MEETING

STATE OF CALIFORNIA

ENVIRONMENTAL PROTECTION AGENCY

AIR RESOURCES BOARD

SCIENTIFIC REVIEW PANEL

ON TOXIC AIR CONTAMINANTS

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A P P E A R A N C E S

PANEL MEMBERS:

Michael T. Kleinman, Ph.D., Chairperson

Cort Anastasio, Ph.D.

Jesús A. Araujo, M.D., Ph.D.

Paul D. Blanc, M.D.

Alan R. Buckpitt, Ph.D.

Stanton A. Glantz, Ph.D.

S. Katharine Hammond, Ph.D.(via teleconference)

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

Beate R. Ritz, M.D., Ph.D.(via teleconference)

REPRESENTING THE AIR RESOURCES BOARD:

Mr. Jim Behrmann, Panel Liaison

REPRESENTING THE OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT:

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

Dr. Lori Lim, Senior Toxicologist

Dr. David Siegel, Retired Annuitant

Dr. Rona Silva, Air, Community and Environmental Research Branch

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REPRESENTING THE DEPARTMENT OF PESTICIDE REGULATION:

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Dr. Svetlana Koshlukova, Senior Toxicologist, Risk Assessment Section

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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 KLEINMAN: Good morning, and welcome. I'd like to call the meeting of the Scientific Review Panel to order. And I want to welcome everybody to this meeting of the Panel on Toxic Air Contaminants. We have attendees here in Sacramento and we also have some people listening and watching on a webcast.

And while I'm women welcoming everybody, I would like to also extend a warm welcome to our returning Panel Member Joe Landolph, who was appointed by the Assembly Speaker earlier this year in the biochemistry and molecular biology category on this Panel.

Joe has appointments in molecular microbiology and immunology at the USC Keck School of medicine and in the USC School of Pharmacy. He's also a member of the USC Norris Comprehensive Cancer Center. And he served on this panel quite a few years ago. You know, he had a long tenure. And so I'm very happy to welcome Joe back.

I do want to remind those who are going to be sneaking to use the microphones because we are webcasting. And also, if you're using a laser pointer for slides, it may not show up on the webcast, so speakers are going to have to be a little more descriptive as they discuss their PowerPoints.

Finally, if everybody can silence their phones or

communications devices, that would be great.

And so now I'd like to first go around the table and have the participants from the Panel just give a very brief introduction, and then we'll also poll the members who are calling in. So we can start with Dr. Landolph.

PANEL MEMBER LANDOLPH: It's a pleasure to com back again. I certainly served with Stan Glantz and Paul Blanc before. It's a pleasure to see all the new members. And I know John Budroe. My research deals with nickel, chromium, and arsenic carcinogenesis. We do a lot of work in cell culture, may transform cell lines, and study the activation oncogenes, knockout of tumor suppressor genes, and the changes in global gene expression that this causes leading to the transformed cell.

And I also teach microbiology and toxicology at USC and I work in cancer, as Mike has pointed out. My primary appointment point is in molecular microbiology and immunology. And then the USC Norris Comprehensive Cancer Center. And I serve on this Panel and also on the Carcinogen Identification Committee Panel of the State of California. Pleasure to be back.

PANEL MEMBER ANASTASIO: I'm Cort Anastasio. I'm a Professor in the Department of Land, Air, and Water Resources at UC Davis, and I study atmospheric chemistry.

PANEL MEMBER ARAUJO: I'm Jesús. Araujo I'm a

Associate Professor or Medicine in the -- at the UCLA School of Medicine, Environmental Health Sciences in the School of Public Health. And I work on the cardiovascular effects of ambient particular matter, as well as in electronic cigarettes.

PANEL MEMBER BUCKPITT: I'm Alan Buckpitt from the Department of Molecular Biosciences in the School of Veterinary Medicine, and I'm retired.

PANEL MEMBER GLANTZ: I'm Stan Glantz. I'm a Professor of Medicine at UC San Francisco. And I'm here in the biostatistics seat.

PANEL MEMBER BLANC: And I'm Paul Blanc from the University of California, San Francisco. I'm Chief of the Division of Occupational and Environmental Medicine there. And my background is in internal medicine, occupational medicine and medical toxicology.

CHAIRPERSON KLEINMAN: Thank you. We are supposed to have two participants on the phone. Kathy, are you there?

Not hearing Kathy.

Beate, are you there?

CHAIRPERSON KLEINMAN: Well, I'll assume that they will announce themselves when they are able to get on line.

As it stands, we do have a quorum for this

meeting. And so we can proceed to our next item of business. So I'd like to again welcome all the panel members and the people who are here to listen in on the proceedings.

And we have two agenda items for today's meeting. The first item is going to be the panel's second review of the Inhalation Cancer Unit Risk Factor, or IUR, for the tertiary-butyl acetate, also known as TBAc.

The IUR was developed using risk assessment methodologies for developing IURs under the Air Toxics Hot Spots Program. The document underwent public review and comment in 2016. OEHHA presented the initial document to the panel in December of 2016 for comment, at which time a large number of recommendations were made and the document has since been accordingly revised and changed. And that document -- the revised Document will be presented today.

An additional written public comment by Lyondell was also made to the SRP in March of 2017. And the response to that public document will also be discussed.

So the lead Panel members for the document were Dr. Araujo and myself. But many of the other Panel members had comments, and so we'll start out with Dr. Araujo and we'll also hear -- but before we do that, we'll hear a presentation from the staff on the TBAc document as it stands now. Then we'll use the time to discuss and

provide additional feedback on the document.

Materials for the meeting have already been provided to SRP members, are available to the public on the OEHHA website. And the website is also noted. If you haven't found -- well, presumably, if you're on the website, you've already found this, but the documentation is available on the web.

So let's start out with John Budroe or -- John.

DR. FAUST: I was just going to introduce John. I'm John Faust, Chief of the Air, Community, and Environmental Research Branch. And I'm just here to introduce Dr. John Budroe, who's Chief of our Air Toxicology and Risk Assessment Section, who will be giving the continued presentation on the unit risk factor for tertiary-butyl acetate.

So, John.

(Thereupon an overhead presentation was presented as follows.)

DR. BUDROE: Good morning, Dr. Kleinman, Panel members.

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DR. BUDROE: I'll be -- this will be starting off with a brief overline -- outline of the document. And I can definitely promise you that you won't be subjected to 90 slides this time around.

So the timelines for this document -- the initial document was released for a 60-day public comment period on August 14th, 2015. The Scientific Review Panel draft was released to the public and the SRP November 14th, 2016. And the first Scientific Review Panel document review was done on December 13th, 2016.

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DR. BUDROE: Now, the changes that were made from the initial version of the document in response to the comments made by the Panel:

Potential residential and worker exposures were added from Bus 2014. And non-cancer health effects information was added. And these two sections are fairly straightforward. And I won't be discussing them further in the presentation. But if the Panel has questions on them, I'd certainly be happy to answer them.

The metabolism section of the document was expanded, including information on carboxylesterase activity in humans and rodents, and methyl tert-butyl ether, or MTBE, and ethyl tert-butyl ether, or ETBE, as TBAc surrogates. Expanded survival data was added to the bioassay section.

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DR. BUDROE: There was a change from poly-3 correction to effective number of animals in cancer dose

response analysis. And the effective number of animals is the number of animals alive on the first day the tumor of interest was observed in any dose group. And I'll be expanding on that later.

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DR. BUDROE: To get into the -- a little bit of a refresh on the core part of the document. The metabolism of TBAc, it's substantially metabolized to tertiary-butanol, or TBA. That inhaled TBAc is rapidly distributed to tissues. And metabolism occurs through hydroxylation, hydrolysis, and/or glucuronidation.

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DR. BUDROE: This is a slightly out of focus metabolic scheme for TBAc. And one of the things that we added to this were at the beginning of the metabolic pathway the types of reactions that were occurring.

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DR. BUDROE: And we added a expanded discussion of the action of carboxylesterases. Bus suggested that the hydrolysis of TBAc to TBA in rats is mediated by carboxylesterases or CEs.

Human and mouse data for CE metabol -- mediated metabolism of TBAc to TBA are not available. However, there are a variety of CEs in both humans and mice, six isoforms in humans, 20 in mice.

And these CEs have a broad substrate specificity and are distributed within a wide variety of tissues, suggesting that this metabolic pathway could be operative in both humans and mice.

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DR. BUDROE: We also have a discussion of MTBE and ETBE, especially MTB as a TBA surrogate. And MTBE is metabolized to TBA in rats, mice, and humans after oral and inhalation exposure. And is a carcinogen in both rats and mice.

TBA also appears in the exhaled breath of humans after both oral intake and inhalation exposure, suggesting that MTBE lacks a significant first pass effect in humans. The MTBE data suggests that TBA may also not experience significant first-pass metabolism in humans. The MTBE data also indicates that MTBE toxicity in humans is probably independent of the route of exposure, which suggests that TBAc toxicity in humans may also be route-independent.

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DR. BUDROE: Now, the TBAc cancer risk assessment is based on the 2-year TBA drinking water study in rats and mice that was done by NTP in 1995. The study population was Fischer 344 rats and B6C3F1 mice. The exposure method drinking water ingestion for up to 103

weeks. In male rats, concentrations up to 5 milligrams per ml. Female rats up to 10 milligrams per ml. And in male and female mice up to 20 milligrams per ml.

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DR. BUDROE: This is a listing of the tumor incidences for the key tumor types in rats and mice: Renal tubule adenomas and carcinomas in male rats, and thyroid follicular cell adenomas in male and female mice. And the 2.5 milligram per ml dose was statis -- the tumor incidence for renal tubule adenomas and carcinomas was significantly increased compared to controls.

In female mice, the high dose demonstrated increased -- statistically significantly increased thyroid follicular cell adenomas compared to controls. And this call type is conceded to progress to carcinomas.

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DR. BUDROE: So the critical effects were renal tubule adenomas and carcinomas in male rats; thyroid follicular cell tumors in female mice. And the male rat kidney tumor data and female mouse thyroid data dose response analysis was conducted using tumor incidences adjusted for the effective number of animals.

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DR. BUDROE: And this change -- this was essentially a change from using a poly-3 correction in the

prior version to effective number of animals in this version. And as I stated earlier, the effective number of animals is the number of animals alive on the first day the tumor of interest was observed at any dose group. Now, a poly-3 correction is generally used when early mortality is observed in treated groups.

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DR. BUDROE: And we went back and looked at the data again. And early mortality was really not present in male rats and female mice in the NTP 1995 study. And the use of effective number of animals is pretty much standard practice in the OEHHA cancer dose response analysis. In fact, I sus -- believe that most, if not all, of the animal bioassay derived cancer potency factor documents that the Panel has seen has used effective number of animals.

The change from the use of poly-3 correction to the effective number of animals resulted in slight changes in the TBAc inhalation unit risk, or IUR, and associated slope factors.

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DR. BUDROE: So this is the tumor incidences with the prior poly-3 adjustment.

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DR. BUDROE: And this is the increased tumor

incidence adjusted for effective number of animals. And the significance of the -- pairwise comparison significance didn't change. You still had a positive trend test for dose response.

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DR. BUDROE: So we calculated cancer slope factors for TBA using benchmark dose software. And a cancer slope factor in animals for -- of 3.1 times 10 to the minus 3 milligram per kilogram day to the minus 1 was calculated from the male rat kidney tumor data set with the high dose eliminated using a first degree polynomial.

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DR. BUDROE: The reason that high dose was dropped was to allow for model convergence. This is a procedure that U.S. EPA acknowledges and feels it's reasonable to do in those circumstances in their BMDS guidance. And the first degree polynomial is used to model the data for goodness of fit purposes.

We also calculated a TBA cancer slope factor of 8 times 10 to the minus 5 milligram per kilogram day from the corrected female mouse thyroid tumor data set using a third degree polynomial multi-stage cancer model.

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DR. BUDROE: The male rat kidney tumor data yielded the highest cancer slope factor value. And we

then converted this animal cancer potency estimate to a human potency equivalent. And this was done -- this conversion was done using a body weight to the three-quarter power scaling.

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DR. BUDROE: So the TBA cancer slope factor for humans was found -- was calculated as 1.1 times 10 to the minus 2 milligram per can kilogram day to the minus 1.

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DR. BUDROE: We then derived a TBA -- a TBAc oral cancer slope factor of 5 times 10 to the minus 3 milligram per kilogram day to the minus 1 from the TBA human cancer slope factor, assuming a TBAc to TBA metabolic conversion factor of 0.71, and a molecular weight ratio, or MWR, of 0.64, which is the ratio of the TBA molecular weight to the TBAc molecular weight.

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DR. BUDROE: A TBAc inhalation cancer slope factor was then calculated from the oral slope factor using the equation below where fractional absorption is 95 percent.

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DR. BUDROE: A TBAc unit risk factor was then derived from the inhalation cancer slope factor using a human breathing rate of 20 cubic meters per day, an

average human body weight of 70 kilograms, and a milligram to microgram conversion of 1000. And this yielded a unit -- inhalation unit risk of 1.3 times 10 to the minus 6 micrograms per cubic meter to the minus 1. So essentially this means that you have -- if you're exposed to a concentration of 1 microgram per cubic meter of TBAc, the corresponding cancer risk is 1.3 in a million.

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DR. BUDROE: So the prior document version had oral slope factors and inhalation slope factors of 7 and 6.7 times 10 the minus 3 milligram per kilogram day to the minus 1 respectively, and an inhalation unit risk of 1.9 times 10 to the minus 6 microgram per cubic meter.

The current version has oral and inhalation slope factors of 5 and 4.7 times 10 to the minus 3 per milligram kilogram day to the minus 1, and an inhalation unit risk of 1.3 times 10 to the minus 6 microgram per cubic meter to the minus 1.

So as you can see, the change from poly-3 correction with effective number animals did not make that much of a difference in the final slope factors in inhalation unit risk values.

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DR. BUDROE: Now, we also have a response to the LyondellBasell March 2, 2017 letter to the SRP. And we

reviewed the contents of the letter. And there wasn't anything in there to justify revising the document in response to the letter contents, but we did prepare responses for the Panel.

These are not exact quotes, but I've paraphrased what was in the letter for the presentation. And Lyondell commented that neither the SRP nor the Proposition 65 Cancer Identification Committee, or CIC, have previously reviewed either TBAc or TBA for carcinogenicity. And the only cancer slope factor approved by the SRP for a chemical not previously designated as a carcinogen by an authoritative body, for example IARC, was MTBE.

The OEHHA response to this is that TBAc and TBA have indeed not been previously reviewed for carcinogenicity by either the SRP or CIC or designated as a carcinogen by authoritative body.

However, neither review by the CIC nor authoritative body, carcinogen designation is required for the SRP to determine that the chemical is a carcinogen.

PANEL MEMBER GLANTZ: Aren't we considered an authoritative body for that?

DR. BUDROE: An authoritative body is kind of Proposition 65 language. So it's like NTP, IARC, U.S. EPA. There's also -- we'll get to talking about the State's qualified experts, and that's its own also

designation lives in its own place.

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DR. BUDROE: Another Lyondell comment was that a pathology working group or PWG that was published --

PANEL MEMBER GLANTZ: I just happened to notice, did you get an email from Kathy Hammond?

PANEL MEMBER BLANC: Yes. Yeah, she's listening. Kathy, glad you're listening. Our system is not allowing you to speak.

Kathy, sorry. I know your listening. I believe you're listening. When the system allows you to speak, please chime in, even if you're interrupting someone.

PANEL MEMBER GLANTZ: But you have to turn on your microphone they said.

I'm sorry, but --

DR. BUDROE: So the PWG that was published in Hard 2001(sic) reviewed the 1995 NTP male rat kidney pathology slides and concluded that alpha 2u-globulin-induced nephropathy and chronic progressive nephropathy, or CPN, exacerbation were the only causative factors in the development of renal tubule tumors observed in males rats exposed to TBA in drinking water. And they felt that the -- they said that the PWG concluded that TBA-related renal changes in rats could not be extrapolated to human health risk assessment and were

unlikely to pose any risk for humans.

