

MEETING
STATE OF CALIFORNIA
AIR RESOURCES BOARD
SCIENTIFIC REVIEW PANEL

SHERATON GATEWAY HOTEL
6101 WEST CENTURY BOULEVARD
LOS ANGELES, CALIFORNIA

MONDAY, JUNE 26, 2006

9:30 A.M.

JAMES F. PETERS, CSR, RPR
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APPEARANCES

PANEL MEMBERS

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Dr. Roger Atkinson

Dr. Paul Blanc

Dr. Craig Byus

Dr. Joseph Landolph

Dr. Charles Plopper

REPRESENTING THE AIR RESOURCES BOARD:

Mr. Jim Behrmann, Liaison, SRP

Mr. Peter Mathews

Mr. Kirk Oliver, Senior Staff Counsel

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Ms. Sheryl Beauvais, Ph.D, Staff Toxicologist(Specialist)

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Environmental Research Scientist

Ms. Carolyn Lewis, Associate Toxicologist

Ms. Lori Lim, Ph.D, Staff Toxicologist

Mr. Randal Segawa, Agriculture Program Supervisor

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APPEARANCES CONTINUED

REPRESENTING THE OFFICE OF ENVIRONMENTAL HEALTH HAZARD
ASSESSMENT

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

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1 PROCEEDINGS

2 CHAIRPERSON FROINES: Let's call the meeting to
3 order. Is this working?

4 So we will officially call the meeting of the
5 Scientific Review panel on Toxic Air Contaminants open.
6 And it's June 26th, 2006.

7 The first item on the agenda is the continuation
8 of the panel's discussion of its draft findings based on
9 the Report Sulfuryl Fluoride Risk Characterization
10 document.

11 I'm not quite sure how to proceed. Roger and
12 Craig were the leads and so maybe we should start with
13 them giving us any update that they would like to make and
14 then we'll go around. I actually sent Emails around this
15 weekend about one problem, and so I have a suggestion, but
16 we can come to.

17 PANEL MEMBER ATKINSON: We had a number of -- or
18 a couple of sort of conference meetings, conference calls
19 including Jim Behrmann from the ARB. And we revised the
20 previous findings to take into account as fully as we
21 could the comments from the last meeting of last year.
22 There it is.

23 PANEL MEMBER BYUS: I think we used a combination
24 of my notes, the transcript, Jim's notes, which there was
25 a rather lengthy discussion. And we tried to piece all of

1 that together and try to make the new findings. We
2 modified the findings. We also added things to the actual
3 report as well in response to that lengthy discussion. So
4 that's what we did.

5 And I think, Lori, is here and she -- you have
6 some PowerPoints, do you not, about --

7 PANEL MEMBER BYUS: She's summarized them.

8 CHAIRPERSON FROINES: At this point, I would
9 prefer -- I talked to Lori ahead of time, and I would
10 prefer that the Panel discuss the findings. And I don't
11 think we need Lori's input at this point. This is, at
12 this stage, an internal issue rather than an external one,
13 unless the Panel would like to see Lori's PowerPoint
14 slides. What's your inclination?

15 PANEL MEMBER BLANC: No, I think let's go forward
16 with the discussion. Paul Blanc here.

17 I would say, just to clarify, I think what you
18 intended in your comment was to say that DPR in response
19 to your input modified its report.

20 PANEL MEMBER BYUS: That's correct.

21 PANEL MEMBER BLANC: Okay.

22 PANEL MEMBER BYUS: Well, in response to the
23 discussions of the Panel and our sort of clarifications,
24 they modified the report.

25 PANEL MEMBER BLANC: And then your findings

1 reflect their original report and their modified report.

2 PANEL MEMBER BYUS: That's correct.

3 PANEL MEMBER BLANC: So that everything is
4 consistent.

5 PANEL MEMBER BYUS: Correct.

6 CHAIRPERSON FROINES: And I think what Paul is
7 getting at is that you are comfortable with the changes
8 that DPR made in the report. And so that a revisiting of
9 the report you think is not necessary at this report?

10 PANEL MEMBER BLANC: Right. And I would say that
11 the findings -- you know, the bottom line of the findings
12 is that this is clearly a Toxic Air Contaminant by all of
13 the criteria upon which we assess such things, and that
14 the report was convincing in that regard. And I think
15 that since that's the major issue, I think the findings,
16 as summarized, are very straightforward.

17 I think that because of the complexity of the
18 technical aspects, which include the parent compound and
19 then the side issue of fluorine exposure, I think that,
20 you know, organizationally it can be a challenging set of
21 findings. And I think you've taken the route of being
22 quite expansive in the narrative rather than some of the
23 findings that we've had that have been more terse. And I
24 think that that opens it up for more potential
25 editorializing.

1 So I think that the big question is assuming that
2 there's a consensus that the principal findings are very
3 convincing and that there might be some room for editorial
4 streamlining, I think we've faced that before in the
5 Panel, where we've given guidelines to our Chairman or
6 working subcommittee with the Chairman to make those final
7 wordsmithing changes and then circulate a tentatively
8 approved document without delaying the approval of the
9 findings, would be the kind of route that I would suggest
10 for this. Rather than spend a lot of time, you know,
11 talking about word choices, because it's a very wordy set
12 of findings. I know Joe you circulated an Email with some
13 suggestions. And John 2 days go you suggested some other
14 logical reorganization, but that wasn't really -- I didn't
15 read your Email as questioning anything fundamental about
16 the --

17 CHAIRPERSON FROINES: No.

18 PANEL MEMBER BLANC: So that's the route,
19 personally, I would recommend. But I think it would be
20 easiest first -- well, most logical first to come to some
21 sense if there's a consensus that people do think it was
22 convincingly summarized as a Toxic Air Contaminant.

23 CHAIRPERSON FROINES: Joe.

24 Bill, can you basically do 2 things. One, let's
25 deal with what Paul's put on the table and address that

1 question, namely, are you convinced in terms of its
2 recommendation of it being a Toxic Air Contaminant, and
3 secondly then that we approve these findings and let me
4 wordsmith a little bit to bring it to final closure.

5 PANEL MEMBER LANDOLPH: So let's see. This is
6 Joe Landolph.

7 PANEL MEMBER LANDOLPH: Yes, I certainly agree it
8 should be considered a Toxic Air Contaminant. I don't
9 have any doubt about that.

10 And I think the document has been well worked by
11 Roger and Craig. And they also -- Lori and the others
12 also put substantial effort in to the 10 pages of comments
13 I sent earlier, so it's a pretty good document.

14 And then the other question was -- what was your
15 other question John?

16 PANEL MEMBER BLANC: Mechanistic.

17 PANEL MEMBER LANDOLPH: Oh, mechanistically.

18 Yeah, it looks like a Toxic Air Contaminant to me from --

19 CHAIRPERSON FROINES: No. No. He meant the
20 process, not that the chemical mechanism works.

21 PANEL MEMBER BLANC: No, the final wordsmithing.
22 Tentative approval --

23 PANEL MEMBER LANDOLPH: On our findings?

24 CHAIRPERSON FROINES: Yes.

25 PANEL MEMBER LANDOLPH: Yeah.

1 CHAIRPERSON FROINES: Well, we'll go through your
2 comments in a minute. What Paul said is since there can
3 be some minor changes to what is in this document, is the
4 panel comfortable if I make some small wordsmithing
5 changes, some changes and then send a draft around, rather
6 than spend hours going through the document itself.

7 PANEL MEMBER LANDOLPH: Oh, some small
8 wordsmithing changes to DPR's document?

9 PANEL MEMBER BYUS: No. No, our findings.

10 PANEL MEMBER LANDOLPH: You've got my comments.

11 CHAIRPERSON FROINES: I think you should raise
12 your comments because they were substantive.

13 PANEL MEMBER LANDOLPH: Okay, whenever you like.
14 Otherwise, I agree.

15 CHAIRPERSON FROINES: So, Charlie, is the
16 approach Paul is suggesting okay with you?

17 PANEL MEMBER PLOPPER: Yeah, its fine with me.

18 CHAIRPERSON FROINES: Craig.

19 PANEL MEMBER BYUS: Fine. It's wonderful.

20 PANEL MEMBER ATKINSON: Fine.

21 CHAIRPERSON FROINES: So I don't know if -- Joe,
22 why don't you give us your comments.

23 PANEL MEMBER LANDOLPH: Sure. One is a year old
24 comment that you had asked me to deal with about a year
25 ago, which was to try and deal with that issue of the

1 carcinogenicity of fluoride, the metabolite of sulfuryl
2 fluoride. So I just recommended a short sentence, which I
3 Emailed to everybody, to you and Craig said it looked okay
4 to him. I recommend some wording along the lines of,
5 fluoride, a metabolite of sulfuryl fluoride, is
6 clastogenic and can induce osteosarcomas in male rats.
7 There is some conflicting evidence that fluoride in the
8 drinking water correlated with an increased incidence of
9 osteosarcomas in male humans." The epidemiological data
10 was conflicting. The animal data is even a little bit --
11 it's a little bit conflicting. It's not perfectly
12 consistent.

13 PANEL MEMBER BLANC: Joe, is it an IARC 3 or 2B
14 or --

15 PANEL MEMBER LANDOLPH: That's a good question.
16 I don't know the answer to that.

17 CHAIRPERSON FROINES: Paul, Peter just said that
18 people can't hear.

19 PANEL MEMBER BLANC: What's the IARC, because I
20 think that the sentence needs to end, you know, with a
21 semicolon. It is an IARC.

22 CHAIRPERSON FROINES: I'm sorry Lynn or.

23 ARB AIR POLLUTION SPECIALIST BAKER: We can hear
24 some but it's hard to hear the rest.

25 PANEL MEMBER LANDOLPH: Yeah, I didn't find that

1 IARC data. I didn't go looking for it either, so you
2 raise a very good point.

3 PANEL MEMBER BLANC: I mean if the sentence is --
4 I don't have any problem with the sentence, but I just
5 think it should say one way or the other, because --
6 otherwise people are going to be doing what I'm doing,
7 which is saying does that make it in the IARC data?

8 PANEL MEMBER LANDOLPH: Yeah, fair enough. I
9 don't know if Lori had looked into that.

10 DPR STAFF TOXICOLOGIST LIM: Lori Lim, DPR. I'm
11 actually looking at my document and I don't have any
12 indication what the IARC classification is in the
13 beginning part. So let me see real quick.

14 CHAIRPERSON FROINES: Well, Joe's opening a
15 little can of worms in the sense that he -- Lori, he's
16 saying the following, "Fluoride a metabolite of sulfuric
17 fluoride is clastogenic and can induce osteosarcomas in
18 male rats. There is some conflicting evidence that
19 fluoride drinking water correlated with an increased
20 incidence of osteosarcomas in male humans."

21 My question for you is, is that finding that he's
22 recommending, is that consistent with the language in your
23 document?

24 DPR STAFF TOXICOLOGIST LIM: I do not exactly use
25 the word "conflicting". I merely presented the thesis

1 finding, which was saying that there was an association
2 between fluoride in the drinking water and also sarcomas
3 in the young boys. The way it's in Douglas's letter to
4 the editor, he implied that there is no correlation, but
5 we have not seen the final, his published study. So I
6 couldn't really weigh them equally to say it was
7 conflicting, so that word was not used in my document.

8 CHAIRPERSON FROINES: You're answering a question
9 I'm not asking. Let me -- what I'm asking is what Joe has
10 proposed has to have -- has to derive from a section in
11 the document, so that his statement is consistent with
12 what is stated in the document.

13 PANEL MEMBER BLANC: I think she just said that
14 they do discuss --

15 CHAIRPERSON FROINES: They do. No, I've read it.
16 But I'm just wanting to make sure that Lori is comfortable
17 with what she's written relative to what Joe's suggesting.
18 That's all.

19 DPR STAFF TOXICOLOGIST LIM: I would agree that
20 it could be classified as conflicting, the fact that they
21 do not have the same results.

22 PANEL MEMBER LANDOLPH: I tried to make my
23 statement very conservative to be consistent with what she
24 wrote.

25 (Laughter.)

1 CHAIRPERSON FROINES: So as far as you're
2 concerned, what Joe's proposing is consistent with what
3 you wrote in the document?

4 DPR STAFF TOXICOLOGIST LIM: Yes.

5 PANEL MEMBER LANDOLPH: John, also that
6 statement -- Lori, correct me if I'm wrong in error -- but
7 my understanding is that statement I wrote is intended to
8 be consistent with what the NAS assessment of the fluoride
9 document is.

10 DPR STAFF TOXICOLOGIST LIM: Yes.

11 CHAIRPERSON FROINES: I'm just worried about
12 consistency. That's all

13 DPR STAFF TOXICOLOGIST LIM: Yes.

14 CHAIRPERSON FROINES: And so go ahead, Joe. So
15 we'll -- is the panel comfortable with that inclusion?

16 Joe.

17 PANEL MEMBER LANDOLPH: I'm happy with it, since
18 I wrote it.

19 (Laughter.)

20 CHAIRPERSON FROINES: No, no, no. Moving on.

21 PANEL MEMBER LANDOLPH: That answers your
22 question.

23 PANEL MEMBER BYUS: Moving on, Joe.

24 (Laughter.)

25 PANEL MEMBER LANDOLPH: Okay. Now, that you've

1 moved us on. And then the other comment I had was one I
2 made about a year ago at that last meeting. I was a
3 little bit worried looking at some of the dissipation
4 data, which is very nice data, in the document from DPR.
5 It looks like it takes almost 4 days for the sulfuryl
6 fluoride to dissipate down to background levels.

7 And so I drafted a sentence which you may modify
8 or reject as you like. It reflects my thinking. The
9 sentence reads, "Due to the neurotoxicity of sulfuryl
10 fluoride and the possible carcinogenicity of a metabolite,
11 fluoride ion, it is recommended that residents of treated
12 homes not enter the homes until 4 days after clearance of
13 sulfuryl fluoride."

14 CHAIRPERSON FROINES: Let me tell you the problem
15 that I have --

16 PANEL MEMBER LANDOLPH: Okay. Let me give you
17 one more thinking --

18 CHAIRPERSON FROINES: Go ahead.

19 PANEL MEMBER LANDOLPH: -- then I'll be delighted
20 to hear your question. I'm concerned that there's no
21 health benefit to this compound for the people. So I'm
22 concerned that I don't want to see people accepting an
23 additional potential toxic risk, particularly if this is a
24 possible carcinogen, when there's no risk versus benefit
25 to gain for them. So that's where my thinking comes from.

1 And then you had another question.

2 CHAIRPERSON FROINES: The problem I have with
3 this is I agree with the sentiment, but this is what --
4 you're talking -- what you're proposing is basically a
5 risk management statement, which doesn't really fall
6 within the purview of this panel. So for us to recommend
7 2 days, 4 days or a year, whatever, really is what happens
8 as a result of our finding this as a Toxic Air
9 Contaminant, which is DPR's mandated role.

10 So I think that whereas the spirit is reasonable,
11 it seems to me that I'm not sure we can really put this in
12 this form.

13 PANEL MEMBER LANDOLPH: Okay. Well, I'll defer
14 to you. You know these procedures much better than I do,
15 so if that's how you view it, that's fine with me.

16 CHAIRPERSON FROINES: I don't think we generally
17 have put in recommendations about control strategies is
18 what this really amounts to.

19 PANEL MEMBER BLANC: Yes. What you could say,
20 if -- in your reading of the document if everybody thought
21 it was there, is that if the finding was that there
22 appears to be a distinct time cutoff, there's a suggestion
23 with a distinct time cutoff point of 4 days which should
24 be, you know, taken in to account in risk assessment.
25 That, one could say, if that's what the data has

1 consistently suggested, that there was some kind of steep
2 fall off after 4 days, and that there's a difference after
3 4 days, if that's in the document. But I fully agree with
4 what you said, I don't think it's appropriate to say there
5 should be, you know, some kind of -- that's up to ARB or
6 whoever.

7 CHAIRPERSON FROINES: Well, that's a question
8 that is there. I mean, if I understand what you're
9 saying, if you have -- if the concentration is like this
10 and then drops off, if that's in the document, then we
11 could note that.

12 PANEL MEMBER LANDOLPH: Yeah. A number of graphs
13 are.

14 PANEL MEMBER ATKINSON: But it doesn't.

15 CHAIRPERSON FROINES: Well, that's the question.

16 PANEL MEMBER LANDOLPH: What did Roger say?

17 PANEL MEMBER ATKINSON: I mean it decreases in
18 something like an exponential amount. So there's no
19 sudden steep drop off.

20 PANEL MEMBER LANDOLPH: It looks more asymptotic.
21 Almost sigmoidal in its increase, so it is asymptotic.

22 CHAIRPERSON FROINES: Well, so then having a
23 sentence that says 4 days -- in other words, what's --
24 going back to Paul's comment, what is the -- is there a
25 statement that could be made that -- you could take

1 Roger's statement that the fall off appears to be
2 exponential and then what?

3 PANEL MEMBER LANDOLPH: And it's approximately at
4 background levels by day 4 after fumigation.

5 PANEL MEMBER ATKINSON: I mean if you were to do
6 it that way, presumably would have to set a limit for the
7 concentration rather than the time. That would seem to be
8 the obvious one if you were wanting to pursue that sort of
9 approach. But if you look on page 38 just looking at
10 Volume 2, it's essentially an exponential decrease
11 approaching, at least in the particular graph I'm looking
12 at, approaching 0 after about 5 days.

13 CHAIRPERSON FROINES: It's -- what's the table?

14 PANEL MEMBER ATKINSON: It's Table -- Figure 5.

15 CHAIRPERSON FROINES: Figure 5.

16 PANEL MEMBER ATKINSON: It is the predicted best
17 bunch of numbers.

18 CHAIRPERSON FROINES: Page what?

19 PANEL MEMBER ATKINSON: It's page 38.

20 CHAIRPERSON FROINES: And what --

21 PANEL MEMBER BLANC: Volume 2.

22 CHAIRPERSON FROINES: Volume 2.

23 PANEL MEMBER ATKINSON: I mean, that's expected
24 to be and it appears to be generally an exponential
25 decrease.

1 CHAIRPERSON FROINES: So if I put in a
2 sentence -- if I put in something after that that says the
3 drop off -- using better language -- but the drop off
4 appears to be exponential achieved and background
5 level -- and approaching background at 4 days, is that --

6 PANEL MEMBER LANDOLPH: Yeah, that would do it.
7 That would convey the spirit of the thing. Are you
8 comfort -- because that we can put in?

9 PANEL MEMBER LANDOLPH: Sure, that's fine.

10 CHAIRPERSON FROINES: It's just a statement of
11 fact. I'm getting all these nods back there. We have the
12 audience agreeing.

13 PANEL MEMBER LANDOLPH: Yeah, I'd be happy with
14 that John. Then that would get across, you know, the
15 feeling -- the idea that we would like to see it as low as
16 possible, and they can do what they want to do with it.
17 That's fine.

18 PANEL MEMBER BLANC: Can I ask the drafters a
19 couple of questions. I would maybe guide John in any
20 wordsmithing that I had. I wasn't sure what your
21 implication was, that I absolutely understood it.

22 At the very beginning when you talk about the
23 substance and refer to it as Vikane and then later in
24 Point 11 refer to the approved use of ProFume --

25 PANEL MEMBER ATKINSON: That's for a different

1 use. That's for food commodity fumigation rather than
2 structural fumigation.

3 PANEL MEMBER BLANC: Right. Therefore,
4 does -- is the implication that everything you're talking
5 about only refers to Vikane? I mean, putting the Vikane
6 in parentheses at the very beginning and then much later
7 talking about ProFume -- first of all, is Vikane the only
8 trade name -- that's the only product on the market is
9 always Vikane?

10 PANEL MEMBER ATKINSON: Well, ProFume is --

11 PANEL MEMBER BLANC: Aside from ProFume.

12 PANEL MEMBER ATKINSON: As far as I know.

13 DPR STAFF TOXICOLOGIST LIM: Yes.

14 PANEL MEMBER BLANC: So there's only a single --

15 DPR STAFF TOXICOLOGIST LIM: For the structural
16 fumigation used in the nonfood commodity fumigation use.
17 So for the food fumigation use, is a separate name but the
18 same chemical.

19 PANEL MEMBER BLANC: Right. And that's currently
20 licensed also.

21 DPR STAFF TOXICOLOGIST LIM: It was approved in
22 2005.

23 PANEL MEMBER ATKINSON: And the use of that isn't
24 evaluated. I mean that's not in number 11.

25 PANEL MEMBER BLANC: Right. Okay. So one thing

1 for our wordsmith to take into account when you read
2 that -- and this could have been my idiosyncrasy in
3 reading it, is that I wasn't prepared suddenly to hear
4 about this other product at Point 11.

5 PANEL MEMBER BYUS: Yes. But we were requested
6 at the last meeting to make that clarification.

7 PANEL MEMBER BLANC: No. No. It would be nice
8 to have it at the very -- maybe a sentence that there's 2
9 products. And, you know --

10 PANEL MEMBER BYUS: But that was part of our
11 discussion, was to really -- even though the document
12 wasn't dealing extensively with the use of that compound
13 on food, because that it potentially might be, we were
14 requested to and did. So we tried to clarify it.

15 PANEL MEMBER BLANC: No, and I absolutely agree
16 with that. I think that's great.

17 CHAIRPERSON FROINES: So basically, Paul is
18 asking for I think a sentence up front someplace that says
19 there are --

20 PANEL MEMBER BLANC: Licensed products.

21 CHAIRPERSON FROINES: Registered users, is that
22 the term to use?

23 DPR STAFF TOXICOLOGIST LIM: Two registered
24 products.

25 CHAIRPERSON FROINES: Two registered products.

1 DPR STAFF TOXICOLOGIST LIM: Yes.

2 CHAIRPERSON FROINES: And Vikane, which is used
3 for and ProFume which is used for and that's the sentence.

4 PANEL MEMBER BLANC: Right. And then --

5 CHAIRPERSON FROINES: Joe, you keep raising your
6 hand, Paul is into his comments --

7 PANEL MEMBER LANDOLPH: Yeah. Let him go ahead
8 and finish. That's fine.

9 CHAIRPERSON FROINES: But if you weren't finished
10 with yours, then I --

11 PANEL MEMBER LANDOLPH: Oh, 10 seconds. On page
12 37 there is a sentence which deals with that comment that
13 I made as modified by Roger and Paul and yourself. It
14 just says, "As depicted in Figure 5, the predicted
15 concentration rapidly decreases during first 2 days
16 following clearance and tends toward 0 around day 6 or 7."

17 CHAIRPERSON FROINES: What page is that?

18 PANEL MEMBER LANDOLPH: Thirty-seven. It's the
19 first of volume 2.

20 CHAIRPERSON FROINES: Okay, I can work with that.

21 PANEL MEMBER LANDOLPH: So that's basically the
22 same sentence.

23 Sorry, Paul.

24 PANEL MEMBER BLANC: No, no.

25 And then I think the only other real substantive

1 question I had was when you refer to target organ toxicity
2 on point 7, and you say it's the brain respiratory system
3 and teeth.

4 PANEL MEMBER BYUS: Is that what we said? Yes.

5 PANEL MEMBER BLANC: I mean I think it would
6 be --

7 PANEL MEMBER BYUS: Fluoride goes to the teeth.

8 PANEL MEMBER BLANC: Yeah, but animals aren't
9 going to die from the teeth, right? I mean, it's the
10 brain and the respiratory system are the target organs for
11 substantive lethal toxicities. I mean, it just -- that
12 really struck me when I read it, it's like -- and since
13 that's a substantive question, that's why I didn't just
14 leave it to John. I would just assume get rid of the word
15 teeth there, because it seems to weaken the point you're
16 making or obfuscate the --

17 PANEL MEMBER BYUS: I'm not sure. Does it cause
18 damage to the teeth?

19 DPR STAFF TOXICOLOGIST LIM: In severe cases the
20 fluoride causes severe dental fluorosis that it could
21 weaken the teeth. So in the NAS Report Committee, they
22 actually made a point that they don't consider it a
23 cosmetic effect that the U.S. EPA had done previously.

24 PANEL MEMBER BLANC: No, I agree with that. It's
25 just that when you're talking about target organ toxicity

1 of a parent compound which kills through pulmonary edema
2 and, you know, brain injury, and then -- that's a very
3 minor point. I don't want to belabor it.

4 PANEL MEMBER BYUS: But the tooth
5 toxicity -- toxicity to -- as I remember the toxicity to
6 bone and teeth and calcium, I mean it is considered a
7 toxicity --

8 PANEL MEMBER BLANC: The fluorosis.

9 PANEL MEMBER BYUS: And it is bad. And it is
10 considered a very -- a non -- you know, it's not a good
11 thing and it's considered a toxicity. So that's why I
12 think what was included in there, among the various
13 organs. It isn't necessarily saying that that was going
14 to be the lethal dose toxicity, which if it were, then we
15 would probably have included it. But if you're just
16 talking about various organs and sites --

17 PANEL MEMBER BLANC: Well, you talk about in
18 terms of target organs.

19 PANEL MEMBER BYUS: Target organs, yeah. And it
20 is, in a sense, one. We'll take it out if you feel it's
21 inappropriate.

22 CHAIRPERSON FROINES: You say the primary target
23 tissues are the -- is teeth a primary target issue?

24 DPR STAFF TOXICOLOGIST LIM: Well, so far we've
25 seen it in all the species -- I mean, some of the species

1 that we tested, so it sticks out. The fluoride will go
2 there. And so --

3 CHAIRPERSON FROINES: No, but I think that -- you
4 see, the point that I would make and I don't know what
5 Paul is thinking, but the point I'm making is these
6 findings are relatively brief, and they are intended to be
7 read by the public, to just demonstrate that a review
8 committee has reviewed the process.

9 Therefore, I think that the findings should have
10 a high degree of specificity, and they shouldn't be
11 encyclopedic in nature. And so in a sense what we really
12 want to do is call attention primarily to those tissues
13 and organs where we view in terms of what was used to make
14 the ultimate decision on it being a Toxic Air Contaminant.

