MEETING

STATE OF CALIFORNIA

ENVIRONMENTAL PROTECTION AGENCY

AIR RESOURCES BOARD

SCIENTIFIC REVIEW PANEL

ON TOXIC AIR CONTAMINANTS

CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY

COASTAL HEARING ROOM, 2ND FLOOR

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

PANEL MEMBERS:

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.

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

REPRESENTING THE AIR RESOURCES BOARD:

Mr. Jim Behrmann, Panel Liaison

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

REPRESENTING THE DEPARTMENT OF PESTICIDE REGULATION:

Dr. Shelley DuTeaux, Chief, Human Health Assessment Branch

Dr. Svetlana Koshlukova, Senior Toxicologist, Risk Assessment Section

Dr. Eric Kwok, Senior Toxicologist, Exposure Assessment

Dr. Marylou Verder-Carlos, Assistant Director

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. I wanted to just get everybody started. I'd like to call the meeting to order. And I want to welcome everybody to this meeting of the Scientific Review Panel on Toxic Air Contaminants.

Sorry.

Welcome also to the people who are attending here in Sacramento, and to the people who are watching and listening to our webcast.

We do not have a person taking notes at this meeting directly, so I hope that everybody will keep their microphones on when they're speaking, turning off their cell phones, et cetera. And the meeting will be webcast and a transcription will be made from both the verbal and visual tapes.

Before I ask the Panel members to introduce themselves, I wanted to announce first that I understand that one of our members, Dr. Paul Blanc, has been reappointed to a new term by the Senate Rules Committee. So congratulations, Paul, I think.

(Applause.)

CHAIRPERSON KLEINMAN: Even more importantly, he accepted.

All right. I'd like to go around the table starting with Joe Landolph for brief introductions.

PANEL MEMBER LANDOLPH: Good morning. Joe --

CHAIRPERSON KLEINMAN: Joe, turn your mic on.

PANEL MEMBER LANDOLPH: Joe Landolph, Associate Professor of microbiology, immunology, and pathology and a member of the USC Norris Comprehensive Cancer Center, University of Southern California.

PANEL MEMBER BUCKPITT: Good morning. I'm Alan Buckpitt. I'm retired from the University of California at Davis, where I served as a toxicologist.

PANEL MEMBER BLANC: Paul Blanc, University of California, San Francisco, Professor of Medicine and Chief of the Division of Occupational and Environmental Medicine.

CHAIRPERSON KLEINMAN: I'm Mike Kleinman. I'm the Chair of the SRP. And I am at UC Irvine. And I'm the co-director of the Air Pollution Health Effects Laboratory.

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

PANEL MEMBER GLANTZ: Stan Glantz, Professor medicine and director of the Center for Tobacco Control Research and Education at UCSF.

PANEL MEMBER ARAUJO: I'm Jesús Araujo, Associate Professor of medicine in the School Medicine at UCLA, and

environmental health sciences in the School of Public Health.

CHAIRPERSON KLEINMAN: Unfortunately, Dr. Hammond can't be with us today. She has an illness in her family that prevents her from coming up.

I also want to mention a couple of administrative matters for the people who are here. There are restrooms and drinking fountains outside the room to the left. And if there's a fire alarm please exit down the stairs and proceed outside the building. And as I mentioned before, if you do have a cell phone, set it to the silent mode, please.

So there are two agenda items for today's meeting. And the first item is going to be an update by the California Air Resources Board staff about the implementation of Assembly Bill 617. The -- and then the second agenda item will be a continuation of the Panel's review of the Department of Pesticide Regulation's draft evaluation report on chlorpyrifos.

So on the topic of Assembly Bill 617, this will be an update. And the bill was a significant piece of legislation passed last year seeking to remedy air pollution problems in certain areas of the state. The bill has a rather ambitious time frame, and the Panel is one of several groups to be consulted in the creation of

the new program.

Today, Karen Magliano who, is the Chief of the Office of Community Air Protection, will update us on progress to date, and describe how we can best provide suggestions and comments to the program.

Karen, thank you for being here, and please go ahead.

(Thereupon an overhead presentation was presented as follows.)

OCAP DIVISION CHIEF MAGLIANO: Great. Well, thank you and good morning. I know you have a very full agenda here today, but I really appreciate the opportunity to talk a little bit about what the program involves, and sort of where we are going forward, and how we can continue to work with the Committee itself.

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OCAP DIVISION CHIEF MAGLIANO: Oops.

Go to the next slide. There we go. Okay.

What I wanted to do is spend a little bit of time though about the overall motivation behind AB 617 itself. It was a companion bill to the extension of our statewide Cap-and-Trade Program, and really a recognition that while we've made tremendous regional progress in reducing air pollution across the state, we still see significant inequities and disparities in certain communities, where

because of concentration of different kinds of sources, they experience much higher air pollution levels than others.

And we really needed a new focus, and a new set of tools to try and reorient ourselves to how we look not only at statewide and regional programs, but also really going down to the community level.

You know, when we look at the progress we've made overall, what we've shown here on the right is a graph that looks at the progress we've made in reducing diesel particulate matter, which obviously is a key toxic air contaminant, and one that is a substantial contributor to risk in communities at the state. But what this does is compare that the progress we've seen in disadvantaged communities compared to other communities in the state.

And while they've both seen tremendous progress, you can see that there's a gap there, where the disadvantaged communities are still seeing levels that are close to twice that we see in other communities. And so that's a key focus of this program is how do we take targeted action to now start reducing those disparities. And so we're saying greater progress in all the different communities across the state.

The other aspect of it is that, you know, many of our programs have tended to focus at one pollutant at a

time. You now we'll have a state implementation plan for dealing with regional ozone standards. We'll have different programs that we're dealing with toxic air contaminants.