Our response is that we reviewed the Hard 2011 article. We discussed some of its conclusions in the prior version, the initial version, of the cancer hazard evaluation section of the document. However, OEHHA disagrees with the conclusions of Hard et al., based on data from Doi et al., 20 -- 2007, and Melnick et al., 2012, as was discussed in the document.

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DR. BUDROE: Another Lyondell comment was that OEHHA's proposed cancer slope factor for TBAc is based solely on their speculation that TBA, the primary metabolite of both TBAc and MTBE, is a genotoxic human carcinogen.

The OEHHA response is that the proposed TBAc cancer slope factor is based on a dose response analysis of the NTP 1995 TBA drinking water study. OEHHA did not state in the document that either TBAc or TBA are genotoxins, and does not propose a mode of action, or MoA, for TBA carcinogenicity.

However, given the limited positive genotoxicity data for TBA, it cannot be stated that TBA is not a genotoxicant. And this is significant to determining if TBA meets the IARC criteria on whether chemicals induce male rat kidney tumors through increased accumulation of

alpha 2u-globulins.

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DR. BUDROE: Another Lyondell comment was that the reason that OEHHA developed an interim risk factor for TBAc, based on the 1995 TBA chronic study, was because ARCO Chemical requested that the Air Resources Board grant a VOC exemption for TBAc, based on its negligible ozone-forming potential.

Our response is that the prior interim TBAc cancer inhalation unit risk factor was developed at the request of ARB, because of a VOC exemption request that was made by Lyondell Chemical Company on February 28th, 2000.

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DR. BUDROE: A Lyondell comment. The interim cancer risk factors developed by OEHHA in 1999 and 2000 for TBA and TBAc were never sanctioned by CIC or reviewed by the SRP.

And the OEHHA response is that interim cancer slope factor and unit risk for TBAc was not reviewed by the SRP, because these values were not intended for use in the Air Toxics Hot Spots Program. The CIC has no statutory authority to review or sanction hot spots or VOC exemption cancer risk factors.

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DR. BUDROE: Another Lyondell comment was that Lyondell requested a formal evaluation of the risk factors in 2011 and a peer review by the State's qualified experts, i.e. the CIC or SRP.

And the OEHHA response is that TBAc was entered into the hot spots evaluation process at the request of several air districts. Any development of either RELs or cancer risk factors would then be peer reviewed by the SRP. The CIC are the State's qualified experts for the purposes of Proposition 65, and has no authority to review peer review -- the peer review evaluations conducted under the Hot Spots Program.

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DR. BUDROE: Another Lyondell comment was that OEHHA failed to engage the CIC in resolving the scientific adequacy of the interim cancer risk factor assumptions. Lyondell's concern that OEHHA has not allotted adequate time for meaningful independent review and public comment, and is now asking the SRP to make a determination of carcinogenicity that is normally the purview of the CIC.

And the OEHHA response to that comment is that Lyondell misunderstands the role of the CIC which are the State's qualified experts for Proposition -- for the purposes of Proposition 65.

The CIC does not have the statutory authority to

review hot spots documents. The SRP is the entity that has statutory responsibility to peer review hot spots documents. And OEHHA believes that the time provided for public comment and the SRP review was adequate.

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DR. BUDROE: And that concludes my presentation, and would happy -- be happy to entertain any questions from the Panel.

CHAIRPERSON KLEINMAN: Okay. Thank you, John.

I understand that Beate and Kathy are able to hear the proceedings, and we are now going to try to arrange for them to be able to voice in on the meeting. So we'll take a 5-minute break before we start with the Panel discussion to allow the technical people to do that.

PANEL MEMBER GLANTZ: I just got another email from Kathy that says, "I am listening. I will announce myself when my oral capacity appears".

(Laughter.)

(Off record: 10:47 a.m.)

(Thereupon a recess was taken.)

(On record: 10:53 a.m.)

CHAIRPERSON KLEINMAN: I'd like to reconvene the meeting now. And before we go on with the questioning, I'd like to give Kathy Hammond and Beate Ritz an opportunity to just introduce themselves.

So start with you, Kathy.

PANEL MEMBER HAMMOND: Hi. I'm Kathy Hammond at UC Berkeley, professor Environmental Health Sciences. And one of my specialties is exposure assessment.

CHAIRPERSON KLEINMAN: Thank you.

PANEL MEMBER RITZ: And this is Beate Ritz. I'm a professor of environmental epidemiology with the Center of Occupational and Environmental Health at UCLA.

CHAIRPERSON KLEINMAN: All right. Thank you. So we'd like to now go on to the next phase of the meeting, which will be to have the Panel members discuss the revised document.

John.

DR. BUDROE: Dr. Kleinman, I'd like to introduce a member my staff, Dr. Rona Silva. She's one of the co-authors on this document, along with Dr. Kathy Vork. And she'll be possibly answering some of the questions on the exposure assessment and non-cancer toxicity section of the document.

CHAIRPERSON KLEINMAN: Thank you.

So I'd like to start with did Araujo who's the lead on the discussion, and then we'll continue from there.

PANEL MEMBER ARAUJO: Thank you, Dr. Kleinman. Thanks so much for the -- for all the work and -- that has

been invested on reviewing these documents, and also in the presentation with the summary of the changes.

The review was very extensive. And overall, I have to say that I am very pleased with all the work that was done. There were several points and issues that were critiqued. And I think that pretty much on all of them - I don't know if I am missing anyone - were addressed.

It has been strengthened and there are like new sections that are described in the summary of changes. The whole exposure sections in the beginning is new with tables and new studies.

There was a critique about the study -- the document not being updated and not including recent studies. And certainly, there is now an effort in including all the new studies, including studies that were published this year.

And several figures were critiqued, several tables were critiqued, and -- in the way how they were presented, and those changes were included.

If anything, I would have to say that the summary of changes was a little bit shy for everything that was done in the document. And I understand that it was in the interests of not making the presentation too extensive. But in the future, maybe you can -- you can go along and show everything that you did, because I think that it --

and for -- and those who didn't read the document and -- in detail as it would have been helpful to read and understand why is that you did many of the changes that you did.

The metabolized section was also expanded and strengthened. So I'm very pleased with that. And I think that I -- even myself have a better understanding from reading the document of what is -- what the TBA and dose and how it's metabolized.

I do have a question. It's about one of the changes that you did. I didn't quite understand the decision that you made and why. It was on the -- on Table 17. On Table 17, you omitted -- in the original presentation of the table, which corresponded to another number. You had presented the data for the male mice, and that you decided to remove that data entirely. I don't know why. What was that decision made?

DR. BUDROE: It was simply that we were presenting the tumor incidences where we did adjust it for effective number of animals. And since the male mice were being considered for cancer dose response analysis, we decided it was not necessary. It's just essentially extra data. So we pared it down to the key species and tumor types that we were developing the dose response analysis on.

PANEL MEMBER ARAUJO: Okay. So that was -- that is -- exemplifies one of the cases in which obviously you don't need to make an explanation in the document why you made that decision, but in the summary of changes, as you could have shown it. And that explain it by itself.

I also agreed with the essence of your responses and -- to the letters. And I believe that your explanations of why con -- what to consider TBAc as a carcinogen, just based on the data derived from the metabolites. I think that it was reported and -- in the document, as well as in the way how you responded to the letter and writers.

CHAIRPERSON KLEINMAN: Okay. Thank you.

I did not have too many substantive changes, most of my comments were very well addressed. Thank you for that. And one thing just reading the document, there was -- you know, it -- the shift in terminology from unit risk factor to inhalation unit risk, and then in the headings it's inhalation unit risk factor. I think it should be one or the other.

DR. BUDROE: Yeah. And we changed that in the current version, because we took a look at the guidance manual and the appendices in there. And what you see in the actual Hot Spots Guidance Manual is inhalation unit risk. So -- and it's -- I went back and looked over some

of the prior cancer documents, and they've really used both. There hasn't been -- there wasn't necessarily standardization, but we're going toward -- looking to standardize on cancer inhalation unit risk, or IUR.

CHAIRPERSON KLEINMAN: Yeah, I think it would be good to, yeah, just make sure that that's clear in the document, because, you know, people will start to look for two different things. And I have a few minor things which I'll give you in writing, you know, just minor changes.

The other thing that was sort of alluded to y Lyondell is that when some of these other agencies declare something -- you know, a substance to be a carcinogen, they have categories, you know, a known human carcinogen, a suspected human carcinogen. You know, they have various gradations.

And in this particular application for this purpose, we're not assigning anything like that, is that correct?

DR. BUDROE: That is correct.

CHAIRPERSON KLEINMAN: So our declaration of carcinogenicity will be seen as different than say an IARC designation or an EPA designation?

DR. BUDROE: That is correct.

CHAIRPERSON KLEINMAN: But that is within the purview of the statutes in California, is that correct?

DR. BUDROE: That is also correct.

CHAIRPERSON KLEINMAN: Okay. I just wanted to make sure we're all on the same page on that.

All right. Then I'd like to start with Dr. Buckpitt, who had some overall comments, and then some minor comments that he's given me in writing and I'll pass on.

PANEL MEMBER BUCKPITT: Yeah, thanks. These are all really minor comments. Again, I'd like to say that I thought you did a really good job making the case for using TBA as your standard. You went through all of the data, looking at the metabolism and how much is metabolized in the various species. I thought you did a very good job essentially blunting the comment that this is all driven by alpha 2-microglobulin. So I think in that respect, this is a well done document.

I had just a couple of things. When you have Figure 4 and -- unfortunately, I didn't put the page number down. But Figure 4 seems late in the document. If you could move that up -- I think it was on page 10. And this is on the metabolism of MTBE.

DR. SILVA: Which?

PANEL MEMBER BUCKPITT: Fourteen, yes.

DR. BUDROE: Okay. So you'd like that moved to the front of section --

PANEL MEMBER BUCKPITT: Moved forward, so that when we read the paragraph -- I mean, I was sitting there saying, oh, geez, did I have to go to the literature - shame on me - to actually see how this is? And you had it in there. Just move it forward, so that it's easily accessible.

DR. BUDROE: Okay. We can certainly do that.

PANEL MEMBER BUCKPITT: And then lines 328 through 335, you talk about the metabolites of MTBE and microsomal cytosolic Incubations. I presume those are the same metabolites. It wasn't specifically stated. But if you really look at the data, they cytosolic fraction is 1 percent or less of the microsomal fraction. I think it's a waste of time to even mention it. Those are microsomal metabolites.

I'm guessing that the data that 1 percent that -- or less that is there is probably contamination of the cytosolic fraction from microsomes. People aren't careful, they get microsomes in their cytosolic fraction.

DR. BUDROE: Okay. Well, that's not a critical section, so we could easily delete that.

PANEL MEMBER BUCKPITT: Absolutely not.

The lines 362 through 367, I think it might be useful to comment that the total metabolites include both the conjugated and unconjugated. Going back to the paper,

they actually used acid hydrolysis to cleave the glucuronides.

DR. BUDROE: Okay. We can provide mention of that.

PANEL MEMBER BUCKPITT: Line 373, you have C-13 labeled as a radioactive isotope, but that's just a stable isotope. And again, it's a minor comment.

The only other two comments so line 912, 913, the authors were evaluating adducts by using accelerator mass spectrometry. I would actually use adducts rather than damage, because damage can essentially be the result of oxidation of DNA basis, and I'll defer to Dr. Landolph if he disagrees.

And then line 1182 you have 8-hydroxy-deoxyguanosine as not an adduct at base. It's really an oxidized base. But it's just terminology.

And I have a few other things, but none of them are critical at all. So good job.

DR. BUDROE: Thank you.

CHAIRPERSON KLEINMAN: Stan.

PANEL MEMBER GLANTZ: Since this is almost all toxicology, I'll defer to my colleagues to know what they're talking about.

PANEL MEMBER BLANC: Any comments on the statistical analysis in terms of the tumor incidence

since -- in the oral comments, it talked about pairwise comparisons, but then talked about trend. And it was not entirely clear how the appropriate trend was being used when I looked at it.

PANEL MEMBER GLANTZ: Well, yeah, actually, now that you mention it, I had noted that. So I think -- I think in the tables, let me -- there are two tables where you have those data, which were -- I'm -- well, do you know the two tables I'm talking about? Yeah.

DR. BUDROE: I believe so.

PANEL MEMBER GLANTZ: Yeah, I think it would have been a better idea -- I'm sorry, I spaced out. I don't think it's going to change anything in the report, but I think it would have been better to have tested for a trend in the data, rather than just do a bunch of pairwise comparisons, which is what you did.

DR. BUDROE: Well, it -- I looked at that pretty exhaustively --

PANEL MEMBER GLANTZ: Okay.

DR. BUDROE: -- and what you're -- this is essentially the pairwise comparisons are for the hazard ID section of the document, is this or is this chemical -- is it or is it not a carcinogen.

And NTP in pretty much every cancer hazard ID document I've ever seen, they used to use chi-squared

comparisons. Now, they that use Fisher Exact. And you can get a trend test, Cochran–Armitage, out of -- if you run the data through the data through BMDS, for example. But it's essentially Fisher Exact is the gold standard. So where we would go, you know, other than that, I'm really not quite certain.

PANEL MEMBER GLANTZ: Well, I guess -- well, no, but the -- I mean, they're not incompatible. But as long as you think that things -- as the exposure goes up, the incident -- the tumor incidence goes up, why you -- can't you just test it against dose, or is it the numbers are too small?

DR. BUDROE: Well, we just -- it's -- we're using the Fisher Exact just to determine if the chemical is a carcinogen or not. Those -- that doesn't enter into the cancer dose response analysis.

PANEL MEMBER GLANTZ: Right. Right. But what I'm -- what -- I mean, the point Paul made up is when you're doing the pairwise comparisons with Fisher Exact tests or chi-squared depends on what the -- how big the numbers are.

You're -- you -- that has less power actually, the testing for a trend, because when you're looking at the pairwise comparisons, you're only looking at part of the data in each comparison, whereas if you test for a

trend, you're using all the data at once. So that's going to give you more power to detect an effect.

I mean, you detected an effect, even using the less powerful approach, so I don't think it substantively changes the document.

But I -- I was sort of surprised you didn't do a trend test. I mean, if you wanted to keep the pairwise comparisons, there's nothing -- you could, but I think you could -- the thing would be stronger, I mean, if you were to show that there is a trend in -- between -- as the dose goes up. I'm not talking about using it to quantify a particular dose-response relationship.

DR. BUDROE: We do include tend trests -- tend trests --

PANEL MEMBER GLANTZ: Trend tests.

DR. BUDROE: -- trend tests results for --

PANEL MEMBER GLANTZ: I didn't see the --

DR. BUDROE: -- both tumor types.

PANEL MEMBER GLANTZ: Well, maybe I missed it, but I didn't see it in those two tables.

PANEL MEMBER BLANC: I don't believe it was in the footer of the tables Was it somewhere buried in the text?

PANEL MEMBER GLANTZ: Yeah, because I went through this and -- I'm just trying to find the tables.

DR. BUDROE: Table 17.

PANEL MEMBER BLANC: Are you talking about what --

DR. BUDROE: Yeah, we actually note there was a significant trend test for dose response in the female mouse thyroid follicular cell adenomas. And that's in footer of the table.

PANEL MEMBER GLANTZ: Oh, okay. I was actually thinking maybe that -- okay. I was actually thinking about a couple table -- earlier tables. But maybe that -- that wasn't -- let me see if I can find them. I don't think this materially affects the report. That's why I didn't mention it. Let me see if I can find where it is.

DR. BUDROE: Yeah, we also mention it in Table 10, where we have the uncorrected tumor incidences. We include the trend test in the footer also.

PANEL MEMBER GLANTZ: I guess, the one -- Oh, okay, the one -- wait. Well, that wasn't it. Hang on.

Maybe I'm missing it here.

PANEL MEMBER BLANC: I think our confusion relates to the earlier table that presents the same animal data, but not reduced. I mean, this is a synopsis, right, Table 10, but doesn't the same animal study appear earlier in the document? Separately for the renal tubules and

then the thyroid, is that not correct?