15 In other words, we can list a 100 different
16 endpoints that may have be seen. But in terms of the
17 public's understanding of the process, for us to emphasize
18 what are the endpoints that actually lead to the decision,
19 that's the place of emphasis, I think.

20 PANEL MEMBER BLANC: Well, just to come back to
21 the reason why the paragraph struck me, Craig, is, you
22 know, as you read through it, it starts with the
23 non-lethal and then with repeated exposures primary
24 tissues are the brain respiratory tract and teeth.

25 And then it goes through in detail appropriately,

1 it talks about 2 weeks of exposure and it's tremors,
2 lethargy, respiratory effects, incapacitation, tetany,
3 convulsion. That's all you know respiratory and brain.
4 Animals treated for 2 weeks showed all these other organ
5 site damages. Thirteen weeks the brain was the primary
6 target organ, okay, the vacuoles and then other things.

7 And it's only in the other effects reported at 13
8 weeks that you hear about fluorosis, as you're starting to
9 get these specific things and that's why I said, well
10 you've got the fluorosis covered and it's not trivial, but
11 I would simply delete the word teeth because its --

12 PANEL MEMBER BYUS: It's deleted.

13 PANEL MEMBER BLANC: -- glaring. Okay good.
14 Those were my only real substantive ones. I have some
15 other wordsmithing notes that I can give to John.

16 CHAIRPERSON FROINES: Charlie.

17 PANEL MEMBER PLOPPER: No other comments.

18 CHAIRPERSON FROINES: So let me make a couple of
19 minor comments. And this goes back to an issue -- here's
20 a sentence that I actually think we should take out, if
21 it's okay with you.

22 You say, "Much of the margin of safety of using
23 this compound in relation to minimizing human exposures
24 relies upon the good work practices of licensed pesticide
25 contractors."

1 PANEL MEMBER ATKINSON: Where is this?

2 CHAIRPERSON FROINES: It's page 2 of the
3 findings.

4 PANEL MEMBER BLANC: What number point?

5 CHAIRPERSON FROINES: Five.

6 "Much of the margin of safety of using this
7 compound in relation to minimizing human exposures relies
8 upon the good work practices of licensed pesticide
9 contractors." I don't think that's within our purview. I
10 don't think that we should be talking, because I don't
11 think we have any evidence, scientific evidence, that
12 talks about how good or how bad work practices of
13 pesticide applicators is.

14 PANEL MEMBER BLANC: That's not your point.

15 PANEL MEMBER BYUS: That's not my point.

16 PANEL MEMBER BLANC: Wasn't your point that these
17 estimates presume --

18 PANEL MEMBER BYUS: Correct.

19 PANEL MEMBER BLANC: -- the use of good
20 practices --

21 PANEL MEMBER BYUS: That's correct.

22 PANEL MEMBER BLANC: -- and therefore would not
23 be applicable to misuse scenarios.

24 PANEL MEMBER PLOPPER: Why not just say that.

25 PANEL MEMBER BLANC: Well, I think that would be

1 a better way of saying. All of the estimates are
2 predicated on approved use practices. And in scenarios of
3 misuse, they're not going to be -- I mean, these --

4 CHAIRPERSON FROINES: What would be --

5 PANEL MEMBER BLANC: It would be 4 days and all
6 that stuff.

7 CHAIRPERSON FROINES: All the estimates are
8 predicated --

9 PANEL MEMBER BLANC: -- on appropriate use
10 practices.

11 PANEL MEMBER BYUS: Right.

12 PANEL MEMBER BLANC: Semicolon, "In scenarios of
13 misuse, these estimates would not apply" -- "...may not
14 apply.

15 PANEL MEMBER BYUS: I don't see the difference in
16 either statement. But the point is -- I mean we
17 discussed it --

18 PANEL MEMBER BLANC: He's saying you cup is half
19 empty and you're saying your cup is half full.

20 PANEL MEMBER BYUS: Okay. We really wanted -- we
21 discussed this also. I mean, that was a big issue. We
22 really wanted to make sure that this is a finding, that
23 all of -- much of what is in the document is based on
24 good -- following the application of protocols very, very
25 carefully. And then if you don't, then the margin of

1 safety and potential exposure to not only workers, but
2 bystanders and whatever, varies considerably from this,
3 and likely to more toxic degree rather than a less toxic
4 degree.

5 So it's a very unusual compound in that regard.
6 That's what -- and that is the point we really want to
7 make.

8 CHAIRPERSON FROINES: What I wrote was that that
9 sentence sounded to me a bit too rhetorical. And I think
10 this is a slightly improved sentence. And I think that
11 "...upon the good work practices of licensed pesticide
12 contractors.", it's a little too general in a sense. So
13 that's fine.

14 PANEL MEMBER BYUS: Okay, we'll change it.

15 PANEL MEMBER BLANC: How about, "There by the
16 Grace of God."

17 (Laughter.)

18 PANEL MEMBER BYUS: Well, it's from everything,
19 from the calculating the amount that goes into the house,
20 how you put the tent on, how you take the tent off, how
21 you vent it. I mean, it's all these practices. And all
22 through the document all of the concentrations are based
23 on all of these assumptions. And we're not saying that
24 they're good or bad. I'm not saying that pesticide
25 applicators do a good or bad job. I mean, that is not

1 what that says. It just says that everything is based
2 upon this and that the Margin of error would go up
3 considerably, depending on whether this practice is
4 followed or not followed, so we'll change it though.

5 CHAIRPERSON FROINES: No, no. That's fine. On
6 number 11, you have when you're in to ProFume then, you
7 have the sentence, "Such use is predicted to result in
8 increased total exposures and possible lower margins of
9 exposures than those calculated in this current risk
10 characterization document. This use was not evaluated in
11 this report."

12 The first thing I would say is I would add the
13 word "...this 'increased' use was not evaluated in this
14 report." But in terms of what's in the document, does
15 this have a basis in the document, Craig, for -- just to
16 make that larger sentence statement?

17 PANEL MEMBER BYUS: Yes, we --

18 PANEL MEMBER ATKINSON: Yes.

19 PANEL MEMBER BYUS: The document was modified in
20 relation to the last. That was one of the points of our
21 last discussion to clarify that, both in the document and
22 in the findings to make sure that there was this
23 consistency, because we all agreed that even though it was
24 not being used extensively now for this, it could be in
25 the future, and that we were -- we thought it was

1 applicable or appropriate for us to do this, provided
2 there was the consistency. So we went back and DPR did
3 change the document to reflect that and then we put it in
4 the findings as well.

5 But I mean we can change the language, but it is
6 consistent and it is in there.

7 PANEL MEMBER BLANC: What does, "...lower margin
8 of exposure mean..."? Does it mean that the lower end of
9 the estimated --

10 PANEL MEMBER BYUS: I believe so, yes.

11 PANEL MEMBER BLANC: It means more exposure?

12 PANEL MEMBER BYUS: Yes.

13 PANEL MEMBER BLANC: Lower margin means more
14 exposure.

15 PANEL MEMBER BYUS: More exposure.

16 PANEL MEMBER BLANC: Is there a way of wording
17 that that would sound like more exposure --

18 PANEL MEMBER BYUS: That's always the difficulty.

19 PANEL MEMBER BLANC: -- and not like less
20 exposure.

21 CHAIRPERSON FROINES: Why don't you just say
22 greater exposures?

23 PANEL MEMBER ATKINSON: Possibly greater
24 exposure.

25 PANEL MEMBER BYUS: It is always the -- it is the

1 difficulty here of dealing with DPR's language versus what
2 we're all used to. And I really don't want to get into
3 that discussion, but we will.

4 (Laughter.)

5 CHAIRPERSON FROINES: Not today.

6 PANEL MEMBER BYUS: Not today. But it is -- I
7 mean, as you all know, it is the difficulty for us is
8 trying to use that language. I'm not saying the language
9 is good or bad, but it's just we are not as experienced
10 with it. I personally am not as experienced with it. So
11 it's always a struggle for me.

12 PANEL MEMBER BLANC: I think one advantage of
13 these kind of findings is, you know, you can translate --
14 I mean, you don't have to stick to their jargon, I think,
15 strictly speaking.

16 PANEL MEMBER BYUS: Strictly speaking.

17 DPR STAFF TOXICOLOGIST LIM: May I say something?

18 In our conclusion on page 102, we actually change
19 the word to say that it would increase -- it would produce
20 greater risk, instead of saying margin of exposure. So I
21 think that's probably better.

22 CHAIRPERSON FROINES: I would prefer to say
23 greater exposures as a matter of science.

24 DPR STAFF TOXICOLOGIST LIM: But right before
25 that it says, "...result in increased total exposures..."

1 in your finding, Item 11. So the few words before then
2 already says increased total exposures, so if you wanted
3 to stop right there, that would be fine.

4 PANEL MEMBER BLANC: Yeah, that would be fine.

5 PANEL MEMBER BYUS: That would probably be the
6 best thing.

7 PANEL MEMBER BLANC: Just get rid of the rest of
8 those three words.

9 PANEL MEMBER BYUS: Get rid of the rest.

10 CHAIRPERSON FROINES: Then the final thing that I
11 have is I want to -- I was -- I had a problem with going
12 from 12 to 15, because I didn't feel as though a reader
13 could understand what was being said. And that is I think
14 that one has to talk about -- one has to show the NOEL and
15 RfC, one has to show the estimate of exposure that was
16 made to subsequently calculate the percent of the RfC and
17 the MOE, and then when one needs to show the ratio as a
18 result of that.

19 And nobody in their right mind could read 12
20 through 15 and understand, for example, what the data in
21 13 and what the -- and so I have a proposal. I actually
22 think that we can leave in that 13, for example. Although
23 I don't -- for example, we have -- there's a sentence that
24 says, "During the first 24 hours after residents are
25 allowed to reenter the houses, the mean sulfuranyl fluoride

1 air concentrations in these houses ranged from .01 ppm to
2 1.78 ppm.

3 Then there are 2 sentences -- then there's a
4 sentence that talks about the ADD, and then you go back to
5 ppm. And so the question is, why do you we need the ADD?
6 We don't use the ADD any place to determine the risk
7 characterization. So we have information in 13 and 14
8 about ADDs which we don't ever use for any purpose. It's
9 simply information. And the question is do we want
10 information -- just that information to fill out this
11 document?

12 And my argument was the ADDs are not what are
13 used to make the ultimate determination. So therefore,
14 what I would propose is, one, to add something that I can
15 write from -- there are 2 paragraphs on page 79 in the
16 document that talk about the MOE and talk about the RfC.
17 And I will add that to show that they're using a higher
18 benchmark, for example, in this particular document. In
19 other words, I'm going to tell -- would say -- would tell
20 the reader what the criteria that DPR used in doing their
21 calculation.

22 And then I would add Table 2 from page 86 and
23 Table 2 on page 86 gives a scenario application phase
24 first 12 hours, 24 hours. It gives the air level. It
25 gives the hours exposed. It gives the air level as a 24

1 hour time weighted average. It then gives the percent RfC
2 and the MOE. And that's the conclusion -- that's the
3 information that DPR used to make their decision of this
4 as a Toxic Air Contaminant.

5 So I think this table actually combined with the
6 other table that shows the RfCs that is already in there,
7 actually shows the reader what the basis of the decision
8 making was. And so if you'll allow me to put in those 2,
9 basically a table and a paragraph.

10 PANEL MEMBER ATKINSON: You'll have to take off
11 the Stack method then in that table, because we don't
12 discuss that at all in the findings.

13 CHAIRPERSON FROINES: You're right. You're
14 right. Let me see here. Yes, that's easy to take out.

15 PANEL MEMBER ATKINSON: And presumably the
16 non-food one.

17 CHAIRPERSON FROINES: Yes. And then I would keep
18 in -- I would put Table 2 as referenced by -- with a
19 reference in Section 15, which is where I think it
20 belongs. Do you agree with that, Craig and Roger?

21 PANEL MEMBER BYUS: Yes, that's fine.

22 PANEL MEMBER ATKINSON: That's good.

23 CHAIRPERSON FROINES: Just put this table linked
24 with 15.

25 Lori, is what I'm saying, are you comfortable

1 with that?

2 DPR STAFF TOXICOLOGIST LIM: Yes. That's Table
3 31, right, I think?

4 PANEL MEMBER BYUS: Right.

5 CHAIRPERSON FROINES: Table 31.

6 PANEL MEMBER BYUS: But make sure we --

7 CHAIRPERSON FROINES: Wouldn't you agree that
8 Table 31 is the piece de resistance in terms of the
9 ultimate decision?

10 DPR STAFF TOXICOLOGIST LIM: Yes, because
11 we're --

12 CHAIRPERSON FROINES: You see, this is what's
13 missing is this information.

14 DPR STAFF TOXICOLOGIST LIM: Right, because the
15 listing is based on the RfC.

16 CHAIRPERSON FROINES: And so it's easy to put in.

17 DPR STAFF TOXICOLOGIST LIM: Yes.

18 CHAIRPERSON FROINES: And it's consistent with
19 what Craig and Roger added in their Section 15, but this
20 way you can look at it rather than reading it. So it's
21 actually -- really more for clarification than substance.

22 So that's my comment. So that means that we need
23 a motion to --

24 PANEL MEMBER BLANC: I move that we approve the
25 findings with the modifications consistent with the

1 transcript of the discussion at this point.

2 PANEL MEMBER ATKINSON: Second.

3 CHAIRPERSON FROINES: Discussion?

4 All in favor?

5 (Ayes.)

6 CHAIRPERSON FROINES: The vote is unanimous.

7 Craig and Roger --

8 PANEL MEMBER BYUS: I'm so happy.

9 (Laughter.)

10 PANEL MEMBER BYUS: I'm going to go get my house
11 fumigated.

12 (Laughter.)

13 PANEL MEMBER LANDOLPH: Then you're going to
14 Hawaii for a week, right?

15 CHAIRPERSON FROINES: You realize that this
16 sulfuryl fluoride is really the tip of the iceberg when it
17 comes to fluoride.

18 PANEL MEMBER BYUS: I know. But I must say we
19 did include a very nice discussion of fluoride toxicity in
20 this document, as well, which is very, very well done and
21 comprehensive.

22 CHAIRPERSON FROINES: And did you 2 decide
23 whether you agree now with fluoride in the drinking water?

24 (Laughter.)

25 PANEL MEMBER BYUS: We're in good agreement, are

1 we not, Lori?

2 DPR STAFF TOXICOLOGIST LIM: Oh, absolutely.

3 CHAIRPERSON FROINES: Okay. Thanks, Lori.

4 DPR STAFF TOXICOLOGIST LIM: Thank you.

5 CHAIRPERSON FROINES: Very good.

6 We had talked about having diesel come next,
7 because of timing issues.

8 PANEL LIAISON BEHRMANN: This is Jim Behrmann.
9 Kirk Oliver has not yet arrived. He would be doing the
10 diesel briefing.

11 CHAIRPERSON FROINES: But, Jim, is it also true
12 that Kirk has to leave almost immediately?

13 PANEL LIAISON BEHRMANN: He'll be here for a
14 period of time, roughly 11 to noon.

15 CHAIRPERSON FROINES: He'll be here at 11 to
16 noon. Okay, so that would give us 45 minutes -- 40
17 minutes on methidathion.

18 PANEL LIAISON BEHRMANN: I believe Mr. Oliver's
19 briefing will take roughly 10 to 15 minutes. It's not a
20 very long briefing.

21 CHAIRPERSON FROINES: I'm just trying to figure
22 out whether we want to have Tobi talk about the pesticide.
23 How long do you think that's going to take?

24 DPR ASSISTANT DIRECTOR JONES: Probably not more
25 than 10 to 15 minutes depending on the questions you have.

1 PANEL MEMBER BLANC: John, I really suggest we
2 start with methidathion, Supracide and just get our feet
3 and see where we're at.

4 CHAIRPERSON FROINES: So, Tobi, let's go with the
5 pesticide rather than your presentation.

6 PANEL MEMBER BLANC: So we're doing Supracide?
7 We're doing methidathion?

8 PANEL MEMBER BYUS: First we're going to have to
9 learn how to pronounce it.

10 DPR ASSISTANT DIRECTOR JONES: You've been
11 practicing.

12 PANEL MEMBER BYUS: We don't seem to be able to
13 do it, myself included on this.

14 (Thereupon an overhead presentation was
15 Presented as follows.)

16 CHAIRPERSON FROINES: I just wanted to say one
17 thing before you start. You know, I think everybody is
18 breathing a sigh of relief because we finished sulfuryl
19 fluoride. But if you look at our findings and you look at
20 the number of times we discussed it and then the time it
21 took for you folks to work on it outside of this and then
22 the subsequent discussions, I think it's a very good
23 example of a very intense and complete effort. And so I
24 think it speaks well for the process. And I wanted to put
25 that on the record so that everybody was aware that this

1 process has been extremely thorough and hopefully we
2 can -- that will be the way to operate in the future.

3 Tobi, go ahead.

4 DPR ASSISTANT DIRECTOR JONES: I want to thank
5 the panel for providing DPR the opportunity to present our
6 methidathion risk assessment to you. I particularly want
7 to thank Drs. Plopper and Atkinson for their review of the
8 draft document and their advice on preparing this draft to
9 bring before you today.

10 I asked Peter to hand out a single-page chart
11 that is taken from our -- it should look like -- Peter,
12 did you hand this out?

13 MR. MATHEWS: (Nods head.)

14 DPR ASSISTANT DIRECTOR JONES: Okay.

15 CHAIRPERSON FROINES: What is it?

16 DPR ASSISTANT DIRECTOR JONES: It's coming. The
17 chart I'm handing out is taken from our 2004 Pesticide Use
18 Report. And it is a chart on the trend of use of
19 organophosphate and carbamate pesticides over the last
20 decade. Methidathion is like a number of highly toxic OP
21 pesticides whose use in California continues to decline.

22 This decline reflects the regulatory environment
23 at the U.S. EPA; the availability and the use of newer
24 safer pesticides; and the inevitably development of pest
25 resistance to older pesticides, like methidathion.

1 signal word "warning". And both have approximately 25
2 percent technical methidathion in them.

3 --o0o--

4 PANEL MEMBER BYUS: I have a quick question on
5 that. What exactly do you mean by this non systemic? I
6 mean, you tried to explain it. I didn't quite catch it.

7 DPR ASSOCIATE ENVIRONMENTAL RESEARCH SCIENTIST
8 GURUSINGHE: See there are 2 main groups of pesticides
9 depending on their mode of activity. Systemic pesticides
10 have to be absorbed by the plant and the plant has to be
11 consumed by the target pest and then it becomes toxic.

12 Whereas, contact pesticides, the target organism
13 doesn't have to consume it. It has to come in physical
14 contact with the pesticide, so it becomes absorbed through
15 the skin or some other mode, which becomes toxic.

16 PANEL MEMBER BYUS: So you have to spray it when
17 the insect is on the plant, rather than spraying the plant
18 and then waiting for them to eat it?

19 DPR ASSOCIATE ENVIRONMENTAL RESEARCH SCIENTIST
20 GURUSINGHE: Yeah. All the pesticides should be on the
21 plant at the time the insect visits the plant for it to
22 have physical contact.

23 PANEL MEMBER BYUS: Thank you.

24 PANEL MEMBER BLANC: And if there are 2
25 licensed -- there are 2 formulations, are both of the

1 formulations called Supracide?

2 DPR ASSOCIATE ENVIRONMENTAL RESEARCH SCIENTIST

3 GURUSINGHE: Yeah. There are different. One is wetttable
4 powder. The other one is emulsifiable concentration.

5 PANEL MEMBER BLANC: But they're both Supracide?
6 They're both the trade name Supracide?

7 DPR ASSOCIATE ENVIRONMENTAL RESEARCH SCIENTIST

8 GURUSINGHE: Yeah.

9 --o0o--

10 DPR ASSOCIATE ENVIRONMENTAL RESEARCH SCIENTIST

11 GURUSINGHE: And currently it's recommended for a variety
12 of different crops. And you can see the recommended rates
13 change. And citrus has the highest active ingredient
14 recommended per acre.

15 Next slide, please.

16 --o0o--

17 DPR ASSOCIATE ENVIRONMENTAL RESEARCH SCIENTIST

18 GURUSINGHE: This is the information that we have with
19 respect to the use patterns of methidathion. I have use
20 1991, because that's the year in which we started the
21 Pesticide Use Report Data System. And then I have taken
22 information for the 10 years of '94 to 2003. As a matter
23 of fact, my colleague will be discussing some of the
24 information that was recently released for 2004. I did
25 not include it in this slide. You may see that there's a

1 slight increase from 2003 to 2004 from about 52,000 pounds
2 to about 61,000 pounds.

3 CHAIRPERSON FROINES: I had a question about
4 that. Is that normal variation, at this point or is there
5 something going on that would lead you to think that there
6 will be a continual increase?

7 DPR ASSOCIATE ENVIRONMENTAL RESEARCH SCIENTIST
8 GURUSINGHE: In my view, probably not, because there's a
9 general tendency, and also the encouragement by the
10 Department not to use organophosphates in areas where
11 there are alternatives. So this ma -- I don't believe
12 that it's going to be a trend setter. Very likely it may
13 be an occasional event that may went up for some local
14 reasons.

15 CHAIRPERSON FROINES: So you would anticipate a
16 continuing decline?

17 DPR ASSOCIATE ENVIRONMENTAL RESEARCH SCIENTIST
18 GURUSINGHE: Yes, I believe this lowering trend will
19 continue. I don't know whether it will plateau off,
20 because there are certain situations where there are no
21 really good substitutes, so they may have to use some
22 amount on some crops until such time we get a different
23 alternative. But right now most of these uses have been
24 replaced by many groups of compounds.

25 One important one is the oils. What do you call

1 them? Sorry -- the oils that are used, heavy chain oils
2 which are effective on many different organisms.

3 PANEL MEMBER BLANC: Do you have some sense of
4 what specifically happened in 1997 and 1998 when the rate
5 dropped nearly in half? It's a far more drastic rate than
6 the general drop in organophosphates that was shown in the
7 figure that was passed out? Was there some very specific
8 thing that caused it to go from 300,000 to 150,000 pounds
9 annually that you're aware of?

10 DPR ASSOCIATE ENVIRONMENTAL RESEARCH SCIENTIST

11 GURUSINGHE: I'm not aware of it, but I can check it for
12 you. And, if necessary, I can report if there is any
13 reported information as to why that sudden drop, whether a
14 lawsuit or something of that nature. I can check it in
15 the literature. If it is reported, I can find it out.

16 PANEL MEMBER BLANC: It would be interesting from
17 a policy point of view, because if it was -- if it's
18 suddenly 150,000 pounds of some other product, we probably
19 should be aware of it.

20 DPR ASSOCIATE ENVIRONMENTAL RESEARCH SCIENTIST

21 GURUSINGHE: I'll check on that.

22 CHAIRPERSON FROINES: Was there maybe an
23 introduction of some alternative?

24 DPR ASSOCIATE ENVIRONMENTAL RESEARCH SCIENTIST

25 GURUSINGHE: That's a possibility.

1 CHAIRPERSON FROINES: Because it's very dramatic
2 in '98.

3 --o0o--

4 DPR ASSOCIATE ENVIRONMENTAL RESEARCH SCIENTIST
5 GURUSINGHE: Yeah. Then this is the distribution by
6 county. As you can see, most of the use of methidathion
7 has been in the San Joaquin valley counties, except for a
8 few, Butte and Monterey county. Almost all of them are
9 concentrated in the southern part of the valley. And as
10 you can see, '91 Tulare county was using the most. And
11 right as of 2003 it's Kern county that's the leading using
12 county. And these are counties that have reported more
13 than 10,000 pounds used in 1991.

14 --o0o--

15 DPR ASSOCIATE ENVIRONMENTAL RESEARCH SCIENTIST
16 GURUSINGHE: Then with respect to the month, there are 2
17 peaks of use for methidathion. The winter use December,
18 January, February, which is mostly on the winter crops
19 around the winter plants, which are the dormant-plant
20 stage on the dormant trees. And summer usage is mostly on
21 the crop itself.

22 PANEL MEMBER BLANC: So you're saying that -- I
23 mean, almonds are not dormant in February. That's when
24 they're blooming, so --

25 DPR ASSOCIATE ENVIRONMENTAL RESEARCH SCIENTIST

1 GURUSINGHE: Yeah, but they may be receiving December
2 January.

3 PANEL MEMBER BLANC: I see.

4 DPR ASSOCIATE ENVIRONMENTAL RESEARCH SCIENTIST

5 GURUSINGHE: You can see that January has the largest.

6 And almond is -- I'll show you later on. Among the crops,

7 almond is one of the major crops, at least in the past.

8 Right now -- yeah, next slide, please.

9 --o0o--

10 DPR ASSOCIATE ENVIRONMENTAL RESEARCH SCIENTIST

11 GURUSINGHE: Okay. You can see almonds have been the

12 largest user in the past followed by oranges. Right now,

13 it's the oranges that receive the most as of 2003 followed

14 by almonds and then a few other crops.

15 Next slide, please.

16 --o0o--

17 DPR ASSOCIATE ENVIRONMENTAL RESEARCH SCIENTIST

18 GURUSINGHE: Then this summarizes the use amounts. As you

19 can see, for the 2 years -- the comparing 2 years, 1991

20 and 2003, up to the 90th percentile. The amounts used

21 have not changed much, but there is a drastic reduction in

22 large amounts of use at the 95th percentile in 2003

23 relative to 1991.

24 CHAIRPERSON FROINES: One question. This data is

25 so dramatic, why are small amounts still being used? I

1 mean, it seems to me that one could argue that if you have
2 a relatively toxic organophosphate and most people have
3 found alternatives, why do people continue to use this
4 material?

5 DPR ASSOCIATE ENVIRONMENTAL RESEARCH SCIENTIST

6 GURUSINGHE: Offhand, I cannot give you as these are the
7 reasons, but I can suggest some. When you look at the
8 trends, it is more efficient with respect to information
9 transferred to larger farms than the smaller farms. And
10 they participate in most of the training and discussions
11 with the county and commissioners who are the ultimate
12 people who communicate with them directly.

