MEETING

OF THE

SCIENTIFIC REVIEW PANEL ON TOXIC AIR CONTAMINANTS

CALIFORNIA AIR RESOURCES BOARD

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# APPEARANCES

MEMBERS PRESENT

Dr. John Froines, Chairperson

Dr. Paul D. Blanc

Dr. Gary Friedman

Dr. Stanton Glantz

Dr. Katharine Hammond

Dr. Joseph Landolph

REPRESENTING THE CALIFORNIA AIR RESOURCES BOARD

Mr. Jim Behrmann

Mr. Robert Krieger

REPRESENTING THE OFFICE OF ENVIRONMENTAL HAZARD ASSESSMENT

Dr. George V. Alexeef, Deputy Director for Scientific Affairs

Dr. James F. Collins, Staff Toxicologist

Dr. David Morry, Staff Toxicologist

Dr. Mark Miller

Dr. Andy Salmon, Chief, Air Toxicology and Risk Assessment Unit

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PROCEEDINGS

CHAIRPERSON FROINES: If we can call the meeting to order.

We do have a quorum for the meeting. So we'll formally open the meeting for June 20th, 2003, of the Scientific Review Panel established under AB 1807.

I'm going to switch the agenda a little bit, to discuss, quote, "administrative matters" at the outset.

And I want to do two things: 1) The first thing is to -- I'd like in fact everybody to introduce themselves.

But in particular I want to introduce two new members of the Panel. On my left is Joe Landolph, who is a professor at the University of Southern California and I'll ask Joe in a minute to say a little bit more about himself. And on my right is Katharine Hammond, who is at the School of Public Health at UC Berkeley.

And so what I'd like to do at the outset is to have, first, the other members of the Panel who are here just quickly say who they are to Joe and Kathy. And then Joe and Kathy can say a little bit about themselves.

So Stan.

PANEL MEMBER GLANTZ: I'm Stan Glantz. I'm a professor at UC San Francisco in the Cardiology Division. I also teach statistics. I'm the biostatistics person on

the Panel. I also do a lot work on tobacco and secondhand smoke. And I'm one of the -- I've nagged DPR since even before John did, with about the same effect.

CHAIRPERSON FROINES: What he's trying to say, Joe, is that he's been on the Panel for a long time.

(Laughter.)

PANEL MEMBER GLANTZ: Not as long as he has, but almost.

CHAIRPERSON FROINES: Paul.

PANEL MEMBER BLANC: Dr. Paul Blanc. I'm a professor of medicine at the University of California San Francisco and chief of the Division of Occupational and Environmental Medicine within the Department of Medicine, the same department as Dr. Glantz. And, like Dr. Glantz, I'm also a member of the Cardiovascular Research Institute.

PANEL MEMBER FRIEDMAN: I'm Gary Friedman. I'm an epidemiologist. And I spent most of my career at Kaiser Permanente Division of Research here in Oakland. I'm officially retired from there, but I still spend about half time working there on various projects. And I'm also a consulting professor at Stanford and I spend about two days a week down there.

CHAIRPERSON FROINES: Okay. So, Joe, tell us a bit about yourself.

PANEL MEMBER LANDOLPH: I'm Joe Landolph. I'm an associate professor in the Department of Molecular Microbiology and Immunology at the University of Southern California. And I have secondary appointments in pathology and molecular pharmacology and toxicology. And I do the usual teaching committee service research.

My research is in the areas of chemically induced neoplastic cell transformation. And we study the cell and molecular biology of that process. We're real interested in looking at all the changes in gene expression that occur in transformed cells and how gene regulation -- the regulation of gene expression that becomes aberrant in the transformed cells. And we've worked with polycyclic hydrocarbons and nickel chromium and arsenic compounds for many years.

I've served previously and still serve on the CIC, where Dr. Froines and I were colleagues on that committee for probably about eight years, I guess. I'm delighted to be joining you on this Committee.

I also served -- I'm serving a two-year term on U.S. EPA Scientific Advisory Board and served on the Drinking Water Committee there. And a short term with Dr. Glantz on the Human Health Research Strategies Review Committee.

And I'm delighted to join you all and hope I can

help you out a little bit here and there.

CHAIRPERSON FROINES: Okay.

PANEL MEMBER FRIEDMAN: Excuse me for interrupting.

What is the CIC? I'm not familiar with those initials.

PANEL MEMBER LANDOLPH: That's the Carcinogen Identification Committee, which is the brother or sister committee to DART, which is the Developmental and Reproductive Toxicology. And those two boards report to OEHHA, the CIC for identification of carcinogens that have not been already listed on the authoritative bodies mechanism.

CHAIRPERSON FROINES: Just to clarify. That committee -- those two committees, the DART Committee and the CIC, were established under Prop 65. So they are -- they focus on chemicals that are to be listed under Prop 65.

PANEL MEMBER LANDOLPH: I also do a little bit of private consulting. If I feel I have any conflicts, I'll let you know and leave the room and have a cup of coffee.

CHAIRPERSON FROINES: This issue of conflicts of course has come up in spades around the issue of Chromium 6. And so that's actually something that -- as we go through in the future, we will actually ask panelists

whether they have conflicts on a particular chemical so that everything is above board, in contrast to what occurred under Chromium 6 where there was a real problem.

PANEL MEMBER GLANTZ: Just for the record, that was not this Committee where the problem was.

CHAIRPERSON FROINES: No, it was a blue ribbon committee established ad hoc by Cal EPA and the president's office. And it did not look into conflict of interest issues sufficiently, and so there was a problem. But I think everybody's sensitized to the issue at this point. So as a particular chemical comes up, we'll have to ask the question to each Panel member the way we might do it on a national research council at National Academy Sciences process.

Kathy.

PANEL MEMBER HAMMOND: I'm Kathy Hammond at UC Berkeley School of Public Health. I'm a chemist and an industrial hygienist. My research is in expression assessment for epidemiology studies. An I've done both environmental and occupational studies. Some of the occupational studies include what came before this Board several years ago in railroad workers' exposure to diesel exhaust. And looking at reproductive effects in the semiconductor industry. More recently looking at lead and bridge workers and hexane exposures among auto mechanics.

Environmentally I've been looking at asthma particulate more recently, both in adult asthma with Dr. Paul Blanc, and a child asthma study in Fresno, the FACES Study. And also I've done a lot of work in environmental tobacco smoke.

CHAIRPERSON FROINES: Great.

I will never forget Kathy's presentation to this Panel when we were taking up diesel. Because the line that she said, I've used about a hundred thousand times. She said diesels are not computers. They don't change on a monthly, bimonthly, six-month basis.

PANEL MEMBER HAMMOND: Especially I said locomotives are not PCs.

CHAIRPERSON FROINES: So we're really pleased to have Kathy and Joe on the Committee. They bring a level of expertise that's really going to be beneficial to us.

For those of you who don't know, we are -- two members of the Committee, Craig Byus and Roger Atkinson, couldn't be here today, but they are ongoing members of the Committee. We have one vacancy in the area of pathology. And we're proceeding to try and fill that position since Peter Witschi retired. So we have one vacancy. But at this point we have essentially a full complement besides that. So we're in pretty good shape.

And now since we're flexing our muscles, what we

need is more chemicals coming before the Committee so we can then complain about having to work too hard.

(Laughter.)

CHAIRPERSON FROINES: So the second administrative item that I want to deal with is -- we've passed around a draft proclamation for Tony Fucaloro, who I think everybody would agree was a great member of the Committee, really made major contributions, of both in a technical sense but also in terms of having a terrific disposition and a very good sense of humor. And Tony was really very -- I don't want to talk about him as though he's passed on or something. But he was really a very contributing, strongly contributing member of this Panel. So we wrote this draft proclamation.

He has already received a letter from Winston Hickox, the Secretary of Cal EPA. So Tony's also been acknowledged by the Secretary. And Jim can make that letter available to the Panel. But what I'd like the Panel to do is take this draft -- there's no sense trying to finalize it today, no sense trying to -- well, Stan.

PANEL MEMBER GLANTZ: I think it's fine.

CHAIRPERSON FROINES: You do?

PANEL MEMBER GLANTZ: Yeah.

PANEL MEMBER BLANC: Reclarify the question. You lost me there.

CHAIRPERSON FROINES: There is a draft proclamation that we want to send, with a cover letter from me to Tony Fucaloro. You have a copy there some place. And what I was saying is that if everybody agrees, that's fine. Then we can bring it to closure. If, however, people want to word-smith it --

PANEL MEMBER BLANC: Let's send it. Yeah, it's more important -- I agree, it's more important it be timely than it be perfect.

PANEL MEMBER HAMMOND: I agree.

CHAIRPERSON FROINES: So why don't we do this. Who don't we say that we will -- what's today -- Friday. If I haven't heard for changes by next, say, Tuesday, we will send it out as is. Is that acceptable?

PANEL MEMBER GLANTZ: I have one -- well, I'd like to make --

CHAIRPERSON FROINES: Why does this not come as a surprise to me? If anybody in this room --

PANEL MEMBER GLANTZ: I'd like to make one slight change and move that we adopt it -- but it's like not controversial.

I would just move --

CHAIRPERSON FROINES: Those of you who are in the room remember the famous lead day we spent, where Stan had about 200,000 changes, as far as I can remember.

Go ahead.

PANEL MEMBER GLANTZ: Well --

CHAIRPERSON FROINES: It really improved the document, no question.

PANEL MEMBER GLANTZ: And by putting it in the record, they couldn't ignore it. But, anyway, that's another story.

It's just under the "Whereas, Tony brought his inimitable sense of humor," I would just say -- I would suggest we amend that to say, "Whereas, Tony brought not only his scientific expertise, but his inimitable sense of humor." So it's clear that we're not just thanking him for telling a lot of --

PANEL MEMBER HAMMOND: "But also his"?

PANEL MEMBER GLANTZ: "But also his," yes.

CHAIRPERSON FROINES: Would you give that to Jim.

PANEL MEMBER GLANTZ: So I'd like to suggest that that amendment -- that we just adopt it.

CHAIRPERSON FROINES: Well, make a motion.

PANEL MEMBER GLANTZ: I so move.

CHAIRPERSON FROINES: Seconder.

PANEL MEMBER HAMMOND: Second.

CHAIRPERSON FROINES: It was seconded.

All in favor, aye.

(Ayes.)

CHAIRPERSON FROINES: Unanimous approval.

So good.

So let's -- I think that's all the administrative issues that I know about.

PANEL MEMBER BLANC: One other administrative issue. I wonder if the record could show unanimously the panel's official wishes to Melanie for a speed recovery.

CHAIRPERSON FROINES: Yes. You want to make that?

PANEL MEMBER BLANC: I'd just like the record to show that the Board officially wishes Melanie Marty a speedy recovery in her period of illness.

PANEL MEMBER FRIEDMAN: I didn't know she was ill.

PANEL MEMBER BLANC: I think it was shared as an E-mail to the Panel. So I don't think I'm divulging something that wasn't --

PANEL MEMBER GLANTZ: I think we should leave it at that.

CHAIRPERSON FROINES: We can talk off-line about the situation.

So I think it's on the record. And if you'd like, I'll take and send a note to Melanie saying that the Panel wanted to express those feelings for her complete and quick recovery.

And I know Gary's a little bit not sure of what we're doing, but --

PANEL MEMBER FRIEDMAN: Well, I certainly support the sentiment regardless of whatever the illness is.

CHAIRPERSON FROINES: -- the details are, yeah.

PANEL MEMBER FRIEDMAN: And I don't have to know what the illness is.

CHAIRPERSON FROINES: I talked to her on the phone on Wednesday. And she was bright, spirited, in a very good mood. And so I think there's every indication that her long-term prognosis is positive. So it's -- she was just her old self. I mean she was just terrific. And so that was very reassuring.

Thanks, Paul.

Any others?

Okay. Onward.

Stan has to leave about noon. So we're going to move along hopefully to complete this meeting by noon. And I suspect we can.

And I just warn Kathy and Joe, that this is not necessarily the routine. When we have a chemical before us, it tends to take a little longer.

Okay. Andy.

Dr. Salmon.

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF

SALMON: I'm just wondering whether you can hear what I'm saying, because I don't seem to have a microphone.

I'm going to start on the first item, which is the consideration of the proposal to adopt modified TEF schemes of dioxins.

Jim, could you pass out the -- I've got paper copies of the slides, which if you could pass copies to the Panel members. And I think we have enough for members of the audience to have some of those as well.

(Thereupon an overhead presentation was Presented as follows.)

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: I'm just going to close this one because that's --

CHAIRPERSON FROINES: Andy, may I say one thing before you start?

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: Certainly.

CHAIRPERSON FROINES: I just wanted to tell the Panel that we had a meeting with Janette Brooks and her staff on Wednesday. And one of the things that we agreed to was the Panel holding a workshop at some point in the future to discuss research findings that are occurring in the area of air pollution as a way of having a discussion about future possible toxic air contaminants that might be

brought before the Panel. So at some point within the next six months we'll be working on a workshop to incorporate the latest scientific findings as a means to try and facilitate the process of that TAC legislation.

I'm just doing a quick switch-around with microphones here so as not to disenfranchise Dr. Glantz. Not that I could ever achieve such a thing.

(Laughter.)

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: Okay. Well, I'm going to just give you a very brief introduction as to what this item is all about here.

So this is the proposal to adopt a revised toxicity equivalency factor scheme. And this would apply to the carcinogenic effect of dioxin-like chemicals.

CHAIRPERSON FROINES: I should say parenthetically before you start, that this topic does not have a lead person from the Panel. So there's nobody here who is going to have the responsibility for the Panel of making a subsequent presentation. So we're going to be taking it up pretty much as we hear it.

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AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: As I'll explain in a moment, this is the first time that you've seen this item. So this is, I hope, an introduction to the topic.

This slide here shows an example of some well known dioxin-like compounds. In particular the polychlorinated dioxins labeled PCDD here are rather ubiquitous and well known pollutants, found at low levels in the general environment as a result of combustion processes primarily.

There are also found in similar situations the polychlorinated dibenzofurans, which are the structure at the top right.

PCBs are to a substantial degree a synthetic compound. Although there is a minor production of those in the -- in combustion processes as well.

We've included just as an information item -- there's quite a bit of interest in the diphenyl ethers. And in fact this is another class of compounds which may have some dioxin-like activity.

There's interest in not only the chlorinated diphenyl ethers but also the brominated diphenyl ethers, which are used as fire retardants.

I want to emphasize we're not talking about those today. But I'm just adding that in as a point of interest to say we are -- they're not that far removed and may well be at some level included in a broader scientific discussion of dioxin-like compounds.

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AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: Dioxin-like compounds have a number of well known toxic effects. They are immunotoxic. They have developmental toxicity. They function as endocrine disrupters at several different points within the endocrine system. And they are carcinogens. One of the interesting things about these effects is not only are these quite severe and dramatic effects in some cases, but particularly with some specific congeners of the dioxins and dibenzofurans the levels at which they are active are very low. So these are in fact among the most potent environmental toxicants that we have to deal with. And there's been a lot of interest over the years in these compounds.

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AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: Although the levels in the general environment are in fact low -- and here you're talking about picograms of barely exposure typically -- it is nevertheless estimated by U.S. EPA that the current levels of exposure to the general population from sources such as food and other general environmental inputs exceed the effect threshold for some of the toxic effects. They're well known as biocumulators.

The major direct source of exposure from the

general population is in fact in food. But one of the reasons why historically we and the Air Resource Board and the Panel have had an interest in dioxins is because air is an important transport medium. Some of the historic and current major sources, in the things like incinerators, which were previously an important source. And as we discussed earlier when we were talking about dioxins in our presentation under SB 25, we think that there's a small but possibly significant input from sources like diesel exhaust and things of that sort. So that there are a number of current sources which are putting dioxin-like compounds into the air.

But the major direct exposure is from food. And the major location, if you like, is there's basically a reservoir source in the general environment because of the way they bioaccumulate and they accumulate in sediments and things of that sort.

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AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: I mentioned just now that we had some consideration of dioxins under SB 25. I'm sure that the Panel members who were involved in this process remember that in all it's wonderful detail. But for the new members, I'll just run through what happened.

We were charged to identify --

PANEL MEMBER GLANTZ: You might tell the new people what SB 25 is.

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: Yes. I'm Sorry.

SB 25 is the Children's Environmental Health Protection Act. And this required that we consider what effects the toxicity -- toxic air contaminants would have specifically on children and other vulnerable sub-populations. And the background of this is that most of the environmental standards which have been set previously in fact were set on the basis of toxicity in -- either in adult animals or certainly directed to protect in the adult human.

And it's become clear that there are special issues in considering impacts on children's health. And this piece of legislation, which was introduced by State Senator Escutia, required us to specifically consider the toxic air contaminants, and also the criteria pollutants. But that's a separate process.

But the toxic air contaminants, we were required to review the toxicity of these identified materials. And to in particular identify the top five, which we felt had a high potential for differential impacts on children's health. But also to identify any others. And we have a timed program by which we are supposed to be reviewing

ultimately all the toxic air contaminants for possible differential impacts on children's health.

And the dioxin-like compounds and the TCDD and the other dioxins and dibenzofurans in particular were selected as one of the top five we should look at with high priority.

CHAIRPERSON FROINES: I think the two things we should do, one of which is, Jim should get to the two new Panel members the final document that discusses the five chemicals so you have that in your file. Secondly, the chemicals that we listed were polycyclic organic matter, lead, diesel, the dioxins -- PCBs -- and acrolein.

PANEL MEMBER FRIEDMAN: Since we've interrupted, could you move the microphone to that side? Because sometimes you turn to the side and I miss a couple words.

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: I don't know whether I am in danger of pulling something over?

Does that work?

Okay, great. Thank you very much.

CHAIRPERSON FROINES: So those were the five that we identified. Kathy's eyebrows went up when I said acrolein. And so you'll find it interesting as you read the document.

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF

SALMON: Yes. Well, we can work with Jim's and make sure that the Panel members all have access to that document.

Anyway, the major reasons why the dioxins were chosen include the widespread exposure; the important endocrine disrupting effects, including impacts on the thyroid and other systems; and immunotoxicity at low body burdens; and the demonstration that young animals are more susceptible than older animals; and, finally, the fact that in fact bioaccumulation and transfer in breast milk is an important exposure, by the way, for the infant human.

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AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: The dioxin-like chemicals have been of interest to the Toxic Air Contaminant Program for many years. And, in fact, the original identification was made in 1986, and this identified the tetrachlorodibenzodioxin, or TCDD and other dioxins and dibenzofurans as toxic air contaminants.

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AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: An amendment to the TAC program subsequently, in fact, added to the list all those materials which had been identified by the federal EPA as hazardous air pollutants. And this in fact broadened the range of chemicals in this class which were identified by the TAC program.

The actual narrow definition of chlorinated dioxins and dibenzofurans under the HAP process is broader than was in the original California TAC identification.

Also, the polychlorinated biphenyls were added as a specific category in the HAP list.

And, finally, in fact all of these chemicals and all their close relatives are -- they all, in fact, fall within the general definition of polycyclic organic matter. So one way or another all of these materials are identified under the Toxic Air Contaminant Program.

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AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: The dose response assessment for dioxin-like compounds that was originally adopted based on the 1986 analysis, this identified carcinogenicity as the critical effect for defining risk to public health, although recognizing the various other effects also occur at very low levels. And a potency slope was calculated specifically for TCDD, which is one of the few chemicals for which a full carcinogenesis bio-assays is available. And this was based on the instance of liver tumors in male mice in an NTP gavage study.

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AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: The problem obviously with this group of

compounds is that there are lots of them, which are very similar. They vary in the degree of chlorination and the positions of the substituants. And although their general patent of toxicity is thought to be similar, the actual effectiveness, the cause of that varies according to the specific structure. And this applies both to the carcinogenic potency and to the other toxic effects.

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The way this has been approached is to use what's called a toxic equivalency factor methodology. It is based on the fact that these compounds are structurally similar. And although few of the individual congeners other than the TCDD and the hexachloros have actually been looked at in specific bio-assays, they have been looked at quite extensively in various more easily performed biochemical assays and shorter term toxicity studies. And it is known that the patent of toxicity is shared between many of the chlorinated dioxins, dibenzofurans, and some of the chlorinated biphenyls.