PANEL MEMBER GLANTZ: You know, that -- I have to say, Paul, now that I'm looking at one more place --

DR. BUDROE: We have the trend test results.

PANEL MEMBER GLANTZ: Yeah, just let me -- I think. I think what happened -- let me -- because the reason I didn't say anything -- now that I look back at my notes here, is that as I was reading it, I had that question, but then you answered it.

So they actually did do the -- the stuff he's talking about they did in the revised version.

PANEL MEMBER BLANC: Got you.

PANEL MEMBER GLANTZ: So I -- yeah, so I was like going through -- I'm just looking at my notes where I said why didn't they do this. But then I went on an found you did it, so never mind.

(Laughter.)

PANEL MEMBER GLANTZ: So I'm happy.

(Laughter.)

CHAIRPERSON KLEINMAN: Thank you.

PANEL MEMBER GLANTZ: That's why I thought I was happy, but then Paul got me all confused.

(Laughter.)

PANEL MEMBER BLANC: It's all my fault.

(Laughter.)

PANEL MEMBER GLANTZ: Everything is always your fault.

CHAIRPERSON KLEINMAN: Paul, did you have any additional comments?

PANEL MEMBER BLANC: I want to make sure I understand the rational argument here just for my own edification. So the argument is -- or the way of addressing the challenge of the lack of data is that the metabolite of this chemical in small animal tests is a chemical which has been shown to be carcinogenic as per the tables we were just talking about. There's no human metabolic data for this chemical, and therefore by analogy, you rely on the metabolic data for MTBE, for which there is human data, and the presumption that since the enzymatic pathway relies on metabolic enzymes that are present in humans, it's a reasonable presumption that the -- that the chemical would be metabolized to the same carcinogen, is that correct?

DR. BUDROE: That is correct. And especially since in rats the bulk of the TBA production is going to be through carboxy -- carboxylesterase activity. And there's, you know, numerous CEs in humans, and they have a broad -- they're not narrowly specific, they're broadly active.

PANEL MEMBER BLANC: Right. So --

DR. BUDROE: So it's -- we believe it's a reasonable assumption to make that that same thing is going to happen -- process is going to happen in humans.

PANEL MEMBER BLANC: So I think at least in your summary, but elsewhere, it would be perhaps more conservative to say the presumptive human metabolite or -- because you -- what you state is it's metabolized to this -- this entity, this moiety, but, in fact, it's metabolized in rodents to that moiety, and presumptively also in humans. So I think that just for -- it would be better science if the word "presumptive" was inserted strategically.

DR. BUDROE: Okay. We can do that.

PANEL MEMBER BLANC: And then I have a very quirky question, which may be absurd, but there were tertiary-butyl acetate ester pharmaceuticals on the market, steroids specifically. And I just was wondering was there never any data filed with the FDA on the metabolism of that? It may be more than one pharmaceutical, but the one I know about is prednisolone one of the corticosteroids was or may still be marketed as the tertiary-butyl acetate ester. Did you ever look at that or hear about that?

DR. BUDROE: We didn't pull it up on any of our literature searches. And sometimes some of that -- some

of the FDA filing data can be pretty difficult to acquire.

PANEL MEMBER BLANC: Yeah, I just think it would be -- I mean, because so much of this -- you know, you're forced, from the lack of data, to go down this route, which I'm not saying is unreasonable, but it would be really nice to be able to either say there is some data from that, or there's no data for that either.

I don't want to hang up the document on that, but I was just -- and I could be completely wrong that that's what it's called, but it's not really an ester of that. It -- just looking at it quickly, it seemed to be that's what that was.

DR. BUDROE: We can take a look and see if there's any data out there that we can get a hold of in that respect.

PANEL MEMBER BLANC: And similarly on the lack of data front, there are two -- there's a statement that's -- I understand why you said it, but it's somewhat, on the face of it, contradictory, which is you say that there's no occupational data. Which is true in the sense of I couldn't at least find any work-related investigations. And then you quote occupational exposure data, which is based on ILO statements or something.

But I think you have to use some wording which makes clear what you mean when you say there's no

occupational data, like there's no occupational data that's -- there's no published occupational data on specific work-site investigations or case reports or whatever. That it's -- somebody came up in the ILO with these statements about what happened, it's irritating, it's this, it's that, right? But you don't have any -- we don't know if that was personal communications or what -- where is that derived from.

But still, you can't on one page say there's no occupational data and then on another page say the occupational exposures are associated with X, Y, and Z.

DR. BUDROE: We can make it clearer that what we're referring to is we haven't been able to find any occupational studies published.

PANEL MEMBER BLANC: Well, any specific -- some wording that makes it clear what it is you mean when --

DR. BUDROE: Right. We'll -- we'll endeavor to clarify that.

PANEL MEMBER HAMMOND: Yeah, I also --

PANEL MEMBER BLANC: Because it must be --

PANEL MEMBER HAMMOND: Yeah, I don't want to interrupt except but I am, of course.

I think -- I have several comments on the occupational data. But I don't know if you want to do this in topics or just go around to the people. I defer

to you, Michael.

I can't hear you.

PANEL MEMBER GLANTZ: I had one --

CHAIRPERSON KLEINMAN: Kathy. Yeah, we can hear you. Stan has another comment that he wanted to interject and then we'll pass the baton to you.

PANEL MEMBER HAMMOND: Okay. Thank you.

PANEL MEMBER GLANTZ: Just to show that I did read it. Actually, you have the name of that office wrong. It's the International Labor Organization not Office. So that's on line 199 of the track changes version.

CHAIRPERSON KLEINMAN: Paul, did you have anything further?

PANEL MEMBER BLANC: No. Those were my salient points.

CHAIRPERSON KLEINMAN: Thank you.

Okay. Kathy, I'll pass the baton to you.

PANEL MEMBER HAMMOND: Okay. I guess I'm looking at Table 1, and I'm looking at versions of tracks just for clarity.

I think that there -- for me, there are things that make it difficult to understand. Like there's an expression here, "near source". It took me a couple times looking at it to realize when we say near source, you mean

as a worker who's right there working with something? And then far source means that they're across the room. And I think here near source means out environmentally near the building in which the material shoots, is that correct?

DR. BUDROE: That's correct.

PANEL MEMBER HAMMOND: Yeah. So I think that that probably should be clarified. I don't know, I would rather -- rather than putting near source, I'd say something like near a building or where it's being used, because otherwise it's just -- there's a whole other research area that does -- uses different terminology.

And then if you look at the first two lines of data 1 hour concentration, and it's the big -- and these are really modeled exposures not measured, as I understand it, is 269 ppb, whereas being near source, which means an environmental exposure. And I'm not sure how near that is, if the paper tells you that. But if it does, we should put that in, like 50 feet away or whatever it is.

But that must be some particular distance and that should be in the -- defined there. That's higher. That doesn't make sense. Occupational exposure is less than far from use.

DR. BUDROE: Okay. Well, we do, to some degree, define what a near-source concentration is in the figure legend. Near source concentrations were estimated at the

facility fence line are 20 to 30 meters from the point source, unless otherwise noted.

PANEL MEMBER HAMMOND: Yes. So, you know, I would say 20 to 30 meters from the facility. So like, you know -- or just facility -- but I wouldn't call it near source, because near source, in my world, means that you're using the material directly, okay? And I don't think we should mix those things.

But then secondly, there's just these values don't make sense. You've got a consumer having -- these first three acute exposure scenarios do not make sense, and --

DR. BUDROE: Right. Well, this was taken from Bus 2014, and it's a compilation of a number of different modeling es -- modeling scenarios. And we don't really vouch for whether they did these correctly or not. We're just essentially reporting what was published in the literature. So, you know, if you went and looked at -- went back and looked at the modeling assumptions, I can't guarantee that they do make sense, but, you know, this is what --

PANEL MEMBER HAMMOND: Yeah, but if you were -- if you were looking at a toxicity study, and you saw a fatal flaw in how they did something, you would note it, you know, or you might even choose not to use it. I don't

think that just copying what's in the literature is appropriate. You know, this may include assumptions of using respiratory protection. I have to assume that that's what's there, but it doesn't say that, and I'm not totally convinced that in all auto repair shops that they actually use respiratory protection. And if they do, that it's effective respiratory protection.

There may be implicit respiratory protection, you know, assumptions here, but it's not. And it is mentioned below that everybody does it, but I'm not sure everybody does it. And if they do, it's probably paper masks that are not all that effective.

So beyond that, I -- since most of these things are not -- I think there should at least be an indication, are all of these measured -- or, I mean, calculated -- just estimates calculated or are they measured?

And if they're estimated calculated, several of these things just -- you know, they're too -- they're not different enough to be worth anything. If they're actually measured, then that's useful.

DR. BUDROE: Well, they are all modeled concentrations. We do mention in the figure legend that we were only able to confirm the model concentrations attributed to ARB.

PANEL MEMBER HAMMOND: And -- yeah. Anyhow, I

just am concerned that the occupational level is tremendously underestimated. Perhaps there could be in the scenario listed at least an indication which of these scenarios are measured values, as opposed to calculated.

DR. BUDROE: Okay. Well, then none of them are measured. They're all calculated.

PANEL MEMBER HAMMOND: That's what I thought. Yeah.

DR. BUDROE: We could make that more explicit in the text.

PANEL MEMBER HAMMOND: Right. Yeah. Well, as I say, I don't -- and this is a minor thing, but in the acute exposure scenarios, if you're going to use scientific notation, use scientific notation. So, for instance, rather 461 times 10 to the 3rd, I'd suggest 4.61 times 10 to the 5th, because at first it's a little jarring to see the microgram per cubic meter to ppb.

But I really do have to say I don't believe the occupational number. And these chronic exposure scenarios, these are all environmental, correct? None of these are occupational, if I understand it.

Oh, I see. Then it's occupational down here. But the near source should be, you know, again made clearer, which ones are -- that it's at the facility fence line or 20 to 50. Near the facility would be better than

near source. Maybe that would be the simpler way to put it. And then have the footnote, you know, at that point, where you do talk about it in -- I know it's down there in the footnote. I read that.

But again, the occupational numbers, the first couple are not credible. And then you look at the others, and they begin to be credible. So I don't even know what they're doing there. How they get those -- those scenarios. I did not go back to the original paper, but I have difficulty believing those values. Is Kathy Vork there? Maybe she can answer that.

DR. BUDROE: Kathy Vork is present, but she didn't work on this section of the document.

PANEL MEMBER HAMMOND: Oh, okay.

DR. BUDROE: Rona Silva did. She's here at the table.

PANEL MEMBER HAMMOND: Okay. Anyhow, those were my concerns. I don't know did anybody actually take a careful look at this table, or is it just kind of put in? I believe it's a little misleading.

CHAIRPERSON KLEINMAN: John, let me ask, when you have numbers with these kinds of disparities, you know, how are those scenarios, you know, played into your final determinations?

DR. BUDROE: It doesn't play into our final

determinations at all. This is really just more informational. I mean, actually the comment was made by the Panel at the last meeting that we should include some of the exposure scenario information that Bus published. And he in turn pulled it from a number of different -- I think developed some of it himself, and the bulk of it was developed by different air districts or ARB. So we included it essentially in the front part of the document as informational item. But it actually won't go into the appendix B part of the cancer TSD.

CHAIRPERSON KLEINMAN: Okay. It might be worth putting in a sentence to that effect --

DR. BUDROE: Okay.

CHAIRPERSON KLEINMAN: -- that, yeah, these are here for informational purposes to give, you know, an idea of the range of potential exposures based on models.

DR. BUDROE: We can do that.

PANEL MEMBER HAMMOND: Okay. That's all. As I say, I would rather see, if you don't think it's too distorting of what Bus said, rather than "near source", maybe call it "near facility".

DR. BUDROE: We can do that.

CHAIRPERSON KLEINMAN: Okay. Beate, did you have any comments?

PANEL MEMBER RITZ: No, I'm fine. Thank you.

CHAIRPERSON KLEINMAN: Thank you.

Cort.

PANEL MEMBER ANASTASIO: No, I didn't have any comments either.

CHAIRPERSON KLEINMAN: Joe, I know you've -- knowing you, you probably did take a look at the document. Do you have any comments?

PANEL MEMBER LANDOLPH: Yeah, I did. I read it fairly carefully. And I wanted to congratulate the authors and their team, which I think did a very strong job, very thorough job of putting the document together. I think they answered SRP's comments in a fair spirit of peer review, and they answered the Lyondell comments in a fair spirit of peer review.

So I thought the document was written in a fairly balanced fashion, and I agree with most of its comments.

I was looking at the TA102 data, and I could see there was a little bit of variability from lab to lab there. One lab says yes, one lab says no. So clearly, the genotoxicity is still not completely nailed down. And that's okay. That's fine.

And I agree that it is a carcinogen and can be treated as such, and that you can make calculations like you've done. So I came into this in mid-stream, so I'm not as critical as the rest of you, but I think the

document is petty good.

CHAIRPERSON KLEINMAN: Okay. Thank you.

So I think that's -- everybody has had an opportunity to provide some additional comments.

I do have a few things in writing that I will pass on. But just to poll the Panel, does anybody feel that there are any major issues that would require the document to come back before the Panel?

Okay. The answer to that was no.

Therefore, what I'd like to do is ask for a motion to request that the document be revised according to the comments that we provided today. And that if the Panel will give me the purview to do this, I'll have the document returned to me. I will just go through it and make sure the comments have been dealt with, and then we will be able to call the case closed, because the State law requires that the agency, OEHHA, seeks our advice and recommended changes. And I think that by have -- you know, once we have these final changes in, the Panel will have fulfilled its statutory obligations, and so I'd like to ask for a motion to do that.

PANEL MEMBER ARAUJO: I have just one comment and -- prior to that, that is in relation to the point of the near source as Kathy was alluding to. So I'm not an expert on this by any reasons. I'm just trying to

understand your point of view, Kathy. So if it is a -- so is it universally accepted let's say from where you're coming from near source is how you define it, as opposed to how it's defined by the authors. And I assume that perhaps is.

However, I also understand why is it that you put the near source in the table, because that how it appear in the paper probably, right?

DR. BUDROE: (Nods head.)

PANEL MEMBER ARAUJO: And the definition of the near source is in the legend of the table. But you still have concerns that this definition is not -- doesn't reflect the more generally-accepted definition. So you propose to change it to another term, and --

PANEL MEMBER HAMMOND: Yes, you have -- you understand correctly. What I was saying maybe it could just be near facility.

PANEL MEMBER ARAUJO: But that introduces another problem, which is when people go and go to the original source, or paper, so they would see what it was they were talking about. So why they're calling this near source versus near facility or whatever. What if, and instead, you know, he either puts like quotation marks on the near source, one possibility, or another possibility that he specifies in the legend of the table near source as

defined by the authors in this paper is, and then gives the definition.

But I think that there is a value of keeping the terminology just as it was used in the paper to facilitate understanding of the document when people go to the original source. What do you think?

PANEL MEMBER GLANTZ: Well, I -- this is Stan. Well, I would -- I think that's a good suggestion, but I would actually -- to have the document itself clearer, I think the suggestion of saying "near facility" in the table, and then in the footnote say in the paper this is called "near source", so that the language in the table -- I mean, this is a point I missed when I went through it. But I think now that it's been brought up, you can say near facility in the table, and then just have a footnote that says in the original paper, the language that was used was near source. And I think that will -- that will get at what you're saying --

PANEL MEMBER ARAUJO: Right.

PANEL MEMBER GLANTZ: -- and also fix the thing Kathy was worried about.

PANEL MEMBER ARAUJO: I would agree, absolutely, yes.

PANEL MEMBER HAMMOND: I agree.

CHAIRPERSON KLEINMAN: Okay. On that note.

John, you can handle those kinds of changes?

DR. BUDROE: We can definitely handle those changes.

CHAIRPERSON KLEINMAN: Okay.

PANEL MEMBER GLANTZ: So I'll move the motion that the Chair suggested.