13 Therefore, it may be that the smaller farms may
14 not have changed their practices that much in relation to
15 the larger farms. That is one possible explanation.

16 PANEL MEMBER BLANC: So since you have the
17 data -- if you'd go back the 3 slides to the acres
18 and -- yeah. No, the next one. Yeah. This is pounds
19 produced. I guess somewhere else you have acres of use in
20 a different -- I guess in this other one. I'm sorry.
21 This is totally organophosphates. But in any event, I
22 think that for your ultimate document or you may want to
23 consider a revision of not just the acres and the pounds
24 but actual number of users, licensed users, because your
25 data that you've just shown -- if you go forward again --

1 would indicate that the actual number of users hasn't
2 changed almost at all, right? Because you've got the
3 percentile of -- 75 percent of the people who use this,
4 use 75 pounds or less and that hasn't changed at all in
5 all these years.

6 So that the bulk -- it's a skewed plot. Most of
7 your pounds and acres of use are the dropout of huge
8 acreage applications of a lot of pounds all at once. And
9 between 1991 and 2003, 80 percent of the people who used
10 it are still using 5 pounds or 25 pounds or whatever.
11 Maybe it's not true. But if you -- John, do you see where
12 I'm going with this?

13 CHAIRPERSON FROINES: Um-hmm.

14 PANEL MEMBER BLANC: It wouldn't take very many
15 large acre large pound users to fall out for you to get a
16 dramatic drop in total pounds and total acreage without
17 having much change in the total number of users. Now
18 maybe that's not true, but you have the data available to
19 you and it would be important to see.

20 DPR ASSOCIATE ENVIRONMENTAL RESEARCH SCIENTIST
21 GURUSINGHE: Very likely the pesticide use database will
22 have each individual case, so it should be able to look at
23 the number of users with respect to the amount used.

24 PANEL MEMBER ATKINSON: But surely that's on a
25 percentage basis not a user basis or not an amount basis.

1 So if the total usage has gone down by 80 percent, I would
2 just view that as telling me that you've gone down 80
3 percent across the Board, since the 2 plots are
4 essentially identical from the 2 years.

5 PANEL MEMBER PLOPPER: It's the same distribution
6 of use.

7 PANEL MEMBER BLANC: Well, it's not, because it's
8 not -- that part where there's a gap there is --

9 PANEL MEMBER ATKINSON: Well, it's not exactly a
10 huge gap.

11 PANEL MEMBER BLANC: Well, anyway, I'd like to
12 see it.

13 PANEL MEMBER ATKINSON: Okay, whatever.

14 PANEL MEMBER BLANC: Just double check. Maybe
15 it's not true.

16 DPR ASSOCIATE ENVIRONMENTAL RESEARCH SCIENTIST
17 GURUSINGHE: Then with respect to the breakdown of
18 methidathion in the environment, you can see with increase
19 in temperature from 20 degrees to 50 degrees, there's a
20 drop.

21 CHAIRPERSON FROINES: I just want to make a
22 contentious -- I'm sorry, because I don't mean to
23 interrupt you. But from a policy standpoint, this is an
24 extremely interesting question, because it really does --
25 one can ask the question, is it possible to essentially

1 eliminate the use of this particular compound over time?
2 And is there an approach that might work well to
3 accomplish that, if that were seen as something that was
4 useful to do?

5 DPR ASSOCIATE ENVIRONMENTAL RESEARCH SCIENTIST

6 GURUSINGHE: Are you expecting an answer from me?

7 CHAIRPERSON FROINES: No, it's --

8 (Laughter.)

9 CHAIRPERSON FROINES: It's a rhetorical question.

10 (Laughter.)

11 CHAIRPERSON FROINES: That's a very good
12 response.

13 (Laughter.)

14 CHAIRPERSON FROINES: No, but this is clearly a
15 compound that is -- you know, you could reasonably ask the
16 question maybe they're using last year's supply. And so
17 that as it goes down, there are reasons why people keep
18 using things. And sometimes it's inertia. And so looking
19 at these kinds of data, does say well maybe we should
20 figure a way to get rid of it all together.

21 PANEL MEMBER BYUS: Well, it's a marvelously
22 effective compound at killing insects on crops. That's
23 why people use it. I mean, it's marvelously effective.
24 It's unfortunately highly toxic, but it's marvelously
25 effective. And they have a lot of experience using it.

1 They don't have to have -- you know, that's a big factor
2 when you're trying to introduce a new compound. You have
3 to prove that it's as effective and as easy to work with
4 and it's difficult.

5 CHAIRPERSON FROINES: But there's also resistance
6 developing.

7 PANEL MEMBER BYUS: Well, I mean, you know, it's
8 just -- we're speculating here, but it's marvelously
9 effective in killing insects and keeping the crops viable
10 and productive.

11 CHAIRPERSON FROINES: Let's go ahead.

12 DPR ASSOCIATE ENVIRONMENTAL RESEARCH SCIENTIST
13 GURUSINGHE: Okay. So you can see the breakdown becomes
14 very rapid with the increase in temperature from 20 to 50.
15 At the same time, when the pH increases with increasing
16 alkalinity, the breakdown becomes rapid. And in
17 combination of both, it becomes even faster.

18 And I put 15 degrees at pH 9 and pH 10. Some
19 situations -- this may be one of the things that you may
20 see in nature. So you can see there's a drastic
21 difference if the pH is -- if the alkalinity is higher at
22 15 degrees the breakdown becomes more faster than
23 alkalinity of 9 pH and temperature 15, which takes 25 days
24 to breakdown, roughly.

25 PANEL MEMBER ATKINSON: So one would presume this

1 is best catalyzed hydrolysis?

2 DPR ASSOCIATE ENVIRONMENTAL RESEARCH SCIENTIST

3 GURUSINGHE: Yes.

4 PANEL MEMBER ATKINSON: So can you fit those data
5 to an equation with either a neutral plus base catalyzed
6 or base catalyzed only? Essentially, get rid of all the
7 numbers and replace it by an expression which allows you
8 to predict the lifetime as a function of temperature and
9 pH.

10 DPR ASSOCIATE ENVIRONMENTAL RESEARCH SCIENTIST

11 GURUSINGHE: Theoretically, yes.

12 PANEL MEMBER ATKINSON: I think it would be wise
13 to do that, because that's one problem I have with a
14 section in the report. There's bunches of numbers but
15 there's no real conclusion to it. So if you could fit all
16 those to an expression like a 1 parameter or 2 parameter
17 expression that would fit them, then that would be
18 excellent.

19 DPR ASSOCIATE ENVIRONMENTAL RESEARCH SCIENTIST

20 GURUSINGHE: Yeah, I'll look at that.

21 Thank you.

22 Next slide, please.

23 --o0o--

24 DPR ASSOCIATE ENVIRONMENTAL RESEARCH SCIENTIST

25 GURUSINGHE: Then with respect to the persistence in soil,

1 you can see on the aerobic conditions, it's the microbial
2 breakdown which is the most important factor of
3 degradation of methidathion in soil. And in soil it
4 undergoes chemical breakdown, photolytic breakdown as well
5 as biological breakdown, which all 3 are involved in soil.

6 Next slide, please.

7 --o0o--

8 PANEL MEMBER ATKINSON: Can you go back one. You
9 state there that it's got a low mobility in soils. And
10 yet in the document on page 17, you've got a comment that
11 suggests considerable leaching potential. So how do you
12 reconcile those?

13 DPR ASSOCIATE ENVIRONMENTAL RESEARCH SCIENTIST

14 GURUSINGHE: Yes. See the unusual thing in this compound
15 is -- the unusual thing in this compound is in nature we
16 come across many different situations than we have tested
17 it for. It's very low solubility in water, but it's found
18 in the river systems in California. It's found in the
19 deep wells in California. So it finds its way for it to
20 move under a certain set of conditions, which we have not
21 tested for.

22 So what we have tested for all suggests that this
23 product should not move in water; it should not breakdown;
24 it should not be in there; but we have found it on all of
25 those places, unfortunately. So there are a certain set

1 of conditions that we have not tested, which allows it to
2 be present in places that we don't expect it to be.

3 PANEL MEMBER ATKINSON: There is a couple of
4 places in the text where "leaching" has been replaced by
5 "leching", so it's become a bit of a lecher apparently.

6 (Laughter.)

7 PANEL MEMBER ATKINSON: So I think you need to
8 fix those.

9 DPR ASSOCIATE ENVIRONMENTAL RESEARCH SCIENTIST
10 GURUSINGHE: Okay. Sorry, I didn't see that.

11 PANEL MEMBER ATKINSON: Otherwise, it should
12 definitely be banned.

13 (Laughter.)

14 --o0o--

15 DPR ASSOCIATE ENVIRONMENTAL RESEARCH SCIENTIST
16 GURUSINGHE: Then with respect to fate, there is no direct
17 information with respect to gas phase atmospheric
18 chemistry or methidathion. And all the information so far
19 with organophosphorus compounds, one would expect it to
20 react with ozone, hydroxyl ions, as well nitrate ions in
21 the atmosphere.

22 And Winer and Atkinson in 1990 showed that the
23 hydroxyl radicals that are important in the breakdown of
24 most of the organophosphorus compounds and the entire
25 lifetime may range from .8 hours to 2 days. And this

1 ions. And I may add one year later, Atkinson and others
2 demonstrated that it is the sulfur that gets oxidized. It
3 is this sulfur that gets oxidized and forms the oxon,
4 which we call methidaoxon.

5 PANEL MEMBER ATKINSON: The number you'd given on
6 page 20 seems to be off by a factor of 2. Anyway, I've
7 got these comments, so I'll give them to you afterwards.

8 DPR ASSOCIATE ENVIRONMENTAL RESEARCH SCIENTIST

9 GURUSINGHE: Okay, sir. I think I have your paper with me
10 also.

11 PANEL MEMBER BLANC: Can you just clarify -- Paul
12 Blanc here -- when you're talking about the half-life,
13 you're talking about the half-life of going from the
14 parent sulfur compound to the oxene compound?

15 DPR ASSOCIATE ENVIRONMENTAL RESEARCH SCIENTIST

16 GURUSINGHE: Yes, I believe that, because that's how they
17 have said -- they have said half-life, but they have not
18 defined in the paper this is the breakdown from that, but
19 I assume that is what they --

20 PANEL MEMBER BLANC: So since what we really care
21 about is the oxene compound?

22 DPR ASSOCIATE ENVIRONMENTAL RESEARCH SCIENTIST

23 GURUSINGHE: Oxon is one of the products, but both are
24 toxic.

25 PANEL MEMBER BLANC: Right. But the oxone

1 certainly isn't any less toxic?

2 DPR ASSOCIATE ENVIRONMENTAL RESEARCH SCIENTIST

3 GURUSINGHE: No, more toxic.

4 PANEL MEMBER BLANC: So is the whole discussion
5 in the document about this half-life at all, this
6 emphasis, a little bit misleading in that it gives you a
7 sense that it's a detoxification half-life, it's really
8 toxification half-life? And what we really care about is
9 what the half-life then of the next thing is, if we knew?

10 PANEL MEMBER ATKINSON: Well, that may be true,
11 but the half-life is still the half-life of the parent
12 compound. It may form less or more toxic products. You
13 have to do that on a case-by-case basis.

14 PANEL MEMBER BLANC: Well, I'm talking about this
15 case.

16 PANEL MEMBER ATKINSON: Yeah, well this case, but
17 apparently there's -- the document states there's no data
18 on the toxicity of the oxon, at least that statement is
19 made somewhere in here.

20 DPR ASSOCIATE ENVIRONMENTAL RESEARCH SCIENTIST

21 GURUSINGHE: In the literature review I did not come
22 across specific information anywhere saying that this is
23 the toxicity of methidaoxon.

24 PANEL MEMBER ATKINSON: It also depends upon the
25 yield of the oxon from the parent compound, and that's not

1 known.

2 PANEL MEMBER BLANC: Well, okay, but my point
3 here is if you have all of this emphasis on the half-life
4 of this nasty substance in your document, the implication
5 for the normal reader would be oh, okay, so we're dealing
6 with something we have to think about in 2 days there's
7 half as much of it. But actually there's half as much of
8 it, but then there's most of what it's going to is
9 something which has the same biological effect, probably.

10 PANEL MEMBER BYUS: Is that true, that would be
11 my question? Is that statement that you just made true?

12 DPR ASSOCIATE ENVIRONMENTAL RESEARCH SCIENTIST
13 GURUSINGHE: It is possible, because methidaoxon is more
14 toxic than methidathion.

15 PANEL MEMBER ATKINSON: Yeah, that would need to
16 be pointed out. There's no doubt about it.

17 PANEL MEMBER BYUS: More toxic to humans and to
18 insects? I mean, this is the sort of -- this is where
19 this toxicity -- see, when I talk toxicity they're often
20 times talking about slightly different than we view this.
21 So I mean so that the use of it in terms of killing
22 insects, is it parallel?

23 DPR ASSOCIATE ENVIRONMENTAL RESEARCH SCIENTIST
24 GURUSINGHE: The general statement has been made in
25 literature methidaoxon, the oxidated product is more toxic

1 than methidathion. I'm not sure whether I can say for
2 sure it's only for animals or for humans or for insects.

3 PANEL MEMBER BYUS: Okay.

4 CHAIRPERSON FROINES: Well, we know by analogy
5 that pure oxon is more toxic than its parent.

6 PANEL MEMBER ATKINSON: To insects or mammals?

7 CHAIRPERSON FROINES: Mammals

8 PANEL MEMBER BYUS: To mammals.

9 PANEL MEMBER ATKINSON: To mammals. Okay, just
10 asking.

11 PANEL MEMBER BLANC: I think it's a more potent
12 cholinesterase inhibitor.

13 CHAIRPERSON FROINES: And so Paul is asking are
14 we dealing with something that's more toxic to human
15 beings in its oxygenated form relative to the sulfur
16 parent compound?

17 DPR ASSOCIATE ENVIRONMENTAL RESEARCH SCIENTIST

18 GURUSINGHE: The way it looks is yes, it is possible that
19 because the oxon is more toxic than the methidathion, it
20 could be that by-product is more -- is a factor that we
21 have to look at. But in the air, the breakdown is rapid.

22 CHAIRPERSON FROINES: Well, I think that what
23 he's saying is that the half-life -- if the half-life is
24 to a more toxic compound, then that's not a detoxification
25 pathway, so the document needs to be consistent in the way

1 it addresses that issue. It needs to be clear, that's all
2 I think he's saying. Is that right, Paul?

3 PANEL MEMBER BLANC: Yes.

4 PANEL MEMBER ATKINSON: The other problem does
5 come up, at least from the atmospheric side, that the
6 yield of the oxon, the amount that's formed when the
7 parent compound is reacted away is not known. It's
8 presumably quite a lot less than 100 percent.

9 PANEL MEMBER BLANC: I think the other question I
10 would have is all this talk about the ox -- the half-life
11 in air, that would apply to pesticide let's say that was
12 aerosolized or sprayed or gets in the air, and how long
13 does it last in the air? You've just told us a few slides
14 ago that when you put it on the plants, it stays on the
15 plants in a sort of, more or less, neutral -- if there's a
16 more or less neutral condition that's less than 100
17 degrees Fahrenheit, it's going to last on the plants for
18 20 days.

19 So then let's say a wind came through and made
20 some go off the plants, then it's only entering -- there's
21 a reservoir for it to continue entering into the air after
22 a spray event.

23 DPR ASSOCIATE ENVIRONMENTAL RESEARCH SCIENTIST
24 GURUSINGHE: But the label gives, if I'm not mistaken,
25 only 5-day reentry period.

1 PANEL MEMBER BLANC: And the basis for that is?

2 DPR ASSOCIATE ENVIRONMENTAL RESEARCH SCIENTIST

3 GURUSINGHE: That's the information that's offered to the
4 Department with respect to the risks involved.

5 PANEL MEMBER BLANC: And --

6 DPR ASSOCIATE ENVIRONMENTAL RESEARCH SCIENTIST

7 GURUSINGHE: That's how they decide the reentry into it.

8 PANEL MEMBER BLANC: Right. And the reentry
9 interval is discussed in your document at some point?

10 DPR ASSOCIATE ENVIRONMENTAL RESEARCH SCIENTIST

11 GURUSINGHE: Not in my document, but I believe my
12 colleagues will be discussing the toxicity to farm workers
13 in the work health and safety aspect of the compound. And
14 Sheryl will be discussing the medical toxicity aspect of
15 the compound. And in a slide I'll be showing in a little
16 while, the methidathion how it migrates from the area it
17 is applied and what the concentrations for the same period
18 which may partly answer some of your questions.

19 CHAIRPERSON FROINES: Why don't we go ahead,
20 because in some respects we're asking you questions that
21 could more correctly come up a bit later.

22 --o0o--

23 DPR ASSOCIATE ENVIRONMENTAL RESEARCH SCIENTIST

24 GURUSINGHE: Yeah, this is the study that I'm going to
25 refer to. Unfortunately, I removed the information, but

1 I'll mention to you, this particular study was done by
2 Aston & Seiber in '97, first reported in '97. Hey studied
3 areas.

4 Lindcove at roughly 500 feet elevation is very
5 close to the places where the pesticide -- this
6 methidathion is applied in city or that area. And then
7 they studied the midpoint, Ash Mountain, which is about
8 1,500 feet elevation, and Kaweah about 6,000 feet
9 elevation. And Lindcove they detected all 3 -- all 2
10 compounds at varying levels, and in the concentrations
11 roughly 10,000 parts per trillion. And they detected more
12 methidathion than methidaoxon.

13 And when you went to the mean elevation, for the
14 same period, they detected methidaoxon more and
15 methidathion less often at the concentration of 200 parts
16 per trillion. So 2,000 parts per trillion, one-tenth
17 roughly. Then when they went to the highest elevation,
18 they detected only methidaoxon for the same period, and at
19 200 parts per trillion, so that means there's another
20 10-fold decrease.

21 So for the same period, they become less frequent
22 and also they breakdown quite rapidly in the air. So that
23 should answers part of the concerns doctor raised.

24 PANEL MEMBER ATKINSON: What time of year was
25 that study done?

1 DPR ASSOCIATE ENVIRONMENTAL RESEARCH SCIENTIST

2 GURUSINGHE: This is from -- let me check -- from
3 June -- yeah, they studied from May 25th to October 17th.

4 PANEL MEMBER ATKINSON: Okay.

5 --o0o--

6 DPR ASSOCIATE ENVIRONMENTAL RESEARCH SCIENTIST

7 GURUSINGHE: Then the second study that I'm going to cite,
8 and I forgot to mention, my colleague Sheryl will discuss
9 this in detail, because they are relating the data from
10 these studies in their estimates. I will just setup
11 the basics of the study, so that they can pick up from
12 there.

13 And this study was requested by the Department of
14 Pesticide Regulation and it was commissioned by the Air
15 Resources Board and conducted by Royce and others at Cal
16 State, Fresno.

17 --o0o--

18 DPR ASSOCIATE ENVIRONMENTAL RESEARCH SCIENTIST

19 GURUSINGHE: And these are the 5 areas they studied -- 4
20 experimental areas. Site at University of California at
21 Lindcove, Exeter High School, and then Lindsay, the
22 Jefferson school and Strathmore, the elementary school.
23 And the Air Resources Board, which is away from all the
24 other places, these are very close to the places where the
25 pesticide is applied. And Visalia is aware and is

1 considered not a potential site. They expect to see this
2 compound.

3 --o0o--

4 DPR ASSOCIATE ENVIRONMENTAL RESEARCH SCIENTIST

5 GURUSINGHE: And in this study in brief, they collected 81
6 samples and there were detections for methidathion as well
7 as methidaoxon. And there were more methidathion detected
8 than methidaoxon detected. And my colleagues will discuss
9 the detailed numbers and the implications of those
10 observations.

11 Then the second study is the application
12 monitoring study done in this particular area in the map.
13 And they applied methidathion to a 15-acre orange grove
14 and monitored the methidathion and methidaoxon over a
15 period. So they had base-line information of 1
16 observation before application and several other
17 applications. One application and subsequent several
18 intervals, where they detected methidathion initially and
19 after some period they detected methidaoxon.

20 So in other words, even in an application you can
21 detect methidaoxon coming up after few -- in this case
22 after 1 and a half days, I believe. And this is the basic
23 information that I came across in the literature.

24 And I think that basically concludes my
25 presentation. And if there are anymore questions, I'll be

1 happy to answer if I know the answers.

2 CHAIRPERSON FROINES: Thank you.

3 PANEL MEMBER BLANC: Do you want to give your
4 transcriptionist a break?

5 CHAIRPERSON FROINES: Pardon me?

6 PANEL MEMBER BLANC: Do you want to give your
7 transcriptionist a break?

8 Do you want to give your transcriptionist a
9 break? It's been an hour and a half.

10 CHAIRPERSON FROINES: You've got your hand in
11 front of your mouth.

12 PANEL MEMBER BLANC: Do you want to give your
13 transcriptionist a break? It's been an hour and a half.

14 CHAIRPERSON FROINES: I still don't understand
15 what you're saying.

16 PANEL MEMBER ATKINSON: Do you want to take a
17 break?

18 CHAIRPERSON FROINES: Yes, we can take a break,
19 because we should have a shift in -- yes, but we're going
20 to have a shift in topic when we come back. So let's take
21 a 5-minute break.

22 (Thereupon a recess was taken.)

23 CHAIRPERSON FROINES: Welcome.

24 ARB SENIOR STAFF COUNSEL OLIVER: Thank you,
25 Chairman Froines and members of the Scientific Review

1 Panel. My name is Kirk Oliver. I'm a lawyer with the
2 California Air Resources Board. And I'm here to discuss
3 with you the resolution of a case. Actually, the first
4 and only case that has been filed against the Panel that
5 went all the way through the litigation process and had a
6 trial conducted in it. And case I'm referring to is, of
7 course, the Apodaca versus SRP, ARB and OEHHA case that
8 was decided back in February of this year.

9 And there are a few times in life where we have
10 the opportunity to celebrate a complete and utter victory,
11 but this is one. So the panel should be very proud of the
12 efforts it put in to its painstaking review of the diesel
13 identification documents that began back in the early
14 nineties, came to fruition in a meeting that was held in
15 April of 1998 up in northern California, at which the
16 Panel forwarded the, basically, landmark review of diesel
17 health effects to the Air Resources Board for
18 identification of diesel particulate as a Toxic Air
19 Contaminant.

20 As you know, the Air Resources Board acted upon
21 your recommendation and named diesel particulate to be a
22 Toxic Air Contaminant and that finding was put in to law
23 in a regulation in Title 17 of California Code of
24 Regulations.

25 Now, although we had garnered the support of many

1 members of the industry during that process and you heard
2 from all of their experts, in fact you convened a special
3 meeting just to hear from them, and the foremost
4 authorities in this field, unfortunately the group
5 consisted of a number of private individuals and the
6 industry filed a lawsuit shortly after the identification
7 to challenge the regulation. And not only that, but to
8 set aside the unit risk factor in the other findings that
9 the panel made on diesel particulate.

10 The plaintiffs argued in this case that the
11 findings that you made and the regulation that ensued from
12 your findings were not supported by substantial evidence,
13 that essentially you had relied on junk science, was their
14 term. And the plaintiffs' cited a number of the basic
15 inevitable uncertainties in the risk assessment process.
16 And this case was actively litigated. It was first filed
17 in San Diego County Superior Court. I believe it was on
18 Christmas eve in the year 1998.

19 Now, in another case in that jurisdiction, a
20 judge denied a discovery request. And the plaintiffs had
21 come to us and said that they really wanted to take your
22 depositions and get in to your thought processes that you
23 had undertaken in doing the findings, which simply isn't
24 supported by law. And we refused. And when this judge in
25 San Diego Superior Court rendered his decision denying a

1 similar request, the plaintiffs dismissed this lawsuit.

2 Unfortunately, they refiled it again in Fresno
3 Superior Court, which they were entitled to do. The
4 dismissal was without prejudice. And the case laid
5 dormant for a couple of years until they sent a letter to
6 the judge asking that the case be reactivated. Again,
7 they approached us and sought discovery, written
8 discovery, of your notes and the thought processes that
9 you went through in doing the identification. They wanted
10 to take depositions of your members. And, again, those
11 things just are not legally supported. They're not
12 authorized by law in this kind of an action or in any
13 other.

14 So we hotly contested that request and won the
15 ensuing hearing before a judge, where we argued the clear
16 legal authorities. And the judge went our way on that.

17 Now, the plaintiffs, however, continued the
18 lawsuit this time and they brought it to trial. A
19 briefing was conducted and concluded about 2 years ago.
20 And having been an active participant in writing that
21 brief, I can tell you the record that you developed in the
22 identification was the ammunition that we needed and we
23 used to write that brief. And the hard staff work and
24 ample record that was developed supporting the
25 identification was the thing that we came back to again

1 and again in that brief.

2 Now, the brief was submitted June 2004, and the
3 trial was conducted a year later. About a year ago, this
4 part of June, 2005 we had a 2-day trial in Fresno Superior
5 Court where we took the record to the judge. Because in a
6 case like this, the evidence in the trial is limited to
7 the record that was developed before you and before OEHHA
8 and before the ARB. And, again, we felt very confident
9 that if we had a judge that reviewed that record in great
10 detail and weighed the evidence that he or she would come
11 out on our side.

12 And fortunately we obtained such a judge, that
13 such a judge was assigned to us, very thoughtful
14 considerate person, and he heard the arguments of both
15 sides. He read the voluminous briefs that were filed by
16 the plaintiffs, as well as ours. And then he took several
17 months to review the 25,000-page record himself. And the
18 results of his review are before you today. The decision
19 that he issued came out in February. And as you can see
20 it's an utter victory for the panel as well as OEHHA and
21 ARB.

22 Now, there are a few portions of the decision
23 that you might find of note. And I'd like to direct your
24 attention to a few of them, because they talk about the
25 SRP's work. And those particularly begin at page 13 of

1 the decision. And there the judge cites what he found to
2 be a nonexclusive list of the substantial evidence that
3 supported your unit risk factor in your own findings and
4 what OEHHA and what ARB did. And you'll note that the two
5 first articles that he cites in his list are both of the
6 Garshick articles. Those were a fundamental basis upon
7 which the plaintiffs made their arguments, citing the
8 uncertainties that existed in both of those studies and
9 the disputes that had been aired fully before you in the
10 scientific community about how those data were to be
11 evaluated.

