MEETING

STATE OF CALIFORNIA

ENVIRONMENTAL PROTECTION AGENCY

AIR RESOURCES BOARD

SCIENTIFIC REVIEW PANEL

ON TOXIC AIR CONTAMINANTS

CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY

SIERRA HEARING ROOM, 2ND FLOOR

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JAMES F. PETERS, CSR
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A P P E A R A N C E S

PANEL MEMBERS:

Cort Anastasio, Ph.D., Chairperson

Ahmad Besaratinia, Ph.D.

Paul D. Blanc, M.D.

Stanton A. Glantz, Ph.D.

S. Katharine Hammond, Ph.D.

Michael T. Kleinman, Ph.D.

Joseph R. Landolph, Jr., Ph.D.

Lisa A. Miller, Ph.D.

REPRESENTING THE CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY:

Ms. Chris Tiedemann, Deputy Secretary, Law Enforcement and Counsel

REPRESENTING THE AIR RESOURCES BOARD:

Mr. Jim Behrmann, Panel Liaison

Mr. Dave Edwards, Assistant Division Chief, Air Quality Planning and Science Division

Ms. Karen Magliano, Chief, Office of Community Air Protection

REPRESENTING THE OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT:

Dr. John Budroe, Chief, Air Toxicology and Risk Assessment Section

Dr. Daryn Dodge, Air Toxicology and Risk Assessment Section

A P P E A R A N C E S C O N T I N U E D

REPRESENTING THE OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT:

Dr. John Faust, Chief, Community and Environmental Epidemiology Research Branch

REPRESENTING THE DEPARTMENT OF PESTICIDE REGULATION:

Ms. Pam Wofford, Chief, Environmental Monitoring Branch

I N D E X

I N D E X C O N T I N U E D

P R O C E E D I N G S

CHAIRPERSON ANASTASIO: Okay. Good morning, everyone. We're going to get started, so if you could talk your seats.

All right. Welcome to the meeting of the Scientific Review Panel on Toxic Air Contaminants. I'd like to welcome everyone who's here in person, and welcome everyone who's watching on the web. My ane is Cort Anastasio. And I've been on the Panel for - I can't remember - maybe five years. And I was recently appointed Chair in December by the CalEPA Secretary, consistent with this policy of rotating Chairs. So other Panel members look forward to your turn as a rotating Chair.

I want to take a minute to thank Mike Kleinman, who's been the Chair for the past five plus years. And we all appreciate his service and his smooth running of past SRP meetings. I'd like to -- oh, one other note about Mike, he's continuing on the Panel as a member. He's also going to serve as a Panel representative on the AB 617 Consultation Group. And we'll be talking about 617 as our third agenda item today.

I'd now like to go around and just have each Panel member introduce themselves. For continuing Panel members, just, you know, your brief general introduction. We do have two new members. Dr. Ahmad Besaratinia, who's

an expert in oncology, if I remember correctly, and Dr. Lisa Miller, who's a pathology expert.

So Ahmad and Lisa, first welcome, and then second, when it's your turn for introduction, give us a little more detail about the type of work that you do. Yeah.

Okay. So I'll go first. I'm Cort Anastasio. I'm a professor of atmospheric chemistry at University of California, Davis.

Ahmad.

On note about microphones. So make sure you press the button so that the green light is on when it's your turn to talk. Make sure to speak into the microphone. And then when you're done, please turn off the microphone.

PANEL MEMBER BESARATINIA: Good morning. I'm Ahmad Besaratinia. I'm associate professor of preventive medicine at Keck School of Medicine of University of Southern California.

Is it better?

Yeah. I'm a cancer biologist by training. Currently, I'm doing research on cancer genetic and epigenetic, mostly evolving tobacco-related diseases as well as sunlight associated cancers in relation to UV radiation.

PANEL MEMBER HAMMOND: I'm Katharine Hammond from UC Berkeley, School of Public Health. I'm a professor of environmental health sciences, and Associate Dean for Academic Affairs. My research focuses on exposure assessment, both epidemiolo -- for epidemiology studies in the workplace and in the environment.

PANEL MEMBER LANDOLPH: I'm Joseph R. Landolph, Jr. I'm an associate professor of molecular microbiology and immunology and pathology, and toxicology at the University of Southern California, and a member of the USC Norris Comprehensive Cancer Center. My work focuses on molecular carcinogenesis, genetic toxicology. And we specialize in nickel and chromium compound carcinogenesis.

PANEL MEMBER GLANTZ: I'm Stan Glantz. I'm a professor of medicine at UCSF. I run the tobacco program. More recently I've gotten involved in cannabis and e-cigarettes, sugar. And I'm in the biostatistics seat on the Panel.

PANEL MEMBER BLANC: I'm Paul Blanc at UCSF. I'm professor or medicine. And my area is occupational and environmental medicine and medical toxicology. And I just want to clarify, Stan's statement that he's gotten involved in research relate to cannabis.

(Laughter.)

PANEL MEMBER GLANTZ: That's true, yes. Yes.

(Laughter.)

PANEL MEMBER KLEINMAN: Good morning. I'm Mike Kleinman from UC Irvine, and I am a environmental toxicologist.

PANEL MEMBER MILLER: Hi, everybody. I'm Lisa Miller. I'm a professor at the School of Veterinary Medicine at UC Davis. I also serve as the Associate Director of Research at the California National Primate Research Center.

My background and training is in lung biology, as well as immunology. I study the influence of inhaled pollutants on early life development, lung development, as well as immune development using multiple animal models.

CHAIRPERSON ANASTASIO: Great. Thank you, all. Just one note Beate Ritz can't be with us today, so we're eight strong today.

A couple of administrative matters. Restrooms and drinking fountains are to the left when you leave the room and down the hall. If there's a fire alarm, please exit down the stairs and then proceed outside the building. And then one final note, we do have a Spanish interpreter with us today. So if you need any interpretation services, I guess please talk with him directly and he'll set that up.

(Thereupon the interpreter spoke in Spanish.)

CHAIRPERSON ANASTASIO: Gracias.

Okay. Today, in our meeting agenda we've got three main agenda items. First is a briefing on the Bagley-Keene Open Meeting Act, the second is a review of the proposed REL, the reference exposure Level, for hexamethylene diisocyanate. And then we'll have a discussion -- or a presentation from ARB about the updated implementation of Assembly Bill 617 and an exploration of the role of the Panel in 617.

So we're going to start with the first agenda item, the Bagley-Keene Open Meeting Act. Chris Tiedemann who's the Deputy Secretary for Law Enforcement and Counsel of CalEPA is here to discuss Bagley-Keene with us. I know we have periodic questions about what the Open Meetings Act covers. And so, Chris, thank you very much for helping to clarify this.

CALEPA DEPUTY SECRETARY TIEDEMANN: Good morning. The Bagley-Keene Open Meeting Act is a expression by the California State Legislature of the importance of the gatherings of multi-member State-appointed public bodies being open to the public, and -- and to provide a opportunity for the public to participate in the meeting by submission of written or oral comments.

The -- it's a overarching and important State law, because of the importance of public policy and public

decisions not being conducted in back rooms. And there are three central components to the act. One is that there be public notice of all meetings of multi-member State bodies, including notice of the items on the agenda that will be discussed at the meeting, a opportunity for members of the public to provide comments on matters on the agenda, and that meetings be publicly accessible.

The bodies covered by the Act - obviously this is one of them - they are multi-member State bodies that are created by statute. There are a couple of exceptions that don't pertain to this body. The Act defines what a meeting is. And the definition is, "Any congregation of a majority of the members of the State body at the same time and place to hear, discuss, or deliberate upon any item within the subject matter jurisdiction of the committee".

The Act -- that definition would lead you to believe that it's only when you're all together in the same room that you're conducting a meeting that's covered by the Act, but that's not accurate. The Act also covers something referred to as serial meetings. And serial meetings are a communication between one member of the committee and another by telephone, face-to-face, or even by email, that then is forwarded to another member of the meeting, then another member of the committee, another member of the committee, to the point that a majority of

the members of this body have communicated about an item within the body's jurisdiction.

So I should have caveated before. A meeting is a congregation of the members of the Committee. An illegal meeting is any such congregation or serial communication that involves a majority of the members of the committee. In this case, that's five people.

So if Dr. Cort were to send an email to Dr. Hammond who then forwards it to Dr. Landolph, then to Dr. Glantz, and then it goes Dr. Blanc, that's a violation of the Act. And serial meetings can get people into a lot of trouble and be very careful about your communications by email, telephone, or in-person with individual members of this committee that may then go to the other members. It's not only a basis for invalidating whatever the committee does, it also can be a criminal misdemeanor. So it's -- it's an important requirement.

There are some exceptions to the meeting and communication rule that are probably particularly pertinent to this body. The -- if the individuals of this body are congregating at a conference that's open to the public and involves discussion of issues of general interest to the public, you can certainly be in the same room at that type of conference. What you can't do at that conference is have private communication between a

majority of Board members about something that -- that is within the jurisdiction of the Board. But there's no requirement that you not all be together at a conference.

Similarly, there's no requirement that you not all be together at a social occasion. The Act does not at all prohibit your individual communications with members of the public. You're free to do that. That doesn't violate the requirement that the decisions of this body need to be made in public.

There are exceptions to the rules of Bagley-Keene for communications with a member of a legislate -- legislative body, such as a legislative committee, so long as the -- there is no communication about the Board's position or another member of the Board's position on a particular matter.

You also are not prohibited from communicating with legislate -- local legislative bodies, even if there were to be five of you communicating with a local legislative body on a particular matter.

Because of the importance in Bagley-Keene about the -- of the public being able to attend meetings, there are special rules about participating in a meeting by teleconference, and maybe some, or all of you, have dealt with that rule, tried to participate by teleconference. If there's a need for you to participate by

teleconference, the location from which you participate must be open to the public, and that location must be listed on the meeting agenda.

So, for instance, if a member were to want to Skype into a meeting from their -- the den in their personal residence, unless they want the public to be invited into their den, that's not going to work.

It could work, you know, to participate from your office at an academic institution, but you would have to realize if members of the public want to come into your office, they have to be allowed to do that.

As I mentioned at the beginning, the meetings have to be properly noticed. The meetings require 10-day notice, and the agenda items have to be provided to the public in advance of a meeting. That's really a requirement for the staff to worry about rather than the individual members. That requirement becomes pertinent when individual members of a State body bring up new matters at a meeting and ask that they be discussed. Your counsel at the meeting will say we can't discuss that at this meeting. We will have to put it on another agenda, so...

And with respect to public participation in the meeting, we are aware that this body has had certain rules about presenting any public comments in writing. And

we're taking another look at that, and particularly because you're considering items such as on the agenda today relating to AB 617. So you'll be getting further advice on that. But for the meeting today, there will be an opportunity for the public to provide comments on that agenda item.

So that's a very brief overview.

PANEL MEMBER BLANC: Can I ask a question? If you're looking at it, and haven't come to a decision, why wouldn't the status quo hold where we don't build in public comment, because actually our -- our efficiency will decline greatly if we are locked into having public comment at every meeting. We'll be bombarded by certain sectors in all likelihood --

CALEPA DEPUTY SECRETARY TIEDEMANN: Yeah, and --

PANEL MEMBER BLANC: -- making public comments. So why, if you're still looking at it, is there going to be public comment today?

CALEPA DEPUTY SECRETARY TIEDEMANN: Because 617 is really a different beast than what this committee generally considers, which is, you know, highly technical scientific information. And as far as today's meeting, we didn't know whether this room would be packed, or whether it would be empty. And it looks relatively empty. And this matter came to our attention last week, and we would

just like to be cautious, as far as not allowing public comment, on something that is quite different than the previous matters that have been considered by the committee.

And the Air Resources Board lawyers and CalEPA lawyers are going to take a close look at it. We're aware of Health and Safety Code sections that provide that the Chair has discretion to only receive written comments. We're very aware of the problem. We're aware of your limited time, and that there may be, you know, a strong preference not to prolong these meetings with public comments. But we need to take a legal look at it, because Bagley-Keene is an important State statute. And we don't want a State body to be in violation of it.

The final answer to that question is, at any public meeting, the Chair has discretion and they routinely exercise it to limit public comments. If there are a lot of people in the audience that want to provide comments, it's not infrequent a Chair of a State body will say each person who wants to speak up at the microphone has one minute to speak, because of time constraints. So it definitely is not the case that the public comment requirement -- it does not require that the public participate in the meetings. That -- they don't do that. And it doesn't require that members of the public get to

talk forever with whatever comments that they have.

For instance, I wouldn't contemplate that someone could get up and read a -- their 300-page scientific analysis of the work that you've already done. The Chair would doubtless use his or her discretion and say we're only allowing two minutes or one minute.

PANEL MEMBER BLANC: Let me follow up and then Stan. So it would be helpful I think if you would state clearly, in light of what you just said, that the fact that there's going to be potential comment today, pending your further analysis, does not set the precedent that because we're doing it today, therefore it will be de facto the new norm. I think that would be helpful.

CALEPA DEPUTY SECRETARY TIEDEMANN: Yeah, we're taking a look at it. So, yeah, I -- I wouldn't say today it's going to be the new norm or it's not going to be the new norm. But it's -- it's something we're looking at.

CHAIRPERSON ANASTASIO: Can I make a comment first and then Stan. So we've discussed this a little bit last week. And our hope is that for technical matters before the Panel that we maintain our previous policy, which is no public comments orally the day of the meeting, but instead written comments from the public prior to the meeting.

Because AB 617 is different, right, it's all

based on community, there was the thought that there might be a desire on the community to have input into those components of the meeting. So we're hoping that we can have -- maintain the status quo for the technical documents, but perhaps for 617 allow public comments. And so the -- Chris and the other lawyers will look into that.

Stan, did you have a comment?

PANEL MEMBER GLANTZ: Yeah. I mean, I think this is actually a serious issue, because I think one of the reasons this committee has worked so well, is that we haven't taken oral comment at the meetings. I participate -- I've been public comment for lots of meetings. I've been on other commissions. And public comments is fundamentally a political way of participating. And this is a committee that's focusing on highly technical matters. And I would even argue that the AB 617 stuff that we're going to be talking about is technical.

And, you know, I think that -- I mean, it's very important to me -- I mean, there's two reasons I think that we shouldn't be taking public comment. One is by getting the material in writing in advance, you can read it and think about it before the meeting. And so the quality of the deliberation is much higher.

And I think it's going to be very, very hard to

come up with a way where we can say, well, we'll deal with 617 in one way, but every other matter in front of the committee in another way. And I think it could really seriously degrade the quality of the work coming out of the committee.

Now having said that, the committee has a mechanism for taking input from the public, and that is we've had workshops from time to time, which are not deliberative meetings. That's where I first met Kathy Hammond. She showed up at a workshop on diesel long before she was on this committee. And so I have no problem with us having workshops on 617. And in the workshops the committee is there to listen, and people come and present whatever it is they want to present, and there's often a discussion. There's no action items connected with a workshop.

And, you know, I think -- I mean, I understand that the Agency has worked very hard to have strong public engagement in AB 617 and I approve of that. I think that's a great thing. But I think we need to be very careful not to break something that's worked very well.

So what I would suggest, if there is a desire to -- and I know this is a little bit formalistic, but if there is a desire to have public input on 617, I would suggest that we suspend the normal SRP meeting -- although

we probably can't do that, because --

CALEPA DEPUTY SECRETARY TIEDEMANN: No, you can't.

PANEL MEMBER GLANTZ: But I think -- I think -- I mean, maybe we would have to do this on a one-time basis. But I think that we ought to just stick with the model we have, which is that if people -- you know, if there are -- if there is a need -- and the workshops have, in the past, always been done at the Panel's initiative, where there's some big issue coming up. Like, we had two or three of them on diesel, for example, where we just say anybody who's interested can show up, and then we listen to what they have to say.

And I think that -- there's precedent for that. That model has worked. It's proven to be very informative. I know we had one on kind of pesticide modeling that I remember. So I think that's -- you guys ought to look at that as the model.

CALEPA DEPUTY SECRETARY TIEDEMANN: Well, we'll take into consideration. Our advice for today is to offer the opportunity to the public to make comments. And it may very well be a moot point.

PANEL MEMBER GLANTZ: But I think going forward, using the -- you know, the precedent that we've used to the -- and the workshops have been very informative

actually. But I think that -- because otherwise, I think you're going to get in a situation where industry, in terms of dealing with documents like the one before us, will come in and sandbag us. And it's also -- when you're dealing with these highly technical matters, I mean, I just don't think it's reasonable for somebody to come put a highly technical critique of a document in front of us in real time and expect intelligent decisions to be made. There are things you need to look and think about before you come to the meeting.

PANEL MEMBER LANDOLPH: Hi. I'm Joe Landolph. I'm appointed by the Speaker of the California Assembly, Mr. Anthony Rendon as his representative to the Panel. So I assume it's okay if I visit his office to visit his staff members, or very infrequently him, to discuss things --

CALEPA DEPUTY SECRETARY TIEDEMANN: Yes --

PANEL MEMBER LANDOLPH: -- is that correct?

CALEPA DEPUTY SECRETARY TIEDEMANN: -- that's completely

PANEL MEMBER LANDOLPH: It's allowed.

CALEPA DEPUTY SECRETARY TIEDEMANN: -- Allowed.

PANEL MEMBER LANDOLPH: And I don't have to inform anybody or invite anybody.

CALEPA DEPUTY SECRETARY TIEDEMANN: No, you

don't.

PANEL MEMBER LANDOLPH: Thank you.

CHAIRPERSON ANASTASIO: Thank you, Stan, and thank you, Joe.

Any other comments or questions for Chris?

All right. Thank you very much, Chris. Look forward to your future analysis.

CALEPA DEPUTY SECRETARY TIEDEMANN: Okay. There are also two ARB lawyers in the room, and they'll be providing further advice on this. So you're lawyered up on it.

(Laughter.)

CHAIRPERSON ANASTASIO: Always a good feeling.

(Laughter.)

CHAIRPERSON ANASTASIO: Okay. We're going to move on to our second agenda item today, which is the HDI REL. So this is proposed reference exposure levels, or RELs, from OEHHA for 1,6-hexamethylene diisocyanate, both the monomer and polyisocyanates. We're going to abbreviate these as HDI for sanity.

These RELs were developed using the risk assessment methodologies for developing RELs under the Air Toxic Hot Spots Program. The HDI REL was released for public review and comment in December 2017. Public comments were only received from the Aliphatic

Diisocyanates Panel of the American Chemical -- sorry, the American Chemistry Council, also known as ACC. They were received by OEHHA in February 2018. OEHHA made changes to their original REL document in response to the ACC comments. And OEHHA will present those changes today.

SRP received a written comment letter dated February 21st, 2019 from the American Chemistry Council. And that letter was distributed to the SRP manels -- SRP members for their review. And copies of those comments are in the back of the room.

The lead Panel members for the HDI REL are Drs. Blanc and Kleinman. And before we get into that, we're going to first here a presentation from OEHHA staff on the HDI RELs document. Then we will have a discussion among the Panel to provide feedback to OEHHA on the document. Of course, feel free to ask questions during the presentation.

The SRP draft report, which is dated February 2019, was sent to the Panel for our review and was also posted on OEHHA's webpage for the public.

And then again, a reminder about your microphone, please make sure you're speaking directly into it and that it's on. This is for the benefit of Jim, our fantastic court reporter, as well as for anyone on the webcast.

So I'm going to turn the meeting over to John

Budroe from OEHHA.

John.

DR. BUDROE: Good morning. My name is Dr. John Budroe. I'm Chief of the Air Toxicology and Risk Assessment Section. And I'd like to present Dr. Daryn Dodge. He'll be making the presentation on hexamethylene diisocyanate monomers and polyisocyanates reference exposure levels document.

Dr. Dodge.

(Thereupon an overhead presentation was presented as follows.)

DR. DODGE: Thank you, Dr. Budroe.

As he mentioned, we -- I have two sets of RELs to present here, one for HDI and one for HDI polyisocyanates.

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DR. DODGE: So HDI -- this is the monomer pictured here. HDI and its various forms are mainly used in automobile spray paints. Auto refinishing facilities may present near-source exposure risks. HDI monomer is volatile with a vapor pressure of 0.05 millimeters mercury at 25 °C.

Upon inhalation, the isocyanates groups on the compound react with lung tissue and macromolecules and can be absorbed systematically. These compounds are known as sensitizers, which means with repeated exposure, a worker

in the industry can become sensitized, in other words can develop what's called isocyanate-induced asthma. So upon ex -- repeated exposure following sensitization, they can have an asthmatic attack at very low levels, levels below -- even levels below the occupational standards.

And this is due to the presence of two isocyanate groups -- I should say two or more on the molecule. If you have something like methyl isocyanate, which is just one isocyanate group on it, it is not a sensitizers, and as far as I know, it doesn't produce isocyanate-induced asthma.

