for those compounds using our new methodology.

PANEL MEMBER BLANC: Can I ask: In that list of

things you're looking at, where would methylene chloride fall?

OEHHA AIR TOXICOLOGY AND EPIDEMIOLOGY SECTION MANAGER MARTY: It's not done yet. So it is still on the Tier 2 list. But we didn't want to bring forth a whole bunch of compounds at the same time for resource purposes, both yours and ours, so we -- it's in the cue.

PANEL MEMBER BLANC: The reason I bring up methylene chloride is because it's obviously metabolized to carbon monoxide. And since the data for the sensitivity of binding a fetal hemoglobin to carbon monoxide is beyond question, isn't that a chemical for which the preferential sensitivity of infants would perforce be beyond question.

OEHHA AIR TOXICOLOGY AND EPIDEMIOLOGY SECTION MANAGER MARTY: I think that's a question for the -- it did end up on Tier 2 primarily because there is not a lot of exposure now to methylene chloride.

OEHHA AIR TOXICOLOGY AND EPIDEMIOLOGY SECTION MANAGER MARTY: But doesn't that come back to the thing that we keep grappling with, which is cumulative exposure for multiple sources? And since infants are clearly exposed to carbon monoxide through many other sources, isn't the incremental potential for exposure quite relevant? And doesn't that give you also methodology for

looking at cumulative exposure perhaps in a cleaner way than with many other things?

OEHHA AIR TOXICOLOGY AND EPIDEMIOLOGY SECTION MANAGER MARTY: Sure. It definitely could.

PANEL MEMBER BLANC: And then another chemical I would ask you about, which I believe might have been -- might have bumped up to the Tier 2, and it's almost a similar issue, which would be carbon disulfide. Given the fact that this Panel has already grappled with the breakdown of metam sodium to carbon disulfide, and even though there aren't point source pollution hot spots from manufacturing in the State of California, it would seem to me that that would be -- and since it is a neurotoxin as potent as the metals you're considering, it would seem to me that that would also be one that would be timely.

OEHHA AIR TOXICOLOGY AND EPIDEMIOLOGY SECTION MANAGER MARTY: It's also in the cue.

PANEL MEMBER BLANC: And is there some point where you would wish feedback from this Panel on positioning within the cue?

OEHHA AIR TOXICOLOGY AND EPIDEMIOLOGY SECTION MANAGER MARTY: Well, sure. I mean when -- I think what we tried to do first was respond to our multiple stakeholders asking us to look at chemical X, Y, and Z as well as the amount of data on certain substances in terms

of differences between infants and children and adults. So -- and looking at our own resources --

PANEL MEMBER BLANC: Right. Because I think that was maybe -- now, I don't want to put words in your mouth, but when you use the word "brainstorming," it seemed to me that that's what you were getting at, was an opportunity at some -- in some form, and it may not be today, for us to be able to give you in advance some of our thinking about what comes to our minds, and so that we don't get in a position of, you know, your group bringing to us five compounds and we say, "Okay, yeah, fine with those five, but" --

OEHHA AIR TOXICOLOGY AND EPIDEMIOLOGY SECTION MANAGER MARTY: -- what about the rest.

PANEL MEMBER BLANC: -- what about such and such?

OEHHA AIR TOXICOLOGY AND EPIDEMIOLOGY SECTION MANAGER MARTY: Yeah. Then I think that's a great idea.

CHAIRPERSON FROINES: Well, I think that the workshop or mini-workshop or whatever we end up calling it is exactly what -- this discussion is exactly the kind of thing I wanted to have in it, because -- and I would like to have it before you bring a bunch of chemicals to us. Because if you remember in the first SB 25 process, it got very contentious because we had a different point of view than you guys had and we argued back and forth. And if we

could have a workshop ahead of time and talk it through and provide you with the input from the Panel, then when you come back formally it makes the process a much smoother, I think. And so I think it's really valuable to have this. And I --

OEHHA AIR TOXICOLOGY AND EPIDEMIOLOGY SECTION MANAGER MARTY: Could we do that for our next batch and not hold off the six that we have, possibly seven, from your review?

CHAIRPERSON FROINES: The answer to that is clearly yes, you know, at your peril of course. But, yes, sure.

OEHHA AIR TOXICOLOGY AND EPIDEMIOLOGY SECTION MANAGER MARTY: I mean part of the reason is --

CHAIRPERSON FROINES: But why don't you let us -- give us some information on what those six are going to be, and we can give you even informal feedback. So if somebody has something that's just going to send them up the wall, you can at least have some pre-notice that that's --

OEHHA AIR TOXICOLOGY AND EPIDEMIOLOGY SECTION MANAGER MARTY: Yeah. I mean part of the reason for bringing forward examples was to -- when you develop a methodology or revising methodology, it's hard to see where the holes are until you try to apply it. So that's

what we've been trying to chug along doing.

PANEL MEMBER BLANC: The other part that -- I know we talked about at the time of the first five chemicals. But there was a presumption that was a presumption in your previous methodology that substances which are teratogenic or fetotoxic are, by definition, substances to which infants and children are more sensitive. Is that -- am I paraphrasing or is that essentially --

OEHHA AIR TOXICOLOGY AND EPIDEMIOLOGY SECTION MANAGER MARTY: No, that -- that's essentially it. We looked for developmental toxicity.

PANEL MEMBER BLANC: And in your summary slides, for example, that's not directly alluded to.

So in the document, which is going to be discussing the methodology, the systematic methodology, will that issue be taken on explicitly or is simply going to be implicit?

OEHHA AIR TOXICOLOGY AND EPIDEMIOLOGY SECTION MANAGER MARTY: It's -- this part is pretty implicit, because the document that we're revising is actually the risk assessment methodology. So if there are developmental toxicology studies on a compound, we'll automatically look at those to see if they should be the basis of a reference exposure level.

We talk about -- there's a section of a document that we actually pulled forward from that prioritization document that talks about why infants and children might be more susceptible or might be the most susceptible population to a specific toxicant.

PANEL MEMBER BLANC: No, I meant more -- so there's no where in this document that's going to say that by definition if a compound is developmentally toxic, therefore children are by definition more sensitive --

OEHHA AIR TOXICOLOGY AND EPIDEMIOLOGY SECTION MANAGER MARTY: I don't think we've said that.

PANEL MEMBER BLANC: -- ipso facto?

OEHHA AIR TOXICOLOGY AND EPIDEMIOLOGY SECTION MANAGER MARTY: I don't think we said that. And part of the reason is sometimes developmental toxicity is not the most sensitive endpoint for a compound. That it's actually --

PANEL MEMBER BLANC: Well, that's always the case, that you may not -- that's like saying if something causes asthma in children, we're not going to talk about that because something -- you know, asthma may not be the endpoint that's most sensitive. I mean I don't think that's the point. The point is that if there was no other toxicity to a chemical but it's developmental toxicity that suggested a sensitivity -- a vulnerability of infants

and children, you would find that it was -- that children were more --

OEHHA AIR TOXICOLOGY AND EPIDEMIOLOGY SECTION MANAGER MARTY:

-- differentially impacted --

PANEL MEMBER BLANC: -- affected than adults; is that correct?

OEHHA AIR TOXICOLOGY AND EPIDEMIOLOGY SECTION MANAGER MARTY: I think it's fairly safe to say that. And in part --

PANEL MEMBER BLANC: Is there --

OEHHA AIR TOXICOLOGY AND EPIDEMIOLOGY SECTION MANAGER MARTY: -- if there's irreservible developmental toxicity, even though it may occur at higher doses, that's a -- you have to weigh that against whatever endpoint might occur in adult at a lower dose that's irreversible. So you end up having to weigh those issues as well.

CHAIRPERSON FROINES: Well, I think --

OEHHA AIR TOXICOLOGY AND EPIDEMIOLOGY SECTION MANAGER MARTY: And clearly then the worst endpoint is going to be that irreversible developmental --

CHAIRPERSON FROINES: But you're getting into something that's too hypothetical. And it's case specific. And I think Paul is arguing that there -- you want to avoid the ideological framework that a

developmental toxicant is -- by definition demonstrates greater risk than adult toxicity.

PANEL MEMBER BLANC: What I'm -- well, I wasn't saying one thing or the other. I do think that there are some social legal ramifications to the policy. But what I do think is you -- I don't think it's going to be helpful not to be explicit. I think that if you leave some of these things go unsaid, it is going to lead to later confusion. Now, there may -- unless there are some statutory reasons why you can't say them. For example, if legal counsel of your agency has told you that in fact you can't argue fetal toxicity because a fetus is not an infant, and the only way you could argue it is to the extent that you show that -- or there's some particular way you have to argue it in terms of the legal mandate, then I think you should try to map that out in your methods.

OEHHA AIR TOXICOLOGY AND EPIDEMIOLOGY SECTION MANAGER MARTY: Well, I think we did that with the prioritization process -- the document -- the prioritization document.

I have to say that the agenda actually had that incorrect. We're not updating the prioritization document. We're updating risk assessment methods. And that was very confusing on the agenda what it said we were

talking about today. And we did go through all those issues in that document, and have not gone back to any of those issues. So could we revise --

PANEL MEMBER BLANC: So can you tell us what is an example of a methods issue that you are dealing with?

OEHHA AIR TOXICOLOGY AND EPIDEMIOLOGY SECTION MANAGER MARTY: Yeah. If you have, for example, information that the toxicokinetics of a compound is different in an infant than it is in an adult and that it impacts the concentration of the ultimate toxicant at the receptor, then you need to consider that when you're doing your risk assessment for that chemical. That's one example of where there is a good reason to say there's differential toxicity between infants and children and adults. There's one example.

If you have something that's a developmental neurotoxicant, it might produce transient neurotoxicity in a mature organism, but an irreversible neurodeficit in a young -- when exposure occurs in a young organism. That's clearly a differential impact. Those are the kinds of things that we looked at.

PANEL MEMBER BLANC: So is something that causes birth defects differentially a toxin for infants in children as compared to adults?

OEHHA AIR TOXICOLOGY AND EPIDEMIOLOGY SECTION

MANAGER MARTY: Yes.

PANEL MEMBER BLANC: Why is that?

OEHHA AIR TOXICOLOGY AND EPIDEMIOLOGY SECTION MANAGER MARTY: Yes, it could be because the --

PANEL MEMBER BLANC: Wouldn't the birth defect be with you for life?

OEHHA AIR TOXICOLOGY AND EPIDEMIOLOGY SECTION MANAGER MARTY: Well, I think we did -- we went through all of this back in 2001. But I don't think we're coming out and making a statement to that effect, in part because it just depends on what the dose response data look like. Is the alcohol differentially -- does it differentially impact children at environmental exposures? The answer's probably no. If you're an alcoholic mother, the answer is probably yes, because you're going to get fetal alcohol syndrome. So I don't think that it's useful really to argue too much about that in generalities, because you're going to have to make chemical by chemical decisions on that.

CHAIRPERSON FROINES: So the answer is that there's not a generic statement to that effect?

OEHHA AIR TOXICOLOGY AND EPIDEMIOLOGY SECTION MANAGER MARTY: No.

CHAIRPERSON FROINES: I had -- are you finished?