These compounds, which I'll refer to as dioxin-like compounds from now on, share a common cellular mechanism of action, which includes activation of the hydrocarbon hydroxylase receptor -- the AH receptor -- which is also important in the enzyme induction response to various other environmental contaminants, including the

polycyclic aromatic hydrocarbons. But the response to the dioxin-like compounds appears to be unique. And this is thought to be because of their extreme persistence that, unlike the PAHs, these compounds are very slowly, if at all, metabolized. And also they have a very high affinity for recepting. The combination of very slow, clear, and some -- and very high affinity means that this particular response has a unique character and severity for the dioxin-like compounds.

And what we do in order to assess the predicted response to a mixture of these compounds is to predict a level of response to the individual components of the mixture by applying a -- if you like, a correction factor which reflects the difference in activity -- in strength of activity between the individual congeners and the reference compound, which is TCDD, and the concentration of the individual congeners. And then these predicted responses are added up because they're assumed to follow the same mechanism and produce the same results.

So this is the standard additivity assumption, which is used in many toxicity situations.

PANEL MEMBER BLANC: And can you just back up for a second on two points.

One is the implication of your comments, your oral comments now, are that specifically the methodology

is focusing on the inhibition of the of the AH receptor as your tool by which to arithmetically calculate equivalency.

Are you implying more than you mean?

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: I think I may be. I'm pointing that out as a common mechanism. The actual basis of the factors is a wide range of different endpoints, which, as I will explain in a moment, are actually a variety of toxicity and chemical endpoints and, where we have them, bio-assay endpoints. It's a case of looking at a whole spectrum of responses.

PANEL MEMBER BLANC: I assumed that. But, you know, taken in isolations your comments could have been read more narrowly.

A second clarification as to your oral comments. Describing a chemical which binds to a receptor but which can't be metabolized suggests a pattern of inhibition rather than induction. Perhaps you want to clarify. Maybe there was a missing phrase there. But otherwise it's a bit circular.

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: Yes. Well, there's two things. Firstly, these compounds are agonists in terms of their action on the receptor. They bind to the receptor and they activate

various of the genetic switching, which the receptor is involved in operating. So various biochemical events are turned on, enzymes are induced, some growth control responses are mortified.

And so in terms of its action on the receptor, these compounds are agonists.

However, the normal mechanism by which AH receptor agonists are cleared from the system is that typically one of the enzymes which is reduced -- sorry -- induced as in response to activation of the receptor -- typically the site for B450 series -- is the active enzyme system which degrades that material. So B450 metabolism in fact removes this compound, which is the receptor agonist, from the cell. And the products, the metabolism are excreted and cleared from the body.

The problem with the dioxin-like compounds is that at least many of them are highly resistant to this particular type of metabolism. So you're looking at half lives of many years. We're talking about a half life of 7 to 10 years being measured for the typical dioxin -- chlorinated dioxins, which is orders of magnitude longer perhaps than is usual for this sort of material.

So that's the -- I don't --

PANEL MEMBER BLANC: No, that was sufficient. I think that clarifies your comments. Thank you.

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AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: This is just a statement in mathematical terms of what we're doing. If you think that this looks very much like the standard sort of hazard-index-type calculation where you add up the toxicity of like-acting toxicants, then you're exactly right.

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PANEL MEMBER GLANTZ: Could you just go back for a second.

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: Certainly.

PANEL MEMBER GLANTZ: Just to -- and this is not my area of expertise. But would you -- this is sort of the guts of what you're doing. And could you just explain where you get the numbers, the Cs and the TEFs?

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: Okay. The TEFs are a ratio between the -- in this case the estimated carcinogenic potency or other toxic activity measure, but in this case we're talking carcinogenic potency -- the ratio between the observed carcinogenic potency of TCDD and the estimated carcinogenic potency of an individual congener, which is signified by the by the "n" here. So the "n" represents the whole set of congeners in which we're interested. And

those TEF values are provided in a table which I will display shortly.

"C subscript n" is the concentration of that congener "n". And that calculation of the concentration times the factor is summed for all the congeners identified in the mixture. And then that is expressed as a total toxicity equivalence, which if we're working here with the carcinogenic potency, then this TEQ in effect would be an equivalent concentration of dioxin -- the TCDD, which we would then multiply by the TCDD carcinogenic potency and also determine the risk.

Or if we were using -- if we were concerned about some other toxic endpoint, we would look at that equivalent concentration of TCDD and determine whether it represented a problem for that other endpoint. But in the specific context of calculations for the TAC program, we're talking carcinogen potency. So we take the TEQ, which is, if you like, a virtual concentration of TCDD, multiply that by the carcinogenic potency, which is calculated from the TCDD bio-assay.

PANEL MEMBER GLANTZ: Okay. Thanks.

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AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: TEFs are derived by looking at a broad range of data. The original California TEFs for a small number of

the dioxin congeners simply looked at the available bio-assay data and a few other things like that. But the more recent TEF approach has looked at a wide range of different endpoints. Chronic toxicity and, in particular, carcinogenicity is the gold standard where it's available. But the results of subchronic and other short-term toxicity data is used as part of the overall evaluation.

Also, in vitro studies and the AH receptor specific bio-chemical endpoints have been measured where possible. And so you have a hierarchy of different toxic and biochemical effects.

An important part in this discussion also has been the actual quantitative structure activity approach. And you may have noticed some numbers which were printed next to the various positions on the core structures that I showed in the first slide of the presentation. These actually represent, if you like, weighting factors for the appearance of a chlorine act to the particular position on the ring. And it's been possible to describe how the toxicity works in structure activity terms for this series. It's a very nice example of the use of not only qualitative, but actual quantitative structure activity relationships.

And this is sort of -- one of the really nice cases where these things work to a decent degree.

Unfortunately we don't have as many good examples in the application of this technique as we would like. But this is one of them.

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AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: I mentioned that there was an initially evaluation and initial TEF scheme developed as part of the California identification for the TAC program.

In 1999, actually, California replaced the original table with what's called the international TEF table, which had been developed actually seen or eight years earlier by a specialist committee set up by the World Health Organization and it's component agencies, IARC and the International Program on Chemical Safety.

So the I-TEF scheme, which in fact had been used sort of in parallel with the California scheme for various programs for several years, was preferred because it covered a broader range of compounds in the dioxin and dibenzofuran groups and included a broader range of endpoints including the other toxicity, the biochemical endpoints, and the structure activity relationships. So it was considered to be a more broadly based scheme. And, in fact, following review by the SRP, OEHHA adopted that I-TEF scheme.

So what's in place for dioxin regulation at this

point is that the dioxin-like compounds are regulated as toxic air contaminants. And the carcinogenic potency of those dioxin-like compounds, which, are either chlorinated dioxins or chlorinated dibenzofurans, is calculated using the I-TEF table. And that was in fact included as an appendix in the Hot Spots Risk Assessment guidelines, which you reviewed. So this is an appendix to Part 2, the cancer potency factors.

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AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: Since the international scheme, the so-called I-TEF, was developed, in fact -- well, the World Health Organization has had an ongoing program of revising and updating this scheme as new data became available. And this is something which has been progressing on its own timetable.

In fact in 1994, WHO added the TEF values for 13 dioxin-like PCBs. These are basically PCBs which adopt a coplanar molecular confirmation and are found to have dioxin-like activity in the bio-assays and bio-chemical tests which are used as the basis of the TEF determination.

So WHO added TEF values for 13 dioxin-like PCBs in 1994. However, up until this point the Toxic Air Contaminant Program hasn't got around to adding those

values to the table.

In 1997, the World Health Organization's ad hoc committee proposed several changes, including updates to the existing values for both the dioxins ands the dibenzofurans and also for the PCBs. This incorporated knew data from various sorts and some changes, including an addition and a deletion in the list of PCBs.

So at this point the 1997 table from WHO is the latest version. And it's the current state of the art, if you like.

There is an ongoing program of revision. But we are told by WHO -- we have spoken to the WHO Committee, and they tell us that there isn't another update coming down the pike in the next year or 18 months at least. They're probably another -- I would guess, another four or five years out from having finalized revision of this table.

But in the meantime, we are proposing to go with the latest and most current version.

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AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: This in fact is -- this publication in the Environmental Health Perspectives summarizes the update. And I've included this mainly to show you the considerable number of international experts who are on this committee.

And it represents a broad international consensus of scientists, including of course many from the United States, but also from various other places as well.

And in fact with the -- I mentioned that we'd spoken to the representatives of the committee. We -- Dr. Ray Mock, a member of my staff, who's been taking primary responsibility for this work, has actually spoken to Dr. Eunice, who's the IPCS Chairman. Dr. Mock is -- you know, we've tried to stay in touch with them as to where they are on their evaluations and how they see the update program going.

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AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: This -- I'm not really expecting to read this slide. But it is shaded to indicate where the TEF values are listed in the different tables and where the changes have occurred. The I-TEF added a few -- well, a couple of extra in particular the value had also changed several of the -- well, changed the values relative to the original California list.

The new '97 table makes three further changes in the values for the chlorinated dioxins. And although, as I say, the modification -- the '94 modifications, the I-TEF table added values for PCBs. In fact as far as the Toxic Air Contaminant Program is concerned, our proposal

to add the values for PCBs is a new proposal.

PANEL MEMBER LANDOLPH: Dr. Salmon, what biological property are they using to measure these toxicity factors? Is it just binding to the receptor --

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: You see, it's a whole range of things. It's a variety of biochemical measures, including things where binding to receptors is measured. And also specific biological responses which are identified as resulting from not only binding but also agonist activity at the receptor. And then it includes a variety of short-term and long-term toxicity endpoints as well.

PANEL MEMBER LANDOLPH: It's a fairly complex calculation --

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: Yes, it's a complex calculation. It also involves an element of judgment.

And the other thing which I should probably take the opportunity pointing out is that these TEFs are not considered -- I mean this is risk assessment, not quantum mechanics. So these TEFs are not sited with enormous precision. Basically the numbers are quoted as either whole -- you know, whole decimals or .5's. So, you know, the values are either 1 or 5 times 10 to the X. And that is considered to be an appropriate level of precision at

which the TEFs should be quoted.

PANEL MEMBER LANDOLPH: And could you tell us in the case of your table there -- the 1,2,3,4,6,7,8-HpCDD is going from .03 to .1 to .01. Is there a more precision, innovative, more modern measurements that they're making that are making these changes?

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: Yes. The more recent versions of the TEF table include a much broader range of difference endpoints and new data which has appeared. So I think it's fair to say that the new values are better in aggregate. I wouldn't necessarily want you to hold me to task on the exact precision for an individual value. But in general that would be true.

PANEL MEMBER BLANC: Okay. But I'd like to follow just up on something that you specifically raised, which is HPCDD.

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: Yeah, the hexachloro, yes.

PANEL MEMBER BLANC: And since in the Appendix A that you provide it's clear that that single change will have the greatest impact in your calculations, reducing equivalency calculations in actual field combinations by about 10 percent --

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF

SALMON: Yes.

PANEL MEMBER BLANC: -- so as a technical question, I think it would be important to know to what extent OEHHA focused their evaluation of the WHO revision specifically on that congener since that will have the greatest single public policy impact potentially from all of these things. Did you do something special about looking at what they had used and have a basis for their 10-fold reduction equivalency? Because it has -- there's two things: One is, yes, it is a 10-fold reduction in equivalency. But also it's second -- well, the third most concentrated-by-weight congener in the field samples that you've supplied in your very useful appendix.

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: Yeah. Well, the -- I mean the WHO -- the full WHO document actually goes through sort of line by line the changes which they made. And, you know, we looked at that. I don't think that we have -- I don't -- well, we haven't had the resources to do what I'd call a fully independent evaluation of all the data. But --

PANEL MEMBER BLANC: Well, it involved -- nor would I expect you to. And I think it is appropriate. It would be an inappropriate utilization of resources to recapitulate the entire WHO document. On the other hand, if there is going to be a targeted piece of the WHO

document that's going to have a big impact in your calculations, it would be reasonable for that one item to make sure that you're satisfied scientifically that the argument that they're using meets your scientific requirement.

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: Yes. We could -- if you're interested in that section, you know, we could dig it out and provide that for the Panel if you wanted that. I mean it's --

PANEL MEMBER BLANC: I didn't want you to dig it up for yourself. I want you to --

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: Yeah -- no, we looked at it. We were satisfied.

PANEL MEMBER BLANC: And you focused additional -- you focused additional attention on that specific chemical is what you're saying?

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: To some degree, yes. I think -- I mean the other interesting point about this is that it -- they're actually going closer to the number that we had for the hexachloro in the original California tables. So I don't know how significant that is. That's a debatable point.

CHAIRPERSON FROINES: Can you help me? I think I know where Paul's talking --

PANEL MEMBER BLANC: Page 37.

CHAIRPERSON FROINES: Yeah, I'm looking at that. But which one are you talking about? Is this the HpCDD --

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: This is the hexachloro -- yes.

PANEL MEMBER HAMMOND: Two double spaces. The blank line right below it.

PANEL MEMBER BLANC: Yeah, it's 1,2,3,4,6,7,8-HpCDD.

CHAIRPERSON FROINES: Yeah, okay.

PANEL MEMBER BLANC: Which under the new guidelines we'd have a 10-fold less -- 1/10 potency, which is okay -- which would not have a lot of meaning if it was a very small component of the mix that you typically would measure. But based on the Marion County incinerator data, for example, of the 128.6 picograms equivalent, on the old calculation that was more than 10 percent. And in the new calculation it would be less than 1 percent of the contribution.

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: Yes. It of course depends on the nature of the mixture. But in that particular case it is a very significant --

PANEL MEMBER BLANC: But the patterns seem to be similar in San Bernardino and West Long Beach. In other words, that seems to be a fairly common by-weight

contaminant in the mix.

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: Yes. And also, the other thing is, that the more highly chlorinated ones tend to be more resistant to environmental degradation. So aged samples often have particularly high abundances of the optor.

One of the other -- I think one of odd features of the previous I-TEF is that in fact the value which they site for the heptachlorodioxin was .1, whereas the value which they cite for the heptachlorodibenzofuran was .01. So what the new vision does actually is too align the values for heptochlorodioxin and heptachlorodibenzofuran.

PANEL MEMBER BLANC: Yeah.

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: So I mean this is based on their evaluation of the specific data that were available to them for these compounds.

CHAIRPERSON FROINES: Kathy.

PANEL MEMBER HAMMOND: I have a couple of questions. First just to help me follow this.

The three columns. The first column is what was initially done?

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: Yes.

PANEL MEMBER HAMMOND: And the second column is

currently -- that's a current --

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: That is what is currently used.

PANEL MEMBER HAMMOND: And then this third column is the proposal --

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: -- is the proposal --

PANEL MEMBER HAMMOND: -- which is the WHO's?

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: That's right, yes.

PANEL MEMBER HAMMOND: Because there are several items -- which Paul has pointed out some of the more important ones -- which have changed by an order of magnitude -- and I certainly agree it makes sense to only use at this point -- use 5 and 1s.

Is there some general -- is there some general reason that you could give why there's been this 10-fold decrease in the potency? I mean is it a new test or new finding? There must be something that's generally happened? Is there a particular --

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: I think it's a general increase in the overall quantity and quality of data. I don't think --

PANEL MEMBER HAMMOND: But is there a particular type of data that has come through? Like is it -- is it

being driven by the fact that there are more of one type of test or something as -- before it was a certain kind of test that was being used, like maybe the quantitative structure activity, and now it's being done by in vivo test or --

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: Yeah, that is in fact true. Basically the quantity and quality of in vivo data --

PANEL MEMBER HAMMOND: So since in vivo has now --

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: -- has increased over the years. So the newer table includes more and better quality in vivo data.

PANEL MEMBER HAMMOND: So of those types of data that could go into informing these toxic equivalency factors, were moving up --

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: Yes.

PANEL MEMBER HAMMOND: -- And getting better data?

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: Yes.

CHAIRPERSON FROINES: Well, that goes to the same question -- I mean Paul was raising that question. Kathy followed up. And I want to make it even more precise in a

sense, because -- I have rather strong feelings about the relevance and significance of the aryl hydrocarbon hydroxylase pathway and how -- whether one should use an inducible enzyme process in a decision-making framework.

I'm not very comfortable with that, because I think there are other pathways that are potentially important, and probably in some cases maybe more important, and a lot has been made out of an interesting finding that you have this cytosolic event occurring that ends up in the membrane, and so on and so forth, that we all know about.

So if one was making decisions based on that, I would start having problems. If you're saying that the actual in vivo data is improving, then I'm more comfortable. So that's why I think -- I think what everybody's asking is, how do we have confidence that something that changes by a factor of 10 is based on data that we would all feel comfortable if we actually got into the details of it?

Kathy.

PANEL MEMBER HAMMOND: And maybe -- and something like this, which strikes me as fairly important and with a lot of implications, maybe there needs to be another column in the table which basically identifies what was the scientific basis upon which the change was made.

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: Yeah. Well, as I say, we do have the sort of line-by-line decision table from WHO which, you know, we can provide.

CHAIRPERSON FROINES: Yeah, but just to make sure. See, I think what everybody here is saying is we can look at the membership of that committee and in some cases feel good about it and in some cases we might not feel so good about it, because we know the perspective of some of the participants. So that that committee may or may not be one that I would necessarily have confidence in.

But I would have confidence in the OEHHA review. And so that's what I -- I think I want to make sure has happened so that we're confident that it's not just -- this isn't just a bookkeeping operation we're going through, but that it's an effort where there has been an evaluation.

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: We have been through the basis, upon a line-by-line basis and looked at it. And, as I say, you're comment about the enzyme induction not being a particular good basis is exactly in line with the way WHO described their hierarchy of evidence in that they state quite clearly that that's the lowest category of evidence

which they examined and that, you know, basically they laid out enzyme induction as not being as good as, you know, receptor response measures. And they laid out biochemical -- you know, further biochemical measures of toxic effect as being better than just looking at the receptor. And they laid out, you know, in vivo measures of toxicity being better than biochemical or in vitro measures and, you know, long-term --

CHAIRPERSON FROINES: I would argue, Andy, that the diolepoxide, which is in every textbook in America on Benzo[a]pyrene carcinogenicity, does not adequately reflect the actual cancers that result from Benzo[a]pyrene. And so if you have questions about Benzo[a]pyrene, we're sure as hell going to have questions about this site cytosolic receptor.

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: Yeah, I think it's clearly acknowledged that the AH receptor story, although it's what you might call a unifying hypothesis, doesn't represent the totality of effects. And in particular, there are a number of other systems, including some of these steroid receptors, both the ones having a role in reproductive endocrinology and the ones having effect on anabolic metabolism, are clearly impacted also by dioxins. And it's obvious -- I mean some of that is, you know, cross-talk between systems and some

of it's probably independent effects. But, yeah, there's more to it than that, John.

CHAIRPERSON FROINES: Joe had a comment and then Paul.

PANEL MEMBER LANDOLPH: That's what provoked my initial question was seeing the numbers change.

I think this document's very well written and I wanted to congratulate you. I actually recommend you maybe condense it a little and make a review article out of it and publish it somewhere.

I would recommend that, if you could, at the back perhaps clip one of the calculations for one of the TEFs or maybe somebody's paper where they did that just so we can see what went into it. So we have a better feel for how numbers were arrived at.

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: We could -- well, we'd perhaps make sense to add specifically the calculation that was done for the hexachlorodibenzodioxin.

PANEL MEMBER HAMMOND: Well, for any that change.

PANEL MEMBER LANDOLPH: Yeah, any of the changes by order of magnitude, that would be useful.

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: Yes.

CHAIRPERSON FROINES: Paul.

PANEL MEMBER BLANC: What I'd like to suggest specifically is that there be a section added to the document which specifically addresses the three PCDPs that change because of this, and focus most of its attention in that section on the HPCDD. And in several sentences summarize in the text what drove the WHO change, and acknowledge this explicitly that this change will impact proportionally equivalency because -- not just because of the numerical change, but because in the field's condition this is a time of -- I think that from a public health policy you need to acknowledge that explicitly, and I think the way to do that is to add a section. I'm not talking about 10 pages of text. I'm talking about an appropriate several paragraphs.