And what AB 617 is doing is now let's look at them together at a community level, sort of under one umbrella, so we can develop more integrated kind of solutions at the community level.

And then the last piece of this, as we all know, is that air monitoring technologies are continuing to advance at a rapid pace. And where in the past when we did our regulatory modeling, they were, you know, resource intensive kinds of monitors, ones that we really couldn't have in a lot of different locations of the state, so we were really looking at more sort of representative sampling. And now, with the advent of, you know, new kinds of monitoring, whether it's low cost sensors, mobile monitoring, satellite monitoring, we can really collect much more granular data at the community level to help us better understand what's going on and then support strategy development.

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OCAP DIVISION CHIEF MAGLIANO: So there are a lot of different pieces of the overall legislation, but they're really designed to work together as an overall

program. A couple of them, of course, are very focused on what we're really trying to accomplish here, which is seeing new reductions within these communities to address the air pollution disparities.

So there will be new sort of community-specific emission reductions programs that look at the mix of sources within those communities and identifying new strategies to reduce emissions. But there's also broader statewide efforts to see, you know, what kind of things and sources do we need to focus on, of those kinds that tend to be concentrated in these communities. And part of that is accelerated retrofit of controls on different kinds of industrial facilities throughout the state.

There's also elements that are associated with gathering better data to understand what's going on in these communities, whether it's air pollution monitoring, but also enhanced data on the emission levels that are coming out from these sources.

There's increased penalty provisions in the bill. The penalty provisions had not been updated in the Health and Safety Code for decades, for example. And then the last piece here that I want to point to, which is really a core of the program is that while we're looking at, you know, a smaller geographic focus at the community level, it's a lot more than that. It's really changing how we

approach the program and working directly with community members on how we develop solutions.

And so part of this is grants to local community groups, so that they can engage in the process, build their technical capacity, and be direct participants in many cases in collecting data, and providing education for community members.

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OCAP DIVISION CHIEF MAGLIANO: So as you heard from Dr. Kleinman, there is a very ambitious schedule that is set aside for the legislation. It was signed just last summer. And the first milestone is coming up in September of this year, which is, in essence, to sort of layout the broad framework and requirements for the program itself, in terms of how do we develop these community emission reduction programs, how do we do well designed air quality monitoring that can really support actions to reduce emissions.

And then the other key piece of this is selecting a first set of communities we're going to be looking at this targeted action. And so that's really been the focus of our effort over the last nine months. And I'll walk through a little bit of sort of what those major elements are.

What happens after September is that the

districts really take front-line responsibilities then for working with local communities in implementing the program itself. So part of that is defining a schedule underwhich they're going to be looking at adopting new rules and regulations for many of these industrial sources, working on the community air monitoring and the community emission reduction programs over the next year. And then those come back to CARB for review and approval.

The other element of this is it's not just a one-time kind of program. There are requirements that we come back annually, look at program progress, but also identify additional communities. So we add to the list of communities that are benefiting from the program over time.

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OCAP DIVISION CHIEF MAGLIANO: Stop doing that.

I'm just going to move that out of the way.

So as I said, we've been trying to incrementally put out new products to help us work through, you know -- and what should the program look like, how do we want to design the program, discuss with all sorts of different stakeholders how we put together a program that really meets the objectives and the overall goals.

So we've been working through a number of different planning documents. One is an initial concept

paper that we put out in February of this year. And that was part of your memo packet that was sent around to you. And that was really laying out our initial thoughts on, you know, how do we approach these different elements of the program? As well as a process for how do we assess and identify which communities we really should be, you know, potentially focusing on first, recognizing that there are many, many deserving communities throughout the state.

And then also looking at implementing some of the funding programs that were associated with this. There was funding that was provided for those community grants, and have just gone through a solicitation and an award process for that, as well as funding that was provided for incentive programs to start getting early reductions in advance of developing these more targeted programs.

And then just last week, as shown in the center on this slide, we released a sort of full-blown draft blueprint of the program. And you can't quite read it here, but it has a very long subtitle, which is really -- this is laying out, you know, how we're proposing to identify and select communities to be included in the program, how the process and the elements of the community emission reduction programs, how to do sort of guidance on designing air monitoring, and then developing the

statewide strategies.

And I know we're hoping that since we just have a short time here today, that we might be able to have a more focused call in July to be able to walk through and discuss more of the elements of the blueprint itself.

But I will kind of try and give some highlights of the major elements that we have in that.

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OCAP DIVISION CHIEF MAGLIANO: So as I said, one of the very first steps is going through and identifying potential communities. And what we've done is solicited recommendations from local air districts on communities they feel that are, you know, very heavily impacted within their regions, but also solicit nominations from community groups and community members themselves.

And so what we're trying to do is pull together a broad list of potential communities that need to be considered, and then walk through a process of determining how we come up with recommendations for a smaller subset in the first year of the program.

So not surprisingly, we have received hundreds of nominations so far. And so right now, working with the local air districts, we're going through the process of really assessing what those cumulative exposure burdens are in the communities, and then coming up with a process

for how we recommend to our Board, which communities we can really focus in the first year.

And as you can see here, we are looking at starting small. We want to be able to make sure that we're successful in this first round of communities, but also want to make sure that we're getting a mix of different regions, different kind of mixes of pollution sources in those communities, because that can serve as models for other communities that have similar challenges, and will also I think help drive broader strategies that can benefit additional communities.

And so we will be coming out in August of this year working with the districts and communities on what the recommendations that our Board should be considering.

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(Discussion off the record.)

OCAP DIVISION CHIEF MAGLIANO: Yeah. That's a really good question and one we've gotten asked a lot.

In many cases, what we're seeing is that it might be a collection of census tracts, for example that tend to have common pollution sources and common air quality challenges, so that by aggregating them together, you can design a program that meets that.

