MEETING

STATE OF CALIFORNIA

AIR RESOURCES BOARD

SCIENTIFIC REVIEW PANEL

ELIHU HARRIS STATE BUILDING

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SAN FRANCISCO, CALIFORNIA

FRIDAY, JULY 8, 2005

9:30 A.M.

JAMES F. PETERS, CSR, RPR
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APPEARANCES

PANEL MEMBERS

Dr. John Froines, CHAIRPERSON

Dr. Roger Atkinson

Dr. Craig Byus

Dr. Stanton Glantz

Dr. Katharine Hammond

Dr. Joseph Landolph

Dr. Charles Plopper

REPRESENTING THE AIR RESOURCES BOARD:

Mr. Lynton Baker, Staff Air Pollution Specialist

Mr. Jim Behrmann

Mr. Peter Mathews

REPRESENTING THE DEPARTMENT OF PESTICIDE REGULATION:

Ms. Mary-Ann Warmerdam, Director

Ms. Tobi L. Jones, Assistant Director

Dr. Roger Cochran

Mr. Joseph Frank, Supervisor, Exposure Assessment & Mitigation

Dr. Wynetta S. Kollman

Dr. Lori Lim, Staff Toxicologist

Mr. Randall Segawa, Senior Environmental Research Scientist

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1 PROCEEDINGS

2 CHAIRPERSON FROINES: This is to formally open
3 the meeting of the Scientific Review Panel on July 8th,
4 2005.

5 We are short two panel members who are unable to
6 attend, Gary Friedman and Paul Blanc. But there is a
7 quorum, and so we will proceed.

8 Dr. Plopper is in attendance, Dr. Landolph, Dr.
9 Atkinson, Dr. Hammond, Dr. Glantz and Dr. Byus and myself.

10 And so we'll proceed with the discussion of
11 sulfuryl fluoride and proceed from here.

12 So, Tobie, welcome.

13 So that for the record this is -- well, why don't
14 you introduce yourself for the record.

15 DPR ASSISTANT DIRECTOR JONES: Is this adequate?

16 I'm Tobie Jones, Assistant Director at DPR. And
17 I'm pleased to be here today to provide you some opening
18 comments on our presentation on our sulfuryl fluoride risk
19 assessment.

20 First and foremost, I want to thank Drs. Byus and
21 Atkinson for working very closely with our staff,
22 providing some excellent comments on improving our draft
23 assessment, and also helping us in preparing making sure
24 that the presentation today is clear for all of the panel.

25 In the course of that review Dr. Atkinson

1 identified the possibility that sulfuryl fluoride is a
2 possible greenhouse gas. And we acknowledge that
3 possibility. And we also acknowledge the desirability of
4 having better data on the fate of this molecule in the
5 air.
6 The administration and the collective Cal EPA
7 family has prioritized efforts to curb the greenhouse gas
8 emissions. And we at DPR look forward to playing a role
9 in that effort and examining our role in the recent
10 Governor's executive order pertaining to greenhouse gas
11 emission reductions.
12 DPR's had a policy of completing risk assessments
13 on all of the fumigants registered as pesticides in
14 California. Fumigants by their nature can lead to
15 exposures. And they represent about a quarter of the
16 pounds of pesticides applied in California. And of course
17 the fumigants have varying degrees of hazards.
18 Our presentation of sulfuryl fluoride today
19 represents our efforts to continue to move forward on our
20 policy to fully assess the risks from fumigants and put
21 appropriate controls in place.
22 I'd like to bring to your attention some changes
23 in the use of sulfuryl fluoride to further illustrate our
24 need to complete the assessment. While we were in the
25 midst of preparing this assessment, a new use of sulfuryl

1 fluoride was introduced as a commodity fumigant. And the
2 use that we'll be discussing today is focused on the use
3 that was in place prior to this, which is solely as a
4 structural fumigant. The use as a commodity fumigant is
5 to treat commodities after harvest.
6 With this new use, we have exercised our
7 authority to ask for additional monitoring data from the
8 registrant. When we receive this monitoring data, we will
9 amend this assessment to cover the new exposures,
10 including bystander, worker and dietary risks.
11 Because of the manner in which structural
12 fumigants are regulated in California, DPR cannot impose
13 restrictions on the use by county-based permits, as we do
14 with agricultural pesticides. Rather we have to
15 promulgate regulations on mitigation measures. And we
16 need your external peer review in order to advance and
17 move forward on those regulations. So we look forward to
18 the completion of this process.
19 As we've seen with other pesticides that have
20 come through the toxic air contaminant process such as
21 methyl parathion, uses and regional distributions continue
22 to change. And for that reason we elected to move forward
23 on the risk assessment we're presenting today rather than
24 wait until acquiring additional data on this new use.
25 PANEL MEMBER BYUS: I have a question.

1 I just became really aware of this recently. I
2 mean I thought we were talking about all uses of sulfuryl
3 fewer fluoride in the state, and apparently that is not
4 the case. I mean just to make sure everybody's clear on
5 what you're saying here.
6 As I understand it, it's all the -- it's being
7 used now to fumigate food commodities like nuts and
8 raisins and grains. And so it's actually -- they're
9 fumigating all of the food products. Correct me if I'm
10 wrong.
11 DPR ASSISTANT DIRECTOR JONES: That's right, or
12 some -- I'll say some food products.
13 PANEL MEMBER BYUS: Some of them. But primarily
14 raisins, nuts and grains, as well the grain structures --
15 the silo fumigation of the structure itself.
16 And so we run -- and so this document really
17 doesn't deal with that aspect of exposure, correct?
18 DPR ASSISTANT DIRECTOR JONES: That is correct.
19 And that's why I wanted to explain to you up front our
20 thinking in moving this assessment forward and recognizing
21 that this other new use -- and, Craig, I think -- we don't
22 know the extent to which that new use will take place,
23 because in part it is replacing or it will replace over
24 time uses of methyl bromide, which is being phased out.
25 So this will be a developing use.

1 And we -- as I indicated, we do want additional
2 data from that use that we will use in amending this
3 assessment to address the new uses. And it will address
4 the food use, as you --
5 PANEL MEMBER BYUS: So it would be basically
6 exposing the silos and the various commodities at
7 different exposure scenarios. And bystanders and those
8 people that live near these place -- which are more or
9 less permanent fixtures, are they not?
10 DPR ASSISTANT DIRECTOR JONES: Yes.
11 PANEL MEMBER BYUS: I mean I would imagine
12 they're not moving them all around, like doing different
13 houses for termites. So I mean there would be a whole
14 different exposure scenario for the bystanders, for people
15 living in the area, that could be significantly different
16 than what we're reporting here in this document for
17 Vikane?
18 DPR ASSISTANT DIRECTOR JONES: That is correct.
19 PANEL MEMBER BYUS: So primarily here -- so even
20 though it says -- in a sense it's sulfuryl fluoride
21 (Vikane) and it's -- so sulfuryl fluoride obviously we're
22 dealing with the toxicity, is common. But the exposure
23 aspect is just for Vikane; is that correct?
24 DPR ASSISTANT DIRECTOR JONES: That is correct.
25 PANEL MEMBER BYUS: Just so -- I mean I just want

1 everybody to realize that. I sort of just became aware of
2 it myself.
3 So thank you.
4 DPR ASSISTANT DIRECTOR JONES: Okay.
5 CHAIRPERSON FROINES: Does -- I used sulfuryl
6 fluoride in my house when I bought it, so that I'm an
7 experienced sulfuryl fluoride person.
8 PANEL MEMBER GLANTZ: That explains your
9 behavior.
10 CHAIRPERSON FROINES: I knew somebody would say
11 that.
12 (Laughter.)
13 CHAIRPERSON FROINES: I am the living example of
14 the brain vacuole, right.
15 (Laughter.)
16 CHAIRPERSON FROINES: You see, you can't --
17 PANEL MEMBER GLANTZ: That's a joke, for the
18 record.
19 PANEL MEMBER BYUS: For the record.
20 PANEL MEMBER GLANTZ: Not clearly, but --
21 CHAIRPERSON FROINES: Yeah, there are doubts
22 among the panel about whether it's accurate or not.
23 PANEL MEMBER HAMMOND: Are we going to take a
24 vote?
25 CHAIRPERSON FROINES: Now, can I ask my question?

1 Can I interrupt you guys to get to the point?
2 (Laughter.)
3 CHAIRPERSON FROINES: That raises I think
4 significant exposure questions that we'll have to deal
5 with over time, I would assume, because it sounds like, as
6 opposed to a home use, that there will potentially be
7 greater amounts in use. Whether that translates to
8 exposure is another question. Is that correct?
9 DPR ASSISTANT DIRECTOR JONES: I don't know
10 whether I could address the question of greater amounts.
11 But it will -- the new uses pose different exposure
12 scenarios. And it's for that reason that we have asked
13 the registrant -- and U.S. EPA also has asked the
14 registrant to develop additional monitoring data for this
15 use. And I believe timing-wise the registrant will be
16 developing that data over the next probably a year to a
17 year -- 18 months, and then we will use that data in
18 expanding this risk assessment. So it will --
19 PANEL MEMBER BYUS: So it adds to the baseline
20 level of fluoride that people have in them from eating
21 these things. It now goes up, how much it goes up from
22 the residue.
23 PANEL MEMBER HAMMOND: Does it get absorbed by
24 the food?
25 PANEL MEMBER BYUS: Yes, as far as --

1 PANEL MEMBER HAMMOND: It does?
2 DPR ASSISTANT DIRECTOR JONES: Yes.
3 PANEL MEMBER HAMMOND: Oh, it does?
4 DPR ASSISTANT DIRECTOR JONES: Yes.
5 PANEL MEMBER BYUS: Oh, yeah. It's in. -- and
6 now will be in your food. And it raises your fluoride
7 baseline level by some amount that's unclear.
8 DPR ASSISTANT DIRECTOR JONES: And I think if
9 you're interested in that element on a current basis,
10 there's a very extensive discussion of its contribution in
11 food as the result of EPA's setting a tolerance for that.
12 And there's very extensive federal register notice on the
13 tolerance petition when this was proposed.
14 So if -- and I could provide that reference to
15 you, John, if you'd like --
16 CHAIRPERSON FROINES: Sure.
17 DPR ASSISTANT DIRECTOR JONES: -- for the
18 committee if you want to read more about that.
19 CHAIRPERSON FROINES: I think the fluoride
20 issue's going to get hotter, you know, because there's
21 this new evidence osteosarcoma that seems to be emerging.
22 And so fluoride in and of itself I think is going to be a
23 topic of some interest over time. So I think it will come
24 back to us in one form or another.
25 The other issue I would raise in terms of

1 thinking about monitoring is the issue of spikes versus
2 integrated determination of exposure. I think that in
3 some of these cases we have very high short-term duration
4 exposures. But then if you take the average of the
5 distribution, it turns out to be much different than the
6 spike would indicate. And so how we addressed short-term
7 high exposure or high concentrations versus the various
8 averaging approaches we might take is an issue. I think
9 that is something that we need to think about over time.
10 And I think we'd be happy to talk with you further. And
11 Kathy's smiling because she knows that she'd be the
12 assigned helper.
13 (Laughter.)
14 CHAIRPERSON FROINES: So let's go ahead. I don't
15 mean to hold you up.
16 DPR ASSISTANT DIRECTOR JONES: Just a couple --
17 just one last point.
18 We provided OEHHA's final findings to the panel
19 earlier this week. And I recognized -- in the course of
20 working through that I recognized the valuable role that
21 Eleanor Fanning formerly played with this Committee in
22 helping with the coordination of providing all of the
23 documents to you. So I apologize for any confusion that
24 we may have created providing you draft findings --
25 preliminary draft findings, but you do have the final

1 findings from OEHHA.
2 I'd like to now turn it over to DPR staff.
3 CHAIRPERSON FROINES: There was a question I had
4 about that, because there were some -- there was a list of
5 nine topics that I read the responses to. But then there
6 was an -- it seemed like there was an OEHHA attachment
7 that I didn't see the response to. And I didn't know
8 whether that was me not finding it effectively or whether
9 it was -- whether there was an issue.
10 And maybe we should just go ahead and worry about
11 that as we get into it.
12 DPR ASSISTANT DIRECTOR JONES: I think that --
13 CHAIRPERSON FROINES: There was this long
14 attachment from OEHHA that was an earlier discussion, and
15 so may have been incorporated and that's where I may
16 have -- so it may have been me.
17 DPR ASSISTANT DIRECTOR JONES: Okay. I think at
18 this point turning it over to our staff. Dr. Wynetta
19 Kollman will be discussing the environmental fate, dr.
20 Roger Cochran will be discussing the exposure assessment,
21 and Dr. Lori Lim will be discussing the health assessment.
22 So I think, unless you have any further questions
23 of me, I will step back and turn it over to DPR staff.
24 PANEL MEMBER ATKINSON: So what's the -- do you
25 have any idea of the expected use of sulfuryl fluoride for

1 commodity fumigation in California?

2 DPR ASSISTANT DIRECTOR JONES: Not specifically.

3 I think --

4 PANEL MEMBER ATKINSON: Is it going to be larger

5 than used for house fumigations or not?

6 DPR ASSISTANT DIRECTOR JONES: I don't know. I

7 perhaps can consult with the registrant, who is sitting in

8 the audience, and see whether they have that. But I think

9 one thing to consider is, in entering the commodity

10 fumigation market, sulfuryl fluoride then competes with

11 other compounds that can be used for some commodity

12 fumigation. And then also in some of the other

13 fumigations pertaining to facilities -- large facilities.

14 Some organizations as a result of the phaseout of methyl

15 bromide have looked at other non-chemical treatments, like

16 heat treatment, that depending on the facility may be

17 used.

18 So I think trying to kind of predict the amount

19 and the comparison of this new use to the structural use

20 is a bit premature. But it's where our use supporting

21 data will be a very important way to be able -- for us to

22 be able to track that.

23 CHAIRPERSON FROINES: There are going to be

24 interesting issues. You know, toxicology's done at 70

25 degrees, because they want to keep the animals happy. But

1 in homes in L.A. and silos you may get much higher
2 temperatures. And so that's going to have potential
3 significance in terms of -- potential exposure -- pardon
4 me -- for the two potentials. But I think that the
5 temperature is a variable that we haven't thought much
6 about, because our toxicology is in one framework and the
7 actual exposure may be in a different context.
8 So as we get into this there are some interesting
9 issues I think.
10 Is that fair, Kathy, what I just said?
11 PANEL MEMBER HAMMOND: Sure.
12 CHAIRPERSON FROINES: Thank you.
13 DPR ASSISTANT DIRECTOR JONES: Okay. Thank you.
14 CHAIRPERSON FROINES: You see the danger of
15 raising the commodity issue at the beginning.
16 DPR ASSISTANT DIRECTOR JONES: Well, I think for
17 the reason -- craig discussed that -- I wanted to make the
18 panel aware of that up front.
19 CHAIRPERSON FROINES: No, I think it's a very
20 important issue.
21 Thank you.
22 Will you keep us informed on the greenhouse gas
23 question too. Because I don't think the panel on any
24 chemical to date has -- that's not been an issue, whether
25 it be ARB or DPR. And so that's a new issue coming down

1 the road.

2 Welcome.

3 (Thereupon an overhead presentation was

4 Presented as follows.)

5 DR. KOLLMAN: I'm going to briefly describe --

6 CHAIRPERSON FROINES: Can you introduce

7 yourselves for the record.

8 Thank you.

9 DR. KOLLMAN: I'm Wynetta S. Kollman.

10 I'm going to briefly describe the physical and

11 chemical properties of sulfuryl fluoride, its application

12 and use patterns in California, and its fate in the

13 environment.

14 --o0o--

15 DR. KOLLMAN: Sulfuryl fluoride is a colorless,

16 reporter odorless gas belonging to the chemical family of

17 inorganic acid halides. The chemical name, trade name,

18 CAS registry number, and the molecular formula and weight

19 are listed in this slide.

20 --o0o--

21 DR. KOLLMAN: Sulfuryl fluoride is non-corrosive

22 to metals, stable to light, and stable up to 400 degrees C

23 when dry. It is soluble in water without hydrolysis and

24 is also soluble in common organic solvents such as

25 ethanol, toluene, and carbon tetrachloride.

1 This slide lists additional physical and chemical
2 properties.
3 --o0o--
4 DR. KOLLMAN: Vikane is an insecticide,
5 rodenticide used for the fumigation of sealed structures,
6 such as dwellings, buildings, barns, vehicles, fumigation
7 chambers, rail cars, and surface ships in port and their
8 contents, such as construction materials, furnishings, and
9 household effects.
10 --o0o--
11 DR. KOLLMAN: Full pesticide use reporting in
12 California was implemented by DPR in 1990. All
13 agricultural use must be reported monthly to the county
14 agricultural Commissioners. The county agricultural
15 commissioners forward these data to DPR, who annually
16 compiles and makes available a pesticide use report.
17 For nonagricultural applications detailed
18 information such as meridian township range and section is
19 not provided.
20 --o0o--
21 DR. KOLLMAN: This slide is a graphical
22 representation of total pounds of sulfuryl fluoride used
23 in California from 1993 to 2002. Total use ranged from
24 1,502,091 pounds in 1993 to 3,042,882 pounds in 2002.
25 The average annual use for this reporting period

1 was 2,211,097 pounds.

2 --o0o--

3 DR. KOLLMAN: Sulfuryl fluoride is used in all

4 California counties. This slide shows use by county from

5 1999 through 2002 for counties with annual use over 60,000

6 pounds.

7 --o0o--

8 DR. KOLLMAN: Use of sulfuryl fluoride occurs

9 throughout the year. This slide shows monthly use for

10 1999 to 2002.

11 --o0o--

12 DR. KOLLMAN: Data addressing the fate of

13 sulfuryl fluoride in soil and biota are not available.

14 That data was not required for federal re-registration due

15 to sulfuryl fluoride's chemical properties and its

16 registration for strictly indoor uses.

17 Following application in aeration of treated

18 structures, sulfuryl fluoride is dissipated into the

19 atmosphere in a gaseous state. There would be little

20 likelihood that residues would leach to groundwater.

21 --o0o--

22 DR. KOLLMAN: Sulfuryl fluoride enters the

23 atmosphere in the gas phase. Once present it may be

24 transformed and then removed through reaction with

25 atmospheric radicals. A search of the open scientific

1 literature produced no citations relevant to the fate of
2 sulfuryl fluoride in the atmosphere or if it absorbs light
3 as wave lengths greater than 290.
4 The uptake of sulfuryl fluoride into cloud water
5 with subsequent hydrolysis is unlikely since it is soluble
6 in water without hydrolysis.
7 PANEL MEMBER ATKINSON: Have you done
8 calculations on that. Has anybody in your department
9 proceeded on that? I mean that's presumably the most
10 likely atmospheric loss process, is uptake into cloud
11 water and then hydrolysis.
12 Do you have any further insights into that?
13 DR. KOLLMAN: No, I don't.
14 CHAIRPERSON FROINES: Roger, why would hydrolysis
15 be unlikely? It would seem likely to me.
16 PANEL MEMBER ATKINSON: Well, apparently it
17 doesn't hydrolyze. But, yeah, the obvious thing you'd
18 write down is sulfuryl fluoride plus two waters gives 2HF
19 and SO3, which then goes to sulfuric acid. But --
20 PANEL MEMBER HAMMOND: Well, I'm not sure if --
21 the question is: Which is unlike, the uptake into the
22 water -- into the cloud water or the hydrolysis?
23 PANEL MEMBER ATKINSON: Well, it's not -- the two
24 are not really -- you can't really separate them. I mean
25 the uptake into the water is clearly not very much. But

1 if hydrolysis does occur, then it essentially just moves
2 the equilibrium and the thing will go through.
3 PANEL MEMBER HAMMOND: Right.
4 CHAIRPERSON FROINES: But if you have -- if you
5 have a thermodynamic issue, that if you are getting
6 hydrolysis, then more is going to be taken up.
7 PANEL MEMBER ATKINSON: Yeah.
8 PANEL MEMBER HAMMOND: Well, and I thought that
9 it -- it doesn't have a low solubility in water I mean in
10 the first place. So --
11 PANEL MEMBER ATKINSON: Yeah. But it's Henry's
12 Law Constant is so low that the -- you can calculate that
13 the washout ratio or washout time or wet deposition time
14 is just thousands of years. But --
15 PANEL MEMBER HAMMOND: Is there any data on --
16 PANEL MEMBER ATKINSON: -- if it hydrolyzes -- if
17 it was to hydrolyze in cloud water, that would be a
18 possibility.
19 PANEL MEMBER HAMMOND: So on what basis do you
20 say that it's unlikely?
21 DR. KOLLMAN: Although it's soluble in water, it
22 doesn't hydrolyze.
23 PANEL MEMBER HAMMOND: Do we know that it doesn't
24 hydrolyze?
25 DR. KOLLMAN: Yes, we do.

1 PANEL MEMBER HAMMOND: Oh, people have done
2 experiments --
3 DR. KOLLMAN: Yes.
4 PANEL MEMBER ATKINSON: But it hydrolyze at
5 higher pH's right?
6 DR. KOLLMAN: That's correct.
7 PANEL MEMBER ATKINSON: So you'd need to do a --
8 need to look up a sort of -- pH's of typical cloud water
9 in different parts of the world. I have no idea. I
10 assume it would be slightly acidic, but that's not
11 necessarily the case.
12 CHAIRPERSON FROINES: And then you would end up
13 with HF.
14 PANEL MEMBER ATKINSON: Yeah. Well, that's not a
15 problem. I mean all the HFC -- CFC's -- sorry -- HCFC's
16 and HFC's lead to HF by exactly the same route ultimately,
17 and you get lots of it. That's not a problem.
18 CHAIRPERSON FROINES: But why do you say that?
19 PANEL MEMBER ATKINSON: Oh, there's so much HF in
20 the earth's crust that another few hundred thousand tons
21 coming down in rainwater isn't a problem. They went
22 through this --
23 CHAIRPERSON FROINES: Unless it's a person who
24 happens to be sitting underneath those thousands of
25 tons --

1 PANEL MEMBER ATKINSON: Well, you don't get it
2 all at once.
3 CHAIRPERSON FROINES: No, I know.
4 (Laughter.)
5 CHAIRPERSON FROINES: I know. It's a tough
6 situation.
7 PANEL MEMBER ATKINSON: But, you know, that is
8 probably the most likely -- at least offhand it would
9 appear the most likely loss process. But if that doesn't
10 happen, then you really are probably faced with a
11 greenhouse gas.
12 Somebody should be looking into what does happen
13 to this compound. Either you need -- in my view, either
14 the companies should be urged to look into it or some
15 agencies do it.
16 PANEL MEMBER BYUS: I mean so if it -- assuming
17 that it were a greenhouse gas at this level of use, how
18 significant is that? I mean if you make an assumption --
19 PANEL MEMBER ATKINSON: It depends upon its
20 ultimate atmospheric lifetime and it's absorption
21 intensities. There are other chemicals --
22 PANEL MEMBER BYUS: Well, a worst-case scenario,
23 what would it be?
24 PANEL MEMBER ATKINSON: I don't know.
25 PANEL MEMBER BYUS: Okay.

1 PANEL MEMBER ATKINSON: I mean they're worried
2 about other things like the -- I think there's some other
3 sulfur fluoride compounds that were in -- it was reported
4 in science a few years ago that have only, you know,
5 thousand tons a year usage. But they build up -- could
6 potentially build up over decades or centuries.
7 CHAIRPERSON FROINES: So the issue of the
8 hydrolysis is undoubtedly pH dependent?
9 PANEL MEMBER ATKINSON: Yeah, undoubtedly. Well,
10 that's already stated in the report. It does hydrolyze
11 apparently at higher pH's.
12 CHAIRPERSON FROINES: Higher pH being?
13 PANEL MEMBER ATKINSON: Somewhere up around 10,
14 if I remember.
15 PANEL MEMBER PLOPPER: What about 7.4?
16 PANEL MEMBER ATKINSON: I don't know.
17 CHAIRPERSON FROINES: Well, that's what I was
18 getting at.
19 PANEL MEMBER ATKINSON: There doesn't seem to be
20 any data.
21 CHAIRPERSON FROINES: Well, but there is the
22 presumption in the document that there is -- sulfuryl
23 fluoride does release fluoride.
24 So would you consider that a hydrolysis --
25 PANEL MEMBER ATKINSON: Yeah, I would assume it

1 would be.

2 PANEL MEMBER PLOPPER: Well, that's what it says

3 in here.

4 CHAIRPERSON FROINES: Well, let's go ahead.

5 DR. KOLLMAN: Well, this is the final slide.

6 Are there any questions?

7 PANEL MEMBER ATKINSON: We're essentially faced

8 with no knowledge whatsoever of the ultimate environmental

9 fate of this compound.

10 PANEL MEMBER PLOPPER: So if it doesn't hydrolyze

11 in a cloud, why does it hydrolyze in the respiratory

12 system? I don't know if it's the same thing, but it's --

13 that's a super-saturated environment.

14 I'm not a chemist. I'm asking this because I

15 don't know.