The other thing that would be helpful that is -- is it safe to assume that the data on Appendix A for these three samples -- airborne samples that were analyzed for dioxin congeners were not analyzed for PCBs at the time?

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: They were not, to the best of my knowledge. I mean the data -- those data were extracted from, you know, other available reports. I didn't have the opportunity to quiz the original authors.

PANEL MEMBER BLANC: So the only example you have that includes all of them is the striped bass?

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: Yes.

PANEL MEMBER BLANC: Which is a --

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: -- which is a fish one, which is perhaps not -- you know, it may be regarded as an infelicitous choice of example, but it was the one which we sort of --

PANEL MEMBER BLANC: Well, clearly, you know, the addition of some equivalency for PCBs is better than none. And you show in the striped bass example that in fact that increases your equivalency by several hundred percent.

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: Of course what isn't reflected in that specific calculation -- and we couldn't reflect it because the measurement wasn't available to us -- is what would have been the potency of those PCBs, you know, as a mixture using the standard previous PCB calculation.

PANEL MEMBER HAMMOND: Because there was no such thing.

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: Well, we didn't -- I mean there could have been a measure of, you know, total PCBs --

PANEL MEMBER BLANC: But it wasn't --

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: Well, if it was done, it wasn't available to us.

PANEL MEMBER BLANC: Right.

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: So unfortunately --

PANEL MEMBER BLANC: And you don't have any airborne example whatsoever that you can cite that has all the numbers?

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: I don't at this point, no; which is, you know -- I mean one of the problems of course is that you don't get that until regulations say it's needed.

PANEL MEMBER BLANC: No, no. The reason why I say this is because it's an important argument in favor of this revision since the net impact is likely to be towards public health protection. Because to the extent that you weren't including the PCBs at all, and now you are going to rate them, even if their -- although their rating factors are generally low, if a striped bass example is also true in the air, it may be disproportionate -- you know, they may be disproportionately present to weight. I have no idea.

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: Yes. I mean I -- I'm sorry.

CHAIRPERSON FROINES: Well, it would seem that they are -- that in some respects they are, from this table.

PANEL MEMBER BLANC: Only according to striped bass table. But I don't know about air what --

PANEL MEMBER HAMMOND: Joe has a comment.

PANEL MEMBER LANDOLPH: I would -- just a sentence or two I would recommend on that last OCDD congener under the PCDDs and the PCDF one, because they also change by order of magnitude.

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: Yes, yes.

PANEL MEMBER LANDOLPH: Just mention -- and in your opinion -- what effect that would contribute to the overall miscalculation since it -- it catches your eye, right, the --

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: Yes. I mean that one is going to also have an effect because it's abundant congener. On the other hand, its actual contribution in any event is small because the overall potency is much lower for that one. And that is -- that's the reason --

CHAIRPERSON FROINES: That's the opposite of Paul's point?

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: Yes, exactly. That is the reason why, as Dr. Blanc has pointed out, the hector is the one that has the largest impact. Although in our calculations the impact

isn't huge. It's like 10 percent.

PANEL MEMBER BLANC: You feel this is -- I'm sorry. You were up.

PANEL MEMBER HAMMOND: Did you include the PeCDD, the second line, in your comment? Because that one actually has increased. And I notice that was offset. You know, Paul pointed out the decrease from the other one. But that increase is offsetting. And that is a common material. So I think in that -- looking at all these -- I mean we can't just look -- include all of these. Because certainly anything where the potency factor is very low, changing it isn't -- to another low number isn't so important. But when it's high and it's prevalent, which is what's happening for -- those are the ones that we're going to have to be particularly careful about.

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: Yes.

PANEL MEMBER HAMMOND: The other comment I wanted to make though was -- I concur with what Paul was saying about looking at, you know, what are the effects when we put this all together in a public health perspective. But I would also ask you look at food. I mean that's striped bass. And air isn't maybe necessarily the major source. We think dioxin is the major -- food is -- ingestion is

the major source. And probably PCBs that's true as well.

So I think that it is important to look at some of the other food sources. And I'm not sure how much data is available.

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: Yeah, I commented before, that food -- you're right, food is the major direct source of intake. Although of course most of the dioxin, which is in the general food supply, actually got there via the air. And most of the general food supply was not raised on farms which have, you know, little PCB dumps in the --

PANEL MEMBER HAMMOND: Fertilizable PCB --

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: There are such places. But they're the -- fortunately the --

CHAIRPERSON FROINES: That's a very important point; namely, that food -- that the air pathway is responsible for the food. So it's not a separate issue.

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: Yes. And so, you know, I think that this is potentially -- I think it's potentially important, you know, to have a good handle on these compounds.

But, anyway, we certainly -- you know, we ought to make specific comments on --

PANEL MEMBER HAMMOND: Is it appropriate -- I'm

still learning my role here, Mr. Chairman.

PANEL MEMBER GLANTZ: You're doing fine.

PANEL MEMBER HAMMOND: But is -- would it be appropriate to ask -- this data's all 15-years old for airborne.

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: Yes.

PANEL MEMBER HAMMOND: If there isn't new data, can we ask that new data be collected to determine how much -- where these things are now and if that's a problem? Or is that totally outside of our --

CHAIRPERSON FROINES: No, we can -- in the past -- we can send a letter to an appropriate agency like EPA and request an update on the literature. That's entire within the realm of this -- in fact this Committee has had an impact at various times precisely because we've sent letters asking for things to occur. And, as Joe knows, on the CIC letters have been sent that end up with bio-assays being done by MTP. So that, yeah.

Now I don't think that the State of California is the body that's going to -- would be doing that research. So it would have to identify who is the appropriate --

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: My understanding is that the federal EPA has recently been doing quite a bit of work specifically on

the question of, you know, the dioxin-like compounds in meat and dairy products and the extent to which that is evidently the major source.

So it's possible that we could, particularly if we lent on your authority, we could get some more data.

CHAIRPERSON FROINES: We can draft a letter and send it from the Panel and --

PANEL MEMBER HAMMOND: I'm not sure whether that's pushing --

CHAIRPERSON FROINES: That's perfectly fine. You can make any recommendation you want.

PANEL MEMBER HAMMOND: Well, I mean I didn't know that there were allocations. But it seems to me that this isn't --

CHAIRPERSON FROINES: Increase our salaries.

PANEL MEMBER GLANTZ: They charge us to attend now, don't they?

CHAIRPERSON FROINES: That's right.

(Laughter.)

PANEL MEMBER HAMMOND: But I think that to the degree that all this work is important -- I think it is. I think understanding its relevance to today's exposures is also important.

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: Yes. I think it would be very helpful.

PANEL MEMBER BLANC: John, can I ask for clarifications from the Chair?

The proposal today, this was coming forward for -- this is a revised statement in response to comments for approval at today's panel.

CHAIRPERSON FROINES: Right.

PANEL MEMBER BLANC: And the clarifications that we're asking for I don't think manifest a wish to delay enactment of this new potency equivalence. And so I don't want to misinterpret my comments. So technically how would you like to proceed?

CHAIRPERSON FROINES: This is very useful because it's educational for Kathy and Joe.

What we have done in the past of course is we have approved documents pending revisions where we considered those revisions did not -- I can't remember the legislative language, but substantively all, you know -- in other words we're not saying that the document is not adequate. We're saying the document's adequate with some relatively minor changes. And so we can approve the document with the understanding that those changes would be made -- if when we see the changes, if they were major problems, we could bring it back. But by and large we would just move forward.

That's our reason -- that's our history.

PANEL MEMBER BLANC: So, Andy, I think we've sort of preempted some of the upcoming slides. But if you'd just run through them very quickly.

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: So I'll try and get through this as --

CHAIRPERSON FROINES: Please don't spend -- given the time constraints, the more you can flip through slides that we've already talked about the issues.

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: Yes, I'll go through these -- these were just the non -- this is just the non-brain-damage version of what we've already been looking at. So I can shoot through this one.

--o0o--

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: These are the actual numbers in the comparison, which we've been talking about. So I think we've probably captured most of the value in this one as well.

--o0o--

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: So --

CHAIRPERSON FROINES: Let's make sure everybody understands that one, because that one is important.

PANEL MEMBER BLANC: And I think that -- again, that that appendix table could be clarified in the same

way that the two paragraphs of text could by a footnote which says the changes are driven by the following two chemicals, one of which went up by .4 and one which went down by .8.

And I also think that the numbers, although they look close, are somewhat deceptive because the percent changes are trivial. We're talking about small numbers. So I think that for the footnote to say this represents an X percent change. I don't know if this table's actually in the document, because mainly it's a slide.

PANEL MEMBER HAMMOND: That's an extract from this. It's an extract from the one you were referring to before.

PANEL MEMBER BLANC: Is it?

No, it's not the striped bass one. It actually isn't in here.

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: The numbers on which this table is based are in the appendix to the document.

PANEL MEMBER BLANC: In the table, see. They're in those two appendix tables, but they're not -- there's not a separate table that looks like this, is there?

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: No, no.

PANEL MEMBER BLANC: Anyway, but I think

clarifying somewhere what the percentage changes would be helpful.

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: Certainly. And if we have the opportunity to expand this with more recent and more relevant data, then we would do well to do so.

PANEL MEMBER BLANC: Yes.

CHAIRPERSON FROINES: I won't hold it up on that basis. Because if we send a letter to EPA --

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: -- it will take forever.

CHAIRPERSON FROINES: -- it will -- you know, we'll all be gray haired, not just a few of us.

(Laughter.)

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: Okay.

--o0o--

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: So, anyway, the effects of the current proposal if adopted would be to continue to use the methodology which was originally adopted in 1986, but to replace the currently used version of the table, which is currently the intermediate one, if you like, the I-TEF table; with the latest version as published by WHO, which updates some of the TEFs for the chlorinated dioxins and dibenzofurans.

And adds to this program the use of TEFs for the coplanar PCBs. And I would -- you know, I need to clarify that if we were to do that, where we had the data for individual PCB congeners available, we would use that to derive a cancer estimate rather than using the bulk measure and mixture slope factor approach for cancer risk for the PCBs.

That is not to say that we would encourage people to ignore the non-cancer effects of PCBs, some of which are not dioxin-like effects. There are of course things like the developmental neurotoxic defects, which are typically the effects of the non-coplanar PCBs. So PCB estimation in a situation where the contamination is so gross that those non-cancer effects are important, the PCB estimation would need still to look at alternative methodologies.

But specifically for estimating cancer risk, it's our belief that the cancer risk associated with PCB exposures is a dioxin-like effect, and that this is the most complete method available to us for estimating that cancer risk. And that's typically what drives the regulation.

PANEL MEMBER HAMMOND: And I'm just a bit confused because I think I'm hearing two things. And maybe I'm just not.

If you have a coplanar PCB and there's a cancer -- there's already a cancer risk estimate made for a particular one, are you saying that this new TEF would replace it or not?

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: No.

PANEL MEMBER HAMMOND: Because this says it in places. But I --

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: No, the existing PCB methodology is not a congener-by-congener method. The existing PCB methodology at the moment uses a bulk measure of some -- of total PCBs and then attempts basically to choose a -- you know, a mixture value, which is by some process --

PANEL MEMBER HAMMOND: So you're saying you would totally disregard that method?

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: For cancer risk we would replace that with the TEF methodology based on the individual congeners, of course where we had those data. If we didn't have those data, then we're not suggesting you ignore the cancer risk. You would have to fall back to the hold PCB methodology if you didn't have the data.

PANEL MEMBER HAMMOND: And have you done any comparison of some settings, as you did here, where you

used the old method and the new method?

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: We haven't gone through a tremendous number of examples, but the -- both we and some of the public comment people have played with that. But in our hands, the cancer risk -- it depends a lot on what the PCB congener mix is. In general, the TEF methodology produces a result which is slightly more public health protective than the bulk method, but it's not dramatically more so. Some of the examples which I will mention just briefly came in to the -- in the public comments claimed that there would be a huge increase. But that's actually based on an error or misapprehension. And --

CHAIRPERSON FROINES: I think, Andy, for the sake of time, if you could move on to the summary of public comments, that would be useful, because there are a number of important comments.

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: Well, I will do that.

--o0o--

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: But what I -- the first comment or -- basically we had a series of comments which were somewhat overlapping, to the extent where several different commenters submitted either parts or the whole of the same

report by one particular commenter. So I guess he was being well paid for that particular report.

But, anyway, to summarize the scope of the comments, a lot of the comments are basically criticisms of the TEF methodology.

And whereas we would have accepted that, you know, comments can be made on the individual choices by the WHO Committee in this revision, our position is that these comments, although, you know, interesting scientific debate, et cetera, are basically off topic, because we already are mandated to use the TEF methodology and we're not proposing to change that. But we had a lot of people saying that they didn't like the TEF methodology in the first place for one reason or another or, in particular, it was imperfect or flawed in some way.

Well, several people quoting one particular consultant pointed out that the actual measurement of dioxin-like congeners both for the dioxins and the PCBs is a relatively difficult and expensive business, and that some -- the only method which really produces a definitive result at the moment is high resolution GC Masspec, which is an expensive method. But some of the other methods which I think were discussed in some of the submissions were clearly not going to be suitable; and we agree, they're not suitable.

I think -- you know, it's not our place to go into great detail about measurement methodology and how the regulators, who of course will be the State Board or the air districts in this case, would chose to implement their strategy. And of course, you know, that is the point at which the questions of cost and feasibility of measurements and so on would come up.

But I think our point at this stage of the process is that these methods -- you know, the high resolution Masspec method does exist. It is used. And, granted, it's a relatively expensive method that can't be used indiscriminately. But since much of the critical problem with this -- with the particular issue we're addressing here is more a matter of source characterization than needing absolutely, you know, congener-by-congener measurements -- I mean the balance of congeners is not going to change on an hour-by-hour basis from a given source in most cases, we don't believe. So we -- it's our sense that, you know, people do use these methods and what we're proposing is not technically impossible or unreasonable. It's just that people have chosen not to do it thus far in many cases simply because they haven't been required to.

The next one -- a lot of people were anxious to criticize our adoption of the TEF for the PCBs and we're

commenting that perhaps the PCB TEFs were in some sense not as reliable as the TEFs for the dioxins or the methodology was in some way less satisfactory for PCBs. We on the other hand feel that the scientific data support the concept that the cancer risk is a dioxin-like effect of the coplanar PCBs; and that although, along with the WHO Committee, we recognize that there are limitations to the methodology and there are some questions which come up with some of the PCB isomers particularly at high dose levels where you're getting things like enzyme induction and induction in metabolism of some of the -- some of the congeners which are more rapidly metabolized, particularly at high doses -- so there are, you know, some, what I'd call, issues around the margins for the PCBs -- nevertheless we feel that this methodology is appropriate for the PCBs.

And, in fact, frankly, we're a little remiss in not having recommended the PCB numbers be adopted at an earlier stage of the process, because this approach for PCBs has been around and recommended for use in scientific risk assessments since '94, since the first update of the original I-TEF table.

The next -- some of the critics actually were upset about our PCB proposal because they misapplied the proposal. They used an extreme value of the TCDD potency

which they had extracted from a recent EPA draft document, which is not what we're proposing. The proposal as we had it before you would use the existing California slope factor for TCDD.

They also used a method where they actually calculated the risk both by the TEQ method and by the mixture value for whole PCBs and added the two risks together, which seems not to be -- certainly it's not what we were proposing, and it doesn't strike us as sensible.

So I'm not quite sure why they did that, other than perhaps to cover the possibility of something really extreme that they couldn't live with.

And they also reviewed several examples which were not particularly relevant to issues for the air program. And we are aware that if the air programs adopt this revised TEF table, there will be some pressure perhaps on other programs to adopt a revised table also. But the point is, as far as this particular action is concerned, this is a proposal for the Toxic Air Contaminant Program and specifically the hot spots guidelines for cancer risk assessment.

PANEL MEMBER BLANC: So in terms of the last three slides, I think you can skip those, which are the detailed responses. We have them documented.

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF

SALMON: Yes, I --

PANEL MEMBER BLANC: I think we're satisfied that you have -- that OEHHA has responded appropriately to the comments that you're receiving. Therefore, I'd like, Mr. Chairman, to move that we accept the proposal for the adoption of equivalency factors, with the caveat that there be minor revisions to the document reflecting the discussion that we have had.

CHAIRPERSON FROINES: I was about to say the same thing, Andy, about your last three slides. So that at least I'm in agreement with Paul.

I do think that before we go to Paul's motion, that I want to give the opportunity to anybody on the Panel to raise questions and then move to the -- I want to be sure we have it on the record that we gave people a chance to make comments before we made a motion.

PANEL MEMBER LANDOLPH: You show instant. I'm not familiar with that. You might want to just describe that in just one or two sentences very concisely.

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: I'm sorry. It --

PANEL MEMBER LANDOLPH: You show incident. You mentioned that --

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: That's the -- I think that's the PCB rice oil

possibly.

PANEL MEMBER LANDOLPH: Page 22.

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: Yes. That's basically a food contamination event.

CHAIRPERSON FROINES: Okay.

PANEL MEMBER LANDOLPH: Just one more question.

On page 23, you have an interesting statement here. Different agonists for the AHR exhibit different dose response curve shapes. I don't know whether you want to elaborate on that concisely. If it's something you don't think drastically affects the overall document --

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: No, I think what we're saying is, that there are -- you know, there's a lot of interesting science going on down, you know, below the level of what we're concerned with the for TEF table. And that's one of reasons why WHO is careful not to exaggerate the precision with which they quote the TEF values.

PANEL MEMBER LANDOLPH: And you don't visualize these as being really significant in terms of affecting the end --

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: Not for the purpose at hand, no.

CHAIRPERSON FROINES: So hearing no further

comments, Paul, make your motion again please.

PANEL MEMBER BLANC: I would move that we accept the proposed adoption of revised toxicity equivalency factors as presented, with the caveat that there be minor modifications to the text consistent with the discussion that we've had here today.

CHAIRPERSON FROINES: Is there a second.

PANEL MEMBER FRIEDMAN: Second.

CHAIRPERSON FROINES: Is there a discussion?

PANEL MEMBER LANDOLPH: I would just thank them for the very nice document they put together under Dr. Salmon's leadership and all the -- that went into this document. It's very well written.

PANEL MEMBER GLANTZ: No, this is a little one.

(Laughter.)

CHAIRPERSON FROINES: It's his first day. Let him think this is the biggest document he'll ever see.

PANEL MEMBER LANDOLPH: No, I didn't say that. I just said I like what I see. I've read bigger ones.

CHAIRPERSON FROINES: So all those in favor of the motion?

(Ayes.)

CHAIRPERSON FROINES: The motion carries unanimously.

Let's move on. Given the time constraint, I want

to move on to the ETS document.

And he promised me he was going to raise his hand. But I think we'll take a five-minute break.

But let's make it a short break.

(Thereupon a recess was taken.)

CHAIRPERSON FROINES: I want to say for the record that Dr. Hammond has in a prior period of time provided consulting to OEHHA on the ETS document. We think that that does not create a conflict of interest.

PANEL MEMBER HAMMOND: Not on the ETS -- not on the new ETS document, if there is one. But to ARB a sampling that would inform them.

CHAIRPERSON FROINES: Oh, to the sampling that provides data for the new document.

PANEL MEMBER HAMMOND: Presumably. And I haven't seen that.

CHAIRPERSON FROINES: We don't think that constitutes a conflict of interest. We will not ask her to be a lead on ETS, although that would make a lot of sense; we'll ask her to be a participant in the discussion, so that there's no question of the appearance of an issue.

So we'll go that way, Kathy.

CHAIRPERSON FROINES: But we think her expertise is invaluable as we move forward in this process.

Given this problem of time, I hope we can keep the slides to -- we don't need to worry too much about background. The panel's relatively familiar with the ETS background. And so sort of an update is what we really need to focus on.

MR. KRIEGER: Okay. Thank you.

(Thereupon an overhead presentation was Presented as follows.)

MR. KRIEGER: Good morning, Dr. Froines and members of the panel.