PANEL MEMBER BLANC: I think I understand. I

don't think -- I don't think I'm fully sanguine about it, but I -- I have a better sense of the direction that you're going, I think. And I will just have to see the document in practice to get a sense. Because the examples that you gave were also so generic as to be not anything beyond what you did before too. So if there's some nuance to it, if you're going to start taking it up to the level of, you know, is sulfonation versus glucoronidation critical to detoxification in a manner that would make sulfonation less effective, then you better think about childhood toxicity, because that level -- and that's a level that's more sophisticated than the level that was in your original programmatic document -- then I guess I understand what it is you're trying to do.

OEHHA AIR TOXICOLOGY AND EPIDEMIOLOGY SECTION MANAGER MARTY: Yeah, that is more what we're trying to do. We're really not updating our prioritization for assessing impacts -- differential impacts on kids. We're really looking at: How do we generate these reference exposure levels? What things have we considered? What is our default method? And is our default method adequate to account for these differences in kinetics and dynamics?

PANEL MEMBER BLANC: Okay.

CHAIRPERSON FROINES: Just two quick comments.

First, there's a growing literature on acrolein

at this point, which I assume that you know. There's lots of stuff in the chemical research in toxicology on addicts and what have you. So the evidence on acrolein is growing, growing, growing.

The second thing I wanted to ask you about, which is not entirely dissimilar with Paul, is Cory-Slechta at New Jersey has done this really brilliant work, where she's looked at -- she's got a Parkinson's model -- mouse model, and she's looked at -- if you postnatally expose mice in their mouse model to manab and paraquat, and then if when the mice are in adulthood you expose them to manab and paraquat again, you are off the charts in terms of the effect in terms of Parkinson's incidence.

And so clearly in in utero or postnatal exposure is having an effect which creates a long-term effect in the adult. And it seems to me that one would argue -- I would argue anyway, that that postnatal exposure to those two pesticides is in fact an example of something that, whatever the mechanism may be, creates a greater risk in the offspring even though it may not be manifested till adulthood.

And so that field -- that whole field of in utero or postnatal exposure having long-term effects in the adult seems to me to be an area that is -- since the science is developing in this area, it's something that

you guys should pay -- be attentive to in the SB 25 methodology.

OEHHA AIR TOXICOLOGY AND EPIDEMIOLOGY SECTION MANAGER MARTY: Yeah, we are aware of a lot of those types of studies where there -- basically people are trying to study the fetal or early-life origins of adult disease. And at this point, it's not simple to use those generically in a generic risk assessment paradigm. You have to -- it definitely has to be chemical specific.

CHAIRPERSON FROINES: Right.

OEHHA AIR TOXICOLOGY AND EPIDEMIOLOGY SECTION MANAGER MARTY: And even then there are not a lot of studies where you can define the dose response associated with that type of phenomenon.

And at the same time there are all these new types of toxicity, if you want to call them that, that are being brought out that no one's ever dealt with; you know, that epigenetic mechanisms, for example, of vinclozolin in the rodent model where you have all of these very odd changes depending on when exposure occurs in a very narrow window. You have all these adult diseases happening in the animals before they're actually old. So these kinds of toxicity are really important in thinking about SB 25.

But, you know, it doesn't fit the traditional risk assessment paradigm, that's for sure.

CHAIRPERSON FROINES: Yeah. But it seems to me that half the science we do derives from the 1970s, and it's about time we got to the 21st century in some respects.

OEHHA AIR TOXICOLOGY AND EPIDEMIOLOGY SECTION MANAGER MARTY: I would agree.

CHAIRPERSON FROINES: I mean we -- you know, you read these documents and they look at genotoxicity and look at traditional tests from the '70s. And that's not where molecular biology is today. And so we are so rudimentary at some level in some of the ways we approach some of these things. and I just think we need as we develop new policy -- in a sense, policy related documents, we need to look at the emerging science as well.

I think that's fair, Charlie. Don't you think?

Janette, I think Melanie is done.

We're really looking forward to the chemicals that you're bringing forward.

Should we break for lunch?

Let's break for lunch.

Sorry, Randy.

Let's be back at 1:15.

(Thereupon a lunch break was taken.)

AFTERNOON SESSION

CHAIRPERSON FROINES: We have presenters, but we don't have an audience.

So I think we're -- Melanie has completed her presentation and discussion.

So, Janette, Bob, welcome.

(Thereupon an overhead presentation was Presented as follows.)

ARB AIR QUALITY MEASURES BRANCH CHIEF BROOKS: Okay. Thank you. Good afternoon.

I'm Janette Brooks and I'm Chief of the Air Quality Measures Branch at the Air Resources Board. And I'm going to talk to you about our plans for 2007 and early 2008 that will result in items that will come before the Panel.

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ARB AIR QUALITY MEASURES BRANCH CHIEF BROOKS: Just briefly, what I'll be covering is I'll do a brief introduction on the Air Resources Board's Toxic Air Contaminant and Identification and Control Program and show you the process steps and the roles of OEHHA, ARB, and the Panel in the identification phase; talk about what our focus will be for the'07-'08 years; and then talk about some of the status of our toxic air contaminant Control actions.

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ARB AIR QUALITY MEASURES BRANCH CHIEF BROOKS: In this slide we show the -- it's the flow diagram for what is in law in terms of how we are to identify substances as toxic air contaminants. And you can see from the slide ARB's role, OEHHA's role, and the Scientific Review Panel's role in terms of reviewing the report for its adequacy and scientific methods.

And in green you see the prioritization and selection of the toxic substance. That's really the foundation of the program. And that will be the focus of our work this year. We need to update the prioritization methodology and we need to prepare a plan and schedule for the identification of future toxic air contaminants.

CHAIRPERSON FROINES: One question.

If we planned a mini -- a workshop on these kinds of issues, would you think that the timing of doing it, say, during the summer would make sense for both agencies?

ARB AIR QUALITY MEASURES BRANCH CHIEF BROOKS: We were thinking maybe the spring. But, Melanie, would the spring be -- late spring be better for you? For us, we would want input as early as we could get from various experts on substances we should be looking at, because we would need to do work on, you know, atmospheric persistence and emissions and all of that if it's a new

substance that we're not looking at at the moment. So as early as possible would be good for us.

CHAIRPERSON FROINES: Tobi, realizing that you're sort of out of this loop right now, would spring -- a workshop where we were talking about possible TACs work okay for you?

DPR ASSISTANT DIRECTOR JONES: I believe so.

CHAIRPERSON FROINES: It would be mainly coming from the Panel. So it wouldn't be like you would be preparing.

Go ahead.

--o0o--

ARB AIR QUALITY MEASURES BRANCH CHIEF BROOKS:

Okay. In terms of the priority that we're supposed to be giving to pollutants for identification and regulation, these are the criteria that we're supposed to be using to do the prioritization. And these are elements of our prioritization methodology as well.

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ARB AIR QUALITY MEASURES BRANCH CHIEF BROOKS:

This slide shows the flow diagram for -- once a substance is identified as a toxic air contaminant, a needs assessment would be prepared in terms of whether or not we need to control that pollutant. And this is the process that we would use to do that.

PANEL MEMBER BLANC: So, for example -- Paul Blanc here -- for diesel exhaust, which was identified as a toxic air contaminant and then the findings of that document were supported by the Scientific Review Panel -- approximately three years ago?

ARB AIR QUALITY MEASURES BRANCH CHIEF BROOKS:

Oh, it was 1998.

PANEL MEMBER BLANC: So it's eight years ago.

How far since then has that gone in this process?

ARB AIR QUALITY MEASURES BRANCH CHIEF BROOKS:

Oh, there's many, many control measures -- diesel control measures that have been adopted since that time. And I'll be showing you a very long list. And control measure development is ongoing. But initially what was done was to prepare a diesel particulate matter control plan where the staff laid out various control measures we thought that we could do. And then we -- and made a commitment for a certain reduction in diesel PM in that plan. And then we've been carrying out that plan. And there's several diesel measures -- diesel particulate control measures that I can show you.

PANEL MEMBER BLANC: That were adopted?

ARB AIR QUALITY MEASURES BRANCH CHIEF BROOKS:

That have been adopted. And I have a slide for your information that lists them that you can keep.

PANEL MEMBER BLANC: Okay.

CHAIRPERSON FROINES: This is an aside.

The diesel issue that you've been working so hard on is a very interesting one, because we really made a mistake, in my view, when we only listed particulate as the TAC. Because the BAP concentration in southern California is one -- the naphthalene concentration in L.A. is 15,000 times that of BAP and it's in the vapor phase. So it's theoretically not included in control strategies for diesel, which was a terrible mistake as far as I'm concerned. It's a real error on our part.

Roger's actually --

PANEL MEMBER ATKINSON: But it doesn't come all from diesel. Gasoline and vapor --

CHAIRPERSON FROINES: No, but a lot does come from diesel.

PANEL MEMBER HAMMOND: More than one of the aldehydes in diesel exhaust, and has -- that would be more than --

CHAIRPERSON FROINES: Well, that's a different -- that's an issue --

PANEL MEMBER HAMMOND: But it's another reason -- it's a problem. You cannot control it.

CHAIRPERSON FROINES: Yeah, yeah, yeah, yeah.

Anyway, so that that's an interesting issue that

we would want to -- may want to talk about later, is what other vapor phase compounds are of consequence.

ARB AIR QUALITY MEASURES BRANCH CHIEF BROOKS:

All right. Now, I'm going to move into the focus of our work for 2007 and '08.

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ARB AIR QUALITY MEASURES BRANCH CHIEF BROOKS:

What we plan to do is develop a toxic air contaminant identification plan. And these are the major elements of that plan. And as we go through, there will be items that we would be bringing to the Scientific Review Panel and there will be steps with our Scientific Review Panel leads on these various elements.

CHAIRPERSON FROINES: Who was the exposure lead?

ARB AIR QUALITY MEASURES BRANCH CHIEF BROOKS:

Roger -- I don't know if Roger ever was formally identified as a lead. But we'd been working with Roger Atkinson -- Dr. Atkinson and Dr. Byus and you, Dr. Froines. So I don't know if you want to change that, but that's how it was a year ago.

CHAIRPERSON FROINES: So Stan is the lead on the methodologic issues. And we're the TAC -- okay.

--o0o--

ARB AIR QUALITY MEASURES BRANCH CHIEF BROOKS:

On the next couple of slides I just wanted to

talk about the approach that we would use for developing the plan and then the roles of the SRP leads. And so we had talked about already the Scientific Review Panel's workshop on substances of public health concern that you might want OEHHA and ARB to further investigate, that may not be candidates right now on our list in the program. And so if we could do that some time in the spring, that would be good.

And then after that meeting, we would meet with the SRP leads on any new substances that we would add to the candidate list. Because, you know, we have an older list and we need to see if there's other things out there that might be of concern and interest to us. That would also be in the spring -- later spring.

Then meet with the SRP leads on revisions to the methodology. We need to finalize the methodology. And we would do that in the summer.