You know, that tends to work in some of the more urban parts of the state. When we go to more rural areas,

oftentimes, you know, a small city itself might be considered a community as well. So we're kind of trying to leave it a little bit flexible, but, you know, it's not -- it's not a giant city, because what we're really trying to do is target down to those smaller scale disparities.

Just quickly to highlight some of the things that we've put out there in terms of how we would assess cumulative exposure. You know falling into three different categories. One, it's obviously what the concentrations are of criteria pollutants and toxic air contaminants, density, and magnitude of emission sources. You know, are we seeing clusters of different kinds of emission sources within communities? But also looking at where it's available if we have air quality modeling or cancer risk estimates as well.

The legislation specifically calls out looking at sensitive populations, but also looking at a focus on disadvantaged communities. And so we'll be looking at, you know, many of those socioeconomic factors, as well as public health indicators. Many of these will come from CalEnviroScreen, but we're also looking at more broadly bringing in other kinds of data sources as well. And that's something we've been continued to seek sort of feedback from people and the kinds of things that we

should be looking at in assessing cumulative exposure.

PANEL MEMBER BLANC: Does the legislation partic -- specifically use the word sensitive?

OCAP DIVISION CHIEF MAGLIANO: It does.

PANEL MEMBER BLANC: Because that's a word that is potentially problem-ridden as it implies an allergic mechanism of effect, often as it's used in biomedical terminology. And sometimes people take issue with that as a word, so you should be cautious of how it can be misread.

OCAP DIVISION CHIEF MAGLIANO: That's a good point.

PANEL MEMBER BLANC: And so sometimes people use the word "susceptible", and then they argue about what's a better word, but it's kind of a mine field, just so you know.

OCAP DIVISION CHIEF MAGLIANO: Okay. That is good to know, because I think the intent was really getting at, you know, people who are more susceptible, children, the elderly, things of that nature.

PANEL MEMBER BLANC: Right, right. That's not really an -- that's not an issue of sensitivity, in that sense. I mean in the standard -- in common biomedical usage.

OCAP DIVISION CHIEF MAGLIANO: Okay.

PANEL MEMBER BLANC: Stan, you look like you want to say anything.

PANEL MEMBER GLANTZ: I think what they meant is pretty clear, but it's the way it's written in the law, so you're kind of stuck with it.

OCAP DIVISION CHIEF MAGLIANO: Right.

PANEL MEMBER BLANC: But just be aware of it.

OCAP DIVISION CHIEF MAGLIANO: Okay. That is good to know. Thank you.

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OCAP DIVISION CHIEF MAGLIANO: So then once we have selected communities, these communities will be selected for either development of community emission reduction programs and/or air monitoring. And we expect that in the vast majority of cases, there will probably be some element of both, so when we look at these sort of up to ten communities, probably most of them will have community emission reduction programs, and then some companion air monitoring to help support that, whether it's helping to further identify sources or track progress over time for example.

But what we've laid out here is really what we've proposed as the major elements that need to be looked at and included in these community emission reduction programs. And a number of these are really laid out in

the statute itself in terms of having emission reduction targets, an implementation schedule, specific strategies, and an enforcement plan.

But we also wanted to make sure that there really was this strong community involvement in developing these, because oftentimes in our prior planning efforts, we've tended to develop a plan for a region. We have an ozone SIP for the San Joaquin Valley, or a PM2.5 SIP for Imperial County. You know and that's sort of bureaucratic, and that's what we're good at doing.

But what we're really looking at here is developing plans with the community members themselves and learning from each other in the process, because we all have things that we understand about communities. And so it's trying to bring people together as part of that process. And so we're proposing that there are community steering committees that work with the air districts on developing these plans.

And we're also looking at making sure that these aren't just paper plans, but we're actually delivering real reductions, and they get implemented. So it's also including metrics for tracking progress and trying to define some really visible concrete things that people can look at. So, you know, defining goals for deployment of certain kinds -- a number of certain kinds of technologies

in the community, or replacement of a certain number of wood stoves, or the other piece of this, which is I think a little bit different is when we go into these communities, we often know that past land-use issues have been a significant contributor to why we're seeing these pollution disparities.

And while the direct authority for addressing a lot of that doesn't result in CARB or the local air districts, it's oftentimes zoning that's done by local governments. What we're trying to do here is, one, identify though what we would like to see happen, you know, whether it is setbacks, or buffers, or trying to find alternate truck routes, for example, to mitigate some of that, you know, proximity kinds of issues. And then identifying strategies on how we can collectively work with these other agencies to try and affect that change.

It's also trying to bring these agencies into these community steering committees, so that we're having more direct conversations about what needs to be done.

CHAIRPERSON KLEINMAN: Karen?

OCAP DIVISION CHIEF MAGLIANO: Yes.

CHAIRPERSON KLEINMAN: On this slide, you've got clear emissions reduction target type things that are relevant. But I think the exposure reduction part of it, which people have control of by themselves --

OCAP DIVISION CHIEF MAGLIANO: Um-hmm.

CHAIRPERSON KLEINMAN: -- might be called out either separately or highlighted, because I think they -- you know, you want them to feel that they have a responsibility for protecting themselves as well, not just waiting for the government to do it for them.

OCAP DIVISION CHIEF MAGLIANO: Right. And that, I think, will feed into when we get to the monitoring one and having data that helps them inform their daily activities and things of that nature too.

The other thing I just wanted to point out on this one is where we're looking at in terms of sort of what kind of air quality objectives are we sort of trying to design these programs around.

So we have our existing regional programs that are, as I said, you know, trying to drive down concentrations throughout a region. You know, ozone tends to be more regional for example. And so what we're suggesting here is that you're really trying to go after, you know, what's causing more of those local disparities, and so where it's applicable, looking at PM2.5, for example, and then obviously, toxic air contaminants in many of these communities. And then that helps sort of drive the emission reduction targets and the technology deployment goals.