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DR. DODGE: Now, HDI monomer is processed into higher moleculate -- molecular weight compounds, known as prepolymers. And these are a very low vapor pressure. A mixture of the HDI monomer and prepolymers in paint formulations are referred to as polyisocyanate mixtures, or what I'll be calling HDI-based polyisocyanates.

These polyisocyanates mixtures are predominantly one of these two prepolymers that's pictured here, the isocyanurate or the biuret or a mixture of both. There's actually very little monomer in the paint formulations. These are the two most predominant, but there are a number of others that are based on the HDI monomer.

Now, differences in form, respiratory tract

deposition and toxicity resulted in separate RELs for HDI Monomer, and the HDI-based polyisocyanates.

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DR. DODGE: So I'll go onto the RELs for the monomer. And I'll start with the acute REL derivation here. Now, there was a lack of sensory irritation data in humans. That's what we like to work with best, if it's -- if it's there. And for the animal studies, we only had lethality data. There was no data out there which -- short-term exposures that looked at the most sensitive indicator of toxicity upon inhalation, which would be inflammation, irritation of the epithelium in the nasal region.

However, we had a three-weeks exposure study, in which the lowest concentration of 0.005 parts per million resulted in squamous metaplasia and goblet cell hyperplasia in the anterior nose section of rats.

There are -- are also some subacute studies, 19 days continuous or 49 days 6-hours per day by Astroff, et al. at -- were at the lowest concentration. He looked at 0.005 parts per million. He saw no significant nasal lesions. He saw non-significant nasal lesions, which I'll talk about later. But at this concentration, he considered them not significant.

PANEL MEMBER GLANTZ: When you use the word

"significant", are you talking about biologically significant or statistically significant?

DR. DODGE: I think in his case it was non-significant statistically.

There's also a human study looking at five subjects around 0.004 parts per million for seven and a half hours, where there was no change in respiratory function. However, this study wasn't really set up to look at the most sensitive indicator of injury, which would be sensory irrigation, so we decided we'd go with the animal studies.

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DR. DODGE: So from these animal studies, it suggested there's a threshold LOAEL/NOAEL around part -- around 0.005 parts per million with multiple exposures.

So we chose as our point of departure for the acute REL a single 5-hour exposure to 0.005 parts per million. At this point of departure we applied a time adjustment from 5-hours to 1-hour exposure, because our acute RELs are based on a 1-hour exposure. This employed a modified version of Haber's Law, which is C to the N power times T. And in this case we used a default of 3 for the N value. So this is in our guidelines where we -- if we do an adjustment from 5 hours to 1 hour, for example, from higher exposure, longer exposure to down to

1 hour, we use an N of 3.

And in this case, when we do this, it assumes exposure concentration is the main toxicity driver, rather than exposure duration. Now, if we had any C times T studies, classic studies, that -- you know, where we could really define what N was, we would use that. And when we don't have enough data, we would use an N of 3.

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PANEL MEMBER BLANC: Can I ask a quick question, which is how would you prefer -- there's certain questions that I have as primary reviewer that you'll have touched on or will be touching on. Do you want me to just save those until we circle back around? What would be most efficient?

DR. DODGE: Did you have any suggestion? I'm fine however you'd like to do it.

CHAIRPERSON ANASTASIO: Yeah. I would suggest if it's going to be a substantive comment that's going to lead to a lot of discussion, maybe we save that till the end.

PANEL MEMBER BLANC: Okay.

CHAIRPERSON ANASTASIO: Perhaps if it's a clarifying comment, like Stan's, then we could do --

PANEL MEMBER BLANC: No, this might -- it's hard for me to know, so I'll just hold off.

CHAIRPERSON ANASTASIO: Yeah, I think that would be more efficient.

DR. DODGE: Okay.

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DR. DODGE: So we then applied the human equivalent concentration, or HEC. This is a pharmacokinetic adjustment from animals to human. And based on the dosimetry model published by Schroeter et al. in 2013, we used a HEC value of 1. In this modeling study, he found that there was a greater wall mass flux to the anterior nasal region of the rat compared to human, about 3-fold greater. So this would suggest that pharmacokinetically, rats are more sensitive than humans by 3-fold.

However, this -- in this model, it was found that then -- there was then a greater wall mass flux, about 3-fold greater, into airways generations 0 to 5 in humans. This is the area con -- for -- of concern for asthma, the bronchial airways. So we considered it a wash at this point and just chose a 1.

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DR. DODGE: We then applied uncertainty factors for the interspecies uncertainty factor toxicokinetic portion. We used a 2, and this is for the residual toxicokinetic differences not addressed in our dose -- in

the dosimetry model by Schroeter et al. The toxicodynamic portion we applied a root 10, and this is for a lack of toxicodynamic data.

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DR. DODGE: For the intraspecies uncertainty factor, we're looking here at the interindividual variance or differences. The toxicokinetic portion we applied a root 10. And this is for the 3-fold greater exposure in mouth breathing versus nasal breathing in humans. This is also part of Schroeter's modeling study in 2013.

And since this is a sensitive airway region in humans that we're concerned with, we applied the 3-fold uncertainty factor.

For the toxicodynamic portion it's 10. And this is for the additional susceptibility of children, particularly those with increased sensitivity -- particularly for children with asthma.

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DR. DODGE: These are all the uncertainty factors I just spoke about. And the cumulative uncertainty factor when multiplied together is 200. So we have an adjusted point of departure of 0.059 milligrams per cubic meter divided by 200, gave us an acute REL -- or draft acute REL of 0.0003 milligrams per cubic meter or 0.3 micrograms per cubic meter.

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DR. DODGE: Now, I'd like to go on to the 8-hour chronic RELs. For the derivation here, it was based on the same study for both of these RELs. There was a long term rat study available, on which to base a REL. It had a NOAEL and LOAEL. However, we had three occupational studies available and two of them were relatively recent. These were conducted in production plants for HDI and the prepolymers.

The one we chose to base these two RELs on was Cassidy et al. 2010. In this study, there was no pulmonary function changes, sensitization or work-related respiratory problems at time-weighted 8-hour exposure of 0.78 parts per billion. And the reason this study was superior, it had a large number of workers exposed, 100. There was a large number of air samples taken over the duration of the study, which was 13 and a half years. There was 237 air samples taken. Exposure was determined when workers were not wearing protective respiratory equipment, and sample collection was only for the full shift duration of 6 to 9 hours.

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DR. DODGE: Now, following public review, we obtained the individual exposure data from Dr. Cassidy in order to calculate a distribution. So rather than base

the point of departure on a mean, we could look at the distribution and make a decision here.

The limit of detection in the study varied by the sampling method between 0.025 and 0.4 parts per billion. And we chose the half -- half the limit of detection, or LOD, for non-detects, and that was 88 Samples out of 237.

The point of departure chosen was the 90th percentile, which is 1.23 parts per billion.

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DR. DODGE: This concentration is also 8.46 micrograms per cubic meter. And it's what is called a free-standing NOAEL, meaning from the study itself, there was only a NOAEL and no LOAEL. Generally, we don't use these studies, but we do under certain conditions. In particular, this study was available and very good. And there was no other worker study available with a LOAEL.

We did have the rat study. However, the dosimetry model by Schroeter suggests, you know, differences in airway region between rats and humans where HDI deposits and causes a toxic response. And we decided that the human data was better for this reason, rather than rely on the rat data for a chronic and 8-hour REL derivation.

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DR. DODGE: So to the value of 8.46 micrograms

per cubic meter, we applied time adjustments for the 8-hour REL, it was just a 5 day over 7 day adjustment. And this is because the occupational study was 5 days per week and the 8-hour REL is based on a 7-day per week exposure.

For the chronic REL, we added to this a 10 cubic meter over 20 cubic meter factor. And this recognizes that for occupational exposure 8 hours per day, the worker breathes about the half -- half the air they're going to breathe in a day. So that's 10 cubic meters. And for a full day, they breathe 20 cubic meters, so that resulted in the 10 over 20 ratio.

Applying uncertainty factors, we didn't need a subchronic uncertainty factor, because the mean worker exposure in the Cassidy study was 13.5 years. No interspecies uncertainty factor is needed. It's a human study, so no extrapolation from a rodent to human.

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DR. DODGE: Intraspecies, the Toxicokinetic portion, we used a 10. And this is for the toxicogenomic variability. A number of gene variants found associated with increased sensitivity in isocyanate-induced asthma. So this resulted in odds ratios that got as high as 10, or close to 10, so that was the reason we used that.

The intraspecies toxicodynamic portion is also

for the toxicogenomic variability, but also because increased sensitivity of children with asthma.

Now, the use of these uncertainty factors for both the toxicokinetic and toxicodynamic portions, we used for two other RELs that we brought before the Panel 2 to 3 years ago. This is for toluene diisocyanate and methylene diphenyl diisocyanate. So many of the -- some of the Panel members are probably familiar with this.

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DR. DODGE: The combined uncertainty factor when multiplied altogether, the -- well, the cumulative uncertainty factor is 100, when applied to the time-adjusted point of departures, resulted in 8-hour and chronic RELs of 0.06 and 0.03 micrograms per cubic meter.

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DR. DODGE: So now I'll speak about the RELs developed for the HDI-based polyisocyanates. So why a different set or RELs?

This is because the polyisocyanate mixtures are predominantly solid or particle, so when sprayed they're in aerosol form. The HDI monomer is a gas. In the pulmonary region where they have their toxic effect is different. For the HDI-based polyisocyanate, this is the pulmonary region is the most sensitive. For HDI monomer, which I just talked about, that's the nasal/bronchi

region.

Now, the RELs for the poly -- HDI-based polyisocyanates are for -- you know, the exposure is -- it's set up for HDI monomer content of two percent or less. And this is because of a study by Pauluhn who has done quite a bit of research on the diisocyanates, not HDI, but TDI and MDI as well. In this study, he looked at polyisocyanate mixtures, which were the same, except one had 0.1 percent HDI and the other had 2 percent HDI.

They exposed rodents in an acute study and found -- I believe it was an acute study or subacute, he found that there was no difference in toxicity, whether the HDI content was 1 -- 0.1 percent or 2 percent.

So what we suggest here is that the polyisocyanate RELs can be used for mixtures that have 2 percent or less HDI content. But for those that are above 2 percent, we suggest that the HDI mon -- the HDI RELs for the monomer be used, at least for that portion that is the monomer, and the remainder, which would be the predominant amount, would be the -- use the polyisocyanate RELs.

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DR. DODGE: So I'll start off with the acute REL derivation. As I indicated, the sensitive region is the pulmonary region. And the most sensitive indicator of that is increased total protein and bronchoalveolar lavage

fluid, or BALF, in rats. And this is from edema fluid leaking into the small airways and alveoli. And, you know, what -- and what it brings with it is the protein and that's what's being measured.

A couple of researchers, including Pauluhn, measured thresholds for this increased protein. In a number of HDI polyisocyanates, or prepolymers. And that's what is the -- is in the table here. So the threshold for this increase, which you might picture as like a NOAEL/LOAEL threshold was pretty close together. It wasn't a large range. It ranged from point -- 4.1 to 1.1 milligrams per cubic meter.

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DR. DODGE: So the threshold or the compound we chose to base the acute REL on was for the -- let me go back -- was for the HDI prepolymer 1 there, which is in bold. That's the lowest threshold of the ones in this table. That is actually predominantly the isocyanurate in that compound.

Now, the author's identified the threshold as the intercept of the concentration effect curve with a line parallel to the X axis at Y equals 1 plus 2 times the standard deviation. So that's at 2 times the standard deviation of the control value.

Again, the point of departure is 1.1. And we

applied Haber's Law -- modified Haber's Law to adjust it from a 6-hour exposure to 1-hour exposure, again, using an N of 3. So this went from 1.1 milligrams per cubic meter to 2 with this adjustment. We then applied the human equivalency concentration adjustment, or HEC as I mentioned earlier. This was based on the regional deposited dose ratio using the MPPD modeling for fractional deposition.

So this MPPD model, multiple particle dosimetry, this does the fractional deposition of three main regions in the lung, the nasal, bronchi/bronchial region, and the pulmonary region. And the resulting ratio, when plugged into the RDDR ratio equation gave us 0.45, suggesting that at least for the pulmonary region, the toxicokinetically humans are more sensitive than the rats. So 0.45 times 2 gave us an adjusted point of departure of 0.9 milligrams per cubic meter.

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DR. DODGE: Applying uncertainty factors, the interspecies toxicokinetic uncertainty factor is a 2 for residual toxicokinetic differences not addressed by the RDDR and MPPD models. Toxicodynamic uncertainty factor root 10 for lack of toxicodynamic data.

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DR. DODGE: Intraspecies uncertainty factors,

toxicokinetic portion was root 10. This is for the relative pulmonary minute volume to surface area ratio being 3-fold greater in infants compared to adults.

The toxicodynamic is a 10 to address the toxicodynamic diversity in the human population, including sensitive populations such as children with asthma.

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DR. DODGE: These are the uncertainty factors -- the cumulative uncertainty factor is 200. So the adjusted point of departure of 0.9 divided by 200 gave us a draft acute REL of 0.00.45 -- 0.0045 milligrams per cubic meter.

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DR. DODGE: I'll now talk about the derivation of RELs for the 8-hour and chronic. And this is based on the same study. It was based on a study by Pauluhn and Mohr, 2001, a 13-week study in rats. There is no long-term studies or chronic studies in rodents, so we relied on a 13-week study in the rats.

And in the table here is the data we used. We couldn't use benchmark dose modeling, because it was essentially an all-or-nothing effect here. At 3 milligrams per cubic meter, it was hard to determine if there was really a response there or not. However, at the next higher concentration of 25 milligrams per cubic meter, there was a pretty strong response for practically

all the endpoints -- pulmonary endpoints that they looked at. So we chose, as our point of departure, 3 milligrams per cubic meter.

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DR. DODGE: The time adjustment to the POD, this was 6 hours over 24 hours times 5 days or 7 days times 20 over 10 cubic meters. This is for the 8-hour REL.

And for the chronic, it was just 6 hours over 24 hours times 5 days over 7 days, which converted it to an annualized concentration, in other words a continuous type of exposure.

We applied the human equivalency concentration. This was -- this -- we also employed the RDD[SIC] model -- or modeling here or equation using the MPPD model. We combined males and female rats in this study, because they had the same toxic response. And the ratio we got was 0.84, which multiplied by the time-adjusted values gave a 8-hour value of 0.9 and a chronic of 0.45 milligrams per cubic meter.

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DR. DODGE: Now applying the uncertainty factors. The subchronic uncertainty factor we applied was 2. And this is because of data also by Pauluhn over -- with a number of -- a number of studies, where we found that acute, subacute exposures, 13-week exposure, there did not

appear to be a progression of pulmonary injury, at least over this exposure duration. So in this case, we used a lower uncertainty factor. Rather than a root 10 we used a 2.

For interspecies uncertain factors, we used a 2 for the toxicokinetic portion for the residual toxicokinetic differences not addressed by the various models here, MPPD and RDDR. Toxicodynamic portion was root 10 for lack of toxicodynamic data.

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DR. DODGE: For the intraspecies or interindividual variation among the human population, we used a 10 for the toxicokinetic portion. And this was again for the toxicogenomic variation or variability. Intraspecies toxicodynamic was also a 10. And this is for increased sensitivity in children with asthma, as well as the toxicogenomic variation.

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DR. DODGE: Here are all the uncertainty factors on the same slide, which accumulatively came to 1,200. So divided by our point of departure -- or our point of departure -- adjusted point of departure divided by 1,200, I should say, resulted in 8-hour and chronic RELs of 0.8 and 0.4 micrograms per cubic meter.

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DR. DODGE: In summary, these are the proposed RELs for both the monomer and HDI polyisocyanates.

Dr. Anastasio, I'm done with the presentation here.

CHAIRPERSON ANASTASIO: Well, we could either go through your response to the ACC comments now and finish the document or we could go to Panel, whatever you prefer.

DR. BUDROE: We usually leave that up to the judgment of the Chair, so...

CHAIRPERSON ANASTASIO: Perfect. Why don't you finish your presentation then. And then we'll have a full Panel discussion on everything at the end.

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DR. DODGE: Okay. So we're going to on to the response to comments?

CHAIRPERSON ANASTASIO: Yes, please.

DR. DODGE: Okay. So during the comment period -- public comment period last year, or actually it started in December 2017, OEHHA received comments from the American Chemistry Council of the Aliphatic Diisocyanates Panel. We also received comments on February 21st of this year from the ACC. We'll be also addressing those at the end.

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DR. DODGE: So back to the public comment period

from last year. The first comment we had was that HDI and HDI polyisocyanates are manufactured in closed systems. Releases to the environment are expected to be very low. And any that are released will react in the environment to produce biologically inert polyureas.

Our response was that we are concerned with the use of HDI-based spray points, in addition to the manufacture of the com -- of the products. California may have up to 4,200 facilities and 15,000 spray painters that use HDI paints. So OEHHA believes the potential exists for exposure to the general public.

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DR. DODGE: The next comment, comment number 2, by the ACC. The EPA school monitoring project failed to detect any diisocyanates, including HDI in any sample. Therefore, diisocyanates should not be an air pollutant of concern.

Our response is that of the 62 schools examined in the 20 -- in the 2009-2010 EPA study, only 6 were near facilities that could potentially have resultant exposure to diisocyanates. Only two of these schools may have been potentially exposed to HDI mon -- HDI. In their study -- in the EPA study, no diisocyanates were detected at these 6 schools.

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DR. DODGE: And going on response 2 continued. The U.S. EPA suggested that the lack of findings was due to a number of reasons: Overreporting of potential diisocyanate emissions; significant reductions in emissions by the time of the study; facility emissions below the detection limit; and facility operations below 100 percent of capacity at the time of the study.

Now, we additionally note that the distance from the source to the school was 0.6 to 1.5 miles. And there was no near-source or fence-line monitoring. So the monitors at the schools may have been too far away to detect any diisocyanates.

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DR. DODGE: Our response continued. In summary, the U.S. EPA School Monitoring Project data were inadequate to support a conclusion that diisocyanates are not an air pollutant of concern for the general population.

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DR. DODGE: Comment number 3. In the 3-week study by Shiotsuka that we used to base the acute REL on, for HDI monomer, the subtle adaptive nasal epithelial responses to injury that occurred at 0.005 parts per million are not considered an adverse effect. The NOAEL of the study was 0.0175 parts per million.

In addition they note that the Astroff short-term studies observed a NOAEL of 0.005 parts per million.

They summed up by saying OEHHA should use 0.0175 parts per million not 0.005 parts per million as the NOAEL for their acute REL derivation or HDI monomer. Use of 0.005 parts per million as a NOAEL is overly conservative.

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DR. DODGE: Our response is that OEHHA considers cellular responses such as by irritant -- caused by an irritant action of a known chemical irritant to be -- irritant to be an adverse acute effect. The types of nasal epithelial changes including squamous metaplasia, epithelial hyperplasia, and goblet cell hyperplasia observed at 0.005 parts per million by Shiotsuka et al. were considered to be adverse effects, and were used in the REL derivation for acrolein.

The Astroff studies considered acanthosis and inflammation to be non-significant at 0.005 parts per million, but were cleary significant at the next higher level of 0.05 parts per million.

These studies suggest that the acute exposure to 0.005 parts per million is a near threshold response, at least for a single exposure. So using a single 5-hour exposure to this concentration from the 3-week study by Shiotsuka is a -- not overly conservative.

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DR. DODGE: Comment number 4. For time extrapolation from 6-hour exposure to 1-hour exposure in the acute REL -- REL derivation, a value of N equal 1 should be used for Haber's Law, not N equal 3 as OEHHA used. OEHHA cited support for N equal 1 for HDI poly -- polyisocyanates in the study by Pauluhn et al. 2002. Recalculation using N equal 3 result in acute REL of 14 micrograms per cubic meter not 4.5.

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DR. DODGE: Or response is that OEHHA uses a health protective default value of N equal 3 in Haber's Law when there are no C time T studies conducted for the particular compound. A value of N equal 1 was used in the derivation of another isocyanate called PMDI or polymeric methylene diphenyl diisocyanate, in which a classic C times T study was conducted by Pauluhn in 2002.

The HDI polyisocyanate study by Pauluhn 2015 varied T. So it was -- it's not a true C times T study. OEHHA reassessed the use of an N equal in the HDI monomer at this point, and the REL derivation presented in the public review draft document, we decided it could not be assumed that HDI monomer would have the same Haber's Law characteristics as PMDI, so the REL derivation was revised using N equal 3.

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DR. DODGE: The fifth comment by the ACC. OEHHA based 8-hour and chronic RELs on the Cassidy occupational study in which the time-weighted average concentration was 0.78 parts per billion was used as the point of departure. Now, I should note that in the public review version of our document, we did use the mean. And then following public review, Dr. Cassidy sent the individual data from which we then used the 90th percent from the distribution as the point of departure.