And then we would apply the methodology and get a list of top priority substances. But as you know, when we just plug in the numbers and the scoring for that prioritization methodology, then we have to go back and look and see -- and make a judgment of from that ranking, which is sort of a screening ranking, what really makes sense to enter into the program for identification. And so we would be doing that, working with the leads, and

then we would write a report up that would go out for public review. And then that report with the responses to public comments would come to you in early 2008.

So that's our proposed plan.

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ARB AIR QUALITY MEASURES BRANCH CHIEF BROOKS:

And although we haven't finalized the prioritization methodology and we haven't done all the research and work with OEHHA that we need to do on these compounds, for various reasons these have -- in our older methodology, some of these compounds have come up as being higher priority. And then there's three substances on there that -- for various reasons that are also of interest. They're not currently candidates, but ones that we would be putting a little bit more work into in terms of this update that we're doing.

PANEL MEMBER BLANC: So let's me see if I understand it correctly.

These are all -- anything that appears on this list is something which has not up until now been listed as a toxic air contaminant? Or some of these are things which are already listed as toxic air contaminants by virtue of being on another list which was grandfathered in as all being toxic air contaminants?

ARB AIR QUALITY MEASURES BRANCH CHIEF BROOKS:

No, Dr. Blanc. These are not toxic air contaminants. This process will be to determine which ones ought to be identified as toxic air contaminants and go through the process.

PANEL MEMBER BLANC: But there's a long list -- well, then maybe I -- just so I'm clear. There is a long list of materials though which are titularly toxic air contaminants but for which there's been no document specifically developed, isn't that correct?

ARB AIR QUALITY MEASURES BRANCH CHIEF BROOKS:

That's right. And in terms of the plan that we're going to do, one of the elements will be to deal with the substances that have been formally identified, take a look at those, talk to OEHHA and see which health values need to be developed for those.

But it gets a little confusing. But there is an element of the plan that deals with formally identified toxic air contaminants. But these are not.

PANEL MEMBER GLANTZ: I think -- I mean apropos to what John said earlier, I think you ought to at least think about diesel exhaust gases and whether that ought to be considered. I mean I don't know one way or the other. But I had sort of assumed that if you're controlling the particulates, that's going to affect the gases. But I'm -- people are nodding their head no. So I think it's

worth at least thinking about whether it ought to be added in.

PANEL MEMBER BLANC: Well, but -- can I go back to this other point?

Isn't it something of a fundamental question as to whether the priority should be searching for new things to add to a lengthy list of toxic air contaminants for which nothing has ever really been done anyway versus going to the list of things which are toxic air contaminants and identifying those substances for which there need to be health documents that would tend to finally drive some kind of regulatory action on the part of the Air Resources Board?

Isn't that I a fairly fundamental question?

ARB AIR QUALITY MEASURES BRANCH CHIEF BROOKS:

Yes. And I mean I know I believe that, you know, we need to look at things that are -- you know, there's a lot of new chemicals introduced every year and in -- we need to keep up with what might be out there.

PANEL MEMBER BLANC: None of these are novel chemicals.

ARB AIR QUALITY MEASURES BRANCH CHIEF BROOKS:

No, but they haven't been dealt with either.

PANEL MEMBER BLANC: Yeah, but there's probably a reason why they haven't been dealt with. And that

still -- that doesn't answer my question really.

PANEL MEMBER GLANTZ: Well, if I can -- I mean I think Paul's making a good point. And I think what you ought to do -- I've worked on the earlier two prioritization documents. And I think a way of reframing what Paul's saying is in deciding which things you're going to move forward, you should not only consider things that are not yet listed as TACs, but also all those HAPs where there hasn't been a risk assessment.

And so the things that you're going to move forward would be either things that haven't been listed as TACs at all or things that are on the list where there isn't a risk assessment yet but it would make sense to do one.

ARB AIR QUALITY MEASURES BRANCH CHIEF BROOKS:

And we can do that. We can do that.

PANEL MEMBER GLANTZ: And I think that's the way to address the point you're raising.

ARB AIR QUALITY MEASURES BRANCH CHIEF BROOKS: In fact that would be the process we would use to do that work, Melanie, right?

PANEL MEMBER ATKINSON: I would like to make the point that the --

ARB AIR QUALITY MEASURES BRANCH CHIEF BROOKS:

That's what we've done in the past.

CHAIRPERSON FROINES: Roger.

PANEL MEMBER ATKINSON: The gasoline engine exhaust will probably pick up about 40 or 50 of the HAPs, which are all present in gasoline exhaust. And which is probably one of the major routes to exposure for many of them.

CHAIRPERSON FROINES: I may not have understood what Stan said, but I thought Paul was saying something a little bit different. And, that is, the point that I made about the fact that we did BAP and nothing ever happened as a result in terms of regulation, I thought that's what he was referring to.

And I'll give you the best example. Having been on this Committee for so long, the second chemical we ever dealt with way back in the early eighties was ethylene dibromide. And at that time there was no ethylene dibromide being used in California whatsoever. Or if there was any being used, it was like that. So we actually named it as a toxic air contaminant, and that goes on a nice list. But nobody used it so there was nothing done about it. It was a complete waste of the Panel's time.

And so I think what Paul's implying -- correct me if I'm wrong -- is that what we would like to do is take up things that we think something will then happen

subsequent to the naming of them as TACs.

PANEL MEMBER GLANTZ: Right. But in fact, again as the person who sort of -- I was, if you remember back as the second longest serving member -- I was the one who pushed through the whole idea of the prioritization documents because of that. And so now the protocol in bringing things forward, it's a combination of exposure and potential toxicity that gets things shoved up to the top of the list. So I think what you're concerned about is addressed in the current protocol.

And what I was interpreting what they're talking about doing is going back in light of new information and revisiting the prioritization document that we approved a while ago to see what should be pushed to the top of the list for -- you know, so that you're dealing with things that are both, you know, toxic and also -- or potentially toxic and are important.

I mean the other one I remember from way back in the beginning was where people wanted to do coke oven emissions because there was a lot of data, but there were no coke oven emissions in California. And I think that was the first one that got dumped off the list as a result of this Panel's recommendations on prioritization procedures.

ARB STATIONARY SOURCE ASSISTANT DIVISIOIN CHIEF

BARHAM: There's another -- this is Bob Barham. There's another interesting situation we're facing, and tertiary butyl acetate is a good example of that. Where we have chemical companies out there designing chemicals that are basically nonphotochemically reactive, where there's little or no health information, but there may be some suggestive information that the compound's a problem. And we're getting a lot of pressure to say it's okay to use this compound as a substitute for photochemically reactive compounds in situations where you could end up with a very wide spread use of something that you don't know what the final outcome's going to be in terms of health effects. And there are a couple of others -- they're escaping me now -- that we're looking at. But TBAC is a prime example of one where Lyondell Chemical in particular is really at the forefront of trying to get us to okay that.

PANEL MEMBER BLANC: Well, I think what I see as being a reasonable approach -- and it should be explicit and not simply presumed -- is that at the same time that you will apply your algorithm that you develop for identification of TAC candidates, you will also simultaneously take the entire list of existing TACs for which there have not been health assessments and separately plug them into the same algorithm and bring to this Committee the top players on that list for our

consideration.

ARB AIR QUALITY MEASURES BRANCH CHIEF BROOKS: That's good. That's fine.

PANEL MEMBER BLANC: Because that's not implicit in the -- explicit in this or implicit in what you're saying. And if I see one and not the other, I won't be happy.

ARB AIR QUALITY MEASURES BRANCH CHIEF BROOKS: Okay.

PANEL MEMBER GLANTZ: Oh, that's ugly.

(Laughter.)

CHAIRPERSON FROINES: I think that's a good discussion.

ARB AIR QUALITY MEASURES BRANCH CHIEF BROOKS: Okay.

CHAIRPERSON FROINES: The interesting thing is there is this tension. Originally the Toxic Air Contaminant law was based on this notion of the belching smokestack, right? I mean it was a point source issue. And then we thought that we dealt with National Ambient Air Quality Standards differently, that that was a different kind of category.

But I think I would argue -- and I hope Roger would too -- that there are compounds that are formed as national -- as California ambient exposures that deserve

to be treated as TACs, even though we might also be developing PM2.5 or ultrafine or whatever standards, and you can say, well, if we have an ultrafine standard we'll deal with the small particles that have nitro PAHs on them. And that may all be true, but it doesn't mean that we shouldn't also address those classes of compounds, carbonyls being the most obvious -- another obvious one, even though they're not belching out of a smokestack someplace, and that they represent a different -- the exposure is different.

And I'd also argue -- and I hope Kathy would agree to this -- and that is that the -- it is worth thinking about generic groups of chemicals like carbonyls. Carbonyls react with proteins. Carbonyls react with DNA, and they do it irreversibly, as we've said today about Methidathion. And so it's worth thinking about compounds whose toxicity derives from certain functional groups that are highly toxic, and not to always be dealing with one chemical at a time.

ARB AIR QUALITY MEASURES BRANCH CHIEF BROOKS: Okay. And on --

PANEL MEMBER GLANTZ: Is that something -- is that something you think you'll be able to do?

ARB AIR QUALITY MEASURES BRANCH CHIEF BROOKS: Melanie says the attorneys have argued no in the

past. But I don't know. That's something we'd have to address. I mean we've looked at --

CHAIRPERSON FROINES: Well, you looked at diesel.

ARB AIR QUALITY MEASURES BRANCH CHIEF BROOKS: -- nickel and nickel compounds.

PANEL MEMBER HAMMOND: That's different.

PANEL MEMBER BLANC: I think that one way that you can deal with it, at least obliquely, is that in whatever methodology prioritization you determine, that there should be a point or a weighting or a scoring that chemicals get if they are in a class which is known to have a class effect. And I don't think that's anything you've ever done. So if something is metabolized to an electrophilic intermediate, they should get some weighting on that regard; or if something is a polycyclic, they get a little plus just for that, you know. That you don't want to overwhelm the scoring system with that, but there should be some category which is class effects in the same way that the FDA would look at a beta blocker in a certain way comparing it to other beta blockers and --

ARB AIR QUALITY MEASURES BRANCH CHIEF BROOKS: I know we were looking at bio-accumulation.

OEHHA AIR TOXICOLOGY AND EPIDEMIOLOGY SECTION MANAGER MARTY: Right now we have overarching effects in that prioritization, like genotoxicity. Many of these

would get a plus because they're genotoxic. And, you know, you have to be a little bit careful about double counting and over-exaggerating so that it hops up in priority unnecessarily.

So we don't necessarily have it as a class effect. But if there is a toxicity that's consistent with that class of compounds, it will be picked up in another way, you know, are they genotoxic, neogenic --

PANEL MEMBER BLANC: But that's only based on their chemical testing on that particular chemical which shows it is genotoxic. You don't have something for "We don't know, but every other chemical that looks like this is genotoxic." In fact, you don't have anything like that. And the bigger problems that happen with your weighting is that things tend to get weighted because there's more data about them; and things for which there's less data but which may be all the more reason that they need the kind of close study is -- you know, the data are missing. And that's why -- maybe, again so it's not double dipping, it should be a default weight that you get if there are no specific data available. But I think that's what John was implying.