12 And there the judge lists both the Garshick
13 studies as the very first studies that he cites as the
14 substantial evidence supporting what you did and what you
15 found.

16 Now, the plaintiffs made a great deal of dispute
17 about the unit risk factor. And they took it on in
18 several different ways.

19 They cited the scientific uncertainties in
20 deriving a point risk value, like was done. They argued
21 that law didn't authorize it also. They also said that
22 there were differences in the types of diesel exposures
23 that occurred back when most of these studies were done,
24 given the facts that the diesel fleet has become a lot
25 cleaner due to air pollution controls that have been

1 placed on those engines, and the fact that the diesel fuel
2 itself that's burned today is a lot cleaner than diesel
3 that was burned before. To the plaintiffs, that rendered
4 invalid all previously conducted studies. But the judge
5 did not agree with them. And you can see the rationales
6 that he used to reject those arguments throughout pages 16
7 through 25.

8 The plaintiffs also argued that the risks -- the
9 unit risk factor was a regulation that somehow bound
10 people out in society, and prohibited them from doing
11 things or required them to do things, and that the unit
12 risk factor was invalid because it wasn't adopted
13 according to the Administrative Procedures Act
14 requirements that pertain to regulation and government
15 rule-making activities.

16 The judge reject that argument also, and said
17 that the unit risk factor is simply what it is. It is a
18 piece of scientific advice that the Scientific Review
19 Panel gives to the ARB and perhaps the world large, if you
20 think about it, about where the panel thinks the potency
21 lies within the range of risk that OEHHA determines in its
22 regulatory documents.

23 There is a part of the decision that I'd like to
24 read to you, and it appears on page 17. And the judge
25 talks about the uncertainty, and he says this, citing one

1 of the reports that appeared in the record that we gave
2 him:

3 "Mark Twain was reported to have said that
4 science is wonderful because it gives such rich returns in
5 speculation for such a trifling investment in fact. To
6 some extent, the same might be said for risk assessment."

7 And then the judge goes on to cite the reasons
8 why risk assessment is absolutely necessary even given its
9 uncertainties.

10 So, he concludes on that page at the bottom:

11 "The unit risk factor is a reasonable estimate that fell
12 within the range of risk which OEHHA was required to
13 establish, if it did not itself set a unit risk factor on
14 its own. The Legislature authorized CARB, OEHHA, and SRP
15 to act even though they did not have precise or exact
16 information."

17 I think the important message that the Panel
18 should take from this decision is that the Panel should
19 continue to do its business the way it's been doing it for
20 all these many years. Since 1986 this panel has been an
21 open, honest forum for the discussion of scientific fact,
22 including uncertainty. And this judge, once he was
23 confronted with one of the records that you developed,
24 came down overwhelmingly on your side and on the side of
25 honest scientific debate.

1 We're here to support the Panel and we're here to
2 provide the legal defense that's necessary if one of these
3 types of things happens again. And we stand ready to do
4 that.

5 Keep in mind, this case is not an appellate case,
6 it's not published in the appellate decisions, it's not
7 something that could be cited by us or by another party in
8 another lawsuit. Interestingly, when the decision came
9 out and we were in contact with the plaintiffs about the
10 house-making chores that have to be done to -- in the
11 heels of a decision like this, that they approached us and
12 offered to forego their opportunity to appeal this
13 decision. Now, one can only speculate about their
14 motivations for doing that. But that was an offer that we
15 accepted, and that puts an end to this lawsuit forever.
16 It will not be appealed. There will not be a chance for
17 this judge's determinations to be overturned in any way.
18 It's done, and its results and its dictates bind all the
19 parties that were party to it.

20 So, I just wanted to congratulate you, bring this
21 bit of happy news to your attention. And if the Panel
22 members have any questions about the decision or its
23 effect, I would be more than happy to answer them right
24 now.

25 CHAIRPERSON FROINES: Questions?

1 PANEL MEMBER BLANC: So does this mean that the
2 judge's statement, and I quote, "Dr. Froines'
3 facetiousness does not justify overturning the SRP's
4 setting of the URF," is not precedent setting then?

5 (Laughter.)

6 ARB SENIOR STAFF COUNSEL OLIVER: Let's just say
7 that it would be a wise comment that any judge in the
8 future would be well advised to take into account in
9 evaluating Mr. Froines' -- Dr. Froines' remarks.

10 (Laughter.)

11 CHAIRPERSON FROINES: You just had to do it,
12 didn't you?

13 (Laughter.)

14 PANEL MEMBER BLANC: It is interesting, by the
15 way, that in that litany of publications that the judge
16 invoked he did include the meta-analysis by Bhatia. And
17 one of the things that we discussed -- you know, have
18 discussed on and off in various context is what is the
19 meaning and weight of meta-analyses. So I think that's --

20 CHAIRPERSON FROINES: He didn't include Alan
21 Smith's meta-analysis.

22 PANEL MEMBER BLANC: He included Alan Smith's
23 testimony, and it was --

24 CHAIRPERSON FROINES: Yeah, but not his
25 meta-analysis.

1 PANEL MEMBER BLANC: That was Bhatia, was the
2 first author on --

3 CHAIRPERSON FROINES: Oh, yes, you're right.
4 Bhatia in '97, that's it. But they didn't include Michael
5 Lipsett's.

6 PANEL MEMBER BLANC: Was that published or
7 testimony?

8 CHAIRPERSON FROINES: That was published.

9 ARB SENIOR STAFF COUNSEL OLIVER: Oh, keep in
10 mind that the judge said that this is a nonexclusive
11 listing. So he didn't mean to --

12 PANEL MEMBER BLANC: That if it didn't appear, it
13 wasn't --

14 ARB SENIOR STAFF COUNSEL OLIVER: Right.

15 CHAIRPERSON FROINES: So is it -- your point that
16 you made I think is worth repeating. And, that is, that
17 traditionally OEHHA has come up with a range of risk, and
18 in diesel we actually made the overt decision to set a
19 unit risk value -- to establish a unit risk value. And so
20 in principle that decision to do that and our right to do
21 it has been upheld?

22 ARB SENIOR STAFF COUNSEL OLIVER: That's correct.

23 CHAIRPERSON FROINES: So that's extremely
24 important, because they could have ruled that we did not
25 have that authority.

1 ARB SENIOR STAFF COUNSEL OLIVER: Yes, you're
2 correct. And in the statutes that create the scientific
3 review panel, the words "unit risk factor" never appear.
4 However, the words "authorizing you to give advice to ARB
5 on the toxicity of substances" do appear. And the judge
6 did an excellent job of laying out the other legal
7 authorities that would -- he found persuasive to authorize
8 the Panel to make such a finding.

9 PANEL MEMBER BLANC: Can I ask you a
10 hypothetical, just in terms of the logic of the decision.
11 If this was a decision referring to input that we'd given
12 on a pesticide, would the statutory support be viewed in
13 your opinion as being any weaker for our actions?

14 ARB SENIOR STAFF COUNSEL OLIVER: I'm no expert
15 on the pesticide side of it. But as far as I know, your
16 role is the same in both processes. So I don't think that
17 would have made a difference to this judge. But, again,
18 that's a hypothetical and speculation on my part.

19 CHAIRPERSON FROINES: Joe.

20 PANEL MEMBER LANDOLPH: Do you expect situations
21 like this to arise frequently in the future? That's the
22 first question.

23 ARB SENIOR STAFF COUNSEL OLIVER: In the, oh,
24 almost 20 years of the Panel's existence, this is the only
25 such instance that occurred. And given the favorable

1 result for the Panel, I think that this would give other
2 parties pause in bringing such a challenge. And we're not
3 aware of any being mounted at this point. So I don't
4 think it will make it more likely. I think it would make
5 it less likely. And although this is not an appellate
6 decision, it is a public document and has obtained wide
7 circulation.

8 PANEL MEMBER BYUS: I think it provides some
9 support for the quality of the legal system and the
10 ability of judges to understand this kind of scientific
11 information and deliberations. I mean this is a major
12 concern in the legal system at all how judges evaluate all
13 scientific information. They're not particularly trained
14 to do it.

15 And it's more and more prevalent in almost all
16 cases that science now becomes more and more important in
17 how the judge evaluates it and understands it as how it's
18 litigated. And for a judge to understand this and to
19 rule, in my opinion, completely correctly, I mean that
20 says a lot for the legal system, and hopefully all of the
21 legal system, you know, it's just not judge specific. But
22 it really is very comforting, at least for me, to know
23 that a judge that's sitting on bench, not necessarily
24 trained, but really must have put in some considerable
25 effort to actually understand this. It was not an easy

1 task, is what I'm trying to say.

2 CHAIRPERSON FROINES: Well, let me just make a
3 comment about that, because -- I don't know what Kirk
4 thinks. But what you just said is absolutely a
5 double-edged sword, you realize. Because under the
6 Daubert decision U.S. Supreme Court decision, judges are
7 getting very actively involved in the science. And
8 that -- and the record of that involvement in the science
9 has not been a very optimistic one. And so that --
10 there's an entire volume of the American Journal of Public
11 Health devoted to -- the entire -- not a volume, but
12 entire issue devoted to the Daubert decision and its
13 implications. And they're worrisome in that respect.

14 And so its interesting that this judge actually
15 got into the science. He could have taken a more
16 conservative approach, which would have been just to look
17 at the adequacy of the record. But in this case he chose
18 to get in to review the science. And, fortunately, that
19 was to our benefit.

20 ARB SENIOR STAFF COUNSEL OLIVER: What the judge
21 did was examine the record to see whether it contained
22 this legal standard of scientific evidence that pertains
23 to regulatory activity in the scientific area. Whether
24 the record had substantial evidence that supported what
25 the findings were -- and substantial evidence doesn't

1 mean, you know, overwhelming evidence beyond a reasonable
2 doubt, especially in this area where the Legislature has
3 authorized us to act without scientific certainty.

4 So he did -- he did the level of legal analysis
5 of scientific information that the law requires him to do.
6 He did no more and no less. And that is what rendered a
7 proper and just result here, because he basically followed
8 the law.

9 CHAIRPERSON FROINES: Thank you, Kirk.

10 ARB SENIOR STAFF COUNSEL OLIVER: Thank you very
11 much.

12 PANEL MEMBER BYUS: Congratulations. I mean I'm
13 sure you had a little bit to do with this --

14 ARB SENIOR STAFF COUNSEL OLIVER: Yeah, I have
15 a --

16 PANEL MEMBER BYUS: -- in writing this in the
17 proper and correct way and with a sufficient clarity.

18 ARB SENIOR STAFF COUNSEL OLIVER: Well, thank you
19 very much. And thank you for the --

20 CHAIRPERSON FROINES: Joe had one more.

21 ARB SENIOR STAFF COUNSEL OLIVER: Oh, I'm sorry.

22 PANEL MEMBER LANDOLPH: Oh, just one quick one.

23 Thank you for coming.

24 In terms of keeping records and keeping files,
25 are we supposed to keep voluminous files on all these

1 things? I mean I can't store them, is the bottom line.

2 What is your view to that matter?

3 ARB SENIOR STAFF COUNSEL OLIVER: You're required
4 to keep your records in the way that you keep records in
5 the normal course of your business affairs.

6 And if this is something that the Panel would
7 like to explore in another session, then that's something
8 we'd be more than happy to come in and talk to you about.

9 But we're only as good as the record that was
10 generated during your deliberations and the findings in
11 the other agencies. And we want to thank you very much
12 for the record that you prepared here. It was easily
13 defendable.

14 CHAIRPERSON FROINES: I gather from what you said
15 though that the rules of discovery in terms of deposition
16 and record keeping are such that you would not anticipate
17 that we would be called upon to provide that information
18 in a deposition?

19 ARB SENIOR STAFF COUNSEL OLIVER: That's correct.

20 CHAIRPERSON FROINES: Great. Thank you very
21 much.

22 ARB SENIOR STAFF COUNSEL OLIVER: Thank you,
23 Chairman Froines. Thank you, members of the Panel.

24 CHAIRPERSON FROINES: It does require that there
25 is no facetiousness in this group.

1 Okay. Onward.

2 Tobi's left us. Randy is...

3 (Thereupon an overhead presentation was
4 Presented as follows.)

5 DPR STAFF TOXICOLOGIST BEAUVAIS: Good morning,
6 everyone. My name is Sheryl Beauvais. I am with the
7 Department of Pesticide Regulation. And I'm going to talk
8 about the data that went into the exposure assessment for
9 the ambient air and bystander exposures today and exposure
10 estimates that came out of the data.

11 First of all I'm going to briefly talk about use
12 just as it relates to the exposure assessment.

13 --o0o--

14 DPR STAFF TOXICOLOGIST BEAUVAIS: This first
15 slide shows the most recent five years of use for three of
16 the top crops on which methidathion is used, almonds,
17 artichokes and citrus. On the Y axis there it's under
18 "Pounds applied per year".

19 And as you can see, the purpose of this slide is
20 just to show you that the amounts on each crop vary from
21 year to year, and that what comes out is the top crop
22 varies from year to year. The slides that Gura showed you
23 over a longer period of time made that same point.

24 Because the weather varies, because pest
25 pressures vary and so forth, because there's some annual

1 variation, we don't use a single year's worth of use data
2 when we're attempting to estimate the duration of exposure
3 to people.

4 --o0o--

5 DPR STAFF TOXICOLOGIST BEAUVAIS: And so when
6 we're coming up with our exposure estimates, we instead
7 come up with a five-year average. And that's what this
8 slide is showing in this -- well, this is a five-year
9 average based on pounds applied. And what's on the Y axis
10 is actually percent annual use. And this is the 2004
11 to -- or 2000 to 2004 in Tulare County, all applications
12 by all methods.

13 And what you can see here is -- well, this first
14 of all makes the same point that Gura made with his slide
15 for annual use across the state; and, that is, that we
16 have dormant spray applications occurring in the winter
17 months and also we have summer use. And when you look at
18 what crops are -- this is mostly on citrus and walnuts is
19 the summer use. This is peaches. And there is some use
20 on almonds, which may be limited to January. I don't
21 know.

22 But at any rate, this is essentially what the
23 major types of use are. And then we've got less use
24 happening in other months in Tulare County.

25 Now, we start with an assumption that people

1 could potentially be exposed throughout the year, but that
2 they are more likely to be exposed during high use months.
3 So the exposure's more likely during these times than
4 during the months of March and April and September when
5 use is down quite a bit.

6 We set an arbitrary cutoff of 5 percent. And we
7 essentially say months that achieve or exceed that, then
8 we're going to say these are the months people are most
9 likely to be exposed.

10 So for the seasonal and annual exposures of
11 methidathion that I'll be talking about later on, this is
12 the data that went into that estimate of nine months. So
13 essentially there are nine months that touch or go above
14 this line.

15 CHAIRPERSON FROINES: Can I ask a question?

16 DPR STAFF TOXICOLOGIST BEAUVAIS: Sure.

17 CHAIRPERSON FROINES: That I've always been
18 curious about.

19 During, say, January and February in that
20 location, are there other pesticides that would be being
21 applied to that same crop during that period of time? In
22 other words are there multiple exposures or is it pretty
23 much a one pesticide pattern?

24 DPR STAFF TOXICOLOGIST BEAUVAIS: So are you
25 asking whether these are being applied in mixtures, or

1 whether --

2 CHAIRPERSON FROINES: No, what I'm really saying
3 is -- are there -- is the actual pesticide load, the
4 actual number of pesticides being applied during that
5 particular period on that particular crop more than this
6 one chemical?

7 DPR STAFF TOXICOLOGIST BEAUVAIS: Okay. And I
8 haven't looked at that question. I would say the answer
9 is going to be yes simply because I know that DPR has been
10 encouraging dormant sprays to switch over to pyrethroids.
11 And they've had a -- I cited it in the exposure assessment
12 a document where they reported on this.

13 CHAIRPERSON FROINES: Randy?

14 DPR SENIOR ENVIRONMENTAL RESEARCH SCIENTIST

15 SEGAWA: Yes, this is Randy Segawa with the Department of
16 Pesticide Regulation.

17 The answer is yes. There are a number of other
18 pesticides used during that period on those same crops,
19 such as chlorpyrophos, diazinon, several different
20 pyrethroids, as well as some newer chemicals as well.

21 Okay. Thank you.

22 PANEL MEMBER ATKINSON: But you'd only use one
23 pesticide on a given orchard.

24 DPR SENIOR ENVIRONMENTAL RESEARCH SCIENTIST

25 SEGAWA: In general, correct.

1 tell you whether you've trapped all of the target analyte
2 in the main section there. Those are analyzed separately.
3 And there was no -- in any of these studies we had nothing
4 in the backup sorbent layer.

5 --o0o--

6 DPR STAFF TOXICOLOGIST BEAUVAIS: For quality
7 assurance, consisted of replicate samples. And 20 percent
8 of those were analyzed. Plus any time there was a
9 detection, the replicate of that detection was also
10 analyzed. There were control spikes analyzed with each
11 set. The limit of detection was set at three times the
12 standard deviation from replicate injections of the lowest
13 standard. For methidathion that was .1 of a microgram per
14 sample, and for methidaoxon it was .25 micrograms per
15 sample.

16 --o0o--

17 DPR STAFF TOXICOLOGIST BEAUVAIS: And continuing
18 with quality assurance: Low levels of -- low level
19 amounts of methidaoxon were found in blanks, both in the
20 method development, the retention efficiency, and the
21 field blanks. This was considered to be a artifact of the
22 sample analysis. And so the way that I dealt with this
23 was to subtract the average, which was this, and -- was
24 the .13 micrograms per sample, which is less than the
25 limit of detection, but it was reported. And this is the

1 range of the amounts that were found. So I subtracted
2 that from the methidaoxon values.

3 PANEL MEMBER BYUS: I'm confused by this.

4 DPR STAFF TOXICOLOGIST BEAUVAIS: Okay.

5 PANEL MEMBER BYUS: In other words you're saying
6 that the compound is there ambiently from where -- I mean
7 it's not part of a biological product. I mean it's a
8 chemical that must have been sprayed some time, right? I
9 mean I don't understand why you would subtract it out
10 necessarily. But what is the object of that? Let me put
11 it that way.

12 DPR SENIOR ENVIRONMENTAL RESEARCH SCIENTIST

13 SEGAWA: No, we do think that the methidaoxon
14 concentrations were overestimated, because they were
15 finding that compound even in the laboratory blanks,
16 something that had never been exposed in the environment.
17 And so we do think it's a laboratory artifact, and that's
18 why we're subtracting it out.

19 PANEL MEMBER BYUS: So I don't understand what
20 that means still. I mean I -- what --

21 DPR STAFF TOXICOLOGIST BEAUVAIS: In interference
22 that caused it.

23 PANEL MEMBER BYUS: What is it -- can you explain
24 to me what that means?

25 PANEL MEMBER ATKINSON: Maybe it was in a lob --

1 PANEL MEMBER BYUS: What do you mean? In other
2 words is it -- how do you chemically identify it? Do you
3 mass spect -- do you see mass spec? So it is in fact
4 recombinant, right?

5 DPR SENIOR ENVIRONMENTAL RESEARCH SCIENTIST

6 SEGAWA: Well, in this case they did not use a mass
7 spectrometer. They used an electronic capture detector,
8 which is not as specific as mass spec. And so that's one
9 of the reasons why we think it's an artifact.

10 PANEL MEMBER ATKINSON: So it's a peak?

11 DPR SENIOR ENVIRONMENTAL RESEARCH SCIENTIST

12 SEGAWA: Yes.

13 PANEL MEMBER BYUS: Is everybody all right with
14 that?

15 CHAIRPERSON FROINES: You think it's an artifact
16 and in fact is not that compound?

17 DPR SENIOR ENVIRONMENTAL RESEARCH SCIENTIST

18 SEGAWA: Correct. Because like we said, they were
19 detecting that compound, even blanks that were never sent
20 to the field.

21 CHAIRPERSON FROINES: Well, his point is then
22 well taken. Because if it's an artifact, then you
23 probably shouldn't be subtracting.

24 PANEL MEMBER ATKINSON: Well, if it isn't a
25 compound, you should be, since it's a peak.

1 PANEL MEMBER PLOPPER: But they don't know what
2 it is.

3 PANEL MEMBER ATKINSON: No, they don't know what
4 it is, that's true. But it is less than the limit of
5 detection.

6 CHAIRPERSON FROINES: So --

7 PANEL MEMBER BLANC: Well, I'm going to ask a
8 different -- I would ask this related question. Your
9 process of determining your limit of detection, wouldn't
10 that automatically have taken into account this false
11 baseline that you never got below?

12 DPR SENIOR ENVIRONMENTAL RESEARCH SCIENTIST

13 SEGAWA: Usually, yes. However, this monitoring study was
14 done back in 1991. And the method that they used to
15 determine the limit of detection would hold up under
16 today's procedures.

17 CHAIRPERSON FROINES: I'm sorry, I missed that.

18 So could you state your answer again.

19 DPR SENIOR ENVIRONMENTAL RESEARCH SCIENTIST

20 SEGAWA: We also think that the limit of detection
21 determined in the study has some uncertainty associated
22 with it because they did not follow the procedure that is
23 in use today.

24 PANEL MEMBER BLANC: Well, whatever procedure
25 they followed, wouldn't it have involved spiking samples

1 and seeing what they could detect?

2 DPR SENIOR ENVIRONMENTAL RESEARCH SCIENTIST

3 SEGAWA: Yes.

4 And if they were getting these false signals that
5 ranged from .1 to .161 --

6 CHAIRPERSON FROINES: No, it's 161.

7 DPR STAFF TOXICOLOGIST BEAUVAIS: Oh, I'm sorry.
8 That's a typo.

9 PANEL MEMBER BLANC: .161 --

10 DPR STAFF TOXICOLOGIST BEAUVAIS: It is .161. I
11 apologize.

12 PANEL MEMBER BLANC: Yeah. -- then wouldn't
13 that -- however they did the calculation of the limit of
14 detection, surely this sort of baseline signal that could
15 never be gotten rid of must have been also in their
16 measurement? Or was the limit of detection done with a
17 different measurement technique than you actually used
18 when you did the study? And I doubt that. Right? It
19 must have been this electron capture for everything,
20 right?

21 DPR SENIOR ENVIRONMENTAL RESEARCH SCIENTIST

22 SEGAWA: Correct.

23 Why they got what appears to be these compounds
24 that are coming out at the same time as methidaoxon. But
25 it's not actually methidaoxon. It's unknown at this --

1 PANEL MEMBER BLANC: No, no, that's not my
2 question. And it comes back to the question of not
3 subtracting this number twice, which is what John asked or
4 Roger asked or somebody asked. I mean if that's already
5 in your limit of detection, then you wouldn't then
6 subtract it again after you do your limit of -- after you
7 get a value -- let's say you get a value of .3. And then
8 why would you subtract .1 from there? Because doesn't
9 your value of .3 automatically take into account that
10 you've got this?

11 DPR SENIOR ENVIRONMENTAL RESEARCH SCIENTIST

12 SEGAWA: It's not clear from the report. We're not sure.

13 PANEL MEMBER BLANC: All right.

14 PANEL MEMBER BYUS: I've got one more question
15 that I have.

16 If you're like, say, averaging .13 micrograms of
17 sample of this artifact, what was your average total
18 number from your field data?

19 DPR STAFF TOXICOLOGIST BEAUVAIS: Well, actually
20 I'm about to show you that.

21 PANEL MEMBER BYUS: Okay. There we go.

22 (Laughter.)

23 PANEL MEMBER BYUS: Per sample. I'm interested
24 in a per sample. Because if you're -- that's why I'm
25 asking. I don't want you to divide by air volume or

1 whatever, because it's on a per sample. So if your
2 signal -- essentially a signal to noise here. So if this
3 is your blank, it's .13 micrograms per sample, your signal
4 was --

5 DPR STAFF TOXICOLOGIST BEAUVAIS: I see what
6 you're saying.

7 PANEL MEMBER BYUS: -- .14, then subtracting this
8 number is going to be inherently totally inaccurate in
9 terms of your measurement. But if your sample number was
10 10 micrograms and you subtract .13, then we're all right
11 with that. That's why I'm asking.

12 Does that make sense?

13 CHAIRPERSON FROINES: Is the GCMS technique so
14 different in sensitivity that you couldn't have looked
15 with that approach in contrast to the electron capture?

16 DPR SENIOR ENVIRONMENTAL RESEARCH SCIENTIST

17 SEGAWA: I'm sorry. Could you repeat the question?

18 CHAIRPERSON FROINES: Well, if you have a
19 significant artifact using electron capture, that might
20 suggest that you should use a GCMS approach. And why not
21 do that? Because that would separate out your -- or
22 presumably would separate out your artifact.

23 DPR SENIOR ENVIRONMENTAL RESEARCH SCIENTIST

24 SEGAWA: You're correct.

25 CHAIRPERSON FROINES: -- could separate out your

1 artifact.

2 DPR SENIOR ENVIRONMENTAL RESEARCH SCIENTIST

3 SEGAWA: Yes, you're correct. And why that was not done,
4 I'm not sure. It was not explained in the report. I
5 presume that they did not have access to that instrument.

6 CHAIRPERSON FROINES: I mean -- okay. That's
7 frustrate.

8 Go ahead.

9 DPR STAFF TOXICOLOGIST BEAUVAIS: Okay. And I'm
10 not going to be able to answer your question after all,
11 because what I have were those --

12 PANEL MEMBER BYUS: Just some time answer. You
13 see why I'm asking it though?

14 DPR STAFF TOXICOLOGIST BEAUVAIS: Yes.

15 PANEL MEMBER BYUS: I'm not trying to be --

16 DPR STAFF TOXICOLOGIST BEAUVAIS: Yeah. Okay.

17 CHAIRPERSON FROINES: Yes, you are.

18 PANEL MEMBER BYUS: Yes, I am.

19 (Laughter.)