In any case, going on with the comment. OEHHA should base the RELs on the occupational threshold limit value time-weighted average concentration of 0.005 parts per million.

Going on with their comment. None of the workers exposed in the Cassidy study showed an accelerated decline of FEV1, or forced expiratory volume of 1 second, or developed occupational asthma. The author stated that their study supports the time -- the threshold limit value time-weighted average of 0.005. A use of 0.005 or 5 parts per billion as the point of departure would result in an 8-hour and chronic REL values of 0.036 and 0.018 parts per billion respectively.

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DR. DODGE: Our response is that there are no

peer-reviewed human exposure studies to derive the threshold limit value of 5 parts per billion. That occupational exposure value appears to be supported only by anecdotal evidence. OEHHA does not use this type of data for REL derivation. OEHHA based the 8-hour and chronic RELs on a peer-reviewed occupational study that observed no pulmonary function deficits or other pulmonary problems in 100 workers exposed to a mean concentration of 0.78 parts per billion of HDI monomer.

And since public review, OEHHA received the individual exposure date from Dr. Cassidy where we then used the 90th percentile of the distribution as the point of departure.

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DR. DODGE: Comment number 6. There are errors in the 8-hour REL calculation for HDI polyisocyanates. The time-adjusted worker exposure should be 6 hours over 8 hours, not 6 hours over 24 hours, as OEHHA has done.

A subchronic uncertainty factor of 2 was used by OEHHA. An uncertainty factor of 1 should be used, since the subchronic uncertainty factor only applies to the chronic REL and not the 8-hour REL derivation.

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DR. DODGE: Our response, number 6 -- to number 6. There was no error in our calculation. The 6 hours

over 24 hours times 5 over 7 days time adjustment first converts to an annualized average concentration, just as in calculating the chronic REL. We then apply a 20 over 10 cubic meter adjustment. And this is because half the air breathed in a day by a worker occurs during that active 8-hour work period.

The subchronic uncertainty factor can be applied to the 8-hour RELs. OEHHA guidelines -- non-cancer guidelines specify that we can use the chronic REL derivation methodology if long term intermittent 8-hour exposures result in cumulative injury, similar to -- similar to a chronic exposure.

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DR. DODGE: Comment number 7. The interspecies toxicodynamic uncertainty factor of 3 for many of the RELs is too conservative and should be a 1. The uncertainty factor is not needed for direct acting irritants on nasal epithelium such as HDI. They have no systemic effects.

And our response is that our guidelines state that a default interspecies toxicodynamic uncertainty factor root 10 is applied to account for the use of key studies employing non-primate species and the lack of data for toxicodynamic interspecies differences.

In addition, HDI glutathione adducts have been found in the bloodstream following inhalation of HDI,

which can then conjugate to proteins distant from the lung. It's unknown if these adducts have a toxic action in the body, but it would be wrong to assume no systemic action from these reactive HDI adducts.

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DR. DODGE: Comment number 8 was that an intraspecies toxicokinetic uncertainty factor of 10 for genotypic variations possibly involved in the development of isocyanate-induced asthma is not relevant and an uncertainty factor of 1 should be used.

HDI monomer and polyisocyanates are direct acting and too reactive to have a role in genotypic variation in GSTs. This refers to glutathione S-transferases for development of isocyanate-induced asthma. Glutathione S-transferases are not required for the reaction of isocyanates with glutathione.

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DR. DODGE: Our response was that genetically-based individual variations in the GST enzyme activities are possible modifiers of susceptibility isocyanate-induced asthma. Individual capability to tolerate oxidative stress varies possibly due to genetic factors. Enzymes of the GST supergene family an utilize a wide variety of products of oxidative stress as substrates and are thus critical in the protection of cells from reactive

oxygen species, otherwise known as ROS.

Exposure to isocyanates causes respiratory symptoms characterized by airway inflammation, eosinophilia, and local formation of ROS. Isocyanates can react with proteins such as albumin to form protein conjugates. The protein conjugates can be immunogenic, and the formation of the hapten complexes can give rise to immunological reactions. In the presence of decreased GSH conjugation related to deficient GST genes, impaired immune response may occur.

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DR. DODGE: Comment number 9. An intraspecies toxicodynamic uncertainty factor of 10 to protect sensitive age groups, such as children, is not supported by scientific evidence.

Childhood asthma is a T2[SIC] driven process, while diisocyanate-induced asthma is a T1 -- Th1 driven process. Thus, if the Th2 pathway predominates in early life, while the Th1 is less well developed, children will be less sensitive not more sensitive to development of diisocyanate asthma, because it is primarily a Th1 driven pathway in humans.

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DR. DODGE: OEHHA response. It is unknown how children will react to HDI monomer and prepolymer exposure

early in life when the immune system is still developing. The development of asthma from exposure to isocyanates is multifactorial. And it is not well understood what the mechanism of isocyanate-induced asthma is in adults, much less children.

Uncertainty factors are assigned based on data gaps. And the lack of knowledge recording the relative susceptibility of infants and children compared to adults represents a substantial data gap.

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DR. DODGE: Now, the final comment here. RELs for HDI monomers and pre -- polyisocyanates is unnecessary, lacks scientific basis, and should be withdrawn.

Since potential exposures to HDI are primarily limited to occupational settings and not the general public, development of RELs for HDI to protect the general public is unnecessary use of OEHHA resources without commensurate public health benefit.

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DR. DODGE: Our response is that exposure to very low levels on the order of micrograms per cubic meter of HDI monomer and polyisocyanates may result in an adverse acute and chronic responses, particularly in sensitive individual.

As many as 4,200 facilities in California may be using HDI-based polyisocyanates in spray painting operations or other -- or for some other purpose. The high potency plus widespread use of these compounds supports the development of RELs for HDI monomer and polyisocyanates.

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DR. DODGE: So that was it for the public review comments. We received, or the Panel received, comments about a week ago or so from the ACC. And now we'll address those comments, if you'd like.

CHAIRPERSON ANASTASIO: (Nods head.)

DR. DODGE: Okay.

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DR. DODGE: Comment number 1, part 1. Squamous metaplasia and goblet cell hyperplasia observed at 0.005 parts per million in the 3-week study are subtle adaptive responses to injury and should not be considered an adverse effect.

Use of the a single 5-hour exposure to 0.0175 parts per million, the next higher dose, as the point of departure for REL -- for the acute REL, not 0.005 parts per million.

Our response is that OEHHA had responded to a similar comment during the public review. The epithelial

changes at 0.005 parts per million resulted from a 3-week exposure, are not considered adverse effects by OEHHA, based on the 3-week -- are -- okay. Let me rephrase that.

The epithelial changes at 0.005 parts per million resulted from a 3-week exposure are considered adverse effects by OEHHA. Based on the 3-week study findings plus the supporting studies by Astroff et al., OEHHA does not consider the use of a single 5-hour exposure to 0.005 parts per million for a point of departure to be overly conservative.

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DR. DODGE: The second part of this comment was that we considered the 1-week rat study by Kopf et al. 2015 to be a more appropriate study to base the acute REL on. In the study, exposure was 6 hours per day, 5 days -- for 5 days to 0.07, 0.027, 0.1, 0.46, and 1.97 parts per million. Exposure to 0.1 parts per million displayed minimal, if any, changes in lung function and histopathology.

Study authors concluded 0.1 parts per million was a borderline NOAEL for upper respiratory tract changes -- or effects, and would suggest that 0.027 parts per million as the NOAEL for the acute REL derivation.

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DR. DODGE: Our response is that the Kopf study

is an unpublished study -- pilot study by Bayer Pharma AG. We were not aware of this study because of that. OEHHA does not generally use these types of non-peer reviewed studies unless it is of adequate quality and the methodology is sufficiently described.

Moderate to severe signs of respiratory distress was observed at 0.46 and 1.97 parts per million during the exposure. At 0.1 part per million, there was borderline neurodegeneration, inflammation, and subepithelial edema in nasal epithelium.

Also, borderline reflexively-induced brady -- I'm not sure how to pronounce that. Dr. Blanc, how do you -- brady --

PANEL MEMBER BLANC: What is it?

DR. DODGE: Bradypnea.

PANEL MEMBER BLANC: I think they mean slow breathing.

DR. DODGE: Yes, slow breathing. That would be a -- that's a better way to pronounce that.

PANEL MEMBER BLANC: I've never seen that term used in a clinical sense.

DR. DODGE: Okay. Well, I'll call it slow breathing. No apparent histopatholo -- pathological or respiratory rate change occurred at 0.027 parts per million.

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DR. DODGE: Continuing on, our response is that the Kopf study lacks some key details, such as figures, tables, and quantitative measurements. The lung function measurements were not well described. Statistical significance of endpoints were not presented. Sacrifice occurred at 3 days after last exposure. There may be enough recovery by that time to miss some adverse effects at lower doses.

Given these study deficiencies and lack of peer review, OEHHA believes that the Shiotsuka et al. 2006 study is a more appropriate basis for the development of a HDI monomer acute REL.

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DR. DODGE: The second comment. Following public review, OEHHA revised the time duration adjustment in Haber's Law equation from N equal 1 to N -- to a default of N equal 3 lacking cite of evidence -- lack of -- citing a lack of evidence.

It is incorrect to say there are no supporting C times T studies supporting an N of 1. C times T protocols in studies for TDI and HDI support an N of 1. Haber's Law does not apply to trigeminal irritation effects. Lack of signs of respiratory tract irritation in the form of breathing rate changes support using Kopf for acute REL

derivation.

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DR. DODGE: Our response to the comment was that OEHHA had responded to similar -- responded to a similar comment during the public review. OEHHA decided there was not enough evidence to use an N equal 1 for Haber's Law equation. We could only find a classic C times T study for polymeric MDI in which N did calculate to 1.

The Pauluhn studies of 2014 and 2015 were not true C times T studies. In these studies, C was held constant while T varied. The Pauluhn studies were designed to develop a rat model for sensitization using high concentrations of HDI and TDI to overcome scrubbing action of the nasal airways, so enough of the chemical could reach bronchial airways. The HDI acute REL is based on low doses affecting the nasal tissue. So there's differences in endpoints here.

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DR. DODGE: Our response continued. OEHHA does not uses Haber's Law for trigeminally stimulated eye, nose, and respiratory air irritation, but this is observed primarily in -- only primarily in human sensory irritation studies.

A reflex depression of breathing, or slowing of breathing, in mice and rats may be trigeminally mediated.

Although, OEHHA generally relies on human data for sensory irritation.

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DR. DODGE: Continuing on with response number 2. Kopf study says borderline decrease in respiratory rate occurred at 0.1 parts per million. However, there is a study by Sangha et al. 1981 that observed 20 to 30 percent reduction in the respiratory rate in mice exposed to 0.062 parts per million. So it was at a lower concentration than 0.1.

As discussed above, the Shiotsuka study is a more appropriate basis for the development of an HDI monomer acute REL.

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DR. DODGE: And comment number 3. The subchronic uncertainty factor that OEHHA applied to the HDI polyisocyanate 8-hour REL is unnecessary -- unnecessary, based on OEHHA's own guidance.

Table 4.4.1 shows that the subchronic uncertainty factor is only used for chronic REL derivation, not for 8-hour RELs. OEHHA should not use a subchronic uncertainty factor of 2.

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DR. DODGE: In our response -- for our response, we note that the 8-hour REL for HDI polyisocyanates is

similar to a chronic REL in that both are to protect humans from long-term exposures to toxicants. Additionally, our guidelines say that the 8-hour REL derivation may use an acute REL derivation methodology or a chronic REL derivation methodology, depending on the nature of the toxic response to the substance.

For HDI polyisocyanates, successive daily exposures can result in sensitization and occupational asthma, decreased lung function, and fibrosis. Therefore, we use the chronic REL for derivation methodology.

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DR. DODGE: Comment number 4, part 1. Again, this is regarding the acute HDI monomer REL. The comment was that the HDI monomer acute REL is unnecessarily overly conservative. The TDI acute REL is 3-fold lower than the NOAEL upon which the 8-hour and chronic RELs were based on. The HDI acute REL is more than a 100-field lower than the study relied on for the 8-hour and chronic RELs.

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DR. DODGE: Our response to this comment is that

(Thereupon feedback in the sound system.)

(Thereupon a discussion occurred off the record.)

CHAIRPERSON ANASTASIO: Since we're at a natural break here, why don't we take advantage of that and reconvene. And then we'll finish through there and then

we'll get to the Panel comments. We'll plan for a 5-minute break and make sure everything is working. At that point, we'll continue.

(Off record: 11:04 a.m.)

(Thereupon a recess was taken.)

(On record: 11:14 a.m.)

CHAIRPERSON ANASTASIO: Yeah. Okay. So we're getting a message from the IT guy that it looks like we're back on air and ready to go. So Daryn, please continue.

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DR. DODGE: Okay. We're going to be finishing up here. This is the final comment divided into three parts.

To get back to the comment here, number 4, part one 1. The reason they thought it was overly conservative is because for the TDI acute REL that was developed 2 or 3 years ago by OEHHA, the NOAEL upon which the -- well, there was a 3-fold lower -- let me see. The acute REL is 3-fold lower than the NOAEL upon which the 8-hour and chronic RELs are based on.

But for the HDI acute REL, it's more than 100-fold lower than the study relied on for the 8-hour and chronic RELs.

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DR. DODGE: Our response was that HDI acute REL -- draft REL is 0.04 parts per billion, based on an

animal study. The 8-hour and chronic point of departure is based on a human study that had a free-standing NOAEL of 1.23 parts per billion. And the difference is about 31-fold rather than 100-fold, as indicated. However, the differences in species, chemicals, study design, endpoint, et cetera could result in significant differences between an acute REL and the 8-hour and chronic point of departure. What really matters most is are the final REL values for the 8-hour and chronic RELs, once uncertainty factors and exposure time adjustments are taken into account.

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DR. DODGE: Comment number 4, part 2. The HDI monomer acute REL is again unnecessarily overly conservative. OEHHA derived a comparison acute REL for TDI based on the human worker exposure level derived by Pauluhn 2014 for respiratory tract irritation and prevention of sensitization. Deriving acute REL using the same methodology by Pauluhn would result in acute REL of 0.015 milligrams per cubic meter.

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DR. DODGE: Our response is that the Pauluhn rat model for an irritation sensitization threshold for TDI and HDI, done by Pauluhn in 2014 and 2015 respectively, is more -- is actually more appropriate for setting an 8-hour

and chronic REL rather than an acute REL. OEHHA should have specified in the TDI REL document from a few years back that the -- that the comparison REL was for an 8-hour chronic exposure. So that might have been a mistake on our part suggesting that this sort of derivation can be used for an acute REL.

The acute REL for HDI is based on short-term irritant inflammatory responses in nasal tissue, which is the most sensitive indicator of acute injury. Pauluhn used high doses of HDI to overcome the scrubbing effect of the upper respiratory tract so HDI could reach bronchial airways.

This was a model for respiratory sensitization in exposed workers, really more appropriate for an 8-hour chronic REL.

--o0o--

DR. DODGE: Comment number 4, part 3. The human study by Brorson et al. 1990 exposed 5 male subjects to 25 micrograms per cubic meter for 7 and a half hours. This is equivalent to 3.6 parts per billion. No changes in vital capacity, FEV1, or bronchial reactivity were observed.

The authors believed the exposure did not pose any serious harm to the mucous membrane of the respiratory tra -- respiratory tract of the subjects.

This would suggest the acute REL is overly conservative.

--o0o--

DR. DODGE: Our response is that Brorson et al. was primarily a metabolism study and was not designed to carefully evaluate and assess the human subjects for sensory irritation. Brorson et al. did not include methodology to assess sensory irritation, and did not include multiple exposure levels, making it less suitable as the basis of an acute REL compared to the rat study that we used.

--o0o--

DR. DODGE: And that concludes the comments.

CHAIRPERSON ANASTASIO: Great. Thank you very much, Daryn. Are there any clarifying questions before we move on to Panel substantive discussion?

Okay. Let's move on then. So, Paul, would you like to start as the first lead?

PANEL MEMBER BLANC: Okay. So I think it's exhaustive, perhaps even exhausting, document that I know you've been working on for a long time.

Can I ask the -- since there was an initial release more than a year ago, it would help the Panel to know what the impediments were that made it have to take as long as it did? Was it the nature of your responding to the initial public comments, including having to obtain

from Cassidy the detailed data and all of that, just for our edification?

DR. BUDROE: Chlorpyrifos.

Chlorpyrifos.

PANEL MEMBER BLANC: Well, you just answered it. Okay.

So -- and I think it's good that there's a big piece of this that's driven by human data. I think that's always great when you can do it. And the fact that you were able to go back and get those data is very -- very good. And also, it really is quite a morass when you have to go into the health effects of the short-chain polymers -- prepolymers, as they're called, because it's -- the literature is so terrible and there's almost no specific data.

So I think given the limitations of the data, I don't know how you could do much more than what you did. I do have some questions and some general comments for you to take with the spirit that they're given.

The first, and perhaps the most important, is a confusion that I had. And I don't know if it comes from my own read or if there's someway of making it less so in the document. And that is that the study that's used for the acute REL, the 2006 publication, which is a pretty brief paper, I couldn't really find where it was discussed

in the background sections to the document that lead up to the final section where you say, okay, this is what we used for the -- this, and this is what we used for that.

When I looked in the -- and I went back again. So I'm sure it's there, but I just -- it's -- somehow the way it's -- it's -- whereas the other research by the same author has several big tables of data that -- the two-year study.

DR. DODGE: Right. I think there was an earlier study. The study originated some years before 2006, right.

PANEL MEMBER BLANC: Right. And then he published -- I mean, my guess is he published at a later date data from the original study that was the relevant --

DR. DODGE: Yes.

PANEL MEMBER BLANC: But it's a brief report.

DR. DODGE: Right. And then --

PANEL MEMBER BLANC: But is it summarized -- is it summarized in the document other than --

DR. DODGE: It is. It should be in there.

PANEL MEMBER BLANC: Where is it, I guess is what I'm saying. And if it is there, is there someway of making it --

DR. DODGE: Well, okay, so the original study was more briefly presented. And then Dr. Shiotsuka came back

in 2006 and I think reexamined the data with a different group of pathologists looking at the slides and came up with his conclusions, which were much more comprehensive. And...

PANEL MEMBER BLANC: I mean, it's in the reference list. I'm not arguing that part.

DR. DODGE: Yeah. You're referring to Sangha, 1984 was the --

PANEL MEMBER BLANC: No. I'm referring to the study -- it's the 2006 study upon which the --

DR. DODGE: Oh, okay.

PANEL MEMBER BLANC: -- REL is based, right? And that appears --

DR. DODGE: Right.

PANEL MEMBER BLANC: It appears in the reference list, and it appears in the section where you say, okay, this is where we derived the acute REL. I get all that. But your standard approach is that once you circle back to what you used for the RELs, they've already -- those papers have already been discussed in the relevant section. And this, I would have expected, would have been summarized and discussed in the acute effects section.

DR. DODGE: So you're referring to Shiotsuka 2006 as being --

PANEL MEMBER BLANC: Yes.

DR. DODGE: -- insufficient -- insufficiently reported in the literature.

PANEL MEMBER BLANC: In the -- in your review.

DR. BUDROE: In the document.

PANEL MEMBER BLANC: But maybe I missed it. Either it's not there, which means that you've got to circle back and put it -- and discuss it.

DR. BUDROE: Well, I think it's partly because it was a reexamination of the Sangha 1984 study. And we had a substantial -- Shiotsuka didn't redo the study. They did a re -- the in-live portion. They did a reexamination of the histopath data.

PANEL MEMBER BLANC: Well, then -- well, there was no way to know that. No way for me to figure that out. So all I'm saying is --

DR. BUDROE: Make that clearer than it is.

PANEL MEMBER BLANC: -- in the section, you need a couple sentences that say, "Later in 2006, so and so went back to this study", and whatever it is.

DR. BUDROE: Okay. What we've got in the document is what appears to be a reexamination of the Sangha --

PANEL MEMBER BLANC: What page.

DR. BUDROE: Page 52, line number 1482.

PANEL MEMBER BLANC: But isn't it in the chronic

section?

DR. BUDROE: That's chronic. Sorry, I've got...

PANEL MEMBER BLANC: So you don't have to solve it here, but what I need you to do is go back and figure out -- either it's so obscure that a normal reader won't see it or it just was in error omitted somehow from the appropriate section. What I think -- maybe what you're saying is that there was embedded in the 2-year study some acute data that was later published, is that what you're saying, where that comes from?

DR. DODGE: Well, you know, I have to tell you I don't recall. I'd have to go back and take a look.

PANEL MEMBER BLANC: Uh-huh.

DR. DODGE: Yeah, we'll take care of that.