OEHHA AIR TOXICOLOGY AND EPIDEMIOLOGY SECTION MANAGER MARTY: There are a couple of actually -- more than a couple -- of programs that the FDA has used and the

EPA is trying to use that look at functional groups on organics, and have tried to correlate that with specific types of toxicity. We could look into that. They're not obviously a hundred percent correct, but they are interesting ways of looking at it.

So there are some software programs already developed looking at that, for carcinogenicity, reproductive and developmental primarily.

ARB AIR QUALITY MEASURES BRANCH CHIEF BROOKS:

Okay. We can look at that.

And we agree with you that the methodology does need to be updated for the reason that you said, where -- it was heavily weighted on exposure information previously. And if you, you know, didn't know what the inventory was, then it would get this low score. But then it would have these, you know, tremendous health effects but it would still score low. And so we're -- that's what we're trying to fix, so that it's more balanced and it's not -- you know, we're planning to delete the air monitoring requirement, because very few have -- very few compounds have that.

And so those are the kinds of balances that we're -- and corrections that we're trying to make. And also we wanted to add a component for children's health, and that was never included in the earlier version.

On this slide I'm --

PANEL MEMBER GLANTZ: Can I just add --

CHAIRPERSON FROINES: Go ahead, Stan.

PANEL MEMBER GLANTZ: Back to this issue of class effects. Because, you know, one of the frustrations of being on this Panel is just everything takes a very long time. And, you know, it might be worth going back to ARB's lawyers and saying like, "If you were going to address things in class effects, how would you do it?" Rather than "Can we do it?" But just say -- you know, find out -- or perhaps -- and if you hit a wall with that, I mean maybe it would be sensible for a report to be developed and brought to this Committee on why it would make sense, assuming it does, to do it this way, that the Committee could then consider and then forward on to whoever might have to go and suggest the law be amended. Because it seems -- I mean I'm not a chemist. But it just seems to me that that would be a much more efficient use of resources, which is a big issue.

OEHHA AIR TOXICOLOGY AND EPIDEMIOLOGY SECTION MANAGER MARTY: Yeah. I think it's sort of a mixed bag what's happened to date, because we have the polycyclic -- hydrocarbons by virtue of being PONs listed. So that's a class. And there are other classes that got listed as HAPs and therefore they're TACs. And then when we do the

risk assessment piece for the identification, it gets awkward because you have to do -- you have to report what toxicity data there are available, and that becomes part of the basis for identification. So you always run into this messy data and in some cases no data for certain members of the class.

So, for example, the BAP document we actually also have 26 potency equivalency factors for other carcinogenic PAHs that we had some data on which to base an equivalency factor. And ditto the dioxins and furans.

So we can list the class, but the risk assessment may not always be what you want it to be.

PANEL MEMBER HAMMOND: That was along the lines of what -- some of my concern, was clearly the prioritization comes from this combining exposure data and toxicity data. And if you don't have toxicity data, then it would go low in the priority list. But meanwhile I would -- so that seemed like a problem. I mean it is a problem.

On the other hand, how do you do a risk assessment without toxicity data? And I mean -- and then how do you deal with your tertiary butyl acetate issue, you know? So they want to go to a substitute for which there's no toxicity data. So you think you want to do that and move it up on the TAC list. But can you do it at

all or not? And I'm not sure, you know, how to balance that. But I think that one piece of that is for some things -- if you look at the -- if a mode of action is along the lines of what John is implying, the mode of action is something that relates to a functional group, you may be able to make analogies to functional groups.

Maybe, you know, what you're saying in terms of when you do one compound that's in the group, at least list the other compounds for which one can make the analogies and say, "These things at least we think can follow in some sort of order of magnitude effect."

But I think it's a big challenge. And I don't know that there's a simple answer. But I think it's something that I would encourage you not to run away from but struggle in this process to try to address that.

CHAIRPERSON FROINES: When I was chairing the NTP Carcinogen Committee, you know, we had to deal with vinyl chloride, which had already been addressed; vinyl bromide; and vinyl fluoride. And our committee voted unanimously that vinyl fluoride should be considered a human carcinogen based on the structure activity in relationships.

So, you know, there clearly are chemical structures which we would all feel pretty confident. Alpha beta unsaturated aldehydes undergo Michael addition

reactions, and those are well known. Quinones are well known. In other words there are classes of compounds for which there's not much ambiguity about their toxicity. And so not dealing with them is really eliminating hundreds of chemicals for which we have pretty good confidence in their toxicity.

OEHHA AIR TOXICOLOGY AND EPIDEMIOLOGY SECTION MANAGER MARTY: It could be part of a 2007 workshop.

CHAIRPERSON FROINES: I agree. I think that's the way to do it. That's --

PANEL MEMBER HAMMOND: That's a good idea. But in that case an action might be worthwhile. I don't know if there's structures to do this. But if one could get some toxicologists who do think about these issues to really prepare some thought pieces about how one could systematically do this or what kinds of criteria one could use to start making some of those extrapolations, and do like a background paper on that or something, if you can do that.

CHAIRPERSON FROINES: That's up to us.

PANEL MEMBER HAMMOND: Okay. I just don't know how to --

CHAIRPERSON FROINES: We'll do it.

Just one last point. And obviously, Melanie, I don't need to tell you this. You know it better than I.

There's lots of new science developing that -- I cringe every time I see a section in a document on, quote, genotoxicity, because it's like -- it's like Bruce Ames in 1975. And it just makes me nauseous to think that that's criteria we're using when in fact if you go to any national meeting everybody's talking about snip, snip, snip, snip, and non-genetic -- you know, non-genetic cancers and what have you. And I can show you lots of slides of beautiful plaque lesions in aortas in animals based on exposures that nobody's taking that kind of thing into account.

So that we really need to upgrade the science that we evaluate.

Yeah, Joe.

PANEL MEMBER LANDOLPH: Yeah, I served on the Science Advisory Board for the U.S. EPA and we did a review of the Human Health Program. And we suggested to them that they needed to accelerate their efforts to use computational toxicology methods, which they're doing very aggressively in the EU because they're just overwhelmed with floods of chemicals and different congeners, different classes. And there's no way that they can keep up with it based on the laboratory database that exists now and the flood of new things being synthesized. And so they're going to look at what the EU is doing. You might

want to talk to them about that.

This is clearly -- the regulatory mandate is almost infinite. And the knowledge base is somewhat small compared to the mandate. So one way to try and make up for that is to use computational toxicology, at least to give you hints, which will help in the prioritization.

CHAIRPERSON FROINES: There's a bunch of articles in Chemical Research in Toxicology that I could actually send you, just to make it easier.

Go ahead.

ARB AIR QUALITY MEASURES BRANCH CHIEF BROOKS:

Okay. We'll move on and talk about the status of our toxic air contaminant control activities and the SB 25 evaluations that we're doing.

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ARB AIR QUALITY MEASURES BRANCH CHIEF BROOKS:

We've looked at the air toxic control measures for dioxins, and they're listed on this slide. And the evaluation is complete in terms of these control measures. And we aren't recommending any other revisions to those control measures for dioxins at this point.

For lead, we've looked at the control measure that we had for lead. And we aren't recommending any revisions at this point for that control measure. But we're keeping the evaluation open because U.S. EPA is

reviewing the National Ambient Air Quality Standard. So if that changes, then that might change, you know, what we might need to do.

PANEL MEMBER BLANC: Why, out of curiosity, would metal melting operations have been the only operation that you looked at?

ARB AIR QUALITY MEASURES BRANCH CHIEF BROOKS:

Because I know that in terms of sources of lead, there's not a lot of major sources of lead out there. And so I'm -- even though I wasn't involved in it, I think this was probably one of the largest sources that we had in the state, and that's why they picked that --

PANEL MEMBER BLANC: Well, it certainly would be the largest in your Hot Spots program. But, for example, I would guess that exterior house refurbishing in San Francisco and Oakland and Berkeley and many other places would be a very large source of ambient lead. Just an offhand kind of question. But I mean I fully agree that I think the dioxin exercise is probably, you know, a waste of time.

But this seems to be a good example of how one can get too hung up in only looking under the light post for your keys because that's where the light is.

CHAIRPERSON FROINES: Well, a good example of that. Have you looked at radiator repair in that context?

ARB AIR QUALITY MEASURES BRANCH CHIEF BROOKS: I don't know. Bob, do you?

ARB STATIONARY SOURCE ASSISTANT DIVISIOIN CHIEF BARHAM: No, I don't believe we have. But --

CHAIRPERSON FROINES: Most radiators that are now produced are plastic. But when they're repaired, they're repaired with lead. And clearly trucks' radiators are lead. And so that's enormous source of lead exposure.

ARB AIR QUALITY MEASURES BRANCH CHIEF BROOKS:

Well, We'll pass that information along.

ARB STATIONARY SOURCE ASSISTANT DIVISIOIN CHIEF BARHAM: But going back to your comment. I believe DHS does have a program in place looking at lead paint exposures and trying to minimize those already also.

CHAIRPERSON FROINES: There's also probably somewhere between a hundred and a thousand Prop 65 suits on various lead. But that's all ingested lead for the most part I think.

--o0o--

ARB AIR QUALITY MEASURES BRANCH CHIEF BROOKS:

Okay. This is a listing of the control measures that we've adopted -- the Board has adopted for diesel particulate matter. And we have other control measures that we're currently developing, and I'll show you a slide of those in a minute. So clearly in terms of diesel

particulate matter we're continuing on, and there is a need for more controls.

CHAIRPERSON FROINES: Can I make one comment about that, with diesel?

There are two kinds of diesel particles. Those that you can trap with particulate filters and those that are formed when the vapors -- hot vapors come out of the tailpipe and the hot vapors condense and form what we call semi-volatile particles. And particle traps don't deal with -- don't deal with volatile vapors that condense to form particles. And we think the toxicity of those volatile particles is very high.

So that one big problem in the control strategies is everybody wants to put in particle traps. And particle traps doesn't deal with particles created by the condensation and nucleation of vapors. And it's like this enormous opportunity lost that -- you can't control diesel without controlling vapors coming out of the tailpipes. And it just hasn't gotten the kind of attention that it needs.

ARB AIR QUALITY MEASURES BRANCH CHIEF BROOKS: Okay.

PANEL MEMBER GLANTZ: And those particles are part of what we identified, right?

CHAIRPERSON FROINES: Right.

PANEL MEMBER HAMMOND: Yes, because they're -- railroad workers are exposed to them.

PANEL MEMBER GLANTZ: Yeah. So that's an important detail for the lawyers.

ARB AIR QUALITY MEASURES BRANCH CHIEF BROOKS:

We're currently working on a draft report for acrolein. So it hasn't been completed yet, and we don't know what our final recommendation will be. We do know that, and agree -- Dr. Froines, you had talked about it earlier with Melanie that there's a lot of new information on health effects of acrolein. And so Melanie and our staff are working together on relooking at those acute and chronic numbers, RELs for that. And so we won't really be able to finish our assessment until we kind of know what more needs to be done and whether the current RELs that we're looking at are correct or not.