PANEL MEMBER ANASTASIO: I have a question for you, Karen. So is this trying to help communities attain current standards or are you going beyond that in some cases and --

OCAP DIVISION CHIEF MAGLIANO: You know, obviously, the current regional plans are designed to make sure that an entire region does attain the standards. You know, part of this is making sure as we're working towards attaining the standards, we're taking some near-term actions within those communities, so they're seeing some more direct benefits, rather than indirect benefits in their communities.

But I think there also can be cases where you may have a region that already attains the standards, but we all know that going below the levels of the standards can continue to see further health benefits. And so this is an opportunity to perhaps focus some additional efforts there as well.

PANEL MEMBER ANASTASIO: I was just wondering are you then expecting pushback from emitters when you try to go below the current standard? I mean, what's the authority to be able to do that?

OCAP DIVISION CHIEF MAGLIANO: Well, I think part of it is when we look at many of these strategies, they're going to have multi-pollutant benefits. And especially

when we're looking at toxics, as you all know there are not safe levels, so that sort of provides an impetus to continue to drive further and further reductions.

But they will also then in turn potentially provide benefits for meeting the criteria pollutant standards as well.

PANEL MEMBER ANASTASIO: Thank you.

PANEL MEMBER ARAUJO: And how are you planning to assess the benefits of the program that you're measuring on health outcomes or...

OCAP DIVISION CHIEF MAGLIANO: That I -- thank you. That's a note I had and I forget to bring it up. So we've had quite a bit discussion about -- what about moving to the next step, which is quantifying health benefits. As Dr. Kleinman noted in our consultation group meeting we've probably spent one and a after meetings just focused on that topic itself.

What we're looking at here is that the primary focus of the emission reduction programs and tracking success is on the emission reductions themselves. But we know that that's eventually going to lead to improvements in public health. And so what we're trying to use the program sort of as a catalyst to start collecting better data, so we can make those connections themselves, providing the data to health researchers. But also, as we

look at engaging with especially other local agencies and they're making decisions about land use and things like that, if we can bring a discussion about the public health impacts of some of these decisions more to the forefront that hopefully that can be helpful in the progress -- process as well.

So at this point in time, we're not looking at setting specific quantitative public health improvement goals, but trying to kind of continue to move forward on collecting better data, so that, you know, maybe over the longer term we might be able to do that.

PANEL MEMBER ARAUJO: Will you be collecting the data -- I mean, the health data or will you be instigating or promoting, you know, installments of RFAs or -- from funding agencies and having research programs or will the State then actually do some of this -- the work?

And also, I noticed that in one of the slides that you mentioned something about cancer. It didn't mention anything about a lot of the other effects on there that these air pollution causes. And a large portion of the mortality is actually attributed to cardiovascular -- study of cardiovascular diseases instead of cancer.

OCAP DIVISION CHIEF MAGLIANO: Um-hmm.

PANEL MEMBER ARAUJO: Cancer is a smaller portion. So how are you considering all these?

OCAP DIVISION CHIEF MAGLIANO: So on your first point, what we're looking at is, you know, hopefully we can work with public health agencies to help collect the additional data. It's sort of beyond what the jurisdiction of the air pollution control districts are. And we really want them to focus on the core mission of emission reductions. But at the same time, if this can provide an opportunity to say there's a huge need out there, and an opportunity, because we're collecting all of this emissions and air quality data, to, in parallel, be able to collect more public health data as well.

And then on the non-cancer part of it, yes, when we're looking at some of these public health indicators, it is certainly going beyond just the cancer risk. So we are looking at characterizing cardiovascular incidences of asthma, low birth weight, for example, because they all contribute to sort of what that health burden in the community is.

PANEL MEMBER GLANTZ: Yeah. I'd just like to second that, because the other thing is those risks change a lot faster than cancer risks.

OCAP DIVISION CHIEF MAGLIANO: Um-hmm.

PANEL MEMBER GLANTZ: And so I think your chances -- excuse me. Your chances of actually seeing an effect in a relatively short period of time are a lot

higher than being able to detect cancer risks. That's not to say that the cancer isn't important. But, you know, for example, if you reduce exposure to fine particle air pollution, you get fewer heart attacks, you know, the same day. And, you know, the risks associated with low birth weight and complications of pregnancy also change quite quickly.

I mean, there's a very robust literature dealing with secondhand smoke that show all of these things, when you create a smoke-free workplace, change within a month by maybe 20, 25 percent. So the effects are fast and big. And the things which are causing those changes related to secondhand smoke are almost certainly a lot of the same thing you're measuring here, like ultrafine particle exposures, oxidant loads, you know, things like that.

So I -- you know, again, I wouldn't ignore cancer, but I think in terms -- if you've got to prioritize what you're going to collect data on, or work with the Department of health or something to collect data on, I would look at the things that Jesús mentioned, because those -- and those also, in many ways, operate through similar biological pathways too. So looking at them all together might -- you know, that will also maybe increase the sensitivity for measuring effects.

OCAP DIVISION CHIEF MAGLIANO: No, that's good.

And actually, at our last consultation group meeting, Dr. Paul English from the California Department of Public Health actually was sort of walking through those various things in terms of time scales underwhich you would actually be able to see some measurable differences and very much a focus on things like asthma cases, and things like that rather than, you know, cancer, which is going to manifest itself over quite long time frames.

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OCAP DIVISION CHIEF MAGLIANO: Okay. So then the next piece of this is community air monitoring programs that will be occurring in many of the communities. Our work starts with a couple of things, which is sort of the basics of just looking at what are the capabilities of current monitoring technologies, you know, understanding what can they tell us, you know, what can't they tell us to start providing some guidance of, you know, if you're trying to understand a certain kind of problem, how do match the right technology with what you're trying to understand?