20 DPR STAFF TOXICOLOGIST BEAUVAIS: Okay. You're
21 right. I can certainly add that information.

22 --o0o--

23 DPR STAFF TOXICOLOGIST BEAUVAIS: Okay. Now, to
24 talk about the ambient monitoring itself.

25 The monitoring was done in Tulare County in June

1 time.

2 And then they had a background site that was an
3 urban site away from citrus groves.

4 --o0o--

5 DPR STAFF TOXICOLOGIST BEAUVAIS: And these are
6 the results from each of these sites. The highest
7 concentrations of methidathion came from the Jefferson
8 School site in Lindsay.

9 And the average \pm standard deviation was .069
10 .144 micrograms per meter cubed. And methidaoxon -- and
11 this is -- I've subtracted the blank already from this.
12 And so if we end up determining that's not the way to go,
13 then these values will change. Methidathion will not.

14 These are the values that were used in exposure
15 assessment.

16 --o0o--

17 DPR STAFF TOXICOLOGIST BEAUVAIS: And the
18 application site monitoring was done in July of 1991. And
19 it occurred immediately before, during and following an
20 air blast application to an orange grove. Sampling was
21 done for a total of two days.

22 And I've got another typo on this slide, because
23 it was actually applied -- it was a 15-acre orchard, not a
24 five acre.

25 They applied a total of 45 pounds active

1 PANEL MEMBER BLANC: -- .069 times 5 is their
2 total amount, right?

3 PANEL MEMBER ATKINSON: Yeah, that's right. So
4 its .07 is -- it's .35 micrograms is roughly -- so it's
5 not much above the limit of detection.

6 PANEL MEMBER BLANC: Or their noise level.

7 PANEL MEMBER ATKINSON: Hmm?

8 PANEL MEMBER BLANC: Or their noise level,
9 because they --

10 PANEL MEMBER ATKINSON: Well, no -- yeah, it's
11 not a lot above it.

12 PANEL MEMBER BLANC: Well, actually with this
13 plus, another 1.3 because they subtracted -- .13 or --

14 DPR STAFF TOXICOLOGIST BEAUVAIS: Yeah, from the
15 oxon only. The methidathion, no correction was made.

16 PANEL MEMBER ATKINSON: Oh, that's right. Just
17 the opposite.

18 PANEL MEMBER PLOPPER: Can you go back one?

19 So that average is for all the days that were
20 sampled, or --

21 DPR STAFF TOXICOLOGIST BEAUVAIS: Yes.

22 PANEL MEMBER PLOPPER: -- is that just one day?

23 DPR STAFF TOXICOLOGIST BEAUVAIS: That's across
24 all 17 samples.

25 CHAIRPERSON FROINES: And --

1 PANEL MEMBER PLOPPER: So that's 16 days' worth
2 of samples.

3 CHAIRPERSON FROINES: Do you have any --
4 obviously you probably don't have any idea why you have
5 that enormous --

6

7 PANEL MEMBER ATKINSON: -- standard deviations?

8 CHAIRPERSON FROINES: -- standard deviation.

9 DPR STAFF TOXICOLOGIST BEAUVAIS: Yeah. There
10 were two days that were quite elevated. And there is a
11 "Results" table in the exposure assessment that lists the
12 individual results. And there was one day, July 10th, at
13 Site J was .56 micrograms per meter cubed. And on July
14 11th, the next day, was .30 micrograms per meter cubed.

15 PANEL MEMBER PLOPPER: Were these samples
16 taken -- was there a record kept of what the application
17 pattern was at that time? I mean because that's --

18 DPR STAFF TOXICOLOGIST BEAUVAIS: There was no
19 information given with the report about that. ARB's
20 policy was to confirm applications afterwards, right?

21 DPR SENIOR ENVIRONMENTAL RESEARCH SCIENTIST

22 SEGAWA: While we do have records of individual
23 applications, the location's only good down to one mile.
24 And so we can approximate the locations, but we don't know
25 the exact location.

1 PANEL MEMBER PLOPPER: So that --

2 PANEL MEMBER ATKINSON: So there must have
3 been -- oh, I'm sorry -- there must have been a number of
4 those which were below the limits of detection then.

5 DPR STAFF TOXICOLOGIST BEAUVAIS: At Site J, not
6 so many on the methidathion. Site J there were only 2 of
7 the 17 samples that were below the limit of detection for
8 methidathion. And 10 -- 11 of the 17 from
9 methidathionoxon. So the oxon is based mostly on that
10 detection limit.

11 CHAIRPERSON FROINES: So I'm still not clear.

12 Do you have records of was there application that
13 occurred on the days where you had the high values? In
14 other words, is there a way to see if there's a logic to
15 the results?

16 DPR SENIOR ENVIRONMENTAL RESEARCH SCIENTIST

17 SEGAWA: It's something we can check on.

18 PANEL MEMBER PLOPPER: How many times a year did
19 they put this material on one orchard? Once, right?
20 Maybe twice a year?

21 DPR STAFF TOXICOLOGIST BEAUVAIS: Maybe twice.
22 Twice is the maximum allowed. So in most cases it would
23 be once, just looking through POR data.

24 CHAIRPERSON FROINES: This is one of the generic
25 frustrations about ambient monitoring that we've talked

1 about many times in the past, so that it's -- and this is
2 a good example of some of the tensions.

3 DPR STAFF TOXICOLOGIST BEAUVAIS: Yeah,
4 unfortunately these are the only data that we have that
5 cover sites that are near applications.

6 Now, the UC site, who are mentioned, the study
7 that was done in 1994, the Aston and Seiber study -- and
8 they also monitored at the Lindcove station. And the
9 concentrations they got there were within the same range
10 for methidathion and much lower for methidathionoxon.

11 CHAIRPERSON FROINES: Why don't you go ahead.
12 We're holding you up on this one slide.

13 --o0o--

14 DPR STAFF TOXICOLOGIST BEAUVAIS: Okay. Going on
15 to the application site monitoring.

16 The application was occurring in this 15-acre
17 orchard here. And generally in this area prevailing winds
18 were out of the northwest and the sample stations were set
19 up this way, with that assumption in mind, where there was
20 one station on the north side and two at the southeast, at
21 progressive distances away from the field.

22 Unfortunately, as you're about to see, the wind
23 directions didn't cooperate during the study. And all I
24 can say is that these are the best data we have available.

25 --o0o--

1 DPR SENIOR ENVIRONMENTAL RESEARCH SCIENTIST

2 SEGAWA: You're correct. The standard procedure now would
3 be to deploy samplers surrounding the field.

4 PANEL MEMBER BYUS: Let the wind blow where it
5 may, right?

6 (Laughter.)

7 DPR STAFF TOXICOLOGIST BEAUVAIS: And if we were
8 dealing with a compound that didn't have decreasing use
9 of -- you know, it might make sense to do more sampling.
10 But it's not a very high priority today compared to other
11 compounds.

12 --o0o--

13 DPR STAFF TOXICOLOGIST BEAUVAIS: Anyway, the
14 results of the ambient -- or the application site
15 monitoring. Again, this is the background sample.
16 Samples 1 through 4 cover the first 24 hours. Sample 1 is
17 the application, and then this is the time period
18 intervals afterwards.

19 Again, Sample 4 was taken during the time that
20 the wind direction was out of the southwest -- or, I'm
21 sorry -- out of northwest. And the blue here is the north
22 station and the yellow and red are the near and farther
23 southeast stations.

24 So just as you predict, methidathion first shows
25 up when the wind direction is favorable to having it show

1 up in those two stations. And that's the first time also
2 that southeast -- which this would have ordinarily have
3 been the station to detect most of the methidathion -- it
4 shows up during that time. And then the wind direction
5 again switched around to the southwest. And so the north
6 station gets a much larger peak.

7 So for the exposure assessment I did a 24-hour
8 time-weighted average of these -- of the north station
9 values here. And for the peak I took this peak here,
10 which was the highest measured in the study.

11 --o0o--

12 DPR STAFF TOXICOLOGIST BEAUVAIS: And this is the
13 same for methidathionoxon. First thing I'm going to point
14 out is that this Y axis is a tenth of -- the scale has
15 been expanded on this one. On the other one it was 3.5.
16 It's now .35 for the top of the axis here. So this a
17 tenth of -- the bars have essentially been magnified by
18 ten compared to methidathion.

19 And we don't see the oxon at all until the wind
20 had switched around following the application. And so the
21 24-hour time-weighted average for methidathionoxon is
22 based largely on the detection limit.

23 And then the peak is -- I took it at the same
24 time that I took the methidathion. So this is my peak
25 here. Because when you add the two together eventually,

1 which is -- you'll end up with a much higher number that
2 way.

3 --o0o--

4 PANEL MEMBER BYUS: I'm a little confused. Was
5 it the same day or with the same wind or was it a
6 different wind for both of these compounds?

7 DPR STAFF TOXICOLOGIST BEAUVAIS: Yeah, these
8 were monitored simultaneously, yes.

9 PANEL MEMBER PLOPPER: Does that mean you
10 interpret this that there is no oxone until three days
11 after the application?

12 DPR STAFF TOXICOLOGIST BEAUVAIS: I didn't hear
13 the question.

14 PANEL MEMBER PLOPPER: Well, if you look at those
15 two slides, I'm trying to figure out what the relationship
16 between the parent compound and the oxone is. Is that --
17 it doesn't even show -- isn't detectable till three days
18 after the application?

19 DPR STAFF TOXICOLOGIST BEAUVAIS: And it's hard
20 to know how much of that is the artifact of the wind
21 direction also; that if the winds had been -- if we'd have
22 had a sampler to capture the application directly downwind
23 during the application and immediately following. Because
24 during samples 1 through 3, which were the application and
25 the first six hours afterwards, the wind direction

1 wasn't -- there was no sampler in the path of the
2 prevailing wind.

3 PANEL MEMBER PLOPPER: And I thought the north
4 sampler was getting you a sample.

5 DPR STAFF TOXICOLOGIST BEAUVAIS: It was -- it
6 was getting a methidathion sample. So, yeah.

7 PANEL MEMBER PLOPPER: But it wasn't getting an
8 oxone sample, so it wasn't there --

9 DPR STAFF TOXICOLOGIST BEAUVAIS: Right.

10 PANEL MEMBER PLOPPER: -- for the first three
11 hours?

12 DPR STAFF TOXICOLOGIST BEAUVAIS: Right.

13 PANEL MEMBER BLANC: Can you go back a slide.

14 On No. 5, which is the one that you say you're
15 using?

16 DPR STAFF TOXICOLOGIST BEAUVAIS: Yes.

17 PANEL MEMBER BLANC: For No. 5, was that at that
18 point in the direct wind?

19 DPR STAFF TOXICOLOGIST BEAUVAIS: No, this
20 follows -- go ahead and back up one more.

21 And No. 5, winds were out of the southwest. But
22 it follows that eight-hour period when winds had been out
23 of the northwest, I guess. I don't know -- I'm not sure
24 exactly what the explanation is for that.

25 PANEL MEMBER BLANC: Well, let me ask a different

1 question.

2 Is there a way that you could model -- since
3 you're measuring not in the direction of wind, it seems
4 that you're not being very conservative in your exposure
5 estimate. Couldn't you use the wind vector as a way -- as
6 a multiplication factor for estimating what the peak
7 exposure would have been, since you could use the
8 combination of the north and southeast -- I mean couldn't
9 you algebraically model what the capture would have been
10 if the wind had been in the right direction, and then come
11 up with a higher number of what the airborne exposure
12 would have been downwind? Isn't that a simple -- aren't
13 there simple models that would do that for you?

14 DPR SENIOR ENVIRONMENTAL RESEARCH SCIENTIST

15 SEGAWA: There are models that will do that, and we have
16 used them for application site monitoring. Unfortunately
17 this study doesn't include sufficient information for us
18 to do those models.

19 PANEL MEMBER BLANC: Because you have northwest
20 but that's not good enough?

21 DPR SENIOR ENVIRONMENTAL RESEARCH SCIENTIST

22 SEGAWA: Correct. We would need a more precise direction
23 and a more frequent measurement. All we have is the
24 average direction for that sampling period.

25 In addition, the exact location of the samplers

1 is somewhat unclear.

2 PANEL MEMBER BLANC: And yet you're using these
3 data to then derive public health safety estimates. And
4 you're using data which is so frighteningly limited and
5 flawed and then taking conservative -- not conservative --
6 I'm sorry -- the opposite of conservative interpretations
7 of these data to then say, well, the exposure is such and
8 such. I mean I at least as a sensitivity analysis would
9 like to see what the measurements are like using some more
10 public health conservative estimate of what these airborne
11 exposures are like. I mean this whole thing is scary even
12 for the pesticide presentations that we're used to, I have
13 to say. I'm not happy.

14 CHAIRPERSON FROINES: I think the point, besides
15 his happiness or unhappiness, to worry about is that this
16 looks like that there is an underestimation of exposure.
17 I think everybody here on this panel would agree to that.

18 And so the question is -- you know, when we get
19 to the health effects issue we're going to have a
20 discussion about acute toxicity and assumptions that were
21 made with respect to LOEL to NOEL estimation. And this
22 data would suggest that that decision was perhaps not as
23 well -- is not justified. And so the issue's going to
24 come up I think as we get further along.

25 So I think that Paul's point is important and,

1 that is, how do we -- how do we make an estimate of
2 exposure given all the problems in the data?

3 DPR SENIOR ENVIRONMENTAL RESEARCH SCIENTIST

4 SEGAWA: The point is well taken. As we go through the
5 rest of our presentation, both from Sheryl as well as from
6 Carolyn Lewis, you'll see that even with the
7 underestimation, we do think it meets the criteria for
8 listing as a Toxic Air Contaminant. And so if in fact
9 that occurs, we will definitely do additional monitoring
10 when we get to the mitigation and risk management phase to
11 see exactly what the current exposures are.

12 CHAIRPERSON FROINES: Randy, but I would actually
13 at this stage not go there yet. Let's leave the
14 designation of Toxic Air Contaminant to the side, and on
15 the assumption that we're still going through a process of
16 evaluation, so that everybody's comfortable.

17 So within that, I think the best thing to do is
18 to move on, but note that there is concern on the Panel
19 about the exposure estimates. And I think it's shared
20 pretty much by everybody, so that it's uniform.

21 So why don't we go ahead with that, sort of
22 check -- the box is checked that there is a concern.

23 --o0o--

24 DPR STAFF TOXICOLOGIST BEAUVAIS: Okay. Just to
25 briefly talk about how exposure estimates are calculated.

1 We estimated -- we assume that 100 percent of the inhaled
2 pesticide is absorbed. And so that absorbed does is air
3 concentration time inhalation rate. I have calculated
4 estimates for infants as well as adults because infants
5 have higher inhalation rates. And for air concentrations,
6 used the highest results that were available. And that
7 was -- for ambient air monitoring, that was the Jefferson
8 School site; for bystander, that was the north application
9 site.

10 PANEL MEMBER BLANC: Can you just clarify, on the
11 Jefferson School, when you say the highest results, and
12 you had that wide standard deviation. Then there was
13 something about 90th percentile.

14 DPR STAFF TOXICOLOGIST BEAUVAIS: Yeah. And I'm
15 about to explain that actually how that's calculated.
16 That's where I'm going next.

17 PANEL MEMBER BLANC: Okay.

18 DPR STAFF TOXICOLOGIST BEAUVAIS: How to
19 calculate the -- how the exposure estimates were
20 calculated. First of all, for acute -- we considered that
21 as lasting from less than a day up until a week, so that's
22 the interval that we're looking at here -- we used the
23 95th percentile of the distribution of the daily
24 methidathion concentrations in air. This is for the
25 ambient air monitoring. For the application site

1 monitoring we simply used the peak concentration that was
2 found.

3 The 95th percentile was calculated assuming a
4 normal distribution. And that was done with the -- by
5 multiplying -- or taking the exponent of the mean -- the
6 estimated mean and the standard deviation of the actual
7 logs of the concentration.

8 PANEL MEMBER BYUS: I'm still -- so for ambient,
9 and that's site J with a big standard deviation, are you
10 using the highest values -- the 95th percentile highest
11 value or -- is that what that means or not?

12 DPR STAFF TOXICOLOGIST BEAUVAIS: What that
13 means, it -- I'm not using the highest value. I'm using
14 the 95th percentile.

15 PANEL MEMBER BLANC: Not the 95th observed.
16 They're using a calculated 95th percentile, if I
17 understand you correctly.

18 DPR STAFF TOXICOLOGIST BEAUVAIS: Yes.

19 PANEL MEMBER BLANC: And --

20 PANEL MEMBER BYUS: Okay.

21 PANEL MEMBER BLANC: -- that may be a
22 non-conservative approach. Because since you can't say
23 what days they were actually spraying on in anywhere
24 nearby, and since you have a distribution which suggests
25 that the samples are not coming from the same universe,

1 rather coming from one universe of time when they were
2 actually spraying and one universe of time when they
3 weren't spraying recently, and you were measuring the sort
4 of tail of what ambient levels are days and days after it,
5 since what you're trying to get at is acute exposure, if
6 there's a bimodal distribution to your data, then you
7 shouldn't use this approach for calculating what your high
8 level exposure are, you're underestimating rather
9 dramatically what your high air exposure is.

10 Does that make sense? So the 95th --

11 DPR STAFF TOXICOLOGIST BEAUVAIS: Uh-huh.

12 PANEL MEMBER BYUS: Right. That's what --

13 PANEL MEMBER BLANC: What you want is the
14 clustered values on that day when it seemed like there was
15 actual spraying. I don't know how many samples that might
16 be. But in this particular case it may be that you only
17 have three samples that seem to represent that, and you
18 average those three or something. I don't know.

19 CHAIRPERSON FROINES: Yeah, it does -- because I
20 think he's right. I think that the -- it does look as
21 though there is a bimodal distribution that we're
22 concerned with here.

23 PANEL MEMBER BLANC: And so it's not simply that
24 it's a skewing that you would correct with a logarithmic
25 correction. It's a different distributional problem to

1 your data.

2 What you need to do is do an actual listing of
3 your samples and look at them and see what is the upper,
4 and is there a cluster of samples or are they all the same
5 days?

6 CHAIRPERSON FROINES: Yeah. If this was an
7 occupational exposure, then the geometric mean would make
8 sense. But this is an environmental exposure where you
9 actually have differing conditions. And in that respect
10 you need to approach it differently.

11 --o0o--

12 DPR STAFF TOXICOLOGIST BEAUVAIS: Okay. For
13 long-term exposures, which are seasonal, greater than a
14 week up to a year; and then annual, which is a per-year
15 exposure. Just used the arithmetic mean of the daily
16 methidathion concentrations -- or methidathionoxon
17 concentrations.

18 PANEL MEMBER BLANC: And can you explain again,
19 is this -- your standard rationale is defining seasonal in
20 this way?

21 DPR STAFF TOXICOLOGIST BEAUVAIS: Yes.

22 PANEL MEMBER BLANC: Because here you really deal
23 with something which is seasonal. You have four months of
24 the year when it's actually used.

25 DPR STAFF TOXICOLOGIST BEAUVAIS: Um-hmm.

1 And you're dividing up into a 12 months or 11
2 months or up to a year.

3 DPR STAFF TOXICOLOGIST BEAUVAIS: Um-hmm.

4 PANEL MEMBER BLANC: Or is it the 9 months based
5 on that 5 --

6 DPR STAFF TOXICOLOGIST BEAUVAIS: It's the 9
7 months rate -- as far as I'm saying, 9 months.

8 PANEL MEMBER BLANC: With those 5 percent?

9 DPR STAFF TOXICOLOGIST BEAUVAIS: Um-hmm.

10 PANEL MEMBER BLANC: And so it's the average of
11 those 9 months is the value for your seasonal value?

12 DPR STAFF TOXICOLOGIST BEAUVAIS: No, my seasonal
13 value is -- or my average is average of the ambient air
14 monitoring.

15 PANEL MEMBER BLANC: For 9 months --

16 DPR STAFF TOXICOLOGIST BEAUVAIS: Yeah.

17 PANEL MEMBER BLANC: -- or for 12 months?

18 DPR STAFF TOXICOLOGIST BEAUVAIS: That was done
19 in 1991, in June and July. So I'm taking the average
20 concentration. So for annual I'm assuming that that's
21 happening -- that those concentrations are received 9
22 months out of 12.

23 PANEL MEMBER BLANC: So that is more conservative
24 because you don't have reason to believe that it's that
25 high? You're taking the worse case scenario, the June and

1 July exposures and then multiplying them times 9 months,
2 is that --

3 DPR STAFF TOXICOLOGIST BEAUVAIS: Yes.

4 CHAIRPERSON FROINES: But you would -- if you
5 were going to do that, you'd prefer to have had the
6 January, February data and not the later data, because
7 it's the early data where you get greater use, right? So
8 you might have greater --

9 DPR STAFF TOXICOLOGIST BEAUVAIS: That we're
10 getting now. No, that wasn't necessarily the case back in
11 1991.

12 PANEL MEMBER BLANC: One thing to comment on in
13 light of the first presentation about temperature and
14 break down -- I mean there's a pretty big difference in
15 ambient temperature in the Central Valley in July as
16 opposed to January, right?

17 DPR STAFF TOXICOLOGIST BEAUVAIS: Right.

18 PANEL MEMBER BLANC: So the persistence of the --
19 airborne persistence would likely be higher in winter
20 months, I suppose.

21 DPR STAFF TOXICOLOGIST BEAUVAIS: Um-hmm. That's
22 a good point.

23 PANEL MEMBER ATKINSON: Well, more than likely,
24 in the winter months the compounds would be present in the
25 aerosol phase or on the surfaces, not in the gas phase.

1 The biggest difference.

2 CHAIRPERSON FROINES: Do you think -- You could
3 also expect that any vapor phase concentrations might
4 increase, so it would be depending upon the inversion
5 conditions.

6 PANEL MEMBER ATKINSON: Yeah. But I would --
7 since the vapor pressure's relatively low I would have
8 expected them in winter time to be more prevalent on
9 surfaces, not in the gas phase.

10 CHAIRPERSON FROINES: Okay.

11 --o0o--

12 DPR STAFF TOXICOLOGIST BEAUVAIS: Okay. And
13 inhalation rates that were used, these are the standard
14 DPR defaults for the various activity levels for one-hour
15 estimates. But I calculated -- for bystander estimates I
16 used the one-hour heavy activity level. And for all the
17 others it's a daily average.

18 --o0o--

19 DPR STAFF TOXICOLOGIST BEAUVAIS: And this is an
20 example for the ambient air of what the calculation looked
21 like taking the 95th percentile concentration. And those
22 are adults. I'm using the adult inhalation rate, taking
23 the 95th percentile air concentration times the daily
24 inhalation rate, and come up with that as the exposure
25 estimate.

1 And for the annual I'm taking the mean
2 concentration times the daily inhalation rate times the
3 high use months, which were 9 times 12 months. So from
4 that this is what the exposure estimate comes out to for
5 the annual absorbed daily dosage.

6 --o0o--

7 DPR STAFF TOXICOLOGIST BEAUVAIS: And these are
8 the estimates that we came up with for acute methidathion
9 and methidathionoxon, and seasonal and annual exposures,
10 and reported in micrograms per kilogram per day.

11 --o0o--

12 DPR STAFF TOXICOLOGIST BEAUVAIS: And for the
13 bystander: For the one-hour absorbed dose -- for the
14 acute estimates, first of all we did do an adjustment to
15 those -- to the concentrations. Because we had a 45-acre
16 application, we adjusted for I guess application rate and
17 field size combined. And what we did was we looked at PUR
18 data and found that the 95th percentile application size
19 is 180 pounds applied per application. And so the
20 difference between 45 and 180 is 4. So we multiplied
21 the -- peak concentration of 3.16 now becomes 12.6.
22 That's the actual value that was used. And at the time we
23 could not determine a -- or I guess a defensible way to
24 compensate for variable wind directions.

25 We've had a suggestion here, and I guess we'll

1 look at that further.

2 PANEL MEMBER BLANC: Can you just go back two
3 slides, I think, to this annual versus nonseasonal,
4 whichever one that would have been.

5 DPR STAFF TOXICOLOGIST BEAUVAIS: That's annual
6 and acute are what I'm showing here. So the difference
7 between the two is going to be the 9 divided by 12.

8 PANEL MEMBER BLANC: Right. And so I want to
9 make sure I understood this again correctly. To get the
10 average exposure over 12 months, how did you get that?
11 Was it the average exposure over 12 months?

12 DPR STAFF TOXICOLOGIST BEAUVAIS: No. What that
13 is -- now, again the average is just the mean
14 concentration that was detected during monitoring.

15 PANEL MEMBER BLANC: But I thought you had some
16 data where you monitored in different months, every month
17 of the year. And you showed that thing with the 5
18 percent.

19 DPR STAFF TOXICOLOGIST BEAUVAIS: And that's use.
20 That's pesticide use.

21 PANEL MEMBER BLANC: That's use, not monitoring?

22 DPR STAFF TOXICOLOGIST BEAUVAIS: Yeah.

23 PANEL MEMBER BLANC: I'm sorry.

24 So you only --

25 DPR STAFF TOXICOLOGIST BEAUVAIS: Yeah. So I'm

1 correcting for the idea that uses a constant throughout
2 the year.

3 PANEL MEMBER BLANC: The use is not a constant,
4 correct?

5 DPR STAFF TOXICOLOGIST BEAUVAIS: Yeah, that use
6 goes up and down. And So I'm -- we're starting with an
7 assumption that when there is higher use, the exposure
8 goes up -- the chances of exposure goes up. And that if
9 there's use that -- we've set a cutoff at 5 percent of the
10 annual use, so that those months where they're getting
11 less than 5 percent, the chances of people being exposed
12 aren't -- you know, on a daily basis or routine basis are
13 much lower.

14 PANEL MEMBER BLANC: Are zero in your algebraic
15 calculation?

16 DPR STAFF TOXICOLOGIST BEAUVAIS: Yeah. So my
17 choices are 0 or 1 here, yeah.

18 PANEL MEMBER BLANC: Okay. And then the 1 you
19 were multiplying times what? You said the average value
20 for July and August or June and July?