CHAIRPERSON FROINES: This is --

OEHHA AIR TOXICOLOGY AND EPIDEMIOLOGY SECTION MANAGER MARTY: Yeah. I should add that the new data is not necessarily usable in terms of the REL development. So the new data is looking at different toxicities. And so I don't want you -- the expectation of the Panel to think that we're going to walk in here with all this adduct data and somehow be applying it in our noncancer risk assessment methods.

CHAIRPERSON FROINES: You mean it reflects some new science.

But let me give you an example of one other point. Acrolein is an alpha beta unsaturated aldehyde. Gluteraldehyde is an alpha beta unsaturated aldehyde with a methyl group stuck on it. That's the only difference. And so there's a whole bunch of silliness when we look at acrolein but we don't look at a compound which is identical except for one methyl group.

And so one of the things that you should do is to look at what are the alpha beta unsaturated aldehydes and -- that have different names because they have different substituents, because they all react by attacking the beta unsaturation and forming irreversable bonds with protein.

So that glutaraldehyde is one that you should think about taking up because it's going to operate identically to acrolein, with a lower vapor pressure perhaps because it's got a methyl group. But it's an example of understanding some of the simplest chemistry that any sophomore organic chemist would understand.

PANEL MEMBER BLANC: So my question would be that -- you had three -- you had six chemicals identified under the Children's Sensitivity Act. One of them was much later, ETS. But of the first five though, three

you've dealt with one way or the other. What, for example, made dioxin be more a priority for the needs assessment than acrolein? Was that an internal -- was that an internal organized decision or you --

ARB AIR QUALITY MEASURES BRANCH CHIEF BROOKS:

Well, I think the work started simultaneously. But there's a lot of differences in what we know about those two compounds. And acrolein's -- you know, there's uncertainty in the monitoring methods, the test methods for that compound. It's very reactive. There wasn't really good emissions information. I mean it's just a -- it's just a more difficult compound to tackle. And major sources of it are secondary formation and fuel combustion. And so it's not very simple that you can just say, "Okay, here's just one source category that we can go after to control for that pollutant." I mean it's all fuel combustion. So it's more difficult.

CHAIRPERSON FROINES: So when you --

ARB AIR QUALITY MEASURES BRANCH CHIEF BROOKS:

So I think it's going -- so it's going to take a little longer.

PANEL MEMBER BLANC: So a needs assessment -- maybe my problem is I don't understand exactly what a needs assessment is in your world.

ARB AIR QUALITY MEASURES BRANCH CHIEF BROOKS:

Okay. In our world a needs assessment is: What are the emissions? What are the health effects of this pollutant? What are the sources of this pollutant? And then we make a recommendation on how best can we further control this pollutant? But also in the needs assessment there would be -- you know, what all is being done in all of our other programs that would also be controlling this pollutant? And with the climate change work, we're going to be looking at the carbon content of fuels. So we think there there might be some, you know, control aspects to it for this compound.

So those are the kinds of things that we need to look at. And it takes longer.

PANEL MEMBER BLANC: Yeah, but -- okay. Then I'm glad you're going into this, because it seems to me a fundamental oddity.

Isn't the whole thing that you did when you bring something to us with this lengthy detailed assessment of sources of exposure and human health effects, isn't that that part of that needs assessment? Why once the Scientific Review Panel says, "We believe the science behind this detailed assessment of human health effects and sources of exposure is scientifically valid" would you then go back and reassess the human health effects and the sources of exposure? Wouldn't the needs assessment be

"Okay, we now realize this is a problem. As you said, what other programmatic areas are already dealing with this? And where do we have the greatest need" -- that your needs assessment might say, "Where do we have the greatest need for additional data?" But it wouldn't be "We can't write the needs assessment because we don't have the additional data." I mean that might be a finding of your needs assessment. I don't understand what the --

ARB AIR QUALITY MEASURES BRANCH CHIEF BROOKS: Well, let me explain. I could explain.

This was a hazardous air pollutant. And so we didn't do one of our comprehensive reports and go through the identification process. So --

PANEL MEMBER BLANC: So you didn't have some of it. Okay.

ARB AIR QUALITY MEASURES BRANCH CHIEF BROOKS: So on this one, you know, we kind of got handed this pollutant, and so now we have to deal with it and backtrack somewhat.

PANEL MEMBER BLANC: And then --

CHAIRPERSON FROINES: Which one are we talking about?

PANEL MEMBER BLANC: Acrolein.

ARB AIR QUALITY MEASURES BRANCH CHIEF BROOKS: Acrolein.

PANEL MEMBER BLANC: So then will that come back? Will the health assessment part then come back to this Panel for an RAC or whatever --

ARB AIR QUALITY MEASURES BRANCH CHIEF BROOKS:

Well, Melanie, you've run the original --

OEHHA AIR TOXICOLOGY AND EPIDEMIOLOGY SECTION MANAGER MARTY: Yeah, we actually already have reference exposure levels for acrolein. But we are updating them with our new methodology. And one of the reasons we're updating them is because ARB's working on their control package. And so they've been asking us, "Do you still have confidence in your REL? Is there new data? What about your new methods? Are you going to be relooking at acrolein?" So that's why we did it as one of the first ones.

PANEL MEMBER BLANC: And is the same thing also true for polycyclics, that you didn't have the health effects and exposure sources data done already?

ARB AIR QUALITY MEASURES BRANCH CHIEF BROOKS:

No, I think the primary focus was on the -- is on the PAHs. And we have a draft, and that's going to be released in the spring for public review. And the recommendations are being decided upon as we speak. But I do know that in terms of the data that they have from the ambient air, they're saying a lot of the -- the

concentrations in the air are going down. And we have a lot of, you know, particulate control measures going into place that are impacting that.

But I can't tell you what the recommendation's going to be at this time, because we don't know yet. It's not completed.

And then the last one that we're working on is environmental tobacco smoke. And we're also working on the needs assessment for that one. And right now the staff is going through looking at local and state ordinances and what's been done around the world beyond what California's already done to control secondhand smoke. And then they're going to be preparing the report. So it's not -- it's in progress, but it's not complete.

PANEL MEMBER GLANTZ: The other thing on that I would suggest you -- which you're probably doing -- is work with the State Health Department. Because there's gotten to be a lot of interest in outdoor exposures in California in the last couple of years, and they've actually collected some more data. And one big issue is in apartments and multi-unit housing, where the smoke goes out one window and goes into the one above it.

So you should -- they've actually -- I was at a conference a few months ago where they were actually presenting some of the data. So you should -- if you're

not working with them, you should be.

ARB AIR QUALITY MEASURES BRANCH CHIEF BROOKS:

Okay. I think that we are. I believe that we are. But we'll make sure.

CHAIRPERSON FROINES: I don't want to prolong things, but I can't let it go by. This notion that PAHs are going down is -- I just think that that is really a mistake to say that. And that I understand that there are regulations going in which if adopted and if implemented will cause changes, but you're also going to go from 15,000 trucks a year to 50,000 trucks a year at the Los Angeles Port. And anybody who says you're going to triple the number of diesel trucks, whatever the new regulations are, and you're not dealing with the vapor phases and what have you, you know -- believe me, benzopyrene isn't the issue of concern of PAHs. It's naphthalene and phenanthrene.

And so that all I'm saying -- and it's not to beat up on you in any way, Janette. It's simply to say the PAH issue -- in the last six years with the particle centers we've shown atherosclerosis, neurologic disease, developmental effects, asthma, we've shown at the existing levels all these diseases that are going on as we speak right now.

And to sort of say things are going to get better

when we've shown in the last five years all these new health endpoints is like -- it's like wishful thinking. And you're not going to get these old diesel trucks off the road. It all depends on this notion that we're going to have all these new diesel trucks on the road that's going to make everything better. Well, you tell me how many Mexican trucks are going to get off the road coming to the Los Angeles Port that aren't 25, 30, 40, 50 years old.

The notion of assuming that things are going to get better because you've got regulations, one has to look at the world of reality as well and think about that, because the science of cardiovascular disease associated with particulate matter has advanced so strikingly that at the levels that currently exist it's going to be a hundred years before that gets dealt with.

PANEL MEMBER GLANTZ: You know, just one other point. Back to acrolein, is it really looks like acrolein is one of the really important actors in terms of cardiovascular disease too. So I think -- you know, I know that you guys have been considering cardiovascular disease more in your risk assessments. But we really need to move beyond just cancer, because acrolein and a whole series of these chemicals are now being shown: 1,3-butadiene and there are a couple others have been

really shown to be very atherogenic.

PANEL MEMBER BLANC: John?

CHAIRPERSON FROINES: Joe.

PANEL MEMBER LANDOLPH: I had a question about this prioritization process. I was wondering. I guess what has bothered a number of us is a rational way to do it. And I was thinking for cancer, which is easier, couldn't you take the toxicity potency factor, multiply it by what you believe is ambient or what people are exposed to, and just get like a simple hazard index, just a very crude thing, and rank things by orders of magnitude, and then just go and pick the ones off the top.

So for cancer that would be fairly easy to do, I think. And then for toxicity I was trying to figure out how to do it. And I guess maybe one way would be you could divide the ambient concentration by the RfC or something like that. So you could have quantitative ranks of what was worth going after first.

CHAIRPERSON FROINES: We do have to keep in mind that cancer's a rare disease and the -- and that the risk from diesel, for example, for cardiovas -- for traffic for cardiovascular disease is much higher than for cancer. So that the fact that we haven't paid attention to atherosclerosis and myocardial infarctions, and the risks are higher than what we've been focusing on with cancer,

is an issue that we're going to have to deal with in the future.

PANEL MEMBER LANDOLPH: Sure. And I agree with what you just said. But, you know, my original point still stands I think. You should be able to do these quantitatively and get a ranking, whether it's for cardiovascular disease or neurologic disease or cancer, and go after the bad actors.

PANEL MEMBER BLANC: Although the point they were making before is that often if they have the cancer potency, they actually don't have the exposure data -- they have no ambient exposure data.

ARB AIR QUALITY MEASURES BRANCH CHIEF BROOKS: Or vice versa.

But where we have that information, we can take it into account. We have a comment call-in also. And we are trying to take into account cancer classifications, the number of organs that are impacted, and all of those things. And when we get this revision done, we'll be working with the leads and then we'll be bringing it back through you to just see if you have any other suggestions. And it is a numerical ranking, a scoring. It will be quantitative in that sense.

CHAIRPERSON FROINES: You've gotten a lot of comments from the Panel -- and I want to move on as much

as possible -- because right now the Panel has taken responsibility for coming back to you and saying, "Here's what we think is important."

So you don't feel like you're getting beaten up by us today at all?

ARB AIR QUALITY MEASURES BRANCH CHIEF BROOKS: No, no.

CHAIRPERSON FROINES: It's not intended.

ARB AIR QUALITY MEASURES BRANCH CHIEF BROOKS: No.