And also looking at existing community air monitoring networks. This is an area where community groups themselves have actually done a lot of work in the last few years in designing and deploying community air monitoring work. And so we're really trying to build off

of sort of lessons learned as part of that process.

And then the third element is providing criteria for if you're going to go out and do this, how do you do it in a well designed way? So, you know, defining what it is you're trying to understand and your objective, and then how do you put together a monitoring program that can really support that?

And part of that, too, is that we know that there are many communities now where we already have a good understanding of what's going on. And these are the communities where we can jump to action. And so the monitoring itself is -- at least in part of 617, is not designed to be just more monitoring for monitoring sake, but really trying to tie it to how is it eventually going to be able to support action in the community? But those actions can be a lot -- a number of different things. So as we talked about, you know it could be from supporting daily notification systems, so that, you know, people can better understand what's going on in the community, and make decisions about their daily activities or support school flag programs.

It could be targeted measurements to better understand what's really coming out of different sources, and do we have a good understanding of them not. And it can also be, you know, how do we track progress over time

in these communities? Are we really seeing that what we're doing is having an effect?

We've also had a large number of discussions with various groups that as we collect this much more granular data at the community level, it's another opportunity to have those connections back with health researchers, because, you know, there's going to be a wealth of information that's probably contained and can be mined within this data to help us better understand community level health impacts.

And then the last piece, of course, which is always critically important is, okay, now we have this massive amount of data, how do we interpret it, and how do we talk with various groups about that? We'll be putting together a statewide data portal. But behind that, you know, it's sort of working together on that, you know, making it meaningful and accessible.

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OCAP DIVISION CHIEF MAGLIANO: There are also a number of other implementation elements that are associated with the program. One of it is putting together a technology clearinghouse that sort of outlines what are the best available technologies out there. The minimum requirements are to really look at stationary sources, but we want too broaden it to also look at mobile

source technologies as well.

There are requirements to really improve the way that we collect emissions data. We've been doing it on more of a regional basis. And now we're trying to get much more, not only granular air monitoring data, but more granular emissions data as well. And I'll talk about that a little bit more on the next slide.

And then we're also putting together an online resource center that will house a lot of this information, especially things that we know will continue to change and add to over time. So best practices on different land-use and transportation strategies, you know, a lot of this information to support community air monitoring and new technologies that are becoming available. And then just sort of education and outreach kinds of components as well.

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OCAP DIVISION CHIEF MAGLIANO: So a little bit more on the emissions reporting. And we've actually just finished a series of workshops outlining sort of what our initial thoughts and approaches on this are. But as a little bit of background, in many cases, emissions data to date has often only been reported once every three years or once every four years. And that was sufficient when we were sort of tracking over the long term over sort of a

regional perspective.

But now that we're truly trying to better understanding what's going on in specific communities, you know, when someone wants to understand what's coming out of this source that's right next to me, what this is designed to do is move to an annual reporting system, so that we can track from year to year to year what's going on with key sources.

The other aspect of it is that there have tended to be different methodologies used in different regions across the state, which then sometimes makes it very difficult to compare, you know, emissions you're seeing from a refinery in the Bay Area to emissions you're seeing from a refinery in South Coast.

This is one that's going to take us some time to do, but we are looking at, you know, are there some more uniform ways of collecting data itself? And then also, are there additional types of data that would help us better understand when we see a change in emissions, why is it happening? Was it because the throughput at the facility increased, or decreased, or was it because pollution controls were put on.

And then there's also options for data certification or verification. You know, we're certainly not looking at this program being equivalent to our

cap-and-trade mandatory reporting system where that verification is very critical, because there are monetary compliance obligations associated with it. But this might be looking at if there's additional, you know, QA/QC that could be helpful in that process.

So I think this is one that -- would really help us get a better understanding of some of what's going on, because we know that there are, as we've been putting more and more data out there in emissions and our pollution mapping tool, there are certainly a lot of data gaps that are out there.

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OCAP DIVISION CHIEF MAGLIANO: The last couple pieces that I just wanted to touch on are funding that was appropriated by the Legislature in this first year to sort get the program off the ground. So the first was 250 million for incentive programs. This was specifically focused on replacing and, you know, accelerating the deployment of cleaner mobile source technologies, so trucks and buses, things of that nature.

The map on the right shows that the bulk of the funding went to the South Coast, the San Joaquin Valley, and the Bay Area, but there's also funding that's provided throughout the state. And then the upcoming budget does have additional funding to continue the program over this

next year. And one of the things that we're looking at is that broadening it beyond just mobile sources, that especially as we get into some of these communities, there may be small business owners, stationary sources, where this funding could be really helpful to achieve further emission reductions.

And then the other part of this is again, you know, focusing these investments in the disadvantaged communities that really need those localized benefits the most.

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OCAP DIVISION CHIEF MAGLIANO: And then the other aspect was funding that was provided for the Community Air Grant Program, which was really this, you know, how do we engage more directly with community members and community groups, and build their capacity for the program. And so there was $5 million that was allocated in the current budget. We released a solicitation for this in February, and recently announced awardees for the program, including an additional five million that's contingent on that being included in the upcoming budget.

And you cannot read this obviously from here, but there were, I think, 28 different groups that we've proposed awards to go through. They're across the state. And a large number of different kinds of projects this is

focusing on from community led air monitoring efforts to community education. I really like to see that there are a lot of youth elements to it of going into schools and starting to sort of build our next generation of community scientists as well. So this is one that we hope to continue to expand over time as we go through the program.

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OCAP DIVISION CHIEF MAGLIANO: So there's -- we've made a lot of progress, but there is still a lot to do even between now and September. As I mentioned, we released the draft blueprint for the program just last week, and we're hoping for an opportunity, and I know Jim has been polling all of you, to perhaps have another focused call on that in July, because we know your agenda today is so full.