16 PANEL MEMBER BYUS: We know it's not that acid.

17 We know it's not pH10.

18 PANEL MEMBER LANDOLPH: No, I think there's a lot

19 of basic questions that just haven't been answered. I

20 mean there may be some enzymatic hydrolysis. There's

21 just -- it's a field which is ripe for investigation. I'm

22 kind of bothered that such a widely used chemical has such

23 a posity of data in the database on the toxicology and

24 chemistry of it around physiological pH. I think there

25 should be some recommendations to the state that this

1 matter be pursued.

2 CHAIRPERSON FROINES: Well, I think that -- I

3 mean I think this discussion is raising a clear

4 contradiction. On the one hand we have the statement that

5 hydrolysis is unlikely. But in the document we have

6 multiple statements that hydrolysis occurs readily and

7 that there are significant questions about whether the

8 fluoride ion is in fact the toxicologic main issue. So

9 there's a -- there's an issue that's cloudy at this point.

10 Pardon my pun.

11 PANEL MEMBER LANDOLPH: Yeah. I mean I agree

12 with that. As I was reading this document, I have to

13 express some skepticism -- and it's just my scientific

14 nose speaking -- that all this toxicity's due to fluoride

15 ion. I think there's something else going on. There's

16 not much discussion about the fluorosulfate ion. There's

17 not any, you know, toxicological discussion of the whole

18 molecule itself and what it might do.

19 I was a little bothered by the pulmonary edema

20 that seems to keep surfacing. And I wonder exactly what's

21 causing that, whether it's the whole molecule or an

22 enzymatic byproduct of that molecule. So there's just an

23 enormous amount we don't know about this compound.

24 PANEL MEMBER PLOPPER: It could also just be the

25 sulfuric acid and hydrogen sulfide.

1 PANEL MEMBER GLANTZ: Could you talk louder.
2 PANEL MEMBER PLOPPER: Oh, sorry.
3 It could be the -- I mean SO2 becomes -- is a
4 toxic compound on its own. Because that's the byproduct,
5 right?
6 PANEL MEMBER HAMMOND: But it doesn't cause
7 pulmonary edema.
8 PANEL MEMBER PLOPPER: Pardon?
9 PANEL MEMBER HAMMOND: But it doesn't cause
10 pulmonary edema.
11 PANEL MEMBER PLOPPER: It sure does.
12 PANEL MEMBER HAMMOND: Does it? SO2?
13 PANEL MEMBER PLOPPER: Well, it depends on --
14 PANEL MEMBER HAMMOND: Oh, at very high levels.
15 PANEL MEMBER PLOPPER: Huh?
16 PANEL MEMBER HAMMOND: At very high levels.
17 PANEL MEMBER PLOPPER: Well, if this -- all this
18 is going to convert to fluoride, then that means there's
19 going to be a lot of sulfate around. I'm not a chemist,
20 but that's my basic interpretation. And parts per million
21 will cause edema. It's very short term, but it's there.
22 It's very toxic, it's very -- it's the same type of
23 pathology pattern. So --
24 CHAIRPERSON FROINES: So I don't know if we're
25 going to get to this, but presumably if the fluorides are

1 coming off, that's a hydrolysis process. And so you're
2 going to end up with sulfate. Wouldn't you?
3 PANEL MEMBER ATKINSON: Yes.
4 CHAIRPERSON FROINES: So --
5 PANEL MEMBER PLOPPER: Doesn't that become H2SO4?
6 I mean -- again, I'm not a chemist, so I'm just -- but I
7 know that's bad stuff.
8 PANEL MEMBER LANDOLPH: And the fluorosulface ion
9 before that.
10 CHAIRPERSON FROINES: Is there any -- well, you
11 may not be the right person, but let's ask anyway. Has
12 anybody looked at the sulfate concentrations in vivo in
13 animal studies?
14 DR. KOLLMAN: That's out of my field.
15 CHAIRPERSON FROINES: Yeah, we'll get to that.
16 DPR STAFF TOXICOLOGIST LIM: Sulfate --
17 pharmacokinetic study.
18 CHAIRPERSON FROINES: I'm sorry. Will you
19 talk -- well, we can ask you questions.
20 Thank you very much. You've raised a lot of
21 interesting questions.
22 So then at least at this point we can say that
23 the data that DPR's been operating with is not sufficient.
24 PANEL MEMBER ATKINSON: Right.
25 CHAIRPERSON FROINES: At least I get three

1 nodding heads on this side. They're ignoring the issue.
2 Randy, are you next?
3 DR. COCHRAN: My name's Roger Cochran. I'm with
4 the Worker Health and Safety Branch at the Department of
5 Pesticide Regulation.
6 (Thereupon an overhead presentation was
7 Presented as follows.)
8 DR. COCHRAN: All previous toxic air contaminant
9 candidates had ambient air levels to which entire
10 communities were exposed. But because of the limited size
11 of the application sites and the limited amount of
12 sulfuryl fluoride, as Vikane, is applied on a given day,
13 the likelihood of community-wide exposure is almost
14 nonexistent. Only application site exposures are likely,
15 with the chemical gone in two to three days, except for
16 residents of the treated homes. Thus, we're assuming that
17 acute exposure is the only potential issue for bystanders.
18 --o0o--
19 DR. COCHRAN: So what is Vikane used for in
20 California? The primary registered use is as a structural
21 fumigant. Mostly this consists of residences, apartment
22 buildings and other commercial buildings.
23 "Fumigation commodity" refers to non-food,
24 non-feed commodities such as pallets, dunnage, furniture,
25 burlap bags, et cetera, like beds and mattresses.

1 "Fumigation other" refers to unspecified reported
2 use of fumigant.
3 Regulatory pest control includes any pest control
4 work performed by public employees or contractors in the
5 control of regulated pests.
6 Vertebrate pest control includes any pest --
7 vertebrate pest control performed by public agencies or
8 work under the supervision of the state or county
9 agricultural commissioner.
10 --o0o--
11 DR. COCHRAN: Where in California is sulfuryl
12 fluoride used?
13 Most building fumigations takes place in the
14 areas where you have most of the buildings located. In
15 this case, Los Angeles County. The Deputy Agricultural
16 Commissioner of Los Angeles County, who deals with
17 structural fumigations in that county, said that there
18 were approximately 120 structures fumigated each day last
19 year, at an average cost of $2,000 per fumigation. He
20 said that the vast majority of the structures fumigated
21 were involved in real estate transactions. And because
22 the real estate market seems to be as active this year as
23 last, they expect about the same number of fumigations in
24 the county this year.
25 --o0o--

1 DR. COCHRAN: Is sulfuryl fluoride used at only
2 certain times during the year? No.
3 CHAIRPERSON FROINES: Can I just interrupt with a
4 comment?
5 DR. COCHRAN: Yes.
6 CHAIRPERSON FROINES: I have -- in my house have
7 done termite -- no, I'm being serious here -- termite
8 eradication three or four times in the last 10, 15 years.
9 And so that there is a time when the real estate
10 transaction occurring and somebody's buying a house and
11 doing the terminate. But I actually think there's a fair
12 amount of people like me who tent their houses because
13 they have termite problems.
14 So I think that seeing it as strictly a real
15 estate issue may -- it may not be an accurate estimate of
16 the number of termite eradications that actually go on.
17 And I stay that not with some expertise; it's just as a
18 homeowner who's had to deal with termites. So it's an
19 interesting --
20 DR. COCHRAN: Could I ask how many times you've
21 had your home fumigated?
22 CHAIRPERSON FROINES: Probably four times. I
23 bought it, once, and then I fumigated -- I'm about to do
24 it again. So say in the time I've owned it, five times.
25 And I think that that's not uncommon in southern

1 California, because you never get rid of them. You know,
2 they just come back and come back and you -- it's a
3 constant battle.
4 DR. COCHRAN: If you're aware of any studies that
5 show that this occurs, we'd be happy to incorporate it
6 into the document.
7 CHAIRPERSON FROINES: No, I -- it was by no means
8 a criticism. It was just I noticed that I -- I noticed
9 that you focus on the real estate. And my experience was
10 a little bit different than that. And I think that that's
11 probably not inaccurate. Although I certainly -- I don't
12 think there's any numbers, because there's no reason why
13 anybody would be -- would people be reporting those?
14 DR. COCHRAN: Whether it occurs repeatedly?
15 There's a number of different alternatives too
16 that are less expensive to use. There's ways of treating
17 different types of infestations with less expense and
18 whatever. It's just -- at this point in time it's an
19 assumption that we've made. And, as I said, if you have
20 data that would indicate otherwise, we'd be happy to
21 incorporate it.
22 CHAIRPERSON FROINES: It's completely subjective.
23 PANEL MEMBER BYUS: I have one brief question
24 about the ship fumigation. It struck me -- I mean do you
25 know much about that? Because I mean ships are huge, and

1 I would imagine the amount of fumigant would be quite
2 large. And it would probably be done at the same place
3 every time. And sort of how -- so that exposure scenario
4 could be considerably different than a house. And --
5 DR. COCHRAN: The exposure scenario on a ship is
6 going to be different. Essentially what they do now when
7 they fumigate a cargo hold is they cause all of the --
8 they anchor the ship offshore. And -- it's not tied up at
9 the dock. And then the crew is evacuated from the ship.
10 PANEL MEMBER BYUS: Good.
11 (Laughter.)
12 DR. COCHRAN: And then the holds are fumigated.
13 And until the level of the fumigant is down to a level
14 that's acceptable, which is on the label, then the crew is
15 not allow back on.
16 PANEL MEMBER BYUS: How do they vent -- I mean
17 they don't actually tent a ship, do they?
18 DR. COCHRAN: They do tarp the holds.
19 PANEL MEMBER BYUS: They do? Really? Okay.
20 DR. COCHRAN: Yeah. What you're trying to do
21 is -- you're not going to keep it in there. And as I'll
22 show you later with a picture of a tent on a house, it's
23 not airtight. But it does tend to retard the material
24 from escaping so that it lasts a little bit longer and
25 performs the function it's intended to do.

1 PANEL MEMBER BYUS: Okay.
2 CHAIRPERSON FROINES: Go ahead.
3 PANEL MEMBER PLOPPER: Can I ask a question about
4 this slide?
5 DR. COCHRAN: Yes.
6 PANEL MEMBER PLOPPER: Is this all of the use or
7 is this just the use associated with Vikane?
8 DR. COCHRAN: This is the use associated with
9 Vikane.
10 PANEL MEMBER PLOPPER: Okay. So this is not all
11 the use then?
12 DR. COCHRAN: No. I'm talking strictly in my
13 presentation about the exposure from Vikane, that
14 particular formulation. We don't have the data yet for
15 the other formulation, that is --
16 PANEL MEMBER ATKINSON: This is fumigation of
17 houses --
18 DR. COCHRAN: This is fumigation -- structural
19 fumigation is what you're looking at for that particular
20 slide.
21 PANEL MEMBER PLOPPER: Just structural
22 fumigation?
23 DR. COCHRAN: Right. Because about 97 percent of
24 the Vikane use is for structural fumigation.
25 PANEL MEMBER ATKINSON: And the other 3 percent?

1 DR. COCHRAN: If you go back to the other slide,
2 it shows the other stuff in there? You can see it's
3 minuscule.
4 Next slide.
5 --o0o--
6 DR. COCHRAN: There are essentially three phases
7 of structural fumigation. There's an application phase,
8 in which the sulfuryl fluoride is piped into a tarped
9 structure and maintained for 20 hours. This is followed
10 by the aeration phase, in which the sulfuryl fluoride is
11 vented.
12 There are essentially two methods utilized for
13 venting the structure. One is the Stack plan, which
14 involves 12 hours of active ventilation through an exhaust
15 stack of unspecified diameter and height with a tarpolin
16 in place, except for a small opening on the side opposite
17 the exhaust fan so that fresher air can flow into the
18 structure.
19 The other form of aeration is the tarpolin
20 removal and aeration plan or TRAP plan. TRAP involves
21 tarpolin removal after only ten minutes of active
22 ventilation through a plastic duct, which is usually
23 secured at the roofline, followed by approximately sixty
24 minutes of active aeration. The home is then closed until
25 the following morning, at which time it is tested to see

1 if there's any remaining sulfuryl fluoride.
2 Once the sulfuryl fluoride concentration in the
3 home drops below five parts per million, the contractor
4 can certify that the home is cleared. And the last phase
5 then is the post-clearance phase.
6 --o0o--
7 DR. COCHRAN: So what does the treated structure
8 look like?
9 The structures are enclosed in tarps. And then
10 the sulfuryl fluoride, as I said, is introduced. And --
11 let me see. I think this structure is going to be
12 ventilated with the Stack plan. And this is the stack
13 here. The chimney is actually here in the back of the
14 structure. But this is the stack that's going to be used
15 for ventilating it.
16 PANEL MEMBER ATKINSON: So which is most used,
17 the Stack or TRAP method?
18 DR. COCHRAN: We're trying to get people to go to
19 the Stack method. But from the industry point of view,
20 the faster that they can turn it over, the more homes they
21 can fumigate. And so they're going to want to try to do
22 it with the TRAP method.
23 --o0o--
24 DR. COCHRAN: This is the picture of a sampling
25 station that's used by the Air Resources Board. It's

1 similar to the sampling stations referred to in the
2 exposure assessment document. Basically it consists of a
3 stand, a sampling tube -- if you hit it a couple of times.
4 There's the charcoal tube at the top. And then there's
5 the pump at the bottom. And the air pump draws the
6 ambient air through the sampling tube at a fixed rate,
7 usually about three to six liters per hour.
8 Can I have the next slide.
9 --o0o--
10 DR. COCHRAN: The air contaminated with sulfuryl
11 fluoride is drawn through a tube containing active
12 charcoal. This is what the sample tube basically looks
13 like, with an 800 milligram activated charcoal front
14 that -- stuff is coming through this, which is glass wool.
15 This is the 800 milligrams of charcoal in the front
16 portion. This is a separator frit. And this is 200
17 milligrams of the activated charcoal in the back portion,
18 and it's kept in place by this frit. So that the air is
19 flowing through the tube in this particular direction.
20 Now, if all of the sulfuryl fluoride is trapped
21 in the front charcoal, then one can be reasonably certain
22 that all of the available sulfuryl fluoride in the air
23 that's drawn through the tube has been collected.
24 However, if you find sulfuryl fluoride in the rear
25 portion, we have what is called breakthrough. And the

1 certainty that we would have that all sulfuryl fluoride
2 has been collected is gone.
3 It's possible of course to add the amount of
4 sulfuryl fluoride from the back portion to the amount in
5 the front portion. But you don't know if you captured
6 everything.
7 The total volume of air can be calculated
8 multiplying the flow rate times the time of operation. To
9 estimate the time-weighted air concentration, the amount
10 of sulfuryl fluoride extracted from the charcoal is
11 divided by the volume of air that was pumped through the
12 tube.
13 There's another technical issue that needs to be
14 considered in this monitoring. And that's in sample
15 collection, which concerns the efficiency of the
16 extraction procedure. When one extracts sulfuryl fluoride
17 from the charcoal, how can you be sure that all of the
18 sulfuryl fluoride adhered to the charcoal has been
19 extracted and measured?
20 The technique used to determine recoveries
21 involves reference samples called field spikes. A known
22 amount of sulfuryl fluoride is introduced into the sample
23 tube under field conditions and then extracted and
24 analyzed to see if the known amount is actually measured.
25 If the measured amount is less than the known amount, then

1 we look at what -- we have what is called the percent
2 recovery.
3 Can I have the next slide.
4 --o0o--
5 DR. COCHRAN: Monitoring studies were conducted
6 in order to measure the concentration of sulfuryl fluoride
7 in the application site air outside of fumigated
8 structures. The original Air Resources Board monitoring
9 study, which was done in 2002, was not acceptable because
10 there was breakthrough in more than 80 percent of the
11 sample tubes. Instead we relied on the monitoring studies
12 that were conducted by Dow Agrosciences under Good
13 Laboratory Practices procedures.
14 Next slide.
15 --o0o--
16 DR. COCHRAN: This slide shows a diagram of a
17 structure that was treated with sulfuryl fluoride. The
18 numbered circles around the structure depict the
19 monitoring stations that were set up at various distances
20 from 5 to 50 feet from the structure. Nearby structures
21 are indicated by the other boxes in the diagram.
22 Aeration was accomplished in this instance using
23 the Stack method. Now, this structure was fumigated five
24 times to give us five repetitions of the fumigation
25 procedure, plus the outgassing, et cetera. The duration

1 of each sampling period varied between one and eight
2 hours, depending upon the phase of the fumigation.
3 For purposes of this exposure assessment,
4 time-weighted averages for the highest sulfuryl fluoride
5 concentrations detected among the 24 sampling stations
6 during a given sampling period within a replicate were
7 used in estimating the bystander exposure. Airs samples
8 collected were corrected for background and an analytical
9 recovery of 83 percent.
10 We had no data on potential differences between
11 outdoor and indoor sulfuryl fluoride air concentrations
12 for bystanders. Consequently we assumed that bystanders
13 would be potentially exposed to the measured application
14 site air concentrations during all stages of the
15 fumigation procedures. Thus, acute bystander exposures
16 during the application phase were calculated using the
17 upper bound of sulfuryl fluoride concentrations and then
18 exposure duration of 12 and 24 hours, respectively.
19 As we assumed it would be unlikely a bystander
20 would be exposed to more than one fumigation per year,
21 annual exposures were based on one exposure per year. And
22 because that one exposure may be the upper bound sulfuryl
23 fluoride concentration, the annual exposures were
24 estimated using this 95th percentile of the 24-hour
25 exposure duration.

1 --o0o--

2 CHAIRPERSON FROINES: Recognizing that the ARB
3 data was problematic because of the breakthrough, when
4 you -- you still had that data. Now, I don't know how
5 serious the breakthrough was. But were the numbers that
6 you saw from the Dow study, were they in any way
7 comparable to the ARB studies? Or was the ARB studies had
8 so much breakthrough, that you couldn't use it at all?

9 DR. COCHRAN: The ARB study had about 80 percent
10 breakthrough, so you can't use it. But they have given us
11 subsequently a study from two other buildings that were
12 fumigated. We just haven't had a chance yet to analyze
13 that data. So we will be able to give you an answer to
14 that and give you the comparison, but to see if the
15 numbers are approximately the same.

16 CHAIRPERSON FROINES: That would be very
17 interesting, I think.

18 PANEL MEMBER HAMMOND: In the difference between
19 the ARB study and the Dow study, did they sample for
20 different time periods or different flow rates?

21 DR. COCHRAN: I don't remember offhand what that
22 is, as to why there was the breakthrough. It can be
23 because your flow rate is different. It can be because
24 the air concentrations --

25 PANEL MEMBER HAMMOND: Well, that's what I'm

1 asking. That's what I'm asking.
2 DR. COCHRAN: Yeah, it can be because of the air
3 concentration is greater. In other words, if the
4 structure is fumigated with a higher concentration --
5 PANEL MEMBER HAMMOND: That's exactly why I'm
6 asking the question. Because if the sampling times and
7 flow rates were comparable, then that means that the
8 breakthrough was due to the concentrations. And that's
9 very important information.
10 So I think even though there's a problem with
11 breakthrough, you don't throw that data away. Those data
12 indicate minimal levels of concentrations. They don't
13 tell you the true concentration, but they're minimal
14 levels. And I think it's very important to understand --
15 you know, to add that data to your set of data even though
16 you know that --
17 CHAIRPERSON FROINES: Yeah, that was precisely my
18 question.
19 PANEL MEMBER LANDOLPH: Yeah, I agree that.
20 They're lower bounds, and you shouldn't throw them away.
21 CHAIRPERSON FROINES: Lynn, do you want to
22 comment? Is that --
23 PANEL MEMBER HAMMOND: And since there's so
24 little data on all of this, it's very important to not
25 lose any of it.

1 CHAIRPERSON FROINES: Tobie, is that okay, if
2 Lynn --
3 ARB AIR POLLUTION SPECIALIST BAKER: Lynn Baker
4 with the Air Resources Board. I can try to help answer
5 your question, Dr. Hammond.
6 The monitoring study that we conducted in 2002
7 was at a higher flow rate than had been used by Dow in
8 their studies.
9 PANEL MEMBER HAMMOND: What was it?
10 ARB AIR POLLUTION SPECIALIST BAKER: It was I
11 think a liter a minute through tubes that were much
12 smaller. They were 400 milligrams in the front section,
13 200 milligrams in the back section at a liter a minute;
14 where the Dow studies had been done at a fraction of that.
15 PANEL MEMBER HAMMOND: Do you know what they
16 were?
17 ARB AIR POLLUTION SPECIALIST BAKER: I know they
18 were less than a half a liter a minute. I can't remember
19 exactly.
20 But also the structures that Dow had monitored
21 had an -- oh, three to six liters an hour by Dow, where we
22 had used a liter a minute. So it's a substantial
23 difference.
24 Also, though, the application rate of the
25 structures that Dow had monitored had an application rate

1 of 16 ounces of sulfuryl fluoride per thousand cubic feet.
2 The house that we monitored in 2002 application rate of 51
3 ounces per thousand cubic feet. So about a three times
4 higher application rate.
5 PANEL MEMBER HAMMOND: So that would imply that
6 the actual concentration was higher in the ARB study as
7 well.
8 ARB AIR POLLUTION SPECIALIST BAKER: I would
9 expect that it would have been higher, yes.
10 PANEL MEMBER HAMMOND: Right. So it is important
11 not to lose that data.
12 ARB AIR POLLUTION SPECIALIST BAKER: Our data was
13 invalidated because we found very little because the --
14 there was so much breakthrough, as Roger mentioned,
15 that -- 80 percent of the samples had breakthrough. And
16 we found as high as -- I can tell you here exactly. We
17 found as high as four and a half micrograms per cubic
18 meter, which was a fraction of what Dow found in their
19 samples.
20 PANEL MEMBER HAMMOND: You mean the total -- the
21 concentration?
22 ARB AIR POLLUTION SPECIALIST BAKER: The
23 concentration -- the concentration in the samples that
24 were collected around the perimeter of the house were much
25 lower. And we saw a breakthrough, as he said, in 80

1 percent of the samples.

2 Now, I don't know if you want me to expand on

3 this, but I can very briefly. Because of that problem,

4 DPR requested us to do additional work. So we did more

5 method development work and did additional studies, as Dr.

6 Cochran mentioned, last summer, and we've just recently

7 given those final reports to DPR. But in those studies,

8 instead of a liter a minute, we used a tenth of a liter a

9 minute.

10 PANEL MEMBER HAMMOND: Which was about -- that's

11 what Dow used.

12 ARB AIR POLLUTION SPECIALIST BAKER: Actually I

13 take that back. We used a twentieth. We used 50 cc's per

14 minute.

15 PANEL MEMBER HAMMOND: And the Dow rates were 50

16 to a 100 cc's per minute?

17 ARB AIR POLLUTION SPECIALIST BAKER: Yeah. And

18 we used the larger tube. We used the 800 milligram, 200

19 milligram. And during the venting period, when you would

20 expect to see the highest concentration, we had backup

21 tubes to ensure that we --

22 PANEL MEMBER HAMMOND: Behind the whole time?

23 ARB AIR POLLUTION SPECIALIST BAKER: Yes, two

24 tubes in series to ensure we wouldn't see any

25 breakthrough.

1 PANEL MEMBER HAMMOND: And You did not have
2 breakthrough?
3 ARB AIR POLLUTION SPECIALIST BAKER: No, we did
4 not have breakthrough.
5 PANEL MEMBER HAMMOND: And are those
6 concentrations included in this report though?
7 DR. COCHRAN: No, no.
8 ARB AIR POLLUTION SPECIALIST BAKER: No.
9 DR. COCHRAN: We just got the study. So --
10 ARB AIR POLLUTION SPECIALIST BAKER: You know,
11 if -- now or later if you want, I can summarize -- I don't
12 want to take --
13 CHAIRPERSON FROINES: I'll call Joe. But this is
14 clearly a very important issue. It does not, however,
15 impact our determination of the report in terms of the TAC
16 character of it. Although obviously it could affect
17 MOE's. But it may have more implications for management
18 issues than for risk assessment.
19 So we should probably go on.
20 PANEL MEMBER GLANTZ: Can I just ask one
21 question?
22 CHAIRPERSON FROINES: Well, wait. Joe was ahead
23 of you.
24 PANEL MEMBER GLANTZ: Oh, I'm sorry.
25 PANEL MEMBER LANDOLPH: You may have this data.

1 You've got a plethora of data here I'm trying to
2 understand.
3 Do you have curves showing -- if the
4 concentration is X in a house being treated, do you have
5 concentric circles showing what the concentration would be
6 at various times, so we could get a feel for how this
7 would impact neighboring houses, approximate to a
8 structure?
9 ARB AIR POLLUTION SPECIALIST BAKER: We do not
10 have the concentrations inside the house during the
11 treatment. But we do -- we did collect -- while the house
12 was treated with the tarp and then during tarp removal and
13 following tarp removal we had concentric rings of
14 samplers, north, south, east, west, at different
15 distances, from 5 feet out to 80 feet, to address both
16 very adjacent concentrations as well as the neighboring
17 house.
18 PANEL MEMBER LANDOLPH: And what are peak
19 concentrations that you might register in, say, a
20 neighboring structure? Approximate to one that's being
21 fumigated.
22 ARB AIR POLLUTION SPECIALIST BAKER: While it's
23 being vented?
24 PANEL MEMBER LANDOLPH: While it's being
25 fumigated and while it's being vented. Do you have those

1 numbers?