21 DPR STAFF TOXICOLOGIST BEAUVAIS: That's the
22 average air concentration.

23 PANEL MEMBER BLANC: Right.

24 DPR STAFF TOXICOLOGIST BEAUVAIS: Okay. And I
25 don't understand your question.

1 PANEL MEMBER BLANC: For the 12-month
2 concentration you're assuming three months of zero -- no
3 exposure and 9 months of yes exposure?

4 DPR STAFF TOXICOLOGIST BEAUVAIS: Yeah.

5 PANEL MEMBER BLANC: And the 9 months of yes
6 exposure --

7 DPR STAFF TOXICOLOGIST BEAUVAIS: -- are at that
8 one rate.

9 PANEL MEMBER BLANC: -- are based at the level
10 that was measured --

11 DPR STAFF TOXICOLOGIST BEAUVAIS: -- during the
12 ambient air monitoring in June and July of 1991.

13 PANEL MEMBER BLANC: Okay. Gotcha.

14 DPR STAFF TOXICOLOGIST BEAUVAIS: Those was the
15 data that I have.

16 PANEL MEMBER BLANC: Right. So you took those
17 two and you multiplied either times --

18 DPR STAFF TOXICOLOGIST BEAUVAIS: Yes.

19 PANEL MEMBER BLANC: -- 9 -- well, actually then
20 wouldn't the seasonal and the yearly come out to be
21 exactly the same?

22 DPR STAFF TOXICOLOGIST BEAUVAIS: Yes, except
23 that the seasonal is without that correction factor. So
24 we're saying daily --

25 PANEL MEMBER BLANC: Oh, I see. Okay, okay.

1 --o0o--

2 DPR STAFF TOXICOLOGIST BEAUVAIS: And for the
3 acute -- again, back with the bystander estimates here.
4 Acute absorbed daily dosage. I took the 24-hour
5 time-weighted air concentration, again multiplied it by 4,
6 and multiplied that by the daily application rate. So we
7 come up with 1.77 micrograms per kilogram per day for
8 infants -- this is for -- these values are for infants.

9 --o0o--

10 DPR STAFF TOXICOLOGIST BEAUVAIS: And this is the
11 concentrations that were estimated for the one-hour
12 absorbed dose. This is a microgram/kilogram per hour
13 assuming an hour of heavy activity level. So the heaviest
14 breathing right there.

15 And absorbed daily dosage, acute, is .84
16 micrograms per kilogram per day for methidathion in
17 adults.

18 --o0o--

19 DPR STAFF TOXICOLOGIST BEAUVAIS: We have a lot
20 of uncertainties, and some of which of we've been
21 discussing here. First is assumption is that air
22 monitoring coincided with maximum use. And we don't have
23 any idea about that. We can note that because the use has
24 decreased since '91, it's likely that the concentrations
25 at that time -- or the concentrations are probably lower

1 than they were during that monitoring period. And, again,
2 referring to Gura's graph where he's showing you how much
3 higher use was in '91 than it has been in recent years.

4 PANEL MEMBER BYUS: That statement's kind of
5 confusing when you read it. You mean -- you can mean
6 maximum use meaning -- is it being sprayed at the time
7 that we're being monitored? That would be one way you
8 could consider maximum use. But you're talking about
9 yearly use as opposed to, I guess, acute use.

10 DPR STAFF TOXICOLOGIST BEAUVAIS: Well, it is --

11 PANEL MEMBER BYUS: I mean in a sense that's
12 what -- I mean it's just a -- if you just clarify that
13 statement a little bit. You follow me? Because that's
14 what I couldn't -- I was having trouble. I had to read it
15 four or five times before I finally --

16 DPR STAFF TOXICOLOGIST BEAUVAIS: Well, I hope
17 it's clear in the exposure assessment, because they're all
18 paraphrased.

19 And then exposure estimates are based on data
20 from one site in the case of the ambient -- for ambient
21 air.

22 CHAIRPERSON FROINES: Isn't it possible -- I
23 understand the point you're trying to make here. And
24 maybe this is what you were saying. But it seems like
25 given a specific application at one time on an almond

1 field, you could have significant amounts that were being
2 applied irrespective of what's happened between 1991 and
3 2003.

4 DPR STAFF TOXICOLOGIST BEAUVAIS: Yes.

5 PANEL MEMBER BYUS: That's what I'm saying.

6 DPR STAFF TOXICOLOGIST BEAUVAIS: Yeah, okay.

7 Yeah, individual application didn't decrease. Gura was
8 showing --

9 CHAIRPERSON FROINES: And if you're setting
10 a -- part of the basis for defining this is the toxic air
11 contaminant is based on an acute exposure, then you have
12 all the potential ingredients for that problem actually
13 occurring, I think.

14 So that's true as a generalization. But in terms
15 of a specific use pattern at a given time, that may not be
16 as relevant.

17 PANEL MEMBER PLOPPER: Actual exposure could be
18 the same where it's being applied.

19 That's what I'm trying to get at, regardless of
20 how much is totally used, depending on where you measure
21 ambient air next to where it's being applied.

22 CHAIRPERSON FROINES: Well, and it's particularly
23 important given the health outcome, which is an acute
24 toxicity, that -- you know, you may have a higher exposure
25 at some point on an individual application under certain

1 conditions.

2 --o0o--

3 DPR STAFF TOXICOLOGIST BEAUVAIS: Okay. And with
4 regard to application site data, maximum concentration was
5 probably not captured in the monitoring study. And the
6 size of the application was not the maximum size that --
7 in current monitoring they would monitor a maximum sized
8 application with the highest application rate and so
9 forth. So I did an adjustment to attempt to compensate
10 for that, multiply it by 4.

11 And also in the case where I had non-detects in
12 methidathion and methidathionoxon -- well, this is for the
13 application site data, this only affects the oxon -- I
14 substitute half the detection limit. And the way that it
15 works out, the result is that the -- if I were to use the
16 limit of detection or the limit of quantification, my
17 average concentration would be higher than, but my acute
18 would go down because my variance would go down.

19 --o0o--

20 DPR STAFF TOXICOLOGIST BEAUVAIS: And other
21 uncertainties in these estimates include the assumption of
22 100 percent absorption. And we have no data about that,
23 so we don't know if that's an overestimate or not.
24 Inhalation rate defaults are based on limited data, so --
25 and also the pesticide use report data were used to

1 estimate months when exposure would be considered most
2 likely. And those are aggregate exposures across a
3 county, you know, on a county-wide basis. So we
4 wouldn't -- we have no idea how they relate to individual
5 exposures.

6 And that's it.

7 CHAIRPERSON FROINES: And there's no -- so
8 there's no attempt to address dermal exposure?

9 DPR STAFF TOXICOLOGIST BEAUVAIS: Not in the
10 air -- not in the ambient air and bystander. Now, there
11 are occupational sections in here, occupational handle and
12 reentry.

13 CHAIRPERSON FROINES: Well, an interesting
14 question about whether there are -- whether the public is
15 exposed dermally or whether it's only occupational. And
16 in our studies in Mexico that we did, we found quite
17 significant dermal uptake in families living near fields.
18 And so it's not -- we have tons of data on dermal uptake
19 associated with families in some proximity to agricultural
20 sites. So it's not something that one can -- and of
21 course then you also have the issue of what happens on
22 roads where you have -- do you have any -- or the
23 pesticide that gets re-entrained. So that there are some
24 other possibilities, when you think about the whole
25 picture.

1 Thank you very much.

2 DPR STAFF TOXICOLOGIST BEAUVAIS: Thank you.

3 CHAIRPERSON FROINES: We realize that it's the
4 data that's problematic. So you shouldn't worry about all
5 the questions.

6 Do you want to break for lunch? It's 12:30?

7 PANEL MEMBER PLOPPER: That would be fine.

8 PANEL MEMBER BYUS: Yes.

9 CHAIRPERSON FROINES: Everybody?

10 Yes, yes, yes.

11 Stoic.

12 (Laughter.)

13 CHAIRPERSON FROINES: Joe?

14 PANEL MEMBER LANDOLPH: (Nods head.)

15 PANEL MEMBER BLANC: 1:15?

16 CHAIRPERSON FROINES: 1:15, yeah.

17 (Thereupon a lunch break was taken.)

18

19

20

21

22

23

24

25

1 AFTERNOON SESSION

2 CHAIRPERSON FROINES: We're officially
3 reconvening the Scientific Review Panel.

4 And the next presentation will be on the health
5 effects.

6 (Thereupon an overhead presentation was
7 Presented as follows.)

8 DPR STAFF TOXICOLOGIST LEWIS: Okay. I'm Carolyn
9 Lewis, and I'm the author of the Risk Characterization
10 Document for methidathion, or Supracide.

11 --o0o--

12 DPR STAFF TOXICOLOGIST LEWIS: The risk
13 assessment process consists of four major compartments:
14 Hazard identification, dose response assessment, exposure
15 assessment, and risk characterization.

16 The hazard identification section identifies the
17 adverse effects of associated with exposure to a chemical.

18 The dose response assessment then determines the
19 "no observed effect" levels associated with these adverse
20 effects.

21 The exposure assessment estimates human exposure
22 levels.

23 And the risk characterization brings together the
24 information in the dose response assessment and the
25 exposure assessment to estimate what the risk is in humans

1 for adverse health effects.

2 --o0o--

3 DPR STAFF TOXICOLOGIST LEWIS: The Risk
4 Characterization Document for methidathion is a
5 comprehensive risk assessment which addresses risk
6 assessment requirements set forth in the Toxic Air
7 Contaminant Act as well as health risk from other
8 exposures scenarios.

9 This risk assessment document consists of six
10 major sections: The introduction, toxicology profile,
11 risk assessment, risk appraisal, tolerance assessment, and
12 reference concentration.

13 The risk assessment section includes threes
14 sections. The hazard identification includes the dose
15 response assessment, the exposure assessment section and
16 the risk characterization.

17 The tolerance assessment section will not be
18 discussed in this presentation because it only has to do
19 with dietary exposure.

20 --o0o--

21 DPR STAFF TOXICOLOGIST LEWIS: The toxicology
22 profile contains all the available toxicity studies for
23 methidathion, including acute toxicity studies submitted
24 to DPR by registrants to register various formulations as
25 well as longer term studies conducted by registrants that

1 there. The oxygen analog is shown at upper left.

2 Other metabolites that were identified: On the
3 lower right are the sulfide, sulfoxone and the sulfone.
4 Various conjugates are shown on the left-hand side. A
5 couple other urinary metabolites included the RH -- what
6 they call the RH compound and the desimonomethyl
7 derivative.

8 --o0o--

9 CHAIRPERSON FROINES: Just one comment.

10 DPR STAFF TOXICOLOGIST LEWIS: Yeah.

11 CHAIRPERSON FROINES: And so -- I don't want to
12 talk about it today, but maybe for the next meeting where
13 we'll take up the topic again.

14 If you could look at the metabolites, you all at
15 DPR, and ask this question: Which of the metabolites do
16 you think could have electrophilic activity in the
17 chemical sense? Because since carcinogenicity is one
18 issue, electrophilicity is -- in a metabolite is a
19 relevant issue. And so something to think about in terms
20 of possible pathways -- mechanistic pathways.

21 DPR STAFF TOXICOLOGIST LEWIS: Actually I meant
22 to mention in that previous slide to -- that the presumed
23 active metabolite is the oxygen analyte. But you had
24 already sort of touched on that on previous topics.

25 CHAIRPERSON FROINES: Well, I think it's the -- I

1 think that it's the active metabolite for the
2 organophosphate toxicity --

3 DPR STAFF TOXICOLOGIST LEWIS: -- the
4 neurotoxicity, yeah. It may not be for the
5 carcinogenicity.

6 CHAIRPERSON FROINES: -- but not for binding with
7 macromolecules.

8 DPR STAFF TOXICOLOGIST LEWIS: Yes, exactly.

9 Okay. Next slide.

10 This is a diagram of a neuromuscular junction.

11 The primary mechanism of action for methidathion
12 is the inhibition of the enzyme acetylcholinesterase in
13 the peripheral and central nervous system.
14 Acetylcholinesterase is represented by the pink dots on
15 the motor end-plate in this diagram.

16 As an impulse travels down to the axon terminal,
17 it stimulates the release of acetylcholine, which is a
18 neurotransmitter, into the synapse, which then binds with
19 the receptors on the motor end-plate. This then
20 stimulates the muscle. The acetylcholinesterase
21 terminates this muscle stimulation by cleaving the
22 acetylcholine. And the acetylcholinesterase in the
23 central nervous system functions in a similar manner
24 between synapses.

25 --o0o--

1 DPR STAFF TOXICOLOGIST LEWIS: The inhibition of
2 cholinesterase by methidaoxon produces a variety of
3 cholinergic signs. The classic signs are excessive
4 salivation, excessive lacrimation, excessive urination,
5 and diarrhea. This is sometimes referred to as the Sled
6 Syndrom.

7 Other cholinergic effects include headaches,
8 pinpoint pupils, nausea, vomiting, difficulty in
9 breathing, muscle twitching, tremors, and convulsions.

10 --o0o--

11 DPR STAFF TOXICOLOGIST LEWIS: In general, DPR
12 considers brain cholinesterase inhibition to be an adverse
13 effect because it is the primary target site. The
14 toxicological significance of the blood cholinesterase is
15 less certain. However, plasma cholinesterase appears to
16 be involved in the detoxification of various plant toxins
17 and certain drugs. Even less is known about the function
18 of red blood cell cholinesterase. However, several
19 regulatory agencies use red blood cell cholinesterase as a
20 surrogate for peripheral nervous system cholinesterase,
21 which is often not available.

22 For these reasons the NOELs for both blood and
23 brain cholinesterase inhibition have been identified in
24 this report.

25 It should be noted that generally blood

1 cholinesterase inhibition is a more sensitive endpoint for
2 most cholinesterase inhibitors. But with methidathion the
3 brain cholinesterase inhibition was often the more
4 sensitive endpoint.

5 --o0o--

6 DPR STAFF TOXICOLOGIST LEWIS: So in the acute,
7 subchronic and chronic studies, we saw cholinesterase
8 inhibition as well as peripheral and central nervous
9 system neurological signs. In addition, there were a few
10 studies in the literature that indicate there was lipid
11 peroxidation in some issues with acute and subchronic
12 exposure. Evidence of hepatotoxicity was also seen in
13 acute and subchronic and chronic studies.

14 Reduced body weights and food consumption were
15 only seen with repeated exposure to methidathion as well
16 as hematological changes, which were suggestive of anemia.

17 An increase in liver tumors was seen in male mice
18 only with long-term or lifetime exposure to methidathion.

19 --o0o--

20 DPR STAFF TOXICOLOGIST LEWIS: There were other
21 adverse effects identified in the more specialized
22 toxicity studies, including evidence of genotoxicity,
23 reproductive toxicity and developmental toxicity.

24 The vast majority of the genotoxicity data were
25 negative. However, there were a few positive studies,

1 including a gene conversion/forward mutation assay with
2 yeast cells and an in vitro sister chromatid exchange
3 assay with Chinese hamster V79 cells.

4 In the reproductive toxicity study in rats, most
5 of the effects were typical of subchronic exposure.
6 However, there was evidence of reduced mating and more
7 maternal care.

8 In the developmental toxicity study, most of the
9 signs again were typical of acute and subchronic exposure,
10 except there was evidence of reduced ossification of the
11 sternebrae.

12 --o0o--

13 DPR STAFF TOXICOLOGIST LEWIS: So the next major
14 section in the risk characterization document is the risk
15 assessment section.

16 The first section is the hazard identification,
17 which is divided into acute toxicity, subchronic toxicity,
18 and oncogenicity.

19 --o0o--

20 DPR STAFF TOXICOLOGIST LEWIS: First off I'd like
21 to point out that -- or emphasize, I guess as you had
22 noted earlier, there is no toxicity data for the oxone --
23 the methidaoxon. There was nothing in the literature.
24 There was nothing that we received from registrants.

25 So the assumption was made that the oxone was

1 equally toxic to methidathion. And this obviously
2 underestimates the toxicity of the oxone since it is the
3 presumed active metabolite, at least for neurological
4 effects.

5 CHAIRPERSON FROINES: Since it's so -- since the
6 issue of oxone is a very obvious one given the other
7 pesticides with peroxon, what have you, why do you think
8 that nobody's ever required industry to conduct studies on
9 that? Because it's such a gap -- obvious gap.

10 DPR STAFF TOXICOLOGIST LEWIS: Yeah, it's an
11 obvious gap, yeah. I'm not sure why --

12 CHAIRPERSON FROINES: But EPA hasn't required --

13 DPR STAFF TOXICOLOGIST LEWIS: Hasn't requested
14 it. I guess we could ask the registrant if they have any
15 data. But I presume it's voluntary, you know, in terms,
16 you know, whether they buy it or not.

17 CHAIRPERSON FROINES: Well, if there's a data
18 gap, it's worth asking, because -- I don't know in terms
19 of requiring. But it seems to me that it's such an
20 obvious missing link, that it's worth thinking about.

21 But go ahead.

22 DPR STAFF TOXICOLOGIST LEWIS: Okay. This table
23 is a simplification of Table 20 in the risk
24 characterization document, which shows the studies that --
25 the main studies that were considered for selecting an

1 uncertainty factor?

2 DPR STAFF TOXICOLOGIST LEWIS: Well, I'm going to
3 go over my rationale. And you can stop me at any point or
4 wait until I finish.

5 PANEL MEMBER BLANC: Okay.

6 --o0o--

7 DPR STAFF TOXICOLOGIST LEWIS: Okay. There are
8 several reasons why an uncertainty factor of 3 was used
9 instead of the default value of 10.

10 One was the brain cholinesterase inhibition was
11 only observed in one sex in one region at the LOEL. The
12 cortex did not appear to be uniquely sensitive to
13 cholinesterase inhibition when you looked at the higher
14 dose levels.

15 There was also not a significant increase in
16 neurological signs until you increased the dose level
17 8-fold.

18 Also, females appeared to be more sensitive than
19 males at the higher dose levels based on their level of
20 brain cholinesterase inhibition and the incidence of
21 neurological signs.

22 And, finally, a NOEL of .2 milligram per
23 kilogram/day was observed at two weeks in the 90-day
24 neurotoxicity study for this same endpoint, inhibition in
25 the cortex, in males.

1 So if you want to comment now, this would be a
2 good time.

3 PANEL MEMBER BLANC: One of the things that I
4 would say is that, having read the OEHHA response,
5 something that struck me about both their response and the
6 initial calculation was why -- did the data not allow a
7 benchmark approach?

8 DPR STAFF TOXICOLOGIST LEWIS: I have a slide
9 that actually -- since that's going to -- I was going to
10 come into that in the risk appraisal.

11 But it was problematic. One of the problems with
12 a benchmark dose approach was selecting a threshold for --
13 what you have to do with continuous data. And regional
14 brain cholinesterase data -- we looked at in-house data
15 when we were examining our cholinesterase policy. And
16 while whole brain data has very small variation compared
17 to, say, the plasma and red blood cell, regional brain
18 cholinesterase data varied significantly. And
19 unfortunately we didn't have a large number of studies
20 like we had with the whole brain to get a comfort level of
21 selecting a level of inhibition that we felt comfortable
22 as calling a threshold.

23 So the only option I could come up with was using
24 the coefficient of variation from the control -- the male
25 control animals in that study as a threshold. And if I

1 did that, you come up with a lower limit on the benchmark
2 dose of .38 milligram per kilogram, which is fairly
3 similar to dividing by uncertainty factor of 3.

4 PANEL MEMBER BLANC: And what was the coefficient
5 of variation for cholinesterase?

6 DPR STAFF TOXICOLOGIST LEWIS: It was 23 percent
7 in that, which seems kind of high. I mean for whole brain
8 you usually see something that's more around 10 percent.
9 But that was not -- you know, that --

10 PANEL MEMBER BLANC: And what would the -- if you
11 used 10 percent as your basically "no effect" threshold,
12 what would your calculation of your benchmark value have
13 been, extrapolating down the curve and using the 95
14 percentile --

15 DPR STAFF TOXICOLOGIST LEWIS: It would obviously
16 be lower. I couldn't tell you off the top of my head
17 since I haven't done that calculation. But --

18 PANEL MEMBER BLANC: Well, again, because we're
19 talking about being public health conservative and because
20 I think that there's certainly a reasonable argument for
21 the 10-fold safety factor as well, I thought the OEHHA
22 argument was fairly strong. I think that doing that
23 calculation would be --

24 DPR STAFF TOXICOLOGIST LEWIS: So would you say
25 that that would be better over dividing by 10?

1 PANEL MEMBER BLANC: Well, it may give you
2 something which is somewhat in between the 3 and the 10
3 value.

4 DPR STAFF TOXICOLOGIST LEWIS: Yeah. You know, I
5 guess I had a problem with using the 10 because it would
6 put the NOEL lower than the subchronic NOEL for the exact
7 same endpoints. So I felt it needed to be at least as
8 high as the subchronic NOEL. And assuming that there is
9 maybe some bio-accumulation with repeated exposure, it
10 seemed logical that you might have a NOEL that's slightly
11 higher than .2 for an acute exposure. And that was --

12 PANEL MEMBER BLANC: Well, I don't know if
13 that's -- I mean I don't know if we don't have to say that
14 that's, you know, necessarily the case. But I guess
15 another corollary to my question, you -- the reduction was
16 59 percent of baseline as to cholinesterase in the cortex.

17 DPR STAFF TOXICOLOGIST LEWIS: Uh-huh.

18 PANEL MEMBER BLANC: But, first of all, this is
19 the whole cortex, right?

20 DPR STAFF TOXICOLOGIST LEWIS: Well, they take a
21 section of it and measure --

22 PANEL MEMBER BLANC: But I mean it's the cortex?

23 DPR STAFF TOXICOLOGIST LEWIS: Yeah.

24 PANEL MEMBER BLANC: So to talk about a regional
25 brain effect in the cortex isn't exactly the same thing as

1 talking about a regional brain effect in the hypothalamus
2 or something. I mean you're talking about --

3 DPR STAFF TOXICOLOGIST LEWIS: -- a big section.

4 PANEL MEMBER BLANC: -- the cortex, you know. So
5 that's one thing.

6 But the second thing is, when -- in these other
7 studies when you're talking about an effect, is it defined
8 as a statistically significant difference in
9 cholinesterase depression?

10 DPR STAFF TOXICOLOGIST LEWIS: Yes.

11 PANEL MEMBER BLANC: So, for example, in the
12 other sections of brain that were tested, it was only in
13 the cortex. But there were other sections that were
14 tested?

15 DPR STAFF TOXICOLOGIST LEWIS: Yes.

16 PANEL MEMBER BLANC: And the depression in
17 cholinesterase was not statistically significant?

18 DPR STAFF TOXICOLOGIST LEWIS: Yes.

19 PANEL MEMBER BLANC: But was there a depression
20 in cholinesterase?

21 DPR STAFF TOXICOLOGIST LEWIS: I have some slides
22 in another file here that I --

23 PANEL MEMBER BLANC: Because I think an important
24 question here is not confusing --

25 DPR STAFF TOXICOLOGIST LEWIS: I don't recall. I

1 think there may be --

2 PANEL MEMBER BLANC: -- the issue of no effect
3 with a statistically significant effect. Because you have
4 small numbers. And what we're trying to avoid here is a
5 beta error, not so much an alpha error, again from a
6 public health protection point of view.

7 DPR STAFF TOXICOLOGIST LEWIS: I'll jump ahead a
8 couple slides.

9 Okay, there.

10 Okay. So there you have the -- the cortex is
11 actually the cortex with a hippocampus included there.

12 And --

13 CHAIRPERSON FROINES: What does that -- I'm
14 sorry. I'm trying to go through this document, to no
15 avail.

16 What is the table --

17 DPR STAFF TOXICOLOGIST LEWIS: -- oh that's from?

18 Yeah, that's a simplification, because the table
19 has a little bit --

20 CHAIRPERSON FROINES: What's the table --

21 DPR STAFF TOXICOLOGIST LEWIS: It's in the
22 toxicology profile. And it should be page 62 on the May
23 25th draft.

24 Anyway, you do I guess -- in the cerebellum you
25 do see what looks like it could be a reduction there at 88

1 percent of the control activity. It doesn't reach
2 statistical significance. And it's hard to say whether
3 that's a normal -- you know, just statistical variation,
4 because, if you -- for example, if you look at the serum,
5 if you go over there in the females, the activity looks
6 like it's reduced. But it's -- basically I've got a flat
7 dose response.

8 PANEL MEMBER BLANC: But let's look at -- I think
9 more importantly is look at the -- how many animals per
10 test dose are there here roughly? Do you have any
11 sense --

12 DPR STAFF TOXICOLOGIST LEWIS: Well, one of the
13 things, they have to be careful -- and I'd have to go back
14 to the report to verify this -- is they don't always do
15 the cholinesterase in all animals that they put through
16 the neurobehavioral test.

17 PANEL MEMBER BLANC: Right. But let's just look
18 at the --

19 DPR STAFF TOXICOLOGIST LEWIS: Yeah, ten animals
20 per sex per dose were measured for cholinesterase.

21 PANEL MEMBER BLANC: Well, I mean if you looked
22 at -- the argument that you make is that, well, we're
23 discounting the reduction because we don't see reduction
24 in the female mice. But in fact you see a very similar
25 dose response. It's just that probably with those small

1 numbers, you know, due to statistical chance, the 87
2 percent, which is not a hundred percent, we'd have them
3 come back to normal. It certainly looks like that's not a
4 "no effect" level at all. It's just not statistically
5 significant for that one group of rats.

6 So if you're going to make your argument that,
7 well, this is some kind of a variance because we see it in
8 males -- that is one of your arguments for using a 3.