PANEL MEMBER BLANC: You have to restate the motion.

PANEL MEMBER GLANTZ: Oh, I do. Okay. Well, so I move that the Panel approved the report, subject to the minor clarifications that have been discussed at the meeting, and that the updated report be delivered to the Chair for approval. And should the Chair think there's anything substantive, he can always bring it back to the Panel. But if the Chair finds that you've sub -- you've correctly made the changes the Panel suggested, then the report would be finished.

PANEL MEMBER BLANC: I'll second the motion. Paul Blanc.

CHAIRPERSON KLEINMAN: All in favor here?

(Hands raised.)

CHAIRPERSON KLEINMAN: Everybody is unanimous. Kathy?

PANEL MEMBER HAMMOND: Aye, yes.

Aye.

CHAIRPERSON KLEINMAN: Okay. It is passed unanimously.

PANEL MEMBER RITZ: Mr too, Beate.

CHAIRPERSON KLEINMAN: Oh, I thought I heard you say it.

Okay. Thank you, Beate.

All right. That concludes the session on TBAc.

We are, wow, remarkably on time. And we're ready to start a briefing on chlorpyrifos. Now, this is an item that's going to be presented by Department of Pesticide Regulation on the Toxic Air Contaminant Program for Pesticides. And they'll be giving us an introduction to their risk assessment for chlorpyrifos proposing that it be listed as a toxic air contaminant.

By law, the health risk assessment supporting a proposed listing of a substance as a toxic air contaminant is to be reviewed by the SRP.

So as a background, Division of Pesticide Research published a draft risk assessment in December of 2015, and received several comments from stakeholders after a public review. In August of 2017, DPR published a second draft, made it available for public comments which closed on October 2nd of 2017. DPR staff has since revised the document in response to those comments. And those comments were sent to this Panel a few days ago for

the initiation of our peer review.

By law, the Panel must review the scientific data on which the report is based, the scientific procedures, and methods used to support the data, and the conclusions and assessments on which the report is based.

If the Panel finds that the report is not sufficiently deficient, we must submit written findings to the DPR Director, who decides if a pesticide should be listed as a toxic air contaminant. So if the Panel finds a report is deficient, then we will advise the Director for accordingly.

Because the document was sent to the Panel too soon before the date of this meeting, and also it has been a long term before -- since the Panel considered a proposed toxic air contaminant, we've asked DPR staff to provide us with a background briefing on the chemical, and an overview of the DPR report, and a description of some charge questions that DPR is specifically asking the Panel to address.

The DPR chlorpyrifos report -- chlorpyrifos -- sorry -- report dated December 11th, 2017 has been sent to the Panel. It has been posted on the DPR website, and that has been noted on the public notice for this meeting.

Let me also take note that the Panel received written comments in a letter dated December 4th from

Californians for Pesticide Reform, and attached to their letter, they also included a copy of their technical comments dated October 2nd, 2017 submitted to DPR on the August 2017 chlorpyrifos public review draft.

They also sent a copy of comments from Health Professionals submitted to the U.S. EPA supporting U.S. EPA's 2016 revised human health risk assessment for chlorpyrifos, and also a copy of a letter dated October 2nd, 2017 to the DPR Director from 84 organizations calling for greater protections from chlorpyrifos for California's children.

The Panel is going to review those comments as part of its review of the report. So with that, I'd like to turn the meeting over to Marylou Verder-Carlos who is the Assistant Director of DPR who will begin the presentation.

PANEL MEMBER GLANTZ: Can I just say one thing?

CHAIRPERSON KLEINMAN: Oh, sorry. Yes, Stan.

PANEL MEMBER GLANTZ: So I'd just like to make a couple process comments. On the report that we just finished, which we all thought was pretty good. It took a year. And I think the law says it's supposed to come -- after this Panel has considered a report, it's supposed to come back to us in something like 60 or 90 days. And, you know, I realize these things are complicated, and

sometimes it takes a little longer, but -- I'm not talking about the DPR, I'm talking about the previous report.

But I think a year is ridiculous. And I think that, you know, you need to come -- at least come close to -- I'm talking to -- hi, John. I'm just complaining that, you know, the previous report took a year to come back to us. And I think the law says it's supposed to be 60 or 90 days.

So I think that, you know, you need to make a effort to at least come close to that. So I don't know if you want to say thinking about how mean I am, but...

(Laughter.)

PANEL MEMBER GLANTZ: And then I'll talk about DPR.

(Laughter.)

PANEL MEMBER GLANTZ: Yeah. Did you want to say anything or -- I'm -- or I just want to put that on the record. You don't have to respond. But if you want to, I'd love for you to do it.

DR. BUDROE: I would say that because of the technical complexity of the document that this was a special case, and we don't envision this happening in the future. It was also partly meeting scheduling also.

PANEL MEMBER GLANTZ: Okay. But even so, I think that the -- you know, the changes that were made to the

working part of the document near the end, which actually led to the risk assessment were not gigan -- I mean, there were some substantial changes there that did affect the risk estimates, but, I mean, most of the changes were the background material that was added.

And I just think, you know, a year is like way longer than 60 to 90 days. And we have had, in the past, a few things. And I'm not saying this has happened in this case. But there have been a couple of reports that are basically getting sat on for political reasons. And I'm not saying that happened here, but I do think that the agency needs to -- if you're not going to at least come close to what the requirements in the law, at least there should have been some kind of justification for that.

And I think that's very important moving forward to get back to where we're -- I mean, I think that the timetable written into the law is one of the good things about the law. And I think that the -- that the agency needs to -- you know, if you can't meet them exactly, to not have it take a year.

That -- I mean, I don't want to hijack the whole meeting for that, but I was troubled by that.

DR. BUDROE: Okay. We will definitely endeavor to have a faster turn around on documents that the Panel wants.

PANEL MEMBER GLANTZ: Yeah, and again, the law has a specific requirement in it. It isn't like me making that up, so we should -- so anyway.

And with regard to DPR, I have to say having this huge report dumped on us two days -- or a day or two before the meeting and all the -- and I would say this to the public commenters, too, that, you know, I understand that this is -- we're just being briefed to help us get going into the document, but it would have been nice to have gotten it a week or two in advance, especially given the length and complexity of it, and the fact that this is going to be controversial. To at least have had a chance to look at the document, and look at the public -- not study them, you know, but to at least look through them to come to this meeting with some idea of what questions we had. It would have made this a much more effective briefing.

I mean, it's like when I tell my students in my statistics class, try doing the problems before I lecture on them. You don't have to do the problems. You don't have to turn your homework in. But if you try them a little bit, you'll come in with a lot sharper questions in your mind and you'll get a lot more out of the lectures.

And, you know, I think that's the case here. I mean, I actually did make an attempt, but it's just

impossible you know. I mean, I got to read -- I read your charge. I opened the document and saw that it was very thick after I printed it out. And I spent a -- I like looked at the public comments, which is what I usually start with when I do this, enough to see that there were some -- there was a broad spectrum of opinions being represented there.

But if I had had a week, or better yet two weeks, to do that, even though I wouldn't have been coming in here with detailed comments on anything, this briefing would have been way more useful. And I just never want to get a pile of stuff dumped on me a day or two before the meeting, you know.

And, I mean, the public commenters do that too sometimes, which I think is not in their interest, because -- because this -- these reports are highly technical, and difficult in many cases. And having the time to be able to go through what everybody says carefully and think about it a little bit before we come in here is, I think, one reason this process has worked so well.

And we just -- and I think if there's someway to tell the public that they -- you know, if they -- that they can't depend on us to read anything they send in two days before the meeting. I mean, it's a joke.

So I hope this never happens again on this report or anything else.

CHAIRPERSON KLEINMAN: Well, I'll take partial blame for having the report delivered at the last minute. And my rationale was that we had gotten access to the early draft, which went out for public comment. And the public comments were quite extensive and did require a lot of rewrite.

And I felt that since we -- you know, the public draft had been available, and we had some idea of what the comments were, I thought it would be useful, even though we were not going to review it today, for us to get this preliminary presentation on it.

So the intent is not to --

PANEL MEMBER GLANTZ: No, I -- I agree that the preliminary presentation is a good idea. I think it's going to be very helpful in going through the document and the public comments and, you know, thinking about it.

But what I'm objecting to is that, you know, I mean, if you're going to send us all this stuff, send it to us with enough time to at least look at it, you know, without trying to do it at midnight the night before. I mean, it's just there -- to me, I mean, it's just like -- and I don't want to go on and on.

I mean, I just got in a huge argument with the

FDA about this on a different issue. But the -- but you know, it's like students turning in, you know, term papers. You know, if you push -- if you guys had just maybe worked all night or a couple of weekends a couple weeks ago, you could have gotten us this stuff in enough time to at least look at. I'm not saying study it.

But, you know, if you're going to send it to us before we had this meeting today, which I think in principal was a good idea, I think it was a very good idea, but you know, we should have gotten it in enough time to let people look at it, given that this is not the only thing we do in our lives.

CHAIRPERSON KLEINMAN: Yeah. Originally, it might not --

PANEL MEMBER GLANTZ: I'll stop beating that, but I was --

CHAIRPERSON KLEINMAN: Yeah. Originally, my thought was just to prevent that kind of, you know, negative reaction just to send the executive summary, which was only 13 pages and then --

PANEL MEMBER GLANTZ: Well, even that -- and I didn't want to take too much time --

CHAIRPERSON KLEINMAN: But, yeah, I agree that we won't --

PANEL MEMBER GLANTZ: But even that, given

everything else I've been having to do and all the other deadlines I've had to meet because of my day job, you know, it just -- even to read a -- because I tried to read the executive summary like at 11:30 at night when I was exhausted. And it's just -- it does not serve the process well.

And I think if somebody has got to stay up all night on this, it should be you guys, to get us in enough time that we can, you know -- I mean, I think this would have been a much more useful meeting had I had the time to read the executive summary when I was awake.

And I just think you need to -- I mean, you need to just -- this has been cooking for a long time. And you've been working on it for a long time. And having, you know, doing whatever you need to do to get us just -- even just a week before the meeting. And it would have been better to have been two weeks, you know, so we could have not come in here with this huge pile of stuff sitting on my dining room table making me feel guilty.

So I don't really want to be ever put in that position again as a member of this panel. I just -- and again, the same thing holds for the public, because we have had substantive -- not on this necessarily, although to some extent on this.

But we've had other documents come through where

we get lengthy public comments coming in at the last minute, and OEHHA has actually managed to have responses to them at the meeting. But it's way better to have not only the comments, but OEHHA's responses before the meeting so we can -- at least for me personally, so I can read it and I think about it before I come in here. But then you can't get in a position of jamming OEHHA either.

So I think there needs to be some, you know, real discipline imposed on this process if it's going to work well.

So I'll stop having -- I mean, but I got real -- I mean, because I try to take this very seriously. And I feel really bad that I got all this stuff sent to me and I didn't get a chance to even skim it.

CHAIRPERSON KLEINMAN: Well, I agree that this has not been optimal, but we will have the chance to go into this in-depth next month. But for now, I'd like to turn this over to Marylou to give us the briefing.

Thank you.

DPR ASSISTANT DIRECTOR VERDER-CARLOS: Good morning. I would like -- first of all, I'd like to introduce our team that worked on chlorpyrifos. While Randy and I are going to be doing the presentation, the team -- our team in DPR is composed of Shelley DuTeaux, our Branch Chief for Human Health Assessment -- Dr.

Shelley DuTeaux. Dr. Svetlana Koshlukova, our Risk Assessor Supervisor; and then Terry Barry, who is our exposure assessor; and Erik Kwok, the supervisor of the Exposure Assessment Branch -- Exposure Assessment Section; Marilyn Silva, who was the main risk assessor for this chemical; and also Carolyn Lewis, who worked on this. So we worked on this for, like you said, a long time.

So Dr. Glantz, we're -- we apologize that this was only two days before. But like Dr. Kleinman said, we would really like to have an in-depth discussion on this next month.

So anyway for -- then Randy Segawa, a special advisor for the Director, who is going to start the presentation. And then I'm going to take over in the -- during the risk assessment part.

(Thereupon an overhead presentation was Presented as follows.)

DPR SPECIAL ADVISORY SEGAWA: Good morning. I am Randy Segawa, Special Advisor the DPR. And since it's been awhile since this Panel has reviewed a pesticide, and a number of you are new, we thought that we'd go over some background information first.

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DPR SPECIAL ADVISOR SEGAWA: Some background information pesticide regulation in general, as well as

the toxic air contaminant requirements for pesticides, and then move on to a brief description of chlorpyrifos.

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DPR SPECIAL ADVISOR SEGAWA: So to begin with, under the Federal Insecticide, Fungicide, and Rodenticide Act, what we call FIFRA, and some other federal and State laws, three agencies within California are responsible for the sales and use of pesticides. Those three agencies are the U.S. Environmental Protection Agency, the Department of Pesticide Regulation, which is part of CalEPA. DPR is composed of six program branches, and we have about 400 employees.

And then the third agency are the county agricultural commissioners.

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DPR SPECIAL ADVISOR SEGAWA: DPR has extensive programs to review, evaluate, and mitigate pesticides. We, of course, register pesticides and we develop mitigation measures. We have a similar process as U.S. EPA. In fact, the process starts with EPA registration. EPA reviews the -- any new pesticide first and makes a decision to register. If they do register it, then it does come to California. If there are no adverse impacts identified or those adverse impacts can be mitigated, then DPR would register the pesticides.

After registration, DPR has a continuous evaluation program, in which we catalog and evaluate pesticide illnesses. We do monitoring for our human exposure, particularly for workers. We do air monitoring. We do water monitoring, and we monitor residues in food.

We have an extensive enforcement program in conjunction with the county agricultural commissioners, and so we evaluate use and violations as those occur, and DPR does receive new studies from pesticide registrants or from others that we look at. As part of the continuous evaluation, we do have a health risk assessment program, where we prioritize and evaluate pesticides for toxicity and for exposure.

If we find that the risks are unacceptable, then DPR would undertake development of mitigation measures. That starts with DPR issuing a risk management directive. This document specifies the scope and the goals for the development of mitigation measures. What exposure scenarios need to be mitigated, and gives us some target levels to achieve.

And then we, of course, would develop those mitigation measures, not only for potential health risks, but potential environmental risks if needed.

DPR also has legal authority to request additional informational from pesticide registrants, if we

find that there is a potential problem and we can evaluate that data and incorporate it into our -- both or risk assessments as well as our risk mitigations.

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DPR SPECIAL ADVISOR SEGAWA: In terms of use requirements, EPA, DPR, and county ag commissioners implement and enforce mitigation measures through use requirements.

And there are three types of use requirements. EPA specifies requirements through product labels. DPR has some statewide regulations regarding the use of pesticides, and then county ag commissioners for a certain set of, what we call, restricted materials can implement some more restrictive requirements as well.

And so DPR can designate some pesticides, including chlorpyrifos, as restricted materials. And these restricted materials have their own set of requirements. The applications need to be made or supervised by a certified applicator. A permit is required from the county ag commissioners before a person can purchase or use restricted material. And the county ag commissioner is required to evaluate specific applications sites and dates, then approve, deny, or condition a permit depending on that evaluation.

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DPR SPECIAL ADVISOR SEGAWA: As I mentioned before, DPR is part of CalEPA divided into six program branches that you see sort of in the middle there. We have our Registration Branch, or Human Health Assessment Branch, Worker Health and Safety, Pesticide Enforcement, Pest Management and Licensing and Environmental Monitoring.

Brian Leahy is our Director, but the five people you see highlighted there, they will be your main contacts for toxic air contaminants led by our Assistant Director, Dr. Marylou Verder-Carlos. And then the risk assessment themselves are authored by the Human Health Assessment Branch, led by Shelley DuTeaux, And Svetlana Koshlukova, and Eric Kwok.

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DPR SPECIAL ADVISOR SEGAWA: So moving on to toxic air contaminant requirements. OEHHA and ARB have their own set of requirements under Health and Safety Code. And then DPR has a separate set of similar requirements under the Food and Agricultural Code.