2 ARB AIR POLLUTION SPECIALIST BAKER: While it was

3 being fumigated, there is some leakage. But their

4 concentrations were on the order of a thousand micrograms

5 per cubic meter around the perimeter of the house. Now, I

6 don't believe -- and I can -- I wasn't prepared to bring

7 my report with me. It's over on the chair. But I don't

8 believe that we measured it out at 40 or 80 feet while the

9 structure was tarped. We did during the venting period

10 and following the venting period.

11 And then DPR also requested us -- after the

12 aeration was all done and the home had been cleared for

13 reentry, after the applicator had gone in and determined

14 that the concentration was below 5 ppm, they asked us to

15 collect two 24-hour samples inside the house for sulfuryl

16 fluoride and chloropicrin, to look at those levels.

17 PANEL MEMBER LANDOLPH: And what maximum values

18 did you get?

19 ARB AIR POLLUTION SPECIALIST BAKER: Inside the

20 house?

21 PANEL MEMBER LANDOLPH: Um-hmm, the adjacent

22 house.

23 ARB AIR POLLUTION SPECIALIST BAKER: Oh, we

24 didn't measure the adjacent house. Inside the treated

25 house. Following aeration we measured a 24-hour

1 concentration of 2400 micrograms per cubic meter. And
2 that was -- so that would be about -- hold on -- would be
3 about 600 parts per billion. So about six-tenths of a
4 ppm, which was below the 5 ppm limit.
5 And we also measured about 83 micrograms per
6 cubic meter for 24 hours for chloropicrin. But that's off
7 the subject.
8 CHAIRPERSON FROINES: Stan, did you have a
9 question?
10 PANEL MEMBER GLANTZ: Yeah. The application rate
11 that were used in the house you monitored and the one Dow
12 monitored were wildly different. And -- I mean what is
13 the more -- what is typical use?
14 ARB AIR POLLUTION SPECIALIST BAKER: Typical for
15 termites is more on the order of the level that Dow
16 treated.
17 PANEL MEMBER GLANTZ: Did you just use these very
18 high rates to try to get an upper bound or --
19 ARB AIR POLLUTION SPECIALIST BAKER: DPR
20 specially requested that we look for a home that was being
21 treated for powder post beetle where they use a higher
22 application rate.
23 PANEL MEMBER HAMMOND: So it was a real-world
24 sampling; it wasn't a test --
25 ARB AIR POLLUTION SPECIALIST BAKER: Oh, yes.

1 Oh, no, it was a real-world sampling, one in -- a home in
2 the Loomis area, which is out east of Sacramento, and then
3 in Grass Valley. Large homes. So not only a higher
4 application rate because of the powder post beetle, but
5 they were larger homes. So more material.
6 PANEL MEMBER GLANTZ: And then of the use, the --
7 I mean how typical is that? I mean is it mostly 95
8 percent termites and of 5 percent that or is there --
9 ARB AIR POLLUTION SPECIALIST BAKER: Something
10 like -- a vast majority of treatments are for termites.
11 We had trouble finding powder post beetle treatments. But
12 they do exist. But I don't know if it's a tenth.
13 DPR SENIOR ENVIRONMENTAL RESEARCH SCIENTIST
14 SEGAWA: This is Randy Segawa with the Department of
15 Pesticide Regulation.
16 Yeah, the great majority of the applications are
17 for termites down in southern California. Powder post
18 beetle is mainly a problem in northern California. But
19 even in northern California the percentage of those
20 applications are quite small.
21 CHAIRPERSON FROINES: Randy, I have a question
22 that is it a little bit of an off -- it's my impression
23 that chloropicrin is generally used now with sulfuryl
24 fluoride, that you generally don't find one without the
25 other. Is that correct? And if that's correct, what are

1 the relative proportions?

2 DPR SENIOR ENVIRONMENTAL RESEARCH SCIENTIST

3 SEGAWA: That is correct, that chloropicrin is used as a

4 warning agent for all structural fumigations. However,

5 that's not the case for the new food uses of it. But for

6 structural fumigation it's always included as a warning

7 agent. The relative amounts are very low. That is,

8 chloropicrin is probably on the order of 1 percent or so.

9 CHAIRPERSON FROINES: Oh.

10 ARB AIR POLLUTION SPECIALIST BAKER: I can tell

11 you, for example, Dr. Froines, the Grass Valley home that

12 we monitored where we measured the highest sulfuryl

13 fluoride concentrations, that home had a treatment rate

14 for sulfuryl fluoride of 40 ounces sulfuryl fluoride per

15 thousand cubic feet, for a total of 202 pounds of sulfuryl

16 fluoride. They used 6 ounces of chloropicrin.

17 CHAIRPERSON FROINES: Why is it -- I've had the

18 impression that -- and this reflects my lack of

19 knowledge -- that the percent of chloropicrin has been

20 rising. Is that faulty?

21 DR. COCHRAN: No, it's not faulty. Roger Cochran

22 again.

23 No, it's not faulty. They're looking at using

24 chloropicrin to replace methyl bromide for some

25 fumigations as well. So they're in the process of --

1 we're in the process of evaluating chloropicrin as a
2 fumigant itself.
3 CHAIRPERSON FROINES: Yeah.
4 Joe.
5 PANEL MEMBER LANDOLPH: I would find --
6 CHAIRPERSON FROINES: And then we can -- go
7 ahead.
8 PANEL MEMBER LANDOLPH: I would personally find
9 it useful to have a short section capturing the
10 discussion, the data on the ambient levels of the sulfuryl
11 fluoride in adjacent houses and all that, because I think
12 that's an issue we should just have a good grip on before
13 the documents is finalized.
14 ARB AIR POLLUTION SPECIALIST BAKER: Dr.
15 Landolph, we don't have any data on concentrations in
16 adjacent houses. We have these concentric rings that are
17 out in the direction of the adjacent homes, but no
18 concentrations in those adjacent homes.
19 PANEL MEMBER LANDOLPH: Okay. And that data I
20 think would be useful too as a surrogate.
21 CHAIRPERSON FROINES: There is information in the
22 document on that already.
23 Thanks, Lynn.
24 ARB AIR POLLUTION SPECIALIST BAKER: Okay.
25 CHAIRPERSON FROINES: That was useful. This is

1 clearly a changing issue, which is going to have lots of
2 implications over time.
3 DR. COCHRAN: Okay. The data derived from the
4 ambient air sampling during a sulfuryl fluoride structural
5 fumigation at the rate that was just indicated. The time
6 we had averaged representing the sulfuryl fluoride air
7 concentration detected among the 24 sampling devices is
8 plotted here.
9 Okay. So what we used is the 95th percentile --
10 or 95 percent confidence limit on each of these various
11 measurements from the five different samples -- or five
12 replicates that you had.
13 Could I have the next please.
14 --o0o--
15 DR. COCHRAN: The absorbed dose through the
16 inhalation route is calculated using the two formulas
17 shown on the screen. The terms are defined below. The 18
18 percent absorption retention factor comes from the data
19 derived in an inhalation pharmacokinetic study in rats.
20 This study will be discussed Dr. Lim in her presentation,
21 which is to follow.
22 Can I have the next.
23 --o0o--
24 DR. COCHRAN: Now, this is derived from
25 chemical-specific ambient air monitoring data from

1 Maxwell, California. The structural fumigations that were
2 provided by Dow Agrosciences. The study investigators
3 corrected the samples for background and an analytical
4 recovery of 83 percent, and the estimates apply to both
5 genders within a given age group.
6 The acute 12-hour absorbed daily dose was
7 estimated to be the daily sulfuryl fluoride exposure that
8 may occur during the first 12 hours of the application
9 phase, calculated using the 95th percentile of sulfuryl
10 fluoride concentration.
11 Exposure was assumed to occur during both indoor
12 and outdoor activities. And we're not differentiating
13 between the air concentrations indoors or outdoors.
14 The acute 24-hour absorbed daily dosage was
15 estimated to be that sulfuryl fluoride that may occur
16 during the entire application phase up to 24 hours a day.
17 The annual absorbed daily dosage is the estimated
18 daily dosage that results from bystander exposure during
19 outdoor activities amortized for one year. And this is
20 from the 24-hour ADD divided by 365 days.
21 --o0o--
22 DR. COCHRAN: But because the Dow-monitored study
23 was performed at the industry's standard application rate,
24 a factor of ten-fold was added to the air concentrations
25 reported to approximate the exposure that could occur at

1 the maximum rate that is legal on the label.
2 The maximum label rate may be used to control
3 structural pests other than termites, as you heard, like
4 powder post beetles. So as a consequence, when we're
5 talking about the exposures, we're looking at what the
6 label allows, and we're assuming that there is a linear
7 relationship between the amount used and the amount of
8 exposure that there will be.
9 PANEL MEMBER GLANTZ: Are the differences that
10 you have with age just reflecting differences in breathing
11 rates?
12 DR. COCHRAN: Breathing rates and body weights.
13 PANEL MEMBER GLANTZ: Okay. Good.
14 DR. COCHRAN: We have a standard assumption on
15 that. And there's a memorandum of understanding between
16 Worker Health and Safety and Medical Toxicology as to what
17 those standard measurements are, so that we're all on the
18 same page.
19 Can I have the next slide.
20 --o0o--
21 DR. COCHRAN: The highest sulfuryl fluoride air
22 concentration's detected during Stack aeration were used
23 to calculate the 95th percentile and average sulfuryl
24 fluoride air concentrations to which bystanders may be
25 exposed during the aeration procedure.

1 As opposed to application phase, the highest air
2 concentrations of sulfuryl fluoride during aeration
3 occurred at 1 hour, and at 4 hours.
4 The acute one-hour ADD absorbed dose is the daily
5 sulfuryl fluoride exposure during the first hour of
6 aeration using the Stack method. A one-hour exposure
7 duration in default breathing rates and body weights were
8 used to get the absorbed dose.
9 The acute four-hour absorbed daily dosage is that
10 which occurs during the first four hours of aeration using
11 the Stack method.
12 And these were the two highest exposures that we
13 saw. And, again, the annual ADD is estimated based on the
14 four-hour exposure multiplied by one day divided by 365
15 days.
16 --o0o--
17 DR. COCHRAN: As noted before, the ADDs had to be
18 adjusted to represent potential exposures that could occur
19 at the maximum label-approved application rates. So these
20 are the ones that we used for -- as the exposures.
21 --o0o--
22 DR. COCHRAN: This slide shows a diagram of a
23 structure that was treated with sulfuryl fluoride in
24 Rancho Cordova. As before, the numbered circles around
25 this structure depict the monitoring stations that were

1 set up at various distances from the fumigated structure.
2 In this case, aeration was accomplished using the
3 tarpolin removal and aeration plan, TRAP plan.
4 This study involved two replicate fumigations,
5 performed at one unfurnished home in Rancho Cordova in May
6 of 1999. The application site data collected at the
7 monitoring stations around this Rancho Cordova home were
8 not used to estimate the upper bound and average bystander
9 exposures in the present assessment because only two
10 replicates were performed and we couldn't estimate the 95
11 percent upper bound.
12 Next slide.
13 --o0o--
14 DR. COCHRAN: The data from phase 1 aeration by
15 the TRAP indicated that after the 1st two hours of
16 aeration sulfuryl fluoride was no longer detectable in
17 ambient air samples collected. Therefore, the duration of
18 bystander exposure during TRAP aeration would be assumed
19 to be two hours for the exposures estimated.
20 In lieu of using the data from the application
21 site monitoring stations, we use surrogate air
22 concentrations derived from those measured during worker
23 general detarping activities in an earlier study. These
24 values were used as surrogates for bystander exposure
25 during the TRAP aeration. A separate set of exposures

1 were not generated for the application phase, as the air
2 concentrations are expected to be the same as those in a
3 Stack plan model, regardless of which method is used
4 afterwards.
5 --o0o--
6 DR. COCHRAN: This table presents the bystander
7 exposures calculated at the maximal application rates
8 during TRAP aeration. The acute two-hour ADD is the daily
9 sulfuryl fluoride exposure that may occur during the 1st
10 two hours of aeration and is calculated from the 95th
11 percentile of sulfuryl fluoride concentrations as measured
12 from the personal air monitoring done during the general
13 detarping. This value was used since it was the greatest
14 sulfuryl fluoride air level measured. And the bystander
15 exposure level should not exceed that of the greatest
16 level experienced by fumigation workers.
17 The exposure -- yeah.
18 CHAIRPERSON FROINES: I'm sorry.
19 In the work that Lynn and his colleagues are
20 doing or have done, are they looking at both Stack and
21 TRAP?
22 DR. COCHRAN: No, they're just -- the new study
23 that they've done is the TRAP removal.
24 CHAIRPERSON FROINES: It's the TRAP. Because
25 these numbers are relatively high, and so that's a matter

1 of some concern, I think.
2 DR. COCHRAN: Yes, which is one of the reasons
3 why we asked them to do the study.
4 PANEL MEMBER BYUS: I have a stupid question.
5 What about when the wind blows? I mean how do
6 you control for that? I mean it seems to me if the wind
7 was blowing, depending on which way it was blowing, it
8 would be diluted relatively quickly, but then it would
9 make more -- as opposed to no wind at all, it might take a
10 lot longer to --
11 DR. COCHRAN: That's a very good question. And
12 as regulators, we're faced with some difficulty. We can't
13 say which way the wind is going to be blowing. So we have
14 to assume that the highest air concentrations that we're
15 measuring -- and they're probably downwind, because
16 there's always air moving, you're going to have to use
17 those values; because it could go to the bystanders, I
18 mean if they happen to be in that direction.
19 So although there will be a bias in your sampling
20 procedure, because we have a number of different
21 replicates -- again, we're always using the highest air
22 concentration that we're monitoring and we're assuming
23 that bystanders could be in that direction. But your
24 question is correct.
25 PANEL MEMBER BYUS: Unless of course it was like

1 a Santa Ana wind blowing, in which case it would all get
2 blown away before you could monitor it.
3 CHAIRPERSON FROINES: In Los Angeles of course
4 you have the daytime western flow. But at night you have
5 an offshore flow. So that what's downwind in the daytime
6 is going to be upwind at night. So that its not quite as
7 simple as -- it's not just a Santa Ana issue. It's
8 essentially a daily occurrence.
9 DR. COCHRAN: Well, that's for the people that
10 live over near UCLA. But if you're in the San Fernando
11 Valley, you don't get that.
12 PANEL MEMBER HAMMOND: Well, you get a
13 different -- they have a different kind of wind pattern
14 that changes through the day.
15 DR. COCHRAN: That's right, right.
16 PANEL MEMBER HAMMOND: I mean it's not the same,
17 but it's a different one.
18 DR. COCHRAN: But it's different.
19 PANEL MEMBER HAMMOND: But it does change; it's
20 not the same. There's not one predominant wind direction.
21 DR. COCHRAN: Right. But what we're doing here
22 is we're trying not to assume that people are going to get
23 a break. We're trying to look at what the worst case
24 situation is.
25 PANEL MEMBER HAMMOND: And hopefully that means

1 that you're keeping track of what the winds -- I mean we
2 care about what the winds are when you're monitoring,
3 right.
4 ARB AIR POLLUTION SPECIALIST BAKER: I was just
5 going to add -- Lynn Baker again. I was just going to add
6 that we collected on-site meteorological data during our
7 two studies, which were -- both houses were of the TRAP
8 method. And the winds during the venting -- during the
9 venting and tarp removal were relatively light. And we
10 ensured that we did have samplers downwind.
11 PANEL MEMBER BYUS: That's great.
12 PANEL MEMBER ATKINSON: Are there any conditions
13 when they don't fumigate houses? I mean any
14 meteorological conditions that stop them from doing it?
15 DPR SENIOR ENVIRONMENTAL RESEARCH SCIENTIST
16 SEGAWA: I'm not sure if there are any label requirements.
17 But I do know in high winds it's difficult to get the
18 tarps in place. And so they won't do it for that reason.
19 PANEL MEMBER ATKINSON: What about rain? Any
20 effect on rain apart from the miserable job of putting the
21 tarps up?
22 DPR SENIOR ENVIRONMENTAL RESEARCH SCIENTIST
23 SEGAWA: I don't think so.
24 CHAIRPERSON FROINES: But ARB wouldn't monitor
25 during rain.

1 ARB AIR POLLUTION SPECIALIST BAKER: We didn't
2 monitor during rain, no.
3 PANEL MEMBER PLOPPER: I have a question.
4 Could you define what you mean by a bystander?
5 If you don't know what the concentrations are distances
6 away from these houses, what is a bystander then?
7 DR. COCHRAN: There's no requirement on this, as
8 far as I know, with the state as to how far buildings can
9 be apart. It changes with jurisdiction. And some places
10 you have trouble walking sideways between buildings. So I
11 mean how -- what is a bystander? If you happen to be in
12 the house that's right next door and there's only about
13 six inches between your building and their building,
14 you're still getting exposed or there's the potential to
15 be exposed.
16 And it's true, I mean we're making the assumption
17 that there's no different between indoor and outdoor air
18 concentrations. I know of only one study in which
19 something like that was measured. And that was done some
20 years ago by my colleague here. And they looked at
21 malathion concentrations outdoors and indoors while there
22 was spraying going on. There was about a four-fold
23 difference between indoor and outdoor air concentrations.
24 PANEL MEMBER ATKINSON: Yeah, it probably
25 wouldn't apply for something like sulfuryl fluoride, which

1 is, you know, clearly gaseous. I mean if you look at
2 things like ozone, there's only a difference of about 50
3 percent indoors versus outdoors particles viewed as being
4 the same indoors and outdoors just due for --
5 DR. COCHRAN: Right, so we're not using it as --
6 PANEL MEMBER ATKINSON: So I would expect you'd
7 have pretty well the same concentration of the compound
8 indoors as outdoors, unless they're using an
9 airconditioning system tightly sealed up.
10 DR. COCHRAN: I think that's a good point.
11 CHAIRPERSON FROINES: I have trouble with the
12 term "bystander," which it sounds like you do too. It
13 seems like there should be another term one could use,
14 like "members of the public" or something like --
15 PANEL MEMBER PLOPPER: Just needs to be defined
16 what it is. I mean is that somebody standing outside the
17 building or two blocks away or --
18 DR. COCHRAN: I think it is defined in the
19 document. But we'll check to make sure that --
20 CHAIRPERSON FROINES: No, no, I'm not quarreling
21 with that. It's a term that gets used -- I've seen it in
22 other documents not relating to pesticides. I've always
23 had trouble with the word "bystander" as though it's
24 somebody who accidentally happens to be standing there as
25 opposed to somebody who lives next door, who is not

1 obviously a bystander, who's a --

2 PANEL MEMBER HAMMOND: Like a neighbor.

3 (Laughter.)

4 CHAIRPERSON FROINES: A neighbor, right.

5 Anyway, don't get sidetracked.

6 PANEL MEMBER GLANTZ: I just have one very

7 parochial question. And I live in San Francisco where the

8 houses are butted right up against each other. How do you

9 apply this stuff in a situation like that, where you can't

10 completely cover the house?

11 DPR SENIOR ENVIRONMENTAL RESEARCH SCIENTIST

12 SEGAWA: For structures that cannot be tarped or are too

13 large to be tarped, they have a method that they call tarp

14 and spot -- tape and seal, where they put plastic and tape

15 around all the doors and windows and seal up all the vents

16 and then fumigate.

17 CHAIRPERSON FROINES: Let's go ahead.

18 DR. COCHRAN: Okay. Next slide.

19 --o0o--

20 DR. COCHRAN: Finally, for non-worker bystanders

21 proximal to non-food commodity fumigation sites, exposure

22 may occur during the application and aeration phases of

23 the fumigation. From the use reporting data I showed you

24 earlier, you can tell that sulfuryl fluoride is not

25 commonly used to fumigate non-food commodities.

1 Therefore, only acute and annual exposures were assessed
2 for bystanders during a non-food commodity fumigation.
3 Because no air monitoring data were available,
4 bystander exposure was estimated assuming a maximum
5 ambient air level of 5 ppm, which is what's allowed on the
6 label. For short-term exposures an upper bound was
7 estimated by assuming that indoor air levels are equal to
8 outdoor air levels and that an individual could be exposed
9 for 24 hours. The annual exposure assumes that there is
10 one exposure per year. As the pesticide use data
11 indicate, that it's not likely again that you're going to
12 see more than that.
13 --o0o--
14 DR. COCHRAN: And, finally, these are the various
15 areas of uncertainty in the estimate of the exposure.
16 There are those technical issues that I discussed earlier
17 concerning the monitoring data. And we have a lack of
18 monitoring data associated with the maximum label approved
19 use of sulfuryl fluoride, so we're having to make the
20 assumption that we have a linear relationship between the
21 amount used and the exposure level.
22 And as people on the panel have indicated
23 repeatedly, that we don't have any data on the differences
24 or potential differences between indoor and outdoor air
25 levels, and we don't have any real data on the movement of

1 the sulfuryl fluoride as a plume off of the site.
2 Are there any questions that the panel would care
3 to ask?
4 PANEL MEMBER BYUS: I just have one comment.
5 It's always -- It's interesting -- I mean you do
6 a nice job in this part of the document on application
7 rates. And applicators, do they just -- I'm a
8 pharmacologist, so I'm always interested in the doses.
9 When they decide to dose a house, do they calculate the
10 volume of it first? Is that when they -- they measure in
11 and calculate the volume and then they use -- multiply
12 that out and that's how they decide how many pounds to
13 apply?
14 DPR SENIOR ENVIRONMENTAL RESEARCH SCIENTIST
15 SEGAWA: Correct. And actually, in the case of sulfuryl
16 fluoride, it's quite a sophisticated method to calculate
17 the correct dosage, not only the volume which they
18 measure, but they also varied the application rate with
19 the type of house, whether it's a slab or foundation, the
20 temperature, how well the tarps are sealing the building.
21 And so there are a number of different factors that go
22 into the dosage.
23 PANEL MEMBER BYUS: And you do a nice job. You
24 do discuss that in the document. And I think that's
25 important.

1 And the other thing you state that's worth
2 mentioning is that since this is a fairly expensive thing,
3 they don't -- they're careful not to apply too much,
4 because it -- not that they don't care, but it does cost
5 them a lot of money. So they're going to only put what
6 minimum amount that is going to do the job, unless there's
7 a mistake, which is always a possibility.
8 CHAIRPERSON FROINES: Okay. Thanks Roger.
9 That's very good.
10 As long as we're making -- are you the next
11 speaker, Randy?
12 DPR SENIOR ENVIRONMENTAL RESEARCH SCIENTIST
13 SEGAWA: Dr. Lim will be the next speaker.
14 CHAIRPERSON FROINES: I just wanted to put on the
15 record officially, formally that Maryann Warmerdam, the
16 Director of DPR, is here attending the meeting. I'm very
17 pleased that she's here to see how this process actually
18 goes on. And hopefully it will help as we proceed in the
19 future.
20 Welcome.
21 (Thereupon an overhead presentation was
22 Presented as follows.)
23 DPR STAFF TOXICOLOGIST LIM: Thank you.
24 I'm Lori Lim. I'm with the Medical Toxicology
25 Branch. And I'm the author of the Executive Summary and

1 the Risk Assessment portion of the document.

2 --o0o--

3 CHAIRPERSON FROINES: Do you want to take a

4 break?

5 Let's take a five-minute break.

6 (Thereupon a recess was taken.)

7 CHAIRPERSON FROINES: Can we get started

8 following our five-minute break.

9 PANEL MEMBER GLANTZ: It all depends on how fast

10 you move.

11 CHAIRPERSON FROINES: It's an Einstein relativity

12 issue.

13 Lori, just -- well, let's wait. We have --

14 Charlie and Joe are out of the room.

15 PANEL MEMBER GLANTZ: And Kathy.

16 CHAIRPERSON FROINES: Oh, yeah.

17 Tobie, during the break Joe Landolph and Charlie

18 Plopper raised questions about the bystander -- the

19 exposure issue. And so I want to move ahead into the risk

20 assessment. But we'll come back to that later, because I

21 think they have some issues that they want to raise,

22 really for clarification rather than anything else.

23 We didn't tell jokes, Kathy, while we were

24 waiting.

25 PANEL MEMBER HAMMOND: I didn't know you were

1 waiting for me.

2 CHAIRPERSON FROINES: Lori, go ahead, please.

3 DPR STAFF TOXICOLOGIST LIM: Okay. This slide

4 lists the drafts and the external review of the risk

5 characterization document, RCD. This RCD is more complex

6 than previous TAC documents because it was written to meet

7 mandates of both SB 950 to address both occupational and

8 general population exposures, and AB 1807 to address

9 ambient air exposures.