Today, as Dr. Froines mentioned, we are updating you on the progress to develop a report on environmental tobacco smoke that will serve as the basis for the identification as a toxic air contaminant.

In our presentation today we will provide background information on the Air Resources Board's Air Toxics Program, very briefly, and update on the development of the ETS identification report.

My name is Robert Krieger. And I will be giving an overview of ARB's exposure assessment. And Dr. Mark Miller from OEHHA will provide an update on OEHHA's health assessment.

CHAIRPERSON FROINES: One of the things I want to mention as an aside -- sorry, from the beginning -- but when I walked out of the Oakland Airport yesterday, there

must have been 25 to 30 people smoking. There clearly was an ETS issue at the Oakland Airport as you go right outside the United terminal. So if you have any dollars left, I would spend a little time at about 5 o'clock in the afternoon in Oakland, because I think you get a lot of ETS. But that aside.

MR. KRIEGER: Well, actually later on in our program we'll talk about -- a little bit about our ambient air monitoring program that we are just concluding finishing right now. And one of those sites happens to be in an airport. So we can talk a little bit more about that, just in general.

This slide here, everyone's aware of this slide. This is our identification control program for AB 1807. Specifically our task or our command here at the Air Board is to look at substances which are toxic to identify them, and then ultimately look at the need to control those toxics as well.

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MR. KRIEGER: This specifically talks about the identification of our substances. And specifically the Scientific Review Panel plays a very important part in this process, to provide us the independent peer review that we need to make sure our documents are based on sound science, which ultimately leads to a board hearing to

identify these. And ETS is in the second stage of the this process where we're assessing exposure. And OEHHA's developing a Part B report.

--o0o--

MR. KRIEGER: As a basis for anything we do to identify toxic air contaminants we use this definition that's in our Health & Safety Code, for which -- which is an air pollutant -- a toxic air contaminant, which is an air pollutant which may cause or contribute to an increase in mortality or in serious illness, or which may pose a present or potential of hazard to human health.

--o0o--

MR. KRIEGER: As background information for you, in February of 1992, our collaborative agreement between the ARB and OEHHA was made to initiate a report on the health effects of the ETS. This was requested by the Scientific Review panel.

CHAIRPERSON FROINES: Can I stop you for a second.

MR. KRIEGER: Yes.

CHAIRPERSON FROINES: I apologize, because I'm the one trying to keep us all on track, and I'm the one deviating now. Paul will tell me that in the minutes now.

PANEL MEMBER GLANTZ: Yeah, right. Just for the new members, this is normal behavior.

(Laughter.)

CHAIRPERSON FROINES: He always accuses me of taking -- this is the prerogative of the chair.

(Laughter.)

PANEL MEMBER GLANTZ: I didn't say it wasn't --

CHAIRPERSON FROINES: I just want to make one comment, one comment only.

I want to make a point for the record here, which is that in 1992 the SRP requested a chemical, in this case ETS -- in other words we requested that OEHHA and ARB bring forth ETS. And that set in motion the process that Bob's talking about.

And I want to say that as a prelude to our discussion about pesticides. Because I don't think it's simply a question of our always waiting on the agencies. We can make requests for where we decide that a substance is of particular public health significance.

So go ahead.

PANEL MEMBER BLANC: And I think the record should show that John got through that entire statement without using the phrase "it seems to me that."

(Laughter.)

CHAIRPERSON FROINES: I was trying to be unequivocal.

MR. KRIEGER: Okay. Thank you, Dr. Froines.

The final draft of this report was reviewed and approved by the SRP in 1997. Subsequently, the National Cancer Institute, or NCI, recognized the importance of the report and incorporated it into their smoking and tobacco control monograph series in 1999.

In June, 2001, ETS was formally entered into our identification process.

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MR. KRIEGER: ARB's approach to developing the ETS report is based on the requirements specifically of AB 1807. Chapter 2 of the report I just mentioned, the 1999 NCI monograph, was used as a starting point for the exposure assessment and, in particular, the indoor and biomarker sections.

MR. KRIEGER: Our exposure assessment will incorporate the information from Chapter 2 in the NCI report. However, it is important to note that much of our exposure assessment is information that was not presented in the report.

CHAIRPERSON FROINES: Let me just tell Kathy and Joe something.

There is no minimum exposure requirement for designating a substance as a TAC. We don't have to have X amount before we can go forward for ARB and OEHHA; that it is different with the Department of Pesticide Regulation,

and you'll learn more about that later. But to the degree that there is exposure, we have decided we can identify a substance as a TAC even if that exposure is relatively low.

MR. KRIEGER: Good point. Thank you.

As in other identification reports, our report addresses the areas required by law. They include information on a substance's chemical and physical characteristics, sources and emissions, a major -- or an estimate of ambient concentrations, indoor and total exposure, children's exposure, and the substance's persistence in the atmosphere.

For the exposure chapter, we have taken a slightly different approach from that of past TAC's exposure assessments. Instead of calculating a statewide population based annual average concentration, we believe it is more appropriate in this case to use a scenario based approach. This approach estimates an individual's daily ETS exposure in several different micro-environments.

Part of the data to do this analysis will come from our ambient nicotine monitoring study. This study was undertaken to provide the data for the gaps that existed in the outdoor near-source concentrations of ETS.

As of today the samples from our last ETS

monitored site are being transported to UC Davis for analysis as we speak.

So we've just completed that study.

With four out of the five portions of the report drafted, staff are currently focused on the exposure assessment chapter, which includes the monitoring efforts. Once the report is completed, it will undergo internal management review and be available to the SRP leads by the end of July.

Now, that concludes my presentation for today, unless you have any questions upon a -- specifically on our approach. And I can turn the presentation over to Mark Miller.

CHAIRPERSON FROINES: Questions?

PANEL MEMBER BLANC: Why don't you just reiterate the five sites. You have alluded to one of them being an airport -- outdoor, in front of an airport.

MR. KRIEGER: Yeah, airport was one of them, a general public exposure. We're also doing a public building. We're doing an amusement park where the children -- to basically pick up our children's exposure. We've done a college campus and a government building.

So hopefully we're picking all the areas up in general exposure, a high-end exposure, and a children's exposure.

CHAIRPERSON FROINES: Do you have an anticipated date that that document would be complete?

MR. KRIEGER: Well, actually, we're incorporated into this document right here. So you'll see all these by the end of July -- at least the leaves you'll see this -- the results of that study into our report by the end of July.

PANEL MEMBER FRIEDMAN: Hasn't smoking been banned from government buildings?

MR. KRIEGER: It's not banned. Well, inside.

PANEL MEMBER FRIEDMAN: You're just doing the outdoor?

MR. KRIEGER: We're doing outdoor. This is strictly outdoor.

PANEL MEMBER FRIEDMAN: Aren't you missing a big component presenting home -- in the private homes where people smoke?

MR. KRIEGER: What we've agreed upon in this study since the air boards primarily focus on outdoor exposures, we'll use the existing data that -- there's quite a bit actually in indoor exposures already. And we're using the date that's currently available for indoor exposures to kind of coordinate a total exposure approach where we take the outdoor measurements with the activity patterns and kind of come up with a total exposure for

each individual's daily exposure.

So the outdoor exposures, there's quite a bit of data gaps existing in the outdoor ambient exposure. So since that's our area of responsibility, per se, that's where we focused monitoring study on.

PANEL MEMBER FRIEDMAN: So what will you do, say, with the government -- the outdoor of the government building data? How will you get that into a total exposure pattern given that many people will never be there?

MR. KRIEGER: Well, it's -- you know, again, I think in importance -- and we're talking about here -- and Dr. Froines mentioned to, for our assessment we, first of all, primarily, the State of California, we prove that there's exposure out there as the basis for identifying something as a TAC.

Now, as far as the Government building, it will be put into more of a general public exposure kind of area. The chapter that we're talking about, we're going to put that into a scenario where a person may be working in that area, a worker exposed to going outside, walking around like the commons area around the Government center is going to be breathing this amount of tobacco, okay, for this short duration of time.

We'll include that into a person's -- well, he

goes home. And, let's say, he's home -- maybe he's a smoker himself. Maybe that's one of the scenarios too. Another scenario is where he's home with a non-smoker. And we're going to put that in to estimate kind of a exposure scenario where a person working in that environment would be exposed to this much environmental tobacco smoke.

It's not -- it's quite different from other TACs where we've taken the general population's weighted exposure throughout the whole state. This way -- we feel that it's more beneficial to do it this way and show that, well, yeah, it's very narrow in the people that are being exposed in the sub-populations, but it gives a good indication of what a person in this environment might be exposed to.

CHAIRPERSON FROINES: It's my understanding, Gary, that the ARB doesn't have regulatory authority over an indoor setting. So that the indoor exposure can be used for dose response in a hazard characterization, but not so much would it have relevance for subsequent regulatory --

PANEL MEMBER FRIEDMAN: Well, it certainly would enter into what the people's exposure would be.

CHAIRPERSON FROINES: Yeah, and I think -- but from a standpoint of this going on to a controlled --

various controls, they wouldn't develop controls for indoor situations.

PANEL MEMBER BLANC: Well, I'm glad that you gave us a little bit more detail on the ambient exposure sampling plan, which had been shared at least in part with some of the leads before. And I think it's very clever in that it will allow you to generalize to the scenarios. And as I understand it, the use of that outdoor space in front of a government building was partly convenience, but should certainly be generalizable to a wide variety of people occupationally exposed in standard egress and ingress to office building situations as well as to people who -- not just people who work but people who have to come to such buildings for services.

So I think that there was a pretty clever choice of a variety of scenarios, given that you don't have an inexhaustible time and resources.

MR. KRIEGER: Right.

PANEL MEMBER BLANC: And I believe that one of the spaces was a mall, wasn't it?

MR. KRIEGER: We were looking at a mall at first. Yeah, we've actually -- before we even thought of these things we have a -- you know, we have several of these places that we wanted to test. And then, like Dr. Blanc said, that it's a matter of can we get permission to these

sites and availability, and were there, you know, smokers on these sites too as well. So, yeah, Dr. Blanc was right. We took careful examination of all those places.

CHAIRPERSON FROINES: Mark.

MR. MILLER: Mark Miller with OEHHA.

As has been mentioned, there was an initial OEHHA document in 1997 which was published by NCI in 1999. And if there are any of the Panel members who do not have a copy of that, we'd be happy to make one available.

For the update, we felt that since the last studies included in the original document were in 1996, that there was a considerable body of literature that had occurred between then and now. And we are updating each of the chapters, which include a review of epidemiologic studies and, as well, animal and biomarkers sorts of materials that have been published since the original document.

The methods are the same as our outline in the original document and will be reviewed in an introductory chapter of this one.

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MR. MILLER: The chapters included individual chapters on developmental effects, a separate one for prenatal and postnatal developmental effects, reproductive respiratory carcinogenic and cardiovascular health

effects.

PANEL MEMBER BLANC: Mark?

MR. MILLER: Yeah.

PANEL MEMBER BLANC: You're citing these chapters as examples, or these are the chapters?

MR. MILLER: These are the chapters.

PANEL MEMBER BLANC: So -- I think this will come up in a different context, but for other or miscellaneous effects that aren't well categorized within these organ systems, how are you handling those? Only in the introduction?

MR. MILLER: What are you thinking, effects?

PANEL MEMBER BLANC: Well, suppose there was an endocrine effect that someone had shown that was not a reproductive endocrine effect. Where would you handle that?

MR. MILLER: Well, the endocrine effects Were handled in the reproductive chapter.

PANEL MEMBER BLANC: And the tissue of sensitization, since it's not solely a respiratory health effect, is all of -- all immunological are subsumed under respiratory effects?

MR. MILLER: That's -- I believe that -- at least primarily those are all under the respiratory section. So whether -- they may include some -- you know, we may

discuss something that either, you know, is not directly apparent, you know, related that at chapter -- but has a more general context. Or of course there are a number of areas that are applicable across several chapters, in which case we made an attempt to put it in the most applicable chapter and then reference it in other locations where that seemed applicable.

PANEL MEMBER BLANC: Well, what I would suggest then, rather than have you add a miscellaneous chapter, which would be a hodgepodge, is to be very cautious in your introduction to highlight those subjects which are somewhat tenuously linked or had to be, you know, forced into a certain chapter, and just highlight where you've put them in your introduction, and acknowledge that they aren't pure -- you know, that sensitization is not purely a respiratory effect, but since you wish to focus on asthma, blah, blah, blah.

I assume you're including the respiratory health effects as upper and lower so that's where nasal effects would be?

MR. MILLER: Yes.

PANEL MEMBER BLANC: That kind of thing would be --

MR. MILLER: And sensory perception is in there.

PANEL MEMBER BLANC: Well, then again, your

introduction better say that you've included sensory perception in your respiratory chapter even though that's not a respiratory word --

MR. MILLER: Perhaps some level of indexing would be appropriate.

PANEL MEMBER GLANTZ: Well, the other thing that you might want -- I mean I've seen a few of the draft chapters, which I think have been quite good actually. But I think that maybe that after you have all the material assembled, you might want to change the chapter names appropriately. So if you were to say sort of reproductive and other endocrine effects, you know, that would fix it. Because I don't think at this point we want them to go and try to rewrite the whole document.

PANEL MEMBER BLANC: No, that's why I suggested handling it. I mean that's in addition to making it clear in the introduction you can handle it. But you may run into things I mean are -- I don't if there's any literature on any renal effects from secondhand smoke. But if there were, would you just say they're all cardiovascular, therefore? I mean I don't know. But it doesn't -- you want to have a document which also makes sense to people from different disciplines.

MR. MILLER: Let me say this about our approach: Our approach was in fact to update the prior document.

And since this was seen as not a -- we didn't want to repeat everything or combine everything. And so that there are two separate stand-alone documents. What we did was at the beginning of each subsection try to summarize in a paragraph the findings previously just as -- so that you could have a sense just from this update of where it stood.

But all of the sections and the subsection numbering and titling we tried to, as well as we could, follow the previous document so that you could match up where you were and go back and look at the original review. So that's how we got to where we were.

PANEL MEMBER BLANC: Well, I think that's a compelling argument to follow up on that. I don't object to that and I don't object to keeping in the same chapter and the same thing. But somehow you need to acknowledge that you're perhaps in certain places stretching what the definition would be so that the reader of the document knows that you know that in fact, you know, certain --

MR. MILLER: And also that they know where to find something if they're looking for a specific thing. I think that's an excellent idea and that we should be able to accomplish that.

CHAIRPERSON FROINES: Let me actually take from what Paul just said and give you a specific example that

came to my mind. Yesterday, I heard an absolutely extraordinary presentation by Frank Gilliland, who's at the University of Southern California. And it really knocked me off my feet. And what he was looking at was GST polymorphisms. And he was looking at asthma incidents in children from 0 to 5 as a result of in-utero exposure. So you have genetics, gene environment interaction, you have in-utero exposure, and you have asthma as an outcome, following birth obviously. And so the question would be how would you -- I actually wanted Frank to come present the data to this Panel because it's so striking. And I don't know whether we'll do that. But it does seem to me that it does -- it does raise a question of where would you put in your system that kind of information?

MR. MILLER: Well, I think the way that it has happened is that those studies that were generated out of a respiratory effect, you know, are in the respiratory chapter, whereas, you know, polymorphisms that had to do with a study that was relevant to reproductive effects are in the reproductive chapter and so on. They're not, you know -- that's the way it's divided up and --

PANEL MEMBER BLANC: That's okay. That's okay.

MR. MILLER: I think we'll do -- you know, we'll take under advisement the suggestion and see how best we can pull that together in a way that we are able to

identify and make clearer and, you know --

CHAIRPERSON FROINES: Well, I just think that -- forgetting the genetics for a moment -- the in-utero exposure to ETS as a long-term predictor of adverse health outcomes is a very important topic, and so it almost deserves some focus in and of itself. But we'll just see as you -- as we see these chapters.

But I would contact Gilliland and get his work, by the way.

MR. MILLER: Yeah, we do reference, you know, some of that. But I don't know about -- anything about what we publish, so...

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MR. MILLER: So our intention is that this is a stand-alone document, but that it's tied with the original document. It includes, where it was possible to develop, newer estimations of attributable risk in those areas that were felt to be causative.

--o0o--

PANEL MEMBER BLANC: Not to say that you were going to not comment on estimates of relative risk where appropriate too?

MR. MILLER: Yes, where we have adequate evidence.

CHAIRPERSON FROINES: As a member of the UCLA

School of Public Health, I apologize.

(Laughter.)

PANEL MEMBER GLANTZ: You should.

(Laughter.)

PANEL MEMBER GLANTZ: We're doing a study of how that paper came to pass. And it's going to get even more unpleasant.

CHAIRPERSON FROINES: James Enstrom's paper --

PANEL MEMBER GLANTZ: -- that dreamt up by Phillip Morris.

CHAIRPERSON FROINES: Go ahead.

PANEL MEMBER HAMMOND: How smoking doesn't cause any lung cancer.

MR. MILLER: So to date where we stand, we've provided most of the chapters already to the leads as individual chapters and have received some comments. The last two chapters will be provided to the leads by the end of this month. And then the reviewed and adjusted document will be provided to the leads by the end of July.

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MR. MILLER: So this is a slide with what we're proposing as a reasonable and doable time line. The draft report should be available to the public for comment by the end of September. By the end of October we'll have held public workshop, and by the end of November responded

to public comments. And of course that -- it does depend a little bit on the degree to which we receive comments. Hopefully by the end of November.

And we should have a revised report then by the end of January, available in early spring to the SRP for their review.

CHAIRPERSON FROINES: And when would the entire report go to the SRP within this context?

PANEL MEMBER BLANC: Early spring.

MR. MILLER: Early spring. I mean that has to happen after public comment and revision, is my understanding.

PANEL MEMBER BLANC: Okay.

CHAIRPERSON FROINES: Thank you.

Any questions, comments?

Joe.

PANEL MEMBER LANDOLPH: If you have a copy of that earlier monograph, I'd love to have one.

MR. MILLER: Yes.

CHAIRPERSON FROINES: Stan.

PANEL MEMBER GLANTZ: I've been -- you know, this sort of is for the new members too, talking about the quality of the report we looked at earlier.

I'm amazed as I go around the world, attend meetings and presentations on secondhand smoke, that the

1997 document is the definitive international document on this question. I mean -- I see Kathy nodding her head. It's just everywhere I go people are quoting that document. I think OEHHA can be really proud of the quality of the work that was produced there. It is the gold standard. And I think having looked -- the Golden Bear standard.

Anyway, the -- and I think that the chapters that I've seen, I've had a few minor comments on them, but I think it's continuing this very high quality document that will come out and I think be a substantial contribution not only to the AB 1807 process, but as another measure of international science as a resource.

PANEL MEMBER FRIEDMAN: I'm not clear on how you're going to append the original report. I mean are you going to have a doubly thick volume --

MR. MILLER: No. This will be a stand-alone. But as I said previously, it's designed in such a way that all of the numbering headings and subheadings are fairly closely aligned with the original document. We refer to the original document throughout it. We try to summarize briefly what the findings were in the original document. We do not try to repeat any detailed information about the studies that were previously reviewed. So it will not -- if you want the original document, you have to get the

original document and look at it. And the way I look at it, the original document plus this document are in fact the document.

PANEL MEMBER GLANTZ: I don't mean to find -- I mean I don't want to -- I mean the way the chapters I've seen are organized, there's one other thing in addition what Mark said. It's each chapter starts out and -- or each -- often sections within the chapter say, "The original document said blah, blah, blah. Here's a summary of the new studies produced since then." And then it ends -- most of the sessions, I think all of the sections, ends with a thing that says the data published since the original document are consistent with the previous findings or lead us to change the original conclusions by either saying the evidence is now stronger or weaker. And if there's some estimate of the risk change.

So it reads pretty well, I mean as a stand alone.

MR. MILLER: As well, we're in the process of developing a small chart for the front of each chapter that will review, you know, really briefly, the number of studies in the original document, the number of studies reviewed in the present document, the findings of the original document, and the findings, you know, if they were changed or left the same in the current update. So that you can look at it and get a sense of, you know,

where do you want to look.