PANEL MEMBER BLANC: Okay. And then also, if truly it's mostly from the data from the 2-year steady, but it's some early data from it, you should also make that clearer, you know, what it is.

DR. DODGE: Okay.

PANEL MEMBER BLANC: Okay. Because --

PANEL MEMBER KLEINMAN: Yeah. On that point though, on page 53 --

CHAIRPERSON ANASTASIO: Is your mic on?

PANEL MEMBER KLEINMAN: On page 53, the discussion on lines, you know, 1484 down, it sounds like

there's data that's being presented by Shiotsuka that was not in the other paper at all. So I -- did he do a reanalysis of specimens, do you think, or --

DR. DODGE: That's what appears to have happened, yes.

PANEL MEMBER KLEINMAN: Okay. So it's not really a reexamination?

DR. DODGE: It's not a new study, yeah.

PANEL MEMBER KLEINMAN: It's not a new study, but it is a new actual analysis of samples and tissues?

DR. DODGE: Yes.

PANEL MEMBER KLEINMAN: So that there is new data that's reporting. And it's not -- because when you said it was just a -- you know, a redo of the original study, it sounded like they just took their data and then tried to publish it in a peer-reviewed journal.

DR. DODGE: You know, they aren't specific, but you can sort of read between the lines that they looked at the original Sangha slides, data, whatever, and they put together a new group of pathologists and reexamined that data.

PANEL MEMBER BLANC: Well, or they could as easily have relooked at their own slides, because he actually published the 2-year study, so -- and I pulled the paper, because I was so confused. And it still

wasn't -- it's a very brief paper. So it doesn't have any tabular data. It just has slides -- pictures of tissue.

DR. DODGE: Yeah. Right. Yeah. I -- I'll have to -- I'll have to review, but I can obtain some information that weren't -- wasn't published. And I have it in the references in the back. I think that might be what you're referring to.

PANEL MEMBER BLANC: I -- I don't think so.

DR. DODGE: So you're looking for the acute data, right, or is it the -- that's --

PANEL MEMBER BLANC: So you're basing the acute REL on this person's work, right, on Shiotsuka, right? Because that's the paper that --

DR. DODGE: I don't think -- the acute -- I think it was the 8-hour chronic study that I based the REL on.

PANEL MEMBER BLANC: The acute REL.

DR. DODGE: No. I think it was the 8-hour and chronic RELs I based the -- I used the Shiotsuka study for.

PANEL MEMBER BLANC: Okay. But that would still be under the acute -- would that still be under the acute or under the chronic? Because we --

DR. DODGE: Are we talking -- we're talking about the monomer, the HDI monomer.

PANEL MEMBER BLANC: Yeah.

PANEL MEMBER KLEINMAN: So on page 77, where you discuss the REL, it's both Sangha and Shiotsuka are listed as the basis.

PANEL MEMBER BLANC: Right.

DR. DODGE: Oh, okay. That's right. It's the 3-week study - I'm sorry. Yeah, that's correct - that we used the acute REL -- or based the acute REL on.

PANEL MEMBER BLANC: Right.

DR. DODGE: And there is --

PANEL MEMBER BLANC: But the 2006 I would have expected would have been discussed at some point where the Sangha study was. And all of that does appear under the chronic section, doesn't it, in the text? Not there, but in the text itself. So it does --

DR. DODGE: Yeah. Okay. I see your confusion there.

PANEL MEMBER BLANC: Can you -- can you clean this up in some way?

DR. DODGE: Yeah, I'll -- yeah, I'll clean it up.

PANEL MEMBER BLANC: And, you know, just there are a couple ways you could do it. One is you could say -- you could have a sentence that would say although this is appearing under chronic -- in the chronic effects section, it will be quite relevant to the acute REL derivation --

DR. DODGE: Um-hmm.

PANEL MEMBER BLANC: -- because of blah, blah, blah.

DR. DODGE: Okay.

PANEL MEMBER BLANC: So if you could take care of -- because I think since that is the data that you used, it's kind of a sensitive issue.

So let me just go briefly over a few other things, not to take people's time a lot. And then I'll give you just my little scribbled notes, so you can go through, and when you see something, you could say it.

Because of the confusing nature of this topic of the isocyanates and where people are exposed to them, and even in light of the arguments that -- that industry makes about nobody is exposed, the section in the -- early on, where you always -- you typically do it where you say what are the major uses and sources.

DR. DODGE: Um-hmm.

PANEL MEMBER BLANC: You know, you're basing it on data, none of which is particularly recent, I mean -- and this is a very changing market and changing applications. I think if it wouldn't be a whole lot of work, just a few more sentences there about what HDI is used for juxtaposed with what the other isocyanates are used for would be clarifying. So from what I can tell,

for example, HDI is not used in foam applications. Am I correct in that?

DR. DODGE: I don't believe so. Yeah, it's --

PANEL MEMBER BLANC: Right.

DR. DODGE: It's the aromatic diisocyanates, such as MDI and TDI.

PANEL MEMBER BLANC: Right. So since that's a very important public exposure issue, it wouldn't be absurd to say, it's used for this and it's -- whereas, certain other applications are typically other isocyanates, if you -- if you wanted to.

But even just on the things it is used for, you say, "Other paint sources include industrial coatings, e.g. for bridges and ships and architectural finishing", and that's based on the big Dow products that are on the market. But I'm not sure that that really captures the potential.

So, for example, it's not just bridges and ships, it's parking lots for their water proofing elastomeric HDI-based thing. There's a lot more parking lots that people do work in than are nearer than bridges, right, which is out in open air? It's just as an example. And it's not just architectural finishing. It's actually furniture finishing, which again is a much different kettle of fish.

So I think with just a little bit more information there, it would underscore why you -- you know, why this matters. I'm not discounting that spray painting is the -- you know, is the major thing.

DR. DODGE: Um-hmm.

DR. BUDROE: Just an additional use that we could be mentioning in the document.

PANEL MEMBER BLANC: Which -- which underscores how the public could be -- how it could be out there in areas that are not inside sealed, you know, reactor vessels, you know what I mean, if that makes sense.

And then my other general point would be there are a lot of places in this document where you use words like -- you know, "very" or "highly", words that are not precise. I mean, what does highly mean? What does very mean? So in places where you can just, you know, be more -- it's greater -- X is greater than Y kind of stuff, where it's twice as high as X, but "very", and "extremely", and all that stuff is not as useful. So it's just a quick read. There's nothing that you have to -- I wouldn't put down in a resolution.

But just as an example of places also where you -- you should think care -- since this is a document that then people use, or read, or quote -- "The ranges for HDI polyisocyanates in Table 1 show that the short-term

ceiling limit 140 micrograms per meter is often exceeded in the breathing zone of spray painters, demonstrating the need for adequate respiratory protection".

Well, first, I'd say demonstrating the need for adequate engineering controls, right? That's the hierarchy of controls is -- I have someone nodding across the room. So when you say things like that, it's like saying oh, you know, just slap a respirator on them and that will solve the problem, right?

There's another point where you say because some researcher said it, that when you get occupational asthma from HDI, it's not as severe as occupational asthma from iso -- from toluene diisocyanate. I don't believe that's true at all. I don't believe there's any data that would suggest it. I don't think there's any biological plausibility to make us believe that. So I would just delete that. Why are you even saying that?

Because some lawyer is then going to say, oh, you know, State of California says --

DR. DODGE: Yeah, that was conclusion by the author. Yeah.

PANEL MEMBER BLANC: Right, but why say a bogus conclusion. Suppose they concluded there's no global warming, are you going to put that in your document, you know what I mean?

DR. BUDROE: So you're suggesting it, in some cases, less can be more?

PANEL MEMBER BLANC: I'm absolutely suggesting that. And one -- and, you know, I'll just give you these notes. You'll see what I'm -- what I'm -- small places.

But this is another sort of generic question that could apply to other documents. I know that you -- you often quite appropriately cite what exposure limits are also in the occupational setting. And this is obviously a major occupational exposure issue. And we're very lucky that California has an HDI standard, which -- which actually federal OSHA doesn't. And you cite the Oregon ceiling limit, I believe. Do you guys ever think about citing what the Europeans set for limits or are you in any way inhibited from doing that?

DR. DODGE: I don't think so. I think it was just more relevant to talk about what the U.S. or -- states and federal levels were. But I -- if you'd like, I could add some of the European levels as well, yeah.

PANEL MEMBER BLANC: If it's useful. You should look. For example, the British have one level only for all iso -- they don't differentiate. They just say, okay, here's the exposure limit for isocyanates, and they don't care if it's HDI, or MDI, or TDI. And it's -- it's -- it's lower, you know, than -- than California's, for

example.

So I thought that was interesting. I don't -- so I think just as sort of a generic point, you might think about going forward.

And you didn't say anything about the American Conference of Governmental Industrial Hygienists who often go back to things that OSHA hasn't looked at for 30 years. Do you happen to know whether they've looked at a TLV for this?

DR. DODGE: Yeah, I don't know if they have or not.

PANEL MEMBER HAMMOND: Yes. Yeah, they have. And I think they have a standard of -- I think it's -- I was just looking at one of your papers, the Cassidy paper, and it's in there. I think it's 5 ppm that -- or 5 ppb. It's only a 1,000-fold difference. 5 ppb is the -- ACGIH TLV is 5 ppb.

PANEL MEMBER BLANC: So that's it.

CHAIRPERSON ANASTASIO: Thank you, Paul.

DR. DODGE: Okay. Thank you.

CHAIRPERSON ANASTASIO: Mike.

PANEL MEMBER KLEINMAN: Great. Thank you.

First, I'd like to echo that this was a very nicely put together report, and very comprehensive. I have a few minor questions, and then I've got, you know,

some specific things that I'll send you copies of to look at.

But one of the things that I think would make this a stronger document is a much more clearer discussion of the difference between asthma, and respiratory sensitization, and reactive airways, because these compounds do a little bit of everything. And I think, you know, some of the comments that you got from ACC were pointed in one direction, rather than the other. I think it would make it a lot clearer to explain you know that, in some cases, you do get something that looks like asthma. You get antigen-specific IgEs for example. And that would be a signal that, you know, something more asthmatic.

But in some cases of respiratory sensitization, you can have the sensitization without necessarily having the antigen-specific response.

DR. DODGE: So not necessarily an immune type of response.

PANEL MEMBER KLEINMAN: Right. But in the -- you do have find -- you know, you mention in several places that there are circulating IGGs. And one of the things that I just wanted to clarify was in some places you just say IgG, and in other places you specified that it's HDI specific, or HDI HSA specific. And I think it would be

good to make sure that if it is, you know, antigen specific, that would be important, not only because it does talk about the immune system involvement, but also speaks to the fact that you're seeing something that's a systemic response. IgE is circulating. So you can have sensitizations in -- you know, that will result in the systemic responses to this, as well as just the tissue-specific ones.

And the other point -- oh, I did want to ask for clarification. When you use the MPPD model, that has the -- you know, a number of inputs, did you do it as an oral/nasal inhalation, or oral, or nasal or, you know --

DR. DODGE: I selected nasal was the -- yeah.

PANEL MEMBER KLEINMAN: Okay.

DR. DODGE: Yeah. I think I have it in the appendix in the back. I might have mentioned that.

PANEL MEMBER KLEINMAN: Because at 20 liters a minute, you know, the -- you -- most people will have probably 40 or 50 percent oral, 60 percent nasal. So there is, you know, a tendency, you know, so --

DR. DODGE: Yeah, I'm kind of -- I am aware of that.

PANEL MEMBER KLEINMAN: Yeah.

DR. DODGE: It doesn't -- your choice is nasal or oral. It doesn't give you a mix, as I recall, or that

multiple path particle dosimetry.

PANEL MEMBER KLEINMAN: No. It actually has a -- well, the model -- the one -- the version I had I believe specified oral/nasal for the human model.

DR. DODGE: Oh, it does.

PANEL MEMBER KLEINMAN: Yeah.

DR. DODGE: Okay.

PANEL MEMBER KLEINMAN: But -- and you may have selected that if it was there. I don't know. But anyway, I just wanted to point that out.

DR. DODGE: Um-hmm. I'll go back and take a look. Maybe I don't have a more recent -- maybe I need a more recent version too.

PANEL MEMBER KLEINMAN: And the other thing -- I don't know if you've considered this, but when you're scaling to the, you know, human equivalent dose, or concentration, you can also scale -- you know, using MPPD, you can actually use a deposition model to get a deposition ratio, human versus rodent, for example. And --

DR. DODGE: Right. There is that selection in there, yes.

PANEL MEMBER KLEINMAN: Yea. So it -- you know -- I -- and I think that would probably support some of the selections of, you know, correction factors or

uncertainty factors, because there is a substantial difference, based on surface area and things.

Oh, the other thing that I was wondering about, in the Haber relationship -- I don't like to call it a law. It's not a law.

(Laughter.)

PANEL MEMBER KLEINMAN: But the C times T relationship, selecting a default value of 3, is there substantiation behind that because, you know, for example, I've done it with something like ozone. And you can clearly see, you know, a non-linear dose response to ozone.

And when you use -- you get a best fit to a C times T, it's really like one and three-quarters or something, 1.7, as opposed to 2 or -- but these com -- you know, all these compounds are different. So I was just wondering, is there a real basis for the number 3 or was that, you know, a guesstimate based on other things?

DR. DODGE: I believe it goes back to our original technical support documents from around 2000 --

DR. BUDROE: 2008.

DR. DODGE: -- where a number -- right, where I think a number of C times T relationships were looked at, and it was determined that a 3 would be sufficiently protective based on all these studies that developed --

that had C times T relationships where you could develop the N. Did you have anything to add, John?

DR. BUDROE: No. That -- that's just essentially -- that -- that is issue was pretty thoroughly vetted in the 2009 non-cancer technical support document, so -- and it was based on empirical data.

PANEL MEMBER KLEINMAN: Right. Thank you.

And when I was looking at other uses of, you know, polyurethane coatings, I was just wondering if there are other, you know -- you know, for example, are there consumer products for -- with polyurethane coatings that you might, you know, hobbyists or other people might be using as well?

PANEL MEMBER BLANC: Yes. I mean, that's what we were talking about before. All these coatings are not -- are available to the public. The question is some -- and some of these furniture coatings are HDI containing. And -- but I mean, if you just talk about isocyanates, you can go down to Ace and buy H -- isocyanate-containing glues, right? Some of the -- some of the super-type glues are not all epoxies, some of them are urethane glues. But I don't know which forn --

DR. DODGE: I don't think that's HDI, but it could be --

PANEL MEMBER BLANC: I think it's MDI is what I

guessed, but I'm saying it's --

DR. DODGE: MID Is probably -- yeah.

PANEL MEMBER KLEINMAN: Okay. But -- okay. Great. Thank you.

So I have some, you know, other, you know, marginal notes I'll send to you. And hopefully those will help. Okay. Thank you.

DR. DODGE: Okay. Thank you.

PANEL MEMBER BLANC: Can -- there's -- his comments brought to mind a couple things I wanted to say. One is that I would differ a little bit. Already, there is a lot in here about IgE and IgG. And, in fact, it's really not understood with isocyanates what these things mean. And it's not clear to what extent the inability to identify IgE as a technical problem with what you're -- what the conjugate is that you're using, because this is a small molecule that binds to larger molecules.

So I don't think you should go down the rabbit hole too much about what -- what is the precise mechanism at that level. But I do think that when you talked about irritant-induced asthma, which clearly has happened, and that is a complication of all of the isocyanates - they're pretty potent irritants. They're not just sensitizers - that you had a statement -- I didn't even circle it, I don't think, but where you said that irritant-induced

asthma is not immunologic.

Well, that's not probably correct at all. It's just not classic sensitization immunology. It's obviously there's immunology involved. It's just not clear what the chronic inflammatory immunological factors are. So I don't think it's necessary to go out on these limbs or be as definitive about some of these things, that which is related to my other comment.

And two other points I forgot to bring up. One of them is I was really interested and surprised at the data on the release of monomer from thermal breakdown, which just surprised me chemically that you could do that. I wouldn't have thought that possible. I know that you can release cyanide and all the other small things.

And that means I suppose every time that there's a large fire in California, you would be releasing some amount of isocyanate monomers, not just cyanide and nitrogen and oxides.

DR. DODGE: Right. It seems to depend on the heat, yeah, how hot they are.

PANEL MEMBER BLANC: So are there no data whatsoever from, you know, urban wildland fires or large conflagrations? But I'm just saying no -- but nobody has bothered to measure this in California?

DR. DODGE: Not that know of.

PANEL MEMBER BLANC: CalEPA has never tried to measure. And you're -- you're solid about the data -- the papers you cite about the thermal, right?

DR. DODGE: Yeah, those are the ones I could find, yeah, regarding the issue of burning the material. But I -- you know, I could do a more thorough search and see if there's thinking else.

PANEL MEMBER BLANC: I mean, clearly, the implications are rather large for a potential air contaminant exposure, right?

DR. DODGE: Um-hmm, yes.

DR. BUDROE: Part of that may be due to the fact that that's more of a accidental release. And, you know, the State agencies that might do air monitoring like, for example ARB, are looking more at facility emissions that are kind of a day-in day-out thing, rather than something that's, you know, impromptu, you know, a wildfire, a large chemical spill, something like that.

PANEL MEMBER BLANC: I guess I would counter argue that we can predict that there will continue to be large wildland fires that includes structural destruction, where urethanes are likely to be found.

DR. BUDROE: Right. Well, I'm talking that's been the past paradigm whether that needs to be --

PANEL MEMBER BLANC: Right. Right.

DR. BUDROE: -- should be considered continued for the future, might need reexamination.

PANEL MEMBER BLANC: Right.

And then my final --

PANEL MEMBER GLANTZ: I think -- I mean, I think Paul raises a good point, but I don't think he's suggesting that you go rewrite the report.

PANEL MEMBER BLANC: No, no, not at all.

PANEL MEMBER GLANTZ: I think it's just a comment that would probably be worth adding.

PANEL MEMBER BLANC: Yeah. You know, there's a successes - I couldn't find it right now - where you say just before you get to the REL -- I think it's before the chronic REL, where you say -- you sort of reiterate the rake of adverse health effects that -- that HDI could have. So you talk about asthma, and you talk about other things, irritation, so forth, so in that context where you talk about it more globally. I don't know, but it's -- it might be.

CHAIRPERSON ANASTASIO: Kathy, do you have something to add?

PANEL MEMBER HAMMOND: Certainly I agree with what Paul is saying. I think that we need to think about fires. And certainly the large wildfires are important. But I think structural fires in the City or anywhere would

also release these. You do have a section where you talk about if it's under 350 degrees, you get this kind of release of chemicals, and it's over 350. So there's some scientific data, maybe laboratory basic data it looks like.

But I think it is worth pointing that out, because fires are routine. I mean, even if they're just residential fires, car fires, if we start -- if these can be released, then these are places where people can be exposed. And certainly I understand why we haven't monitored that to date. These are very difficult compounds to monitor. And you don't just kind of pick up a pump and go with them. You have to be prepared for that, but it may be something to think about.

But it might be worth adding a few sentences that this could be a significant exposure in cities and in -- any -- anywhere cars and houses burn, as well as wildfires that go over other areas.

PANEL MEMBER BLANC: And this -- it also relates to the long involved section about how many people would you anticipate in the California population are pre-sensitized to isocyanates. And you went through a lot of stuff about that. At one point - I left a note for you - but you said you really referred to the incidents of occupational asthma. But the incidents is actually

irrelevant. What you care about is the prevalence, because people don't have it and then it goes away, so once they're sensitized.

So if you had an incidence of 2 people per million per year, and they're going to sensitized for the rest of their lives. And then their average life is another 40 years, then it's 80 per million is the prevalence in the population. So that's one thing.

But the other thing is the places where people are sensitized are likely to be geographically concentrated near the sources where they got sensitized. So it's a very -- what you did is very, very conservative, even so, you know, because if I got sensitized at the auto body shop that I work in in the mission in San Francisco, which is probably -- I live not so far from the auto body shop in the Mission, where I got sensitized. I don't live the Dunsmuir and commute to work in the auto body shop.

So the cases of people who are sensitized are not evenly distributed across the population of California. And then also, you need to be very cautious. You actually, at one point, say people who have airway hyperresponsiveness will be more responsive to isocyanates, be hyperresponsive to the irritant effect of -- now you're not talking about being sensitized. You're just talking about --

DR. DODGE: Right.

PANEL MEMBER BLANC: -- what happens when someone has airway hyperresponsiveness and they're exposed to an irritant. But you have to be very cautious when you say that, because the data are actually not cross-chemical -- chemically affirmative of that. So for sulfur dioxide, people who are hyperresponsive are clearly much more responsive to sulfur dioxide. But if you look at ozone, people who are hyperresponsive are not particularly more sensitive in a predictable way to concentrations of ozone.