We'll be doing an update to our Board at the end of this month. We've been kind of doing that, you know, every three months or so to keep them apprised, but it's another opportunity for public discussion. We'll also be doing some workshops. We've been going out actually and doing tours within the communities and being able to talk directly with community members. And we also have sort of multi-stakeholder consultation group that Dr. Kleinman serves on as well, that continues to provide another forum for bringing together a lot different perspectives and

feedback on the program.

We're then looking at, you know, based on that continued discussion, releasing an update to the blueprint in August, and then also our recommendations for sort of what that first year of communities would actually be. And then it will be considered by our Board in September.

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OCAP DIVISION CHIEF MAGLIANO: And I know that there are many different, you know, aspects of this that are of particular interest and expertise of this group. These were just a few questions that Jim and I and Dr. Kleinman had thought about, but we're certainly -- you know, very much want to have a broad discussion about this. But something to perhaps tee up and think about, especially as we go into potentially another discussion in July, and that is we've talked a little bit, you know, the factors that we should be looking at as we assess cumulative exposure.

This is one where, you know, we're sort of taking a first cut at this year. But as we go forward in time, you know, how we continue to expand on how we look at that, and really look at the true cumulative impacts of all these different pollutants.

How this enhanced emissions data and enhanced air monitoring data really can be used to help support better

health assessments. And then, you know, as I mentioned, as we have all this data, how do we interpret and communicate health risks to community members. So I think that's the end of my slides. I am certainly willing to entertain additional questions you all might have.

CHAIRPERSON KLEINMAN: Thank you, Karen.

I know we've kind of interrupted you during your thing, so --

OCAP DIVISION CHIEF MAGLIANO: Right, which is great.

CHAIRPERSON KLEINMAN: -- many of our questions were sort of covered. Does the Panel have anything?

Yes.

PANEL MEMBER LANDOLPH: I'm fully supportive of everything you said and what the legislature did. I think it's great. I have a question, and I don't mean to put you the spot, but I work in Los Angeles at USC. And, you know, that Exide plant, of course, has made the new for decades, and there have been extensions for decades of the permitting. Has anything been done to try and stop abuse of this permitting extension process? I mean, you know, the air was polluted, the soil is polluted, it's a lower socioeconomic community, so it certainly falls under your guidelines. And I know they're making progress on it now.

But, you know, it just strikes me in all this

when you have a hot spot sticking up like that, which is just disastrous, and the community needs help, has anything been changed to cut through that and be able to attack such a problem faster?

OCAP DIVISION CHIEF MAGLIANO: I think that there's a -- you know, I can't speak too directly to that one, but I think there are a couple of things. One, when we're looking at a situation like Exide obviously, oftentimes there are multiple agencies that are involved with it. And I think one of the things that the Exide situation has done, and we're hoping to continue through AB 617, is a better process for coordinating and linking these various agencies together to be able to address the problem.

I know, for example, that the South Coast Air Quality Management District, you know, partly in response to this, partly in response to situations related to chrome plating, for example, is doing a lot more in terms of when they're issuing notices of violations to facilities, they're making sure that other county agencies are aware of what's happening there. So you're creating, I think, a better feedback mechanism for being able to more quickly address some of these situations as well.

PANEL MEMBER LANDOLPH: Thank you.

CHAIRPERSON KLEINMAN: Well, now the Panel is

being polled for a date to have a conference call to further discuss the blueprint, once you've had a chance to read it. So I think at this point, we will thank Karen for the presentation, and I think we'll be prepared to, you know, discuss it, you know, after we've, you know, really had a chance to explore the blueprint and perhaps come up with some useful suggestions.

OCAP DIVISION CHIEF MAGLIANO: Great. Looking forward to it. Thank you again.

CHAIRPERSON KLEINMAN: Jesús, did you...

PANEL MEMBER ARAUJO: I'm just trying to -- I had a couple of questions. One, is, you know, what is the scope and how big are you really planning to go after -- when you're talking about communities, how big are those communities, and are you talking about whole districts, and are you talking about communities within districts, and is there a specific aim about the population that you're going to reach or what was asked before any intentions of, you know, you want to drop like, let's say, levels of air pollution in certain places, any targets, or is this more like a general program of just trying to foster or promote environmental health and without specific targets, and whatever comes from it will be measured and will be...

OCAP DIVISION CHIEF MAGLIANO: Yeah, good

questions. So maybe I can give you a couple of examples of communities that we know air districts are considering and gives you kind of a sense of scale for example.

So, for example, in the Bay Area, they are looking at one of their first communities would be West Oakland. So, you know, not the entire city of Oakland, but really trying to focus on that area that has some unique air pollution challenges. There are also, you know, areas in the San Joaquin Valley where some of the community advocates are very interested in, you know, a small cluster of communities that might represent in total 5,000 residents or so. So it really is trying to target smaller areas where there are some very focused problems that we can try and get at, where you're tending to see some clusters of individual sources that are contributing to those sort of disparities that we are seeing overall.

And so it's intended really to -- it doesn't replace what we're already doing as part of our regional programs, but it sort of layers on top of that, so that we're starting to see, you know, how can we start closing that gap that we're seeing in that initial. We're not setting -- as I said, you know, we're looking at for PM2.5, you know, wanting to make sure that you are achieving helpful levels of PM2.5 in those communities.

With toxics, we're not setting a specific percent

reduction goal, per se, but really looking at, you know, over a short timeframe, we've been saying here right now, five years, what can you do to maximize reductions that you can see and a focus directly within the community itself, because I think that was part of the impetus for the legislation itself is that when you've had these broad regional programs, sometimes it didn't -- you weren't really looking at necessarily where the reductions were occurring.