PANEL MEMBER GLANTZ: The one thing I -- I think that's a really good approach and it avoids a lot of duplicate efforts and things. The one thing I would suggest, that the one exception I think you ought to make to this general approach though is when you write introductory chapter. I think that should be a comprehensive introduction that covers the full body of evidence, not just the new evidence.

MR. MILLER: Yeah, you'll be seeing that chapter by the end of this month.

PANEL MEMBER GLANTZ: But I think -- because I think just as the current document is widely utilized, I think this one will be too. But I think having a nice summary at the beginning of everything will be -- will make it more useful to the general public.

PANEL MEMBER FRIEDMAN: I guess what confused me was your third last line of the first point says, "Original document to be appended for sake of reader." That's what I wondered, if you're actually --

MR. MILLER: We're not attaching it.

PANEL MEMBER FRIEDMAN: Okay.

CHAIRPERSON FROINES: Thank you very much.

Stan, what time do you have to leave?

CHAIRPERSON FROINES: Oh, about Noon or --

CHAIRPERSON FROINES: Then I'd like to take just a few minutes before we go to formaldehyde and fluorides, in case you have to leave. Just so that you're aware of -- I wanted to talk about the DPR letter and status so that you have that before you go.

And just for the Panel I'd like to review the history briefly. And then we can have a discussion.

Basically I sent on September 11 -- I didn't prepare a PowerPoint slide, so I'm sorry. But September 11, 2002, I sent a letter to Allen Lloyd as head of the ARB, Mike Kenny, who was then Executive Officer, Joan Denton, the Director of OEHHA, and Paul Helliker, talking about trying to get an update from them on future Scientific Review Panel activities that would be coming to the Panel from their agencies.

As a result of that letter Helliker sent me a letter on October 10th, in which he said -- and I realize this is a bit of a paraphrase, but I'll --

PANEL MEMBER GLANTZ: For the new people, you might just identify who he is.

CHAIRPERSON FROINES: Oh, Paul Helliker is the Director of Department of Pesticide Regulation.

On October 10th, Mr. Helliker sent me a letter in which -- and I'm going to oversimplify it for the sake of time -- but he said, "Thank you for your interaction with

DPR," and "We are essentially not going to be bringing chemicals to the Panel in the foreseeable future, although we intend to keep working with you. And as chemicals come up, we will bring them. But we're essentially canceling everything that's currently in the basket."

As you know, I then sent -- as a result of that, on January 31st, 2003, I sent a letter to Helliker that everybody here except for the new members of the Panel has seen -- that basically I commented on Helliker's letter and said that I thought that the tack they were taking was not appropriate from a public health standpoint, and that we wanted to continue working with them and we wanted to continue working with the pesticides that we already had committed to as well as issues of risk assessment methodology, exposure assessment, and what have you.

I then met with Jim Behrmann and I met with Mr. Helliker on February 14th. And at that meeting -- and I should say for the record that that was a very good meeting. And it appeared to Jim and myself that Mr. Helliker basically agreed with everything -- with most everything that was in my letter to him earlier, and that we were anticipating a new approach different than what had been contained in his letter. And he said he would get back to us with a response within a couple of weeks.

We have never heard a response from him that

memorialized that meeting and discussed the future relationship. I sent him an E-mail saying, "I hadn't heard from you." He sent an E-mail back saying he would get back to me within a week. I didn't hear for three or four weeks. I sent a second E-mail and I still haven't heard back.

So as of now, the current situation is that we have not had a response from DPR based on our meeting with Mr. Helliker and we haven't had a formal response to the letter that I sent.

And I think that's an accurate representation of the history.

Elinor or Jim, do you -- am I missing something?

So the bottom line is we are essentially on hold waiting for Mr. Helliker.

Now, I should say that at the meeting that we held with Paul Gosslin and Paul Helliker there were two representatives from the Legislature -- legislative staff from Byron Sher's staff at the meeting, and they strongly -- and I can't tell you how strongly -- supported the idea of DPR bringing pesticides to this panel. They made it -- they were absolutely unequivocal and actually suggested that they might hold a public -- a legislative hearing on the matter were this issue not resolved.

So that's also in the background. And you've

seen the letters between Helliker and Sher on methyl bromide. And I won't say anything more about that unless somebody in the Panel wants to ask about it. But basically -- except to say that DPR has essentially said to Senator Sher and Representative -- Assembly Member Laird that they will not bring methyl bromide to the panel.

So at this point we are in a situation where we have had no response from DPR. And, in essence, we're -- I guess you would say we're on hold. But there doesn't seem to be -- now recognizing that there is serious budgetary issues going on, this item could be lost within that context. So I don't mean to point fingers. But on the other hand, as you know, Helliker sent a very detailed letter, took time to write a very detailed letter to Senator Sher and Assemblyman Laird, and we haven't had the courtesy of a similar response.

So, we're basically in a position of waiting at this point, unless somebody has a brilliant strategy to move this forward.

PANEL MEMBER BLANC: John, has there been any indication of involvement from relevant public interest groups? For example, the Natural Resources Defense Council. Or are you aware of any legal suits or petitions from the public to force the pesticide branch to move

forward?

CHAIRPERSON FROINES: Well, first question I have is to Jim and Elinor. Has the Panel received the Pesticide Action Network Report?

MR. BEHRMANN: No.

CHAIRPERSON FROINES: Do we have it? Could we have a copy of it?

MR. BEHRMANN: I do not have a copy.

CHAIRPERSON FROINES: Elinor, you have a copy. Can you make it available to Jim? And he can circulate that. Because there was a very lengthy report done by the Pesticide Action Network, which I think you'll all find rather interesting. It was highly critical of DPR. And it pressed for DPR -- pressed in their report for DPR to bring more substances to this Committee. So there is and external public interest group that actually has taken the issue up.

There are no lawsuits as far as I know from public interest groups on this matter. So that as far as I know that hasn't happened.

And the Legislature's clearly focusing on the budget. So that I don't think that anybody's interested in holding hearings at this point.

But it's --

PANEL MEMBER BLANC: Well, then to follow up, I

wonder whether the -- I wonder whether if you could approach a legal counsel for the ARB and ask them to give you an opinion as to what the standing of such groups might be in such actions so that we would understand what our role might be. Of course we're completely neutral point of view. But I think that would be -- I think we have every right to ask counsel to give us an opinion on that subject since we might become involved one way or the other.

CHAIRPERSON FROINES: Well, I think that's -- we certainly can do that. And Jim can make a note of that.

But I wanted to raise -- I never -- I'm glad you said that because it raises another issue. As everybody, with the possible exception of the new members, knows that when a substance is brought before this Panel, one of the legislative requirements is that the agencies develop a risk assessment to estimate the public health risk associated with that particular substance.

Now, under the Clean Air Act amendments of 1990, 189 compounds were designated as HAPs. And those compounds have been grandfathered in as toxic air contaminants. So they -- so we have 189 HAPs that are now toxic air contaminants. However, OEHHA has through their acute and chronic REL process developed risk assessments. I don't know, Andy, how many of the HAPs have had a cancer

risk assessment done.

But the question is: Shouldn't compounds that have been grandfathered in as HAPs, shouldn't the risk assessments be then brought before this Panel for review and approval? And so methyl bromide, for example, is a HAP. And I would argue that under the 1807 statute -- and I'm not a lawyer -- that that compound should come -- the risk assessment done by DPR should come before this Panel for its review the same way we're going to review ETS.

So just because something has been grandfathered in doesn't mean it no longer has to have a risk assessment developed and a review by the SRP. So there is an outstanding legal issue which I think we should ask the ARB and OEHHA lawyers about. Because it seems to me that if there is a compound "T" loan, for example, or compound "X," that is a HAP. Therefore, a TAC -- it does seem to me that that compound -- OEHHA should develop a risk assessment and that risk assessment should be brought forth for review.

And so I think that's the issue that I don't know the answer to. But it seems like a relevant one because it affects a large number of chemicals.

And, Andy or George, I don't know if you want to comment, not so much on the question I'm raising but on whether you think there are a number of HAPs that haven't

come before the Panel in terms of cancer potency document.

OEHHA DEPUTY DIRECTOR ALEXEEFF: George Alexeeff, Deputy Director for OEHHA.

In terms of the legal interpretation it would be best to ask the Air Resources Board, because their legal staff primarily advises the SRP here. We have one attorney in our department, who primarily focuses on Proposition 65. So she's not as familiar with the statutes under this program. So I think in the end it would be ARB's legal advice that would be definitive as far as it could go.

In terms of the HAPs, yeah, we always jointed with the Air Board, took the position that we would have to -- if we developed the potencies for those things that were grandfathered in, that we'd bring them before the Panel here. And of course we had this overlapping law called the Hot Spots Program, which was -- while the TAC program focuses on area-wide exposure, the Hot Spots Program focuses on specific hot spots within the State.

So that also has a lot of chemicals, we also are required to bring those to the Panel here. So -- and all of the hazardous air pollutants are part of the Hot Spots Program.

And now we have this new program which was mentioned earlier today by Dr. Salmon about the Children's

Environmental Health Protection Act. So under that program we're supposed to review all of the hazardous -- all the toxic air contaminants and bring them back to the panel. So we have another reason to bring them all back to the Panel again whenever we time develop them.

So far we've brought to this Panel over on the potency side, including these TEFs and things, over 200 potency -- cancer potencies to this Panel for review. And probably another -- well, they are probably another 150 to 200 other levels, acute or chronic reference levels, that this Panel has seen. So we've actually brought quite a few to the Panel under the assumption that the statute reads that we're too bring the issue regarding identification as well as the issue on potency and risk assessment to the panel. And it also served us well to get good peer review on those levels from this panel.

CHAIRPERSON FROINES: Thank you, George.

I just want to make one comment for Kathy and Joe. When 1807 was passed in 1982, I guess, it was anticipated there that the Panel would take up six ARB/OEHHA toxic air contaminants a year and six pesticides a year. As George points out, we have had well over 200 compounds from OEHHA and ARB and we have had three in 20 years from DPR.

And hence the tension that exists around this

topic.

PANEL MEMBER GLANTZ: Well, that's more or less what I was going to say.

The other thing, they have been just foot dragging. And we had a brief period where the sun seemed to be coming out from under the clouds over the last couple of years and things started to move a little bit. But this latest set of correspondence is very troubling. Because I mean I think that, budget issues aside, they're basically ignoring the law again.

CHAIRPERSON FROINES: You see, the budget issue is one that people here probably are not aware of. Because DPR, unlike OEHHA and ARB, actually derives significant income from mill tax. So -- and they've gotten an increase in the mill tax, so that they actually have been impacted somewhat less than some of the other state agencies. That's my impression. And I may be wrong, but that's my impression.

OEHHA DEPUTY DIRECTOR ALEXEEFF: Well, the budget decisions aren't over yet for the year, so we're still seeing how it's all going to play out.

But you're right. The DPR is -- their funding -- their proposal is to have all their funding based on their assessments, various assessments that they have, including the mill tax.

PANEL MEMBER FRIEDMAN: If there is a pesticide that really constitutes an important public health hazard, say, under the Hot Spot Program, is there any reason why OEHHA can't take it up and just say, "Well, DPR's not doing it. But we think it's important and, well, let's us do it."?

OEHHA DEPUTY DIRECTOR ALEXEEFF: Well, that -- I guess it would also require some legal interpretation. In the statute the way it's written, we provide health consultation in both evaluating health protective pesticides to DPR as well as in developing their report.

So if DPR is unable to develop a report, I guess those kinds of questions could be asked. And, again, we'd have to consult with ARB attorneys to see what the legal ramifications. But our primary response has been to provide some sort of support review. We have some specific functions in the statute where we provide findings of the pesticides, as you've seen, and our efforts have been to try to support the DPR in that basis.

So --

PANEL MEMBER GLANTZ: Well, you know -- I mean I don't want to prolong this discussion. But I mean I think -- as a friend of mine says, "When the handwriting's on the wall, read it." And I think the handwriting with DPR has been there for years and, that is, they just don't

want to pay attention to this law. And I mean I think that we should sort of continue the current discussions. But at some point it might be appropriate for the Panel to send a letter to Senator Sher, who's the Chairman of the Environmental Committee, and his counterpart in the Assembly, pointing this out and suggesting that if the Legislature wants pesticides addressed as toxic air contaminants, maybe they need to amend the law and have DPR not do it. Because they're clearly not doing it.

I mean I -- many of you -- we all were appointed by different appointing authorities. And I'm here appointed by the State Senate Rules Committee. And some years -- many years ago when David Roberti was still the Chair of the Rules Committee, President Pro Tem of the Senate, when they reappointed me, I actually wrote him a letter and said, "You know, you might want to just repeal the pesticide component of AB 1807 because it's being ignored. And you don't want to have the fiction that it's being dealt with." And that caused a bit of a flurry for a little while. But I think we're sort of back to that point where we really -- I think the most useful think we could do is to simply point out the reality of the situation to the Legislature and say, you know, "You have this law. It's being ignored. You should either recognize it's being ignored or change the law so that

someone who has an interest in pursuing the goals of the law will do it." Because DPR clearly doesn't want to do it.

CHAIRPERSON FROINES: Well, what I'm asking the Panel by bringing it up is basically your advice so to how to proceed, if at all. And shall we wait for the Helliker response? Shall we send the letter you're talking about? How do you want to proceed?

PANEL MEMBER GLANTZ: Well, I think what you suggested. I mean the fact is the budget is still what everybody's thinking about up there. It's a convenient excuse. There is a transcript of this meeting, which presumably DPR will get to see, if they care. And I would suggest we wait a bit longer till the current dust settles. If we had some satisfactory movement out of DPR in the month or two, or however long, fine. If not, then I think that we should send a letter to the appropriate authorities just saying that this is not working.

And because it's really not -- we don't have any authority to compel them to do anything. I mean, as you pointed out earlier, we have made suggestions to the ARB and OEHHA. I mean you mentioned the ETS. There have been several. And They've generally been receptive to those suggestions. And we've attempted -- and this is for the benefit of the new members -- to take some of the same

procedural actions that worked very well with OEHHA and ARB, and get DPR to do them; for example, prioritizing. We put in place a prioritizing process. And that was sort of moving on pesticides, and then that stopped to get people to bring us compounds that are not just easy but important.

And, you know, if they're not going to do it, we can't compel them to do it. All we can do is go back to these -- the policy makers and just point out to them that it's not -- that DPR is just simply ignoring the law. You know, it's true there are budget -- times are tough budgetarily for everybody. But, you know, you still have to obey the law.

PANEL MEMBER BLANC: I think, John, it's a little unclear to me as a Panel member what you are inclined to as Chair. And I need to hear that in order to appropriately reflect back to you. Rather than for me to suggest what you should do, I'd like to hear what you would like to do in the interim. And then I'd be happy to give you feedback on whether that is appropriate.

CHAIRPERSON FROINES: At this point, I basically agree with what Stan said. I think we should give them a couple of -- we're not giving them anything. That's bad phraseology. That we should wait for a period of a month or two, hoping that we'll get a response from the agency

and perhaps hold subsequent meetings with them to discuss it further.

And then if that doesn't -- if it just doesn't happen, then I would send a message to the Panel and basically recommend that we take it to the next step, which would be to the Legislature who enacted the legislation to begin with.

PANEL MEMBER BLANC: Well, I would suggest a couple of modifications of that, if not inconsistent with that plan. But one is that I would recommend against you meeting individually with the head of DPR again as a next step. I think that would be giving them good feedback from inappropriate behavior. And I think the next step, regardless of whether you receive a written response from Mr. Helliker or not prior to our next fall meeting, is that you formally invite him to come and speak to the Committee. And he either needs to accept or decline that. And that would be further documentation of their willingness or unwillingness to be responsive to this Committee.

CHAIRPERSON FROINES: And you would do that prior to any communication with the Legislature?

PANEL MEMBER BLANC: And that would be in the same time sequence. If we refuses to come or depending on what he says when he does come, you would follow through

the Legislature in response to that. And I would actually invite a representative -- if he does accept to come, I would invite a representative from the Legislature to come as well to that meeting.

And the other thing in the interim is that I would pursue understanding what the legal implications are both in terms of our involvement and in terms of public interest groups.

CHAIRPERSON FROINES: Kathy.

PANEL MEMBER HAMMOND: This is probably naive. But as a new member I guess I have some prerogatives to be naive. But I'm feeling we're all busy people. And we don't have much time and -- but it's a certain responsibility to the people of California who are supporting us in our work, the reasons that we serve here. And part of that responsibility as I understand it is to be providing scientific advice for the people of California to the Legislature and to these agencies on matters that come before the Air Resources Board, OEHHA, and the pesticides. And it seems to me that we're not being enabled to fulfill our responsibilities. And to me that seems pretty serious. I take that -- I feel like I have a responsibility on this Board -- or this Panel that I may not be able to fulfill. And I just want to express concern about that.

CHAIRPERSON FROINES: Yeah, good.

Do you agree with Paul's -- I think that -- I didn't mention the legal advice, but I took that as a given. And Paul's proposal basically says that we will wait for a period of time and then invite Mr. Helliker to the next meeting, irrespective of whether he gives a written response or not.

PANEL MEMBER HAMMOND: I was -- that probably depends on when the next meeting is.

PANEL MEMBER GLANTZ: Yeah, I actually don't think -- I think we should wait a while and give him a chance to respond. But I mean -- again, maybe I'm being cynical from having these people come to these meetings, and they tap dance around. I remember one where we spent 45 minutes arguing about what the word "drift" meant and whether pesticides drifted. And then it turned out that there was some obscure -- they redefined the word "drift" in their regulations. So that drift actually meant it was -- the pesticide was applied in the wrong place, not the wind blew it there.

And I don't really think anything would be gained by having a meeting with him. I think the correspondence between John and the Legislature and him is pretty clear. And I think that he can either respond or not respond. And if he responds in a timely manner with a reasonable

response in writing, then we should proceed and try to work collaboratively. And if he doesn't, I think we should simply inform the policy makers that we perceive this as a problem. I don't think him waiting for however long it's going to be before we meet again, which will probably be several months, it's worth the wait. I don't think there'll be any value to it.

PANEL MEMBER BLANC: Well, I -- yeah, I must have misunderstood your comments because I interpreted your comments as saying we should wait at least several months --

PANEL MEMBER GLANTZ: No, I think we should wait a month or two, tops. You know, I think we should give --

CHAIRPERSON FROINES: We're going to have a meeting -- I would point towards a meeting three months from now would make the most sense. We certainly will have an agenda three months from now. So I think that -- I don't think the timeframe is too --

PANEL MEMBER GLANTZ: Okay. Well, I think we -- why don't we -- I do agree with what Paul said about I don't think you would need to take your time to have any more private meetings with him.

PANEL MEMBER BLANC: And the other --

PANEL MEMBER GLANTZ: I do agree with that. I don't see where anything's going to be gained. I mean I

think that the facts, the positions are out on the table. And really it's their decision to make of whether they want to kind of go back to where we were a few months ago where things seemed to be moving and pick up the ball and continue moving them, or to maintain their current position which is essentially that they're not going to do anything. And they know what we think. We know what they think. And I think they -- I mean we should just see. If they change their position, fine. Then we move forward. If they don't change their position, then I think we should just let the appropriate authorities know that we perceive this as a problem.

CHAIRPERSON FROINES: I think that there's -- I think that there is a reason for a meeting, and so I don't entirely agree with Paul and you, in the following context: I think if we don't hear from Mr. Helliker and -- if that's what happens, and that's entirely possible, that's one thing. But if he sends me a letter and requests a meeting, then I feel that there is an obligation to meet with the agency head who requested the meeting. So I think that's --

PANEL MEMBER GLANTZ: Oh, no, no. No, I'm not saying that you should refuse ever to meet with him. I thought you were talking about you originating the meeting. I think if they --

CHAIRPERSON FROINES: Well, I would argue -- let me just finish, Stan. What I would argue is that he -- if he requests such a meeting, we should consider having one. But it could be in the context of having him come to the Panel for that meeting.

PANEL MEMBER BLANC: That's exactly what I wanted to say. You -- I'm out of turn, so --

PANEL MEMBER LANDOLPH: No, you go right ahead.