So just when you say things like that, you should -- they're probably not necessary exactly to your argument. I'm just not sure. And I know that's part of the argument with children have asthma -- in children, but you should finesse it in some way, if that makes sense -- if what I'm saying makes sense.

DR. DODGE: Yeah, I think so. That statement about hypersensitive people. It's -- it was part of our REL development. And we described -- you know, we tried to describe who we're trying to protect and who they can't protect --

PANEL MEMBER BLANC: Well, you could say they --

DR. DODGE: -- with these RELs.

PANEL MEMBER BLANC: -- it's conceivable that they might be, or something, but it's not a --

DR. DODGE: Yeah.

PANEL MEMBER BLANC: And finally, the one last point that I wanted to bring up and I forgot was the data which are quite robust on cross-shift change from exposure to isocyanate that you have decided some --

DR. DODGE: Cross-shift, you mean --

PANEL MEMBER BLANC: Cross work-shift change.

DR. DODGE: Um-hmm.

PANEL MEMBER BLANC: And these are people who are not necessarily sensitized, right?

I mean, you take a group of workers, and you look at the whole group of workers and you say the cross-shift fall in FEV1 related to exposure is X, right?

DR. DODGE: You mean the change from their respiratory function compared to before and after exposure in the same day or the same week?

PANEL MEMBER BLANC: Yes. Yes. Yes. Yeah.

DR. DODGE: Yeah.

PANEL MEMBER BLANC: It's usually the -- it's usually across one shift, but you can do it across the workweek.

DR. DODGE: Um-hmm.

PANEL MEMBER BLANC: Are those data not at all relevant to the acute effects of...

DR. DODGE: Yeah, that is a good question.

PANEL MEMBER BLANC: I mean, you've already used the study for the chronic and the subchronic, right -- 8-hour and the chronic. You've used the human data. Although not the cross-shift data, I guess. It was decremental lung function over time.

DR. DODGE: I think what you're describing is a possibly that it could be like a recurrent acute effect. Maybe they're normal.

PANEL MEMBER BLANC: Yes. Yes.

DR. DODGE: You know, everything is fine, and then the --

PANEL MEMBER BLANC: And I'm not saying that you redo your acute REL substituting those data for the animal study that you used. But it might be worth alluding to it in your narrative of acute effects, or saying in your --

DR. DODGE: I see what you're saying, yeah.

PANEL MEMBER BLANC: Where you do discuss it, which is in the chronic health effects section, you might say something about this could potentially be considered an acute effect as well.

DR. DODGE: Okay. Yeah. Because these workers have been exposed for some time and you start seeing these effects just with cross-shift changes, you know, I don't know how much a factor that their previous exposures, you know, of months and years had with these changes. So

it's --

PANEL MEMBER BLANC: Well, the only way to --

DR. DODGE: It's kind of a difficult issue.

PANEL MEMBER BLANC: The only biological way to say that it's related to how long they've been exposed is if they've become sensitized. But if they haven't become sensitized, then there isn't a particular reason to invoke the chronicity of it. At least I wouldn't ignore it altogether. I wouldn't change something fundamentally that you've done, but I think it's worth shout -- give a shout out to --

DR. DODGE: Okay. Yeah, I understand.

PANEL MEMBER BLANC: -- is what I'm saying.

DR. DODGE: Um-hmm.

CHAIRPERSON ANASTASIO: Okay. Thank you, Paul. Thank you, Mike.

I'd like to go around now to the other Panel members. We'll start with the veterans and then I'll go to our newcomers.

Kathy, would you like to start?

PANEL MEMBER HAMMOND: Thank you.

Just adding a few things. I want to thank you for --

THE COURT REPORTER: Can you pull the mic closer?

PANEL MEMBER HAMMOND: Closer. Okay. Is this

better?

Okay. I want to thank you for including the amount of air breathed during the workplace is 10 cubic meters. And it's different at work then when you're sleeping. That's really nice to see that. I hope your friends at the pesticide area could learn from you, but I'll cite that. Thank you for that.

And also, I want to thank you for talking about the fact that exposures didn't show up in the school study doesn't mean there aren't problems. And in previous studies such as perchloroethylene many years ago, a couple decades ago, ARB found that from auto repair shops - something similar to spray painting here - the -- using spray cans that have perchloroethylene in them led to neighborhood levels of perchloroethylene that were deemed to be sufficient to cause -- present a carcinogenic hazard to the neighbored. So given that kind of background, this would follow from that. So I think you're totally justified in all of that.

I have a few little things. One is that you go back and forth in different places in the document between ppb and ppm, micrograms and milligrams per cubic meter. And I think we've talked before. I think it's better if try -- try to keep it in one of those units for most readers, you know, to make sure that they can follow.

DR. DODGE: I do try to do that, but sometimes the number of zeros past the decimal point just gets too many to handle. If I --

PANEL MEMBER HAMMOND: Yeah. Well, actually what happens is there's like 0.035 ppm, and 35 ppb is easier to -- so it actually -- anyhow, it's a suggestion.

A smaller error, I think, would be on page 7, lines 125 and 26, you say that the ceiling concentration is 1 milligram per cubic meter, which would be 1,000 micrograms per cubic meter. But then if you go down to line 141, you say the short-term ceiling limit is 140 micrograms per cubic meter.

Unless I've misread something there, I think 140 is the -- the longer term. It's the 8-hour time-weighted average number, not the ceiling number. Do you follow what I'm saying?

DR. DODGE: Yes, I'll correct that, if that's necessary.

PANEL MEMBER HAMMOND: Okay. Yeah. Right.

In Table 1, I would like to see more data that -- you do cite papers that have more exposure data, so -- but I'm always looking for more exposure data some place to say that. And -- but that's kind of your call. I don't -- it's not important.

And this is a question both for you and maybe

Paul. On page 26, line 716 you mentioned in rare cases hypersensitivity pneuomonit -- pneumonitis, that's actually really quite serious. And I didn't know if you -- I may have missed it that you talked about it later, but that this has been associated with spray painters using HDI.

I don't -- didn't see that come up later. I forgot to do a search. I meant to and I forgot to.

DR. DODGE: I think that might be the only place I mentioned it.

PANEL MEMBER HAMMOND: Right. I mean -- and I would defer -- I would really defer to Paul on that.

PANEL MEMBER BLANC: I think what she means -- you know, I asked ask you about that section where you talk about in summary, HDI can cause asthma and can cause irritant-induced -- allergic asthma and irritant-induced asthma with high exposures. That would be the place to circle back and say, "In rare cases has been associated with hypersensitive pneumonitis". It is very rare. And most of the rare cases, even as rare as they are, have been TDI to my understanding. So I would be double sure that those were well documented to be HDI, and that you didn't pull that from a generic --

DR. DODGE: No, I wouldn't -- I wouldn't -- I wouldn't include it if it was TDI, but I can check to make

sure.

PANEL MEMBER BLANC: Double check that it wasn't a generic statement.

DR. DODGE: I was -- I'm pretty sure it was the HDI-based polyisocyanates that these people were exposed to.

PANEL MEMBER BLANC: Yeah. Yeah.

CHAIRPERSON ANASTASIO: Let me interject here.

PANEL MEMBER HAMMOND: Yeah, I'm sorry.

CHAIRPERSON ANASTASIO: Just. We have lunch waiting for us, and we have another agenda item after lunch. So Panel members, if you have small corrections, I'd ask that you email them to John. Are you the point of contact?

DR. BUDROE: Yes.

CHAIRPERSON ANASTASIO: Okay. So if we have small corrections, typographical errors, or things that don't quite make sense, please email that to John. If you have larger matters, let's have the discussion of those now, okay?

PANEL MEMBER HAMMOND: Just one last thing. The Cassidy paper ends up being pretty important for your study, right, for all of this? You're depending on that. And I notice it's true that they said that they did not have an effect. And I was going back looking at the

paper, and, in fact, the controls had more pulmonary function loss than the people who were exposed.

But the controls were people who were exposed to other materials. And I think it makes me have some hesitation about the paper.

I mean, certainly to say that -- I mean, I'm not clear that there's no effect, because the controls have -- are exposed to rare earths. I don't know anything about the rare earths and how they affect the lung. But they also are exposed just to plain particulate matter at very high levels, averaging from 900 to 6,200 micrograms per cubic meter. And again, I think those would affect lung function.

So the controls have this other exposure that's affecting lung function. And so the fact that there was no affects seen in the exposed workers might -- there might even be a healthy worker effect or healthy survivor effect, where only healthy people went into that work. They're just issues that one would worry about. And it is an industry-sponsored study.

So thank you, but good work.

DR. DODGE: Oh. Thank you.

CHAIRPERSON ANASTASIO: Thank you, Kathy.

Joseph.

PANEL MEMBER LANDOLPH: Yes. Hi. I thought t

was a very nice document. I mean it's very clear you guys worked very hard on this and your colleagues, reviewed by 3 reviewers, including Dr. Budroe. So it's very solid document. It can get tedious in points -- at points, but that's just because there's so much data in it.

I had a question. If I understood you right that the monoisocyanates don't produce asthma. And I was thinking why should that be? And are you getting a -- maybe a cross-link on a protein, and that's making it more haptogenic or something, is that known?

DR. DODGE: I don't know if it's known for sure, but that's probably one theory, yeah.

PANEL MEMBER LANDOLPH: So it might be worth, you know, a line or two on that.

And I had another question. Thinking about the reactivity of HDI, it reminded me of the, you know, benzopyrene diol epoxide, because I'm a carcinogenesis person. And the question I had was does HDI bind to the DNA of cells, is that known? And what provoked me to think about that was, A, its reactivity, and B, the squamous metaplasia and hyperplasia that you're getting. And I wonder if they've done a 2-year study on any of these compounds?

DR. DODGE: I -- you know, since this was a non-cancer document, I really didn't look into the cancer

end of things. I know there's a problem with TDI and there's some concern about that particular compound being carcinogenic, but I'm not sure about HDI.

PANEL MEMBER LANDOLPH: Has been -- TDI been listed as a carcinogen?

DR. DODGE: I am -- I don't think so. John, do you have anything to add?

DR. BUDROE: Not -- I don't think so either, but we'd have to go back and check to be absolutely sure.

PANEL MEMBER LANDOLPH: Okay. So those are just some thoughts for you. Yeah, on page 54, there was this discussion about the hyperplasia and the squamous metaplasia being linear as a function of dose. And right away I started thinking about carcinogenesis again. So maybe there are some -- some hints that there might be carcinogenesis to watch out for.

Let's see, on page 93, there's this discussion about these changes being adaptive rather than adverse on lines 20 -- I'll write this down for you -- 2587 to 2590. I thought maybe that was a -- clearly a value judgment. I'm not so sure the authors are right on that. You know, they keep mentioning their adaptive rather than adverse. And I'm not so sure that that's true.

On page 94, you discussed a large genotoxic diversity. I don't know what that language meant. It was

page 94 line 2614. I think you were trying to say something, but I couldn't figure out what it was.

DR. DODGE: Oh, okay. I'll clear up that sentence.

PANEL MEMBER LANDOLPH: It just looked like it could be said more simply.

DR. DODGE: Okay.

PANEL MEMBER LANDOLPH: And I think -- I think that's it. And I'll send you some of these notes to make it easy for you.

DR. DODGE: Okay. Thank you, Dr. Landolph.

PANEL MEMBER LANDOLPH: But I enjoyed reading the document. It's a hell of a lot of work, and it's a very interesting document.

Thank you.

CHAIRPERSON ANASTASIO: Thank you, Joseph.

Stan.

PANEL MEMBER GLANTZ: So I also thought you did a really nice job. And I -- I mean, I always start by reading the public comments and the responses to comments. And I thought you did a good job on those. And the one thing that I, you know, think about a lot of are the applications of the uncertainty factors. And I thought you did that properly, and, you know -- and justified what you did, so that's my comment.

The other thing I guess I would add, unless one of the people who hasn't spoken yet comes up with some fundamental problem nobody's identified at the end, I think -- and there's been no question about the actual RELs. So my -- at the end, I'm hoping we can like tentatively approve the document, so we don't have to have it come back, because it is very -- I thought it was very nicely done, as I said.

CHAIRPERSON ANASTASIO: Yeah. Thank you, Stan.

Now, we'll get to our new members. Lisa, would like to start? Any comments?

PANEL MEMBER MILLER: I guess I just wanted to echo some of Paul's --

THE COURT REPORTER: Pull the mic a little closer.

PANEL MEMBER MILLER: Oh, sorry.

Can you hear me now?

(Laughter.)

PANEL MEMBER MILLER: Okay. So I wanted to echo some of the comments that Paul made about the definition of asthma sprinkled throughout. I think it's really -- particularly for what you're describing here, I think it's really, really important to define what that is, because we know in human populations that this disease is highly -- I mean -- that's redundant. It's heterogeneous

without question.

And I think a few sentences indicating this for the reader who is not familiar with this disease phenotype. Particularly in humans, it's -- it would be imperative to clarify that. In this case, asthma is -- I suspect in all of these -- in the human studies, asthma is specifically defined as based upon clinical diagnosis and not by mechanism. And I think that's important, because that has implications back to how -- whether HDI or the polys are triggering these responses.

So it sort of gets you out of the trying to pigeonhole some of these pathways or some of these -- either HDI or polyisocyanates into a specific mechanism, because we just don't know what those mechanisms are.

So again, I think clarifying the heterogeneity of asthma would help the reader. And understanding that just because you have airways hyperresponsiveness doesn't necessarily mean you are atopic, for example, right?

The other -- the other part that sort of raised my antenna was the description of the immune responses here. You have to be careful that just because you don't see IgE or IgG doesn't necessarily mean it's not there. It just could be that you didn't wait long enough to actually detect that response.

So because it takes -- it can -- it takes a

couple -- at least a minimum of a couple of weeks to elicit this -- a specific response to anything. So I think just because you don't see it, doesn't necessarily mean you don't have a response. I think that needs to be clarified.

And then just a comment. Last but not least, I was really struck by the paucity of data on -- in both infants and children. And, you know, certainly that that's an area -- that's a significant data gap. And I understand that the exposure levels are -- you know, are calculated to take into consideration the susceptibility of children to these compounds, but I think it would also be helpful to clarify that just because we don't have data on this population doesn't necessarily mean that these levels -- or the calculations -- I don't know if you can specifically say this, but it doesn't mean that -- that these extrapolations are, you know, accurate.

And, in fact, they may even be more susceptible than what you're proposing to -- you know, in terms of the exposure level, so I just want to stop there.

CHAIRPERSON ANASTASIO: Thank you, Lisa.

Ahmad, any comments.

PANEL MEMBER BESARATINIA: Yes. I wanted to echo all the other Panel members. It's a large body of work. Excellent. I just wanted to follow up on your response to

comment 8 of the ACC, their first set of comment, which you highlighted in your presentation.

On page 22, the upper slides, the last paragraph, you put forward this model that isocyanate may react with proteins, particularly albumin and form adducts. And these adducts might elicit immunoreaction, be immunogenic, and you have also indicated that the GS -- the genotype might influence this process, meaning that reduce GSH can result in higher levels of albumin adducts.

My question is I've been through this draft that was provided. I didn't see any human biomonitoring studies that basically back-up this proposed model. And I also checked the literature. There are just a couple of in vitro models. I was wondering what your thoughts are on that?

DR. DODGE: I -- I don't really have anything to add about that. There are some studies out there that you're probably aware of - I might have mentioned them in the document - that look at these kinds of relationships, you know, what the adducts formed and -- but I just don't have anything to add more than that.

PANEL MEMBER BESARATINIA: Yeah. There were a few genotyping studies, SNP studies, for GSDs, but they were looking at other endpoints. I was just wondering if you can find somehow -- as I said, there are a couple of

in vitro studies, which may help strengthen your argument here. Maybe you want to take a look at them.

DR. DODGE: Sure. Why don't you send them to me, because I -- yeah, we -- we often don't refer to in vitro studies in our documents that much, but, yeah --

PANEL MEMBER BESARATINIA: That's because of the lack of --

DR. DODGE: -- I'd be happy to take a look and summarize, yeah.

PANEL MEMBER BESARATINIA: -- yeah, in vivo studies. Yeah. And given the highly reactive nature of these compounds, the likelihood of these chemical interacting with albumin, I think it's -- it still remains a matter of question, so they can come back and --

DR. DODGE: Okay.

PANEL MEMBER BESARATINIA: Thank you.

CHAIRPERSON ANASTASIO: John.

DR. BUDROE: Just a quick note and -- about Dr. Landolph's question earlier, TDI is a carcinogen. It's listed in Prop 65. We have a hot spots cancer potency value you for it.

CHAIRPERSON ANASTASIO: Thank you, John.

Thank you, Panel members, for all your comments. I would like to encourage everyone, again, to send your smaller comments to John. And also some of the discussion

we had, I think it would be helpful -- lisa, for example, your points, if you could send those to John, so that they could incorporate that into the documents. From what I've have heard, in echoing what Stan had said, you know, our comments really don't change at all the RELs. So that's very solid, and that's the most important piece of the document.

But we do have a number of comments that we think will improve it. But I would recommend that we don't have an additional meeting on this, but rather that the Chairs perhaps look at the revised version to make sure that their comments are properly incorporated. And so I cannot remember now what the process is. Stan has been here much longer than I have.

PANEL MEMBER GLANTZ: So the process -- yes, since I'm the oldest.

PANEL MEMBER BLANC: I'd like to move that we accept the document as submitted with the proviso that the comments are addressed in minor revisions.

PANEL MEMBER GLANTZ: And that the Chair have the authority to sign-off on behalf of the Panel.

PANEL MEMBER BLANC: Right. And so basically it comes to you, and if you have any questions, you could run them past any of the Panel that you might want to.

CHAIRPERSON ANASTASIO: Okay. That's sound good.

PANEL MEMBER GLANTZ: Second.

PANEL MEMBER KLEINMAN: I have a question or discussion on it. In the document, OEHHA is recommending that HDI and HDI polymers be designated as a toxic air contaminant. Now, I know we went through a lot of discussion about the need -- you know, what that means for chlorpyrifos. And I didn't remember that being part of the discussion with TDI or -- you know, previously. So I'm just wondering does that automatically happen? Does it -- you know, if the document is approved, does it become a TAC, or is that another step, or --

DR. BUDROE: Well, HDI has already been identified as a TAC by virtue of its status as a federal hazardous air pollutant, or HAP. So it's already a -- it's already a toxic air contaminant.

And the one section we have in -- the chemical as a toxic air contaminant especially affecting infants and children, we do recommend that it be identified as a TAC that may disproportionately impact children, pursuant to the appropriate Health and Safety Code section. But it is already a TAC.

CHAIRPERSON ANASTASIO: Okay. Great. Thank you, John.

So we had a motion. We had a second. So let's have a vote. Essentially, that we will have OEHHA submit

the revised document to me, and then assuming everything looks fine, it will be approved.

All in favor?

I can't remember. Does this need to be a voice vote?

PANEL MEMBER KLEINMAN: Aye.

CHAIRPERSON ANASTASIO: No.

THE COURT REPORTER: I don't know. I can't tell you what to do.

PANEL MEMBER BLANC: No, it's fine. You just note in the minutes that it's approved unanimously.

CHAIRPERSON ANASTASIO: Okay. I'll just make a count.

Okay. So all in favor?

(Hands raised.)

CHAIRPERSON ANASTASIO: All right. Let the record reflect that that was unanimous in favor of the motion.

So this then wraps up the Panel's required actions on the HDI document. Thank you again to OEHHA.

We will now take let's say a 25-minute break for lunch. Lunch has been brought in for the Panel. And we will reconvene at 12:50 for the AB 617 presentation.

Thank you very much.

(Off record: 12:25 p.m.)

(Thereupon a lunch break was taken.)

A F T E R N O O N S E S S I O N

(On record: 12:51 p.m.)

CHAIRPERSON ANASTASIO: Okay. We're back. Welcome back from lunch, everyone.

Our third agenda item today is an update on the implementation of Assembly Bill 617 creating the Community Air Protection Program. This Panel is specifically listed in the law as a resource for CARB staff to consult when implementing the legislation. And as you remember, we were briefed and discussed -- and we discussed AB 617 in three of our meetings last year.

Since our last meeting in July, CARB adopted the program blueprint and made their selections of the initial 10 communities for the program. And they also adopted an emissions reporting regulation that makes things more uniform across the state.

Today's presentation and discussion is going to focus on a few items. One is something we talked about at our last meeting really defining an ongoing role for the SRP with AB 617. And then three other topic areas will be presented for our consideration.

I would like -- this is going to be the time I was going to remind people that we had a Spanish interpreter, but we don't appear to have a Spanish interpreter right now, so we'll just leave it at that, I

guess.

So next I'd like to turn the meeting over to Karen Magliano who's the Chief of CARB's Office of Community Air Protection. ANd she's going to present this agenda item, and she'll introduce the other speakers.

Karen.

(Thereupon an overhead presentation was presented as follows.)