And so what the program is now trying to do is, you know, within these communities making sure that we're actually targeting action so that it happens within those communities themselves. And they're seeing more direct rather than sort of trickle-down benefits to reducing pollution.

PANEL MEMBER ARAUJO: Yeah. So what I'm thinking is that this is a wonderful opportunity, not just for -- also to get to know more about the -- about the problem, not only to monitor or to the metrics of the exposures. And some of the best studies have come as -- in terms of cardiovascular endpoints. And it came from longitudinal studies --

OCAP DIVISION CHIEF MAGLIANO: Um-hmm.

PANEL MEMBER ARAUJO: -- that were looking at variations of cardiovascular rates and sort -- and across

different cities exposed to different levels of pollution.

So here you have an opportunity of targeting small communities versus other communities that would be a neighbor or in close proximity to those communities, and you can see, you know, these are -- these communities are probably exposed to similar levels of pollution or affected by similar factors.

OCAP DIVISION CHIEF MAGLIANO: Um-hmm.

PANEL MEMBER ARAUJO: But some will be in the program for -- they will be like an active and target, or active promoting of this environmental health, and others will not. So there will have the opportunity to actually see and you really see reductions --

OCAP DIVISION CHIEF MAGLIANO: Um-hmm.

PANEL MEMBER ARAUJO: -- in the risk. And maybe the big question, you know, whether it is really any additional benefits of going beyond the current regulation. So that would be a really important endpoint, because some of these studies have shown that there is no threshold that they -- that the effects are linear --

OCAP DIVISION CHIEF MAGLIANO: Right.

PANEL MEMBER ARAUJO: -- and that it doesn't really matter. It's just that the more that you get exposed, the more effects that you will have. The less that you are exposed, the more benefits that you will --

and this could actually test it, you know.

OCAP DIVISION CHIEF MAGLIANO: Um-hmm.

PANEL MEMBER ARAUJO: But your starting pretty soon --

OCAP DIVISION CHIEF MAGLIANO: Yes.

PANEL MEMBER ARAUJO: -- and if you don't really have like details about any of these things. So there is a risk that you're getting to a program of this magnitude, and five years from now you realize oh, wow, we should have done this, we should have done that. Now, we don't -- and money is -- the money has been pent.

And if you haven't really, you know, acquired of all the different things that you need to program even ahead of, and then you may have lost the opportunity. So I would really encourage, in trying to move really fast, you know, in planning well, how is it you're really going to acquire all these data, how is that -- you know, whether it is like, you know, partner with -- if it is a State-based or you could even partner with federal agencies.

OCAP DIVISION CHIEF MAGLIANO: Um-hmm.

PANEL MEMBER ARAUJO: You know, how about have you gone to the NIH or the federal EPA and see whether they would be interested in doing studies or large-scale studies where they can look at these experiments, because

in a way it's an experiment, you know.

OCAP DIVISION CHIEF MAGLIANO: Um-hmm. No, that's good point.

PANEL MEMBER ARAUJO: And you're starting September 18th, right?

OCAP DIVISION CHIEF MAGLIANO: Yes, there is. It is. It's a very ambitious schedule. You know, part of that is why we don't want to start too large, because we want to make sure -- we're going to learn a lot in the initial part of the program, and so --

PANEL MEMBER ARAUJO: Right.

OCAP DIVISION CHIEF MAGLIANO: -- starting smaller. But there also -- you know, we know we will continue to improve the program over time. There's constant reports back to our Board, you know, to be able to make mid-course corrections. And I think part of that I think is a good point on, you know, as we learn things how do we beat that back and making sure that it is an opportunity to take advantage of a broader data collection effort.

PANEL MEMBER BLANC: Can I ask also in terms of the interface with other programs of the -- under the aegis of the Air Resources Board, in your initial identification of prototype communities to pilot work, will you also be including in that communities in which

the salient air pollution issues include agricultural sources and not be inhibited by the ways in which to a certain extent OEHHA and DPR's efforts are siloed from each other?

OCAP DIVISION CHIEF MAGLIANO: So one of the things we are looking at as we select this sort of initial mix of communities is make sure that it is a pretty broad range. So, you know, obviously, you know, there are communities that are impacted by freight, for example, communities that are impacted by maybe more urban mixes. But we've also definitely wanted to include in there communities that are more impacted by rural sources, agricultural sources.

You know, especially in the San Joaquin Valley there's a lot of interest in pesticide impacts. And so, you know, that may be something that as we think about the types of communities, that's certainly one of the recommendations that's coming from the valley advocates is they would like to include communities that are impacted by those agricultural sources, as well as oil and gas operations as well. So we are trying to capture a pretty broad net of these initial communities, because it can help drive a lot of -- a broad range of scope of actions, but as well as then also prompting that need for coordination with many other agencies within CalEPA as

well.

CHAIRPERSON KLEINMAN: Are there any other questions for Karen at this time?

If not, we'll look forward to being on the conference call sometime this -- in July.

And with that, we'll move to our second agenda item, which is the evaluation of chlorpyrifos as a toxic air contaminant. This is the third time the Panel has met in person to discuss the draft evaluation that was submitted by Department of Pesticide Regulation, or DPR.

And at our last meeting, there was a -- the Committee requested that DPR consider the developmental neurotoxicity endpoint as a criteria for establishment. So the DPR has sent to the Panel on June 1st an addendum report. And that report contains revisions based on the discussions with this panel, at the previous two meetings. The new addendum represents a significant amount of new work. And it's been in a state of continuing improvement, and so we're looking forward to hearing the staff presentation on the latest changes and the status of the addendum.

I want to state for the record that the Panel has also received written comments from Dow AgroSciences, a joint letter on behalf of California's Citrus Mutual, California Cotton Ginners and Growers Association, and the

Western Agricultural Processors Association, and written comments from Californians for Pesticide Reform.