And under Food and Ag Code, Air Resources Board is required to monitor for pesticides in air at DPR's request. DPR is required to assess the human health risks from pesticides in air. We have some companion regulations that specify the criteria for designating a

pesticide as a toxic air contaminant, and then DPR is required to mitigate health risks from pesticides in the air as needed.

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DPR SPECIAL ADVISOR SEGAWA: So first element of the TAC program is monitoring. This is primarily done by the Air Resources Board, but DPR also conducts some air monitoring. In general, there are two types of air monitoring, that's conducted. One, that we call application site monitoring. This is in the immediate vicinity of a field to estimate acute short-term exposures.

Then we also conduct ambient air monitoring. This occurs in communities or regions of high use during periods of high use to estimate seasonal or longer term exposures.

Then more recently, sort of separate from our TAC program, DPR now has, what we refer to, as an air monitoring network that was initiated in 2011. When we started in 2011, we were monitoring three communities statewide for 31 different pesticides and their breakdown products.

Beginning in 2017, we're in the process of expanding that air monitoring network. For this year, it currently includes four communities, then beginning in

2018 we'll expand it to eight. And that monitoring does include monitoring for chlorpyrifos.

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DPR SPECIAL ADVISOR SEGAWA: Second element to our TAC program is risk assessment. Under State law, the risk assessment must include evaluation of certain issues, including the potency of the chemical, mode of action, levels that could cause adverse affects. Then in addition, State law requires OEHHA to provide its funding to the SRP for its consideration as well.

State law requires DPR's risk assessment to undergo review by OEHHA, as well as the Air Resources Board. In addition, DPR must release the draft risk assessment to the public. And then, of course, the Scientific Review Panel must also review the assessment to determine if it's seriously deficient based on the data, procedures, and methods used in the report, and the conclusions. And then after these reviews, DPR does finalize the risk assessment and moves on to risk mitigation.

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DPR SPECIAL ADVISOR SEGAWA: If you haven't read the Food and Ag Code and you probably should at least -- your portions that you're responsible, this is an excerpt out of State law, particularly as it pertains to the SRP.

And so it does layout the requirements of the issues that you need to review. Dr. Glantz also lays out the timeline that we're responsible for as well, both the Panel, as well as for DPR. And probably the key legal requirement is there in subsection (c), where the Scientific Review Panel determines that the health effects report, whether or not it is seriously deficient. That's the key finding that you need to make.

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DPR SPECIAL ADVISOR SEGAWA: After the review, is complete, then DPR's Director determines whether or not to designate a pesticide as a toxic air contaminant. We have the criteria in State regulations. And for non-cancer effects, that criteria has a threshold level that is 10 times below the air concentration determined by the Director to be protective of human health, which is a little bit confusing. It's probably best to give you an example. We completed a risk assessment for chloropicrin back in 2010.

That risk assessment included a reference concentration of 4.4 parts per billion. And so DPR listed chloropicrin as a toxic air contaminant, because air concentrations that were monitored and modeled indicated that concentrations exceeded 0.44 parts per billion. And those pesticides that have cancer effects, there's also a

similar criteria for those.

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DPR SPECIAL ADVISOR SEGAWA: DPR designates a pesticide as a toxic air contaminant using a formal rulemaking process, the process that is standard for the State of California. We also list federal hazardous air pollutants as toxic air contaminants as well. The flowchart there shows the -- can be lengthy process for doing rulemaking.

In the case of listing a pesticide as a TAC, it's somewhat more of an abbreviated process. There is a public hearing though. There's a public comment period. And, of course, DPR needs to respond to all the comments in writing. And so the process can take several months from beginning to end.

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DPR SPECIAL ADVISOR SEGAWA: Once a pesticide is designated as a toxic air contaminant, then DPR must determine the need for and the appropriate degree of mitigation.

If mitigation measures are needed, then DPR would issue a risk management directive that does contain the regulatory target levels the air concentrations that we want to try to achieve. State law requires DPR to develop those mitigation measures within two years, or we need to

submit a report to legislature explaining why we weren't able to meet the two-year deadline.

And State law requires DPR to consult with specified agencies in developing the mitigation measures, including OEHHA, Air Resources Board, county ag commissioners, and some other agencies.

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DPR SPECIAL ADVISOR SEGAWA: Currently, DPR has listed eight pesticides as being toxic air contaminants that went through the evaluation process. Those eight pesticides are listed there on the slide. In addition, we have listed 38 other pesticides, because they are designated as hazardous air pollutants under the federal Clean Air Act.

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DPR SPECIAL ADVISOR SEGAWA: Any questions about what DPR does in general?

No. Okay. Moving on then to chlorpyrifos.

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DPR SPECIAL ADVISOR SEGAWA: To give you some background information before we actually start discussion of the risk assessment. Chlorpyrifos is an organophosphate insecticide primarily used on agricultural crops. In the table there, you can see the annual use in California since 2013. Use on agricultural crops

comprises more than 99 percent of the uses. And so other uses could be things like golf courses, cemeteries, things like that, but the bulk of the use is for agricultural crops.

Dow AgroSciences is the registrant for the most highly used products, and you'll see some comments and responses from them as well.

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DPR SPECIAL ADVISOR SEGAWA: In the table, you can see that for the last few years, use has been declining. In fact, if you go back further to like the early 2000s or so, use of chlorpyrifos was in the neighborhood of two million pounds per year. And so since that time use has decreased significantly.

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DPR SPECIAL ADVISOR SEGAWA: Chlorpyrifos is used on more than 60 crops. It is one of the more commonly used pesticides in California. But there are a handful of crops that do account for most of the use. Almonds, alfalfa, orange and other citrus crops, walnuts, cotton, and grapes comprise the majority of the use.

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DPR SPECIAL ADVISOR SEGAWA: In terms of application methods, a little over a quarter of the applications are done by aircraft, both fixed wing

aircraft as well as helicopter. But most of the applications are by ground, usually either with a ground-rig, a ground boom sprayer or airblast sprayer. And if you're not familiar with airblast sprayer and that term, this is equipment used primarily for orchards and vineyards to spray the foliage.

And, of course, some of those orchards can be pretty tall, and so these airblast sprayer spray the chlorpyrifos, so it reaches the tops of the trees.

You might be interested as to what the breakdown is between the more specific application methods. And unfortunately, our Pesticide Use Reporting System doesn't give us the specific methods. It only gives us whether it was an air method, ground, or other.

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DPR SPECIAL ADVISOR SEGAWA: In terms of where chlorpyrifos is used, it's primarily used in the Central Valley, as well as central coast and Imperial County regions. In the Central Valley, most use would be for almonds, walnuts, alfalfa, cotton, and grapes. In the central coast, it's actually primarily used for broccoli and other cold crops. Down in Imperial county, it's primarily alfalfa and cotton.

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DPR SPECIAL ADVISOR SEGAWA: There are currently

some use restrictions to reduce the exposure to bystanders. Chlorpyrifos is a restricted material, and so it does require a permit from county ag commissioners. In addition, there are label requirements to address bystander exposures. And so between the EPA labels, and the county ag commissioner permit conditions, there are restrictions on how chlorpyrifos can be applied. In addition, there are some setback distances. Minimum distances between the sensitive sites and application. That distance varies with the method of application, and the rate of application.

And so for aircraft, depending upon the application rate, the distance -- the setback distance is between 250 to 500 feet.

For sprinkler and ground-rig applications, the distance is 150 to 400 feet. And for airblast sprayers, the distance is 150 to 500 feet.

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DPR SPECIAL ADVISOR SEGAWA: And that's sort of it in terms of the uses and background information for chlorpyrifos.

Questions about that?

Okay. Moving then -- on then to the risk assessment then.

DPR ASSISTANT DIRECTOR VERDER-CARLOS: Okay. So

we -- I just wanted to give you a short history of how we have -- chlorpyrifos has been assessed on the risk assessment side, since 1992 between EPA and DPR up to the present.

So in '92 and '93, DPR did a risk assessment on dietary, and occupational and indoor assessment. In 2006, U.S. EPA had issued a risk assessment, a final one and had a reregistration eligibility document that implemented mitigation measures and required setbacks and other label changes to protect bystanders, workers, and the environment.

And then in 2011, they also had a preliminary assessment, again after 2006. And in 2014, they had another revised risk assessment. In 2015, DPR issued our first draft risk assessment based on the 2014 risk assessment as well. And also at the same time, we designated chlorpyrifos as a restricted material in July of 2015.

We also then issued recommended permit conditions, like Randy said, to all county ag commissioners with more stringent requirements on the labels than the EPA labels that were out. In 2016, EPA issued one issue paper in April of 2016, and then a revised risk assessment in November of 2016.

In early 2016, they also then proposed to revoke

all tolerances -- food tolerances for chlorpyrifos, but then in March of 2017 of this year, they withdrew that proposal. And then for DPR in -- we issued a second draft risk assessment in August and then this one that you received a couple of days ago.

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DPR ASSISTANT DIRECTOR VERDER-CARLOS: Based on the August 2017 risk assessment, we also then based -- we also added more restrictions for the use of chlorpyrifos that was effective in October of this year as well.

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DPR ASSISTANT DIRECTOR VERDER-CARLOS: So the scope of the --

PANEL MEMBER GLANTZ: Could I -- could I just ask a question --

DPR ASSISTANT DIRECTOR VERDER-CARLOS: Sure.

PANEL MEMBER GLANTZ: -- because I remember reading about the EPA putting forward this proposal and then revoking it when the new administration came in.

And, I mean, historically, California, at least for all the things I've been aware of from being on this Panel, has usually been stricter than the federal EPA.

So given that the federal EP -- and usually about 10 years ahead of them in their thinking too, I have to add.

(Laughter.)

PANEL MEMBER GLANTZ: So given that we had a situation where, you know, up until this March, the EPA was talking about simply revoking the food uses of these things, I mean, is that -- it just seemed again, based on my extremely cursory review of this, that you're not proposing to go as far as they were, is that true?

DPR ASSISTANT DIRECTOR VERDER-CARLOS: That is true. We -- I mean, based on the risk assessment, because we based our risk assessment in like -- on the 2014 risk assessment of EPA, the -- although we did review the 2016 documents, we did not base our endpoints on that -- on those documents.

PANEL MEMBER GLANTZ: Well, so one thing -- and again, this would have been nice to have had a little more time to think about this, but I mean one question I'm going to have is like what was wrong with what the EPA did in 2016, and why are you not using it?

Because again, my -- and we've, in the past, had like joint workshops with the U.S. EPA on organophosphate pesticides. I remember one of them was held at UCSF. And you know, I walked out of all of those thinking that the California their thinking was much better, and more scientifically sound and less politicized than the U.S. EPA.

And so, you know, I think just so you're ready for the meeting, I mean, I'm going to want to know what's wrong with what the EPA did? And frankly, having the Trump EPA throw the report out is almost an endorsement of the early report.

(Laughter.)

PANEL MEMBER GLANTZ: You know, so I think that's going to be a very serious question that's going to need to be addressed here. And, you know, if -- I don't know if you've -- how much you've addressed it in the pile of stuff we got, but it better -- if it isn't really thoroughly justified in there now, I would strongly urge you to like do that tomorrow, and get it to us in enough time to read it and think about it, so that we can keep this process moving forward.

DPR ASSISTANT DIRECTOR VERDER-CARLOS: Thank you. And we will -- we have a more robust discussion about this hopefully in January, and when you have already read all the documents, but we did try to address that issue in our document.

PANEL MEMBER GLANTZ: Okay.

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DPR ASSISTANT DIRECTOR VERDER-CARLOS: So the scope of the risk assessment is on non-dietary short-term exposures, and also the acute exposure on the dietary

side. And also, we did aggregate exposure, and only bystander exposures. And really for bystander it includes people around the site of application, who can be exposed to spray associated with the application. And it may include farm workers around that area and their families.

The handlers however are not included in this risk assessment. Chlorpyrifos is a very, very big database. And so, because, as a TAC also, we address bystander exposures and that's why this one is what we're addressing at this point.

Next slide.

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DPR ASSISTANT DIRECTOR VERDER-CARLOS: Oh. So at this point --

PANEL MEMBER HAMMOND: Excuse -- excuse -- excuse me. This is Kathy Hammond.

May I ask a quick question?

DPR ASSISTANT DIRECTOR VERDER-CARLOS: Sure.

PANEL MEMBER HAMMOND: Yeah. So you're saying why -- clearly, there must be a reason. I did not understand why you're saying the applicators are -- risks are not being -- and exposures are not bing addressed.

DPR ASSISTANT DIRECTOR VERDER-CARLOS: You mean the handlers, right, mixer, loaders, and applicators.

PANEL MEMBER HAMMOND: Yes.

DPR ASSISTANT DIRECTOR VERDER-CARLOS: Well, for the TAC process, the bystanders is the risk that we are identifying. That's how we are going to assess the risk for bystanders. That's the TAC process for us.

PANEL MEMBER HAMMOND: Okay.

DPR ASSISTANT DIRECTOR VERDER-CARLOS: And we will be addressing the handlers once we get -- after we finish the bystander exposures.

PANEL MEMBER HAMMOND: Okay. So you will be doing it eventually?

DPR ASSISTANT DIRECTOR VERDER-CARLOS: Yes.

PANEL MEMBER HAMMOND: Thank you.

DPR ASSISTANT DIRECTOR VERDER-CARLOS: Oh, yes.

PANEL MEMBER BLANC: But not as part of this document?

DPR ASSISTANT DIRECTOR VERDER-CARLOS: No. Yeah.

PANEL MEMBER BLANC: And can we expect that there will be adequate air sampling data in your document, as this has been a continual -- continuing limitation in many of the pesticide-related documents --

DPR ASSISTANT DIRECTOR VERDER-CARLOS: Yes.

PANEL MEMBER BLANC: -- that we have received?

DPR ASSISTANT DIRECTOR VERDER-CARLOS: Yes. We have air -- we have included the air monitoring, because we've been monitoring for chlorpyrifos for a while with

ARB as well. So the document would have ambient air monitoring as well.

DPR SPECIAL ADVISOR SEGAWA: But as you'll read, we're relying primarily on computer modeling to estimate the exposures.

PANEL MEMBER BLANC: But are you -- are you seeing whether your computer modeling is consistent with the air sampling you've done in terms of validation.

DPR SPECIAL ADVISOR SEGAWA: Yes.

DPR ASSISTANT DIRECTOR VERDER-CARLOS: So, at this time, our risk assessment reflects our most current scientific understanding and comprehensive data review of potential for toxicity to humans.

Next slide.

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DPR ASSISTANT DIRECTOR VERDER-CARLOS: So for the risk calculation summary, we calculated the risks as margins of exposure. And for chlorpyrifos, we generally considered target -- a target MOE of at least 100 as health protective. And then we also calculated from route-specific points of departure, oral, dermal, and inhalation, and then we aggregated and combined those MOEs.

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DPR ASSISTANT DIRECTOR VERDER-CARLOS: So for the

conclusions on the draft risk assessment conclusions to summarize, dietary exposures are exposures from residues in food and drinking water, and also dermal exposures resulting from spray drift would not pose a health risk to humans. That's the MOEs greater than 100 for children and women of child-bearing age. And then for the -- but the risk assessment also found that there are several scenarios of concern --

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DPR ASSISTANT DIRECTOR VERDER-CARLOS: -- which include hand-to-mouth exposure in children, inhalation exposure to children and women of child-bearing age, and various aggregate exposures from combined media, and lastly, exposures to aerosols in the near air application sites, which was the driver of the MOEs that were less than 100, so the inhalation exposure. And that's the reason why we're taking it to the Panel for your review.

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PANEL MEMBER GLANTZ: Just to continue reacting, based on not having read it. But you know, the general process that we followed in here is to worry about sensitive subgroups. And, you know, from what I understand from the -- from skimming through it, I mean, the neurotoxic effects on children and fetuses are really important.

And so why are you defining the risk -- you know, the acceptable levels when you're excluding probably the most important subgroups, based -- again just based on reading the newspaper and skimming through some of what you sent already?