OCAP DIVISION CHIEF MAGLIANO: Great. Well, thank you, Cort. And thank you, everybody. I know you've had a chance to have a quick lunch, and then we will dive back into this next agenda topic.

And in the spirit of interagency collaboration we have multiple speakers and multiple agencies this afternoon that will be covering different aspects of the program.

So I'm going to start with just a very short recap of the program itself, and what's happened in the, I think, 9 months since we actually last met, and then turn it over to John Faust from OEHHA to really get into some of the things that we were talking last time about. What's that continued role and engagement with the SRP? We've had several conversations with the Chair and members, and this is sort of a follow-up to that.

And then we'll close with Dave Edwards of CARB

and Pam Wofford of DPR to talk a little bit more about some of the other aspects of the program that are really going to help provide data to support these areas where we think we can continue to coordinate with the SRP.

So with that, if we can go to the next slide.

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OCAP DIVISION CHIEF MAGLIANO: I just covered sort of the topic areas that we're going to go over here. So why don't we go to the next slide.

--o0o--

OCAP DIVISION CHIEF MAGLIANO: Again a quick recap. Last September, our Board took a number of different actions related to the program. The legislation laid out a very ambitious time frame and specified that we needed to come back to our Board to really get the program up and rolling. So one of the first things that they did, if we go to the next slide --

--o0o--

OCAP DIVISION CHIEF MAGLIANO: -- is adopted what we're calling the Community Air Protection Blueprint. And what this does is layout the broad program requirements, and, in essence, operating instructions for the program.

So that includes both statewide strategies that both we and the local air districts are embarking on, both regulatory measures, incentive funding and other kinds of

tools and resources that are being developed, but then also lays out specific criteria for focused action that it's going to be taken in a number of initial communities across the state.

So the blueprint talks about how do you do that in partnership with the communities, and strong public engagement, and community partnerships. It lays out the process and criteria, which we went through last year, in identifying those communities, and what we'll be doing every year, because the legislation actually says that every year we need to go through another consideration process to look at the potential for adding additional communities to the program over time.

And then the final two pieces are laying out the criteria for how you conduct effective community-level air monitoring, how you define the objectives that you're looking for, and then given that, what are the kinds of approaches that need to be looked at with a particular focus on you're collecting data to support subsequent action to develop strategies to reduce both emissions and exposures in these communities. And then, of course, using that to help develop community emission reduction programs.

And so what the blueprint does is it outlines sort of the scope of things that need to be looked at, the

types of technical information that needs to be developed, and then the process of working with communities in pulling together those programs.

Next slide.

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OCAP DIVISION CHIEF MAGLIANO: So as I mentioned, the Board also approved 10 initial communities to launch the program, which are shown on the map here. The orange dots indicate the locations of those 10 communities, and the blue color highlights the local air districts where those communities are.

PANEL MEMBER GLANTZ: So that's happened since we last met?

OCAP DIVISION CHIEF MAGLIANO: That's has all happened, right. So both beth approval of the blueprint and approval of these 10 communities has happened since we last talked to you, I think it was, in June or July of last year.

And the goal here was really to select a diverse mix of communities across the state, that captured a lot of different kinds of pollution challenges that we know a broader set of communities across the state face, with the idea that these can then serve as models for similar communities as we grow the program over time.

I'm going to talk a little bit more, and with

some background, about sort of a high level profile of these communities later in the presentation, but just wanted to tee up that this is sort of our starting point here.

And then last slide.

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OCAP DIVISION CHIEF MAGLIANO: And then as I mentioned, in each of these communities, the air districts are working with local community steering committees that they've convened. And these steering committees are against supposed to represent a mix of different people from the community. So not only community residents, but bringing in local government who often has a role in decision making in processes that affect these communities, as well as local industry stakeholders, because we want everyone to be together at the table, as well as encouraging local public health officials to participate as well.

So just as we had a ambitious schedule for getting the blueprint and the 10 initial communities chosen, there's also very ambitious schedules for the air districts to now work with their communities and develop these programs.

So community air monitoring needs to begin by July of this year, so really just a few short months from

now. And then the community emission reduction programs need to be taken through the local air district boards by September of this year, and then they actually come back to our Board. And then we'll also be going through a process of continuing to look at the potential for adding additional communities that we'll be coming back to our Board with later this year.

So that's kind of the broad background context. And, Cort, I didn't know whether you wanted to pause for questions or kind of jump into the heart of the presentation, and then maybe have an opportunity for questions.

CHAIRPERSON ANASTASIO: Yeah. Why don't we save questions for the end.

OCAP DIVISION CHIEF MAGLIANO: Okay.

CHAIRPERSON ANASTASIO: But are you finished with your portion?

OCAP DIVISION CHIEF MAGLIANO: I'm finished with my slides. So now I would turn it over to John Faust of OEHHA.

CHAIRPERSON ANASTASIO: So let me say one thing, John, before you again. So we have our Spanish Interpreter. If there's anyone who would like interpretation, please let us know.

(Thereupon the interpreter spoke in Spanish.)

CHAIRPERSON ANASTASIO: Okay. Thank you very much.

DR. FAUST: All right. Thank you. Yeah. So good afternoon. I'm John Faust with the OEHHA, and Chief of its Community and Environmental Epidemiology Research Branch. So what I'm going to do is present on some scientific topics that OEHHA and CARB would like to advance in the coming years and take advantage of the expertise of this group where we can.

So the presentation I'm going to make largely follows the material that we've assembled in a short document that was distributed to you and is available in the back of the room.

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DR. FAUST: But first, I'll just touch briefly back on the statutory role for the SRP and the implementation of AB 617. The law gives the SRP a consultation role in two different areas. One in the preparation of an air monitoring plan regarding the availability of toxic air contaminant and criteria air pollutant advance sensing monitoring technologies, and existing community air monitoring systems, and the need for and benefit of establishing additional community air monitoring systems, as well as CARB's preparation of the statewide strategy, both of which you have seen materials

from in the past year and Karen just recently touched on.

So here, we're proposing to engage the SRP role in several areas that relate to the efforts currently underway in AB 617. So this slide identifies briefly sort of these -- these three scientific topics. And I'll go into a little bit more detail shortly.

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DR. FAUST: But these areas are, one, health risk values for contaminants in AB 617 communities, the second is addressing cumulative exposures in communities, and the third is tracking community health benefits through indicators.

So for each of these three topic areas, and this follows the material that was distributed, I'm going to talk a little bit about the background around why we feel the topic is important, sort of describe our overall approach, what some products we could produce which would be sort of where the intersection of the SRP's role would be, and a little bit about the timeline at least for this initial phase, knowing that this is sort of the beginning of a new phase of the work, where we're going to be looking to provide -- basically, support for the information that's becoming available through the program.

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DR. FAUST: So just to go to the first -- first

topic area. So the air monitoring and emissions reduction efforts in the AB 617 communities is going to be generating extensive data on emissions in the presence of toxics in California communities. And of these specific chemicals that are identified, some are likely to be without existing health guidance values, like RELs or cancer potencies, or different types of information that might help make knowledge about levels of exposure meaningful to regulators and community members.

So there's this idea that there's going to be this gap that needs to be addressed. So we proposed to prioritize the work following the development of an inventory. And there's the possibility that filling these gaps can follow different -- different paths.

So, as I said, we prefer to first review available data sets on the air pollution and their levels across the selected communities, and then from this information priority substances will be identified for further evaluation. And these priorities would be reviewed by consultation and by public review. So we intend to have a -- an open process for moving this forward.

So I described two paths for potentially following up on the evaluation of chemicals. One is to use current methodologies and processes, much as you've

already seen, and, for example, the way you've discussed this morning, such as the development of reference exposure levels and unit risk factors for specific chemicals.

But we also foresee a need to be able to provide information to communities more quickly, if possible. So we're thinking about sort of another path that provides expedited methods for addressing or giving meaning to the levels of pollutants that maybe don't have existing health guidance values.

So, for example, read-across approaches could potentially be developed when already available data for data-rich substances are applied to data-poor substances, which may be considered similar enough to use --

PANEL MEMBER GLANTZ: What's a read-across approach?

DR. FAUST: Yeah. So -- so it's -- it's an overarching concept sort of where -- where we think about, you know, data-poor chemicals that have some similarities to more data rich chemicals, for example, structural similarities, or similarities in known pathways of toxicity sort of upstream pathways. So this is an area that we're very interested in developing it further. And towards that end, for example, OEHHA will be hosting a symposium this spring on read-across approaches to sort of

inferring toxicity from known data sets that could be potentially applied to more data-poor chemicals, for example, where there aren't, you know, existing long-term studies, for example.

So it's -- it's thought to be a way of sort of moving more quickly without weighting for all that additional information to be developed. And sort of on this vein, but a separate approach, would be to adopt values from other programs where we have some prior work that has been done either by other State programs or federal programs where there might be a chance to leverage that information to move more quickly in developing or looking into health guidance values that we don't have.

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DR. FAUST: So just to touch on the potential work products. So initially we proposed to produce a summary of the chemical-specific information that we're gathering in the AB 617 communities. And then using this inventory, we'd propose priority substances in the communities for the development of health guidance values, as well as the rationale for their selection.

And then from there, as a later phase, we'd propose new or updated health guidance values for these priority substances. And these would be reviewed by the SRP and the public as well.

So as for a specific role for the SRP, in addition to the sort of traditional role that you've had in evaluating documents of the type you've seen this morning, you could also review the proposed priorities that we provide -- that we document and provide input as to whether they're reasonable, and offer suggestions for adjusting those. And additionally, the Panel could provide input on proposed alternative approaches and their adequacy for characterizing potential risks from specific chemicals.

PANEL MEMBER GLANTZ: So if I could just ask a question. So are you -- so there's -- the role that we've historically played, as you saw before, is we approve things. So are you going to be presenting these things for us to approve or just to look at and give you advice?

DR. FAUST: Well, I think there may be an opportunity for both. I think when we think about sort of the pathways that chemicals follow, those that sort of lend themselves to the more traditional approaches, I think we'd want to put through in that way.

For sort of emerging approaches, particularly those that maybe aren't as explicitly identified in say existing methodologies, I think we'd want to get your input on sort of the appropriateness of those approaches, and any advice you might have on how to make that as

strong as possible.

PANEL MEMBER GLANTZ: Well, just -- you know, I mean, this is sort of an ongoing discussion, but -- and I'm not trying to make more work for us, but the -- you know, I think one thing to think about is whether -- I mean -- and I realize you're talking about a much more expedited process, and one where judgment is playing a bigger role in some of these things.

But you know, it might be worth actually having the Committee approve stuff to give you sort of an independent imprimatur. I'm not saying you should, but I -- you know, looking down the road and the people who are unhappy with what you come up with, you know, it might be worth the trouble.

I mean, if all we're doing is advising you, I mean, giving advice is a lot easier than approving things.

DR. FAUST: Okay. Thank you. I will definitely keep that in mind as we think about our options.

So just this last column just touches on the timeline. Karen had already mentioned sort of the timeline for the implementation of the air monitoring by July of this year, and the emissions programs getting in place by October of this year.

So we foresee the emissions inventories, for example, are going to be available this spring. And that

we'll be able to begin pulling that information together, as part of this process of identifying potential priority substances that we could -- we could bring forward. So we foresee that we could bring you information that starts this process by the end of this year.

All right. So unless there's other questions on this first item, I'll just --

PANEL MEMBER KLEINMAN: So if we have, you know, a point where the emissions inventories are pulled together, that would seem like a good point to get the Panel involved by, you know, providing the emissions inventories for the various locations. We could help with identifying, you know, where the key chemicals are, and begin to look at where, you know, improved guidance is needed. And I think that would be a way that we could be helpful.

DR. FAUST: Okay. That would be sort of in formulating our criteria for what might make a chemical move to the higher priority.

PANEL MEMBER KLEINMAN: Go back to, you know, the emissions reduction, you know, which emissions reductions can be, you know, very -- are going to require, you know, regulations and various things, and, you know, picking out where to start, and which would have, you know, the most impacts and that sort of thing. I think we could be

helpful with looking at some of that as well.

PANEL MEMBER GLANTZ: You know, just to add to that, I mean, that is a role we've played in the past, in terms of, you know, prioritizing things for listing with TACs in that bill that required identification of substance of particular concern for kids.

And so developing the kind of priority lists and helping come up with the algorithm for doing that is something we've done before, and where we ended up again taking a formal action.

I mean, the other thing where we might be able to be helpful, you know, we have developed these technical support documents which layout the rules for, you know, doing different kinds of risk assessments, which, in fact, came up earlier in the discussion about the RELs. And I mean it may be that going through a process of getting a formal approval for a new protocol for these -- the kind of things you were talking about earlier, you know, might well help you guys out in terms of when people come and challenge what you're doing.

DR. FAUST: That was a good suggestion. Thank you.

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DR. FAUST: All right. So at this point, I'll move to the second topic. So this one relates to

addressing cumulative exposures in communities. And part of the selection of the AB 617 communities is the recognition that these places face burdens from multiple sources of pollutants in their air. And there are different types of tools available that have been developed to assess cumulative risks and impacts.

For example, the methodology adopted as part of the Air Toxics Hot Spots Program enables the consideration of cumulative risks from multiple pollutants, including both carcinogens and non-carcinogens, but generally from singles sources. But this type of approach is data intensive and requires understanding risks from individual chemicals or mixtures.

Other approaches to evaluating cumulative impacts have been developed that use both quantitative and semi-quantitative information about multiple sources of pollution. Typically, these are applied at a -- to a geographic area, and the tools results screen to identify areas facing higher cumulative burdens.

So an example of this is OEHHA's CalEnviroScreen tool, which, through a series of indicators, is used to characterize different contributions to both pollution and different types of vulnerability at a screening level. So with this in mind, we plan to look at the data that are collected in the AB 617 communities to explore how we

might better understand cumulative impacts, as well as think about assessing and addressing them.

And we'll also consider how existing approaches are able to characterize this type of impact, and what novel approaches might be developed to more fully or accurately characterize the cumulative health risks from pollutants.

So in this case, we propose to develop case studies that could illustrate cumulative risk concerns, and characterize the extent to which current tools are able to address cumulative risks. And then following case studies, we propose to look at potential ways to supplement or enhance existing approaches to cumulative impacts analysis. And in this case, these materials would be brought to the SRP for comment.

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DR. FAUST: So with respect to timeline, the proposed work in this area is also dependent on the emissions inventories that are becoming available this year. And we'll be talking a little bit more about data that will becoming available in the coming years shortly. But it's going to be sort of an ongoing basis that we'll be learning about these emissions that are occurring in communities. And as new communities are selected, we'll be able to have opportunities to think about different

situations, in which cumulative risk concerns are present.

So the initial materials describing case studies could be brought to the SRP, as we've gathered this information as late as -- or as earlier as the end of this year. And then as a later phase, the SRP would be brought materials to propose ways of doing enhanced analysis of cumulative risk and impacts.

So I don't if there's any questions on this particular topic?

PANEL MEMBER LANDOLPH: Dr. Faust, so just as an example, I mean myself and Dr. Besaratinia sit in East L.A. You know, we work at USC at the Medical Center. So how is this going to start? Who is the lead on this? Who puts it together? Who gets it going?

DR. FAUST: Well, this would be jointly shared between CARB and OEHHA. I mean, we certainly have quite a lot of information available already about describing burdens in different communities. We know about certain sources. We know what sort of conditions exist. We have population measures that tell us something about potential vulnerabilities.

But there's going to be this new layer of information that takes a closer look in -- in the AB 617 communities, for example, probably at a -- at a deeper level than we have already. And we'll be starting to look

at how that information can be folded in or identified as new cumulative concerns that we didn't know about before, or basically it provides information that can illustrate more plainly what cumulative concerns might be present.

PANEL MEMBER LANDOLPH: And you understand you'll have to be careful, because some of these communities have not been treated well. You know, particularly the one where I am where they have Exide not far from there. So stuff like that can't be allowed to be waived for years, and years, and years, and years. It's got to be dealt with, that type of thing.

Okay. Thank you.

PANEL MEMBER BLANC: Isn't the most challenging piece of this going to be the impacts part, if what you're talking about is human health effects data?

DR. FAUST: Maybe you could say a little more about -- you mean, in terms of documenting by health endpoints?

PANEL MEMBER BLANC: Yes.

DR. FAUST: Well, that sort of gets to my third scientific topic that we're going talk about, where we're -- we're thinking about tracking benefits to communities from emissions reductions, and what sort -- of

PANEL MEMBER BLANC: Well, that would be prospective, but I understood that you -- part of this was

actually documenting what the cumulative impact has been up to this point or is it only -- you're only intending on tracking longitudinally changes over time after something is implemented?

DR. FAUST: Well, yeah, you're correct. The third item is sort of more forward looking and what sort of studies we can put in place.

Yes. The way -- I mean, the way we have looked at cumulative impacts has been somewhat retrospective, you know, in that we gather data about what we know about, sources in communities and how much -- how much -- what the emissions estimates are in communities.

PANEL MEMBER BLANC: No, I -- but aren't -- so you're not looking at health impacts at baseline, or -- you're only going to -- the only aspect of health -- of outcomes you're going to look at in terms of population health is going to be prospectively, because I had understood on what you just said, that there would be some element of looking at the cumulative burden.

DR. FAUST: Yeah. I mean, we do look at health data a little bit, sort of -- but more as a vulnerability factor, such as where there's high levels of -- or high rates of emergency department visits for asthma. And we sort of, at least for example for the CalEnviroScreen tool, we fold that information into what we call the

population vulnerability measures.

I mean and that's sort of this broad semi-quantitative way of looking at cumulative impacts, where you're basically describing places that host multiple burdens and have potential vulnerabilities.

PANEL MEMBER BLANC: So just to follow up, take the study that Dr. Hammond has been involved in for some time, the Fresno Childhood Study that John Balmes on the Air Resources Board is also involved in, are you conceptually thinking of looking at those data as part of the baseline what is the state of the health of the community, since Fresno is one of your communities?

DR. FAUST: I think it's possible. I have to say, I mean, this is sort of the beginning of phase. And we want to think about what sources of information are going to be helpful for characterizing those potential cumulative impacts.

PANEL MEMBER BLANC: I think there's also a big birth cohort in the Oakland area, isn't there, or Richmond, or includes part of that? I mean, there are -- I'm just curious if it's going to be a matter of what -- you know, what you -- if there's going to be some systematic way of you all trying to ferret out data that may already exist in terms of cohorts that are going to be relevant to your study?

I'm not sure, for example, if the USC-based childhood lung function communities include or are adjacent to any of the Southern California communities that you're interested in.

OCAP DIVISION CHIEF MAGLIANO: And I will just say that obviously making that connection directly to health impacts is a long-term and challenging endeavor. But what we have been doing in the near term at least is trying to pull together what are those existing data sets that are out there, and at least some high level characterization of, you know, what are the baseline health vulnerabilities that are in these communities? And then what John is talking about here is then how do we sort of start building forward from there?

PANEL MEMBER LANDOLPH: I meant to ask on the first page that you had, the first 10 areas were they chosen on the basis of uniquely bad toxins and carcinogens, and bad levels of these, and high exposure to people? What was the chief criterion that provoked picking these 10?

OCAP DIVISION CHIEF MAGLIANO: They were -- and I'll go into a little bit more detail after John. But basically, they are all in the very high percentiles in CalEnviroScreen, for example, especially when we look at things like toxic air contaminants, PM2.5, diesel

particulate matter. They also all had high levels of poverty, low income, so sort of that social economic vulnerability. And then they also all had very high indicators of health indicators that are often typically related to air pollution.

So within that, then sort of our next tier was then to look at how do we get a good mix of different kinds of pollution challenges within all those highly impacted communities?

PANEL MEMBER LANDOLPH: Thank you.

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DR. FAUST: Okay. So I'll turn to the third topic. So the third one relates to the tracking of community health benefits that may occur as a result of emissions reductions. And this is a topic that's already received a great deal interest across different groups with respect to both the AB 617 program and the State's Climate Programs.

So potential exposures, doses, and subsequent health effects can be assessed with different degrees of ease and reliability. And here, the issue is around both scientific and data challenges, as well as how studies can be conducted successfully in communities to demonstrate benefits.

There are some available data and emerging tools,

such as data that come from biomonitoring or biomarker studies that can tell us something about exposures or changes in exposures. And health outcome data are also potentially useful for this purpose. So our proposed approach here, in contrast to the other topics, is to develop a stakeholder engaged process, and convene experts in a -- in a public forum or symposium. And here, we would introduce the relevant scientific topics, consider challenges, and move towards identifying potential near-term metrics or measures that may be helpful.

So here, we'd like to invite the SRP members to participate as the -- as experts in their various disciplines, as part of a group with others, as well as AB 617 community members to consider information on this topic.