PANEL MEMBER BLANC: You said that they know what we think and we know what they think. Does the public know what we think and what they think? I think -- I believe that it would be important to have him in a publicly available transcript, the appropriate documentation of the status of things. And that's why I don't think you should meet with him again privately and that's why I do think that if he offers a meeting, you say yes and the meeting will be with the entire panel in open reported session.

PANEL MEMBER GLANTZ: I agree with that.

PANEL MEMBER BLANC: Because actually we have not had -- you say we've had people from DPR. But we actually haven't had very high level representatives from the DPR anytime recently, I recall. I think the last time that anybody came from DPR, it was a very low level of people who couldn't actually answer any questions. That's my

memory.

CHAIRPERSON FROINES: Well, that was one of the reasons they there was that -- how should -- what do you say -- tension at the meeting, because we were having an update on a process and there was nobody there from the agency. And I think it rubbed everybody the wrong way. I mean it was disrespect of this panel to be having an update on a very important process and have no representative from the agency at the meeting. So it caused a certain degree of tension. And maybe things were then overstated that might not have been said so otherwise. And we can avoid those kinds of issues. But the -- it was -- I think it didn't show the kind of respect that this panel deserves.

So that's the plan. Does that seem reasonable?

So we'll wait for one or two months --

PANEL MEMBER HAMMOND: Joe has a comment.

CHAIRPERSON FROINES: Oh, I'm sorry, Joe.

PANEL MEMBER LANDOLPH: No, that's okay. I just had a question just for my information.

Who is Mr. Helliker's immediate superior? And then are any orders coming down from that line not to have us involved? What is known about this?

CHAIRPERSON FROINES: Well, we've made the Secretary of Cal EPA aware that these discussions are

going on. We have not -- in the spirit of collegiality, we haven't escalated this up to Winston Hickox as Secretary.

That clearly is an option that we can consider. But we haven't done it because we've tried -- I've tried -- I mean you haven't seen any news stories. You haven't seen any public, you know, outcry or what have you. We have basically tried to do this the way you should. I mean to treat Mr. Helliker with respect and to approach him and try and deal with the situation directly.

So up to now we have not gone to Senator Sher in that sense, and we haven't gone to Winston Hickox. And so I would still argue that we should continue this process and things can escalate over time. But at this point it seems to me that we're still at that level.

PANEL MEMBER LANDOLPH: So I think you answered my question, which was you don't have the impression that there's any marching orders from higher-up authorities --

CHAIRPERSON FROINES: Quite the contrary.

Now, you can -- this Panel can recommend that we take this right to the Secretary right now. I mean there are lots of options. And so the question is what makes the most sense. And so far I've been -- made the decision that the first step was to communicate with the director of the agency.

PANEL MEMBER BLANC: I think that if he answers you in a timely fashion going forward -- it's already not in a timely fashion by the --

CHAIRPERSON FROINES: It can't be timely.

PANEL MEMBER BLANC: But if he answers you well in advance of the next meeting, then you invite him to come to the next meeting. If he doesn't answer you, I think you invite him to the next meeting, and you copy your invitation to the head of the EPA, and you send the letter to the EPA saying, "We have invited Mr. Helliker to the meeting. This is why we're inviting him. We believe it is imperative that he come to this meeting and he accept our invitation."

CHAIRPERSON FROINES: Everybody comfortable with that?

So I think we've gone as far as we can go on this topic. And I think it's clear.

And I think it's important that we know that we have this on a transcript, because I think that pesticides represent some of the most important toxic air contaminants in California, and so there's a public health issue here. This is not simply an academic question. This is a matter of people's lives. And so this -- we need to -- this needs to be resolved in the long term.

Okay. Thank you for that.

Let's do formaldehyde first. I think we can do it rather quickly, Andy.

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: Okay.

PANEL MEMBER BLANC: This is not an action item, is that correct?

CHAIRPERSON FROINES: Yes, it is an action item.

PANEL MEMBER BLANC: This requires a resolution on our part?

CHAIRPERSON FROINES: No, we're going to end up basically appointing two leads to pursue the petition in place. So it's relatively straightforward, as much as anything there is.

(Thereupon an overhead presentation was Presented as follows.)

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: We have for you here just a very brief presentation of the OEHHA response to the petition from the formaldehyde group. And so I'll hand over to Dr. Dave Morry to actually run the --

CHAIRPERSON FROINES: Just One question before you start.

Dave, are you going to talk about the SRP procedure that we developed in 1989?

STAFF TOXICOLOGIST MORRY: Well, our response is

based on comparing the petition with that procedure. But I won't --

CHAIRPERSON FROINES: Well, the reason I ask that is with Kathy and Joe here, who haven't been part of --

PANEL MEMBER HAMMOND: It was written up though.

CHAIRPERSON FROINES: Okay. Gary was actually the lead on benzene some years ago when a petition came in for reconsideration. So he's up to speed. And I think Stan's been around so long, if he's not up to speed, we're not going to worry about it.

PANEL MEMBER GLANTZ: I think I invented it.

(Laughter.)

BOARD MEMBER BLANC: Could the record just show that Dr. Glantz is leaving.

CHAIRPERSON FROINES: Yes. And we still have a quorum, but Dr. Glantz has left.

And so go ahead. Kathy, so you're comfortable, and Joe, with what you've read about the process?

PANEL MEMBER HAMMOND: I feel it's pretty clear here.

CHAIRPERSON FROINES: Okay.

PANEL MEMBER LANDOLPH: Yes.

STAFF TOXICOLOGIST MORRY: Looking at the first slide then.

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STAFF TOXICOLOGIST MORRY: OEHHA's response to this petition is that we think the petition is premature on a change of determination of carcinogenicity. IARC and EPA have both determined that formaldehyde is a carcinogen by inhalation. And OEHHA agreed with that in our original risk assessment for formaldehyde.

Neither IARC nor EPA has changed their minds on this or reviewed it since then.

The petition does not present any clear grounds for reconsidering the question of threshold, which was one of the other questions that information can be submitted on it.

And the petition does not relate -- it discusses new epidemiological evidence, but it does not relate that evidence to the basis of the original OEHHA risk assessment.

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STAFF TOXICOLOGIST MORRY: The petition refers to a rather hefty risk assessment that was done by the Chemical Industry's Institute for Toxicology. And it says that this institute -- that this assessment shows a much lower potency for formaldehyde. But this risk assessment is based on a new calculation based on the same data, the same animal bio-assay that the OEHHA risk assessment is based on. So it's not really new evidence. It's really a

new analysis of evidence that already exists -- or exists and was already considered in OEHHA's original risk assessment.

The calculations -- this is a very complex risk assessment. And the calculations that are involved in this risk assessment have not been peer reviewed. There hasn't been any publication that -- peer reviewed publication that has presented this risk assessment.

And actually the material in here, which was submitted to us by this formaldehyde group, is not complete enough for us to completely reproduce and criticize this model and the risk assessment derived from the model.

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STAFF TOXICOLOGIST MORRY: There are three new studies on epidemiology of formaldehyde -- workers exposed to formaldehyde, which are going to be published soon. And so the U.S. EPA is currently putting on hold their evaluation of formaldehyde until these three are published. And OEHHA likewise would like to wait for publication of these three epidemiological studies, which will give more direct evidence on the carcinogenicity of formaldehyde to humans who are directly exposed.

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STAFF TOXICOLOGIST MORRY: So basically our

recommendation is that this petition is premature, that we don't really have a -- they haven't really met the criteria for a petition to reconsider the risk assessment for carcinogenicity formaldehyde.

Well, I can answer any questions.

PANEL MEMBER FRIEDMAN: There's one thing I -- I didn't have a chance to read this very carefully, but there is I think some paper -- was Collins an author of --

STAFF TOXICOLOGIST MORRY: Which one are you -- there's two Collins' involved here.

PANEL MEMBER FRIEDMAN: I thought that there was some mention in there that there was a new study by him that you hadn't seen --

STAFF TOXICOLOGIST MORRY: I think that's one of the three epidemiological studies that I referred to.

PANEL MEMBER FRIEDMAN: Oh, that still has not been published?

STAFF TOXICOLOGIST MORRY: Wait, I'm not sure about this. Collins -- no I think that's a paper that has been published and I think that was a review of the epidemiological studies and that it -- I'm not quite sure about that.

PANEL MEMBER BLANC: There's the 2001 study of adverse pregnancy outcomes. And the other is the updated med analysis on cancer. So the med analysis would not be

new data. It would be --

STAFF TOXICOLOGIST MORRY: Yeah, I think the med analysis is the one that the petition tried to present that as a, you know, strong argument. And our argument is it that this is a new analysis of the data, but it's only a small part of all of the evidence that applies to the question of identification of formaldehyde as a carcinogen.

CHAIRPERSON FROINES: Jim, has the panel seen my E-mail with Aaron Blair?

PANEL MEMBER BLANC: Yes.

CHAIRPERSON FROINES: So you've all seen that. So I wrote to Aaron asking what the status of these are. And he's responded that there are -- confirmed the fact that there are three studies pending. And so there's no -- one of studies, the NIOSH study, there are some pre-prints floating round. But it's still not been published yet and it's not on the web either. So of the three, we've -- one really doesn't have assess to the data on any of the three, as far as I know.

PANEL MEMBER HAMMOND: Well, the one was in press. That's why I say maybe that --

CHAIRPERSON FROINES: That's this Wes Stainer study, I think.

PANEL MEMBER HAMMOND: No, that was the

British --

CHAIRPERSON FROINES: Oh, is that right?

PANEL MEMBER HAMMOND: That's what it says.

CHAIRPERSON FROINES: Oh, that's the one --

PANEL MEMBER HAMMOND: So that one maybe we could get.

CHAIRPERSON FROINES: It may be on -- you know --

PANEL MEMBER HAMMOND: It makes sense to --

CHAIRPERSON FROINES: -- the Environmental Health puts their studies that are in press on their website. So it may be possible to find that one.

PANEL MEMBER HAMMOND: Well, on the other hand I think that it certainly makes sense to wait for those three studies. I just can't see doing anything without those.

CHAIRPERSON FROINES: Although it will raise an interesting issue, because there are an enormous number of studies in the literature already. And so it raises a methodological and philosophical question about what does one do and what gets one three new studies? Does that change everything that you've thought about formaldehyde before because of those three studies, or how does it influence it? So it's a complicated issue I think. And we'll see how it turns out.

PANEL MEMBER HAMMOND: Actually that to me is a

procedural question. I would -- I guess I'd assume that that would be -- OEHHA would make the initial determination. And they'd say, "Oh, my golly, you guys. You have to see this whole new study that changes it." Or they say, you know, "Just for your information, you might know this new study that confirms what we've been saying all along," or "We dismiss it. It looks different, but we don't think it means anything because it's so badly done," or whatever. But I assume OEHHA does that first; is that right?

CHAIRPERSON FROINES: Yes. But I would like --

STAFF TOXICOLOGIST MORRY: Well, the identification of formaldehyde as a carcinogen was based on IARC and EPA. And what they said is that there's some evidence for carcinogens sitting in humans, but sufficient evidence in animals. So the classified as 2A. So the initial identification of it as a carcinogen does not rest mainly on the epidemiological data or did not -- does not rest on the epidemiological data that existed at time, which was 1992 or something.

CHAIRPERSON FROINES: But the OSHA standard gave great weight to the epidemiological data in that.

OEHHA DEPUTY DIRECTOR ALEXEEFF: If I could -- this is George Alexeeff with OEHHA. Just to clarify. As Dave pointed out and you indicated you saw the basic steps

we looked at, there's three major areas that the panel has asked us to consider when we review these petitions. So one is: Does the carcinogenicity or the basis for listing change? And that's not going to change regardless, and they're not claiming it's changing.

So in these three studies, went and changed the listing, it would still be a TAC and it would still be a carcinogen. The other one is is there a threshold or non-threshold issue? That could come into place if one felt there was some mechanistic issue which claimed that. I don't think that they're claiming that in this case. So in this case it's not a threshold issue.

So the whole issue's resting on potency. Is it as potent as the potency that was adopted by this panel, or is it changing? The model that they submitted looks very in-depth at the ability to cause carcinogenicity in the nasal passages of rats, and it's less potency in humans in the nasal passages, looking at some sort of concordance.

These three studies that are in press, two of them are discussing the presence of leukemia in the workers. So the way this could change the way that the issue plays out is -- and what one would ultimately have to look at is, does one think that the only type of cancer of concern in workers is nasopharyngeal and is the model

relevant? And then if leukemia is now an issue, is the model relevant.

So those are things that we have to try to understand. And that's where -- so it plays out really in the whole potency arena and less in the actual designation arena.

PANEL MEMBER HAMMOND: But my question still is that, I would understand that the first look at all that's from OEHHA when that comes to us?

OEHHA DEPUTY DIRECTOR ALEXEEFF: Yeah. The petitions go to the Air Resources Board. And then we look at them and make a recommendation to the panel. But in the past also the panel has appointed someone to look at them concurrently so that when it comes to a head, it can be discussed, you know, completely and then a decision made.

CHAIRPERSON FROINES: I just wanted to make a couple of comments.

The one place where I would add to what George said is that the approach taken by CIIT in terms of the risk assessment has significant risk assessment implications. It's not your standard approach to risk assessment. And so there's another issue which will go way beyond formaldehyde; and, that is, how do we do risk assessments? And so that one of the issues that we're

going to be -- will come into play, which is a -- it is a complex issue, is how are we going to pursue this approach, these approaches for risk assessment in the future, not only for formaldehyde but beyond formaldehyde? So that there's another major policy and methodologic issue that we're going to be confronted with in the future.

PANEL MEMBER HAMMOND: But my understanding is that they haven't provided enough data for you to really follow through the whole risk assessment; is that correct?

STAFF TOXICOLOGIST MORRY: Well, they didn't provide it with the initial petition. They, you know -- we could -- I've been getting information from them to try to flesh it out and reproduce it. But it's a very, very complex model or set of models.

CHAIRPERSON FROINES: And on this one, we as a panel will rely on you folks evaluation of those risk assessment models from the methodologic standpoint. Given the nature of the expertise on this panel, we may actually go outside and ask some friends in the academic community for their input as well. And so there could be two processes going on. And as we all know, that there are some really -- there are people outside who were thinking about these issues as well.

So that at some point there may be a two-pronged

approach to this of as we move forward.

Andy, were you going to say something?

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: There was one small point I was going to make as an aside, that, you know, obviously the centerpiece of this CIIT report is the use of a self-proliferation model. And it is a large and highly sophisticated one. It's possibly worth pointing out that in fact the original OEHHA formaldehyde risk assessment, which you reviewed -- whenever it was. Was it '92?

STAFF TOXICOLOGIST MORRY: '92.

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: That one in fact also -- I mean it was a much less complex model. But it's not as if we completely ignored the issue and were using one of the old default straight-line analyses; which I think is one of the assertions which was in the petition, that we were using an unmodified traditional default approach, which is not true. We had already in fact paid considerable attention to the issues which triggered the CIIT model. And obviously that we continue to pay attention to those. And we continue to explore what we can do with them.

But I think the panel should understand that this is perhaps an evolutionary rather than a revolutionary proposal which they're arguing for.

CHAIRPERSON FROINES: Paul.

PANEL MEMBER BLANC: John, I'm a little confused.

If OEHHA had received this petition and their was response was as it is but didn't also say, "and also we're waiting for more data," then I think what you would be saying is that then there would be someone from the panel would be the lead of the viewing both the original petition and OEHHA's comments on the petition, and then we would at a future meeting bring the matter to closure. But since they're saying, "and also we await these three other studies to review, then are we saying that, first, we need the see OEHHA's follow-up on those three studies as well as an addendum to this memorandum that they have prepared in response to the petition and at that point there would be review here in OEHHA or are we going to review it twice, once based on what they've written now and then again based on what they say on the three studies?

CHAIRPERSON FROINES: Well here's what I think. I had one concern, George and Dave, about your review and that was it focused on more on procedural issues, the adequacy of peer review and so on and so forth. And your review did not go into an in-depth scientific evaluation of the literature. So as far as I'm concerned, from this panel's standpoint, we want to both deal with your

assertions and arguments about the procedural issues, as well as we want to look -- I think we want to look at the science around which the petition was based.

And so I would like to appoint two leads at this stage who could begin the process of looking into the formaldehyde science that underlies the basis of the petition. And as we get the epi and further evaluation, then that can be -- the preparation that goes on now can be added to in the future for the leads.

And so what I hear you saying is why don't we not appoint leads now, but do it later. And I would prefer to appoint leads now so we can begin to look at these scientific issues underpinning the petition.

PANEL MEMBER BLANC: I still think it may be a little bit immature because basically I don't know -- we haven't had people independently looking at the scientific issues before there's been some initial digestion of it by OEHHA. And if you're saying that OEHHA hasn't really address the content of this self-proliferation and other issues related to this risk assessment, then how is it that the lead is supposed to comment on whether OEHHA --

CHAIRPERSON FROINES: No, the lead is just to begin the process. For us -- we're going to have to do it anyway.

PANEL MEMBER BLANC: Why?

CHAIRPERSON FROINES: Because in the end the Panel has to make the finding. Gary wrote a letter that said there was no new information and we should -- it should not go forward. And so the Panel makes the ultimate determination in a recommendation to the to the heads of ARB. So we're going to have to do it -- the panel has to make the determination. And all I'm arguing for is we can wait until more information comes in or we can assign some leads now who can get started and have the process develop over time. And I can go either way. But I would prefer to start it now because I think formaldehyde is a -- is a difficult issue. I think that the leukemia data that's going to come in is going to be -- is going to end up being complicated. And so the degree to which we can have a couple people who started to think about this issue early on I think it would be advantageous. If nobody agrees with that and everybody would like to wait, then we can do that too.

PANEL MEMBER LANDOLPH: Well, you know, I read this, and I agree with OEHHA's comments. I guess some things in hear bothered me -- and I agree with Dr. Morry. I would like to see CIIT publish in the open scientific peer review literature whether parts of their model are crucial to that risk assessment. I also have to declare a conflict of interest as I sit on the SAB, Scientific

Advisory Board for a couple of years. I think EPA's name has been used a lot in here. I'm not sure that the statements are here represent EPA's position. I would like to see a letter. And I might suggest you write to EPA and ask them what is their precise scientific position at this point in time. Because I think their name is being used. And I'm not certain that that represents their position. I think there's some overreaching or imputation to EPA of positions which they haven't solidified yet. And that bothered me a little bit in here.

CHAIRPERSON FROINES: We can pursue that. But I should say that there are a number of journals out there. I don't think CIIT's going to have any problem getting this in the peer review literature. I think anybody who says that this approach isn't going to make it in the pier review literature doesn't understand the current status of the referee journal process.

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: In fact the -- I mean the de-position model which they use is published. And our point in the comment was that in fact it's the sole proliferation model which is crucial to the conclusions of the risk assessment. And certainly there's a substantial literature of models of this type. But for whatever reason, you know, up to the

present time that crucial element of the proposal hasn't been published in the open literature and subject to full discussion.

And the other thing is I think that -- we have had some discussions with EPA about exactly where they are on the process obviously. And it's rather common knowledge that they've had a team led by Dr. Jerabeck, which has been working with CIIT on this issues for some considerable amount of time. They have been conspicuously noncommittal about making any conclusions, and up to the present time, on the basis of their consideration of the CIIT model. And, in fact, I think I right in saying, it was Dr. Jerabeck who pointed out to us the existence of these forthcoming new publications and implied that their consideration of the formaldehyde situation, you know, was basically that they were waiting to see what came out of these investigations. Because they thought that those would have a very major impact on the way they looked at the whole situation, including their view of the status of the CIIT model.

CHAIRPERSON FROINES: How would you answer, Andy -- how would you answer Joe's question about whether EPA considers what's been done a, quote, peer review document or not? I mean I've oversimplified it, but I think that's --

OEHHA DEPUTY DIRECTOR ALEXEEFF: Well, actually I've been the one discussing it with U.S. EPA. And they were close to completing their reevaluation of formaldehyde for their iris process. And they were at that point planning on using this model as part of the process. But the draft I guess has not yet come out. But that's been their inclination. So they have now put that on hold pending the review of these documents, these epi studies.

CHAIRPERSON FROINES: But you're suggesting that they are at least as far as you know comfortable with this methodologic approach?