CHAIRPERSON FROINES: But all these issues that -- the thing that's interesting to me is how much things have changed in the past decade and how what we thought was advanced science ten years ago is now just -- we're just so much further along. And so how you then take -- you know, Janette, what it is is, how do you take research and when does research become mature enough to be used in a regulatory context? In other words, when is research ready for prime time? And that's the kind of issues that we're really getting at today. Because, you know, I can tell you all sorts of fancy research findings. But you would look back at me and say, "I can't use that yet. It's not ready yet." And so that's the kind of issue that we really need to come up with. But hopefully we can suggest some research that's mature enough where it

does have regulatory --

ARB STATIONARY SOURCE ASSISTANT DIVISIOIN CHIEF BARHAM: Oh, that would be very helpful, because we have people coming through the door all the time saying, "This study is the light of science," and we should be using it. And Melanie tells us, "Well, maybe that's not quite ready yet for" -- but to the degree that we can learn that, it would certain help our evaluations.

CHAIRPERSON FROINES: Yeah. So we get really excited about what we do, you know, everyday. And then we want you to use it, like yesterday you should have had this done. And it just not -- it doesn't work that way.

ARB STATIONARY SOURCE ASSISTANT DIVISIOIN CHIEF BARHAM: And then there's always the courts that come into play.

CHAIRPERSON FROINES: Yeah. Well...

ARB AIR QUALITY MEASURES BRANCH CHIEF BROOKS:

Okay. And then in the next just two or three slides I have the control measures that we've adopted since the program began.

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ARB AIR QUALITY MEASURES BRANCH CHIEF BROOKS:

And then these are the ones that we're working on right now, we're developing right now. And the composite wood products is for formaldehyde control. And the other

three are diesel particulate measures.

And that's all I have for you.

CHAIRPERSON FROINES: Is there somebody at -- is there -- not to open Pandora's box. But is there anybody at ARB or OEHHA who's looking at the potential toxicity of biodiesel fuel? Because everybody's racing towards it and -- you know.

ARB STATIONARY SOURCE ASSISTANT DIVISIOIN CHIEF BARHAM: You know, I was -- go ahead, Melanie.

CHAIRPERSON FROINES: Rancid -- if you take fat and you leave it out it becomes rancid. It produces all sorts of carbonyls, which we've been talking about. And biodiesel is a process of burning fat to produce carbonyls. And so there's obviously 200 years of science on the rancidification of fats, and everybody treats biodiesel as though it has no toxic properties and it's natural.

PANEL MEMBER BLANC: John, that's like suggesting that eating donuts is toxic.

CHAIRPERSON FROINES: Eating donuts is clearly not toxic. It's good for you.

(Laughter.)

CHAIRPERSON FROINES: But is there any biodiesel -- is somebody looking at biodiesel at ARB?

ARB STATIONARY SOURCE ASSISTANT DIVISIOIN CHIEF

BARHAM: Well, not that I'm -- are you aware of something? I'm not aware of --

OEHHA AIR TOXICOLOGY AND EPIDEMIOLOGY SECTION MANAGER MARTY: There's a --

PANEL MEMBER GLANTZ: Melanie's always the spoilsport.

OEHHA AIR TOXICOLOGY AND EPIDEMIOLOGY SECTION MANAGER MARTY: There's a couple of folks from ARB -- from different parts of ARB than Janette and Bob who asked us what do we know about the toxicity of the combustion products of biodiesel. And we've been trying to see what's in the literature. And there are very, very few studies.

At the same time, some of the folks -- the ARB has contracted with some folks to do chemical speciation and compare certain chemical characteristics of the biodiesel emissions with regular diesel and the newer, lower sulfur diesel. So they're at least aware of -- the fuels program is aware of it. One of the reasons they're moving towards it is less the toxicity aspects and more the greenhouse gas carbon cycling aspects.

But they don't want to -- they want to make sure they're not making a huge mistake by moving towards biodiesel as part of the fuel --

CHAIRPERSON FROINES: Why don't we finish up,

because I don't want to keep Tobi from waiting.

ARB AIR QUALITY MEASURES BRANCH CHIEF BROOKS:

That is it for us.

CHAIRPERSON FROINES: That's great. Thank you very much.

That was exactly what we hoped would happen. We raised new issues and stuff that we can pursue.

Thanks, Bob; thanks, Janette, Melanie.

(Thereupon an overhead presentation was

Presented as follows.)

DPR ASSISTANT DIRECTOR JONES: While Randy is pulling up this brief presentation on DPR's air quality initiative, I just want to say that we anticipate at least one, if not -- bring one, if not two, pesticides before the Panel in 2007, probably endosulfan and chloropicrin.

So since you're kind of looking at your calendar for this next year, let me just throw a pesticide component.

PANEL MEMBER BLANC: Well, I'd be happy to take the lead on chloropicrin.

DPR ASSISTANT DIRECTOR JONES: I'm sorry. Say that again.

PANEL MEMBER BLANC: I'd be happy to be one of the leads on chloropicrin.

DPR ASSISTANT DIRECTOR JONES: I'll leave that to

the Chair to make the assignments.

Thank you, Dr. Blanc.

CHAIRPERSON FROINES: I think that if I can -- we've been heavily, heavily using Roger Atkinson on exposure. And one of our exposure experts that just returned from seven months of doing -- you know, having no work to do, may be assigned to one of these.

PANEL MEMBER GLANTZ: She was frolicking --

CHAIRPERSON FROINES: She was frolicking in Europe, yeah.

DPR ASSISTANT DIRECTOR JONES: Well, I think as we get a little closer, I'll advise you. But it's most likely that will be -- our endosulfan risk assessment will be ready prior to the completion of chloropicrin.

CHAIRPERSON FROINES: Before chloropicrin?

DPR ASSISTANT DIRECTOR JONES: Before pic, right.

CHAIRPERSON FROINES: I think there will be a high degree of interest in chloropicrin.

DPR ASSISTANT DIRECTOR JONES: Oh, I'm sure there will be.

I had hoped that it would be the other way around. But Methidathion and lots of data on chloropicrin have moved it back.

Okay. Let me proceed with this brief item. I think, Dr. Froines, you had asked for this as an

informational item.

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DPR ASSISTANT DIRECTOR JONES: And we -- DPR launched a pesticide air initiative in the spring of 2006. And it's intended to be a comprehensive initiative to improve air quality statewide as it relates to pesticides.

While the primary focus of the initiative is to reduce VOCs from pesticides, it will also have the benefit of reducing air toxin emissions.

We're taking regulatory steps to meet some existing commitments we have by 2008 and develop an approach for future reductions. And so in launching that initiative we held a series of workshops in August of last year to present the concepts we're looking at.

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DPR ASSISTANT DIRECTOR JONES: And this is just a little bit of background. Some of you are well versed in this, but I thought I'd go ahead and play through this.

VOCs and nitrogen oxides react to form ozone. Pesticide active ingredients and inert ingredients, many are VOCs. And the Air Resources Board and air pollution control districts under the Federal Clean Air Act developed state implementaion plans to reduce VOCs and NOx.

The 1994 State Implementation Plan required DPR

to reduce VOC emissions from pesticides by 20 percent between 1990 and 2005 in five specific nonattainment areas in the state.

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DPR ASSISTANT DIRECTOR JONES: And This is just to give you an idea of where pesticides fit in in the VOC contributors for the San Joaquin Valley. So there's no single source that is very high. There are a variety of sources that are relatively low.

And for the 2001 emissions in San Joaquin Valley, pesticides come in at about 5 percent.

And that's the formulated products.

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DPR ASSISTANT DIRECTOR JONES: In order to carry out our activities under the SIP, we maintain an inventory of VOC emissions from agricultural and commercial structural application of pesticide products. And let me just say that we don't include consumer pesticide products because those are covered under ARB's Consumer Product VOC Reduction Program.

VOC emissions from pesticides are calculated based on the VOC fraction in a product times the amount of the product used. And then ARB uses that information modeling to estimate their ozone concentrations.

CHAIRPERSON FROINES: So that would include

inactive components as well as active components?

DPR ASSISTANT DIRECTOR JONES: That's correct. Because our use report captures both amount of product used and amount -- and then calculates amount of active ingredient used. And so the amount of product is what we're considering.

And then our data goes in --

PANEL MEMBER BLANC: I think John is asking a question which is -- you know, there's generally speaking a discrete list of volatile organic hydrocarbons, which I guess in pesticide formulation parlance are generally considered inert ingredients, right? They're emulsifiers or whatever they are.

But would an organophosphate or a chlorinated hydrocarbon active ingredient pesticide, which could contribute to the burden of volatile organic hydrocarbons, even though it doesn't -- wouldn't be very likely I think to appear on a sort of standard list of what are volatile organic hydrocarbons. Would that get calculated in?

DPR ASSISTANT DIRECTOR JONES: We -- and I'll see how far I get before I get too far away and grab Randy for the explanation.

When we were tasked to participate in the State Implementation Plan back in the early nineties we had to come up with a methodology for measuring the VOC potential

of pesticide products. And we selected the use of a -- what's called a thermogravimetric method of analysis. And basically what it measures is the volatility of a product. It's not so -- our methodology is different than ARB uses for their consumer products and other entities.

So we don't go back to that master list, Paul. We're just using the -- and Randy can give you the detail of that analytical method. But at that time we were looking for a relatively straightforward, least costly method that we could then go out and require registrants to develop TGA data on all of their products.

And I think some of you may recognize as we move through this that volatility and other aspects of ozone formation are kind of coming to a head now.

But let me -- I think let me get to the point where we are now. So our data feeds in to ARB's modeling that estimates ozone concentrations based on VOC and NOx. And then they continue to adjust their modeling based on their ozone, because they're measuring the criteria pollutant, ozone.

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DPR ASSISTANT DIRECTOR JONES: We use the VOC estimates and our pesticide use report data and calculate VOC emissions for all years beginning with 1990. So our start date was 1990. And then each day -- each year we

update that inventory annually based on our most recent pesticide use report and VOC fraction data.

The inventory focuses on the May to October peak ozone production period for each year in the five nonattainment areas of the state.

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DPR ASSISTANT DIRECTOR JONES: The characteristics at this time of emissions is that the VOC emission patterns parallel pesticide use. More than 90 percent of the emissions come from agricultural sources except for the South Coast. Not surprisingly, the fumigants are the highest contributors in all areas.

And then, secondly, the emulsifiable concentrate pesticide formulations are the high contributors.

And, Dr. Blanc, that I think kind of gets to the heart of your question where the EC concentrations -- or EC pesticide formulations, you know, will have an oil solvent-based material; and compared to, let's say, a formulation that is a wettable powder formulation.

So that is -- fumigants in the EC formulations are two areas of concentration.

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DPR ASSISTANT DIRECTOR JONES: The 1994 SIP off of which we're operating mainly affects the San Joaquin Valley. And we had a commitment to 12 percent reduction

by 1999. And at that time we met that goal. But then the pesticide use has gone up.

And then our commitment dates for Ventura and the southeast desert are coming up.

So those are three of the five nonattainment areas in the state.

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DPR ASSISTANT DIRECTOR JONES: We have a commitment to meet our -- and reduce VOC emissions to meet those commitments by 2008. The corollary to that is that there will be a reduction in human health risks from pesticide exposures. And then as part of the state implementation currently under development by ARB and the districts, we will develop a new commitment for that new SIP.

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DPR ASSISTANT DIRECTOR JONES: So our initiative, to bring you kind of back full circle, our initiative has four components. And I'd say these are kind of a sliding scale from regulatory down to collaborative efforts.