9 DPR STAFF TOXICOLOGIST LEWIS: Well, I'm not
10 saying that it's an aberration. I'm just saying --

11 PANEL MEMBER BLANC: No, but you're saying it
12 appears to be a gender-specific effect.

13 DPR STAFF TOXICOLOGIST LEWIS: Oh, I see. Oh,
14 okay.

15 PANEL MEMBER BLANC: What I'm saying, this
16 doesn't convince me --

17 DPR STAFF TOXICOLOGIST LEWIS: You're not
18 convinced. Okay.

19 PANEL MEMBER BLANC: -- that it's gender specific
20 with 10 test animals in each thing.

21 And I do think it would make -- I would like to
22 see at least the benchmark calculation with a, you know,
23 90 percent cholinesterase as being your threshold.

24 CHAIRPERSON FROINES: I still can't find this
25 graph.

1 DPR STAFF TOXICOLOGIST LEWIS: Okay. Page 62 in
2 the toxicology profile.

3 CHAIRPERSON FROINES: Page 62 --

4 DPR STAFF TOXICOLOGIST LEWIS: -- of the risk --
5 volume 1 of the risk characterization document.

6 Table 17.

7 PANEL MEMBER BLANC: It's page 61 actually.

8 CHAIRPERSON FROINES: No, that's a dog study.

9 DPR STAFF TOXICOLOGIST LEWIS: Uh-oh, there's a
10 blank page there.

11 PANEL MEMBER BLANC: It's not there.

12 DPR STAFF TOXICOLOGIST LEWIS: The page breaks
13 got all -- okay. Oh it's further. I see it.

14 CHAIRPERSON FROINES: Yeah, I got it. It's on
15 page 82.

16 DPR STAFF TOXICOLOGIST LEWIS: Yeah, the page
17 break got all mess up.

18 CHAIRPERSON FROINES: It's at page 82.

19 DPR STAFF TOXICOLOGIST LEWIS: Yeah, 82.
20 Something must have happened in the conversion to the PDF.

21 Okay. Okay. Well, I'll make a note of that and
22 take that into consideration.

23 CHAIRPERSON FROINES: This is a crucial issue.
24 And I don't know how we want to address it right now. I
25 guess my inclination would be to have taken Paul's

1 comments. But I know I have things to say about it, and I
2 assume Charlie will and others. Because it seems to me
3 this is a fundamental issue in this document. And if we
4 talk about nothing else, we need to come to some consensus
5 on how we think this should be approached.

6 So I guess what I would argue at this point,
7 unless the Panel disagrees strongly, is why don't we go --
8 continue going through your presentation and then we'll
9 take it up probably next time. And in the meantime you
10 can look at the benchmark issue that Paul's raising.

11 Is that reasonable?

12 DPR STAFF TOXICOLOGIST LEWIS: Okay.

13 CHAIRPERSON FROINES: You're comfortable, Paul,
14 with taking -- going through her slides at this point?

15 PANEL MEMBER BLANC: Yeah.

16 CHAIRPERSON FROINES: But I can say, it's going
17 to become a point of significant contention, I think.

18 --o0o--

19 DPR STAFF TOXICOLOGIST LEWIS: All right. This
20 is now a simplification of Table 21 in the RCD. And it
21 includes only the guideline studies that met FIFRA
22 guidelines or were found acceptable by FIFRA guidelines.
23 This includes several developmental toxicity studies, a
24 reproductive toxicity study, and a 90-day neurotoxicity
25 study.

1 In the developmental toxicity study, only the
2 maternal effects that were seen after several days of
3 exposure were considered subchronic effects.

4 In the reproductive toxicity study all of the
5 parental effects and all of the effects in the pups were
6 considered subchronic.

7 CHAIRPERSON FROINES: I should say,
8 parenthetically, that I think that one of the most
9 significant problems as we go through this is this gavage
10 as to the method of introduction of the chemical to the
11 body. And that I would predict much -- perhaps more
12 significant toxicity if we had talked about it in terms of
13 inhalation. And so because the gavage method obviously
14 has its own limitations and we need to come -- we can come
15 back to that.

16 But go ahead.

17 DPR STAFF TOXICOLOGIST LEWIS: Yeah,
18 unfortunately there were no inhalation studies available
19 at all from the --

20 CHAIRPERSON FROINES: Yeah. And the gavage, it
21 means that you're going to end up with a -- well, anyway,
22 let's not get into it. We'll talk about it later.

23 PANEL MEMBER BLANC: But, again, parallel with
24 the discussion we just had, I think -- just like you need
25 to hear something more now.

1 In your table as you show it you have the effects
2 in bold that are the -- that were the low level effects,
3 right?

4 DPR STAFF TOXICOLOGIST LEWIS: Yes.

5 PANEL MEMBER BLANC: So it's, for example, around
6 75 percent inhibition at the 26 level in 90 days, right?

7 DPR STAFF TOXICOLOGIST LEWIS: Right.

8 PANEL MEMBER BLANC: And in the data themselves,
9 was there still some inhibition but not statistically
10 significant in .2? You're calling it a "no effect" level.
11 Is that because it's not statistically significant or
12 because there was no effect?

13 DPR STAFF TOXICOLOGIST LEWIS: It was because it
14 was not statistically significant. There might have been
15 some low level inhibitions and --

16 PANEL MEMBER BLANC: Can we see what that looks
17 like?

18 DPR STAFF TOXICOLOGIST LEWIS: Yeah, I think I
19 have the table of that.

20 DPR SENIOR ENVIRONMENTAL RESEARCH SCIENTIST

21 SEGAWA: Right here?

22 DPR STAFF TOXICOLOGIST LEWIS: Yeah, In that
23 other file.

24 PANEL MEMBER BLANC: If that's okay with the
25 group. Because I think it's relevant.

1 DPR STAFF TOXICOLOGIST LEWIS: Okay. In this one
2 you see the red blood cell cholinesterase inhibited also
3 at the LOEL as well as inhibition in the striatum.

4 Now, at two weeks you only see -- and I just show
5 this for the cortex -- you see the inhibition in males
6 that's statistically significant. You did not see any
7 other differences in -- statistically significant
8 difference in the brain cholinesterase inhibition at two
9 weeks in the other regions.

10 However, by 90 days, or 13 weeks, you started to
11 see inhibition in the striatum in females as well as the
12 hippocampus.

13 There is I guess at three what looks like it
14 could be a significant -- or not significant -- a
15 reduction in activity in females and -- that's 13 weeks --
16 and also in the males in the cortex.

17 PANEL MEMBER BLANC: So this is the detail data
18 from the --

19 DPR STAFF TOXICOLOGIST LEWIS: Yeah, it's
20 simplification, because I cut out some of the time points
21 just because it was impossible on the slide like this to
22 include it all. But it does show -- because actually they
23 measured the cholinesterase activity 2 weeks, 4 weeks, 8
24 weeks and 13 weeks. So I'm just showing the 13 weeks
25 except for the cortex, where I showed the 2 weeks one.

1 PANEL MEMBER BLANC: So every else here is 13
2 weeks?

3 DPR STAFF TOXICOLOGIST LEWIS: Yeah, so
4 everything else is 13 weeks.

5 PANEL MEMBER BLANC: So at -- it's hard to argue
6 that there's a difference between the value of 2 weeks and
7 13 weeks for cortex in the males. And that's the no
8 effect -- that's the low effect level --

9 DPR STAFF TOXICOLOGIST LEWIS: Yeah, 10 -- yeah,
10 I've got the --

11 PANEL MEMBER BLANC: So the 3 -- the 3 column is
12 your "no effect" column, is that --

13 DPR STAFF TOXICOLOGIST LEWIS: Yeah, yeah. I've
14 got the milligram per kilogram dosage underneath the PBMs,
15 which is the top number.

16 PANEL MEMBER BLANC: Well, I would say that if
17 you're going to do the benchmark exercise with the other
18 values, you probably would want to do a parallel benchmark
19 exercise with these data, at least to see what it's giving
20 you.

21 CHAIRPERSON FROINES: But irrespective of that,
22 Paul, we have a -- we obviously have a problem here of the
23 classic debate about P values is to find public health
24 endpoints.

25 PANEL MEMBER BLANC: Well, that would be around

1 that, wouldn't it?

2 CHAIRPERSON FROINES: Well, if -- well, but --
3 let's see what the benchmark shows. But irrespective,
4 respective I don't -- I would not take three parts per
5 million as a "no effect" level.

6 PANEL MEMBER BLANC: Well, I mean that's what I'm
7 saying. That's another way of -- I'm not disagreeing with
8 you. It may be a "no effect" level, but it's pretty close
9 to being a "low effect" level, if you look at this.
10 Because if I use a cutoff of 90 percent as being normal,
11 then I haven't reached that at the three parts per million
12 here, because I haven't come up to -- I haven't come to a
13 hundred percent certainly. But I --

14 CHAIRPERSON FROINES: Right.

15 DPR STAFF TOXICOLOGIST LEWIS: One of the
16 problems that's going to come up with this study is,
17 because you have several regions that are affected, which
18 one are you going to pick. I guess I would have to do all
19 of them and see what comes out lowest?

20 PANEL MEMBER BLANC: Well, that would be the most
21 conservative, wouldn't it?

22 DPR STAFF TOXICOLOGIST LEWIS: Yeah.

23 CHAIRPERSON FROINES: I think that I would be
24 willing to make an argument that this data and the
25 previous data shows that three parts per million is a low

1 effect level, if you ask the question from a conservative
2 standpoint. In other words, is there a trend? And the
3 answer is clearly there's a trend. And so given the
4 uncertainties in exposure, given the uncertainties in the
5 route of administration, and on -- we can go on and on, I
6 think one would be very -- I would be very hesitant to
7 think that this would be considered, as OPHTHALMIA said,
8 endpoint was considered to be mild. But let's come --
9 we'll come back to it. But I think this is an important
10 issue.

11 DPR STAFF TOXICOLOGIST LEWIS: Okay. I assume
12 there aren't any more questions about the selection of the
13 acute neurotoxicity study, other than how the NOEL was
14 derived. So I'll go on to the chronic toxicity studies.

15 --o0o--

16 DPR STAFF TOXICOLOGIST LEWIS: This table is
17 again a simplification of the table in the risk
18 characterization documents, Table 22. And it only
19 includes those registrant studies that met FIFRA
20 guidelines, with the exception of the last study that was
21 done, a non-guidelines study in monkeys. And this was
22 only included for comparison with the other species.

23 The lowest NOEL and LOEL observed with chronic
24 exposure to methidathion was in the dogs -- in the 1-year
25 dog study, based on an increase in liver enzyme levels in

1 genotoxicity is that it's a little bit out of the 1970s.
2 I mean it's sort of the EPA defines 100 short-term tests
3 and everybody sort of does them and then you have these
4 long tables of whether they're positive or negative. And
5 if you look at molecular approaches to mutational
6 frequencies now, you would argue that that sort of
7 traditional tests really don't stand up to modern
8 molecular biological evaluation of gene -- of effects on
9 genes.

10 And so there's the problem of sort of giving
11 almost too much weight to some body of tests that are
12 almost anachronisms in some way, although are useful. And
13 I could give you examples of, you know, the studies that
14 were done on the big blue mouse on diesel where you found
15 all sorts of mutational -- mutations occurring that were
16 not seen elsewhere. So there's that issue.

17 But the other question is: How would you
18 interpret this particular clinical finding in humans
19 relative to your -- all your sort of more classic tests?

20 DPR STAFF TOXICOLOGIST LEWIS: Well, I'm having a
21 little trouble finding that.

22 CHAIRPERSON FROINES: It's on page 16 of the
23 draft that --

24 DPR STAFF TOXICOLOGIST LEWIS: Oh, here we go.

25 I think one of the problems with this study is

1 you don't know what these workers were exposed to. You
2 don't know if it was, you know, just methidathion. I mean
3 they -- methidathion was one of the things, but it wasn't
4 the only thing that they were exposed to. So these
5 chromosomal aberrations could be due to any, you know, one
6 of the pesticides that they were working with. So it's
7 probably -- it's difficult to interpret. I mean it might
8 support that it is genotoxic, but you couldn't say with
9 any certainty that that was --

10 CHAIRPERSON FROINES: Well, I think that there --
11 the point that Paul's been making all along has been we
12 need to be careful not to dismiss things where we don't
13 have -- where things aren't perfect, as opposed to giving
14 them too much weight at the same time. In other words, we
15 need to take -- we need to say, "Okay, how are we going to
16 approach this evaluation." And you put it in. I just
17 read it.

18 And so the only point I'm making is I -- you
19 know, one would have to ask what other pesticides were
20 they exposed to? Is there any evidence in chromosomal
21 damage from those pesticides? In other words you have a
22 positive study and then you say but there are other -- may
23 be other exposures. Well, that will dismiss it, but it
24 doesn't necessarily justify its dismissal. And we just
25 need to be careful about that.

1 DPR STAFF TOXICOLOGIST LEWIS: Yeah. I actually
2 did not even think about discussing this in the weight of
3 evidence for oncogenicity. And I certainly can add a
4 discussion of that in there. And I'll look at the other
5 pesticides that they were exposed to.

6 CHAIRPERSON FROINES: Well, it would be useful to
7 look and see what other pesticides they may have been
8 exposed to.

9 And, secondly, it is a finding of chromosomal
10 aberrations. And in your document -- in your
11 presentation, you're saying that there is some evidence --
12 there may be, or there may not be, some evidence of
13 chromosome. And so to the degree that they have any
14 commonality, then they're not -- then one wants to not
15 just ignore it.

16 DPR STAFF TOXICOLOGIST LEWIS: Okay.

17 CHAIRPERSON FROINES: And not make too much of it
18 either.

19 DPR STAFF TOXICOLOGIST LEWIS: Yeah, not put --
20 yeah.

21 Okay. So as a result, the linear low-dose
22 extrapolation approach was used to estimate cancer
23 potency. Because of the incidence -- a higher incidence
24 of mortality at the high dose level in this study, the one
25 that met FIFRA guidelines that we used to calculate the

1 cancer potency, we used a time-to-tumor model. The
2 potency estimated with this approach ranged from .34 per
3 milligram per kilogram/day for the maximum likelihood
4 estimate up to .53 per milligram per kilogram/day at the
5 95th percent upper bound.

6 --o0o--

7 DPR STAFF TOXICOLOGIST LEWIS: Oh, and I should
8 point -- could you go back to that.

9 --o0o--

10 DPR STAFF TOXICOLOGIST LEWIS: I should point out
11 that U.S. EPA concluded that methidathion was a possible
12 human carcinogen. However, they did not consider the
13 weight of evidence to be sufficient to calculate a cancer
14 potency. They didn't think there was an increase in the
15 proportion of malignant tumors or a shortening of the time
16 to tumor. And for that reason, they I guess didn't feel
17 like the evidence was strong enough to calculate a cancer
18 potency.

19 CHAIRPERSON FROINES: Well, I should say just in
20 rebuttal, friendly rebuttal, EPA has not yet developed a
21 risk assessment and unit risk value for diesel.

22 DPR STAFF TOXICOLOGIST LEWIS: Oh.

23 CHAIRPERSON FROINES: And you heard today that we
24 won a court decision because we did take the step to
25 develop a unit risk factor.

1 So I think that the fact that EPA hasn't done it
2 doesn't necessarily mean -- that that means that one
3 couldn't do one and shouldn't do one.

4 DPR STAFF TOXICOLOGIST LEWIS: Yeah. That
5 reminds me, I did do the unit risk calculations for
6 methidathion. They're in the document. I didn't have
7 them on my slides. So if you want to see them, they're in
8 the weight of evidence, oncogenicity section.

9 CHAIRPERSON FROINES: In my lifetime we may see
10 an EPA diesel risk assessment, but I'm not sure.

11 (Laughter.)

12 DPR STAFF TOXICOLOGIST LEWIS: Okay. The next
13 section in the risk assessment section is the exposure
14 assessment, which is divided into four sections, a
15 dietary, drinking water, occupational, and ambient and
16 application site air exposure. And I'm going to talk
17 about the last section.

18 --o0o--

19 DPR STAFF TOXICOLOGIST LEWIS: And since Gura and
20 Sheryl have spent a fair amount of time talking about the
21 air monitoring use for the exposure estimates, I'm not
22 going to go into those in any detail.

23 This table simply summarizes the estimated
24 exposure at the application site and the Jefferson School
25 site. And these exposure doses represent the combined

1 I'm looking at this table.

2 DPR STAFF TOXICOLOGIST LEWIS: In the report
3 there is no one-hour value. That's new.

4 CHAIRPERSON FROINES: No, I'm -- I was actually
5 looking at the table in the OEHHA document, and the
6 numbers are different.

7 DPR STAFF TOXICOLOGIST LEWIS: Oh, that's because
8 they calculated them with their ten-fold --

9 CHAIRPERSON FROINES: No, no. This is --

10 DPR STAFF TOXICOLOGIST LEWIS: Oh, really?

11 CHAIRPERSON FROINES: No, it's okay. There's
12 obviously a difference in -- no, they are listing your 130
13 as correct, but then they list the adult as 260.

14 DPR STAFF TOXICOLOGIST LEWIS: Oh, I think I
15 corrected these because Sheryl found some error in her
16 exposure estimates. So the adult numbers changed
17 slightly. Yeah, I forgot about that.

18 CHAIRPERSON FROINES: Okay. So this is the
19 correct number then?

20 DPR STAFF TOXICOLOGIST LEWIS: Yeah, this is
21 correct.

22 Okay. Next slide.

23 Or is that all you had to say?

24 CHAIRPERSON FROINES: Yes.

25 --o0o--

1 DPR STAFF TOXICOLOGIST LEWIS: Okay. The risk
2 for cancer is calculated by multiplying the cancer potency
3 factor by the human exposure dosage. In general, a risk
4 of less than 1 in a million is considered negligible.
5 According to the Toxic Air Contaminant Act, the criterion
6 for listing a pesticide as a TAC based on its cancer is
7 that the risk is greater than one in a million -- or one
8 in 10 million or 10 to the minus 7.

9 CHAIRPERSON FROINES: Could I ask you a question
10 about that?

11 DPR STAFF TOXICOLOGIST LEWIS: Yes.

12 CHAIRPERSON FROINES: I'm sorry for interrupting.

13 DPR STAFF TOXICOLOGIST LEWIS: Uh-huh.

14 CHAIRPERSON FROINES: Because you told me to --

15 DPR STAFF TOXICOLOGIST LEWIS: Yes. Well,

16 actually --

17 CHAIRPERSON FROINES: I do that very cautiously.

18 This listing criteria for TAC is a risk of 10 to
19 the minus 7. Is that a legislated value? It's worded
20 that --

21 DPR STAFF TOXICOLOGIST LEWIS: No, it's just --

22 CHAIRPERSON FROINES: -- because I've never seen
23 it.

24 DPR STAFF TOXICOLOGIST LEWIS: -- I think the
25 legislation -- and, Tobi, correct me --

1 DPR SENIOR ENVIRONMENTAL RESEARCH SCIENTIST

2 SEGAWA: It's a regulation. It's not part of the Act.

3 It's part of the regulation.

4 CHAIRPERSON FROINES: Is that a regulation that
5 you -- that DPR established?

6 DPR SENIOR ENVIRONMENTAL RESEARCH SCIENTIST

7 SEGAWA: Correct.

8 CHAIRPERSON FROINES: So 10 to the minus 7 is
9 your decision of an acceptable level of risk basically?

10 DPR SENIOR ENVIRONMENTAL RESEARCH SCIENTIST

11 SEGAWA: No. That's our criteria for listing as a TAC.

12 DPR STAFF TOXICOLOGIST LEWIS: The acceptable --
13 well I shouldn't say that. This -- because management
14 decision.

15 CHAIRPERSON FROINES: Yeah. So how does an
16 acceptable level of risk differ from a TAC designation?

17 DPR STAFF TOXICOLOGIST LEWIS: It's ten-fold
18 lower.

19 CHAIRPERSON FROINES: No, I understand the
20 numbers. I don't understand. I'm just asking about the
21 rationale. Is it just a ten-fold safety factor for
22 conservatism? Is that what I --

23 DPR SENIOR ENVIRONMENTAL RESEARCH SCIENTIST

24 SEGAWA: Yes.

25 CHAIRPERSON FROINES: Yeah, okay. Because it's

1 awfully -- it's an awfully conservative number obviously.

2 DPR STAFF TOXICOLOGIST LEWIS: (Nods head.)

3 So the risk estimates for cancer at the Jefferson
4 site range from 5.8 times 10 to the minus 6 to 9.0 times
5 10 to the minus 6, thus being sufficiently high to trigger
6 the listing of methidathion as a toxic air contaminant.

7 --o0o--

8 CHAIRPERSON FROINES: I have one other question
9 about this. And I know I'm just setting Joe up for the
10 next time we meet. But the -- I shouldn't have gone into
11 a joke about Joe. I'm sorry.

12 PANEL MEMBER LANDOLPH: I'm not going to wait
13 anyway.

14 CHAIRPERSON FROINES: I'm sorry. It'll come back
15 to me.

16 DPR STAFF TOXICOLOGIST LEWIS: So I should go on?

17 CHAIRPERSON FROINES: Go ahead.

18 DPR STAFF TOXICOLOGIST LEWIS: Okay. The next
19 section in the risk characterization document is the risk
20 appraisal, which discusses uncertainties related to the
21 hazard identification, exposure assessment, risk
22 characterization. It also compares DPR's risk assessment
23 with U.S. EPA's and discusses various issues related to
24 the Food Quality Protection Act.

25 --o0o--

1 DPR STAFF TOXICOLOGIST LEWIS: And I was just
2 going to highlight some of the major issues discussed in
3 this section. We already discussed the BMD analysis for
4 the cute NOEL. That is one of the major areas of
5 uncertainty, is how the NOEL was estimated.

6 The other major issue is whether there is this
7 threshold for the carcinogenicity due to the very high
8 incidence of the hepatotoxicity. There was a study -- a
9 couple studies in the literature suggesting there's lipid
10 peroxidation in the liver with acute and subchronic
11 exposure. And that could be a possible mechanism, but we
12 didn't feel the evidence was sufficient to assume a
13 threshold.

14 CHAIRPERSON FROINES: Yeah. Well -- but not
15 necessarily. I mean you may have -- that's why I asked
16 the question about what are the electrophilic compounds
17 that might bind micromolecules. Because if you have
18 something that you can predict will bind DNA, you have
19 that; or if you have ROS generation, you'll certainly get
20 lipid peroxidation. And there is that T bars data in your
21 document, which is I think probably what you're using.

22 But I don't think lipid peroxidation of itself is
23 evidence for -- threshold mechanism.

24 DPR STAFF TOXICOLOGIST LEWIS: Yeah. I think
25 another possibility, it could just be increased cell

1 proliferation, you know, due to just getting more rapid
2 turnover of cells and getting problems with DNA.

3 CHAIRPERSON FROINES: Well, lipid peroxidation
4 means you're going to have some free radicals around. And
5 so the question is: Where do they come from?

6 --o0o--

7 DPR STAFF TOXICOLOGIST LEWIS: The next -- the
8 other major area of uncertainty in the hazard
9 identification is in the potential for pre- and postnatal
10 sensitivity to methidathion. The NOELs in fetuses and
11 pups were all greater than in adults in the available
12 developmental and reproductive toxicity studies. However,
13 cholinesterase activity was not measured in any of these
14 studies. Nor is there a developmental neurotoxicity study
15 available for methidathion.

16 There was one direct dosing study in the
17 literature which found evidence of increased sensitivity
18 in weanling rats based on a reduced LD50 value in weanling
19 rats compared to adults.

20 It should be noted that U.S. EPA recommended that
21 the FQPA factor for infants in children be reduced from
22 10X to 1X based on the available developmental and
23 reproductive toxicity studies. And they did not think
24 that there was a need for a developmental neurotoxicity
25 study.

1 give you a risk of 1 in 10 to the minus 6?

2 DPR STAFF TOXICOLOGIST LEWIS: Okay. Say that
3 again.

4 PANEL MEMBER LANDOLPH: So it's just using the
5 cancer slope factor --

6 DPR STAFF TOXICOLOGIST LEWIS: Uh-huh.

7 PANEL MEMBER LANDOLPH: -- and guessing at a
8 risk -- setting a risk at 1 in 10 to the minus 6.

9 DPR STAFF TOXICOLOGIST LEWIS: Uh-huh.

10 PANEL MEMBER LANDOLPH: Did you calculate a
11 concentration --

12 DPR STAFF TOXICOLOGIST LEWIS: Of air
13 concentration?

14 PANEL MEMBER LANDOLPH: Yes.

15 DPR STAFF TOXICOLOGIST LEWIS: Actually I did --
16 well, I'll get to my reference concentration. I
17 calculated a reference concentration based on the
18 carcinogenicity.

19 PANEL MEMBER LANDOLPH: Right. Yeah, that's what
20 I'm getting.

21 How would that stack up compared to your NOELs
22 there?

23 DPR STAFF TOXICOLOGIST LEWIS: Well, it's very
24 low. It's in parts per trillion. And my NOELs are
25 milligram per kilogram, so it's kind of hard to do a

1 direct comparison. But it is the lowest air concentration
2 calculation. If you compare the acute RfC to the chronic
3 RfC, it's, you know, orders -- you know.

4 PANEL MEMBER LANDOLPH: And so had you given any
5 thought to regulating this compound based on the cancer
6 potency rather than on the acute and chronic toxicity
7 study data?

8 DPR STAFF TOXICOLOGIST LEWIS: Well, I'm sure it
9 will be taken into consideration when they decide what
10 sort of mitigation they need to do for methidathion.

11 PANEL MEMBER LANDOLPH: Because they'll obviously
12 differ by orders of magnitude?

13 DPR STAFF TOXICOLOGIST LEWIS: Yeah, yeah.

14 But issues -- I think I should probably let Randy
15 or Tobi address this, since I don't do the mitigation.
16 But usually the acute toxicity is the most immediate
17 problem that we address. And then the longer-term
18 exposure toxicity gets addressed later on.

19 PANEL MEMBER LANDOLPH: The only reason --
20 obvious reason I raised that is because it would seem that
21 to be health protective, you would want to go with the
22 cancer potency data.