OEHHA DEPUTY DIRECTOR ALEXEEFF: Well I think the -- U.S. EPA has done a lot in this area. In fact when we went back to methylene chloride where we first were using from kinetic models and things like that, and U.S. EPA had gone a certain extent and we had gone not as far in terms of how many models we wanted to use. And the Panel adopted -- you know, came up with an approach where we did not incorporate as many models as U.S. EPA had incorporated. So they've been very much on the forefront of using these extra models.

But suffice it to say, it would be helpful to have an SRP member or two as a lead at this time. There's several issues that we've brought up here. One is the

panel made a major statement when they wanted us to only open the process in terms of peer review information. It did not want us to bring non-peer reviewed information as a basis for opening up a chemical back to the Panel. So it is a big issue.

Now, in this case the model's extremely complicated. So to publish it would probably have to require several publications on different -- you know, each of the components of the model, how they work together. It would be useful to have some input from a panel member or two as to how much peer review is required in order to consider the model published, as we continue to try to understand the model and even -- and validate the model so we can reproduce the model.

So one issue is that procedural issue right off the bat. And since it will be complicated, it would probably be worthwhile to have someone give us their input.

CHAIRPERSON FROINES: Well -- so I agree with you. I don't agree with Paul. Because I think that this is a sufficiently complicated process that's underway, and it's going to have a number of -- there are a number different issues involved and they're all in a number of different stages. And so having some person or persons from the SRP assigned just to get involved at this stage I

think within the long run going to be beneficial. And so I would argue that we appoint two people to serve as leads at this stage, and we can -- you can expand that if we felt that it was necessary.

OEHHA DEPUTY DIRECTOR ALEXEEFF: We've already made a tentative recommendation to the Air Resources Board to deny the petition. I mean you already -- that's what we've written here already. So at one point we kind of complete our view. At the same point we've kept the door open simply because we would like to understand more about this model. But it might require them to resubmit a petition at that time and say, "Okay, here's our new package with all the documentation."

So in one sense --

CHAIRPERSON FROINES: Are you willing to accept the Chair's --

PANEL MEMBER BLANC: Sure. I'm reassured by what you said. Just my trepidation was that somehow by the back door you were denying the petition, and you were forcing me to accept the petition by de facto at the beginning of the process of re-reviewing the entire basis.

CHAIRPERSON FROINES: No, we have to --

PANEL MEMBER BLANC: So as long as you're saying this is what you want, I mean we're comfortable with it.

CHAIRPERSON FROINES: And at this point what --

I'll tell you who I would like to have as the two leads. And I would certainly be open to changing my perspective on it. One of whom I -- since I was the lead person in 1992 on formaldehyde, I think I would be the lead person now. Not because I really want to, but because I think I have the history in this compound.

The second person I think should be the lead is Joe. The fact he's on the SAB is absolutely not a conflict of interest, just because you are one of many millions of people interacting with EPA. I have funding from EPA, you know, doesn't consider.

And what I'd like to do is have toxicology people representing the leads at this point because that goes more directly to some of the risk assessment.

But I'd like to also ask Gary, is as the new epi comes in, if he would work with Joe and me to review the epidemiologic studies.

PANEL MEMBER FRIEDMAN: Yeah, that's what I was thinking, that in terms of modeling, it's not -- I don't have the expertise. But when those three studies come in and have evidence about leukemia, why I'd be happy to get involved at that point.

CHAIRPERSON FROINES: So I think that at this point if Joe -- Joe hasn't stood up screaming no.

PANEL MEMBER LANDOLPH: What does that involve

what you need me to do?

CHAIRPERSON FROINES: Well, I'll work with you off-line. It takes a couple pints of blood and --

PANEL MEMBER LANDOLPH: No blood.

(Laughter.)

CHAIRPERSON FROINES: But those of us who have been leads have actually survived the process.

What it does is it means that we work to some extent with OEHHA as this process develops so that we -- when it comes to the panel, when the panel ultimately gives its evaluation, there has been some interaction. Although, we have to -- ours has to clearly be independent since we make the final determination. But there can be some interaction and that's basically what happens.

So, George, I think that's what we'll do. And I think Gary will be the lead then on the three epi studies as they come in. And I don't know -- is there any other epi on formaldehyde that we're -- clearly we don't need to worry about non-cancer effects because the petition doesn't really address that.

So I think it's just the three cancers --

OEHHA DEPUTY DIRECTOR ALEXEEFF: I think it would be helpful to us if Dr. Friedman could look at the new studies in the context of the existing information. Because, as I indicated, part of the question is the

concordance between the animals and the humans and to get a sense as to, you know, is formaldehyde acting in a very specific manner and a very specific location in tissues in humans and animals, or is it more generalized or is it so -- it might be helpful to look at some of the other evidence that also leads up to that, at least in terms of an IARC review or --

CHAIRPERSON FROINES: Okay. Somebody said we get a '95 IARC review as a starting point.

PANEL MEMBER FRIEDMAN: Yeah, could you send me the material you'd like me to do that.

OEHHA DEPUTY DIRECTOR ALEXEEFF: When we get the studies we'll provide you -- you know, some review of the past information that's available in the literature and then the additional studies.

PANEL MEMBER FRIEDMAN: Okay.

PANEL MEMBER LANDOLPH: If you could send me some of that too, that would helpful to review.

CHAIRPERSON FROINES: You and I can actually meet and -- in fact, formaldehyde is one of the chemicals in my risk assessment course, so that you can even come to the risk assessment course and we'll give you a grade.

(Laughter.)

PANEL MEMBER LANDOLPH: I'd prefer lunch.

(Laughter.)

CHAIRPERSON FROINES: In fact your first test to be you lead the class on formaldehyde.

Anyway. Okay.

Onward and upward to fluoride.

That was very useful. In fact all these topics so far have gone reasonable smoothly.

Our job is to review this document to determine first -- for Joe and Kathy, can I just read before you start what our job is.

The language says:

"If the Scientific Review Panel determines that the health effects report is not based on sound scientific knowledge, methods or practices, the report shall be returned to the State Board and the State Board in consultation and with the participation of the office shall prepare revisions of the report which shall be resubmitted within 30 days following receipt of the panel's determination."

So we are making a judgment on whether or not the report has sound scientific knowledge, methods or practices. And if we don't think so, we return it to the agency. But for minor changes we can approve it, recognizing that those minor changes will be incorporated.

PANEL MEMBER HAMMOND: But this would go into effect if we approve it?

CHAIRPERSON FROINES: That's correct.

(Thereupon an overhead presentation was Presented as follows.)

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: Well, this item is your further consideration of a chronic reference exposure level for fluorides, which will be part of the Air Toxics Hotspots Program's risk assessment guidance.

I'll start with a very brief introduction to the program for the benefit of the new members.

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AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: OEHHA has developed guidelines for use under the Hotspots Risk Assessment Program. And the way this works is that OEHHA has prepared these risk assessment guidance documents. And there are also some supporting tools such as a software program which is being developed by the Air Resources Board.

And then the actual risk management activities under the Hotspots Program of course are taken by the local air districts -- the air pollution control districts are the risk managers for this program. And the objective of this program is to regulate risks caused by point sources of emissions of toxic chemicals.

The chemicals which are included are anything

which is a toxic air contaminant, plus a certain number of other items which were previously identified by various mechanisms, including previous deliberations by CAPCO, which is basically a cooperative body that includes the air districts -- or the air pollution control officers.

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AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: Anyway, the guidelines which we developed included a list of acute reference exposure levels, a list of cancer potency values, a list of chronic reference exposure levels, and then a manual on exposure assessment methodology. And then there's also a final manual which is a summary of the more detailed information on the first four parts.

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AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: The chronic reference exposure levels are health protective levels -- excuse me, this thing's misbehaving -- includes -- these are used to assess chronic non-cancer health effects. And a chronic reference exposure level is defined as a concentration in air at or below which no adverse health effects are anticipated following long-term exposure.

Once we emphasized that chronic reference exposure is designed to be a safe level, not an effect

level. It's designed to protect most people, including sensitive individuals. Although we're not able to necessarily account for really extreme idiosyncratic responses.

And following on from my earlier point that this is designed as a safe level, exceedance of the REL does not necessarily result in adverse health consequences, although in our judgment it may do so.

And the risk assessment methodology in which these apply uses the calculation of a hazard quotient, which is basically an annual average concentration divided by the chronic reference exposure level. And what -- basically if that quotient exceeds one, then the conclusion is that there is potential for adverse effect.

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AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: Prior to current considerations the methodology guidelines in the first 22 chronic RELs were adopted in February of 2 --

PANEL MEMBER BLANC: Andy, I don't think you have to read this whole slide.

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: Okay. Well, this is -- we've got 78 adopted so far. The one which we are working today is fluorides, including hydrogen fluoride, which you initially saw

several meetings ago, but has been subject to various discussions, improvement, and modifications. And this basically is a revisiting of this summary following our changes in response to your earlier comments and suggestions.

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AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: This derivation uses a benchmark dose concentration approach to derive the chronic reference exposure level. That was in fact on an epidemiological study. We also updated the literature review to include additional animal toxicity endpoints for comparison. And we have made a number of changes in response to comments at previous meetings.

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AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: The basis of the derivation is an epidemiological study of fertilizer plant workers. We include details here of the derivation. The basis is the benchmark that is concentration. We adjust for exposure continuity.

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AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: We include an intraspecies uncertainty factor of 10 to allow for the fact that the study population is an occupational cohort and that the target population for

chronic reference exposure level is the general population.

And we provide a chronic reference exposure level of 30 micrograms per meter cubed as the reference exposure level.

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AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: In addition to the inhalation level, airborne fluoride salts in particular may appear as solids which would settle out on crops. And, therefore, there's a possibility that a risk assessment under the Hotspots guidelines would need to use a multimedia approach. And, therefore, an oral chronic reference exposure level is provided.

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AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: This is in fact based on a risk assessment which was performed for the California Drinking Water Program in developing the public health goal for fluorides in drinking water.

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AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: The chronic oral reference exposure level again uses a variety of analyses based on human health data.

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AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: And these are basically summarized in a very extensive NRC report in 1993. And they have a number of original data sources there as well.

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AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: Study populations included the general populations of several United States cities. And the suggestion there is that there should be a chronic oral reference exposure level of 0.04 milligrams per kilogram day. And in this particular case the study population did include children who are probably the sensitive subpopulation for this endpoint, which is dental fluorosis.

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AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: The comments which we have addressed in the recent changes are additional uses in sources of fluoride and hydrogen fluoride are described in the toxicity summary. We also refer to a recent draft toxicological profile which was published by ATSDR. We mentioned some recent data indicating animal reproductive and nervous system effects. We address the issues of inter-individual variation in fluoride intake and background fluoridation. We haven't in fact got a systematic modification of the

reference exposure levels to address that. But we point out that these need to be considered when determining the impact in the multimedia risk assessments.

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AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: And that's basically it.

DR. COLLINS: I'd like to make a comment. Jim Collins.

The recommended REL is on page 9 of this. Actually the slide was miscopied from an earlier presentation. But on page 9 of the updated document is our recommended chronic reference exposure level.

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: Sorry about that. Please look at page 9, not the slide.

So, anyway, the Panel's had quite extensive discussion of a number of aspects of this. But obviously we particularly like to hear whether you feel that we've addressed your earlier comments and request for changes.

PANEL MEMBER BLANC: Well, I have a technical question to start with.

You refer to changes in the document reflecting the previous discussion are underlined.

And I doubt that the version we've received actually has those underlined since there's very few

underlines and --

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: Yeah, I think that may -- we may have --

PANEL MEMBER BLANC: Sorry. I know it's a technical problem. But it just makes it a little bit hard to track the changes that you've made.

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: Yes, unfortunately I think one of the things that's happened is that the -- that there's been so many generations of changes that we are finding it difficult to illustrate those accurately. The changes which were made in response -- Jim do you want to -- can you summarize --

DR. COLLINS: I have lined copy, which has a lot of stuff. Which if you'd like to see since you're the one that made many of the comments that we needed to address.

On page -- I hope it's the same page -- 11, as noted, the paragraph --

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: I think we have a different -- what's the heading number, Jim?

DR. COLLINS: "As noted" -- there's a long paragraph that starts "As noted" on page 11.

PANEL MEMBER BLANC: Yeah.

DR. COLLINS: That was in response to your thing about you thought that maybe we ought to lower the chronic

REL because there were other sources of fluoride. So this is our response to that.

Plus there was some comment about plotting not just exposure versus -- I'm sorry -- fluoride concentration versus getting density change for fluoride concentration times the year -- number of years. And when Andy did that, he found out that he could not really get a good fit for any of the models. Although the number you would come out with is close to what we ended up recommending.

So that whole paragraph was added in response to those kind of questions.

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: I think the point there was that Derry Berry and the earlier analyses of the study both relied on the observation that basically the most useful exposure measure was a concentration measure rather than an exposure times time measure. And this seems to be a feature of the data. Dr. Blanc suggested that we ought to at least look at and examine more closely whether we could use, you know, a dose-time-integral dose measure and get a better estimate from that.

So we actually did that analysis and confirmed our earlier statistical treatment which says that basically there's too many other confounding issues on the

available exposure parameters, and particularly the changes in the endpoint with passage of time and age and things like that.

For some reason we can't really do a good analysis based on the dose time integral. But we did go a little bit further in trying to do that and we sort of got -- it didn't work, but it suggested that if it had worked it would have produced about the same answer as the analysis we did use. I think that's how I would describe it.

PANEL MEMBER BLANC: Let me ask the question algebraically in a different way maybe just so I'm reassured that this analysis that you did addresses question.

You have a group of workers exposed to the airborne levels of fluoride, and you show that there's a dose response with higher levels of airborne fluoride exposure and a tendency towards more fluorosis of the bones. That's basically -- and there's a slope that you show, like this. And you calculate a benchmark, no effect dose. That is to say the airborne level which wouldn't give you any fluorosis essentially, right?

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: Right.

PANEL MEMBER BLANC: And that assumes that the

intercept is -- that there's a zero zero intercept, but actually the intercept is somewhere above zero.

Does it matter -- I think we're safe to assume that these workers didn't grow up with fluoridated water systems. Does it matter in your calculation of your benchmark dose if you have a population which has an intercept which is different because their baseline fluoride exposure is higher by water because of public health reasons -- if you're using the slope, are you immune from an effect of being not conservative enough in calculating your intercept based on the data and population which you didn't have baseline oral fluoride exposure of a significant degree or not?

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: We think that -- we think that it would be appropriate to take into account -- if you had a population with an exceptionally high background oral exposure through drinking water, you might want to take a cautious approach to any exceedance of this reference exposure level. In other words I'm saying in the extreme case, no, we wouldn't be conservative enough, but most of the time we would be fine.

PANEL MEMBER BLANC: And why is it that you would be fine? Because isn't the level, when water is intentionally supplemented with fluoride, considerably

higher --

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: Well, the actual -- the water level, for instance as used in a public health goal, actually does use a relative source conjugation calculation. And so, you know -- I mean there's allowance for the fact that there is other sources of fluoride besides food. And there's also a question of how much fluoride you're actually putting in at the benchmark dose level, which, remember, is a null effect level in this study. We're not making, you know, a big contribution to the amount of fluoride. The issue of if there's a large background mainly relates to the question of the oral reference exposure level.

PANEL MEMBER BLANC: Did you follow that?

CHAIRPERSON FROINES: I followed the last part that was -- but I didn't follow the first part.

PANEL MEMBER BLANC: Kathy, do you -- am I --

PANEL MEMBER HAMMOND: Let me see if I can restate this. And then I'll know. I'll be able to answer whether I followed it.

And this is actually a step further back. Okay?

You're trying -- in this whole document you're trying to address the total exposure. And where the Air Resources Board comes in is because airborne fluoride can deposit on crops and lead to ingestion exposure?

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: Well, that's a small part of it.

PANEL MEMBER HAMMOND: Ingestion route?

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: Yes.

The main concern is the inhalation route.

PANEL MEMBER HAMMOND: Oh it remains inhalation --

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: The main concern is the inhalation route. But because there is the possibility that some fluoride-containing materials, which would be solid fluoride salts, you know, after they've been emitted might sediment out, it's necessary to have an auxiliary level, which is the oral level, to feed into a multimedia risk assessment methodology, which is specified in the guidelines.

PANEL MEMBER HAMMOND: So a total exposure would be inhalation, plus ingestion from food, plus ingestion from water?

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: Yes.

PANEL MEMBER HAMMOND: And because ingestion from water is a given, regardless, for other public health reasons --

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: Yes.

PANEL MEMBER HAMMOND: I guess less in California than elsewhere. But I guess in some places; is that right?

Anyhow, there is ingestion from water from California?

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: Oh, yes.

PANEL MEMBER HAMMOND: So you have that as a given.

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: Yes. But it --

PANEL MEMBER HAMMOND: So that reduces your margin for how much you can allow inhalation?

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: But the inhalation study population that was used were drinking water that contains fluoride. It may or may not have been --

PANEL MEMBER HAMMOND: The --

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: But everybody's water contains --

PANEL MEMBER HAMMOND: No, no. But this is '63.

PANEL MEMBER BLANC: In 1963?

PANEL MEMBER HAMMOND: It was '63, Derry Berry.

Is this Derry Berry you're talking --

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: Yes. But I mean there are -- there always have been natural abundances of fluoride.

PANEL MEMBER HAMMOND: Only in certain places. Was this place -- was this area --

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: It's only in certain places --

CHAIRPERSON FROINES: We're about to vote in Santa Monica whether to fluorinate our water. So it's not --

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: Yeah, but it's only in certain places that the natural abundance is up to the level of the supplementation. But there are a lot of places where it's -- you know, it's some fraction of that.

PANEL MEMBER HAMMOND: But you could look -- this is an occupational exposure.

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: Yes.

PANEL MEMBER HAMMOND: So it's in a location, a geographic location. You could look, does geographic location have high fluoride naturally or not? Rather than just speculate. One doesn't need to speculate about that, right?

DR. COLLINS: Yeah, I think the Tennessee Valley Authority had -- those people were working, so we can find out --

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: Yeah, that's what it was --

PANEL MEMBER HAMMOND: But I think we shouldn't assume that they have -- the current average level of fluorination for the country is not what should be assumed.

OEHHA DEPUTY DIRECTOR ALEXEEFF: Yeah --

PANEL MEMBER HAMMOND: So I think the answer, Paul, is, no, I don't follow it.

CHAIRPERSON FROINES: Well, I think the answer, if I understand it, is that we have no way to estimate what the oral exposure to fluoride was in that study.

PANEL MEMBER HAMMOND: Well, you could estimate it because you could --

CHAIRPERSON FROINES: Based on --

PANEL MEMBER HAMMOND: There is geological data whether this fluoride naturally --

CHAIRPERSON FROINES: No, no. But I'm saying that based on what we currently have, without going back to do a further study, we don't have any estimate of the fluoride.

PANEL MEMBER HAMMOND: I mean I think that most

areas of the U.S. were considered to have very low levels of fluoride in the water naturally and only occasionally very specific places. Some place in Texas, you know, and --

PANEL MEMBER BLANC: Let me go back to the question because I partly -- all right. Partly I didn't have the benefit of the underlining. But the "as noted" paragraph on page 11, which was written I think in faithful response to the comments that were made here the last time this came up, may reflect my inability to express appropriately what -- completely what the question was. And part of it had to do with the -- I don't even remember all the details, especially about the time issues and all that. But the other issue, which I'm still trying to grapple with, is -- you have figure one on page 10, right?

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: Yes.

PANEL MEMBER BLANC: Okay. Now, figure one on page 10 reflects the dose response for the bone changes?

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: Right.

PANEL MEMBER BLANC: And your benchmark calculation?

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF

SALMON: Yes.

PANEL MEMBER BLANC: And I'm going to assume that these people had virtually no fluoride in their drinking water or minimal. If they had -- had they worked in an area that had standard supplemental fluoride to their water, which is a condition that would describe a healthy portion of the U.S. population, would not that curve have been shifted to the left? Wouldn't the data have shown that -- wouldn't it have appeared as if lower levels of airborne exposure gave you bone changes because of --

DR. COLLINS: Probably.