10 The first draft dated March 2004 was sent to

11 OEHHA and ARB for comments. The DPR responses to their

12 comments are included in Volume IV of this current draft.

13 An August 2004 draft was sent to the SRP, ARB and

14 OEHHA; and as well as presenting at the DPR's Pesticide

15 Registration Evaluation Committee meeting and posted for

16 public comments.

17 OEHHA provided draft findings based on the

18 content of their draft.

19 The SRP leads, Dr. Byus and Dr. Atkinson provided

20 us comments on the August 2004 draft. Their review

21 resulted in an April 2005 draft. And after we made

22 additional changes, the final draft was completed and

23 stated June 2005 and is now being presented at this

24 meeting.

25 --o0o--

1 DPR STAFF TOXICOLOGIST LIM: Before I get into
2 the specifics about sulfuryl fluoride, I want to give an
3 overview of the risk assessment process and define some of
4 the terms which I'll be using in this presentation.
5 The process starts with a question regarding
6 toxicity and exposure. What is the toxicity of the
7 pesticide? This is answered by reviewing the toxicology
8 studies to determine the toxicity endpoints of concern.
9 We use both published and registrant submitted studies.
10 In this review we also seek answers to the question on how
11 toxic is the compound. This is established by doing
12 dose-response analysis of the data.
13 For exposure, the question is: What is the human
14 exposure? The main divisions are the workers and the
15 general population. As shown in Dr. Cochran's
16 presentation, these two groups are further subdivided
17 according to the age and exposure scenario.
18 These then lead to the question of: What is the
19 risk of human health from exposure to the pesticide? We
20 take into consideration the data on toxicity and exposure,
21 as well as uncertainties and limitations of these data to
22 come up with quantitative risk estimates.
23 At the conclusion of this process,
24 recommendations are made to the risk management whether
25 exposures need to be mitigated or not. For AB 1807 the

1 recommendation would include consideration about TAC
2 listing.
3 In the next few sides, I will go over the steps
4 on hazard identification, dose response assessment, and
5 risk characterization in more details.
6 --o0o--
7 DPR STAFF TOXICOLOGIST LIM: When we reviewed the
8 toxicology studies for hazard identification,
9 no-observed-effect levels, or NOELs, for treatment related
10 effects are identified for each study. This is presented
11 in the toxicology profile of the risk assessment document.
12 This step is tied in with the dose response
13 assessment where we figure out the relationship between
14 dose, response, and the duration of exposure. Out of this
15 assessment is a determination of the critical NOELs and
16 endpoints. The critical NOEL is generally the lowest NOEL
17 of all available toxicology studies which did not cause
18 any treatment-related effect for the duration of concern.
19 Sometimes the lowest NOEL is rejected because of problems
20 with the study. The critical NOEL would protect humans
21 from effects at higher doses for the same duration of
22 exposure.
23 One way to visualize this process is in terms of
24 a sieve as shown in this slide, where 300 ppm is selected
25 as the critical NOEL. The study with the critical NOEL is

1 referred to as the critical study or the definitive study.
2 This critical NOEL is used for two calculations
3 to quantify the risk: Reference concentration and margin
4 of exposure.
5 --o0o--
6 DPR STAFF TOXICOLOGIST LIM: The reference
7 concentration is the human exposure which should not be
8 exceeded. It takes into account the differences in intake
9 due to differences in inhalation rate between laboratory
10 animals and humans, as well as between age groups in a
11 population. For the latter case, infants have the highest
12 inhalation per body weight, and would result in the lowest
13 reference concentration.
14 It also incorporates uncertainty factors to
15 account for uncertainties and limitations in the database.
16 And this will be discussed further in the next slide.
17 --o0o--
18 DPR STAFF TOXICOLOGIST LIM: This slide lists the
19 three types of uncertainty factors used in the risk
20 assessment. Each of the factor reduces the NOEL, with a
21 default being a ten-fold factor.
22 First is the factor to account for the
23 intraspecies variations between human individuals. This
24 includes differences in response, which may be due to
25 factors such as age, gender, genetic disposition and

1 health and nutritional status.

2 Interspecies factor is used when there is

3 extrapolation data from laboratory animals to humans.

4 This essentially assumes that humans are more sensitive

5 than the most sensitive laboratory animal to the effects

6 of a chemical. The default ten-fold factor may be further

7 subdivided into a three-fold factor for pharmacokinetic

8 and a three-fold factor for pharmacodynamic differences

9 between species.

10 A third uncertainty factor is used when a

11 required study has not been conducted, or a toxicity

12 concern not addressed in the existing database. One

13 example is the lack of a developmental neurotoxicity study

14 for chemicals which cause neurotoxicity.

15 CHAIRPERSON FROINES: Lori, can I ask you one

16 question?

17 DPR STAFF TOXICOLOGIST LIM: Yes.

18 CHAIRPERSON FROINES: The estimate of 18 percent

19 that you used in your document, there's a paragraph where

20 you talk about using a ten-fold safety factor to address

21 the uncertainties in that 18 percent value. Is that the

22 interspecies -- is that uncertainty factor that you've

23 referred in the document the ten-fold interspecies docu --

24 DPR STAFF TOXICOLOGIST LIM: That's in addition

25 to the adjustment for the absorption. We're talking about

1 the ten -- the interspecies ten-fold is taking care of age
2 and gender, whatever that we don't know. That's in
3 addition to it. And that 18 -- I'll talk about the
4 18-percent factor much more later.
5 CHAIRPERSON FROINES: Okay. Go head.
6 --o0o--
7 DPR STAFF TOXICOLOGIST LIM: These are the
8 equations to calculation the reference concentration. The
9 first equation converts the NOEL usually from an animal
10 study to a human equivalent NOEL. That is, we ask them
11 the question: What would be the air concentration when
12 inhaled by humans to get the same dose, given the
13 differences in inhalation rates? This value is amortized
14 for 24 hours so that the RfC is a 24-hour time-weighted
15 average.
16 PANEL MEMBER GLANTZ: If I -- You used this
17 equation in the -- I don't remember if it was the
18 executive summary, but the beginning of the document where
19 you have a typical calculation. And I think you need to
20 put this in there, because I was sort of guessing what the
21 numbers were.
22 I think the other thing that I guessed was the
23 conversion between parts per million and mass per unit
24 volume. So I think it would just -- I kind of got stuck
25 there till I puzzled it out. You should include that.

1 Do you know the place I'm talking about?
2 DPR STAFF TOXICOLOGIST LIM: Yes, it is in the
3 technical summary,
4 PANEL MEMBER GLANTZ: Yes.
5 DPR STAFF TOXICOLOGIST LIM: Yeah.
6 I have provided actual calculations in the
7 appendix, but I could move it forward, cut and paste -- I
8 mean copy and paste.
9 The second equation then applies -- oh, the last
10 term on number of days is not used for a single day
11 exposure.
12 The second equation then applies the uncertainty
13 factors to the human equivalent NOEL to derive the
14 reference concentration. This could range from a ten-fold
15 when a human study is used to a thousand-fold when an
16 animal study's used and there's a missing required study.
17 --o0o--
18 DPR STAFF TOXICOLOGIST LIM: The critical NOEL
19 and the reference concentration are used to quantify the
20 risk of human exposure to the chemical. This risk can be
21 expressed in two ways: As a percentage of the reference
22 concentration or by a margin of exposure.
23 --o0o--
24 DPR STAFF TOXICOLOGIST LIM: The first equation
25 expresses the risk of human exposure as a percent of the

1 reference concentration. Both the exposure and RfC terms
2 are in ppm's.
3 In the second equation a margin of exposure is
4 calculated, is in the equation. When the human exposure
5 is expressed as an absorbed dose, the NOEL is also
6 converted to an absorbed dose. And I'll get into
7 absorption factor effect on this equation later.
8 PANEL MEMBER BYUS: So in a sense the -- pardon,
9 just to clarify -- the absorbed dose only -- the
10 absorption -- the percent absorption number only affects
11 the margin of exposure, not the reference concentration;
12 is that correct?
13 DPR STAFF TOXICOLOGIST LIM: Precisely.
14 PANEL MEMBER BYUS: Everybody understand that?
15 So that really the other --
16 PANEL MEMBER HAMMOND: What? Say that again
17 please.
18 PANEL MEMBER BYUS: Why don't you say it, Lori.
19 DPR STAFF TOXICOLOGIST LIM: And you can see that
20 in the reference concentration we used in only the air
21 concentration. Whereas in a margin of exposure we put in
22 the absorption factor. That's only if the human exposure
23 term is expressed as absorbed. If it's not expressed as
24 absorbed, then we will not adjust the NOEL as absorbed.
25 So we're just trying to get it to be equal in the same

1 term.

2 So the absorption factor only affects the margin

3 of exposure calculation in the sense that we put it there.

4 Is that clear?

5 PANEL MEMBER ATKINSON: Well, surely, doesn't

6 that affect the reference compound as well? If it's taken

7 from a rat model and humans are being exposed, if there's

8 any difference in the absorption factor between the two

9 species.

10 DPR STAFF TOXICOLOGIST LIM: Oh, definitely. I

11 will talk about that later. But generally the reference

12 concentration is an air concentration expression.

13 CHAIRPERSON FROINES: But it doesn't affect the

14 MOE, Roger.

15 DPR STAFF TOXICOLOGIST LIM: Right.

16 PANEL MEMBER ATKINSON: I know.

17 CHAIRPERSON FROINES: Because you assume similar

18 absorption too -- they assume similar absorption.

19 PANEL MEMBER ATKINSON: Right.

20 DPR STAFF TOXICOLOGIST LIM: Yeah.

21 Okay. These two terms --

22 PANEL MEMBER BYUS: Sorry. That's all right. Go

23 ahead.

24 DPR STAFF TOXICOLOGIST LIM: These two terms are

25 related. When a human exposure is at 100 percent of the

1 RfC, the MOE is equal to the total uncertainty factor used
2 to calculate the RfC. And I have an example of math here
3 on this slide.
4 --o0o--
5 DPR STAFF TOXICOLOGIST LIM: This slide shows
6 that if we assume that an infant exposure is at 0.12 ppm,
7 which is the RfC, then taking it to -- express it in terms
8 of milligram per kilogram per day using a default
9 inhalation rate of 0.59 cubic meters per kilogram per day,
10 that would result in an exposure dose of 0.30 milligram
11 per kilogram per day. And you divide -- you're taking the
12 NOEL of 300 milligram per kilogram per day, divide that by
13 the human exposure, you would get the 1,000. So this does
14 show that the math works out. So if the exposure had to
15 be in 50 percent of the RfC, then the MOE would be 2,000.
16 --o0o--
17 DPR STAFF TOXICOLOGIST LIM: This slide, with a
18 backward number line and not to scale, illustrates where
19 different levels are in terms of the NOEL, reference
20 concentration, and the listing criterion. An animal NOEL
21 of 300 ppm, on the far left, is equivalent to a human
22 equivalent NOEL of 122 ppm for infants. This is adjusting
23 for only inhalation rate between the animals and humans.
24 When a 1,000 uncertainty factor is applied, it results in
25 0.12 ppm as a reference concentration. Taking it ten-fold

1 lower the list criterion is now at 0.012 ppm.

2 --o0o--

3 DPR STAFF TOXICOLOGIST LIM: This slide shows the

4 major section of volume 1, the health risk assessment,

5 where the questions from the risk assessment process are

6 addressed.

7 CHAIRPERSON FROINES: I should say just

8 parenthetically that some years ago we had a workshop on

9 these kinds of issues. And Dale Hattis from Clark

10 University presented data, as well as some other people,

11 and their -- they determined that sometimes our use of

12 ten-fold safety factors is not adequate. So it's actually

13 an open question that still is in the research rather than

14 regulatory context.

15 DPR STAFF TOXICOLOGIST LIM: The hazard

16 identification and dose response assessment in Sections

17 III and IV. Risk estimates are presented in IV.C of other

18 volume.

19 --o0o--

20 CHAIRPERSON FROINES: I'm sorry. I brought that

21 up because I wanted -- because there were so many

22 important issues in the workshop on these kinds of risk

23 assessment estimates. I think, Jim, that transcript from

24 that meeting would be available for DPR to take a look at.

25 Because it was a very, very important meeting in terms of

1 looking at some of the assumptions that go into these risk
2 assessment calculations. So you might find it useful
3 sometime.
4 Sorry. Go ahead.
5 DPR STAFF TOXICOLOGIST LIM: This slide
6 highlights in red the areas which pertain to AB 1807
7 looking at the exposure of the bystanders. And they're
8 the focus of the rest of my talk.
9 I will first summarize the findings from the
10 toxicity studies in the toxicology profile. Then I will
11 present the risk assessment for bystanders.
12 --o0o--
13 DPR STAFF TOXICOLOGIST LIM: What is the toxicity
14 of sulfuryl fluoride? The database -- that we have
15 limited -- consists primarily of toxicology studies with
16 laboratory animals exposed to sulfuryl fluoride by
17 inhalation.
18 In 2002 U.S. EPA made a decision to require a
19 developmental neurotoxicity study, but later waived this
20 requirement when the registrant accepted an additional
21 uncertainty factor of ten-fold instead of conducting the
22 study. So in this risk assessment the factor is included
23 in the determination of the reference concentration and
24 the MOE for the general population.
25 There were reports of human toxicity to sulfuryl

1 fluoride due to intentional and accidental exposures when
2 the house was tented for fumigation or when the treated
3 house was not aerated sufficiently.
4 CHAIRPERSON FROINES: Is it common for EPA to do
5 that?
6 DPR STAFF TOXICOLOGIST LIM: This is the first
7 case.
8 CHAIRPERSON FROINES: That's a -- that's a -- to
9 say, "Don't do the study, just throw in a factor of 10"?
10 DPR STAFF TOXICOLOGIST LIM: This is the first
11 one that I know of.
12 CHAIRPERSON FROINES: Boy, it's a little
13 shocking, isn't it, when you think about it, because it's
14 so --
15 PANEL MEMBER HAMMOND: Well, especially because I
16 think some of those accidental exposures had neurotox
17 effects, right?
18 CHAIRPERSON FROINES: It would seem like a
19 developmental neurotox study would be very useful.
20 Tobie.
21 DPR ASSISTANT DIRECTOR JONES: This is Tobie
22 Jones. I just want to comment.
23 I think -- my toxicology staff may correct me,
24 but I think the whole issue of EPA requiring developmental
25 neurotoxicity studies came out of the Food Quality

1 Protection Act of 1996. And so I think, as Lori explained
2 in this case, if a registrant chooses not to develop that
3 study, then the Agency applies an additional ten-fold
4 safety factor.
5 So I think -- it's a trade-off. But the
6 developmental neurotoxicity studies as a regulatory
7 requirement is a relatively new issue.
8 CHAIRPERSON FROINES: That's interesting.
9 Well, I think Kathy's point's very well taken. I
10 mean to the degree that there is evidence of
11 neurotoxicity, then you would like to see one.
12 DPR STAFF TOXICOLOGIST LIM: Yes, I would like to
13 see one definitely.
14 (Laughter.)
15 DPR STAFF TOXICOLOGIST LIM: Okay. There reports
16 of -- oh, I already did that. Let's see.
17 Study on workers involved in fumigation
18 procedures suggest that some -- suggested neurological
19 deficits. Unfortunately some workers in these studies
20 were also exposed to methyl bromide, another neurotoxic
21 fumigant, and their exposure to sulfuryl fluoride were not
22 quantified.
23 --o0o--
24 DPR STAFF TOXICOLOGIST LIM: In answer to the
25 question of what is the toxicity of sulfuryl fluoride, the

1 first type of study we looked at is the pharmacokinetic
2 study. There is only one pharmacokinetic study which was
3 conducted in rats exposed to S35 sulfuryl fluoride by
4 nose-only inhalation for four hours. When the rate of
5 activity was measured seven days after exposure, the
6 respiratory tract contained the highest level of
7 radioactivity, with lower levels in the spleen, kidneys,
8 brain and other tissues.
9 Fluoride, as the primary metabolite, were
10 measured only in the plasma, kidney, brain and urine.
11 Fluoride levels in these tissues returned to background
12 levels after exposure. Fluorosulfate as an intermediate
13 was also measured in the urine and blood. Sulfate was
14 also detected. And the levels of these metabolites are on
15 Table 2, page 26 of the document.
16 The primary route of excretion was via the urine,
17 with some small amount in the feces.
18 The sum of radioactivity in the tissues at the
19 end of seven days and the cumulative excretion of
20 radioactivity in the urine and feces over the same
21 seven-day period was added to a total of 18 percent of the
22 administered dose. This is considered the absorption
23 factor and used to estimate the human absorbed doses in
24 the exposure assessment. The uncertainty associated with
25 the use of this factor will be discussed further in this

1 presentation.

2 --o0o--

3 DPR STAFF TOXICOLOGIST LIM: The toxicology

4 database for sulfuryl fluoride showed three major target

5 organs:

6 The Brain. Clinical signs were observed after

7 acute and one to two weeks exposure at concentration of

8 greater -- equal to or greater than 300 ppm. And these

9 signs included tremors, lethargy, convulsion,

10 hyperactivity, and motor incoordination.

11 Histologically, one striking finding is the

12 vacuoles, a clear area in the cerebrum of all the species

13 tested, the rats, mice, rabbits and dogs, after repeated

14 exposure to a concentration generally less than 300 ppm

15 for two weeks or longer. The cause and consequence of

16 these vacuoles are unknown.

17 A second target organ is the respiratory tract

18 where inflammation and alveolar macrophage aggregates were

19 observed in lungs of rats and dogs after chronic exposure.

20 These could be a result of chronic irritation.

21 Epithelial hyperplasia of the nasal tissues were

22 reported in the rats and rabbits, again with repeated

23 exposure.

24 As a result of exposure to fluoride, dental

25 fluorosis was absorbed in animals after repeated

1 exposures.

2 Other effects involving the kidney, including

3 hyperplasia and degeneration and glomerulonephropathy, as

4 well as thyroid epithelial hypertrophy and body weight

5 reductions.

6 --o0o--

7 DPR STAFF TOXICOLOGIST LIM: This slide shows a

8 picture of the vacuoles found in brain tissue of rats

9 exposed to sulfuryl fluoride for 13 weeks. The vacuoles

10 were localized primarily in the basal ganglia region of

11 the brain. This and other studies showed that the

12 increase in incidences were related to the dose and

13 duration of exposure. The increase incidences, however,

14 did not correlate with the doses which resulted in

15 clinical signs. That is, some animals show vacuoles in

16 the brain, but not clinical signs. It could be that more

17 detailed neurological examination and/or extensive -- more

18 extensive histopathology are needed. The nature of these

19 vacuoles has not been identified. The inside of these

20 vacuoles did not stain for lipids, myelin, glycogen, or

21 neural tissues.

22 --o0o--

23 DPR STAFF TOXICOLOGIST LIM: Here are the results

24 of some types of studies in the database. Sulfuryl is not

25 considered an oncogen or mutagen.

1 PANEL MEMBER LANDOLPH: Could you stop there a
2 second.
3 DPR STAFF TOXICOLOGIST LIM: Sure.
4 PANEL MEMBER LANDOLPH: The discussion of
5 carcinogenicity I think I would recommend making some
6 modifications and through -- here and throughout the
7 document. I would not say that those studies are
8 negative. I would say that those studies actually have
9 some positive results. You could say that they're not
10 conclusive and they need to be expanded. But I certainly
11 would not say that they're negative. In one study they
12 were osteosarcomas and in another study they were benign
13 bone tumors. Those are not negative studies.
14 DPR STAFF TOXICOLOGIST LIM: This is sulfuryl
15 fluoride only. I think what you're referring to was
16 fluoride.
17 PANEL MEMBER LANDOLPH: Oh, fluoride, yeah, which
18 is a component of -- which it generates.
19 DPR STAFF TOXICOLOGIST LIM: Right. So what I
20 need to do is add the fluoride carcinogenicity paragraph
21 on to that section.
22 PANEL MEMBER LANDOLPH: Yeah, I've made some
23 specific suggestions for that. I would do that.
24 I also think we might even consider recommending
25 that sulfuryl Fluoride go to the NTP to have a full

1 carcinogenicity study on it. And the same thing -- I
2 might as well do the genotoxicity now too.
3 Again, I think the characterization of that as
4 negative is not precisely accurate. There were some
5 positives in V79 Chinese hamster cells for mutagenesis and
6 for chromosome breakage.
7 DPR STAFF TOXICOLOGIST LIM: Again, that's for
8 fluoride.
9 PANEL MEMBER LANDOLPH: For fluoride, yeah, which
10 is a metabolite of sulfuryl fluoride. So you might -- I
11 would recommend that you'd qualify those statements.
12 Because in some instance within the document the data on
13 genotoxicity was called equivocal in your very nice
14 fluoride appendix. And it's not really equivocal, because
15 if it's positive in mammalian cells but negative in
16 bacteria, it's just doing different things. The
17 physiology is different. So I wouldn't call that
18 equivocal.
19 And I would urge you to be cautious here. The
20 reason why is underlying all this is if sulfuryl fluoride
21 and/or its metabolites turn out to be genotoxic
22 carcinogens, then you're talking about a three log or more
23 shift in the NOELs and the dose response curve. We're not
24 there yet. But I would urge you to be real careful on how
25 you state that.

1 DPR STAFF TOXICOLOGIST LIM: Okay.
2 CHAIRPERSON FROINES: Can I ask a question
3 about -- to Joe.
4 In the document that you wrote with your
5 recommendations, is everything you just said included in
6 that document?
7 PANEL MEMBER LANDOLPH: Yeah, a little bit in a
8 more articulate fashion than the way I just said it. It's
9 lengthier, but yes.
10 CHAIRPERSON FROINES: It is?
11 PANEL MEMBER LANDOLPH: It's more organized,
12 yeah. It's all here.
13 CHAIRPERSON FROINES: I think that there is one
14 sort of generic point, which is that we need to be -- we
15 need to look at metabolites as -- when we -- I mean this
16 came up with metam sodium, for example. And that clearly
17 the metabolites were highly toxic. And so that it's
18 important to -- as an overall policy I think to look at
19 the toxicity of the metabolites as representative of the
20 toxicity of the parent. Since we know there's a lot of
21 fluoride released, to only look at the studies on the
22 parent would underestimate the impact of the metabolites.
23 PANEL MEMBER LANDOLPH: And obviously the Bassin
24 study, which unfortunately has not been published, from
25 Harvard, which you were so kind to point out to us,

1 indicating that there might be some increased incidents of
2 osteosarcomas in young males -- young boys. When you add
3 all this together, it's beginning to get a little bit
4 worrisome. So I would just recommend you encapsulate that
5 all in the section. And I've made some recommendations to
6 help you do that, which I e-mailed to Randy earlier.
7 DPR STAFF TOXICOLOGIST LIM: Yes, I do have it.
8 And I have it here.
9 And now that we talk about it, I want to ask you
10 a question on the Bassin study. So the thesis work is
11 completed. Is the thesis available, do you know?
12 CHAIRPERSON FROINES: I don't know what you sent
13 to Lori. But all I had was a newspaper article basically.
14 PANEL MEMBER BYUS: I can answer that question.
15 I called a friend of mine after you pointed this
16 out to me at the EPA, who works on -- a toxicologist who
17 works on fluoride in the water. She explained to me
18 exactly what's happening with that study. That was a
19 thesis study from Harvard. There's a National Academy of
20 Sciences committee right now which is reviewing all the
21 data on fluoride toxicity. It's looking over that study.
22 She read that study. She couldn't get it to me
23 electronically. She didn't have it electronically.
24 It was a study done by a woman, a graduate
25 student who -- and it is unpublished currently. Very well

1 done, she said, where she used -- she analyzed other
2 people's epidemiological data and put a fresh spin on it
3 by bending it out by age, where she did find an increase
4 in eight to nine year old males in osteosarcoma, not
5 females. But she was very cautious in her writing and
6 very careful not to draw any conclusions because of the
7 exposure aspects of it, not knowing how -- because you can
8 be exposed to fluoride from multiple sources.
9 And the National Academy of Sciences is looking
10 over that -- this committee that's currently EPA has asked
11 the NAS to do this -- just looking over that study in
12 detail. It should be finished in February.
13 There is the other additional data, however, in
14 addition to this that -- there's a significant amount of
15 data with fluoride being used to prevent increased bone
16 density. Ten years ago it was used a lot to increase bone
17 density. They subsequently found out it was toxic. And
18 so there's a whole plethora of sort of bolus fluoride use
19 of data given to a huge number of people for that purpose.
20 And they're also evaluating all of that data.
21 And so there will -- there should be early next
22 year a whole new review of the current state of the art of
23 where fluoride is, using that Harvard study, plus
24 primarily this new bunch of human data with fluoride as a
25 drug. Which has now been removed from the market because