So that's -- I mean, that's another thing I think you're going to need to make a really strong case for, because if I was coming at this -- and again, I have not had the benefit of studying the document, but I would be saying that, you know, those are the sensitive subgroups that you should be using to base the risk assessment on, you know, and making sure that the exposure -- acceptable exposure levels are set, so that you have at least 100 marginal exposure for these particular people. I mean, am I missing something?

DPR ASSISTANT DIRECTOR VERDER-CARLOS: Well, so --

PANEL MEMBER GLANTZ: Based on being totally uninformed.

(Laughter.)

DPR ASSISTANT DIRECTOR VERDER-CARLOS: You always have a caveat to say that.

PANEL MEMBER GLANTZ: Yeah. Well, I don't want to make it sound like -- but, I mean, again, you've -- and I appreciate that you're coming in here to help us get

into this, because it is going to be complicated. But these are just sort of obvious questions that come up. And I'd rather put them -- you know, pose them now and give you guys a chance to think about it, and maybe come up, you know, either with a clear justification, if it's not already in the document, or come back and say we're going to change the document. And that would save one iteration through this whole process.

So you don't have to answer it right now --

DPR ASSISTANT DIRECTOR VERDER-CARLOS: Okay.

PANEL MEMBER GLANTZ: -- if you don't want to.

DPR ASSISTANT DIRECTOR VERDER-CARLOS: Okay. Well --

PANEL MEMBER GLANTZ: But if you want to, that would be fine too.

DPR ASSISTANT DIRECTOR VERDER-CARLOS: Yeah.

PANEL MEMBER GLANTZ: But I'm just -- you know, you -- I'm trying to help move things forward more quickly.

DPR ASSISTANT DIRECTOR VERDER-CARLOS: Right. So the risk assessment addresses actually children 1 to 2 years old, because they're the most vulnerable based on the risk assessment and also women of child-bearing age. So the neurodevelopmental effects -- well, I'm going to get to it on the next slide, is the -- is that the --

--o0o--

DPR ASSISTANT DIRECTOR VERDER-CARLOS: We addressed it with an uncertainty factor. And actually, we would really like the Panel to address that based on the charge questions that we're going to ask you. So there are things that we are really asking for you to address.

So the charge questions -- probably the document that you have is not the same order that we have it here, but we wanted to categorize it, so that it's more readable for the presentation.

So we would really like your comments on the choice of acetylcholinesterase inhibition as a toxic endpoint, and to consider the extensiveness of the chlorpyrifos database, as well as the approach, feasibility, and available database for selecting an alternate endpoint. So we would really like your comment on that.

And then also for the choice of uncertainty factors that we use, because we did use the physiologically based pharmacokinetic/pharmacodynamic modeling. But there is also rodent data that is available to us. The PBPK used the human data, and then -- but there's also rodent data that we received a comment on for us to be using. So we would like your comment on that. And then we also did a 10x intraspecies uncertainty factor

and then 10x for the neurodevelopmental effects.

And then in connection with the neurodevelopmental effects, we would like your comment on how we could use the human epi data to qualitatively or quantitatively inform the dose response relationship, because that's been -- you know, we -- we have reviewed a lot of the literature that has epi data on the effects of neurodevelopmental effects for chlorpyrifos.

--o0o--

DPR ASSISTANT DIRECTOR VERDER-CARLOS: And then the rest of the charge questions. We would also like your comment on using the 21-day steady state point of departure values to evaluate the risk associated with dermal, inhalation, and non-dietary oral exposure from spray drift. Normally, for acute exposures, it's just, you though, one and a half hour or one hour exposure.

But for our risk assessment, we would really like to know if a 21-day is appropriate, because if it -- we use just a one-to-one, one and a half hour exposure, it might underestimate the risks to individuals residing in areas of high chlorpyrifos use already.

So because acute points of departure do not, by themselves, account for the elevated level of cholinesterase inhibition already present in such populations. So that's where we start off.

And then for the -- our choice also of using the agricultural dispersion model to estimate air concentrations for fixed-wing aerial applications as a surrogate for air concentrations for ground boom and airblast. Since there are no data to address ground boom and airblast applications, and we know that that's an exposure scenario that we would really like to address, we used the fixed wing aerial application as a surrogate for those two exposure scenarios. So we would like your comment on that to see if that's appropriate or not.

And then lastly, we would also like your comment on the choice of adjusting air concentrations for inhalable fractions, how will those adjustments be made. Because when a spray drift cloud is comprised of aerosol droplets of varying sizes, and we're not sure if -- so what -- in our risk assessment, we did not quantify those inhalable fractions and those that are not. So we would really like your comment on how should we address that or not. But in this assessment, we did not adjust for inhalable fractions.

--o0o--

DPR ASSISTANT DIRECTOR VERDER-CARLOS: And then for concluding remarks. The risk assessment evaluated aggregate exposure through inhalation exposures because that's the criteria for a TAC. And like we said, that is

really the one that drove the risk assessment is the inhalation risk. And we will make an in-depth presentation on the risk assessment on January 23rd. There's already a date for that.

And we can provide original studies to the Panel, if you need that, but we do need affirmation of status to be able to give you those documents, because they're proprietary. But at the same time, we would also like to offer that if you would like published literature studies, if you would like us to send them to you, let us know, we can send you a link of all the published literature that we have reviewed, and we can send those to you, so you don't have to print them out and -- or search for them. So if you would like to do that, we can do that for you.

DPR SPECIAL ADVISOR SEGAWA: So I have a standard form here that describes the handling requirements for confidential data, if you choose to request that. And so I need you to read this, and sign it, and return it back to us either today or you can email it back to us at a later date.

CHAIRPERSON KLEINMAN: Stan.

PANEL MEMBER GLANTZ: So I just had a couple of other questions. So I -- there were a bunch of public comments that were submitted, a couple of which seemed to come in pretty late. And I just wanted to make sure that

the -- that you guys -- that your responses to those comments, do we have those for all of the comments that were submitted?

DPR ASSISTANT DIRECTOR VERDER-CARLOS: Yes.

PANEL MEMBER GLANTZ: Okay.

DPR ASSISTANT DIRECTOR VERDER-CARLOS: So there were also comments that were submitted to this August risk assessment that were addressed during the December draft of 2015. So we also sent you our responses to those comments. So all of the comments that we got, including the December 2015, which was also Dow -- some of Dow's comments. So we also sent you a lot of -- all those comments.

PANEL MEMBER GLANTZ: Yeah. Okay. But they're -- in particular, there was this one that came in from a bunch of -- I mean, Mike mentioned a bunch of public health groups or something. But just again looking at the very beginning of it, it sounded like that came in very late in the process. Are you responses to -- do you know the ones I'm talking about? They had a green letterhead. That -- we just got this a couple days ago, and I didn't bring them with me.

Do you know the -- it was -- it was the one with the like 89 organizations signed it or something. Has DPR responded? Because I got the impression that came in

very, very late. And I mean, is there a response to that? Do you know what I'm talking about.

PANEL LIAISON BEHRMANN: Yes, Dr. Glantz. Those were primarily comments that were submitted by those organizations back during the -- during the -- back during the public comment period on the DPR document, and also on the U.S. EPA document. Those groups wanted to convey to this Panel the fact that they had participated earlier in the process. And they also commented that they planned -- once they see this new DPR document, that they will also be commenting on this new revised document.

PANEL MEMBER GLANTZ: Okay. Well, so, but DPR doesn't have -- so what's DPR's response? Is there DPR's ease response to the earl -- see, that's the thing I got confused about. It's like that's what I thought they said, but like -- so has DPR responded to those earlier comments, and is that available to us or --

PANEL LIAISON BEHRMANN: That's in the package that you just received on Monday.

PANEL MEMBER GLANTZ: Okay. So DRP's responses to that stuff, including the issues they raised with the EPA report, because that's going to be material in this --

DPR ASSISTANT DIRECTOR VERDER-CARLOS: Yes.

PANEL MEMBER GLANTZ: So we have DPR's responses to that?

PANEL LIAISON BEHRMANN: Yes.

DPR ASSISTANT DIRECTOR VERDER-CARLOS: Yes.

PANEL MEMBER GLANTZ: Okay. And then -- and then I would just, if -- if these other groups or anybody else is thinking of responding to the December 2017 document, again, I would really urge them to not wait until two days before the meeting to submit the comments. I think they should be submitted -- I mean, we can't control that, but my advice to the public would be they need to get them in quickly, so that DPR has a chance to respond to them. Because I have to say, and I've said this many times, that when I review these documents, I always read the executive summary and then the public comments and the response to comments to sort of try to see what the big issues are. And then so I can judge how well they're being addressed.

So I think it is really important that that stuff be to us with not only the comments, but the response -- although, you know, if these groups only deliver it two days before the meeting, it's not fair to DPR to expect them to have responded.

So everybody needs to do this with enough time that we can get the comments and the responses are enough before the next meeting to have time to read them, and carefully consider them.

So that's a message both to the public and to the

DPR. And if -- and as I said, if the public comes in at the last -- you know two days before the meeting, you know, then they can't complain that DPR didn't have time to respond. But I think, at the same time, I don't want to get DPR's responses two days before the meeting either. So everyone will have a lot of time over the holidays.

(Laughter.)

PANEL MEMBER ANASTASIO: Can I ask a question about the data that you're asking us if we'd like to have. How many data are we talking about, and what is the data?

DPR SPECIAL ADVISOR SEGAWA: The original studies on which the risk assessment is based. There is -- of course, we relied on open literature, but much of it relied on studies submitted by the registrants.

PANEL MEMBER ANASTASIO: Well, how many studies are there, roughly?

DPR SPECIAL ADVISOR SEGAWA: Two or three hundred.

PANEL MEMBER ANASTASIO: Two or three hundred.

DPR SPECIAL ADVISOR SEGAWA: There were --

PANEL MEMBER GLANTZ: There were 5,000 what?

DPR ASSISTANT DIRECTOR VERDER-CARLOS: They narrowed it down from that.

DPR SPECIAL ADVISOR SEGAWA: They looked at approximately 5,000 studies and included two to three

hundred in the risk assessment.

PANEL MEMBER ANASTASIO: So we would be getting copies of two to three hundred?

DPR SPECIAL ADVISOR SEGAWA: Correct.

PANEL MEMBER GLANTZ: So that's two or three hundred --

DPR SPECIAL ADVISOR SEGAWA: If you want it.

PANEL MEMBER GLANTZ: So that's two or three hundred proprietary studies submitted by industry, is that what you're talking about?

DPR SPECIAL ADVISOR SEGAWA: It's a mixture.

DPR ASSISTANT DIRECTOR VERDER-CARLOS: It's the volume.

PANEL MEMBER GLANTZ: Well, you should cover and talk into the microphone for the reporter.

DR. DuTEAUX: Dr. Shelley DuTeaux. I'm the Branch Chief for Human Health Assessment with DPR.

The volume of data -- unlike maybe some other chemicals that this Panel has looked at, the volume of data for chlorpyrifos is enormous. This chemical has been studied since about 1971. And not only has the registrant, Dow Elanco now Dow AgroSciences, done extensive laboratory animal tests, there's open literature on all the subjects that we've covered in the risk assessment document, including exposure assessment,

bystander -- bystander exposure, indoor dust exposure, epidemiology, in vivo, in vitro, and in silico methods. So it's a voluminous data set.

When we do a comprehensive risk assessment, we do a systematic literature search, and then we narrow down the articles that actually end up being informative for the risk assessment. And we include those in our references. And you'll see an extensive list of references at the end of the risk assessment, as well as additional references that are on a memo, which is attachment number 2, which goes into much more detail about the exposure assessment, which I think Dr. Anastasio will be very interested in.

The volumes we're talking about are done under contract labs, like Jackson and others. These volumes are literally -- we call them volumes, and we're not joking, bigger than Shogun. And we have, oh my gosh, Ann, do you have an idea of how many we have?

God, it has to be more than 20.

So you're talking pounds of paper.

PANEL MEMBER BLANC: Yeah, but we could tell you which study we wanted to look at.

DR. DuTEAUX: Exactly. You can tell us what studies.

PANEL MEMBER BLANC: Yeah, so --

DR. DuTEAUX: And they're all listed in the references. And then what we were --

PANEL MEMBER BLANC: So I would suggest that anybody who thinks it's a possibility that they might want some -- to see a particular study, just turn in the signed form today, and they'll have it. And then --

DR. DuTEAUX: And then the specific one.

PANEL MEMBER BLANC: -- if you decide that you want to see a particularly pivotal, or troubling, or intriguing study, you can ask -- we could ask for it.

DR. DuTEAUX: Exactly. Yes.

PANEL MEMBER BLANC: And it would also probably -- I would probably encourage panel members to ask for at least one, so that you could get a sense of what an industry proprietary study looks like, so that you can have empathy for the staff --

DR. DuTEAUX: Right, I know.

(Laughter.)

PANEL MEMBER BLANC: -- if nothing else.

DR. DuTEAUX: I agree, Dr. Blanc, is alluding to the fact that the summary of these contract lab studies is usually about 100 pages long. Then they include individual animal data points for every single measurement, in every dose group, every gender, and every generation.

So that's why these studies are so enormous to look at. And the other thing that Dr. Verder-Carlos was alluding to was a list of the open literature manuscripts. What we'd like to do is be able to provide you a PubMed public link, so you can see all of those in their abstract form. And then click, as you are, because each of your own organizations, be it UCLA or USC, has an ability to get those full text manuscripts per your university's designated status with your literature search, and your libraries.

So but we'd be able to provide that electronically, so you can at least have access as quickly as possible.

Any other questions on the literature?

CHAIRPERSON KLEINMAN: Okay. I'd like to amplify Dr. Blanc's suggestion. It will be a good idea to at least get a look at one of these documents. But I think as we read the article, we can identify specific things that we want to question, and come back and just request those specific items.

I've got -- you know, one of the charge questions was referring to the uncertainty factors used. And could you tell us a little bit more about -- not having, you know, really read into the report yet, but are you -- for example, 10x for the intraspecies. Now that's -- in

occupation hygiene, that's sort of standard going from an average to a more sensitive worker.

Do you think that's reasonable to go from a healthy adult to a one-year old kid?

ASSISTANT DIRECTOR VERDER-CARLOS: Dr. DuTeaxu.

DR. DuTEAUX: Get into detail in January, if that's --

DPR ASSISTANT DIRECTOR VERDER-CARLOS: Yeah. SO we were hoping to get into that in January. But Dr. Koshlukova, would you like to address that.

DR. KOSHLUKOVA: Svetlana Koshlukova. I'm the senior toxicologist of the risk assessment section.

So for chlorpyrifos, we used an intraspecies uncertainty factor of 10. This is a default, and we have extensive discussion of whether this is sufficient or not to cover from the median to the most sensitive individual. But at this point, we do not feel we have enough data to quantify what the difference might be, and as such chose to use the default.

In terms of the -- intra -- interspecies, animals to humans, we felt that the model that we used to establish the point of departures -- points of departure, sufficiently -- it's for human, therefore we can reduce it to one.

CHAIRPERSON KLEINMAN: Okay. Thank you.

PANEL MEMBER BLANC: I think that's where likely there could be the most questions. I think you'll really have to work diligently to convince us that both parts of that equation are sufficiently viewed with confidence to allow that presumption. And that may be where the comment in terms of the metabolism in children, for example, may come into play, even though you state you have an added 10-fold uncertainty factor for neurodevelopmental -- lack of newer developmental data.

So I bring that up, because often we've found that we can, by a factor of three rather than 10, because half of the equation seems to be satisfying enough. And I think this will be an area in which we'll be looking to comment from OEHHA in particular as well, since they deal with this much more frequently than the Pesticide Branch. I don't -- could I hear from OEHHA, if they're prepared -- or preparing themselves to address that for us in January?

PANEL MEMBER GLANTZ: Well, isn't this going to be fun?

(Laughter.)