23 DPR STAFF TOXICOLOGIST LEWIS: You would or --

24 PANEL MEMBER LANDOLPH: I would think you would.

25 DPR STAFF TOXICOLOGIST LEWIS: Yeah.

1 PANEL MEMBER LANDOLPH: I mean I would.

2 DPR STAFF TOXICOLOGIST LEWIS: Yeah.

3 CHAIRPERSON FROINES: That's what they would take
4 up in their risk management phase in terms of how to
5 approach it.

6 PANEL MEMBER BLANC: Can I ask methodologic
7 question about the process -- the algebra of the division
8 between the NOEL over the -- I'm sorry -- the --

9 DPR STAFF TOXICOLOGIST LEWIS: -- the MOE?

10 PANEL MEMBER BLANC: -- the MOE calculation.

11 DPR STAFF TOXICOLOGIST LEWIS: Yes.

12 PANEL MEMBER BLANC: When you use the NOEL,
13 however you arrive at that in the MOE, the NOEL is based
14 on animal studies where they're given a known amount to
15 adjust, and then --

16 CHAIRPERSON FROINES: Where what, Paul? I'm
17 sorry.

18 PANEL MEMBER BLANC: The animals are given a
19 known amount of the toxin to ingest or it's by gavage, or
20 whatever, their exposure's defined. The whole purpose of
21 the ratio calculation is you're saying, "Okay, this is
22 what it takes in animals," taking into account this sort
23 of safety calculation of the low effect -- the "no elect"
24 level. And its a ratio then to the airborne exposure
25 values that you've calculated.

1 But children, for example, who are getting this
2 airborne exposure are already dosed with a fair amount of
3 pesticide residue -- and children more than adults because
4 it's all in fruit like apricots and oranges and apples.

5 So shouldn't there really be an adjustment to the
6 ratio calculation taking into account that this airborne
7 exposure that you're developing a safety factor is
8 superimposed on a dietary hit that they've already
9 received?

10 DPR STAFF TOXICOLOGIST LEWIS: Actually in the
11 document I didn't plan on showing -- well, I do have some
12 backup slides. But I didn't show the aggregate exposure,
13 but it is calculated in the document where you add the
14 dietary exposure for children and for adults.

15 PANEL MEMBER BLANC: But it doesn't come into
16 your policy decision of: Has this reached the threshold
17 to be a toxic air contaminant?

18 DPR STAFF TOXICOLOGIST LEWIS: Well, it already
19 reached it before it --

20 PANEL MEMBER BLANC: Well, only for some of the
21 calculations, not for all of them, right?

22 DPR STAFF TOXICOLOGIST LEWIS: Well, my
23 understanding -- and this is getting out of my area -- is
24 once it gets tripped, it's tripped -- I mean it's, you
25 know --

1 PANEL MEMBER BLANC: No, but don't you do this
2 whole thing in your findings about how, well, yes, it
3 meets the threshold for toxic air contaminant but it
4 doesn't reach a threshold for any remediation?

5 DPR SENIOR ENVIRONMENTAL RESEARCH SCIENTIST

6 SEGAWA: Yes, you're correct.

7 PANEL MEMBER BLANC: So in fact it's not all or
8 nothing?

9 DPR SENIOR ENVIRONMENTAL RESEARCH SCIENTIST

10 SEGAWA: Well, the risk management phase will address not
11 only the air exposure as well as dietary occupation
12 exposure. So we will look to see if all or any of the
13 exposure scenarios need mitigation.

14 PANEL MEMBER BLANC: Yeah, but I'm talking about
15 your findings. Is there -- not your findings -- your
16 executive summary as currently written.

17 DPR STAFF TOXICOLOGIST LEWIS: Oh, at the time I
18 think I indicated that the mitigation did not appear to be
19 needed for the application site. But since we added the
20 one-hour exposure, those have dropped under a hundred now.
21 So that would suggest mitigation may be needed for that.

22 PANEL MEMBER BLANC: Well, maybe -- okay. So
23 maybe in this case it worked out in the end so it didn't
24 matter. But in fact it is true that you could have a
25 scenario where you had reached the threshold for one thing

1 but not another, but if you had taken into account what
2 the -- I mean this is what you had to go through with
3 fluoride, wasn't it, that you looked at to an extent that
4 this -- that the -- so I'm curious just from a policy and
5 threshold point of view in terms of the logic of the whole
6 methodology of the --

7 PANEL MEMBER BYUS: Well, in addition to that
8 it's the whole cumulative issue of organophosphate,
9 exposure from all organophosphates, I mean how you make
10 them additive synergistic, how you do those kinds of
11 calculations. So some mechanisms are, although albeit not
12 exact, they are very, very similar. I mean it gets to
13 that question.

14 PANEL MEMBER BLANC: And I think that one thing
15 that would be nice to see in your revision if it's not
16 there already is some acknowledgement of that. If -- as a
17 caveat, you know, okay, you know, we've done this
18 calculation, but it should be borne in mind that this
19 calculation doesn't actually take into account the -- this
20 raw ratio doesn't take into account the fact that the LOEL
21 is based on one root of exposure or whatever, you know.
22 But the presumption, there seems to be a logical
23 shortcoming to the whole idea.

24 DPR STAFF TOXICOLOGIST LEWIS: In the discussion
25 or issues related to Food Quality Protection Act we talk

1 about the cumulative toxicity issue with OPs. And mainly
2 that focuses on what U.S. EPA has done related to that.
3 But we have not proposed any, you know, changes in that
4 whole area. It's a difficult issue, you know.

5 PANEL MEMBER BLANC: Well, it should just be
6 knowledge in your executive summary.

7 DPR STAFF TOXICOLOGIST LEWIS: Yeah, that it
8 is -- that it's an underestimation, you know. And also
9 with possible underestimation due to the methidaoxon.

10 PANEL MEMBER BYUS: There's also the subset of
11 individuals with increased sensitive to organophosphates.
12 So they lack that enzyme, clears it --

13 DPR STAFF TOXICOLOGIST LEWIS: Oh, yeah, yeah.

14 PANEL MEMBER BLANC: And isn't it consistent
15 with -- and our Chair should comment on this. But our
16 previous approach to the SB 25 evaluations, did we take
17 into account certain exposures for which the children
18 might not be more sensitive in milligram per kilogram, but
19 their exposure would be greater for whatever reason?

20 CHAIRPERSON FROINES: Yes.

21 PANEL MEMBER BLANC: And in fact if this is a
22 pesticide residue which accumulates on fruit, and if
23 children have a high fruit diet, then their cumulative
24 exposure is going to be that much greater.

25 DPR STAFF TOXICOLOGIST LEWIS: Well, hopefully

1 we've addressed some of that greater exposure in children
2 in our exposure assessment, because we have exposure
3 estimates for infants as well as adults. Also, the
4 dietary exposure has dietary estimates for children based
5 on consumption data for children's. So hopefully we've
6 addressed some of that.

7 PANEL MEMBER BLANC: And you combined the two.

8 DPR STAFF TOXICOLOGIST LEWIS: Yeah, and we
9 combined the two, yeah.

10 PANEL MEMBER BYUS: Yeah, actually I think the
11 occupational setting around what you'd call -- we've had
12 this problem in Coachella Valley, children become exposed
13 because their parents worked in the fields and they get it
14 on their clothes. And then they're -- they're sitting --
15 they have it on the car seats. And the children wind up
16 playing a lot in the cars, and they get exposure that way,
17 through -- I don't know whether that's occupation or
18 whatever it is. It's not something you'd put in to the
19 NOEL, but I mean it's just --

20 DPR STAFF TOXICOLOGIST LEWIS: Yeah, it's hard
21 to, yeah, estimate --

22 PANEL MEMBER BLANC: Are there different reentry
23 times for artichoke treatment than for --

24 DPR STAFF TOXICOLOGIST LEWIS: Sheryl, do you
25 recall if the reentry intervals are different for

1 artichokes than the tree crops?

2 PANEL MEMBER BLANC: Because I have to say that
3 having harvested artichokes myself, the dermal exposure
4 factor is quite high.

5 DPR STAFF TOXICOLOGIST BEAUVAIS: Artichoke
6 harvesting isn't in here because of the restriction on
7 when the methidathion is applied. You apply it prior to
8 budding.

9 PANEL MEMBER BLANC: Oh, okay.

10 CHAIRPERSON FROINES: You apply it -- I'm sorry.

11 PANEL MEMBER BLANC: Prior to budding.

12 DPR STAFF TOXICOLOGIST BEAUVAIS: Budding. So
13 that's why it's not an issue specifically for artichokes
14 because of restrictions specifically for methidathion.

15 PANEL MEMBER BLANC: Thanks.

16 CHAIRPERSON FROINES: Are you finished?

17 DPR STAFF TOXICOLOGIST LEWIS: I was just going
18 to go through the reference concentration calculations, if
19 you're interested.

20 CHAIRPERSON FROINES: Sure.

21 DPR STAFF TOXICOLOGIST LEWIS: It would be really
22 quick.

23 All the NOELs used in this risk assessment were
24 all NOELs. So to derive a reference concentration, it was
25 first converted to an equivalent human inhalation NOEL by

1 dividing by the respiratory rate in humans, and then
2 dividing by an uncertainty factor of a hundred. This
3 gives you the RfC in milligrams per cubic meter. That's
4 then converted to ppm's by multiplying times molecular
5 volume divided by molecular weight.

6 --o0o--

7 DPR STAFF TOXICOLOGIST LEWIS: So the RfCs
8 calculated with this approach are 5.1 micrograms per cubic
9 meter for acute, 3.4 micrograms per cubic meter for
10 seasonal, and 2.5 micrograms per cubic meter for chronic.
11 Oh, and then the ppb's -- equivalent ppb's are underneath.

12 --o0o--

13 DPR STAFF TOXICOLOGIST LEWIS: On the next slide
14 I have my calculation of the cancer RfC. If you take the
15 negligible risk level of 10 to the minus 6 and divide it
16 by the cancer potency factor, you get an RfD for cancer.
17 You can convert that then to a concentration by dividing
18 by the inhalation rate in humans. Using this approach you
19 get a cancer RfC for methidathion of 6.8 nanograms per
20 cubic meter, or .5 parts per trillion.

21 --o0o--

22 DPR STAFF TOXICOLOGIST LEWIS: So in conclusion,
23 the MOEs for ambient air are all greater than a thousand
24 for acute seasonal and chronic exposure. For the
25 application site, however, the MOEs were all less than a

1 thousand, triggering the criterion for listing
2 methidathion as a toxic air contaminant based on its
3 neurotoxic potential.

4 The cancer risks for methidathion were also
5 greater than the negligible risk level, and again
6 triggering the criterion for listing methidathion as a
7 toxic air contaminant.

8 And that's it.

9 CHAIRPERSON FROINES: Good. You did it.

10 DPR STAFF TOXICOLOGIST LEWIS: All right. Is it
11 3 o'clock yet?

12 (Laughter.)

13 CHAIRPERSON FROINES: So how should we proceed?

14 PANEL MEMBER BLANC: I think that in order at
15 least to give them some guidance, we need to comment in
16 some form on the DPH response to the executive summary or
17 the alternate DPH executive summary, bearing in mind that
18 there was some changes that you had mentioned that made
19 the two out of synch.

20 But otherwise how are they supposed to respond if
21 they don't get a sense --

22 CHAIRPERSON FROINES: I missed the first part --
23 the who was executive summary --

24 PANEL MEMBER BLANC: There was this memo from
25 OEHHA that diverged very substantively from the executive

1 summary of --

2 CHAIRPERSON FROINES: Yes.

3 PANEL MEMBER BLANC: -- the pesticide people for
4 the same documents -- or the same material, right?

5 CHAIRPERSON FROINES: Yes.

6 PANEL MEMBER BLANC: And unless we as a committee
7 give some feedback to the DPR about that, I don't know how
8 they're supposed to respond to it.

9 CHAIRPERSON FROINES: Well, it's a question of
10 what we want to take up now. Because she's going back and
11 looking at bench -- doing a benchmark calculation. And
12 she's made some adjustments where in fact that the acute
13 MOE for DPR is now below 100. So at least with respect to
14 the acute, we're still talking about the 10 versus 3
15 issue, Paul.

16 Is that -- that's what you're referring to?

17 PANEL MEMBER BLANC: Well, that's the most
18 substantive divergence. But I think that it would be
19 helpful to look carefully at where the two executive
20 summaries tend to differ from each other, and for you to
21 meet with them and sort of come to terms with what of that
22 is just style or what is substance, and are there parts
23 where you have a substantive difference of view or can
24 they be adjudicated? Because I think that I certainly
25 would be more comfortable with a closer congruence of

1 those two documents.

2 CHAIRPERSON FROINES: I think my view is that the
3 two documents are essentially the same with one major
4 difference; and, that is, the LOEL to NOEL conversion.
5 But aside from that, I think the documents are almost
6 identical.

7 DPR ASSISTANT DIRECTOR JONES: Yeah. And --
8 Paul, this is Tobi Jones.

9 When you talk about the two executive summaries,
10 I think there are two things: There's an executive
11 summary the staff prepared from a document we've presented
12 to you today regarding ambient and off-site exposure. The
13 findings that OEHHA prepared are what they're required to
14 prepare based on their review analysis of that.

15 And I think John is correct; it seems to me
16 there's that one substantive difference about the use of 3
17 versus 10.

18 And I think -- you know, you've provided some
19 tasks to Carolyn about some further calculations on BMD.

20 But I just want to clarify. There are not two
21 executive summaries. There's --

22 PANEL MEMBER BLANC: No, no, no. No, I was
23 imprecise.

24 CHAIRPERSON FROINES: No. What I was
25 understanding is that there is this big fat document,

1 which is the one I'm talking about; and then there's the
2 small OEHHA document. And so I'm taking those. And I
3 didn't -- wasn't thinking about your executive summary,
4 unless Paul was.

5 But we've raised the issue of the benchmark dose.
6 We've raised the question of if something isn't
7 statistically significant, do we therefore ignore it. And
8 that's an issue. We talked about the conservatism or lack
9 thereof of the exposure estimates. We've talked about the
10 gavage method of administration. So we have exposure,
11 method of administration, difference of opinion
12 about -- well, our view about statistical significance and
13 how one wants to look at that. There's the OEHHA
14 document. And I can't think of the other things that came
15 up. There were others. Obviously the food, fruit issue
16 is another question.

17 And as far as I'm concerned, if there was a way
18 for OEHHA and DPR to resolve that difference, that
19 would -- that doesn't put us in the position of our having
20 to be the adjudicator within that process. I think we all
21 would be comfortable. And so that's one thing I -- as
22 part of the benchmark discussion maybe you can talk with
23 DPR -- OEHHA and see if that can be worked out.

24 I think those are the --

25 PANEL MEMBER BLANC: Yeah, you alluded to the

1 other one, which is -- but I want to reemphasize, which
2 is -- because it could have a very big effect on your
3 statistical algebraic calculations, which is two issues of
4 exposure, the exposure calculation and the school, wherein
5 you had used a mathematical model to come up with a 95th
6 percentile on a logarithmic distribution, which I think is
7 the incorrect approach. And I think that you may come up
8 with a considerably higher level if you look at the
9 cluster of high values, which may actually reflect an
10 exposure day.

11 And, secondly, I -- I know Roger is very
12 skeptical. But I would like you to go back and look at
13 the wind direction values that you have as hard as you can
14 look and see if in fact, aside from the four times
15 multiplication, which I agree with because apparently they
16 used one-fourth as much as maximum treatment on that test
17 plot, whether there is any way of vectoring out what a
18 higher estimate of values would be if there was monitoring
19 in the direction that the wind actually went in.

20 CHAIRPERSON FROINES: I'm getting two heads
21 nodding back there. Is that reasonable?

22 Well, obviously we're not going to go around the
23 room and have Charlie and Roger give points of view today,
24 because it's -- we're close to quitting time.

25 But do other members of panel have

1 recommendations that they want to make for additional work
2 between now and the next meeting? At the next meeting
3 clearly we're going to go around. Joe has written a lot
4 of comments. Charlie worked with -- as the lead and so
5 will have comments. Craig I think is feeling good. And
6 sulfuryl fluoride's gone, so he's silent.

7 PANEL MEMBER BYUS: Very quiet.

8 CHAIRPERSON FROINES: And Roger may have comments
9 on the --

10 PANEL MEMBER ATKINSON: I do have, yeah.

11 CHAIRPERSON FROINES: But he'll tell us about --
12 he needs to tell us about those comments.

13 PANEL MEMBER ATKINSON: I may have another series
14 on the environmental, which I took forward to somewhere --

15 CHAIRPERSON FROINES: So there'll be comments
16 from the Panel at the next meeting. And so my only
17 question for today as we sort of move to closure is: Do
18 you have other suggestions that you can give right now for
19 them to consider in the interim?

20 Joe.

21 PANEL MEMBER LANDOLPH: And, you know, I wrote
22 mine down for you to make it easy for you.

23 I would also suggest that in the discussion, the
24 use of the term "oncogenicity," I would prefer
25 "carcinogenicity," because I always think of carcinogenic

1 chemicals versus oncogenic viruses. And we usually use
2 "carcinogenicity."

3 And I think if you make a nice summary table of
4 that slide you just showed with the very beautiful
5 calculations and put that up front -- in the document and
6 up front, maybe in the executive summary, that would help,
7 so we could see actually where the carcinogenicity levels
8 were for the risk of one in a million compared to the
9 NOELs and LOELs. That would be really easy to grasp that
10 immediately.

11 DPR STAFF TOXICOLOGIST LEWIS: So you're talking
12 about the reference concentration?

13 PANEL MEMBER LANDOLPH: Yeah, that would be
14 great.

15 CHAIRPERSON FROINES: I also mentioned the
16 ability of metabolize to binding with macromolecules. And
17 I'll work on that too in the interim. So I'll come in
18 with some ideas for you. Because I'm interested in what
19 kind of protein binding there might be.

20 Charlie, do you have a comment at this point?

21 PANEL MEMBER PLOPPER: Yeah. Would it be
22 possible for the health defects and the exposure people to
23 get together and come up with some kind of a realistic
24 assessment? Because most of these toxicity studies are
25 gavage, which means that's a bolus type of dose. But we

1 don't really have a bolus's exposure assessment. And it's
2 very difficult to figure out what's going on here if you
3 don't have both, particularly when the sites that --
4 there's these major differences in local concentration at
5 the time of an application. We don't really know what
6 that is. And it's going to -- somehow there has to be
7 some resolution there. Because what you're saying is that
8 likely most of the occupational exposure's inhalation.
9 But the toxicity danger's gavage. But they're both bolus
10 exposures. And somehow that seems to be the biggest
11 problem here of deciding whether this is an overestimate
12 or an underestimate of risk.

13 CHAIRPERSON FROINES: Joe.

14 PANEL MEMBER LANDOLPH: And I noticed reading
15 through your cancer risk assessment calculations, some of
16 them ranged as high as 10 to the minus 2 for the workers.

17 DPR STAFF TOXICOLOGIST LEWIS: Oh, yes.

18 PANEL MEMBER LANDOLPH: You know, so what are you
19 going to do about that? You obviously communicate this to
20 your risk managers or whatever when you finish.

21 DPR STAFF TOXICOLOGIST LEWIS: Um-hmm.

22 CHAIRPERSON FROINES: Craig or Roger.

23 PANEL MEMBER BYUS: Yeah, I agree with you,
24 Charles. I think also may be important with the
25 carcinogenicity mechanism if it's more sort of tumor

1 promotional in aspect. Theoretically to get those effects
2 you need the presence of the stimulus regularly. If you
3 have more episodic exposure, it's no longer promotional.

4 DPR STAFF TOXICOLOGIST LEWIS: I should point out
5 though, the subchronic and chronic studies are dietary.
6 So it's not so much a bolus than -- yeah, it's the acute
7 ones -- or in the developmental toxicity ones that are
8 gavage. But, yeah, I just wanted to point that out.

9 PANEL MEMBER BYUS: But you hit on all the things
10 that I --

11 CHAIRPERSON FROINES: I have a policy question
12 for you. Andy, maybe you can help on this.

13 It's my understanding that in California for a
14 chemical to be identified as a carcinogen, one needs one
15 species with two studies, two species, human evidence --
16 in other words, there are a set of criteria which is a
17 matter of policy the state has historically used.

18 In this study -- in this particular determination
19 we essentially have one study in one species. And my
20 question is: Does that meet the policy criteria for
21 defining substances of carcinogen?

22 Obviously we're not -- we're going to continue to
23 pay attention to this issue. But there is a cancer policy
24 I think --

25 OEHHA AIR TOXICOLOGY AND RISK ASSESSMENT UNIT

1 CHIEF SALMON: Yes. Well, it applies in specific --
2 sorry. Andy Salmon, OEHHA.

3 The policy -- the specific laying out of that
4 policy tends, you know, to appear in slightly different
5 processes than this particular one. I think the TAC
6 process, you know, what defines it as a carcinogen is your
7 judgment as the expert panel rather than a specific narrow
8 guideline.

9 The usual criteria would be two independent
10 studies. Those independent studies might be just two
11 separate studies in -- you know, at different times and
12 laboratories. Now, you -- I think that you have those.
13 You have --

14 DPR STAFF TOXICOLOGIST LEWIS: Yeah, we do. Two
15 studies --

16 OEHHA AIR TOXICOLOGY AND RISK ASSESSMENT UNIT
17 CHIEF SALMON: Yeah, there are two independent studies.

18 CHAIRPERSON FROINES: There are two studies, but
19 one study they don't discuss, and they basically say it
20 doesn't meet criteria for -- study.

21 OEHHA AIR TOXICOLOGY AND RISK ASSESSMENT UNIT
22 CHIEF SALMON: But I don't think that our decision
23 criteria in other programs for carcinogenicity make any
24 reference to whether it meets FIFRA guidelines or not.
25 It's a question of whether it produces a positive result

1 which is considered reputable.

2 And so in this case I think you have -- you
3 certainly have the two independent study criteria. I
4 think --

5 CHAIRPERSON FROINES: Well, then we should see
6 the data from that other study.

7 OEHHA AIR TOXICOLOGY AND RISK ASSESSMENT UNIT

8 CHIEF SALMON: Well, I think it would be use -- I mean we
9 I think in OEHHA have a tendency to certainly take note of
10 the compliance of a study with good laboratory practice as
11 a -- you know, if you like an endorsement of its value.
12 But we certainly don't dismiss or ignore studies.

13 CHAIRPERSON FROINES: So as I understand what
14 you're saying is -- of course this panel doesn't have a
15 cancer policy, so we can do pretty much what we choose,
16 and do.

17 OEHHA AIR TOXICOLOGY AND RISK ASSESSMENT UNIT

18 CHIEF SALMON: Yes.

19 CHAIRPERSON FROINES: But the point is I'm asking
20 is -- so there are no criteria that DPR or OEHHA or ARB
21 has to use in terms of deciding whether to bring something
22 to the Panel?

23 OEHHA AIR TOXICOLOGY AND RISK ASSESSMENT UNIT

24 CHIEF SALMON: No.

25 CHAIRPERSON FROINES: In other words they can

1 decide to bring the carcinogenicity issue to the Panel
2 even if there's only one study?

3 If OEHHA or DPR considered that, you know, they
4 would value your opinion on the topic, then they --

5 CHAIRPERSON FROINES: Okay. I just want to --

6 OEHHA AIR TOXICOLOGY AND RISK ASSESSMENT UNIT

7 CHIEF SALMON: -- they're entitled to ask for it.

8 CHAIRPERSON FROINES: I'm just wanting to be
9 clear on what the guidelines are so we're all on the same
10 page.

11 OEHHA AIR TOXICOLOGY AND RISK ASSESSMENT UNIT

12 CHIEF SALMON: Well, I don't think they're rigid
13 guidelines. But as a general principle, we look at things
14 and see if there are two independent studies, which are --
15 you know, sometimes it's a rat study and a mouse study.
16 Sometimes it's, you know, I mean we have brought forward
17 things where we've had two species but -- sorry -- one
18 species but two sexes. So --

19 CHAIRPERSON FROINES: Well, then I think it would
20 be useful to have a page or something in the document that
21 gives some of the results of that study, rather than the
22 study just being ignored and said, you know, "They don't
23 meet the guidelines and so, therefore, we're not going to
24 provide you any information from them."

25 OEHHA AIR TOXICOLOGY AND RISK ASSESSMENT UNIT

1 CHIEF SALMON: From our perspective, it's important
2 supporting evidence in terms of building a case for
3 consideration.

4 CHAIRPERSON FROINES: Then I think we should have
5 something to look at about it, even within its
6 limitations.

7 Thanks.

8 Thanks, Andy.

9 Tobi, I assume that you agree with what he says,
10 because I didn't see your head grimacing.

11 So it's 3 o'clock. Do I have a motion to close?

12 Do you have --

13 PANEL MEMBER BLANC: Yeah, before I put that
14 motion on the -- could you, Mr. Chair, just acknowledge
15 what it is that we put off that was -- did appear on the
16 agenda. I don't believe we completely the agenda, as
17 we --

18 CHAIRPERSON FROINES: The agenda piece that
19 wasn't taken up was basically a discussion with Tobi about
20 DPR's future plans in terms of their approach to
21 pesticides.

22 Is that a reasonable way of saying it?

23 DPR ASSISTANT DIRECTOR JONES: It's air quality
24 initiative.

25 PANEL MEMBER BLANC: So that will be deferred to

1 the next meeting?

2 CHAIRPERSON FROINES: That will be deferred to
3 the next meeting.

4 And that is for information purposes really only.
5 We don't -- I don't think we have -- there's nothing --
6 that was just something I requested because I saw an
7 article in the newspaper. And so it was just to keep
8 everybody informed.

9 PANEL MEMBER BLANC: Okay. Then I move to
10 adjourn.

11 CHAIRPERSON FROINES: Second.

12 PANEL MEMBER BYUS: Second.

13 CHAIRPERSON FROINES: I think the presentations
14 were really quite good today. And so thank you very much.

15 And we did it by 3. So meeting's adjourned.

16 (Thereupon the California Air Resources
17 Board, Scientific Review Panel adjourned
18 at 3:00 p.m.)

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2 I, JAMES F. PETERS, a Certified Shorthand
3 Reporter of the State of California, and Registered
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14 IN WITNESS WHEREOF, I have hereunto set my hand
15 this 12th day of July, 2006.

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