1 they reviewed -- they found it was toxic.
2 CHAIRPERSON FROINES: So there is a National
3 Academy Study. But that means that EPA probably has that
4 epi steady.
5 PANEL MEMBER BYUS: It has the epi study. She
6 was reading it to me from --
7 CHAIRPERSON FROINES: So maybe you -- I don't
8 know where you would find it at EPA.
9 PANEL MEMBER HAMMOND: No, wait. If the
10 dissertation is completed --
11 PANEL MEMBER BYUS: It's completed. You can get
12 it.
13 PANEL MEMBER HAMMOND: -- then you can get it,
14 right?
15 PANEL MEMBER BYUS: Sure. You can get it from
16 Harvard. She got it from Harvard.
17 DPR STAFF TOXICOLOGIST LIM: That was my original
18 question. If it's completed, then we could certainly ask
19 a librarian to get it.
20 PANEL MEMBER HAMMOND: And that I think become a
21 citable reference.
22 PANEL MEMBER BYUS: It's citable.
23 CHAIRPERSON FROINES: Okay.
24 DPR STAFF TOXICOLOGIST LIM: I just wanted to add
25 that we're very fortunate that at our branch a fellow

1 toxicologist, Dr. Ruby Reed, is a member of the NAS
2 Fluoride Panel.
3 CHAIRPERSON FROINES: So, she is?
4 DPR STAFF TOXICOLOGIST LIM: Yes.
5 CHAIRPERSON FROINES: That's great.
6 DPR STAFF TOXICOLOGIST LIM: And so she's my
7 primary consultant on the fluoride issues.
8 CHAIRPERSON FROINES: Oh, she probably has the
9 study.
10 DPR STAFF TOXICOLOGIST LIM: She's probably
11 looking at it. While she cannot tell me any of their
12 conclusions or deliberations, we're pretty much up on
13 what's available. And some -- you know, I discuss these
14 issues with her. Okay.
15 CHAIRPERSON FROINES: Yeah, she -- Joe.
16 PANEL MEMBER LANDOLPH: Yeah, also I noticed in
17 your summation -- incidentally, which I thought was very
18 nice on the oncogenicity of the sulfuryl fluoride, and all
19 the -- the whole volumes were very well written -- I
20 noticed there was also mentioned that sulfuryl Fluoride
21 caused hyperplasia in lower animals and also hypertrophy
22 of the thyroid and depletion of collagen of the thyroid in
23 lower animals. So I would almost suggest a cautionary
24 note that these effects have been noted, and we should
25 look more closely to the future about whether there is a

1 potential for this to cause -- sulfuryl fluoride to cause
2 tumors of the thyroid and/or the kidney. It's something
3 we should be looking for.
4 CHAIRPERSON FROINES: Where's the hyperplasia?
5 PANEL MEMBER LANDOLPH: Hyperplasia of the
6 kidney.
7 DPR STAFF TOXICOLOGIST LIM: I will add those
8 points in my document.
9 Looking on page 2 of your comment on the second
10 paragraph. Lets's see, that's 1, 2, 3, 4, 5 -- line 5 it
11 says, "The fact that sulfuryl fluoride is positive in
12 some types of assays and negative in other types of assays
13 does not make an equivocal genotoxin." You mean fluoride
14 and not sulfuryl fluoride, right?
15 PANEL MEMBER LANDOLPH: Yeah, probably fluoride,
16 yeah. Sorry.
17 DPR STAFF TOXICOLOGIST LIM: Okay. And that also
18 later on in that same paragraph about the oncogenicity,
19 again that's about fluoride?
20 PANEL MEMBER LANDOLPH: That would be fluoride,
21 yeah. Sorry.
22 DPR STAFF TOXICOLOGIST LIM: Okay. I just wanted
23 to make that clear.
24 PANEL MEMBER LANDOLPH: Yeah, sorry.
25 CHAIRPERSON FROINES: I mean I think it's true --

1 I think it's fair to say that the number of chemicals that
2 come before us that are themselves the ultimate toxicant
3 is virtually zero, with the exception of ethylene oxide or
4 other epoxides. But anything else requires some either
5 enzymatic bio-activation or in this case hydrolysis.
6 So that in general we should treat the
7 metabolites as representative of the parent compound.
8 PANEL MEMBER LANDOLPH: And, again, there's no
9 data on whether sulfuryl fluoride can bind covalently to
10 macro molecules. I don't think anybody's ever looked at
11 it. So it's something that -- there's a lot of things
12 that should be done.
13 CHAIRPERSON FROINES: Is that your impression,
14 Lori.
15 DPR STAFF TOXICOLOGIST LIM: The genotoxicity
16 studies show that these are negative. But you're correct.
17 PANEL MEMBER LANDOLPH: Yeah, nobody's looked at
18 them, yeah.
19 DPR STAFF TOXICOLOGIST LIM: Right. Yeah, we
20 could do literature search and try to get as much as we
21 can, all that we can. And then we stop and -- documents.
22 CHAIRPERSON FROINES: Well, it's a problem
23 because the -- you know, we're at a place where we have
24 these historical genotoxicity studies that were basically
25 products of the seventies that certainly don't reflect the

1 modern molecular biology that we use for looking at
2 mutagenicity. So it's at this strange place where there's
3 a gap between the research side of things and the
4 regulatory side.
5 So go ahead.
6 DPR STAFF TOXICOLOGIST LIM: Let me just add that
7 on page 47, which is a short blip on genotoxicity, there
8 is one study that used isolated hepato -- and look at a
9 scheduled DNA synthesis, and the study was negative.
10 CHAIRPERSON FROINES: So if you have -- so we
11 don't need -- so you can take Joe's comments and consider
12 making subsequent changes from that?
13 DPR STAFF TOXICOLOGIST LIM: Yes, I think for all
14 the oncogenicity section. Right now I only talked about
15 sulfuryl fluoride. So I could just tag on fluoride that
16 discussion from my appendix and sort of copy and paste it
17 there.
18 CHAIRPERSON FROINES: Yeah, I mean if you want --
19 I mean seems to me without getting into word processing
20 issues, if you want to have some summary data in the main
21 document and additional document in the appendix, that
22 would seem to me okay. But it's your call, however you
23 want to approach it.
24 DPR STAFF TOXICOLOGIST LIM: But the point's well
25 taken. And I will add that information.

1 Let me just sort of start again.
2 So sulfuryl fluoride is not considering oncogen
3 or mutagen. No tumors were found in rats on those
4 oncogenicity studies. However, the findings of
5 hyperplasia in the kidney and nasal tissues and
6 hypertrophy in the thyroid epithelial cells indicate
7 preneoplastic events.
8 It does cause reduced rabbit fetal and rat pup
9 body weights in the developmental and reproductive
10 toxicity studies.
11 --o0o--
12 DPR STAFF TOXICOLOGIST LIM: After the review of
13 the toxicology database, the next step is to identify the
14 critical studies with duration of exposure similar to
15 those determined for human exposure. That is, if humans
16 are exposed to sulfuryl fluoride for eight hours, ideally
17 we should have a study that tells us what is the toxicity
18 for that eight hours. In reality we have animal studies
19 of predetermined exposure duration and many more human
20 exposure scenarios.
21 --o0o--
22 DPR STAFF TOXICOLOGIST LIM: For bystander
23 exposure during structural fumigation application and
24 aeration, the air concentration declined with time, as
25 shown in the second column. During application for the

1 first 12-hour period the air concentration was relatively
2 constant. Then it declined over the next 12 hours.
3 During aeration the highest exposure was measured at the
4 first time point. For example, the first hour was Stack
5 method and the first two hours with the TRAP method. With
6 non-food commodity fumigation the assumption was 24 hours
7 continuous exposure at 5 ppm.
8 There was an earlier question about the use on
9 food commodity fumigation which was recently approved I
10 think like three or four months ago about the exposure.
11 The maximum limit for that use is set at 1 ppm right now,
12 instead of the 5 ppm. So I would expect that the 5
13 standard exposure would be lower. However, with the food
14 commodity fumigation you can have more frequent
15 fumigation, so you would expect repeated exposure
16 scenarios and more people would be exposed.
17 CHAIRPERSON FROINES: Well, one of the issues
18 is -- as we all know, those of us who do this kind of
19 work, inhalation toxicology studies are extremely
20 difficult, very expensive and what have you. But, you
21 see, this slide is really interesting insofar it shows the
22 contradiction though that we get into, that we basically
23 have high exposure at 12 hours or high exposure at 1 hour.
24 And yet our database is based on these 6-hour studies.
25 Well, the 6-hour studies is not a reflection of the actual

1 conditions in which people breathe this material. So that
2 the toxicology and the exposure are discontinuous in that
3 sense. And it's really unfortunate.
4 Although I also know how difficult it is to do
5 inhalation toxicology where you would -- but it's not
6 impossible. So that this is not -- has nothing to do with
7 this document. It's just sort of a statement -- a general
8 statement. But it does reflect -- the problem we have is
9 that our toxicology does not necessarily reflect our
10 exposure conditions.
11 DPR STAFF TOXICOLOGIST LIM: And with the
12 pesticides -- because there's a part of the registration
13 process is to require these upfront toxicology studies.
14 And then later on you might discover additional human
15 exposures in there that's not addressed.
16 So it should be a -- process, but it is actually
17 more a sequential process.
18 CHAIRPERSON FROINES: Interesting.
19 DPR STAFF TOXICOLOGIST LIM: Since we don't have
20 any toxicity studies with these same exposure conditions,
21 we amortized the exposure for human and the animals on the
22 daily basis, so that these two terms can be used for the
23 calculation of the risk later.
24 --o0o--
25 DPR STAFF TOXICOLOGIST LIM: This slide is a

1 summary of the studies with acute effects. The study
2 number refers to the reference numbers in the document.
3 The air concentration, ppm, from the studies were
4 converted to exposure in milligram per kilogram per day
5 term to allow comparison between studies which were
6 conducted for different durations and different species.
7 Study No. 8, in blue --
8 PANEL MEMBER GLANTZ: I just have one question --
9 because I may have now figured this out. But in the
10 study -- in the -- when you say NOEL/LOEL, are you saying
11 that the NOEL is the first number and the LOEL is the
12 second number?
13 DPR STAFF TOXICOLOGIST LIM: Yes.
14 PANEL MEMBER GLANTZ: Okay. I think when you
15 have these tables, you need to make that clear, because
16 I -- when I read it I thought you meant it was a NOEL or a
17 LOEL, rather than that you were presenting a NOEL and a
18 LOEL.
19 DPR STAFF TOXICOLOGIST LIM: Oh.
20 PANEL MEMBER GLANTZ: So I was -- I was all ready
21 to like jump all over you.
22 PANEL MEMBER HAMMOND: Two columns.
23 PANEL MEMBER GLANTZ: Yeah, I think it would be
24 clearer if you made it two columns.
25 DPR STAFF TOXICOLOGIST LIM: Well, if I added two

1 columns -- I don't know. It's more that I was trying to
2 fit everything on one page.
3 PANEL MEMBER GLANTZ: I know. But it is
4 totally --
5 DPR STAFF TOXICOLOGIST LIM: Like additional
6 columns --
7 PANEL MEMBER GLANTZ: -- yeah, but it was like
8 totally confusing.
9 DPR STAFF TOXICOLOGIST LIM: I could add a
10 footnote.
11 PANEL MEMBER GLANTZ: Yeah, and that -- yeah, and
12 it kind of looks like it could be a ratio.
13 PANEL MEMBER HAMMOND: Yeah, I could bring it as
14 a ratio.
15 PANEL MEMBER BYUS: That is really -- it looks
16 like it's a ratio. So you really have to fix that.
17 DPR STAFF TOXICOLOGIST LIM: Would a footnote do,
18 or should I squeeze a column in there?
19 PANEL MEMBER GLANTZ: And the other thing is --
20 you know, because this was one of the things that really
21 bothered me when I read the report. Like if you look --
22 so for rat number 7 there was no effect at 300, right?
23 DPR STAFF TOXICOLOGIST LIM: Yes.
24 PANEL MEMBER GLANTZ: And what you're saying is
25 that the LOEL is a greater than 300, but there -- wasn't

1 actually measured --

2 DPR STAFF TOXICOLOGIST LIM: No.

3 PANEL MEMBER GLANTZ: -- right?

4 Well then I think you should just say "not

5 available" or "not measured". And, likewise, for rat

6 number 1, you know, which -- you had a LOEL at 334 and you

7 don't really know what the NOEL is, because they didn't --

8 now that I understand what the table's showing, they

9 didn't actually do a study where they actually found a

10 NOEL. So I think for the ones where you don't have a

11 NOEL, you should just say "not available," because people

12 will know that the NOEL is going to be lower than the

13 LOEL, but this makes it sound like you actually know what

14 the no observed effect level is.

15 DPR STAFF TOXICOLOGIST LIM: Okay.

16 PANEL MEMBER LANDOLPH: No, but she's just saying

17 that that's an upper bound. It's below that. I don't

18 have a problem with that.

19 PANEL MEMBER GLANTZ: Yeah, I understand. But to

20 me I think -- I mean I don't think what's written there,

21 now that I understand it, is wrong. But I think it's

22 misleading, because to me -- when you say to me something

23 is a NOEL, what that says to me is that you did an

24 experiment where you kept lowering the dose and you

25 actually got to a dose where you didn't detect an effect.

1 So it's an affirmative finding and it's saying that that's
2 a dose where you couldn't find anything.
3 When you have a LOEL, the LOEL that you present
4 is actually a function of the experiment. Because if you
5 say, you know, that the -- say in rat number 1 that the
6 LOEL was 334. That's probably the lowest dose they had
7 tried or lowest exposure level that tried. And so that's
8 saying that that's the lowest level you looked at and you
9 still found an effect. But the actual LOEL could be well
10 below that.
11 So I really think that when you don't have an
12 affirmative evidence that something is a NOEL, meaning you
13 did an experiment at that dose and didn't find an effect,
14 then you should say you don't know what the NOEL is. Even
15 though -- I mean now that I understand this, I think it's
16 not -- it's not a lie, but I think it's misleading.
17 CHAIRPERSON FROINES: Well, if it's a question of
18 getting things on one page, I think you can put footnotes
19 and it will be clear.
20 DPR STAFF TOXICOLOGIST LIM: Well, I will explain
21 it one way or another.
22 PANEL MEMBER GLANTZ: Okay. But I feel really
23 strongly. If you don't have a direct measured NOEL, then
24 you shouldn't put a number there. I feel really --
25 because that looks very misleading.

1 DPR STAFF TOXICOLOGIST LIM: Okay. I could fix
2 that.
3 CHAIRPERSON FROINES: It's one of these strange
4 things that this kind of risk assessment is dependent upon
5 the doses that you select for the study. So you're always
6 limited by those doses. And so if it helps, I guess -- I
7 mean you can put an NA or something in there. But I would
8 have a footnote that says if there was not a -- there was
9 not a dose below the level that was -- or something like
10 that.
11 PANEL MEMBER GLANTZ: Or I would even say -- for
12 the NOEL, I would say "unknown," because you don't know
13 what it is because you didn't -- there's no data there.
14 PANEL MEMBER ATKINSON: But for rat 1 it's
15 clearly less than 334.
16 PANEL MEMBER GLANTZ: Yeah, but that is given in
17 the definition of what a -- a NOEL is always less than the
18 LOEL. So if you're -- see, to me when you say the LOEL
19 was 334, what that's saying is they did an experiment and
20 that was the lowest dose they tried and they still found
21 an effect. And that means the NOEL is somewhere below
22 that.
23 If the -- on the other hand, in rat number 7,
24 they're saying they tried 300 and they didn't find
25 anything. So there are two different statements. And I

1 think to put a number in when you don't know what it is,
2 I -- I think you should just say "unknown" or something.
3 PANEL MEMBER BYUS: Well, sometimes they
4 experimentally test it and just didn't find it.
5 PANEL MEMBER GLANTZ: Well, no, that's right.
6 PANEL MEMBER BYUS: And in document she -- all
7 the information is there. I do sort of agree with you.
8 But I don't know exactly what term I would have used.
9 "Not determined" maybe or "not observed" or whatever.
10 DPR STAFF TOXICOLOGIST LIM: I think somehow I
11 could make that more exact.
12 PANEL MEMBER GLANTZ: Whatever terminology you
13 want. But I just don't think there should be a number
14 there if you don't know what the number is.
15 DPR STAFF TOXICOLOGIST LIM: Well, one of the
16 things that I -- the other thing that I do is, other than
17 the formatting, which is really minor, but it allows me to
18 just look down on that column of the NOEL. That's the
19 first set of number. And then you could easily pick out
20 and say, "Well, this one is less than 200," just right
21 there, and to say, "Okay, I need to deal with this study."
22 As if I had like "NA" there --
23 PANEL MEMBER BYUS: See what she's saying?
24 DPR STAFF TOXICOLOGIST LIM: -- then I would
25 say -- then I've got to look back to the LOEL and then

1 still have to come up with some idea.
2 PANEL MEMBER BYUS: She's picking less than 200
3 as the NOEL.
4 PANEL MEMBER GLANTZ: Yeah. But, you see, I
5 think that -- that to me -- that's the thing --
6 PANEL MEMBER HAMMOND: It's a way to look down
7 the column to get information.
8 PANEL MEMBER GLANTZ: Right. And what I -- the
9 information that I think you should get looking down the
10 column is that you don't know what the NOEL is in several
11 of the studies.
12 DPR STAFF TOXICOLOGIST LIM: Right. But then the
13 second purpose was to line them up and make a comparison,
14 saying that of all these studies, where these things fall
15 out. And so --
16 PANEL MEMBER GLANTZ: Right. But I think you
17 could --
18 DPR STAFF TOXICOLOGIST LIM: A sort of visual
19 tool.
20 PANEL MEMBER GLANTZ: Yeah. But I think it's --
21 I mean I can tell you when I read the report, I got
22 totally confused by this. And I think that -- I think
23 that what you should do is have two different columns,
24 that are right next to each other so people can compare
25 them, and then when you have -- and the only numbers that

1 are in the tables should be numbers that were actually
2 observed. And so if they -- if the lowest -- if all you
3 know is the LOEL, that's an important -- I mean that's
4 interpreted very differently, which just says to me,
5 "Well, the NOEL is somewhere below that." But you don't
6 know if it's one milligram per kilogram per day lower or
7 if it's way lower.
8 CHAIRPERSON FROINES: Lori, I think if you
9 have -- what I would do would be to -- let's take number
10 1. So you have a column of LOELs. Under the column of
11 NOELs I think it would be entirely accurate to say "not
12 determined," because that's what actually happened.
13 Nobody -- there was no experiment that determined that
14 value. So if you say something like NA, not applicable,
15 will just further confuse people, I think.
16 PANEL MEMBER GLANTZ: Well, I was thinking "not
17 available." But "undetermined" is --
18 CHAIRPERSON FROINES: "Not determined" reflects
19 what actually happened, because it is an experimental
20 point. So I think that was -- that's a more accurate way
21 of -- and so then the reader sees -- and you can put a
22 footnote saying, "Where it is not determined, one would
23 anticipate a lower value were it to be so," or something
24 like that.
25 PANEL MEMBER GLANTZ: Yeah.

1 CHAIRPERSON FROINES: That's pretty clumsy
2 language, but -- I don't know.
3 DPR STAFF TOXICOLOGIST LIM: I was anything about
4 having --
5 PANEL MEMBER BYUS: In this case did you
6 actually -- let me just add. I mean did you actually
7 choose the NOEL less than 200?
8 DPR STAFF TOXICOLOGIST LIM: Oh, I'm going to go
9 into it now.
10 PANEL MEMBER BYUS: Okay.
11 CHAIRPERSON FROINES: Let's go ahead.
12 DPR STAFF TOXICOLOGIST LIM: Right.
13 CHAIRPERSON FROINES: So the recommendation from
14 the panel would be to make that modification in terms of
15 the table.
16 DPR STAFF TOXICOLOGIST LIM: Right, to say "not
17 determined."
18 CHAIRPERSON FROINES: Yes.
19 DPR STAFF TOXICOLOGIST LIM: Let's see, where am
20 I?
21 Study No. 8, in blue, showed the lowest NOEL at
22 less than 200 milligram per kilogram per day. This NOEL
23 was not selected as a critical NOEL because of several
24 limitations in this study. The effect was transient,
25 occurring at the first one to two minutes of exposure.

1 And this finding would be difficult to use to extrapolate
2 to hours of human exposure.
3 Also, the actual exposure concentration was not
4 reported in the study.
5 And, three, there were lack of sufficient details
6 in reporting of the data as the data was shown only in
7 graphs.
8 At the next higher NOEL of 300 ppm there was
9 three studies, number 7, 3 and 11, highlighted in yellow.
10 And the critical study is number 7.
11 --o0o--
12 DPR STAFF TOXICOLOGIST LIM: Study 7 was selected
13 as the critical study because --
14 CHAIRPERSON FROINES: Could you go back -- could
15 you go back just -- here's an issue that we need to think
16 about a little bit, I think, just as a prelude to this.
17 You'll notice that your LOEL for number 1 is 334. And you
18 chose the NOEL of 300. But if you apply a safety fact
19 because number 1 is a LOEL, you're going to get a
20 different RfC than you will if you used 300. And I think
21 it will be lower. And so we have a problem of when we
22 have a LOEL that you would normally apply even a
23 three-fold safety factor or something -- whatever it might
24 be, that may end up dominating your risk number as opposed
25 to the NOEL that you selected.

1 Am I clear?
2 DPR STAFF TOXICOLOGIST LIM: Yes.
3 PANEL MEMBER HAMMOND: It's not even a safety
4 factor. But you were saying, if you're going to make an
5 assumption -- make sure I understand you. You're saying
6 if you're going to make an assumption of a NOEL in the
7 absence of data, based on a LOEL, that that assumed NOEL
8 for this purpose would have been something that would have
9 been at least effective two or three.
10 CHAIRPERSON FROINES: What I'm saying is that if
11 you take -- if you take 300 from number 7 -- and I haven't
12 thought about this before this minute, so pardon me for
13 raising it. But it just popped into my head.
14 PANEL MEMBER GLANTZ: That's one of the vacuoles.
15 (Laughter.)
16 CHAIRPERSON FROINES: If you take the 300 and you
17 divide it by your three uncertainty factors of a thousand,
18 that gets you down to .3 -- .3. Pardon me. If you take
19 the 334 and you use your safety factor of a thousand --
20 let's assume a safety factor of 3 for the LOEL to NOEL
21 conversion. Then you're down basically three-fold below
22 what you got from your number 7. So that there's -- So
23 there's a contradiction.
24 PANEL MEMBER HAMMOND: I'm sorry.
25 CHAIRPERSON FROINES: Go ahead. I'm sorry.

1 PANEL MEMBER HAMMOND: Excuse me.
2 But I don't think you want to use the word
3 "safety factor" because they're two different concepts.
4 CHAIRPERSON FROINES: Uncertainty factor.
5 PANEL MEMBER HAMMOND: Right.
6 I mean so I think that what one's saying is once
7 you're going to make an assumption that the NOEL -- you're
8 going to assume a NOEL based on the LOEL. And when you do
9 that, if I'm hearing you correctly, you're saying you
10 would typically divide by three?
11 CHAIRPERSON FROINES: Or ten.
12 PANEL MEMBER HAMMOND: Well, I mean whatever it
13 is -- and that's what the whole thing has. It has nothing
14 to do with where you go from there, because from there it
15 goes the same way. But I think the real question is as
16 soon as you assume there's any factor, whether it's 2, 3
17 or 10, that immediately anything that has an unknown NOEL
18 in this table, like a 334, is immediately going to become
19 lower.
20 CHAIRPERSON FROINES: Right. If you took --
21 PANEL MEMBER HAMMOND: As an assumed NOEL --
22 -- if you took the traditional approach -- if you
23 took the traditional approach, the tradition approach
24 would have you do -- the first step would be to take the
25 334 and divide it by 10, which would give you 33.4. You

1 would then divide by the thousand --

2 PANEL MEMBER HAMMOND: I mean everything has that

3 happen.

4 CHAIRPERSON FROINES: -- and so you would be down

5 to .0334 as opposed to .33.

6 PANEL MEMBER GLANTZ: But the problem I think

7 with what you're suggesting, John, is that you do that

8 when you don't have any direct observations of a NOEL.

9 And here they do. And, you know, the NOEL --I'm going to

10 go back and argue with you about the 200 in a minute. But

11 if you just look at the other studies, you've got three

12 studies, number 7, number 3 and number 11, which have a

13 direct observed NOEL of 300, which is less than 334.

14 So I think that -- if you didn't have any

15 directly observed NOELs, then I would agree with you. But

16 since they've got a directly observed NOEL at 334 -- at

17 300, then, you know, it may be that that LOEL that they

18 found is just, you know, barely above the level that you

19 start seeing things. So I think, since they have directly

20 observed no-effect levels, it's more reasonable I think to

21 use the directly observed levels rather than an

22 extrapolated level from a LOEL, because you don't know how

23 much -- you know, when you get a LOEL, you don't know how

24 much above the NOEL dose that experiment happened to be

25 because you don't have any data.