DR. SIEGEL: Hello. I'm Dr. David Siegel with OEHHA. And we did submit our findings on the document. And you have received those as of Monday. So we have indicated our thoughts on that.

PANEL MEMBER GLANTZ: That's another thing I

looked at. I used the "look rather than "read", but I looked at about half of it. And it's clear that there is some differences of opinion between OEHHA and DPR. And it would be useful if DPR had anything to say about what OEHHA said to know what this is before -- well, before the meeting. And even -- I don't want to start like a -- whatever an infinite process, and, you know -- because I think those are going to be big issues in the discussion. And, you know, DPR gave us their report. OEHHA gave us their reactions. It's not unusual for OEHHA to have a slightly different view of these things than DPR does. But it would be useful to get in advance DPR's comeback.

And even if OEHHA wanted to -- had any reactions to what DPR said, you don't have to go through it at really, you know, every little thing. But I think that is -- you know, again, from what little I know, that's going to capture a lot of the big issues in dealing with this report.

And so I think the more of that that we can get in time to read and think about before the meeting, rather than having to like make stuff up on the fly or raise issues that then come back three months later, that would be really, really helpful.

So I'm not trying to make huge amounts of additional work for everybody, but I -- I think those -- I

just can't stress the value that I see in the public comments and the response to comments, and sharpening, you know -- thinking about these documents.

You know, and I mean one of the other things I got a sense of. And I only got about halfway through a quick read of the OEHHA document. But there are questions about this issue of the appropriate endpoint that should be used. And I think that's going to be -- and then also the question of animal versus human data, because in these things nothing is ever perfect.

So I think the more those issues can be, you know, laid out for us. And, you know, the specific questions, and pros and cons of these different approaches, you know, the more we can help get that focused and see what the controversies are, that is going to really help move this process forward.

DPR ASSISTANT DIRECTOR VERDER-CARLOS: Yes, we -- so what you're saying is we should be able to send our responses to OEHHA's findings before the January 23rd meeting. Okay.

PANEL MEMBER GLANTZ: Yeah, that would be very helpful. And then if OEHHA -- I don't think we want to set up an infinite loop here, but -- because I think the issues will be pretty clear. But if DPR says something that makes OEHHA's, you know, teeth hurt, you know, I'd be

interested in what OEHHA -- I mean, part of it -- I mean, I've been in things it's like didn't you read what we said before? We don't need to repeat ourselves.

But if there are things that, you know, in light of DPR's response that OEHHA thought were clear or, you know, that that brings up some other issue, I would really like to see that, you know, as soon as we could get it just because that's -- I think that -- I think a lot of the issues that are probably going to come up are going to get highlighted there. And I think that will assist at least me in trying to wade through all this stuff.

Is that okay? I mean, I think we're going to end up doing that anyway, and it would better to get it done now, than have the meeting in January, and then -- and have you go -- I mean, is that okay?

This is what happens when I get to look at something a little bit.

(Laughter.)

PANEL MEMBER GLANTZ: Blanc was much smarter, he didn't even look at it.

DPR ASSISTANT DIRECTOR VERDER-CARLOS: Yes, we will. So we will work -- we will work on that, and then work with OEHHA and see if we can --

PANEL MEMBER BLANC: But I think I -- since this -- the purpose of this meeting, is I understand it,

is to sort of lay groundwork. So rather than simply say, well, we wrote our comments, which you didn't have time to look at, could you perhaps summarize for us on this one particular point of the correction factor inter -- intraspecies, with humans, of only 1, whether OEHHA had an opinion on that. Well, it's within humans, right?

DPR ASSISTANT DIRECTOR VERDER-CARLOS: The inter. You're saying interspecies. Within humans is the intra, so this is a 10 is what -- or the 1, are you asking for the PBPK model?

PANEL MEMBER BLANC: Yeah, I'm sorry That one, yeah. Yeah, intraspecies model of 1, going from rats to humans, sorry, right, essentially?

DPR ASSISTANT DIRECTOR VERDER-CARLOS: Right.

DR. LIM: This is Lori Lim. I'm the senior toxicologist with OEHHA.

In the DPR's document, a -- the PBPK model was considered to be close to a human model. So because of that, the interspecies, which is extrapolated using data from animal to humans was considered not needed. While we looked at the data, we -- we agree at the human data in the model, but we did not believe that that model represented true human. So we want to back off from it, and say, well, you should at least apply a three-fold factor, because standard default for animal to human

extrapolation is a 10-fold.

PANEL MEMBER BLANC: So in other words, what I -- what I had anticipated, which is you accept half the equation, but not the PK --

DR. LIM: Well, the model is a PK and PB model, so it's hard to split it.

PANEL MEMBER BLANC: Right, and you -- and so the -- right. But so you accept some of it, but not all of it.

DR. LIM: We're saying that this model is half human, if you want to look at it that way.

(Laughter.)

DR. LIM: Not true human. And we went -- in our findings, we went into details about why it didn't -- it -- there's not enough human data, especially for the inhalation component of the model that they weren't any human inhalation toxicity study to support that component.

PANEL MEMBER GLANTZ: Was Kathy Hammond saying something?

PANEL MEMBER BLANC: Inadvertently.

PANEL MEMBER HAMMOND: Oh, I'm sorry.

DR. LIM: So anyway, there's that problem with lack of human inhalation toxicity study. And then the use of the in vitro human plasma in liver samples that, you know, we have some questions about that too. So we just

didn't think that was -- it's the same as though a human study was conducted, a well-conducted human study. Let's put it that way.

PANEL MEMBER BLANC: Well, that's very helpful to hear that stated, so that it can give us a framework from which to look closely at that part of the document.

And so I would just prepare the Pesticide Branch for --

DPR ASSISTANT DIRECTOR VERDER-CARLOS: To respond to that?

PANEL MEMBER BLANC: Yes, and for the likely eventuality that you will err on the conservative side -- the health protective side of allowing a 3-fold but not a 1-fold interspecies factor. So you should be prepared for that, but give it your best shot.

CHAIRPERSON KLEINMAN: There -- yeah, I'm also curious, because there are a lot of organophosphate pesticides out there. And a lot of human exposures to thing likes malathion, parathion, and all of that. And none of that data gave you enough information on acetylcholinesterase inhibition in terms of exposures that you could draw analogies from real-world data and check your model?

DPR ASSISTANT DIRECTOR VERDER-CARLOS:

Chlorpyrifos is the only organophosphate that has

a very robust PBPK/PD model. That's the only one that they -- that the scientists did a very robust PBPK model. And that's what we had relied on for that interspecies of one 1x. And to the point of the human data, they did use -- what's this called -- fused -- infused human tissues. And that's what they used -- the protocol is the same as they used for organ transplant. And that's one of the -- that was fully explained in the risk assessment and that's why we used an uncertainty factor of 1 instead of 3 or a 10.

DR. LIM: I think you're referring to a whole human study. And there are two studies the Nolan study and the Kisicki study that are used to -- in the model. These are intentional dosing of the human studies. And yeah, they were specific on chlorpyrifos.

CHAIRPERSON KLEINMAN: Kathy or Beate, do either of you have a comment?

PANEL MEMBER RITZ: Yeah. This is Beate. I actually do. I'm very surprised that there's absolutely nothing on the effect in elderly. Since I'm the author of one of the papers that shows that it -- that chlorpyrifos is actually associated with Parkinson's disease. So neurodegeneration I think really needs to be looked at, but I find nothing in here. Is that because these papers are too new or is there another reason?

DPR ASSISTANT DIRECTOR VERDER-CARLOS: Dr. Ritz, so that was an epi study, correct --

PANEL MEMBER RITZ: Oh, yes.

DPR ASSISTANT DIRECTOR VERDER-CARLOS: -- that was reviewed. So we -- based on the risk assessment that we did, the most susceptible population was the 1 to 2 year olds and women of child-bearing age, but we will be -- we will take a look. We did not -- I don't think that we looked at that specifically as an epi study, but I will check with -- no, we did not.

DPR ASSISTANT DIRECTOR VERDER-CARLOS: So the Epi data that we looked at was on neurodevelopment.

PANEL MEMBER RITZ: Right. So I would encourage you to at least look for neurodegeneration, and for both Parkinson's and Alzheimer's.

PANEL MEMBER GLANTZ: Do the DPR people know the studies -- the specific study she's talking about or -- no. So they shook their head no. So I think it would be helpful for Beate for you to send the references to DPR, and -- just so they don't have to go get -- looking for them.

PANEL MEMBER RITZ: Yes, that's easy.

DPR ASSISTANT DIRECTOR VERDER-CARLOS: Thank you.

PANEL MEMBER RITZ: Can I send them to Jim and he forwards them?

DPR ASSISTANT DIRECTOR VERDER-CARLOS: Yes. Jim said yes.

PANEL MEMBER RITZ: Okay. Good.

PANEL MEMBER HAMMOND: Beate, are you done?

CHAIRPERSON KLEINMAN: Okay. I'd like to give other Panel members an opportunity if they have questions that would like to raise?

Cort.

PANEL MEMBER HAMMOND: This is Kathy.

CHAIRPERSON KLEINMAN: Oh, yes, Kathy, go ahead.

PANEL MEMBER HAMMOND: Sure. Sure. So this is -- I noticed that you talked about the inhalation fraction, and whether or not that was included. And I just would like, because there's various definitions for that, for you to remind me of what your definition of inhalable fractions are?

CHAIRPERSON KLEINMAN: Kathy, you're fading out.

PANEL MEMBER HAMMOND: Can you hear me now?

CHAIRPERSON KLEINMAN: It's better.

PANEL MEMBER HAMMOND: Let me try something.

Okay. Let me try this.

PANEL MEMBER HAMMOND: The -- my question was about the inhalable fraction. And I wanted to know a little more, since you had kind of highlighted that point, about what your definition there was.

DR. DuTEAUX: Dr. Hammond, this is Shelley DuTeaux again. In our risk assessment you'll find that we assumed that all chlorpyrifos -- airborne chlorpyrifos was available. So we assumed it was all inhaled, which is unlike an FDA development drug where you look at a percent of inhalable fraction, or as you know, criteria pollutants, where there's a certain size fraction.

So our question to you in the charge questions is if we change our approach of considering all airborne chlorpyrifos as being inhalable to a fraction that would be inhalable, then what would your suggested approach as the Panel be for us to do? So, essentially, I think we're ask --

PANEL MEMBER HAMMOND: I can give you -- Okay. So I can give you an upfront kind of thing. But I wasn't sure about your definition of inhalable. If you use the occupational definition of inhalable, you know, that is actually 50 percent of 100 micron particles are taken into the respiratory tract. So I don't know if that's the definition you're using, as opposed to some people in the environmental world loosely use, what we call, respirable and inhalable, which are much smaller particles. So when you say inhalable, which definition are you using?

PANEL MEMBER GLANTZ: So the questions she was asking I think -- you're kind of fading in and out, Kathy.

I think she's said there were two different definitions of inhalable, and which one are you using, right, Kathy, is that the question?

PANEL MEMBER HAMMOND: Correct. Correct.

DR. DuTEAUX: Again, we haven't used one yet. But if we do, then what is appropriate. And I think Professor Hammond said that in the occupational health world they use 50 percent of 100 micron particles taken in. But then in environmental health worlds it's respirable fraction, which would be approximately, I guess, less than 10 microns.

CHAIRPERSON KLEINMAN: Actually, I think what Kathy --

DR. DuTEAUX: Isn't that correct?

CHAIRPERSON KLEINMAN: Go ahead, Kathy.

PANEL MEMBER HAMMOND: Just to say upfront, you definitely should be using out of, you know, kind of minimum is the wrong term. But the point would be that you should -- I think that you've probably done correctly as is what you've done. But if you were to use any size selection, it should be the occupational definition, not the environmental definition of inhalable, because it's just -- the concept of -- is the critical concept there.

And the point is that a lot of material gets into the body. It doesn't make it to the alveoli, but it still

makes it into the body and is available to cause the kind of effects endpoints that you're looking at, even if it's larger than the size particles that can make it to the alveoli. But the alveoli are not the target organ in this case. So it's really important not to go that direction.

And I understand you haven't done that yet either. But if, for any reason, you were going to do that, I would say make sure that you don't go that way.

And then the other question I had was do you have any data on the size distribution of the particles.

DR. DuTEAUX: The size distribution. So the modeling -- the monitoring data was captured for a particular size or type of particle in the cloud. And then the modeling actually also has a size distribution. So when we look at the airborne concentration, the spray drift modeling that we used, you'll be able to see that and ask additional details about that as well.

PANEL MEMBER HAMMOND: It's really important to know the size distribution for any of this conversation. But as you may well know, and again I lean to favor in what you've already done anyway. But if one was going to go down that path to be aware of it, for instance the size distribution changes, and as you get further away from the source, in this case, the particles may well get smaller with evaporation of the vehicle.

You know, so it's not like what's right near the source, if you're talking about community exposures, but certainly is going to have an effect. So I think your choice was a good one, but I haven't read the document in detail. But just on the surface of what you've said so far, I support what you've said. But if you're under a lot of pressure, just make sure you do not go the direction of thinking of the alveoli as the target vehicle -- target organ.

DR. DuTEAUX: Right. And thank you for that. Again the -- we have two different models that play here. We have an airborne distribution model, and then we also have a PBPK/PD model. And in the PBPK/PD model, the way that the modeler developments wrote the code was that there's a certain amount that, you know, of the size fraction that might get into the deep lung. But, of course, acetylcholinesterase effects are not in the alveoli.

But you can see very clearly in our description how much was assumed by the model code actually then went up through the mucociliary pathway, was then ingested, and was considered a whole-body dose, or site-specific dose through that route. So the model is very specific when it comes to that.

And then just a note on the atmospheric modeling,

the -- we made some very conservative assumptions in that modeling. And one of which is that we treated the droplets like their water, i.e. there is no vaporization of the size. And so the size kind -- maintains its size in diameter far afield, and doesn't evaporate. And so that's one thing that's also another conservative assumption that we put in.

PANEL MEMBER HAMMOND: So I actually disagree that that's a conservative assumption. I think that that's an assumption that would lead to -- if you did -- if you did do it, if you were to actually --

PANEL MEMBER BLANC: Kathy. Kathy. Kathy, Paul Blanc here. Are you using a speaker phone?

PANEL MEMBER HAMMOND: No, I'm using a -- I've got a plugged in headset, but I guess it's not working well.

PANEL MEMBER BLANC: It's not working. I wonder if you could unplug that and just use --

PANEL MEMBER HAMMOND: Oh, I'll try it. Sure. Is this better?

CHAIRPERSON KLEINMAN: A lot.

PANEL MEMBER HAMMOND: Okay. My apologies.

PANEL MEMBER BLANC: Yes, yes.

PANEL MEMBER HAMMOND: Okay. Sorry. Yeah, I've just got it to my ear now.

Okay. What I'm saying is that rather than calling that a conservative assumption, I think it's the exact opposite of that. That it actually leads to an underestimate, if you assume the particle size does not change. Because again, if you take everything that comes in, which is what you did, then it makes no difference, of course, and I get that, and I support that.

But you are getting any pushback or you're trying to look at what it would be if you took it -- made another set of assumptions, then I would say that the -- what you -- you do have to take into account the fact that the particle size will change, I mean, is a pretty critical piece of that.

And then that would make more things, biomonitoring, available. Does that make sense? Or we talk about that, if you want, like you know, later, off -- after this meeting or something.

DPR ASSISTANT DIRECTOR VERDER-CARLOS: In January?

DR. DuTEAUX: In January?

PANEL MEMBER HAMMOND: I January, sure. But I just want to -- I mean, I guess what we're trying -- I really appreciate getting this heads up on what you all are doing, because it helps to focus as we reviewed the document. But I also want to give you a heads up on how

I'll be looking at it.

DR. DuTEAUX: Sure. And that's why we posed it as one of the charge questions, because we think it's very important as well.

PANEL MEMBER HAMMOND: Sure, uh-huh.

That's why I'm taking it seriously, right, right. Yeah.