So here, the work product, at least in the beginning, is a public symposium or a forum with presentations and participation by experts in relevant fields. And ultimately, we'd like to see how this sort of effort can be applied in a community environment. So we'd like to include a focus on approaches that used community-based participatory research.

So some of the topics could include whether there's potential for the use of biomonitoring or biomarker studies and data, how health outcome data can be

collected and used effectively, and what sort of best practices can be applied in community-partnered research efforts conducted by researchers.

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DR. FAUST: So just regarding the timeline, I think we're thinking, given sort of the emerging data for this year, this is something that would be initiated in the early part of next year.

PANEL MEMBER GLANTZ: Well, you know this is an area where I think the research that's been done on secondhand smoke can be very, very informative, because there's a quite good literature showing, for example, when you pass clean indoor air laws, heart attacks drop or asthma admissions to hospitals, strokes, complications of pregnancy, you know. And these -- these effects occur pretty quickly. And it's probably because you're -- people are being subjected to less air pollution.

And so I would really look at that literature. The Surgeon General's report a couple years ago on secondhand smoke had a pretty good review of that. And then subsequent to that coming out, there was some really good meta-analyses looking at complications of pregnancy and low birth weight.

And these are things that all happen within a couple of months of, you know, passing strong smoking

laws. And there's a dose response with the stronger the law is, the bigger the effects. So, you know -- and also we did a paper showing ambulance calls dropped. And I mean the effects are on the order of around 15 to 20 percent changes, which are pretty big.

And I realize that in the kind of environmental clean-ups you're doing, you're talking about the effects are probably going to be more gradual, in terms of phasing in rather than of sudden change, which is easier to detect. But I think looking at the endpoints people are used in those models. And you might even be able to use them as predictive models to try to estimate what you think might happen. There's a pretty well-developed literature there, some of which I wrote, of course.

(Laughter.)

PANEL MEMBER GLANTZ: But not all of it.

PANEL MEMBER HAMMOND: I have a few points. Thank you this is helpful to find out where we were going and what our roles are expected to be. I do think that the endpoints are going to be difficult and because the changes are likely to be slow. And if the changes are slow, then the health outcomes are going to have to be slow.

So I think there is going to be a need to be realistic with the communities. Clearly, we can't see

those health effects. As Stan said, it's a very interesting counterexample. When you can have a law that changes things suddenly you can see those effects. We can have a certain faith that things will happen.

Some of the studies we did that Paul alluded to Fresno though were looking at daily exposures and how those affect the outcome. And there are, just by seasonal differences, much higher levels in different seasons for some of the different pollutants. So some of those might be ways we could look at, but I think you do have a big challenge there.

I'd like to go back to a couple of your earlier slides. One is the first issue is you said priority substances, and you just eluded right over that. How are the priority substances being chosen, who has chosen them, what's there?

DR. FAUST: Well, that's all -- that would be all part of the process. I mean, first, is sort of an information --

PANEL MEMBER HAMMOND: But we're going to start monitoring them in July without even knowing what they are?

DR. FAUST: Well, that -- that process is already -- that's -- I mean, there's been a separate process where decisions have been made at the district

level.

PANEL MEMBER HAMMOND: Well, I mean, this is a little bit of what I'm finding a little confusing, because the other piece I wanted to get to is the statutory role of SRP in all of this, as I understand it, is part of it is in the monitoring for these and the -- and how we should be monitoring? And clearly, if that's one of our roles, and the monitoring is starting soon and we haven't been involved, I -- we'd kind of like to go back to that. I don't see the statute -- although I think it's important, I don't see the statutory responsibilities being some of these things you're laying out that need to be done. And I think we have a lot of expertise to help in those as well, but I think we need to start with what we're required to do.

And the two things you listed were on the monitoring plan and then the reduction, how to do the reduction of emissions. So it seems like we should focus on those first. And I'm concerned that the monitoring is starting, as far as I know, without identification of priority compounds and without input from this group as to what they should be or how they should be chosen.

OCAP DIVISION CHIEF MAGLIANO: Good questions. So the statute, right, lays out that responsibility. And really what it does is that in developing the pieces that

went into the blueprint that our Board approved last September really wanted us to talk with a wide range of people including the SRP. So when the statute talked about monitoring plan, it was really those criteria that we put into the blueprint last September, like how do you approach doing monitoring, and how do you approach doing the emission reduction programs?

This is now moving into work -- the community is working with the local air districts. And part of what we've done there is -- because sometimes, yeah, there is going to be a paucity of existing information, that they're really looking at what are the types of sources, and things like that, what's the type of information they're trying to collect better information on? And that can be a whole range of different things.

PANEL MEMBER HAMMOND: I mean -- I guess -- I mean, I'm looking at being told that there are these two statutory responsibilities. And this first one that we're talking about sounds like the train has already left the station, that the decision is already being made without having consulted us. I mean, you know, I'm not going to go home and cry. But the question is whether are we still responsible for this? Is this something we should think about? I'm thinking about the HDI we talked about this morning.

OCAP DIVISION CHIEF MAGLIANO: Um-hmm.

PANEL MEMBER HAMMOND: Is that something we wanted to started monitoring in certain places? Would we think about that? Would we want to say, as we think about what's -- we want to look at, at least use the rich database of all the hot -- you know, the hot spot data where you set standards already. We have someway to interpret all that work as done. You know, where we have emissions data, where we have some information to start looking more carefully, that's at least part of what I think about. But I think it's also good to think beyond that.

But I'm not saying what you've done is wrong, but I'm just thinking I feel like if we're supposed to be consulted on that and be talking about that, we haven't done that. And it's -- it's -- if the sampling is going to start in the summer, the monitoring, it's kind of late.

OCAP DIVISION CHIEF MAGLIANO: Right. And part of what we realized as we were going through this is that because each community is so different, we didn't want to prescribe a certain set of chemicals that every community needed to monitor. We instead approached it by setting up a thoughtful process that they needed to go through to look at what they were interested in monitoring.

So what we're seeing now is that we go forward as

they start collecting more information, whether it's through monitoring or the new emissions reporting data that's coming forward, we are going to have that much richer database that we then think it would be extremely useful to come back to this group in terms of continued engagement, both whether it is along the lines, as John was saying, we've -- we have our long-standing set of chemicals we've looked at, but some of those may not have health risk values. And what we're seeing now in these 10 communities may help us better prioritize where to focus our efforts, but it could also lead to guidance on these are really important chemicals and perhaps they are ones that should be monitored more broadly in some of these communities as well.

PANEL MEMBER BLANC: So if I could follow up on this specifically. Well, let's say east L.A. community input decides that they want to measure formaldehyde, because they've heard that formaldehyde is so terrible, but they're not measuring acrolein at all. So that's final. Just go ahead and not measure acrolein, but they'll measure formaldehyde?

OCAP DIVISION CHIEF MAGLIANO: Well, part of this is bringing together, not only the interests of the communities, but also the expertise that CARB and the local air districts bring in understanding sort of suites

of chemicals that you really want to be looking at together. And so part of that is putting together monitoring plans that help define what should be looked at. And it's an opportunity to say, perhaps, it's this, plus something other --

PANEL MEMBER BLANC: But that must have already happened based on -- what you're saying is that -- that part has already happened. So what is -- what are there for the things that they have decided to monitor, since they're about to go into the field?

OCAP DIVISION CHIEF MAGLIANO: Given the very quick time frame, they are actually still in the process of figuring out what it is that they're going to be monitoring for. That's happening actually in the next couple of months, or so.

PANEL MEMBER BLANC: And are you planning therefore on -- in those two months -- in that two-month window for us to provide you any feedback? Is that part of what you guys are thinking?

OCAP DIVISION CHIEF MAGLIANO: We had not contemplated that, but it was certainly something that if you think it would be useful to come back to this group and give a report about what kinds of things that they are looking at monitoring for, we'd be happy to do that. This is also something that's probably an incremental program.

So many of them will be beginning monitoring in July, but we know that they will probably likely continue to work on those efforts. And there may be important information from this group that could help further guide how they can continue to look at it, as well as communities beyond the initial 10.

PANEL MEMBER KLEINMAN: But the communities, you know, that have been chosen, they were chosen on the basis of specific problems?

OCAP DIVISION CHIEF MAGLIANO: Um-hmm.

PANEL MEMBER KLEINMAN: And so they got some guidance about how to -- you know, what monitoring they were going to start to implement. And so if it's a particulate matter problem, they're getting monitors, and learning how to use them, and figuring out where to deploy them. But I think what would be very, you know, timely, since that step has already been done, if that information got consolidated into a report --

PANEL MEMBER HAMMOND: Um-hmm

PANEL MEMBER KLEINMAN: -- each -- each of the ten communities. We picked it because of this. This was the initial approach to developing the monitoring. This is the deployment schedule, and these are the toxic release inventories that support all that. And I think we could take, you know, these things a couple of communities

as a time and really look at them, and then perhaps have some insights into how to synergize that data. You know, what can we learn that's going to, you know, apply to a much broader cut?

So, you know, if that's possible, I -- you know, I'd really encourage, you know, that sort of interaction with the Panel.

OCAP DIVISION CHIEF MAGLIANO: No. I think that would be an excellent idea. And I think that's kind of what we're seeing as how we approach all of these, is that we're going to learn a lot from these, and then how do we take that to become best practices as we move forward?

PANEL MEMBER HAMMOND: Yeah. Thank you. And I agree both with Paul and Michael. I think -- and with you as well, I guess. I strongly support the idea of the community-based participatory research. I think this is great. I think it's good to come from the community. But I don't think it's fair to ask them to just, on their own, come up with all of this. And the idea should be in consultation. We should be of service to them to help them.

And that's, as Paul was suggesting, as one example of some of that. Another example might be the idea of there might be some suite of things that will be monitored across all 10 communities at the same time as

there are others that would be specific and trying to work on things like that.

But do you actually have documents now where you've laid out for the communities, following up on Michael's question, each community a tentative list of what they're going to be doing -- looking for and monitoring, because acquiring the equipment to do the monitoring and setting that up takes time. And it seems like we're running into this -- so if there is such a list, and if that's -- is it the local air districts and the community that have come up with these things, and do you want any overall State, I mean, as such as you all are working on, where are we there?

OCAP DIVISION CHIEF MAGLIANO: Sure. So the way that we've established it is that, yes, the local air districts work with the communities, because they each have expertise to be able to bring to what they're trying to understand and then the most appropriate ways to collect that information.

And so, as I mentioned, they're right in that stage now of sort of matching those two pieces of information together. Given the very short time frames, what many of the local air districts have done is they do have a portfolio or a suite of different kind of monitoring equipment and technologies that they have, that

they can be able to deploy in these communities, because it does take time to do purchasing, and things of that nature.

PANEL MEMBER HAMMOND: So two comments on that. First, we have to be careful not looking for the keys under the lamp post, right? So we know how to measure these things, so we'll measure these things, and we'll keep measuring what we've measured. And I think we want to do some of that. I think we do.

But the question is -- and this should be coming from the community, what are some things we need to be doing that we haven't been doing, or also just stepping outside of, you know, the 1970 criteria pollutant kind of issue.

And then secondly, I'm sure you're aware of this, but there are communities, some on this list that I happen to know, that are highly distrustful of their local air district. And therefore, if there were something coming, if you all have a presence, that there's a sense that there's something else beyond the district that they can rely on, I think that that would enable a lot of faith in the State government and in the sense that, as a state, we're working towards something.

OCAP DIVISION CHIEF MAGLIANO: Right. And you're absolutely correct, there's a lot of relationship building

that's taking part of this program. And that is part of having CARB establish the overall framework. But, you know, in addition to just having the smaller geographic scale of communities, it is trying to approach it very differently than we have our traditional criteria pollutant, toxic air pollutant programs.

And so the range of technologies that might be used also reflect that, everything from, you know, in some cases, the lower cost sensors, which can provide some better information on spatial variability, but also new mobile monitoring techniques, a lot of the new optical sensing kind of techniques. So trying to bring a lot of different kinds of methods to bear in terms of collecting this more granular data to support the program.

PANEL MEMBER HAMMOND: Again, I -- I think I applaud some of that, but I'm sure you at CARB are aware of there are these problems -- some of the mobile things are -- the errors in some of these monitoring equipment can be greater than the spatial variabilities that you're trying to determine.

So if your measurement is plus or minus 20, with the spatial variability is plus or minus 10, you know, you're not going to capture it. And -- but you think you have. So I think that it is important that -- that we're aware -- we're balancing all those things through there.

I mean the science still has to be done in the midst of responding to the needs of the community and what their desires are.

OCAP DIVISION CHIEF MAGLIANO: And it's understanding what the data can tell you and what it can't tell you. And that's all part of the trying to enhance our communication with each other as well as part of this process.

DR. FAUST: Okay. Well, I don't have anything else regarding the presentation. I mean, I think we've -- we've had discussion as we go. I don't know if there's any other follow-up questions regarding scientific topics that we'd like to bring up now.

PANEL MEMBER HAMMOND: On the health indicators, which were not part of our role, but I think there's a lot of expertise in this room on that, I think, again, there may be a -- one might think about balancing the needs of the community and the particular -- they may have particular health things, but it's worthwhile to make sure that the pollutants that are present are suspected of the contaminants of causing certain things. And they may not be aware of some of those relationships. It probably again is worthwhile having some across-the-board things that are measured, like what's in CalEnviroScreen, pre-term birth, or asthma admissions, and then having

community-specific outcomes of some sort.

The biomonitoring is actually the -- you know the State is doing a lot of that as well. Is that going to be actually brought into this? Is that partnered to this?

DR. FAUST: Well, I think in the future, we might have the potential to do that kind of thing. It's sort of in its early phases of considering. But we do see a role for that type of information to be helpful in this context.

PANEL MEMBER HAMMOND: I think it's important that we are clear that biomonitoring is monitoring exposures, if that's what we're really looking at as distinct from outcomes. I mean, there is a gray zone. It passes through, but something -- some biomonitoring will be outcomes, but most of it I think that we're doing now tends to be exposure related.

And so I would rather not have people be in a panic because they have a detectable level of chemical X 3,4,5-trimethyl chicken wire is in blood. Oh, my God. What does that mean? But at the same time, you know, being respectful in looking at that.

So I think thinking that through and being clear is this an outcome -- a health outcome, is it an exposure, or is it in that area of transition?

DR. FAUST: Okay. Thank you. Important point.

PANEL MEMBER BESARATINIA: I have a more general question with regard to community engagement. The way that you're engaging the community, perhaps it was covered. I wasn't here in previous meetings. I'm wondering, members of the community or representatives of the community that are included into your programs or engaged in this, are they working -- are they going to work on a volunteer basis or are there incentives or some sort of compensation for them that kind of engages them and motivate them to participate in these program?

The reason that I'm asking is at our university, USC, many of our research programs rely heavily on communities. And we have noticed that the participation and engagement of the community greatly increases once there is some sort of, you know, incentives for them. And it helps the research to move greatly.

So I'm just wondering is -- if this is included into your program? Of course, that's all dependent whether or not there is budget for that.

OCAP DIVISION CHIEF MAGLIANO: So right now, the community steering committees, which include both community members and other organizations is all on a volunteer type of basis. We certainly recognize that that's a big commitment of their time to be able to do that. So there's always going to be that balance there.

If there's lots of meetings and information to get through, but you don't want to place too large of a burden on the community members.

But in parallel to this, the Legislature has allocated some funding to provide grants to community-based organizations, just more broadly, even beyond these 10 communities to help community-based organizations, tribal organizations better participate in the program. So in some cases, these grants are going to organizations to develop their own monitoring. But in other cases, they are educational elements or ways that they can help their community members better participate in the program. So it's kind of a combination overall.

Sure. So we just had -- in the interests of time, I think we can go through this fairly quickly, some additional background information that will help feed into the things that John was just talking about. And you had mentioned Dr. Landolph about, you know, how did we select these communities overall? And as I had mentioned, if we can go to the next slide --

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OCAP DIVISION CHIEF MAGLIANO: -- there are many, many communities across the state that are highly burdened. So really, what we looked at was trying to get a mix of them with a lot of different kinds of pollution

sources, because it helps us develop a mix of pollution strategies, as well as getting a range of different air district and community-based organizations involved in the program.

And the number 10 that we selected really was also consistent with the resource -- funding resources that were available to make sure that we felt we could be successful in this first 10.

So as we'll -- as John talked about and Dave and Pam will talk about, there's a lot of more detailed information that's in the process of being developed for these communities, in terms of technical information on community-level emission inventories that we'll be able to bring back to this group.

But what I wanted to do was just give a really high level overview of some of the sources in these different communities, and that's kind of what led to this set of 10 that we selected.

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OCAP DIVISION CHIEF MAGLIANO: So if we start -- if you remember the map, I'm going to go from north to south in the state.

In the Bay Area, it was West Oakland and Richmond. You know, both of these have port-related communities in them. There's a lot of impacts from

freight. We hear a lot about truck impacts, particularly in West Oakland. In Richmond, it added another dimension of you have large oil refineries as well. And so we were able to also look at some of those impacts of large stationary sources in that can community.

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OCAP DIVISION CHIEF MAGLIANO: Then we go to Sacramento, a little bit different. The community is South Florin, which is just a few miles down Highway 99 from here. And this is your more traditional sort of commercial, light industry, residential community, but they're also impacted by the traffic that flows by on Highway 99.

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OCAP DIVISION CHIEF MAGLIANO: Next, we go into the valley. Here, we were able to get a mix of both -- a urban community in South Central Fresno, as well as a more rural community. Shafter is in sort of the southwest portion of Kern County in the San Joaquin Valley. So you've got the more urban, residential, light industry traffic mix in Fresno. Shafter, they have concerns about oil and gas operations, and concerns about pesticides come up very frequently in this community as well.

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OCAP DIVISION CHIEF MAGLIANO: Then if we move to

South Coast, there are three communities here, which span from sort of the Wilmington, West Long Beach, Carson area along the coast, very close to both freight operations, but also oil refinery complex. Then you move inland to East L.A., as many of you were just talking about. Again, still impacted by the freight industry, rail, as well as a lot of light industry kind operations. And then moving further inland into San Bernardino, the community of Muscoy, where there's a lot of concern about the proliferation of warehouses, distribution centers, and then associated freight traffic.

So in the South Coast it kind of provides a nice grouping of three communities that capture the full flow of the freight industry in the region from the coast moving goods inland into the San Bernardino area. So there will be a lot of connectedness of the strategies that are developed.

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OCAP DIVISION CHIEF MAGLIANO: Imperial County, another more rural situation. This community actually extends from Calexico on the border up through a small rural community of Heber and then up to El Centro. So again, the different range of kinds of pollution impacts in this community.

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OCAP DIVISION CHIEF MAGLIANO: And then the last one is a group of communities in San Diego. They're called the Portside Environmental Justice Communities. And so it includes Barrio Logan, National City, Sherman Heights. These are a series of communities that all border the port area in San Diego. They also have a lot of light industry impacts. I don't know if many of you recall the work that was done in the early 2000s in Barrio Logan that really highlighted a lot of the impacts from chrome plating and Chrome VI, for example. This is a chance to go back there and see how things are doing.

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OCAP DIVISION CHIEF MAGLIANO: So that's kind of the quick overview of sort of the range of kinds of sources. That will obviously translate into inventories of specific substances, both in the inventory and the air monitoring.

So what I wanted to do next is turn it over to Dave Edwards and then Pam from DPR to talk a little bit more about the extensive work that's going on to also collect better emission inventory data that will really be critical to the program.

AQPSD ASSISTANT DIVISION CHIEF EDWARDS: Great. Thanks, Karen.

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AQPSD ASSISTANT DIVISION CHIEF EDWARDS: And, yeah, thank you for having me present today.

So what I wanted to do is to give a general overview of what we've been working on with respect to the emissions reporting statute requirements that were in AB 617 and where we're at with the development of that regulation at this point.

So as John was really alluding to in his portion of this presentation, the inventory really is a foundation for many different programs that we have at both the Air Resources Board and many other State agencies. They really do rely on the inventory data.

A couple of years ago, a sort of precursor to AB 617, AB 197 passed, where it basically had us look at an integrated approach to emissions data, looking at GHG criteria and toxics air contaminants data to be able to establish trends across time, and particularly looking at the mandatory reporting facilities.

And what sort of I think came as an outcropping of this is that we started to look at how we present inventory in a more broader visually accessible method, really increase the data transparency and public right to know.

And so when we did this, looking at the -- particularly in some of the emissions data that we had, we

began to see a lot of different gaps that were appearing. And the main reason being is that historically, particularly on the criteria side, you're looking at maybe a SIP, so a one-year planning inventory, or on the toxics side with the AB 2588 Program, you're looking at data coming in maybe once every four years, annually in cases of some larger facilities, but very inconsistently across the state.

And then you overlay that with the air districts, particularly for the stationary sources, do collect the data separately, and there's 35 of them. So there was conceivably 35 different ways that emissions were estimated and calculated.