1 PANEL MEMBER HAMMOND: But --
2 CHAIRPERSON FROINES: But, see, Stan, from a
3 toxicologic standpoint -- what you just said is what a
4 statistician would say. But from a toxicologist's point
5 of view, it depends on what you decide is your most
6 relevant endpoint. So it doesn't matter what's on that --
7 those numbers don't matter because you actually have to
8 decide what is the endpoint that we consider the most
9 important for purposes of this process.
10 PANEL MEMBER GLANTZ: Well, that's a different --
11 no, I agree with that too. But that's a third point.
12 But what I'm just saying is that if -- let's
13 assume -- see, because then what you would be saying is
14 the slight tremors, body-weight loss you think should be
15 the most important endpoint. And if that's what you
16 think, then I would say, okay, then you take the 334 and
17 apply it through your uncertainty factor. But what I --
18 but if you were to take all of these things as -- you
19 know, equally weighted, then I would take a directly
20 observed NOEL over a LOEL as long as the directly observed
21 NOEL was below all of the other LOELs, which except for
22 Study 8, which we can come back to, is the case.
23 CHAIRPERSON FROINES: Well, actually there's a
24 literature on this. And Kenneth Crump has written about
25 it over the years. I understand, Kathy has written about

1 it over the years. And in his work on benchmark dose,
2 he's been very articulate. And the problem with the NOEL
3 is that it is also an experimental point, and it could be
4 much too high or much too low. You never really know with
5 a NOEL. What the NOEL is is you didn't find anything.
6 The advantage of a LOEL at some level -- the advantage of
7 a LOEL at some point is that you did find something.
8 And so I think we should go on and -- because
9 this is a general discussion. But I think that the point
10 is that we shouldn't necessarily lock ourselves into the
11 NOEL unless it's the study that we think is the crucial
12 endpoint that we want to establish. I think --
13 PANEL MEMBER GLANTZ: I don't want to beat this
14 into the ground. But I mean if you were to take a LOEL
15 and apply an uncertainty factor and end up with a level
16 that was below all of the observed NOELs, I wouldn't
17 object to that as a decision, because that's going to be
18 health protective, you know. But what I'm just saying is
19 all things being equal -- you see, and in this case --
20 see, the bigger problem I have is discounting Study No. 8.
21 Because what happened in Study No. 8 is you got a LOEL
22 that was -- with a relatively short-term exposure that was
23 below the other NOELs.
24 CHAIRPERSON FROINES: Let's hold it --
25 PANEL MEMBER GLANTZ: You know, the question

1 there is --

2 CHAIRPERSON FROINES: Let's let Lori make her

3 argument before -- because this poor woman is not a --

4 we're blathering away while she's waiting to make -- also,

5 I want to make point, when I said something about you --

6 when I said something about you as a statistician, me as a

7 toxicologist, that was a joke.

8 (Laughter.)

9 CHAIRPERSON FROINES: Go ahead, Lori.

10 DPR STAFF TOXICOLOGIST LIM: Actually I think Dr.

11 Glantz now probably qualified like a risk assessment,

12 because that's just one of the things that we do, think

13 about that if you do have -- even if you have an

14 experimentally determined NOEL, that gives you greater

15 confidence of where the toxicity ends. And that's one of

16 the key things we would consider. And I do agree with you

17 also. It too could be -- they would be writing risk

18 assessments in that we -- I did consider those numbers.

19 And what if I apply uncertainty factors? So -- because

20 both are correct in those two points.

21 But there's another thing that we also look at,

22 is again the quality of the study. I tracked down this

23 particular study, it's on page 27 on the bottom, for that

24 Study No. 1. In this particular study, the animals were

25 exposed to up to six hours to 1,000 to 15,000 ppm. So in

1 some way by presenting milligram per kilogram per day
2 value is actually a little bit misleading. And that's my
3 fault trying to simplify the table. And then they were --
4 so it was --
5 CHAIRPERSON FROINES: Which one are you referring
6 to?
7 DPR STAFF TOXICOLOGIST LIM: Page 27 on the
8 bottom.
9 CHAIRPERSON FROINES: The bottom one? Okay.
10 DPR STAFF TOXICOLOGIST LIM: Yeah, that last
11 study.
12 PANEL MEMBER HAMMOND: Male rat, starting that
13 paragraph?
14 DPR STAFF TOXICOLOGIST LIM: Yes, by Dow
15 Chemicals, 1959. This one is acute toxicity studies where
16 they're trying to figure out what the LD 50 levels were.
17 And then after two to three hours exposure to
18 lowest dose of 1,000 ppm, this is where the rats starting
19 to show the slight tremors and the slight weight loss.
20 There's one death in this group after two hours exposure.
21 Then there was an estimated LC 50. And this is how the
22 NOEL was derived. And so --
23 CHAIRPERSON FROINES: That's very useful. I
24 wouldn't use that study.
25 DPR STAFF TOXICOLOGIST LIM: You wouldn't use the

1 study?

2 CHAIRPERSON FROINES: Not that study, based on

3 its design quality.

4 DPR STAFF TOXICOLOGIST LIM: Right. So that's

5 why it was not used.

6 So, again -- so looking at the NOEL where there's

7 experimental, we determined a lot in looking at the

8 quality of the study. And that's how we come up with our

9 final decision.

10 CHAIRPERSON FROINES: Go ahead.

11 DPR STAFF TOXICOLOGIST LIM: Dr. Glantz, do you

12 want to talk about Study No. 8? Because I'm not going to

13 go into that.

14 PANEL MEMBER GLANTZ: Yeah, because -- I mean

15 just looking at the table, it would seem to me that you

16 should use 200 or something less than 200 as a NOEL,

17 because again the NOEL -- because something appearing in

18 20 minutes seems pretty fast.

19 DPR STAFF TOXICOLOGIST LIM: Yeah, again, that's

20 my fault. Like I explained when I was reading this slide

21 was the effect was actually transient occurring the first

22 two minutes of the exposure. The total study was 20

23 minutes. But they found the effect in the first two

24 minutes. And it would make it very difficult to

25 extrapolate that finding to a human exposure that we're

1 talking about hours. So that's why that study was not
2 selected.
3 PANEL MEMBER HAMMOND: You know, but I guess I'm
4 confused. You're saying the rat was actually exposed for
5 a short -- just for a very short period of time and the --
6 or the transitory effect just lasted a short period of
7 time?
8 DPR STAFF TOXICOLOGIST LIM: Right. Just right
9 after they got exposed they recorded that. And then they
10 were normal after that.
11 CHAIRPERSON FROINES: But were they -- what was
12 the measure?
13 PANEL MEMBER HAMMOND: But the duration of the
14 exposure of the rat was how long?
15 DPR STAFF TOXICOLOGIST LIM: The study was --
16 it's on the bottom of page 28. The duration was 28
17 minutes.
18 PANEL MEMBER HAMMOND: Because one of the
19 things -- and this gets back to what --
20 DPR STAFF TOXICOLOGIST LIM: I mean 20 minutes.
21 PANEL MEMBER HAMMOND: -- Dr. Froines was
22 mentioning earlier about that issue of the disconnect
23 between normally having these very long chronic exposures
24 in the animals and our concern in a material like this of
25 being short and acute exposures. This is an exception to

1 that, where we have an animal study that does look at an
2 acute exposure, right?
3 DPR STAFF TOXICOLOGIST LIM: Yes.
4 PANEL MEMBER HAMMOND: Now, I don't know whether
5 the transitory respiratory health effect -- how
6 significant that was as a health outcome. But I do think
7 that the fact that it was something that did happen
8 there is important.
9 DPR STAFF TOXICOLOGIST LIM: Right, at 4,000 and
10 10,000 ppm the level would be way, way, way higher than we
11 would expect. Because I think if that was done in a level
12 that's closer to what we would expect humans, I think that
13 would be an excellent study.
14 PANEL MEMBER HAMMOND: Right.
15 What -- you know --
16 CHAIRPERSON FROINES: But I wanted to say at
17 200 --
18 PANEL MEMBER HAMMOND: -- I never felt that very
19 comfortable with this, what are the occupational
20 exposures, which keep getting -- they really were never
21 discussed carefully here. But is there a chance that some
22 of the workers would have those exposures?
23 DR. COCHRAN: No. Not that kind of
24 concentration. They would have to be in self-contained
25 breathing apparatus.

1 PANEL MEMBER HAMMOND: You know, I did have
2 discomfort throughout the document with the idea of
3 saying: Since you're supposed to have self-contained
4 breathing apparatus if it's over 5 ppm, they can't be
5 exposed over 5 ppm. I certainly have observed in my
6 career workers being exposed above the levels where they
7 should be better protected. And I don't think we can
8 assume that because they're not supposed to be exposed at
9 a certain level that they're not in fact exposed.
10 I would be happier with data that showed that.
11 CHAIRPERSON FROINES: I'm confused. How do we
12 get a LOEL of 200 out of this study?
13 DPR STAFF TOXICOLOGIST LIM: It's extrapolating
14 from the time to 24 hour per day.
15 PANEL MEMBER HAMMOND: Those two are per day?
16 CHAIRPERSON FROINES: Oh, yeah, yeah. Okay.
17 DPR STAFF TOXICOLOGIST LIM: I should have
18 included air concentration in that presentation there too.
19 In fact I have that in the actual table on page
20 33 that included the actual ppm concentrations for these
21 studies. But it's already in tiny point. So rather than
22 apologizing for not -- you're not able to see these
23 slides, I -- you know, I was trying to truncate the table.
24 So that's what happened.
25 CHAIRPERSON FROINES: Yeah. It seems to me that

1 that's the problem of this extrapolation to a 24-hour
2 period where you're getting these what are clearly acute
3 responses at 4,000 ppm. And then because just by
4 adjusting you assume you're going to get a response at --
5 the same response at 200 milligrams per kilogram per 24
6 hours seems to me to be a stretch toxicologically.
7 DPR STAFF TOXICOLOGIST LIM: Right. And that's
8 why we decided not -- this is not appropriate.
9 PANEL MEMBER GLANTZ: I'm convinced
10 statistically.
11 (Laughter.)
12 CHAIRPERSON FROINES: Well, I --
13 PANEL MEMBER GLANTZ: No, no, I agree. I mean if
14 you're giving this very high level for a very short time
15 and getting a transient effect, I don't think it's -- I
16 agree with you, it's not appropriate to assume you would
17 get the same effect if you delivered that same dose very
18 slowly.
19 PANEL MEMBER BYUS: Correct.
20 PANEL MEMBER GLANTZ: It's sort of pharmacologic
21 point of view, I think.
22 PANEL MEMBER BYUS: It is -- I might add, it's
23 much clearer -- well, it's clearer in the document than it
24 is in these tables, the way she's just trying to show it
25 in different ways on the bigger table. And on page 33 it

1 is clearer. And that was really probably why you
2 discounted that study, not the reasons that you said.
3 (Laughter.)
4 CHAIRPERSON FROINES: So, Lori, at long last move
5 ahead.
6 And there's always a certain degree of learning
7 that we all do on this panel as we go through it, and so
8 that it's useful. But it doesn't --
9 DPR STAFF TOXICOLOGIST LIM: Well, I learn too as
10 I go through this document again and trying to reflect to
11 the comments. So it's both ways.
12 Okay. Now, we can talk about the critical study
13 for the acute exposure.
14 Study 7 was selected study as the critical study
15 because of the quality of the study and the determined
16 NOEL level. This study by Albee, et al., was an acute
17 neurotoxicity study where female rats were exposed to
18 sulfuryl fluoride six hours a day for two days. There was
19 no treatment-related effect in the Functional
20 Observational Battery, which contained 31 types of
21 observations and measurements.
22 In addition, the animals were tested for grip
23 performance, landing foot splay, motor activity and the
24 electrodiagnostic responses examined within 24 hours after
25 the final exposure. The NOEL was 30 ppm, or 300

1 milligrams per kilograms per day, the highest dose tested.
2 While the NOEL was from a two-day study, it was
3 used as a single day acute NOEL because other studies,
4 Studies No. 3 and 11, indicated that the acute NOEL should
5 not be higher than 300 ppm. In particular, Study 11
6 showed that the mortality could occur at 600 ppm.
7 --o0o--
8 DPR STAFF TOXICOLOGIST LIM: With an acute
9 critical NOEL of 300 ppm, human equivalent NOEL is 122 ppm
10 using equation one that I've shown in the previous slide.
11 The second term of the equation is the inhalation rate
12 adjustment, with the rat inhalation rate of 0.95 cubic
13 meters per kilogram per day and infant inhalation rate of
14 0.59 cubic meters per kilogram per day. The last term is
15 the amortization for daily exposure.
16 The reference concentration for acute bystander
17 exposure is 0.12 ppm after the application of the
18 1,000-fold uncertainty factor. This 1,000-fold
19 uncertainty factor consisted of a 10-fold factor each for
20 intraspecies variation, interspecies extrapolation, and a
21 lack of a developmental neurotoxicity study.
22 --o0o--
23 DPR STAFF TOXICOLOGIST LIM: This slide shows the
24 conversion of the 300 ppm to an absorbed dose using a
25 default rat inhalation rate of 0.95 cubic meters per

1 kilogram per day and an 18 percent absorption factor.
2 This value is used to calculate the margin of exposure.
3 --o0o--
4 PANEL MEMBER GLANTZ: Can you just go back.
5 Because I -- could you go through -- because I couldn't
6 figure this out when I read the report, how you got that
7 18 percent, again. Because I thought the 18 percent was
8 some more -- oh, it was some more directly measured
9 experimental number. Or, no --
10 DPR STAFF TOXICOLOGIST LIM: That came from the
11 rat pharmacokinetic study.
12 PANEL MEMBER GLANTZ: I'm sorry.
13 Pardon me?
14 DPR STAFF TOXICOLOGIST LIM: That came from the
15 rate pharmacokinetic study.
16 PANEL MEMBER GLANTZ: The 18. So that --
17 DPR STAFF TOXICOLOGIST LIM: Yeah.
18 PANEL MEMBER GLANTZ: Okay. I'm sorry. I
19 misread this slide. So the 18 -- okay. So the 18 percent
20 was a directly measured experimental value?
21 DPR STAFF TOXICOLOGIST LIM: Yes.
22 PANEL MEMBER GLANTZ: Okay. Never mind. I
23 misread something.
24 CHAIRPERSON FROINES: It was -- but it's a
25 measure of the sulfur -- radial labeled sulfur.

1 PANEL MEMBER GLANTZ: Yeah.
2 CHAIRPERSON FROINES: And whether or not it
3 reflects, for example, fluoride may be a different issue.
4 PANEL MEMBER BYUS: Have you got that study,
5 John? Did you get a copy of it? I heard you requested
6 it.
7 CHAIRPERSON FROINES: Yeah, I did.
8 PANEL MEMBER BYUS: And did you look it over?
9 Was it --
10 CHAIRPERSON FROINES: No, I haven't looked it
11 over. But the --
12 PANEL MEMBER BYUS: Was it a -- Let me just ask
13 that question, because I mean this has been a concern of
14 all of ours, the 18 percent and the quality of that
15 pharmacokinetic study, because it could affect these
16 numbers to some extent, at least the margin of exposure
17 numbers. Was it an integrated time dosed curve? You
18 follow me?
19 In order to get extended absorption you integrate
20 the curve over time, like the serum curve. That gives you
21 the extent of absorption. Rather than measuring something
22 at the end of seven days, which is what I -- you know what
23 I'm trying to say? In order to get the true extent of
24 absorption, fractional absorption of the applied dose you
25 integrate the time concentration curve.

1 DPR STAFF TOXICOLOGIST LIM: Okay. This is back
2 on slide number 15. The tissue level was the
3 radioactivity measured at the end of seven days -- seven
4 days after exposure. So it's not --
5 PANEL MEMBER BYUS: Right.
6 DPR STAFF TOXICOLOGIST LIM: Okay. And the urine
7 and feces is a cumulative dose over that seven-day period.
8 So they collected by hours.
9 PANEL MEMBER BYUS: Okay. So they know the total
10 amount of radioactivity that came out in the urine and the
11 feces --
12 DPR STAFF TOXICOLOGIST LIM: -- over that
13 seven-day period.
14 PANEL MEMBER BYUS: -- over the seven days.
15 DPR STAFF TOXICOLOGIST LIM: Plus what's
16 remaining in the tissue.
17 PANEL MEMBER BYUS: Plus -- okay.
18 DPR STAFF TOXICOLOGIST LIM: Does that answer
19 your question?
20 PANEL MEMBER BYUS: All right.
21 PANEL MEMBER HAMMOND: And did --
22 PANEL MEMBER BYUS: Yes.
23 PANEL MEMBER HAMMOND: Sorry.
24 PANEL MEMBER BYUS: Go ahead.
25 PANEL MEMBER HAMMOND: In the metabolism, did

1 they actually observe that it was metabolized to fluoride
2 and sulfate or deduced that?
3 DPR STAFF TOXICOLOGIST LIM: Those levels were
4 measured, and --
5 PANEL MEMBER HAMMOND: So they measured the
6 sulfate -- it was as sulfate?
7 DPR STAFF TOXICOLOGIST LIM: Yes.
8 PANEL MEMBER HAMMOND: It was actually sulfate
9 and fluoride?
10 DPR STAFF TOXICOLOGIST LIM: Yeah, that's on page
11 26 table 2. But they only measure in the urine and blood
12 and nowhere else. And only certain hours.
13 PANEL MEMBER HAMMOND: So is the assumption that
14 the unabsorbed dose is exhaled -- just exhaled gas? But
15 they didn't measure that ever? They didn't do a
16 measurement of that?
17 PANEL MEMBER GLANTZ: How would you do that?
18 DPR STAFF TOXICOLOGIST LIM: It's labeled on S35
19 on the sulfur. So -- I think I mentioned something here.
20 Okay, wait. Radioactivity -- I mention in the
21 study, radioactivity in the expired air was monitored for
22 24 hours and they did not detect any radioactivity. So
23 they stopped monitoring.
24 PANEL MEMBER PLOPPER: So that's not what you
25 got?

1 DPR STAFF TOXICOLOGIST LIM: No.
2 CHAIRPERSON FROINES: I think that the --
3 there are two issues from my standpoint. And I don't know
4 about Joe, Charlie or others.
5 My sense is that you have this obligate nose
6 breather, the rat, and it's breathing in this material.
7 And I would guess that the 18 percent might be an upper
8 bound. Because if you're a kid playing next door, I think
9 you may have a tendency to breathe a lot of the sulfuryl
10 fluoride. A lot of it's going to go out, and not as much
11 is going to be absorbed. So the -- but I don't know. I
12 don't have any idea actually. I don't think any of us can
13 say what it actually is. One could even think that it
14 might be higher. But in general I would think that it
15 might be lower. The 18 percent might be an upper bound.
16 The important thing is that we acknowledge that
17 there is uncertainty in this 18 percent. The problem with
18 a bright line or specific value is that we assume -- you
19 know, we don't really deal with inter-individual
20 variability in humans. And so we have no idea what the
21 range might be in a human population. So that this is a
22 guesstimate which probably isn't unreasonable, but we
23 don't really know. And so -- you do have a paragraph that
24 you nicely talk about the uncertainty.
25 And the -- I had marked it. But then you talk

1 about a safety factor -- no, you say an additional
2 ten-fold factor was included in the reference
3 concentration calculation. Oh, no, I'm sorry. That's the
4 developmental toxicity. But someplace in here I thought I
5 remember -- and I thought I marked it.
6 PANEL MEMBER BYUS: She does. There is a
7 paragraph. I can't find --
8 CHAIRPERSON FROINES: And I thought I marked it
9 some -- that you had made some adjustment for the
10 uncertainty in the 18-percent value.
11 Am I remembering it wrong?
12 DPR STAFF TOXICOLOGIST LIM: It's not an
13 adjustment on the 18 percent but an adjustment to say that
14 even though we think that there's an 18 percent, there are
15 other things that could affect the actual internal dose.
16 So we say that -- we applied -- we went ahead and applied
17 the ten-fold interspecies extrapolation factor even though
18 we already sort of make some corrections regarding the
19 inhalation rate and consider the absorption. So this is
20 another umbrella over everything else.
21 CHAIRPERSON FROINES: So the uncertainty in this
22 18 percent value is included within your ten-fold
23 interspecies number?
24 DPR STAFF TOXICOLOGIST LIM: In sort of
25 qualitatively, yes. We're saying that we still don't

1 know.

2 So the opposite way of looking at that is that

3 just because we make corrections with our 18 percent, we

4 didn't say -- we didn't decrease the ten-fold, saying,

5 "Oh, we already took care of absorption, so it should be

6 less than ten-fold" No, we're saying even though we look

7 at the absorption, we're still going to want that

8 ten-fold.

9 CHAIRPERSON FROINES: I can live with that.

10 DPR STAFF TOXICOLOGIST LIM: Okay. While the

11 emphasis of this presentation is on acute exposure, I want

12 to say a few words about the critical NOELs and effects

13 for repeated exposures. For each of the duration the

14 critical NOELs will protect against effects of the higher

15 doses as indicated in the third column.

16 For one to two weeks of exposure the critical

17 NOEL was 100 ppm based on brain lesions (vacuoles) found

18 in rabbits exposed to 300 ppm for two weeks. These

19 investigators also looked at the effects of sulfuryl

20 fluoride in rats. While they did not find any lesions in

21 the brain at 300 ppm, the kidneys showed changes described

22 as hyperplasia of the collecting tubules, basophilic

23 epithelial cells in the proximal tubules, and increased

24 relative kidney weight. Reduced maternal and fetal body

25 weights were reported in rabbits exposed during gestation

1 days stage 6 to 18.

2 For chronic toxicity the critical NOEL was 30 ppm

3 also for brain vacuoles in rabbits exposed to 100 ppm

4 sulfuryl fluoride for 13 weeks. At doses higher than the

5 critical NOEL there was lesions in the rats, mice and

6 dogs. Other effects involved the teeth, kidney and body

7 weight.

8 For chronic toxicity, again there were effects in

9 the teeth, brain, kidney and brain. The critical NOEL was

10 5 ppm based on lung inflammation in rats after repeated

11 exposures in a reproductivity toxicity study.

12 --o0o--

13 DPR STAFF TOXICOLOGIST LIM: The exposure

14 assessment was already described by Dr. Cochran. For AB

15 1807, the group of concern is the bystander. In this

16 group, the focus is on infants for this presentation

17 because they had the highest exposure per body weight.

18 And only their exposures are discussed further.

19 --o0o--

20 DPR STAFF TOXICOLOGIST LIM: This is a summary

21 table of the infant exposures which could occur while

22 outside of a structure or commodity chamber during

23 fumigation or aeration, as well as inside a residence

24 during these activities.

25 These values were from the use of sulfuryl

1 fluoride at the submaximal application rate. And only
2 submaximal application rate exposures are presented here
3 because these exposures already pose potential health
4 concern. These exposures are would be 10- to 14.5-fold
5 higher if the fumigation were done with a maximally
6 allowed application rate.
7 During fumigation the outside air concentration
8 was 0.8 ppm during the first 12 hours -- these are
9 time-weighted average numbers -- and 1.12 ppm during the
10 entire 24-hour period. These were equivalent to 0.36 and
11 0.50 milligram per kilowatt per day absorbed doses
12 respectively. During aeration, their exposures are much
13 higher when the TRAP method was used and lower when the
14 Stack method was used.
15 With non-food chamber fumigation the highest
16 possible bystander exposure was 5 ppm, or 2.3 milligram
17 per kilogram per day absorbed dose.
18 --o0o--
19 DPR STAFF TOXICOLOGIST LIM: After the NOEL and
20 reference concentration determined and the human exposures
21 are estimated, the next step is to calculate the risk.
22 --o0o--
23 DPR STAFF TOXICOLOGIST LIM: This slide is an
24 expansion of the previous table to include the risk
25 estimates, highlighting columns 3 and 5.