The first being emission -- fumigant emission reductions.

The second being managing emissions from the liquid EC products themselves.

Third being innovative technologies in how

pesticides are applied.

And the fourth being pest management.

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DPR ASSISTANT DIRECTOR JONES: For fumigant emission reductions, we want to look at reducing how much goes in, largely to the soil, and how much comes out. We will be proposing regulations within the next few months for all of the fumigants to capture reductions on the order of approximately four tons per day.

Randy, to my left here, is leader in developing this package. It has not gone public, and so we can only tell you at this point the staff are looking at a wide array of opportunities. But it will likely limit the methods of applications of fumigants. And these are largely for soil application. But, again, the corollary that will address the air toxin issues.

We're acutely aware that research is needed for additional emission reductions. And then we will incorporate restrictions from risk assessments in the future. And I think by telling you all that we're bringing -- we'll be bringing chloropicrin forward within the next year or so, that's an illustration of when we complete that process with you all listed as a TAC and incorporate mitigation into that, that will bring to bear on fumigant emission reductions.

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DPR ASSISTANT DIRECTOR JONES: Our effort for liquid EC formulations is in the form of launching a reevaluation to cause the reformulation of liquid ECs. In the San Joaquin Valley about 45 percent of the VOC inventory is due to liquid emulsifiable concentrates. We've sent notices to registrants regarding 700 high VOC content products in the liquid emulsifiable concentrate category. And we expect to be notifying the registrants this spring on specific requirement for reformulation. And I'll just say that is a controversial step on the part of DPR.

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DPR ASSISTANT DIRECTOR JONES: In the area of innovative technologies, again on the sliding scale that I mentioned, this gets into the area where we're looking and working with both the agricultural industry and the application industry for opportunities in application technology that can reduce drift VOCs and pesticide use.

And I think in the area -- just by way of illustration, in the area of fumigants, the uses of tarps that had been developed over probably the last five to eight years that helped keep fumigants in the soil until they carry out their biocidal activity and break down is one of those areas.

In the area of field application of pesticides, better nozzles and more directed nozzles that allow more targeted application and lower pesticide use is one of the areas.

This will have a beneficial effect on the water quality impacts. It's one of the other areas that is one of our challenges. And we continue to need to identify technologies and promote their adoption and find incentives for that adoption. I think some of the programs that USDA manages in the way of grants to farmers is one of the illustrations of that. And hopefully there will be more.

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DPR ASSISTANT DIRECTOR JONES: And in the area of pest management practices, we're looking at what we're calling strategic pest management partnerships. We're working with a variety of grower groups and commodity groups to look at their pest management needs and, where possible, identify if they can use a wettable powder formulation as opposed to an emulsifiable concentrate formulation, promote that. And part and parcel of this of course is demonstration research to illustrate the value of either other products or other ways of doing their pest management. A part of this item is promoting pest resistant cultivars, and that has some ups and downs.

And then for purposes of our partners at Department of Food and Agriculture, pest exclusion is one of their challenges. And of course I think many of you are familiar with a pest like Mediterranean fruit fly, that when that does come in to the state, it poses challenges for farmers. And so promoting pest exclusion of those pests that are difficult for California agriculture is one of the things that we have to mindful of.

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DPR ASSISTANT DIRECTOR JONES: The steps that we're engaged in now is that the draft SIP will be released in the early winter of 2007, it will be incorporated into the ARB SIP which will be presented to the Air Resources Board in spring of 2007.

We'll be coming out with our proposal on the fumigant regulations probably within the next month to two. And we hope to have our reevaluation actions completed in 2007. That doesn't mean we're going to have reformulated products by the end of the year, on the one hand; on the other hand, provide clear direction to the registrants whose products are affected by that effort.

So any questions?

Okay. Thank you very much.

CHAIRPERSON FROINES: This must be a difficult

time to do all this, because the economy of agriculture is so problematic at this point, that I think you're really taking on an enormously important but difficult task at this stage. It must be interesting to see the dynamic between the two agencies.

DPR ASSISTANT DIRECTOR JONES: Well, I think Randy could comment on -- Randy's really been on the front line on this since last spring. I mean well before that. But I think trying to bring together kind of some, I would say, somewhat disparate activities into this initiative have been a real challenge. And it is a very interesting time.

CHAIRPERSON FROINES: Well, the economy is very -- really problematic. And of course globalization has something to do with it as well.

So it's going to be interesting to follow this process. So I'm aware at least from my own reading and things that, you know, we're dealing with chloropicrin, but there's this much larger set of issues outside of any specific chemical or what have you that's driving all this.

DPR ASSISTANT DIRECTOR JONES: Well, I think the first thing you'll see will be this spring when we come out with the fumigant emission reduction regulations that apply to methyl bromide, chloropicrin, MITC, and

1,3-dichloropropane. Those are the four major -- those are the four fumigants used in production agriculture in the field.

PANEL MEMBER BLANC: So dichloropropane is still used?

DPR ASSISTANT DIRECTOR JONES: Oh, yes, yes. And as --

CHAIRPERSON FROINES: Six million pounds.

DPR ASSISTANT DIRECTOR JONES: And as methyl bromide has been phased out under the Montreal protocol, the uses of 1,3-D have come in behind that.

PANEL MEMBER BLANC: Is it still being manufactured in state as well?

DPR ASSISTANT DIRECTOR JONES: Yes, it is.

PANEL MEMBER BLANC: So is that something that -- for our other people, is that something that -- from the point source manufacturing has ever -- is that a toxic air contaminant already?

DPR ASSISTANT DIRECTOR JONES: It's a HAP.

CHAIRPERSON FROINES: And I think it's manufactured in southern California, isn't it?

DPR ASSISTANT DIRECTOR JONES: I think it's manufactured in northern California.

Oh, really?

PANEL MEMBER BLANC: It was Occidental, wasn't

it --

DPR ASSISTANT DIRECTOR JONES: No, it's Dow Agri-sciences.

CHAIRPERSON FROINES: Where are they located?

DPR ASSISTANT DIRECTOR JONES: Over in the East Bay.

CHAIRPERSON FROINES: Really?

PANEL MEMBER BYUS: Perhaps this isn't totally relevant, but I'm just echoing what you're saying, John. I mean I think the data showing the importance of the population eating large amounts of fruits and vegetables and nuts continues in the cancer literature and obesity literature and cardiovascular literature to show enormous positive effects on the population. And the only way you're going to get them to do this is if you provide it -- agriculture provides it cheaply and in convenient forms like the little spinach in bags, for example, which the consumption of spinach just by putting it in bags and making it easily marketable has gone up ten, twenty-fold, till E. coli was found in it.

(Laughter.)

PANEL MEMBER BYUS: But this is extreme -- I mean, you know, and all the attempts to extract the single lycopene components and the phyto-chemicals and whatever is in plants and have people take individual pills so then

they can go and eat their fast food have all proven relatively unsuccessful. I mean now there's still a lot of work to be done, but the data continues to show that eating large amounts of fruits and vegetables is extremely valuable and enormously important to the health of the populous. And so providing it cheaply and conveniently is really important. So pesticides are a big part of that. I mean you can't do it -- I mean nothing against the organic people, but I have my skepticism. And I'm saying it's extremely important that this work be carried out and that we want people eating this stuff. And it's the only way -- and it's a very important way of doing it, at least from my point of view. So I encourage you to, you know --

DPR ASSISTANT DIRECTOR JONES: I think for, you know, that example, Paul, that carrots is such an interesting example. California carrot industry has been very resourceful in developing products that consumers want. And so the little bag of baby carrots that are very easy to put in lunches for kids, you know, is really marvelous. Well, the carrot industry is one of the -- in the southern San Joaquin Valley is one of the large users of metam sodium for the pests that affect carrots in the ground.

And so trying to achieve that balance where, you know, based on the work that this Panel did and reviewing

our report on metam sodium and the active entity of MITC was very important. And we'll be coming out just within a few weeks on the control measures for managing metam sodium application and MITC release. And of course the extent to which farmers are able to work with the applicators who make this -- and make this work and be able to continue carrot production that is --

PANEL MEMBER BYUS: It's very important. I mean we can't lose sight of that.

And then the simple-minded idea of exporting all of this food industry to other countries where there are less stringent regulations in terms of population-based problems with over-pesticide use maybe won't affect us directly, but the number of people that it affects is quite large. So I mean your efforts here are extremely important, I think all our help in the --

CHAIRPERSON FROINES: I would remind you, however, that one doesn't have to use pesticides on donuts.

(Laughter.)

CHAIRPERSON FROINES: And so donuts are clearly better for you.

(Laughter.)

PANEL MEMBER BYUS: Yeah, right, John.

CHAIRPERSON FROINES: And so I rest my case.

PANEL MEMBER GLANTZ: I've been trying to convince my wife that donuts were a vegetable.

(Laughter.)

CHAIRPERSON FROINES: We finally have gotten to prove that donuts are better for you.

(Laughter.)

CHAIRPERSON FROINES: Can I have a question just off topic -- on topic actually --

PANEL MEMBER GLANTZ: That was a joke, for the record.

(Laughter.)

PANEL MEMBER GLANTZ: For those were jokes.

CHAIRPERSON FROINES: I don't think we're going to get sued on that part of the conversation. I think we're safe.

But in terms -- Lyn, in terms of ARB, is anybody looking at emissions from the Dow plant for ARB's perspective?

PANEL MEMBER GLANTZ: And also emissions from deep fryers. They're used to make donuts.

(Laughter.)

DPR ASSISTANT DIRECTOR JONES: You know, John, let me -- before Lyn launches in, I realize I may -- Randy may be correct. I think the production facility I am thinking of is sulfuryl fluoride.

And so I honestly do not know where 1,3-D is produced. So my apologies. You know, Dow has two very important fumigants. And you all just finished sulfuryl fluoride. But the production facility for that is up in northern California. I don't know, Lyn may have a handle on where 1,3-D is produced.

ARB AIR POLLUTION SPECIALIST BAKER: I thought it was actually out of state, but I don't know. But we have not been asked by DPR to ever do pesticide monitoring around a manufacturing facility.

CHAIRPERSON FROINES: But wouldn't that be an ARB authority anyway? DPR wouldn't ask you that, would they?

ARB AIR POLLUTION SPECIALIST BAKER: No, I guess they wouldn't, no. No, that would be --

CHAIRPERSON FROINES: You know, there's this big pesticide plant -- I mean this big chemical plant in southern California which, as far as I can tell, nobody ever does any monitoring and they produce loads of chemicals and they're all quite -- you know, they're not particularly good for you.

ARB AIR POLLUTION SPECIALIST BAKER: They do, Dr. Froines. They do have to report under the Air Toxics Hot Spots Program, the 2588 program, their emissions to the local air district and then to a risk prioritization to see if they need to do -- to reduce their emissions to

reduce their hot spot risk.

CHAIRPERSON FROINES: Well, I understand that, and I've followed 2588 since it was passed. And my level of confidence in some of the data that -- and the timeliness of the data is -- I must admit being a skeptic. And so having somebody doing some spot checking is not inappropriate, I think.