So with AB 617, came into statute requirements for annual emissions data reporting for criteria and toxics for stationary sources. So this can sort of begin to fill in some of the gaps for trend analyses, where maybe we were getting data points every three or every four years historically.

Looking at also developing unified statewide reporting, so method consistency, emission factor consistency across the state. Looking at also being able to collect other relevant facility-level data, so location information, very detailed information about stack heights, stack parameters, which are really integral for

doing a lot of the analysis, such as cumulative exposure burden analysis, et cetera.

And then also it did provide some options for us for data certification or verification.

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AQPSD ASSISTANT DIVISION CHIEF EDWARDS: So in December, we went to the Board to get our regulation approved. There were six main -- sorry, there were three main applicability requirements in the regulation, and then a fourth to help support community inventory development in the AB 617 communities.

The regulation was adopted by our Board in December. However, they did direct us to have a 15-day change or a make some modifications before sending it and getting it approved through the Office of Administrative Law.

And the main one of these is to modify the applicability criteria. What we had originally was sort of a community-specific approach, where we were looking at sources within AB 617 community boundaries. The direction that we did receive was to expand that to a more statewide perspective to not only be able to assess what is going on in the AB 617 communities, but also across the state. And then also we're looking at some revisions to definitions, some of the reporting requirements and contents.

The -- so this is sort of where we're at right now, and we'll talk a little bit about next steps in a second.

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AQPSD ASSISTANT DIVISION CHIEF EDWARDS: So I did want to, after giving that overview, at least sort of look at the main regulatory elements that is in the regulation. So we have the applicability. And this was our main thrust. We realized that getting method consistency, particularly in some of the more broader -- larger more complex sectors like a refinery or cement plant will take time. So we're looking at a phased-in approach for implementation.

And the first one that we really wanted to tackle was who is actually subject to this reporting regulation, who needs to report the data on an annual basis of their criterion toxics.

The second piece we wanted to address was the reporting requirements, so to at least set up a system that has some common emissions data reporting requirements, add a little bit on the data transparency. So we do have requirements now that a facility or an air district must report the emission factors used and the methods used to quantify the different types of emissions that we're seeing.

And then also acknowledge that this is a very collaborative partnership between CARB and the air districts, as they do have that more feet on the ground and have a knowledge of the stationary sources.

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AQPSD ASSISTANT DIVISION CHIEF EDWARDS: So where we're at moving forward. We've been working the past few months, since our December Board meeting, with different community representatives, air districts, an industry stakeholders to propose some different ways to address the applicability at a statewide level, as opposed to a more specific community level.

I can say what we're sort of moving towards -- our original proposal was looking at all permitted sources within a community boundary that was as established by the steering committee. What we've expanded to is a criteria threshold of 4 tons of a specific criteria pollutant emissions, and then also a series of sector-based toxics thresholds, where there's either a zero threshold for bringing that sector in, such as metal plater that emits chromium or cadmium to -- to throughput based activities, such as a gas station emitting 25 -- or sorry, selling 25,000 gallons of gas station a year or more, or an auto body shop that has -- that uses 30 gallons of paint, for example.

So we are -- we're -- what we're looking at here is a way that -- to establish thresholds that protect public health, but also bring in the statewide perspective to this emissions reporting regulation.

And the reason I was able to mention those is that we actually just posted our draft 15-day reg text about 20 minutes ago.

(Laughter.)

AQPSD ASSISTANT DIVISION CHIEF EDWARDS: So what we're doing, it's a -- broader than just a regular 15-day process, for those of you familiar with it. We're actually conducting workshops starting tomorrow through the end of next week, five across the state. We'll basically be going over what we're calling our draft potential 15-day change reg text. We'll be looking for feedback at these five workshops regarding the thresholds, the types of sectors that we're bringing in, with the idea that we'll get some informal comments working with different stakeholders across the state.

And then in -- sometime in the spring have our formal 15-day comment package where there's formal comments et cetera, and then a second 15-day, if we need to.

And then the idea is by the end of the year, hopefully have approval by our Office of Administrative

Law for this regulation to go into effect.

Thank you.

PANEL MEMBER GLANTZ: Well, so as Kathy was -- and Mike were talking about earlier, I mean, this list of what those things to be monitored are is a really key decision. I mean, do you envision any role for us in all of that?

AQPSD ASSISTANT DIVISION CHIEF EDWARDS: Yeah. I think the -- as far as the -- in the sort of implementation part of the day-to-day collection of the data, probably not. I think once we actually begin to get this data coming in to be able to potentially synthesize it and sort of we can present that type of information to you. And then I think how that then would be able to inform some of the items that John is talking about.

PANEL MEMBER GLANTZ: But there's the question of what do you measure?

AQPSD ASSISTANT DIVISION CHIEF EDWARDS: So as -- as far as what is -- what is being measured, I mean we do have the sort historical knowledge of what types of pollutants the -- these different sectors emit over time. This is more of an emissions inventory, not so much of a monitoring type of regulation. So it's looking at the emissions -- the estimated emissions that are occurring from a facility over a given year time period as opposed

to what the ambient concentration is at a given time. So we do hope that this will help inform some of the processes. I hope that clarifies.

PANEL MEMBER HAMMOND: Maybe -- may I ask a question following up on that?

AQPSD ASSISTANT DIVISION CHIEF EDWARDS: Yes.

PANEL MEMBER HAMMOND: So are -- if I have a facility, is it the same reporting requirements as the Toxic Release Inventory or how does it differ from that?

AQPSD ASSISTANT DIVISION CHIEF EDWARDS: So, yeah. Okay. That's --

PANEL MEMBER HAMMOND: Is it supposed to be all-encompassing, everything I emit besides H20 and CO2 or what?

AQPSD ASSISTANT DIVISION CHIEF EDWARDS: Yeah. So in the near term, I mentioned earlier it's sort of a phased process. So in the near term it will be -- the reporting of air toxics and criteria will be based on what the air district requires right now. So if there's a specific set of toxics or a source test requirement, that will be -- that will be able to stay in place.

Over time, as I mentioned, we will be forming work groups on establishing with air districts, and industry, and others a set of consistent methods that need to be followed at a statewide level.

PANEL MEMBER HAMMOND: I guess I misunderstood you earlier. I thought you had said something about toxic air contaminants that have to report -- if -- do they have to report if they emit any of the toxic air contaminants?

AQPSD ASSISTANT DIVISION CHIEF EDWARDS: Yeah. We're basing the list of toxic air contaminants on the AB 2588 Hot Spots Appendix A1 list, which is about 450 air toxics.

PANEL MEMBER HAMMOND: So do -- so does that mean that these 10 communities -- in these 10 communities, all facilities that emit will be required to basically report on those 450 compounds, and it might be zero for a lot of -- for most of them.

AQPSD ASSISTANT DIVISION CHIEF EDWARDS: Yes.

PANEL MEMBER HAMMOND: But they actually will be required to report zero in that case, is that correct or -- I mean --

AQPSD ASSISTANT DIVISION CHIEF EDWARDS: Yes.

PANEL MEMBER HAMMOND: -- are they going to have to report for each -- there's a list of hundreds of compounds.

AQPSD ASSISTANT DIVISION CHIEF EDWARDS: So they're not going to have to do an actual -- like let's say it's a gas station, for example. So they're not going to have to go through that whole list of 450 toxic

compounds. There's a -- there's a list of maybe three or -- three to five or so that would be relevant to that.

PANEL MEMBER HAMMOND: You would -- who will decide what's relevant, the gas station, the air district, or CARB?

AQPSD ASSISTANT DIVISION CHIEF EDWARDS: At this point, it's the air district. And moving forward, it will be a -- we will be updating our reg. It would be more of a CARB/air district/stakeholder process to determine that.

PANEL MEMBER HAMMOND: I was just going to ask where the community came in there.

AQPSD ASSISTANT DIVISION CHIEF EDWARDS: Yes.

OCAP DIVISION CHIEF MAGLIANO: The other thing, just to clarify, as Dave said, initially we were thinking of doing this only within the 10 communities. But based on discussion at our Board meeting and public testimony, we have actually expanded that scope, so that we will be getting this better information not only in those 10 communities, but those sources throughout the state over a phased-in schedule.

CHAIRPERSON ANASTASIO: Okay. Thank you.

We have one more.

OCAP DIVISION CHIEF MAGLIANO: One more. Pam comes to the -- as I mentioned, you know, information about pesticides emission inventory is a companion to the

work that Dave is doing. So Pam has a few slides to talk about what those efforts are as well.

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DPR ENVIRONMENTAL MONITORING BRANCH CHIEF WOFFORD: Hi. Glad to be here. Closer. Is that better?

PANEL MEMBER GLANTZ: You can pull the mic closer.

DPR ENVIRONMENTAL MONITORING BRANCH CHIEF WOFFORD: So I don't have to like lean forward completely.

Thank you.

My name is Pam Wofford. I am the Branch Chief for the Environmental Monitoring Branch within the Department of Pesticide Regulation. And I was asked to come give a brief -- very brief overview of some of the information that is available on the pesticide use within the State of California, and also some of the proposed ideas we have on pesticide emission inventory.

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DPR ENVIRONMENTAL MONITORING BRANCH CHIEF WOFFORD: Thank you.

The Pesticide Use Report database actually was started in 1990 upon regulations of a full reporting of all pesticide applications in California.

Currently, there's about 81 million records in

this database. And those are kind of separated out by two different sets of information. The first sets of information include what most people think of as agricultural use. That's use on orchards, on field crops and vegetable crops. And that's about 80 percent of the information in the database. And that is actually reported per application. So we have extensive data on each application that actually occurs in the state since 1991.

In addition to that, another 20 percent of the database is made up of what we call our non-ag or non-production ag applications that are made to livestock, post-harvest applications, structural applications, landscape, golf courses, and rights of way. And both of these different records are pretty different in what they provide for information. So go ahead.

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DPR ENVIRONMENTAL MONITORING BRANCH CHIEF WOFFORD: And as you can see, the production ag reports, as I said, are on each application.

PANEL MEMBER GLANTZ: Back up.

DPR ENVIRONMENTAL MONITORING BRANCH CHIEF WOFFORD: Oop, yeah. Back up. And so for each of those records for each application that's made -- oh, it's got a time thing on it.

You hit -- thank you.

Oop.

PANEL MEMBER GLANTZ: Go in and turn the timer off.

DPR ENVIRONMENTAL MONITORING BRANCH CHIEF WOFFORD: Go back. Thank you.

So for -- like I said, for each record on the applications for production ag, you get the product applied, the crop it was applied to, the amount applied, the date and time of application, the application method as far as if it's aerial, ground application, or other, the acres treated and also the location of the application down to the public land survey section area, which is a mile by mile.

For the other 20 percent of those records, it's more of a summary data. And that comes, it will give you the product and crop, but the total amount by the -- for the month, and for the acres by the month. And that's just down to the county. So those are more the summary of those applications that are used more for, like I said, landscaping and livestock and the other applications.

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DPR ENVIRONMENTAL MONITORING BRANCH CHIEF WOFFORD: So with this said, DPR has a massive data that is available on the use of pesticides. But for the

consideration under the community programs under AB 617, the use of the actual reports would not actually reflect emissions. As you all know, a pound of pesticide applied did not necessarily mean a pound of pesticide emitted.

So that would require the Department to -- if it was going to do an emissions inventory, to actually develop emission factors for each active ingredient that is registered and by application method. The emission factor actually just that fraction of the active ingredient that would be coming off of an application due to drift or volatilization.

Once we determine those emission factors, they could be put back into the pesticide use for each record, and actually multiplied to the pounds used for that AI and that method to actually come up with the emissions inventory that would be more appropriate for use for looking at that.

PANEL MEMBER GLANTZ: Do those emission factors exist?

DPR ENVIRONMENTAL MONITORING BRANCH CHIEF WOFFORD: I will get into that.

PANEL MEMBER GLANTZ: Okay.

DPR ENVIRONMENTAL MONITORING BRANCH CHIEF WOFFORD: We do have a good handle SO far on fumigants. But as I said, I'll go into that more.

We could then use that emissions inventory to calculate total emissions for individual active ingredients based on various spatial scale. It could be statewide, it could be county, air basin, down to community boundary levels for the communities under AB 617.

So as I said, there are over 1,000 registered AIs. And this would require an immense amount of work and commitment by the Department. So the Department is proposing to start with some information that we do have, and we do have a good handle on. And that would be the emission factors that we have developed for fumigants. We've done quite a bit of work on soil fumigants through our Volatile Organic Compound Regulation reporting, and through our work on mitigation measures, and have actually determined emission factors for all of the different soil fumigants and application methods.

And through the VOC regulations we require within the nonattainment areas reporting with a method code each individual application and the method that was used to apply. So we're able to determine for each of those applications, the actual emissions for them.

And we would be able to use that data to extrapolate for some of the other statewide applications that don't have actually codes reported for them. That

would be our initial step into this emissions inventory.

The next step that we propose taking is then looking at the organophosphates. We've actually done some work with chlorpyrifos looking at its emissions. We have some studies in-house that have been from air monitoring studies on applications of a couple of organophosphates with aerial and ground that we could model and try to attempt to determine emissions from, and then extrapolate to other organophosphates and include those next into the inventory.

And that would give us actually quite a bit or most of the pesticides that tend to be of highest concerns to communities. And after that, then we would need to go into a lot more in-depth work to incorporate the rest of those active ingredients. But there is the potential for us moving currently, like I said, with the fumigants and the OPs for this 617 community outreach.

So any questions on that?

PANEL MEMBER LANDOLPH: It looks like a lot of nice data you're going to gather. Could the epidemiologists use this or could your department use it to look for possibilities of correlation with certain pesticides towards induction of Alzheimer's and other neurologic diseases?

DPR ENVIRONMENTAL MONITORING BRANCH CHIEF

WOFFORD: I would have to leave that up to the toxicologist to determine. But this would be give the Department also information to use in risk assessments then.

CHAIRPERSON ANASTASIO: Thank you, Pam.

Any other questions?

PANEL MEMBER KLEINMAN: Yeah. The organophosphates, you know, provide a very good opportunity for testing out modeling and biomonitoring as well, because I know that some acetylcholinesterase levels were measured. So is that something that is possible in the -- in the near future to kind of integrate that?

DPR ENVIRONMENTAL MONITORING BRANCH CHIEF WOFFORD: As not being a toxicologist, I would have to leave that to someone else to answer.

(Laughter.)

CHAIRPERSON ANASTASIO: John, do you want to weigh-in on that?

(Laughter.)

DR. FAUST: As a toxicologist?

(Laughter.)

DR. FAUST: It is possible. I mean, I would have to, I think, think about the feasibility of what we're talking about. But, I mean, it's -- you know, it's an important piece to think about as we're moving forward in

the information that we can pull together for demonstrating some of these exposures.

CHAIRPERSON ANASTASIO: Anything else?

Stan.

PANEL MEMBER GLANTZ: Well, you know, so just listening to this to just make your already extremely complicated problems more complicated, you know, I think you ought to also be thinking about secondhand smoke and secondhand cannabis smoke. And if you go back to when we did the listing of secondhand smoke as a toxic air contaminant, part A of the report actually has data on outside emissions, and they were a lot bigger than one would have thought.

And I think with the -- with the, you know, expanding cannabis market, that's going to be an issue too. And a lot of -- you know, the use of these products tends to be concentrated in the same communities that you're talking about.

So I would at least go back and take a look at part A of the secondhand smoke report, and, you know, see what -- because there's some good modeling in there too, to see how that could play into what you're doing, and then maybe -- I know that the California Tobacco Control Program out of the Department of Public Health is putting a strong emphasis on health disparities and targeted

communities.

So that might fit in quite nicely with what you're -- what you guys are doing. And they -- they also have a pretty -- pretty active engagement with community organizations in these impacted communities too. So there might be some good synergy there.

OCAP DIVISION CHIEF MAGLIANO: Yeah. And we're actually working closely with Paul English in tracking California to try and make those connections. That's a good suggestion.

CHAIRPERSON ANASTASIO: Great. Thank you.

PANEL MEMBER MILLER: Can I ask a quick question?

CHAIRPERSON ANASTASIO: Yes, please.

PANEL MEMBER MILLER: I had a quick question for all of three of you -- oh, sorry -- for all three of you. How will the health surveillance take place? Is there going to be a uniform approach in how this is going to be done in terms of getting consistency in reporting or will it be sort of a grassroots type of approach for each community.

DR. FAUST: I think that's all part of the conversation that we're going to be wanting to have through this -- through this process going forward. I mean, I think, yeah, the merits of different types of approaches need to be -- need to be considered very

carefully. And I think the sort of the reality check on what is feasible also needs to be considered very heavily before starting any particular study.

PANEL MEMBER MILLER: Thank you.

CHAIRPERSON ANASTASIO: Any other comments from the Panel?

No. All right. Well, thank you, Pam, and Dave, and John, and Karen for the presentation. Clearly, an ambitious program. Definitely an important one. I can sense the Panel is itching to give input, which is great. But I think something Karen pointed out is very important, you know, this is kind of an incremental and iterative process.

And so whatever starts in July of 2019 is not the way it's necessarily going to be for the rest of the program. And I'm sure as you learn things that -- and perhaps get our input, things will be modified.

OCAP DIVISION CHIEF MAGLIANO: And I think the suggestion to be able -- as we start getting this information, to be able to synthesize it, consolidate it, come back to this group both in terms of what we're just seeing with that core information, how that then feeds into the topic areas that John suggested, and then does help sort of feed that iterative process, and hopefully continuing development of best practices, et cetera. And

I think your role will be really key in that.

So thank you.

CHAIRPERSON ANASTASIO: Yeah. You're welcome. Thank you.

Our final agenda item, number 4, consideration of administrative matters. I just have one thing here. So Jim Behrmann and I have talked about trying to plan SRP meetings further into the future. I know we've gotten into a situation a few times where the availability of the SRP Panel has been limiting the progress that we can make.

So Jim is going to try to -- well, take a step back. We're going to try to have three additional meetings in the next year. And the idea would be we're going to meet roughly every three to four months. Jim is going to send out a poll to the Panel asking for your availability over the course of roughly four weeks in each of these windows. And so when you get that please reply, and pleases try to be as open with your time as you can.

I know a lot of us are teaching. There will be only one meeting in each of these windows. So if you're teaching Monday, Wednesday, Friday, please don't block out Monday, Wednesday Friday for the entire window. At worst, you'll miss one class. So try to make Jim's job easier and to try to get us to meet more frequently, we're going to try to do this new thing. So look forward to that from

Jim, and we'll see how it goes.

Any other administrative matters from the Panel before we close?

PANEL MEMBER BLANC: Does OEHHA -- does OEHHA have a clue as to what we might be looking at coming down the pike?

CHAIRPERSON ANASTASIO: John is smiling. I'm going to take that as a yes.

(Laughter.)

DR. BUDROE: John Budroe. And, yeah, we'd like to bring a toluene REL document to the SRP next. And then probably the document after that will be cobalt cancer potency factor document.

CHAIRPERSON ANASTASIO: Yeah. Thank you, John.

The other thing we'd like to do for our next meeting, which will probably be June or July is have an overview to try to look at the next year, think about what's coming down the pike in addition to toluene and cobalt.

Any other administrative matters?

PANEL MEMBER KLEINMAN: Well, if there is open time in one of our agendas, it might be useful to revisit the priority list that was created years ago, and see if there is anyway we can update that, or at least look at that, and see if there are new things that we would like

to recommend to OEHHA to look into for developing new, you know, RELs?

CHAIRPERSON ANASTASIO: Yeah. I agree with that. And, you know, the Panel has talked about having input on the priorities and what comes down the pike. So I think at our next meeting we'll certainly have that as a topic -- an agenda item.

PANEL MEMBER GLANTZ: Yeah. There actually are a couple of documents that were approved that -- for different -- different lists. I mean, maybe the thing to do is go dig those out, see what actually happened, and then maybe have OEHHA come back with some suggested changes.

CHAIRPERSON ANASTASIO: Yeah, that's a good idea. Just make this note.

Okay. Any other comments?

If not, can I get a motion to adjourn.

PANEL MEMBER KLEINMAN: So moved.

PANEL MEMBER GLANTZ: Second.

CHAIRPERSON ANASTASIO: And can I get a vote. All in favor of adjourning say aye?

(Aye.)

CHAIRPERSON ANASTASIO: Let the record reflect, it was unanimous.

Thank you.

(Thereupon the California Air Resources Board, Scientific Review Panel adjourned at 2:24 p.m.)

C E R T I F I C A T E O F R E P O R T E R

I, JAMES F. PETERS, a Certified Shorthand Reporter of the State of California, 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;

That the said proceedings was taken before me, in shorthand writing, and was thereafter transcribed, under my direction, by computer-assisted transcription.

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 9th day of March, 2019.

JAMES F. PETERS, CSR
Certified Shorthand Reporter
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