1 The 24-hour TWA human exposure in column 2 is
2 compared to the reference concentration 0.12 ppm. The
3 absorbed doses for these exposures in column 4 and the
4 NOEL of 54 milligram per kilogram per day as an absorbed
5 dose I used to calculate a margin of exposure.
6 In this table all exposures exceeded the
7 reference concentration, and the margins of exposure were
8 less than 1,000, the benchmark needed for acceptable
9 exposure. At the maximal rate of application for
10 structural fumigation, the risks would be substantially
11 greater than those shown here.
12 --o0o--
13 DPR STAFF TOXICOLOGIST LIM: The final step in
14 the risk estimate is an appraisal of the risk, taking into
15 consideration the uncertainties and limitations in the
16 exposure and toxicology data.
17 --o0o--
18 DPR STAFF TOXICOLOGIST LIM: In the calculation
19 of the absorbed dose from the air concentration, an 18
20 percent absorption factor was used. This was from a rat
21 pharmacokinetic study with the assumption that rat and
22 human absorption are similar. Once absorbed, we assumed a
23 three-fold difference in the pharmacokinetics of sulfuryl
24 fluoride between species.
25 This factor -- this absorption factor is used to

1 convert both the critical NOEL and the animal study from
2 human exposure to absorbed dose terms. Since the same
3 factor is used for both the numerator and the denominator,
4 it is cancelled out. So mathematically, the factor has no
5 impact on the margin of exposure calculation.
6 The absorption factor is not used in the
7 reference concentration calculation.
8 --o0o--
9 DPR STAFF TOXICOLOGIST LIM: However, the
10 magnitude of this absorption factor is important
11 biologically if the absorption of so sulfuryl fluoride in
12 humans and laboratory animals after inhalation exposure
13 are different. This difference may be due to chemical or
14 biological factors. The end result could be either higher
15 or lower human absorbed dose compared to the current
16 assumption.
17 For example, rat breathing frequency, about 60 to
18 100 per minute, is much higher than that for humans. The
19 slower human rate means more residential time for the
20 transfer of sulfuryl fluoride from air to blood in humans
21 than in rat. A higher absorbed dose would be expected for
22 humans.
23 On the other hand, the transfer of sulfuryl
24 fluoride from the air to the blood could be limited by the
25 chemical solubility between these compartments. While we

1 don't have data for sulfuryl fluoride, studies with
2 volatile compounds show that rat blood/air coefficients
3 are one and a half to two-fold higher than those for
4 humans. This then could result in higher internal dose in
5 the rat than in humans.
6 In addition, these studies show a direct
7 correlation between rat and human blood/air coefficient.
8 That is, for the compounds that were examined in the
9 studies, the rat blood/air coefficient for a particular
10 compound was predictive of the coefficient for the humans.
11 These studies also showed that the octanol/water partition
12 coefficients was not predictive of the blood/air
13 coefficient.
14 --o0o--
15 DPR STAFF TOXICOLOGIST LIM: This slide lists the
16 uncertainties associated with the toxicology and critical
17 NOEL selected.
18 First, effects observed in laboratory animals
19 were assumed to also in humans. This was a necessity
20 since we don't have human data to establish a critical
21 NOEL. But we do assume humans are more sensitive than
22 animals, using a ten-fold interspecies uncertainty factor.
23 Second, when the acute NOEL from a six hour a day
24 study is amortized to 24 hours, the assumption is that the
25 dose-time response is linear. This may not be the case as

1 the NOEL for a 24-hour continuous exposure, for example,
2 could be lower than the amortized value.
3 Another certainty is the application of the NOEL
4 derived from constant air level in the animal studies to
5 human exposures with declining air levels, such as during
6 application and aeration of structural fumigation. One
7 would expect the NOEL to be higher if the laboratory
8 animals were also exposed to decreasing air level.
9 --o0o--
10 DPR STAFF TOXICOLOGIST LIM: And finally
11 fluoride, which exposure was not assessed in this
12 document. In the footnote of the risk assessment, I noted
13 that the NAS work on fluoride, which started in 2003 at
14 the request of the U.S. EPA, is still ongoing, with a new
15 date of spring 2006 for completion. This work was to
16 examine the drinking water standards and assess the total
17 fluoride exposure.
18 Based on the comparison of toxicity with sulfuryl
19 fluoride and sodium fluoride, it is clear that fluoride is
20 involved in the dental fluorosis observed after treatment
21 with either compound.
22 As for the brain vacuoles and lung effect, it is
23 reasonable to assume that fluoride may be involved since
24 the pharmacokinetic studies detect fluoride, which is
25 inherently toxic depending on the concentration and

1 exposure duration. This fluoride would be expected to add
2 to the total fluoride body burden.
3 In addition, the metabolic intermediate,
4 fluorosulfate, may also be involved. There's little
5 toxicology information on the toxicity of this compound.
6 Or none that I could find really.
7 --o0o--
8 DPR STAFF TOXICOLOGIST LIM: In order to see if
9 fluoride is involved in the brain and respiratory effects,
10 the individual animal data in the 13-week toxicity studies
11 were examined. In these studies, increased incidences of
12 effects in these organs were found in the dose groups with
13 the elevated mean plasma fluoride level.
14 However, examination of the individual data
15 showed some exceptions. The first column is the seven
16 animals -- individual data for the seven animals treated
17 at 300 ppm sulfuryl fluoride. For example, in this
18 13-week study with rabbits exposed to 300 ppm, the brain
19 of animal #5 did not show vacuoles even though the plasma
20 fluoride level was similar to other affected animals. The
21 nasal effect severity was also not consistent in all
22 animals.
23 This lack of direct correlation could be due to
24 varying fluoride level intake from the drinking water and
25 feed during the course of the study or individual

1 variations in response to fluoride. It could also be that
2 the plasma fluoride level measured for only one time point
3 was not a good indicator of tissue levels, especially
4 after repeated exposures. Data on brain fluoride levels,
5 especially in affected regions, would provide more
6 definitive determination of whether and how fluoride was
7 involved in the toxicity of sulfuryl fluoride.
8 --o0o--
9 DPR STAFF TOXICOLOGIST LIM: While we don't know
10 what the fluoride exposure levels were from the inhalation
11 of sulfuryl fluoride, three scenarios for chronic
12 exposures are provided in this slide using different
13 assumptions regarding local exposure and residue in the
14 tea leaves. These were singled out because of potential
15 high exposures. Tea plants are known to accumulate
16 fluoride from the soil. The constant sources of fluoride
17 exposure were the dietary exposure, which is the sum from
18 the uses of sulfuryl fluoride on food commodity
19 fumigation, the use of cryolite which is metabolized to
20 fluoride. And cryolite's used as an insecticide used on
21 fruits and vegetables, primarily grapes, potatoes and
22 citrus. It's a solid. It's not a fumigant.
23 PANEL MEMBER BYUS: What is it again -- what is
24 cryolite, I mean, exactly? It's not -- do you know what
25 the chemical is?

1 DPR STAFF TOXICOLOGIST LIM: The chemical
2 formula?
3 PANEL MEMBER BYUS: Yeah.
4 DPR STAFF TOXICOLOGIST LIM: I don't remember
5 what it is. But it is metabolized to fluoride. So it
6 contains fluoride. It's a solid, and it is put on leaves.
7 And it's also a naturally occurring compound.
8 PANEL MEMBER BYUS: Grapes? A lot of grapes?
9 It's a lot of grapes?
10 DPR STAFF TOXICOLOGIST LIM: Yeah, grapes,
11 potatoes and citrus. Grapes, yes.
12 So the dietary included the uses of sulfuryl
13 fluoride on food commodity fumigation, cryolite, and the
14 background fluoride levels in food estimated by the U.S.
15 EPA, as well as drinking water based on a 1 ppm standard.
16 That's the fourth row there -- fifth row.
17 The maximum total fluoride exposure is shown in
18 column 2 where worker exposure was set on the highest
19 exposed group, which is the chronic exposure of the tent
20 crew during applications of sulfuryl fluoride at the
21 maximal application rate, and the maximum fluoride residue
22 measured in brewed tea, assuming a consumption rate of two
23 8-ounce cups per day.
24 The average total fluoride exposure was based on
25 the tent crew exposure at submaximal application rate and

1 average tea residue level.

2 And the last scenario used, in the last column,

3 used the worker exposure set at the chronic RfC for

4 sulfuryl fluoride in this document and an average tea

5 residue. The total fluoride exposure in this scenario

6 would be the U.S. EPA chronic RfC of 0.06 milligram per

7 kilogram per day for fluoride.

8 PANEL MEMBER BYUS: I'd just like to commend Lori

9 for doing this analysis, because -- and DPR, because they

10 really tried here to -- the object of this was to

11 determine really what the baseline fluoride was from all

12 sources and through -- and then if sulfuryl fluoride

13 really increased it significantly and what percentage --

14 would make it even more toxic.

15 And so I think we should commend them for really

16 doing this kind of an analysis of this in terms of

17 adjusting total environmental exposure.

18 DPR STAFF TOXICOLOGIST LIM: I need to share the

19 spotlight with Dr. Byus, because he's the one who gave the

20 suggestion.

21 (Laughter.)

22 DPR STAFF TOXICOLOGIST LIM: Maybe I wasn't

23 supposed to say that.

24 PANEL MEMBER BYUS: But you did it. You did the

25 analysis. And as I said --

1 DPR STAFF TOXICOLOGIST LIM: Maybe it was a
2 setup.
3 PANEL MEMBER BYUS: -- I commend you for it,
4 because it is very, very difficult, this sort of multiple
5 exposure-type scenarios, and you ran this sort of -- and I
6 think it was very -- because I didn't know how -- it could
7 have come out significantly different.
8 CHAIRPERSON FROINES: It's clear we're creating a
9 conflict of interest issue here.
10 (Laughter.)
11 PANEL MEMBER BYUS: Go right ahead.
12 DPR STAFF TOXICOLOGIST LIM: Okay. Based on the
13 information currently available, bystander exposures to
14 sulfuryl fluoride are of potential health concern. Even
15 at the submaximal rate application, the exposures far
16 exceeded the reference concentration, and the marginal
17 exposures were less than the benchmark of 1,000 for
18 acceptable exposure.
19 While not discussed in this presentation, the
20 exposures of workers and residents reentering the
21 fumigated homes under many scenarios pose health hazards
22 and need to be reduced.
23 The recommendation is for sulfuryl fluoride to be
24 listed as a TAC since the bystander exposures exceeded
25 one-tenth of the RfC.

1 Additional toxicology and exposure data for
2 sulfuryl fluoride and fluoride are needed to refine the
3 risk assessment and to address the uncertainties in the
4 risk estimates.
5 --o0o--
6 DPR STAFF TOXICOLOGIST LIM: I'd lke to -- now,
7 the final slide is to acknowledge the work of many
8 toxicologists at the Medical Toxicology Branch who
9 reviewed the toxicology studies used in this volume.
10 I also would like to acknowledge the reviewers of
11 the draft documents from the Branch. And all the names
12 are listed here.
13 And I need to add Dr. Ruby Reed's name on this
14 list since she was my primary consultant on the fluoride
15 issues.
16 Questions?
17 CHAIRPERSON FROINES: That's great. That was
18 really a very fine presentation. Thank you very much.
19 Let me just deal with some administrative issues
20 first. We would now normally go to Roger and Craig for
21 any comments from them as the leads. And then we would go
22 around the room and have comments from panel members -- or
23 questions and comments.
24 So that would be where we are at right now. It's
25 also 12:45. And so do people want to continue and pursue

1 that or do you want to break for lunch? Or what's
2 everybody's interest?
3 PANEL MEMBER PLOPPER: Lunch.
4 PANEL MEMBER GLANTZ: Why don't we have a -- can
5 we get lunch in the building?
6 Why don't we take a half hour break for lunch.
7 And we could bring -- maybe finish eating here or
8 something so we can move forward with this.
9 CHAIRPERSON FROINES: I don't think you can --
10 who's in this building?
11 PANEL MEMBER GLANTZ: Can't do that?
12 No canteen?
13 DR. ALEXEEFF: Directly outside, right outside to
14 the right there's two places close by.
15 CHAIRPERSON FROINES: Could you bring it back in,
16 George? Can you get something to bring it back in?
17 DR. ALEXEEFF: Yeah, you can bring it back in.
18 CHAIRPERSON FROINES: So is everybody comfortable
19 with a half hour? Because --
20 PANEL MEMBER HAMMOND: Assuming you can bring
21 stuff back here.
22 CHAIRPERSON FROINES: Or wherever. I mean the
23 point is not to come back --
24 PANEL MEMBER HAMMOND: We can bring food back in,
25 you're saying?

1 CHAIRPERSON FROINES: It's whatever you're
2 interested in doing.
3 Tobie, are you happy with a half hour lunch
4 and --
5 DPR ASSISTANT DIRECTOR JONES: That's fine.
6 CHAIRPERSON FROINES: Well, I think we have a
7 consensus. Although everybody's kind of what, more soft
8 spoken than they normally are.
9 So let's break. And let's come back here --
10 let's be ready to start by 1:30.
11 (Thereupon a lunch break was taken.)
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1 AFTERNOON SESSION

2 CHAIRPERSON FROINES: So we're back to work

3 again.

4 So to follow the traditional order here. Roger,

5 you've been working on the exposure side. So the question

6 is: Questions for DPR, comments, recommended changes,

7 anything that you think is necessary.

8 PANEL MEMBER ATKINSON: Okay. As probably being

9 somewhat evident, I've had a lot of comments to DPR during

10 the process. Most of them have been taken into account.

11 The last lot we were on a conference call on

12 Tuesday. So there's still some additional comments that

13 are hanging from there, that I assume you are going to

14 take into account.

15 My major concern at the moment is still the lack

16 of data concerning the environmental fate of sulfuryl

17 fluoride. I would urge you to look at the literature. I

18 realize it's not -- there's no reference given in the

19 actual text, but concerning the solubility and hydrolysis

20 of the compound in water, to try and assess whether or not

21 uptake by clouds and hydrolysis there will be -- they'll

22 be important. If it isn't, then we've potentially got a

23 greenhouse gas.

24 I see no -- I would not expect it to react with

25 OH radicals, NO3 radicals or ozone, nor to fertilize. So

1 I would guess that if it doesn't get taken up by clouds
2 with hydrolysis, then it's going to have a long lifetime.
3 And that's really it. Otherwise I'm fine with it
4 as it stands now, subject to the things we talked about on
5 Tuesday and I think an expanded version on the hydrolysis
6 question.
7 CHAIRPERSON FROINES: To the degree that there's
8 information available?
9 PANEL MEMBER ATKINSON: Yeah.
10 CHAIRPERSON FROINES: Let me ask you a pointed
11 question then.
12 If we by the time -- when we finish going around
13 the room, if there's a sentiment that the document -- that
14 we would approve the document, or at least take a vote on
15 the document, are you comfortable with them making the
16 changes that you're talking about now, or would you
17 require another meeting with another draft?
18 PANEL MEMBER ATKINSON: No, if we have sort of
19 consultation from DPR -- or at least if I had some
20 interaction with them on it, then that's fine. I'm
21 perfectly happy with helping to assist on that specific
22 question.
23 CHAIRPERSON FROINES: I'm not prejudging anything
24 in terms of the discussion. I'm just saying -- I just
25 want to be clear as we move around the room.

1 So Craig.

2 PANEL MEMBER BYUS: I really don't have anything

3 to add. Most everything -- or everything I suggested that

4 DPR do or change or add or the document, they did

5 willingly. And I think it really made the document good

6 and I'm happy with it.

7 CHAIRPERSON FROINES: So from your standpoint,

8 you're at a place where -- leaving DPR aside -- in terms

9 of the panel -- this discussion amongst the SRP, you're

10 satisfied that the document meets the legislative

11 criteria?

12 PANEL MEMBER BYUS: Yes.

13 CHAIRPERSON FROINES: Okay. Where to go next?

14 Stan.

15 PANEL MEMBER GLANTZ: All the things I had wanted

16 to ask about have been discussed, and I'm satisfied.

17 CHAIRPERSON FROINES: Kathy.

18 PANEL MEMBER HAMMOND: I just would like to just

19 reiterate my concern about the exposures and both -- we

20 have a small amount of data, which -- I know it's hard to

21 gather this data. But I'd like to make sure that we

22 understand better the peak exposures, the short-term

23 exposures, the distances from this, and also the exposures

24 of the workers. And I don't like making -- there being

25 assumptions about what the exposures are based on what the

1 recommendations are.
2 Other than that, I'm fine.
3 CHAIRPERSON FROINES: Well, help me with what you
4 want, having said that.
5 PANEL MEMBER HAMMOND: Well, I would rather, if
6 the document -- if we don't have data on something, I
7 would rather the document said that. If we don't know
8 what the workers' exposures are, just say that. If we
9 don't know something, we should say it. And I think it
10 would just make -- that's all.
11 CHAIRPERSON FROINES: Is that clear for Randy and
12 Lori and Tobie?
13 DPR SENIOR ENVIRONMENTAL RESEARCH SCIENTIST
14 SEGAWA: Um-hmm.
15 CHAIRPERSON FROINES: Because Tobie's looking a
16 little wide-eyed.
17 DPR ASSISTANT DIRECTOR JONES: Can you say that
18 again.
19 PANEL MEMBER HAMMOND: I was concerned about
20 parts of the document that make statements like -- the
21 label says you shouldn't be exposed to more than 5 ppm's.
22 So we assume that -- without self-contained breathing
23 apparatus. Therefore, we assume that was the maximum. No
24 one's exposed above that. I don't think that's an
25 appropriate assumption.

1 So if the data don't exist, then I would rather
2 you say that, there's no other data. And then you make
3 some assumption. And I think it's good to call out when
4 there's lack of data.
5 DPR ASSISTANT DIRECTOR JONES: I think the only
6 caveat -- and I think the staff can work with that -- is
7 since we're operating under a structure of the label is
8 the law, those applying -- and there's statements on
9 pesticide labels that say that very directly. So if in
10 fact a company is allowing it's workers to go into an
11 environment without the appropriate personal protective
12 equipment and are being exposed, they have both a problem
13 of legal consequences under our statute and under the
14 Occupational Safety -- OSHA standards.
15 So I think staff can find a way to address it.
16 But I think in terms of our looking at exposure scenarios,
17 we have to assume that people are following the label. We
18 understand that there are circumstances where they may
19 not. But they are breaking the law, both from following
20 pesticide law and from worker safety laws.
21 PANEL MEMBER HAMMOND: Okay. Maybe a better way
22 for me to say that then -- okay, let me back it up -- is
23 to say that in doing the risk assessment and for the
24 documents and the assumption of the exposures, that the
25 assumption -- that the assumptions are that first the law

1 is followed. And given that, that would lead us to this.
2 But the way it's written, it actually at least appeared to
3 me that you were saying that nobody was exposed above 5
4 ppm. And unless we know that, I wouldn't state that.
5 DPR ASSISTANT DIRECTOR JONES: I understand.
6 CHAIRPERSON FROINES: This is -- I mean this is
7 clearly the classic problem of law versus science, where
8 something that is truth in a legal sense may not be
9 truthful in a scientific sense at all. And so we always
10 live with different definitions of truth.
11 And so I think what Kathy is saying -- correct me
12 if I'm wrong -- is that recognizing your constraints with
13 respect to the law, it would also be reasonable to have
14 some language about uncertainty, to say that the actual
15 exposures may require further evaluation to ensure -- and
16 so on and so forth -- to reduce the uncertainty about
17 the...
18 So I think it's correct -- yeah.
19 PANEL MEMBER HAMMOND: Yeah, and I think the
20 point for why you're doing it -- as I think about what
21 you're trying to do in the document is you're trying to
22 say, given that level, is there a residual health risk?
23 That's basically in a sense what the document is trying to
24 do. So you're saying if people are following the law, do
25 we still have a problem? And that's what you're trying to

1 address in the document. So as long as it's couched in
2 that way, then I feel fine.
3 CHAIRPERSON FROINES: Yeah, I think -- I don't
4 think it takes a lot of writing. But I think it takes
5 some pinpointing where you -- where there is uncertainty
6 acknowledging it essentially. I think that's the -- what
7 she's looking for.
8 Does that makes sense?
9 DPR ASSISTANT DIRECTOR JONES: Yes.
10 CHAIRPERSON FROINES: See, my job is to watch the
11 heads nodding and then figure out where we are.
12 DPR STAFF TOXICOLOGIST LIM: At least for me I
13 could tell that I could add that in my conclusion. That
14 would be a big point.
15 PANEL MEMBER HAMMOND: Thank you.
16 CHAIRPERSON FROINES: Joe.
17 PANEL MEMBER LANDOLPH: You want to do Charlie
18 first?
19 CHAIRPERSON FROINES: Well, Charlie's the new
20 scientist on the block, so I always want to give him, you
21 know, some deference.
22 PANEL MEMBER LANDOLPH: I wanted to congratulate
23 Dr. Jones and all the staff. I think you did a very nice
24 job. The document's very detailed, it's very thorough.
25 I have given you my written comments to help you,

1 so it's easy to respond. And I would say certainly on
2 page 4, paragraph 4, lines 3 to 5, I indicated that I
3 thought this sentence on oncogenicity for fluoride should
4 be moved to the end of the paragraph. And I would suggest
5 reworking it, because it seems that there's almost already
6 an upfront presumption that it would not be expected to be
7 oncogenic in humans. I think that's maybe hanging
8 yourself out there a little bit too far.
9 I would suggest something like: "The evidence
10 for the carcinogenicity of fluoride, an active metabolite
11 of sulfuryl fluoride, is therefore considered weak and not
12 conclusive at present. Further studies are needed to
13 conclusively determine whether fluoride is carcinogenic."
14 That way you'll protect yourself, and just state it
15 exactly the way it is without -- it almost sounds like
16 you're making a pre-conclusion up front before we have
17 enough data.
18 So I have a lot of statements like that. And
19 I'll just be concise and not mention all of them.
20 On page 18 paragraph 3, it's just a fantastic
21 section there which has human illnesses. And I wondered
22 if you could discuss in a document whether the shortness
23 of breath was reversible or irreversible in humans. As
24 soon as I saw shortness of breath, I started thinking of
25 RADS. And I wonder if anything like that has reared its

1 ugly head here. And you might just make a few sentences
2 there.
3 And also answer whether the symptoms of numbness
4 of the hands, confusion, memory loss, et cetera, are
5 reversible or irreversible on exposure to sulfuryl
6 fluoride, if that's known.
7 DPR STAFF TOXICOLOGIST LIM: May I explain?
8 PANEL MEMBER LANDOLPH: Please.
9 DPR STAFF TOXICOLOGIST LIM: I think Roger can
10 talk about this data information from the Pesticide
11 Illness Program, whether there's any follow-up on that.
12 Can either Joe Frank or Roger answer that
13 question for you right now?
14 MR. FRANK: My name's Joe Frank. I'm responsible
15 for the Exposure Assessment Program.
16 That's not a problem. We have a physician in our
17 branch who will be able to answer the questions you would
18 like answered. And we can put down the implications of
19 those, whether they're transient, whether he thinks
20 there's a -- you know, lasting effects.
21 PANEL MEMBER LANDOLPH: Yeah, thank you. I think
22 that will be very important.
23 And while I've got you, also is it possible to
24 extract or abstract any concentration data from those
25 illness reports?

1 MR. FRANK: Generally not.
2 PANEL MEMBER LANDOLPH: Okay. Thank you.
3 And then on page 57, paragraph 1, line 4 --
4 CHAIRPERSON FROINES: Thank you.
5 PANEL MEMBER LANDOLPH: Thank you.
6 -- there's a statement that fluorosulfate was
7 considered to be nontoxic. I would not put that statement
8 in. I would say it's presumed a metabolite of this
9 molecule, and studies need to be done to address whether
10 or not it is toxic.
11 And also Dr. Plopper will get to you about
12 sulfate as well. So I'll let him do that.
13 Then a question I had about the pulmonary edema.
14 Since I saw that I started thinking of phosgene. And my
15 question is: Are there then any parallels between this
16 pulmonary edema and edema induced by phosgene? Is this
17 a -- or is this a more prosaic type?
18 DPR STAFF TOXICOLOGIST LIM: I'm not familiar
19 with the toxicity of phosgene. I can certainly look it
20 up.
21 PANEL MEMBER LANDOLPH: And then a question: Is
22 this pulmonary edema reversible or irreversible? That's
23 something you might address in a document.
24 Let's see. I just have a couple more and then
25 I'll stop.

1 CHAIRPERSON FROINES: That's okay.
2 PANEL MEMBER LANDOLPH: I thought the appendix
3 review on fluoride was terrific. I really want to
4 congratulate you on that. In fact, some of it's so good,
5 like Dr. Froines mentioned earlier, I thought you might
6 want to take a few sentences from there and put it up
7 front, because if viewed that sulfuryl fluoride is a
8 pro-drug for fluoride and other things, maybe a few
9 sentences might come out of there. It's very, very well
10 written.
11 And then you probably want to address somehow --
12 if you can get a copy of that PhD. thesis by Bassin,
13 somewhere in there. Because I'm worried that there may be
14 a potential lurking for oncogenicity of fluoride, which is
15 a metabolite of this. With the appropriate
16 qualifications. And then I mentioned the hyperplasia of
17 the kidney and the collagen depletion, et cetera, as
18 potentials for carcinogenesis.
19 And I already mentioned my comment about the
20 genotoxicity assays, not to state that they're blanket.
21 Overall equivocal, but they're positive in some assays.
22 Because you have things like microtubule inhibitors, which
23 are uniformly negative in bacteria because they don't have
24 chromosomes, but they cause clastogenesis in mammalian
25 cells. So please take that view.

1 And other than that, I have other small things,
2 which you can look at yourself to see if they're helpful
3 or not.
4 And the only final thing I'm thinking of would be
5 somehow if you could write a short section or add to your
6 section this discussion of the neighbor effect, we'll call
7 it, rather than the bystander effect for clarity. I think
8 it's our responsibility and yours to make sure that the
9 neighbors would be protected if someone is fumigating a
10 house. And a discussion we heard earlier that when the
11 tent is up, there's leakage's that it's not airtight,
12 worried me a little bit. And particularly Stan's
13 discussion that the million dollar houses plus in San
14 Francisco are right next to one another, I think somehow
15 that has to -- we have to come to grips with that.
16 So if you could think of a concise way to put
17 that in, particularly with the concentric circles of
18 concentrations of the sulfuryl fluoride from the point of
19 fumigation outward, I think that would be very helpful.
20 If there's some kinetic data on how it dissipates, a few
21 graphs would be very useful too.
22 CHAIRPERSON FROINES: That may be difficult
23 because they really don't have the ARB data yet. And so
24 maybe, if there is an update -- I don't know what you
25 think. I don't think they really have the information

1 that you're asking for.