ARB AIR POLLUTION SPECIALIST BAKER: We've never considered that, but we certainly could look at pesticides around a pesticide manufacturing facility.

CHAIRPERSON FROINES: There is some logic to the idea.

ARB AIR POLLUTION SPECIALIST BAKER: I'm sorry?

CHAIRPERSON FROINES: There's some logic to the idea of -- if you have a pesticide manufacturing taking some samples on the levels that come out of the plant isn't exactly --

ARB AIR POLLUTION SPECIALIST BAKER: We would -- I would assume that if their production facility was at all efficient that they wouldn't be releasing too much of what they were trying to make into the air. There may be some. But they wouldn't have a very efficient --

CHAIRPERSON FROINES: No, I agree. I mean we take industrial hygiene students to this particular chemical manufacturing. And everything -- you know,

everything's pipes and tubes and there's no real emissions unless they're fugitive. So I agree with you. But to the degree that you think --

PANEL MEMBER BLANC: Well, as a minimum fact I think would be useful to the ARB from a quality control point of view of your methodologies for ambient air assessment, don't you think, since you should be getting at a minimum whatever your background levels are?

ARB AIR POLLUTION SPECIALIST BAKER: I'm only aware of one facility in California that makes any of the pesticides that we have done monitoring for for DPR, and that's a metam sodium manufacturing facility.

PANEL MEMBER BLANC: And did you do such ambient air assessment as a quality control measure for your laboratory?

ARB AIR POLLUTION SPECIALIST BAKER: Not for that. But we actually did a source test I believe at the request of the air district.

CHAIRPERSON FROINES: Well, you know -- not to prolong this, but, you know, we all are aware of the fact that chemical manufacture's basically an enclosed process and it should not have significant emissions. But we're also aware of the fact that there have been huge emissions at chemical plants in Texas and Louisiana. So there is a history to problems. And so one can't just automatically

assume that everything is perfect because the engineering of these facilities are theoretically reasonable.

ARB AIR POLLUTION SPECIALIST BAKER: Agreed.

PANEL MEMBER BLANC: Okay.

CHAIRPERSON FROINES: Thank you, Tobi.

Thanks, Randy.

PANEL MEMBER BLANC: So that last item -- the last item on the agenda had to do with just future scheduling. But usually that isn't something we're able to do at these meetings.

CHAIRPERSON FROINES: We needn't do that. We were going to, one, say how wonderful it was that you published your book. That was one thing we were going to do.

We were going to just ask Kathy if there was anything based on her floating around Europe that she thought would be particularly relevant.

PANEL MEMBER HAMMOND: Well, I thought I would bring back to the Panel some information that relates directly to some of the work that we did on the ETS document.

I was in Geneva working with the World Health Organization at the Tobacco Free Initiative from March to July. And my very first day there -- oh, some of you may know, but just let me back up and say a very important --

one of the most important public health treaties in history went into effect about a year ago, and that's the framework convention on tobacco control. And I don't know what the current number is, but about 164 signees that -- nations that have signed on to this, not including the U.S. And they had -- just before I arrived the Conference of the Parties, that is representatives from all the countries that signed, had had their first meeting in February, just before I came. So on my very first day --

PANEL MEMBER GLANTZ: Just so people understand, the Conference of the Parties is where they get together and write the rules for implementing the treaty.

PANEL MEMBER HAMMOND: And, you know, it's very important. This is like, you know, for tobacco control around the world. And so my very first day at WHO they told me that the biggest issue that came up at the Conference of the Party, the thing that people felt they needed more than anything else was information on the health effects of environmental tobacco smoke. And I said, "Well, do I have a" -- you know, "do I know something about that for you," you know. And they knew that I knew about it.

So I said -- you know, that kind of led to some ideas and the eventually working with people both from ARB and Stan and other people. We were able -- I was able to

kind of talk to them about the idea of possibly republishing the Cal EPA report. You recall the first report for the nineties was republished by the National Cancer Institute, who's not intending to republish this one. And yet I think there's a lot of important information.

So the thought was we would -- WHO would republish this, and the entire document would be published in many copies to be distributed throughout the world. And the executive summary would be translated into the six U.N. languages. So everyone got very excited about this.

But I was very upfront from the beginning about what some of the controversial issues, particularly the breast cancer issue, you know, and how that was, you know, controversial. And I wanted make sure they knew what they were getting into.

And so they -- you know, there was some caution. And so they asked me what kind of peer review the document had undergone for that. And I wrote a memo to the head of TFI about that peer review process, which basically was the internal peer review at ARB and then the Scientific Review Panel and what we had done. Fortunately people shipped me a whole bunch of documents, so I was able to give everybody who was interested in it copies of the actual documents and the transcripts from the SRP

meetings. And you talk about all the different drafts, that it was an open process. And I also gave them all the comments, the Section C.

And the idea had been originally they were going to commission three or four people to do an independent peer review to make sure they wanted to put the WHO -- on it. After they looked at what was already done, they were so impressed they said, "There's no more peer review needed." You know, they were quite impressed. They also, you know, looked over some of the material in the -- particularly in the breast cancer section and decided to go ahead. So --

PANEL MEMBER GLANTZ: Can I just interject one thing?

You know, Yumiko Mochizuki, who is the head of this unit at the WHO, is -- before she got into tobacco was a breast oncologist.

PANEL MEMBER HAMMOND: And she also knew the epidemiologist who'd done the work in Japan that was important in the study.

So they actually asked me to present to the World Health Assembly, which is the meeting of the WHO from all the countries around the world that meets every year annually. I was asked to present to them the findings of the Cal EPA report. So those were presented there as

well. I mean those are the findings.

So this really got a lot of attention, and people were really quite excited about it.

And then at the World Conference on Tobacco Health in July there was actually a press -- they held a press conference where they announced that WHO was going to publish these -- to do this republication.

Now, it's been -- we had hoped it would be out by now. It's not out by now. There are some forces obviously working to try to maybe make that not happen, particularly given -- I don't know even if this committee knows about the Surgeon General's report has come out. So the Surgeon General's report on passive smoking has come out. Even though most of that report was written in 2000, 2001 -- so it's really more out of date -- it looks like it's more recent because it came out a year later than the Cal EPA report. So that was released on June 23rd, I think, of 2006.

So there has been an effort by the U.S. Government to get -- and CDC to have WHO not publish the Cal EPA report. But they say they're going ahead doing it. But it hasn't happened yet.

CHAIRPERSON FROINES: What did the Surgeon General's report say about breast cancer?

PANEL MEMBER HAMMOND: Well, they -- remember

that all they could say that there's sufficient evidence, there's suggestive evidence, there's insufficient evidence to make anything or sufficient evidence that there's no association.

We determined in California that there was sufficient evidence, that the Surgeon General's report said there was suggestive evidence. So it was one step down.

Also, there was -- the press conference was covered and was -- the information was picked up around the -- around the country some more information came out, especially about the breast cancer aspect.

PANEL MEMBER GLANTZ: The Surgeon General's report, Kathy and I were both involved in it in the first draft of the report --

PANEL MEMBER HAMMOND: We're not supposed to talk about it.

PANEL MEMBER GLANTZ: No -- well, now that it's out, this is all foible.

The first draft of the Surgeon General's report had an affirmative negative statement. It said there is evidence that there is no effect of passive smoking on breast cancer. And the final report, after much yelling and screaming, said that they actually did separate pre- and post-menopausal women and they did their own

meta-analysis, which to within rounding error came out the same as the OEHHA report.

The reason that they only said suggestive rather than causal was because they said that there's -- that there's no evidence that active smoking increases the risk of breast cancer based on studies done up to about 2001. And as you recall, in the Cal EPA report there's an appendix on active smoking that updates that. And the CDC is in the process of revisiting the active smoking issue now, and my guess is, will change their mind in the next year just based on talking to Terry Pechacek.

But it was -- there were quite a few important people who got involved in the Surgeon General's due process to force a reconsideration of the first draft. And as Kathy said, while the report came out in 2006, it was actually written about 2002, I think.

PANEL MEMBER HAMMOND: But I guess the main point I was going to bring is that there is a lot of interest world-wide in the Cal EPA report. And it has now been reported more widely.

I want to to thank those of you who were so responsive in helping me from a long distance getting me materials to help do that. But people were -- and when they looked at what it was and they looked at the documents and the processes, they were quite impressed.

And it was really quite --

PANEL MEMBER GLANTZ: Yeah. And if you go to the WHO website, it's up there now. It says they are going to be publishing it. And it has a link to the current ARB site. But they're going to be putting it out as a WHO --

PANEL MEMBER BYUS: Why did NCI decide not to publish? Or shouldn't I ask?

PANEL MEMBER HAMMOND: They weren't even asked actually.

PANEL MEMBER GLANTZ: Well, they were never really -- it was never really pushed with them. But there's a lot of strum and drum back and forth between the NCI and the CDC generally. And there was -- when I kind of broached the idea with some people I know at the NCI, they were afraid that if they did that, the CDC would get pissed off. And since the WHO was interested in it, it just didn't seem worth pushing.

PANEL MEMBER HAMMOND: And the idea with the WHO publication, I mean if it happens, what I'm happy about is that they will actually distribute it to all the WHO regional offices, they'll be going out to the countries, and there'll be these translations. So it will truly be, you know, available. And as I say, I think that the -- you know, a lot of this material is available. The executive summary with the summary of facts is out there.

So I think people here really think -- you know, you've done a lot of work that is already having an effect around the world and being useful to people. And they are using it and incorporating it into the tobacco control materials, the smoke free environment initiatives that they're developing now, that again are being used around the world. So this is all supporting that.

PANEL MEMBER GLANTZ: Yeah, they are -- another thing I had worked -- because we're a WHO collaborating here at UCSF. They are putting out a document -- a policy document on what governments ought to do about secondhand smoke, and relies very heavily on the Cal EPA ETS report. It also uses the Surgeon General's report, which is generally a pretty good document too. But, you know, they're very -- it relies -- I mean they talk about breast cancer. It's discussed in terms of this as a causal relationship, et cetera, et cetera. And that should be -- well, nothing ever happens quickly at the WHO. But I reviewed what they said was the last draft of that document about two months ago.

CHAIRPERSON FROINES: Thank you.

I guess we can entertain a motion to adjourn.

PANEL MEMBER BLANC: So moved.

PANEL MEMBER BYUS: Second.

CHAIRPERSON FROINES: I guess this doesn't take

much discussion?

All in favor aye.

(Ayes.)

CHAIRPERSON FROINES: It's unanimous.

(Thereupon the California Air Resources Board, Scientific Review Panel adjourned at 3:00 p.m.)

CERTIFICATE OF REPORTER

I, JAMES F. PETERS, a Certified Shorthand Reporter of the State of California, and Registered Professional Reporter, do hereby certify:

That I am a disinterested person herein; that the foregoing California Air Resources Board, Scientific Review Panel meeting was reported in shorthand by me, James F. Peters, a Certified Shorthand Reporter of the State of California, 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 in any way interested in the outcome of said meeting.

IN WITNESS WHEREOF, I have hereunto set my hand this 18th day of January, 2007.

JAMES F. PETERS, CSR, RPR
Certified Shorthand Reporter
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