PANEL MEMBER BLANC: Wouldn't that change your benchmark calculation?

DR. COLLINS: It might. My understanding is these were really minimal changes in these workers.

PANEL MEMBER BLANC: Yeah, but that's what you used as your significant and/or -- effect. Wasn't that what you used for your --

DR. COLLINS: It was minimal during --

PANEL MEMBER BLANC: -- for your outcome?

DR. COLLINS: -- minimal change, yeah.

PANEL MEMBER BLANC: Because that was what you used as your outcome measure?

DR. COLLINS: Right.

PANEL MEMBER BLANC: So you're not saying that

that's not a valid outcome measure?

DR. COLLINS: No, no.

PANEL MEMBER BLANC: So is there a way using available data of hypothesizing what the shift of this curve would be were they to have not high levels of oral fluoride but sort of standard current U.S. population oral --

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: Yeah, we've -- I think we've -- George, you were doing --

PANEL MEMBER BLANC: Or having done that, I just don't understand that you did do that.

OEHHA DEPUTY DIRECTOR ALEXEEFF: You know, it wasn't done. But it's -- this is George Alexeeff.

There's a couple of issues. And, Jim, you can -- or, Andy, you can correct me if I've got this wrong. But basically, okay, you have the dose response curve developed from the worker study. So like the low REL, the lowest exposure level was 18.9 milligrams per cubic meter. That's what -- so if you assume the person breathed at 10 cubic meters a day, then the person took up 18.9 milligrams of fluoride per day. Okay, inhaled that much, let's say.

Now, on the drinking water side though it's one part per million. And if you assume that's one milligram

per liter, you drink two liters a day. So that basically would be two milligrams per day of water.

So at least on the worker's side I think in the initial part of this analysis on this curve, the worker exposure would dominate an oral exposure if it's not a really high oral exposure.

But now when we get down to the extrapolation, now the water exposure is dominating the total exposure when we get down to the level that we're proposing as our reference level.

So I think you're right, the water exposure would shift it over. It would add to it. It would not add it a lot at the top end of the curve from where we're extrapolating from.

PANEL MEMBER BLANC: And, therefore, would it have changed the benchmark algebraically? I mean I'm not -- I don't think the answer --

OEHHA DEPUTY DIRECTOR ALEXEEFF: It probably would have. We haven't done the calculation. I guess one could estimate -- you know, sort of assume a certain amount of exposure, do a calculation, change it slightly.

I don't know. If you added one or two more milligrams to the top of a scale, Andy, you've done -- would you think that would change the benchmark dramatically or -- if it was 20 instead of 18 at the

lower --

PANEL MEMBER HAMMOND: I'm not sure actually -- I'm not sure that's the right direction you want to go. Because I think the assumption, Paul, is that these people were not exposed. So this is a -- the curve is correct. The question is -- if you were protecting workers, then you'd be concerned about their background. But I think you can interpret this as if you -- you can interpret this as being a total fluoride intake problem, right? So the curve would be correct in terms of saying what your benchmark dose is for fluoride intake.

The question now would be to apply it today is the bare multiple sources. But if we assume these people had no fluoride in their water, then the curve doesn't shift. It doesn't matter. And this is a good curve.

PANEL MEMBER BLANC: I'm not saying the curve isn't good for the population that we're --

PANEL MEMBER HAMMOND: Right.

PANEL MEMBER BLANC: But they're extrapolating a benchmark dose.

PANEL MEMBER HAMMOND: Well, does the -- but I'm going to assume the benchmark dose is taking into account the fluoride in the water?

PANEL MEMBER BLANC: No, it doesn't.

PANEL MEMBER HAMMOND: You don't have to move the

curve. But what you have to do is think of it that the benchmark dose does take that into account. I agree with that.

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: The multimedia risk assessment which would be required, yeah, should if it was well done take into account all the different sources, including not only drinking water, but also dietary. That's how the multimedia risk assessment is supposed to work.

I think there's an issue here in that many people under the Hotspots Program, and even when it's suggested it might be a good idea, would perhaps not necessarily do the -- you know, the full dress multimedia risk assessment that would look at the possibility that some individuals would have higher versus lower fluoride intake.

On the other hand, we do have an uncertainty factor built in -- you know, safety factor, if you like -- which is explicitly designed to cover, quote-unquote, inter-individual variability. And that includes inter-individual variability in, you know, other exposures and sources as well as sensitivity --

PANEL MEMBER HAMMOND: But in looking -- and when you come up with your REL, I think the question that Paul's getting at -- notice my question much earlier, is: Did you make an assumption that people were drinking

fluoridated water?

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: No, we didn't make that assumption.

PANEL MEMBER HAMMOND: See, I guess I would have thought that the assumption should be people are drinking fluoridated water and that how much more fluoride can they get to get to the same point on this curve, which is a different way of phrasing --

OEHHA DEPUTY DIRECTOR ALEXEEFF: Saying the same question --

PANEL MEMBER HAMMOND: -- the same concern, right.

But I would have just taken -- a curve is okay, but there's an underlying background exposure. Now, how much can you add to it with airborne exposure? But the REL should take into account an assumption of fluoridated water --

PANEL MEMBER BLANC: See, you're in an odd situation. I mean this is an unusual situation in that the timeframe of the air exposure data that you're using is at a timeframe and of a population which the human condition is changed somewhat. Now, you can -- maybe the argument is that your 10-fold safety factor takes that into account sufficiently. Maybe the argument would be, okay, for the purposes of hypothesis testing we have

redone this, throwing in: Suppose they had had a baseline fluoride level that it was this much higher and the curve was shifted towards -- would have implicated slightly greater sensitivity if we assumed the same slope but a different baseline and it would trivially change our benchmark calculation.

What I was -- the whole drinking water discussion the last time around was really I think trying to get at that question even if it wasn't expressed from our side clearly enough. And this is a really unusual situation. If this was occupational data that was from the 1990s, then it wouldn't matter.

CHAIRPERSON FROINES: But what was the interspecies uncertainty factor again?

OEHHA DEPUTY DIRECTOR ALEXEEFF: No, it wasn't inter. Intra.

CHAIRPERSON FROINES: Infra. That's what I meant.

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: Ten, yes.

CHAIRPERSON FROINES: I know what it is. I want to know what it is attempting to address.

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: Well, variations in sensitivity between individuals from any source whether as a result of

individual constitutional differences or differences of exposure or prior experience or whatever.

CHAIRPERSON FROINES: This is an intraspecies?

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: Yes. So there's differences between different individual human beings in exposed population is what it is.

CHAIRPERSON FROINES: Within -- it's with --

PANEL MEMBER BLANC: -- in humans.

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: -- within the human population.

PANEL MEMBER BLANC: And I think it's mostly, we hear -- theoretically it would be addressing the fact that children with growing bones --

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: Yes, that's the biggest --

CHAIRPERSON FROINES: Well, see, if I understand what Paul just said -- correct me if I'm wrong -- then what this factor of 10 is for is not what Paul was just addressing.

PANEL MEMBER BLANC: No, it's not.

CHAIRPERSON FROINES: So it's not covering the issue he's referring to.

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: It potentially covers a number of things. But

the most important single thing is the difference between children and adults.

CHAIRPERSON FROINES: Well, that's a problem with safety factors --

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: Yes.

CHAIRPERSON FROINES: -- isn't it, is that we can call it anything we want? And, therefore, it's a fudge factor, not a -- so that is it legitimate to say that, well, it was essentially to cover children but now we're dealing with background and so we're going to include that and the magnitude should therefore be 10?

PANEL MEMBER BLANC: I don't want to get --

PANEL MEMBER HAMMOND: That's not the way to go about it.

PANEL MEMBER BLANC: Andy, I don't want to drag this Fluoride thing out forever. And I don't -- I could easily be convinced that, you know, that this is -- that the algebra of this would in the end mean that this is a trivial point and that it's not substantive. And I would be happy to, you know, tentatively accept this, you know, with the two provisos: One is that you do the calculation that I ask. You don't necessarily have to put it full force in a document, but there could be a couple sentences that somehow get at this point. Unless you find that it

really is a big impact. Then I think you got to rethink this.

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: Yes.

PANEL MEMBER BLANC: And the other thing that would be helpful is if you could just send me in the mail the true underlined copy just so I can see it.

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: Can I also just read you -- or to draw your -- so I won't read the whole thing, just draw your attention to it -- the last paragraph of the summary. And what we're saying here, consideration should be given to populations with high fluoride intake and for individuals even -- basically what we're saying is if they are having an exposure which is already close to the oral REL, then the exposures to fluorides, you know, from the source being considered in the hot spots, which would be at the oral or inhalation reference levels we proposed, might be deleterious. In other words what we're saying here is that a multimedia risk assessment should take into account all the background exposures.

Now, perhaps what we're saying is that we need to actually say that in English rather than in --

CHAIRPERSON FROINES: Well, I'll tell you an -- that's one of questions that Elinor and I were talking

about last night. Because on the plane yesterday the man sitting next to me, who refused to shut up so I could actually read this document, kept asking me about was fluoride in drinking water safe, because that's the question he has. And I said, "I can't read this document and answer your question." And so the issue -- there is this other public health issue, which is when you do look at this, it does seem to appear that your chronic REL for fluoride and the amount that people are currently drinking in their fluoridated water and from other sources is problematic.

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: Its possible that --

CHAIRPERSON FROINES: More than problematic.

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: There's a narrow margin of safety between what's -- if you like, what's a nutritional requirement. I mean that's how I see the requirement for fluoride in drinking water to protect.

CHAIRPERSON FROINES: I read this document as saying that the current amount that we are drinking is in excess of what you consider safe.

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: No, that's not what we're saying.

PANEL MEMBER HAMMOND: We have .04 milligrams per

kilogram day times 70 grams a person is 2.8 milligrams. And this table has people coming out above that in the -- from drinking water already, before we have any other.

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: Yeah, but the -- the chronic reference exposure level is a safe level, not an effect level.

PANEL MEMBER HAMMOND: Yeah, but do you want to set your safe -- but I read this to --

CHAIRPERSON FROINES: If you take here calculation of 70 times 4 --

PANEL MEMBER HAMMOND: And not even getting to kids.

CHAIRPERSON FROINES: And then you have back here that there are people who are drinking 7 milligrams a day. 2.8 and 7 seem to me to be numbers that suggest that 2.8 isn't entirely safe. Maybe we're reading it wrong, but we have the same -- we get the same --

PANEL MEMBER HAMMOND: And then I'd worry about children. It gets even worse.

OEHHA DEPUTY DIRECTOR ALEXEEFF: I think the -- are you saying that the document is suggesting that, based upon the analysis, that the drinking water standard is not safe? Is that what the concern is --

PANEL MEMBER HAMMOND: I think that's an interpretation one could make.

OEHHA DEPUTY DIRECTOR ALEXEEFF: Okay. So one of the differences though is that -- I would say that, you know, the chronic REL here is using our standard procedure, that we develop a benchmark dose and divide by 10. And as you can see, the amount of data we have for our chronic reference level calculation is limited. But in terms of the oral PHG, public health goal, developed, we actually had a lot more data, and I think that that -- you know, we were able to look at the issues of both, you know, the improvements from fluoridation as well as potential hazards from fluoridation.

So I think that the -- I don't think you can use the chronic reference level to sort of question the public health goal, because the public health goal probably has better data set in terms of defining what that level should be.

Maybe I've misunder --

PANEL MEMBER HAMMOND: I think what we're saying -- I mean you could -- what I'm saying is -- I'm not saying that I believe that drinking water is a problem. I'm not saying that. I'm saying someone reading this document could make such a case.

CHAIRPERSON FROINES: Well, let me just --

PANEL MEMBER HAMMOND: And if you have better data that tells you that the current level in drinking

water is in fact not a hazard, I think it ought to be in here because I think it -- this document could be very easily misread.

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: Well, it is in there because the PHG is that analysis. And our oral REL is --

PANEL MEMBER HAMMOND: But I don't think you can --

CHAIRPERSON FROINES: Well, let me just state -- I'm with Kathy on this. And this is a -- we are approaching this from the over -- the simplified man-on-the-street level. Because this guy who was on the plane yesterday is going to -- I told him -- he said, "How can I read this?" And I said, "Well, you go to the website and it'll be on the website." So this is a travel agent who's going to go to the website and read this. And if he's smart enough to do the calculation Kathy just said, he's going to be worried.

I think you need a sentence or something in there that somehow dispels the concerns that are going to arise.

PANEL MEMBER HAMMOND: No, it's -- I think as soon as you have this number right here in front -- people aren't going to read the whole document. This number's enough of a number, right? You know, doesn't someone take a TLV, you know, any standard and they look at those

numbers and compare to what they're exposed to. The ozone standard, you take and you look at the two next to each other.

OEHHA DEPUTY DIRECTOR ALEXEEFF: So we could add a clarification to that. It sounds like a clarification.

CHAIRPERSON FROINES: I think it's something very minor. But I think something that will help somebody who's not us understand it and not feel they need to worry. Although maybe we should be worrying about our fluoride. Maybe we're too accepting of --

OEHHA DEPUTY DIRECTOR ALEXEEFF: No, there's actually -- there are a number of studies that have looked at fluoridation of water. And you have population studies and they're a lot of information. But we could put a clarification in here. And the actual -- as you point out, the reference level that we come up with is probably like 10 percent of the exposure of the PHG. But that's not to suggest -- or maybe not quite that much. It would be a third or so.

PANEL MEMBER HAMMOND: But let me approach it from a different point of view. Because in the end, if this is -- if one's going to have to regulate the people who are emitting it -- the fact that it's emitting fluorides maybe might be affected by this. If I were working for them, I'd say, "How can you tell me that I'm

impairing the public health when what I do exposes people to far less than what they're getting in the drinking water, that the public's putting into the water?"

So I don't see how we can have a standard that -- if we believe it's safe to take it into the drinking water, because that's been well established, and I believe you, then I don't see how you can turn around and say it's not safe in another setting. So I think you have to take the drinking water level and apply it here and look at this dose. I mean that worries me to kind of have these different standards, because we're still all people.

And I also know what you're saying in terms of the fact that you took -- you followed the standard procedures and this is the number you get -- you get to go through that. And it may be that this is a case where the therapeutic window is very narrow and the difference between a therapeutic and a hazardous -- but if that's really true and we really believe that, then maybe factors of 10 aren't appropriate in the standard risk model. And good risk assessment is following the right thing and not -- or not using the full data, maybe.

I haven't -- not part of this background, and so I'm reading this naively, I know.

OEHHA DEPUTY DIRECTOR ALEXEEFF: Well, maybe we can add some clarification to the document regarding this

issue and the relationship of the two or the interrelationship of the two, which would be helpful.

CHAIRPERSON FROINES: I think that's acceptable.

PANEL MEMBER BLANC: Yeah, sure.

CHAIRPERSON FROINES: We'll look at it. We'll vote now, but we'll --

PANEL MEMBER BLANC: So I'd like to move the pending -- assuming those clarifications that were discussed today, that this document be accepted.

CHAIRPERSON FROINES: You'll get a chance to see it.

PANEL MEMBER HAMMOND: I'd like to abstain.

CHAIRPERSON FROINES: What?

PANEL MEMBER HAMMOND: I would like to abstain.

CHAIRPERSON FROINES: No, but you will get a chance to see what they do. And if it's not acceptable, we'll bring it back to the --

PANEL MEMBER HAMMOND: I just want to abstain.

DR. COLLINS: Then we can't do anything.

CHAIRPERSON FROINES: Sure you can.

DR. COLLINS: There's only four of you.

PANEL MEMBER HAMMOND: No, it's just the number -- the quorum's present.

CHAIRPERSON FROINES: Abstain is a vote.

DR. COLLINS: Okay.

PANEL MEMBER BLANC: There's not a second though yet.

CHAIRPERSON FROINES: Make the motion again. Maybe it will wake some --

PANEL MEMBER BLANC: I'd like to move that we accept the document presumptively based on the clarifications that were discussed at this meeting.

PANEL MEMBER LANDOLPH: I'll second.

CHAIRPERSON FROINES: Discussion?

PANEL MEMBER HAMMOND: I am concerned either that this level is -- that the oral reference exposure level is too low or that we've got a problem with drinking water. I guess to me that means -- maybe I'm being naive with this.

CHAIRPERSON FROINES: George, can you speak to that, or Andy?

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: Well, the oral reference level is the PHG, which is one of the things that regulates the amounts of fluoride that is put in -- what makes the inhalation level --

PANEL MEMBER HAMMOND: Okay. And I have to translate to it put within this public health benefit -- PHG --

OEHHA DEPUTY DIRECTOR ALEXEEFF: Public health

goal.

PANEL MEMBER HAMMOND: I mean that's already been established, is that what you're saying?

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: Yes, that's out there and has been for some time. We're not proposing that. We're referencing it.

PANEL MEMBER HAMMOND: Okay. I see.

So they've already dealt with the --

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: And it's not unusual that we would have significantly different standards for different routes of exposure.

PANEL MEMBER HAMMOND: Well, that I understand.

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: And --

CHAIRPERSON FROINES: But let me ask you this: Does the PHG, which that -- part of the problem is Kathy nor I have read it. Does the PHG address the issue of the amount of fluoride in our drinking water now relative to the PHG that was established?

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: Yes, the PHG is about how much total fluoride is there in your drinking water from all sources.

CHAIRPERSON FROINES: And you speak to the issue of whether the current levels constitute a health risk --

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: PHG does, yes.

CHAIRPERSON FROINES: You do?

AIR TOXICOLOGY AND RISK ASSESSMENT UNIT CHIEF SALMON: Yes.

CHAIRPERSON FROINES: Well, I think that -- that would seem that that's part of the clarification you can put in this document, is simply me to reference that in some sort of way that stands out.

But then I think Kathy should take a look at the PHG. And if it's a problem, then bring it back. I mean we'll come back --

PANEL MEMBER HAMMOND: We don't do the PHGs though, do we?

CHAIRPERSON FROINES: No. But if we have a problem, we can raise it with them with this -- that's not -- nothing's foreboding.

PANEL MEMBER HAMMOND: Yeah, I mean if you breathe 20 cubic meters a day and you have 20 microgram per cubic meter standard with your air, then the intake is only .28 milligrams. So it's quite a bit less than the intake that's allowed. It's almost a factor of 10 from the intake from the oral reference exposure. So it's --

OEHHA DEPUTY DIRECTOR ALEXEEFF: Correct. And so part of it is that the -- you know, the fluoridation is --

it also involves a risk benefit issue as well. So the whole PHG. Wherein this case, there's -- you don't have that balance.

So in one sense the standard could be a little bit -- if you're going back to the air district, why would you allow this -- why are you restricting emissions from a facility greater than what you allow in water? Well, the reason is because -- well, first of all, the water is based upon how much exposure you get elsewhere. So if we up the amount of emissions we're allowing on the facility, we have to change the water standard, which is not, you know -- which is not reasonable. And, second of all, there is a whole risk benefit decision process made in the water, of which isn't appropriate in the air pollution issue.

So I mean there's -- but I think what would be helpful though is just to clarify how much is coming from water, how much is coming from air, what's the relationship between the water standard -- the water goal and the air level. And I think that will just -- I think that will help there.

CHAIRPERSON FROINES: Okay. So I'm calling the question then based on that clarification.

All those in favor of the motion, raise your hand.

(Hands raised.)

CHAIRPERSON FROINES: Four and one abstention.

So the vote is four in favor, none opposed, one abstention.

And we can entertain a motion at this point for closure.

PANEL MEMBER BLANC: I move that we adjourn.

PANEL MEMBER FRIEDMAN: Second.

CHAIRPERSON FROINES: Discussion?

All those in favor say aye.

(Ayes.)

CHAIRPERSON FROINES: The meeting is adjourned. Thank you very much.

(Thereupon the California Air Resources Board, Scientific Review Panel meeting adjourned at 1:30 p.m.)

CERTIFICATE OF REPORTER

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

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

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

IN WITNESS WHEREOF, I have hereunto set my hand this 7th day of June, 2003.

JAMES F. PETERS, CSR, RPR
Certified Shorthand Reporter
License No. 10063