2 PANEL MEMBER LANDOLPH: Well, just tell us what

3 they do have, and I'd be happy. It just seems to me --

4 you know, I was looking at Los Angeles County, and I mean

5 there's just a truckload of fumigation going on. And it

6 seems to me this should have all been sorted out a long

7 time ago, before this molecule was put in the public

8 domain like this. So I'm a little disappointed that that

9 database is still in such a state of posity.

10 So I'll be delighted with whatever you find that

11 you can put in there, and that would be helpful.

12 CHAIRPERSON FROINES: Well, what's the question

13 you're --

14 PANEL MEMBER LANDOLPH: Well, I want to know how

15 much is getting into, you know, proximate houses. Or are

16 these levels serious? Should we not consider them? Or

17 are they levels that should be considered in terms of the

18 toxic --

19 CHAIRPERSON FROINES: So you're saying -- you're

20 interested in the question of relative to the -- you're

21 actually --

22 PANEL MEMBER LANDOLPH: Let me capsulate for you.

23 CHAIRPERSON FROINES: No, let me just say that

24 we're on a little bit of a borderline here, because what

25 you're asking is in fact a risk management issue. And so

1 it's not necessarily appropriate for this document. But
2 what you're asking, if I understand it, is given the NOEL
3 and the RfC, and given what we know about exposure, do we
4 anticipate a public health problem in terms of proximity
5 to Vikane use for fumigation? I think that's what you're
6 saying.
7 PANEL MEMBER LANDOLPH: Yes. So if you fumigate
8 your house and I'm living next to you are me and my family
9 at risk of any health problems? That's realty the
10 question.
11 CHAIRPERSON FROINES: And that's -- that is close
12 to an issue for risk management in terms of setting the
13 standards. So it's really out of our jurisdiction in a
14 sense. But if you could put something in that showed a
15 comparison of values that have been measured versus your
16 NOEL estimates, something -- I think it shouldn't be
17 overdone. I think if there's anything you could put in,
18 it would be -- am I being clear?
19 PANEL MEMBER LANDOLPH: Yeah. Yeah, you're being
20 very -- extremely clear.
21 And thank you for all your effort. It's a very
22 nice document. And these are comments just intended to
23 help you out a little bit.
24 DPR STAFF TOXICOLOGIST LIM: Can I add a little
25 bit to this.

1 The way I understand the monitoring studies are
2 done with a monitor from the structure away from in
3 different directions. For every study, the highest point
4 is not necessarily right next to the house. Okay? So
5 being a neighbor you of course would be concerned. But
6 that's not -- may not necessarily be the case. And there
7 could be points, depending on the wind or whatever, that
8 it could be away from the house. And we picked the
9 highest point of that particular study when we did the
10 exposure. If that helps.
11 PANEL MEMBER LANDOLPH: Yeah, it helps.
12 PANEL MEMBER BYUS: My suggestion would be to
13 simply define what you mean by bystander in a clear term.
14 Say, for example, these are the kinds of people or
15 exposure scenarios for bystanders: Walking by while the
16 house is being vented; living next door within X number of
17 feet. Just explain what those scenarios are about what do
18 you mean by bystander. Because I think -- I think that
19 did come out of this discussion this morning, that it is
20 kind of a misleading term. It means somebody who's sort
21 of, to my mind, transiently walking around near there who
22 isn't normally there. And that -- and you sort of think,
23 "Well, what about the people that live right next door?"
24 So it's sort of what are the kinds of exposures that might
25 qualify under "bystander". That's how I would do it, and

1 not -- because we -- you know, not get into drawing more
2 graphs or whatever.
3 DPR STAFF TOXICOLOGIST LIM: Well, we could
4 clarify then the exposure assessment as though it's in the
5 risk assessment.
6 PANEL MEMBER BYUS: Correct. I mean because you
7 do it for the people that are putting the tarp on and off
8 and that kind of thing. But "bystander," I think you just
9 need a little bit more kind of relevant types of who those
10 people might be.
11 DPR ASSISTANT DIRECTOR JONES: This is Tobie
12 Jones.
13 If I could ask: If we clarified that and clearly
14 indicated -- and I'll leave it to Lori and Roger to work
15 this out -- that since we are not -- we are assuming that
16 people inside neighboring houses are exposed to the same
17 concentration as people outside, that we're trying to --
18 we're trying to account for this since we have no data to
19 speak to that.
20 PANEL MEMBER BYUS: Right.
21 DPR ASSISTANT DIRECTOR JONES: And then clarify
22 what we're including as bystander.
23 CHAIRPERSON FROINES: Yeah, that would be fine.
24 PANEL MEMBER BYUS: That's great.
25 CHAIRPERSON FROINES: That's good, because I

1 think this discussion clarified what Joe was really asking
2 for. And I think -- it seems reasonable.
3 So you're okay, Tobie, on this?
4 DPR ASSISTANT DIRECTOR JONES: (Nods head.)
5 PANEL MEMBER LANDOLPH: And, yes, I'm happy that
6 they go ahead and take care of business as they feel
7 appropriate. Contact me if they need to. But I'm sure
8 they can take care of it just fine, as Roger said.
9 CHAIRPERSON FROINES: You're volunteering your
10 house to do studies when you --
11 (Laughter.)
12 PANEL MEMBER LANDOLPH: No, I'm volunteering your
13 house --
14 PANEL MEMBER HAMMOND: Your neighbor's house.
15 PANEL MEMBER LANDOLPH: And that is a joke.
16 CHAIRPERSON FROINES: Charlie.
17 PANEL MEMBER PLOPPER: I'd just like to say I
18 think it's an excellent document too. And I'm concerned
19 about one thing and, that is, you're downplaying the acute
20 responses to the respiratory things, because that happens
21 with lots of toxicants. That's almost the respiratory
22 system's response to a toxic stress. And when I -- and
23 then you add pulmonary edema to that, you may be actually
24 playing that issue down. I think that would be my
25 concern.

1 And the other thing is the sulfates. And
2 sulfates are lung -- or toxic compounds for the lung, and
3 particularly if they're respired. And that's what that
4 acute study would telling me. And I think you should just
5 explain that, is what my concern was.
6 Were there any documents that talk about the
7 workers on this that have any problems with the nasal
8 cavity? Did they talk -- do they do tests for smell, for
9 instance? Because there's a lot of literature now that
10 suggests that when something has that kind of a toxic
11 response in the nasal cavity, that it's carried by the
12 nerves right into the -- goes through -- goes passed the
13 blood brain barrier and straight into the brain. And
14 that --
15 PANEL MEMBER BYUS: Is that true?
16 PANEL MEMBER PLOPPER: Oh, yeah. In fact --
17 CHAIRPERSON FROINES: When you drive on your
18 freeway, all those ultrafine particles are going through
19 your olfactory bulb into the brain.
20 PANEL MEMBER PLOPPER: Right, exactly.
21 PANEL MEMBER BYUS: Wow.
22 PANEL MEMBER PLOPPER: And most of those things
23 are considered to be relatively inert as they go through.
24 But this is not. And so I would be a little concerned
25 about that. You know, there's probably no data, but it

1 would be interesting -- I wouldn't discount if they did
2 any studies about anosmia or any other sorts of things,
3 because that kind of a toxic response that soon would say
4 to me that the nasal cavity was really attacked. And that
5 could explain the difference in the -- between fluoride
6 tests and tests with this compound in terms of nervous
7 function -- or central nervous system function, different
8 route.
9 DPR STAFF TOXICOLOGIST LIM: You're referring to
10 the studies with the structural fumigator --
11 PANEL MEMBER PLOPPER: Yes. I mean I don't know
12 if they did. But it would be worth knowing that,
13 because --
14 DPR STAFF TOXICOLOGIST LIM: This is described on
15 page 52. They did an olfactory study. In fact, that was
16 reduce olfactory function. But I don't see any
17 examination of the nose that's listed here. I could
18 double check to make sure.
19 PANEL MEMBER PLOPPER: Well, I'm just bringing
20 that -- because that's a -- turning out to be a very good
21 sentinel, a very sensitive one. So if it's there, you
22 should put it in. I'm more concerned that you might be
23 erring on the side of being -- not setting your levels low
24 enough. Just based on that.
25 So that's mainly my concern.

1 CHAIRPERSON FROINES: Well, let me try and -- the
2 first thing you said was that there was less -- perhaps
3 less than complete or under-interpretation of the data on
4 respiratory effects. So just in terms of bringing -- so
5 they understand what we're asking them to do, what would
6 you recommend?
7 PANEL MEMBER PLOPPER: Well, I mean obviously
8 there needs to be some more studies. But I think it would
9 be worth not trying to downplay those issues and just
10 treat them -- you know, you -- yeah I think you've done a
11 reasonable job of picking your NOELs and discounting that
12 study. But I don't think that you should throw that study
13 out. You should just point out that the details are not
14 there enough. Because from my perspective, that was --
15 that's the first entry point we use for picking a compound
16 that's a respiratory toxin, is what happens when you give
17 them a relatively whopping dose and you get -- that's how
18 the respiratory system responds. And I can think of about
19 six things that are now identified as toxicants that
20 respond like that. And then you can take that and divide
21 it -- that dose and divide it by a thousand and then you
22 get a toxic -- a long-term toxic response.
23 DPR STAFF TOXICOLOGIST LIM: I have a section
24 here on page 56 under "Hazard Identification with
25 Respiratory System Effects."

1 CHAIRPERSON FROINES: Page what?
2 DPR STAFF TOXICOLOGIST LIM: Fifty-six, on the
3 top part, where another -- we talked about this. It seems
4 like it's -- I really need to talk more about it, because
5 I just barely mentioned it toward the end of that first
6 paragraph.
7 So would it be sufficient if I bring in the
8 workers study information to say that during the -- but
9 they didn't look at -- either they did or they didn't.
10 And add more information to that paragraph?
11 PANEL MEMBER PLOPPER: That's what I was thinking
12 of, yes.
13 DPR STAFF TOXICOLOGIST LIM: Okay.
14 CHAIRPERSON FROINES: Okay. And then the second
15 thing you said was -- I'm sorry, I --
16 PANEL MEMBER PLOPPER: The sulfate issue. And I
17 don't know -- I can't ask them to write a new document and
18 I'm not -- I just think it's worth noting that --
19 CHAIRPERSON FROINES: If there's any literature.
20 Well, I mean there's enormous literature on sulfuric acid
21 and its carcinogenicity. But you're not talking so much
22 about that, because at that pH you're not going to have a
23 lot of sulfuric acid in the lung, I would assume.
24 PANEL MEMBER PLOPPER: Well, I don't know. I'm
25 not a chemist. All I know is when you put sulfur and

1 oxygen together and you put it in the lung, you get
2 problems. So I don't know about sulfate.
3 CHAIRPERSON FROINES: Well, that's a good
4 question. At pH 7.4, thereabouts, if you have sulfate,
5 you're going to have probably not a lot of -- I don't
6 know. It's a good question.
7 PANEL MEMBER PLOPPER: Until it gets absorbed.
8 And what happens when it gets absorbed? The doses that --
9 or the amounts that I saw bound in the nasal cavity and
10 the respiratory system seemed very high because -- the
11 estimates seem low because it's per gram. But you talk
12 per surface. And per surface area that's a lot of
13 material. Because that means almost all the cells have
14 got it. Because it's not like a liver where it's in
15 pieces. It's everywhere. And I thought that was a lot.
16 DPR STAFF TOXICOLOGIST LIM: So in terms of
17 trying to add that type of information --
18 CHAIRPERSON FROINES: Are you more concerned
19 about systemic sulfate effects or lung sulfate?
20 PANEL MEMBER PLOPPER: No, I'm just thinking in
21 terms of what does it mean to have all this sulfate --
22 that much sulfate stuck in the tissues that long
23 afterwards in terms of what that's doing to toxicity.
24 Because it sounds to me like it's a lot. I think cells
25 would have a difficult time dealing with that.

1 CHAIRPERSON FROINES: They would also have -- I
2 mean there's the acute issue of what happens with sulfate
3 uptake in epithelial cells, et cetera, et cetera, in the
4 lung. And do you -- are we going to produce any sulfuric
5 acid, which we know is problematic?
6 What I would do would be to do some -- a bit more
7 literature work. We know that sulfuric acid when it's
8 breathed as a fume is quite toxic. In fact, when I was on
9 the NTP we considered sulfuric acid as a lung carcinogen.
10 So that if you have a lot of sulfuric acid in the lung,
11 clearly it's a carcinogen.
12 So in order to protect yourself, I think you
13 should probably look at the sulfate literature a bit and
14 decide what might be appropriate to --
15 PANEL MEMBER PLOPPER: Just mention it,
16 because -- just for that, because it may turn out that
17 that's what compounds the problems with the fluoride.
18 CHAIRPERSON FROINES: You think there -- we don't
19 know how much sulfate is generated from this compound in
20 the lung, do we?
21 DPR STAFF TOXICOLOGIST LIM: It was only
22 measuring that urine and blood, as I recall. So we don't
23 know the total.
24 CHAIRPERSON FROINES: So we don't -- there's
25 probably no estimate of sulfate in the lung then, I would

1 guess.
2 DPR STAFF TOXICOLOGIST LIM: Not in this study.
3 CHAIRPERSON FROINES: And this is the only study.
4 So we're sort of -- you may want to -- you may want to say
5 this is the only study and this is an issue that's
6 unresolved and further information would be helpful. I
7 mean cover yourself by acknowledging that there is some
8 uncertainty and that it's something that deserves further
9 attention. Obviously sulfuric acid's quite toxic.
10 DR's. LIM: Would that be sufficient without any
11 more reviews or -- how far do I need to go --
12 PANEL MEMBER PLOPPER: I think it would be. We
13 don't -- I don't think the information is there, but it's
14 certainly --
15 CHAIRPERSON FROINES: My guess is the information
16 isn't there. And so what you're going to do is to make --
17 write a short statement that says this is an issue that
18 deserves further study, and there is clearly toxicity
19 associated with sulfates. And so --
20 PANEL MEMBER PLOPPER: Could you assume that if
21 the -- whatever the fluoride burden is, if you divided it
22 by two, that's the sulfate? Which is still -- it's quite
23 a bit.
24 CHAIRPERSON FROINES: So you're just
25 acknowledging that you're aware of the fact that this is

1 an unresolved issue, I think would be...
2 And there was a third -- you had respiratory
3 sulfate and -- what was the third?
4 PANEL MEMBER PLOPPER: That's it. I think every
5 else that I was concerned about somebody else brought up,
6 so --
7 CHAIRPERSON FROINES: Okay. I'm the last one,
8 and I'll be brief.
9 I think that it might be useful to -- your
10 discussion of the two papers on page 52 is quite nice, I
11 thought. And when you're over here talking about the risk
12 assessment and you talk about selection of endpoints, I
13 would actually put a -- when you're over here and you're
14 in the brain vacuolation and malacia -- oh, you do? I'm
15 sorry. What I was asking you to put in, you have put in.
16 (Laughter.)
17 CHAIRPERSON FROINES: My fault.
18 (Laughter.)
19 PANEL MEMBER HAMMOND: Smart.
20 CHAIRPERSON FROINES: Okay.
21 DPR STAFF TOXICOLOGIST LIM: I've got good leads.
22 CHAIRPERSON FROINES: All right. So that's good.
23 We cleared that one up pretty fast.
24 (Laughter.)
25 CHAIRPERSON FROINES: I just wanted to make one

1 comment here. The Eisenbrandt-Nitschke article in -- it's
2 in the published literature, it's on page 57 -- you have,
3 "This discussion emphasized the role of fluoride in the
4 toxicity of sulfuryl fluoride, but lacked detailed
5 analysis. Indirect effects (adrenal cortex hypertrophy,
6 hyperglycemia, and lymphoid tissue necrosis) observed with
7 sulfuryl fluoride were attributed to fluoride ion as well
8 as stress."
9 One, I think you can take the parentheses out of
10 that sentence because I think it's all part of the
11 sentence and the parentheses actually aren't needed.
12 But to the degree that sentence raises some
13 fairly significant issues, namely, affects on the adrenal
14 cortex and hypertrophy and hyperglycemia; and all I was
15 going to say is that if there's anything else that you can
16 say to fill that out a little bit more, it would be I
17 think useful. It's not -- it may be that what you've got
18 in there is reflective of the level of discussion in the
19 paper.
20 DPR STAFF TOXICOLOGIST LIM: Right. That's why I
21 said that they emphasized the role of fluoride in the
22 toxicity but lacked detailed analysis of -- yeah, the role
23 of fluoride in the toxicity -- of these in --
24 CHAIRPERSON FROINES: Yeah, that -- all I'm
25 saying is that that sentence is so provocative that to the

1 degree that you can add anything more about those
2 endpoints, it would be useful. So its really a writing
3 issue, not more than --
4 DPR STAFF TOXICOLOGIST LIM: I'll reread the
5 paper and see what I can find.
6 CHAIRPERSON FROINES: Yeah, just reread the
7 paper.
8 And let me just -- I think that's it. I have all
9 these places -- oh, the other issue that you raised was
10 the nasal issue and the olfactory or other uptake.
11 PANEL MEMBER PLOPPER: Right. She was going to
12 expand that.
13 CHAIRPERSON FROINES: Can you -- yeah, can you
14 add something.
15 DPR STAFF TOXICOLOGIST LIM: Yeah, I'm going to
16 go back to look at the papers and see what olfactory study
17 was done to describe that a little bit more.
18 CHAIRPERSON FROINES: Okay. That's it. That's
19 it for me.
20 So further discussion. And what we need to know
21 is, given the discussion that the panel's heard as we've
22 gone around the room, is the panel comfortable approving
23 the document, recognizing that there are further changes
24 that are going to be required?
25 Three nodded heads, four nodded heads, five

1 nodded heads.
2 PANEL MEMBER GLANTZ: Why don't you make a
3 motion, Craig.
4 CHAIRPERSON FROINES: Do you want to make a
5 motion?
6 PANEL MEMBER BYUS: Yeah, I'll move we approve
7 the document subject to the changes that we've all
8 discussed and given to you.
9 PANEL MEMBER ATKINSON: Second it.
10 CHAIRPERSON FROINES: Good.
11 Any further discussion?
12 All in favor?
13 (Hands raised.)
14 CHAIRPERSON FROINES: The vote is unanimous.
15 So we appreciate all your efforts.
16 PANEL MEMBER GLANTZ: Now, do we have to adopt
17 findings?
18 CHAIRPERSON FROINES: Yes. And we agreed to --
19 we have some findings actually that OEHHA developed that
20 will be useful for our -- to use as a starting point. And
21 we're going to send those findings to the two leads. They
22 can edit them and send them back. And then I'll edit them
23 and then we can send them around and approve the findings
24 at the next meeting.
25 And in the meantime I'm going to send a letter,

1 if everybody agrees, to Maryann that says -- it's just a
2 one-page letter saying we've approved -- we voted to
3 approve the document. And then they can get on with the
4 regulatory process that follows. And that we will then
5 send the findings subsequent to the next meeting, if that
6 works for you.
7 Okay. And I think that what Craig and Roger are
8 basically going to do is be responsive to the discussion
9 here today, but also in the end cut down what is much
10 longer than what we need. And then we'll send them around
11 so everybody -- and Stan will clearly have edits. We know
12 that.
13 (Laughter.)
14 CHAIRPERSON FROINES: No disrespecting hint?
15 And then I'll do it. And then we will approve
16 them and send them out at the next meeting -- after the
17 next meeting.
18 PANEL MEMBER GLANTZ: Okay.
19 CHAIRPERSON FROINES: And so that's that.
20 We anticipate --
21 PANEL MEMBER BYUS: I think we're going with the
22 new shortened review --
23 CHAIRPERSON FROINES: Well, that's right.
24 PANEL MEMBER BYUS: And so we're going with the
25 new format -- new format findings -- findings format.

1 CHAIRPERSON FROINES: Basically a five-page
2 document of that.
3 And we need to say something about the
4 regulatory -- that the risk has been assessed to meet the
5 statutory requirement. But I can work on that, so don't
6 worry about it.
7 The second thing -- the last thing in terms of
8 administrative matters, we are planning to have another
9 meeting this year, perhaps in October or November. And
10 we're going to be taking up another pesticide.
11 Tobie, what -- say it.
12 DPR ASSISTANT DIRECTOR JONES: Methidathion.
13 CHAIRPERSON FROINES: Right. That one. The M
14 word.
15 And so here comes the hardest part of the day.
16 We need two leads for this pesticide. And Craig and Roger
17 I think have done their term. And so -- and Stan's
18 certainly done his turn.
19 So, Charlie, would you be willing to do it?
20 PANEL MEMBER PLOPPER: I guess so, if I don't
21 have to pronounce it.
22 CHAIRPERSON FROINES: And there's only one
23 exposure assessment person left in the room.
24 PANEL MEMBER HAMMOND: So I do the exposure us
25 assessment part?

1 CHAIRPERSON FROINES: Yeah. Would you?
2 PANEL MEMBER HAMMOND: (Nods head.)
3 CHAIRPERSON FROINES: I don't know anything about
4 this chemical, so that I don't know how demanding it's
5 going to be.
6 So it will be Kathy and Charlie, Tobie.
7 DPR ASSISTANT DIRECTOR JONES: Okay.
8 PANEL MEMBER ATKINSON: So what class of chemical
9 is this? Is it an organophosphorus or what?
10 DPR SENIOR ENVIRONMENTAL RESEARCH SCIENTIST
11 SEGAWA: It's an organophosphate pesticide.
12 PANEL MEMBER ATKINSON: Oh, okay. I'll be happy
13 to assist on the environmental effect.
14 PANEL MEMBER HAMMOND: Oh, Good.
15 CHAIRPERSON FROINES: Good.
16 PANEL MEMBER ATKINSON: Since we've probably done
17 all the published organophosphorus in the atmosphere.
18 CHAIRPERSON FROINES: The other thing for the
19 next meeting is I would like to have a part-day workshop,
20 if everybody agrees, on -- and I'll work on this with you
21 and invite some people to come and present and discuss
22 what substances would be appropriate -- should be taken up
23 by ARB as future TAC candidates. And have Jeannette
24 Brooks talk about their prioritization process, which has
25 been -- we think is with about complete. Is that right,

1 Lynn.

2 ARB AIR POLLUTION SPECIALIST BAKER: Correct.

3 CHAIRPERSON FROINES: And so I think that we did

4 diesel in 1998. We did ETS June 24th, 2005. That's a

5 seven-year hiatus. But we did about 200 risk assessments

6 in between that were the 2588 risk assessments. So

7 that -- but the issue of what TAC's should be being

8 brought to the panel -- and, for example, we might

9 consider recommending ultrafine particles or we might --

10 you know, who knows, I mean. And so the issue of what

11 compounds as scientists would we recommend, we can invite

12 some people who could make some recommendations, if that

13 would be reasonable.

14 PANEL MEMBER PLOPPER: That's a good idea.

15 CHAIRPERSON FROINES: So we will spend half a day

16 on ARB issues and then half the day on DPR issues.

17 PANEL MEMBER HAMMOND: So this is all a one-day

18 meeting.

19 CHAIRPERSON FROINES: One day meeting. And we

20 would start it at 9, not 9:30, and so on and so forth.

21 PANEL MEMBER HAMMOND: 9 p.m.

22 CHAIRPERSON FROINES: So that's it.

23 Does somebody want to make a motion to --

24 PANEL MEMBER GLANTZ: I so move.

25 CHAIRPERSON FROINES: Second?

1 PANEL MEMBER BYUS: Second.
2 CHAIRPERSON FROINES: To --
3 PANEL MEMBER GLANTZ: -- adjourn.
4 CHAIRPERSON FROINES: To adjourn.
5 PANEL MEMBER BYUS: I'm sure that's what you
6 meant.
7 CHAIRPERSON FROINES: Can we have a vote.
8 All in favor.
9 (Hands raised.)
10 CHAIRPERSON FROINES: We're adjourned.
11 Thank you very much. Very productive day.
12 (Thereupon the California Air Resources
13 Board, Scientific Review Panel meeting
14 adjourned at 2:20 p.m.)
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1 CERTIFICATE OF REPORTER

2 I, JAMES F. PETERS, a Certified Shorthand
3 Reporter of the State of California, and Registered
4 Professional Reporter, do hereby certify:

5 That I am a disinterested person herein; that the
6 foregoing California Air Resources Board, Scientific
7 Review Panel meeting was reported in shorthand by me,
8 James F. Peters, a Certified Shorthand Reporter of the
9 State of California, and thereafter transcribed into
10 typewriting.

11 I further certify that I am not of counsel or
12 attorney for any of the parties to said meeting nor in any
13 way interested in the outcome of said meeting.

14 IN WITNESS WHEREOF, I have hereunto set my hand
15 this 21st day of July, 2005.

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23 JAMES F. PETERS, CSR, RPR
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