PANEL MEMBER ANASTASIO: This is Cort Anastasio. I want to follow up on some of Kathy's points. Shelley, are you saying not allowing the drops to evaporate is conservative, because you're not allowing the chlorpyrifos to evaporate from the drops?

DR. DuTEAUX: Yes. I mean, we're treating it like it has a vapor pressure of water --

PANEL MEMBER ANASTASIO: Right.

DR. DuTEAUX: -- instead of it's true vapor pressure.

PANEL MEMBER ANASTASIO: And so part of that is you're not considering any risk from gas phase chlorpyrifos?

DR. DuTEAUX: It's vapor phase.

DR. DuTEAUX: Our modeler.

DR. BARRY: I'm Terry Barry. I'm the modeler for the environmental concentrations. So let's back up a little bit. So the AGDISP model is a first principles

physics-based --

PANEL MEMBER GLANTZ: Can you pull it closer.

DR. BARRY: I could hear myself, so I was thinking you could hear me.

Okay. The AGDISP model is a first principles physics-based model, and it models droplets as an ensemble cloud. What we assume the chlorpyrifos is it's not volatile. So the AI itself does not disappear and go into the vapor phase, but the droplets do get smaller. As you go down wind, they evaporate. There's gravitational settling. There's deposition. In fact, you can lose material, you know, off the model domain too, if you go far enough, because it's 2,608 feet is the reasonable border, you know, for the model. And then you'd have to hand it off to a gassy blue model, and then you're talking about actual vapor size. You know, vapor -- no droplets anymore basically, just vapor.

So the conservative part that Shelley was pointing to is that we assume that the AI is not volatile, so it doesn't disappear. It doesn't get smaller. It doesn't, you know, mix vertically significantly.

PANEL MEMBER ANASTASIO: Right, but that's only conservative because you're assuming that the gas phase material has no toxicity.

DR. BARRY: Right. And you will get to that in

the document, because EPA made a judgment call that vapor phase is not something that they were looking at, because you could not get 10 percent acetylcholinesterase suppression at the saturated vapor pressure. And we elected to go with their judgment on that, so that's why we didn't look at vapor phase. So -- and the aerosol phase does plenty obviously.

PANEL MEMBER ANASTASIO: But the vapor phase is an open question potentially for the neurodevelopmental toxicology.

DR. BARRY: Well, that's for you guys to debate, right?

PANEL MEMBER ANASTASIO: Oh, okay.

DR. BARRY: So doe that --

PANEL MEMBER HAMMOND: Right. Does that -- So you start with -- you have a drop of a chemical in it and it changes size and then perhaps goes into the vapor phase. It will only go into the vapor phase, of course, by the, you know, the -- but other ever -- but the point really is that you will inhale that much vapor. And you can't say -- and I think you haven't done this, all right. So I'm even talking about the U.S. EPA thing.

But you can't say, oh, it all goes into the vapor phase, so we don't have to take it, so it's not in the particles. We're only monitoring the particles. But, in

fact, you've also said that it can't go into the vapor phase that's why we can ignore it. It's kind of a little bit of a --

DR. BARRY: We're not really ignoring it.

Oh, I'm sorry. I thought you were finished.

PANEL MEMBER HAMMOND: No, you aren't. You aren't --

DR. BARRY: Oh, okay.

PANEL MEMBER HAMMOND: -- but I mean it sounds like the EPA did.

DR. BARRY: So the primary drift part is the mass that's released from the aircraft during the application. And the AGDISP model handles that mass that's released from the aircraft, and it distributes it according to a droplet spectra that's produced by the nozzles on the aircraft and how fast it's going, what kind of aircraft it is, and things like that.

So all of the mass that is release from the aircraft is accounted for by the model, and then it's distributed down wind according to physics. So that's what we're using for our primary drift inhalation estimates. Vapor phase is going to be more related to secondary drift, which would be off-gassing from the application after the application is finished. And that's what EPA was pointing to with the vapor phase not being

something that they were going to look at.

The thing about the AGDISP model is the droplet spectra goes to be extremely small. And the question about the inhalable fraction actually is, okay, so do we do 100 microns, do we do 150, 200 microns, 50 microns, you know, we need to -- if we're going to adjust, we need to decide how we're going to adjust and that droplet spectra changes both with distance and with height.

Okay. So there's -- it's -- it's quite complicated. So we elected so far --

PANEL MEMBER HAMMOND: Right.

DR. BARRY: So we elected so far to assume that 100 percent of the droplet cloud at a particular point, which is going to be the inhalable height of a child or the inhalable height of an adult at a particular distance down wind is going into the person. And some of those droplets are 250 microns, 350 microns. I mean, they're big, but we've assumed they're all inhaled right now.

So the question for you guys was should we still do that or should we look to try to really refine this model -- this exposure to what we know about the droplet spectra because model will give you all of the droplet spectra at any height and any distance. It's a pain to produce, but I could give it to you.

PANEL MEMBER ANASTASIO: Is there an example size

distribution in the documents?

DR. BARRY: Yes.

PANEL MEMBER ANASTASIO: Okay.

DR. BARRY: In the appendix of the memo at the end, I printed out the air concentrations and then it's the per below 100 microns I think or below 10 microns, but I can give you guys more data, if you want it. So I characterized what would happen if you made adjustments, you know.

CHAIRPERSON KLEINMAN: But I think it's important to keep in mind that what you're talking about is an aerosol.

DR. BARRY: Yes.

CHAIRPERSON KLEINMAN: And you've got these liquid droplets, and they're really suspended in saturated vapor. The vapor doesn't go away.

DR. BARRY: Oh, right. Right.

CHAIRPERSON KLEINMAN: So --

DR. BARRY: The model accounts for that.

CHAIRPERSON KLEINMAN: The model will capture --

DR. BARRY: Um-hmm.

CHAIRPERSON KLEINMAN: -- the amount of vapor that's there, and so because that's going to give you a constant background --

DR. BARRY: Right. Yeah.

CHAIRPERSON KLEINMAN: -- you know, moving alond.

DR. BARRY: In fact, there has been a refinement to AGDISP model to account for the higher humidity in the cloud. They just -- in fact that's why we're using the version we're using accounts for that.

And the other thing that -- you'll see it in the memo, but the other thing about the AGDISP model is that it's -- it's been -- it was reviewed -- it was reviewed at -- Spray Drift Task Force workshop back in the nineties. It's used for regulatory purposes by EPA. I mean, this is not a, you know, sidebar model. We're using a really well established model here for a purpose that it's meant to be used for.

So going forward, as you look at the documents, you know, just keep that in mind.

PANEL MEMBER ANASTASIO: I think what mike was saying, and maybe he can clarify this, you're saying it's saturated in chlorpyrifos not water?

CHAIRPERSON KLEINMAN: Yeah.

PANEL MEMBER ANASTASIO: Right, but you're talking about water, saturated in water?

DR. BARRY: I'm talking about droplets with chlorpyrifos in them.

PANEL MEMBER ANASTASIO: Okay. You're talking about higher relative humidity in the cloud?

DR. BARRY: In the cloud of droplets. And each droplet has a certain amount of AI in it. I mean, that's what the model is doing. Yeah, and you can get the droplet spectra anywhere you want down wind. You can actually get it on field too. I mean, it's -- you know, you could get it for that too.

Well, actually, that's going to be what's released. That's the droplet spectra of the nozzle itself, so...

PANEL MEMBER ANASTASIO: While we're on AGDISP, one comment about charge question number 4. You assumed a fixed wing aircraft application, because there's no data for the other two application methods. I don't think our Committee has the expertise to know whether that's a good assumption or not. So my suggestion is before the January meeting, try to seek out people who might have that expertise. I would think somewhere in the U.C. system there must be people who do this, and they may be able to help you with that question, because I'm not sure that we have that expertise.

CHAIRPERSON KLEINMAN: Well, it looks like we're going to have a very exciting month ahead of us --

(Laughter.)

CHAIRPERSON KLEINMAN: -- just going through this.

Does anybody else have, you know, additional questions that we want to ask? I think we've sort of run the gamut on this, and we'll -- you know, I think one of the approaches that we can take now going forward is first off to look at, you know, the charge questions, which I guess represent some serious uncertainties that DPR has, and look at them and, you know, see whether what's, you know, in the report gives us enough information. If not, come up with a wish list of what we need to be able to answer the charge questions.

Because this is so complicated, I don't think our normal procedures of hire -- you know, of assigning one or two people as leads is going to be as effective as a lot -- you know, each area touches on different people's expertise.

And I think I would prefer, you know, after everybody has had a chance to really look at the document that we each carve out a section and -- you know, so for example, obviously, the epidemiology Paul and Kathy and Beate are probably closer to, you know, the human exposure data, and also the occupational exposure data, you know. And we each have our various toxicologic bents.

So if you could get back to me with, you know, what areas you would like to take the lead on, I think I would like to see this one done with sort of individual

responsibility for, you know, things that we're good at, rather than trying to cover the entire base, because we're all going to read this.

This is really an interesting document. It's a very interesting issue, and it's the first one we've had in, I guess, more than a decade, so I'd like to see this done really well.

On the -- now, our next meeting is scheduled for January 23rd. And so we'll be ready to start, you know, a really in-depth review at that point.

PANEL MEMBER RITZ: So, Mike, this is Beate. I Actually have to un, but I'm happy to review the epi, especially everything neurotoxic related.

CHAIRPERSON KLEINMAN: Okay. Great. Thank you, Beate.

PANEL MEMBER RITZ: And if you need me to review other parts, just let me know.

CHAIRPERSON KLEINMAN: Will do.

PANEL MEMBER RITZ: Okay. I will sign off then --

CHAIRPERSON KLEINMAN: Okay.

PANEL MEMBER RITZ: -- unless you have something else?

CHAIRPERSON KLEINMAN: No, I think we're just about to wrap-up too.

PANEL MEMBER RITZ: Okay. Thank you so much, Mike.

CHAIRPERSON KLEINMAN: Thank you very much for joining us.

PANEL MEMBER RITZ: Happy Holidays.

CHAIRPERSON KLEINMAN: So just from the brief interlude here, I'm not going to, you know, make a prediction that we'll be anywhere near done on the 23rd, but I think we'll be able to make some really good inroads. And I think eventually, we will be able to schedule, you know, to get this through and done.

I do want to congratulate DPR on a very, you know, interesting document. I think -- you know, what I've seen of it, it looks, you know, really well done. You've responded to a lot of public comment already. So at least the initial work is there. It's a strong start. And I think we will be able to make good use of it.

PANEL MEMBER GLANTZ: You know, to that end, you know, I haven't looked at the schedule, but, I mean, I think it would -- since I agree with you, the chances we're going to finish this at the next meeting is pretty small. So I really think the staff ought to schedule several meetings now so that -- because -- you know, because scheduling is always hard, so that we can keep this thing moving forward at a good clip.

And if we finish faster than we want or we -- not than we want, faster than -- and we run -- and we don't need anymore meetings, I've never met a person who objected to a meeting being canceled.

(Laughter.)

PANEL MEMBER GLANTZ: But I think -- I think we want to -- we don't want to wait till January 23rd and so oh, we need to meet again, and then we end up meeting in April, because of scheduling problems. So I mean, Jim, I think ought to get on -- get this worked out now and for like having -- you know, schedule like three more meetings after that. We probably won't need them all, but to get it on the calendar.

PANEL LIAISON BEHRMANN: Okay.

PANEL MEMBER ANASTASIO: I have one point as well. I don't know in all the documents you gave us, if the 2016 EPA report is among them. It would be helpful to have access to that.

DPR ASSISTANT DIRECTOR VERDER-CARLOS: Yeah, we can -- we did not provide it in your packet, but we can certainly. It's available online, so we can download it and send it to you.

PANEL MEMBER ANASTASIO: Yeah, that would be great. And then is the SAP report separate from that?

DPR ASSISTANT DIRECTOR VERDER-CARLOS: Yes. Yes.

PANEL MEMBER ANASTASIO: Okay. That would be use --

DPR ASSISTANT DIRECTOR VERDER-CARLOS: The SAP review came after their April -- the issue paper that they came out with in April, there was an SAP review, and that was the review that was given to them. And then the November 2016 document was the last one that came out from EPA on chlorpyrifos.

PANEL MEMBER ANASTASIO: Okay. I think it would be helpful to have those last two pieces.

DPR ASSISTANT DIRECTOR VERDER-CARLOS: Okay.

PANEL MEMBER ANASTASIO: Thank you.

CHAIRPERSON KLEINMAN: So, you know, in response to Stan, we probably should allow a month after the next meeting to allow DPR to respond to whatever comments. And I suspect there will be a lot of them. So can we schedule something like the -- let's say the week of the 12th of February or go on to the 20th maybe would be -- the week of the 20th.

PANEL LIAISON BEHRMANN: This is Jim Behrmann, the panel liaison. We will poll the Panel for the -- all of the months after February. You're going to want to allow time for staff to revise the document, and then to send it out and have time for you to review it.

So giving the DPR staff a month say to revise the

document, we wouldn't to meet before March 23rd, but we will -- I think that's being quite ambitious actually. So --

PANEL MEMBER GLANTZ: Well, you know, I'm ambitious. I mean, I think we should schedule like a month -- a meeting every month now. And if we get there -- I mean, we'll have to see what we demands are put on DPR at the January meeting, and if we think that there's not enough time for them to deal with it and get the document back and give us enough time to read it, we always cancel a meeting, you know.

But I think we just -- I think -- you know, getting back to my earlier comments about the first document that it took a year. I think, we -- you know, we don't want to drag this process out just cause of scheduling. And, you know, so that -- my suggestion would be to try to have something on people's calendars every month for the next several months, and then we could just cancel them, if we don't need them.

But if we decide -- if decide we decide we need it, then scheduling something that quickly for most people is really hard, because you're talking about a whole day.

PANEL LIAISON BEHRMANN: As I said, we will poll the Panel, and I would ask that the Panel also be, if you can, make yourself as available as possible. We will have

to probably accept the fact that we will not have meetings with the entire Panel. It's very seldom that we're able to get all nine members, but we will poll and strive to do so.

DPR ASSISTANT DIRECTOR VERDER-CARLOS: Also, if there are questions before the January 23rd, you can please contact us, so that we can provide you with anything that you will need to review the document.

CHAIRPERSON KLEINMAN: Yeah. I think in terms of the logistics, we probably ought to funnel questions through Jim, because I guess we're not allowed to really caucus about things. And this way if it goes to Jim, he can send things to everybody and we can all see things, so we're not, you know, sending a lot of the same repetitious material over.

PANEL MEMBER GLANTZ: Yeah. Although, I can say that, you know, this is where it's good that I've been here forever. You know, there's -- it's not -- we cannot have a quorum to have a unnoticed meeting, but there have been other things that I've been involved with, where there have been meetings of one or two members with the appropriate State staff. I mean, I've done this several times to kind of hash things out in between the meetings, so that we don't have to waste a lot of time of the whole committee on some highly technical point that, you know, I

or one of the other members is upset -- not upset. That's the wrong word, but wants to -- doesn't understand or wants to discuss.

So, I mean, there's not -- for the new -- relatively new members of the panel, I mean, if -- I think if anybody thinks it would be useful for one or two people to have a meeting with the DPR or OEHHA staff outside of the regular meeting process, that is permitted.

And you can call people. You can talk to them on the phone. You can do that. The thing we can't do is have a quorum of the Committee all, you know, deliberating. So, you know, I think -- I think fundamentally -- I mean, I think keeping Jim in the loop is a good idea, but there's no reason to overly bureaucratize the communication either.

CHAIRPERSON KLEINMAN: Okay. Well, if there are no other items to be brought before us, I would ask for a movement to adjourn.

PANEL MEMBER BLANC: I move.

CHAIRPERSON KLEINMAN: Paul moves.

PANEL MEMBER ANASTASIO: Second.

CHAIRPERSON KLEINMAN: Second by Cort.

We are adjourned.

(Thereupon the California Air Resources Board, Scientific Review Panel adjourned at 1:28 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 3rd day of January, 2018.

JAMES F. PETERS, CSR
Certified Shorthand Reporter
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