And with that introduction, I'll turn the microphone over to Dr. Shelley DuTeaux who's the Chief of DPR's Human Health Assessment Branch to introduce the presentation.

(Thereupon an overhead presentation was presented as follows.)

CHAIRPERSON KLEINMAN: And again, while they're setting up, just want to remind everyone talk into your microphones, so that we can get a good transcription of this. Thank you.

DR. DuTEAUX: Good morning, everyone.

Okay. So as Dr. Kleinman, Chair of the TAC SRP said earlier, we are in the hopefully final stages. We're nearing the final stages of evaluating chlorpyrifos as a pesticide toxic air contaminant. The document that you received last -- week and a half go is an addendum to the December 2017 draft TAC evaluation -- toxic air contaminant evaluation. So when I use the word TAC, that's what it stands for.

This morning -- sorry.

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DR. DuTEAUX: This morning with me today -- and again I'm Dr. Shelley DuTeaux. I'm the Branch Chief of

the Human Health Assessment for the Department of Pesticide Regulation. And joining me is Dr. Svetlana Koshlukova, the senior toxicologist for the Risk Assessment section at DPR; Dr. Eric Kwok who's a senior toxicologist for the Exposure Assessment Section, again with DPR; and Dr. Marylou Verder Carlos, our Assistant Director and Chief Science Advisor for the Department.

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DR. DuTEAUX: So for today's presentation, we have kind of five chunks that we'd like to go through. The first is a brief overview of the additional data and analyses that were added and are reflected in this addendum, per request either from scientific partners or from this Panel.

Next, we're going to be going over the process for deriving the chlorpyrifos point of departure for developmental neurotoxicity from in vivo animal data. Net, we're going to help lead a discussion of proposed changes for the final document. Then we'll have a review of toxic air contaminant authority as it's noted in the Food and Agricultural Code for pesticide TACs. And then we'll have a brief discussion on the sufficiency or insufficiency of the document to meet the needs as per regulation.

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DR. DuTEAUX: So starting off with the additional data that we have been asked to include in this addendum. And just briefly, the reason why we decided to proceed with an addendum as opposed to a revised TAC evaluation document is that you will note that the document itself is over 100 pages long with close to 200 pages in appendices. If we would have added that in track changes or otherwise to the existing December draft, your overall document would have exceeded 650 pages.

So we thought it best to pull out all of the new data and have it as a separate document. So this is what is in front of you as the addendum.

The newly added content that I'll be going over is in order of how it appears in the addendum. So if you have your hard copy and you'd like to follow along, please do so. And the additional data and analyses were added on specific topics. Based it on suggestions that we received either at the January or March 2018 SRP hearings, as well as questions received from our partner State agencies, and inquiries from individual SRP Panel members.

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DR. DuTEAUX: So starting off again in order of the addendum itself, the first that we added as a reanalysis of the registrant submit a -- submitted FIFRA guidelines study, which is noted in the document as

Hoberman, 1998. This was done by Dow AgroSciences. And our reanalysis -- although it was included in the previous three drafts, our reanalysis had a special emphasis on brain morphology changes following in utero exposure to chlorpyrifos. And that reanalysis, along with the tables, is found in pages six through 12.

We were also asked to do a thorough analysis of recent in vivo animal studies with developmental neurotoxicity outcomes. And for this, we took a deep dive into Carr et al., 2017, Gómez and Giménez et al., 2017 and 2018, Lee et al., 2015, and Silva et al., 2017. There's an extensive discussion from pages 12 through 16, as well as in the risk characterization sections on pages 54 through 57. These documents create the basis for our point of departure and we'll be discussing those in great detail later this morning.

We were also asked to look at additional animal data. Specifically, we were asked to look to see if there was an primate data, and there were. So we've gone back and added those analyses from Coulston et al., 1971. We were also asked to look to see if there were any genotoxic potentials for chlorpyrifos. And so we added further analysis for that from Muller et al., 2014. And those are found on pages 16 through 17.

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DR. DuTEAUX: Moving on. We were asked to update the epidemiological studies. And so to that end, we have added additional cohort studies from the Philippines, Central Ohio, the Zhejiang Province in Chian, and Mexico City. We also were asked to specifically and critically analyze the quantitative exposure analyses in the human epidem -- epidemiology studies, which we've done. And you'll find that on pages 18 through 24.

We've added a brand new section on delayed neuropathy and neurodegenerative effects or organophosphates, with some specificity towards chlorpyrifos. That was at a request of Dr. Beate Ritz, so I'm sad to not see her with us today, if she would have had any questions about what we covered. But in general, we covered human case reports, or epi studies, animal studies, and mechanistic studies on delayed neuropathy, Parkinson's disease, and Alzheimer's disease. And a special note that we also included information on a -- an extended cohort in Egypt, where they're studying late adolescent pesticide workers. And it's not delayed neuropathy, but extended effects is what I would call it. And you'll find those analyses on pages 24 through 47. It's an extensive section.

We also added new sections on additional human effects, including respiratory effects on pages 48 through

53, and obesity, per Dr. Araujo's suggestion on page 54.

We also added a new section on recent advances in PBPK modeling. There was a brand new paper that came out from Colorado State University. And so we have included our synopsis of that as well.

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DR. DuTEAUX: We were asked to include two additional age groups in our exposure assessment in the development of our margins of exposure. So to this document, besides the other two age groups we included in the December 2017 draft are infants, so those below age one, and children, six to 12 years old.

We did a new analysis on secondary drift exposure assessment, as we could through the available data. We based that on DPR's air monitoring network data. And that's found on page 68. We also did a reanalysis of house dust data. And we are including new data Gunier et al., from Brenda Eskenazi's lab, 2016; a re-estimation of internal doses from the 1999 data and the 2006 data. And that's found on pages 68 through 70.

We also revised the dietary exposure assessment with updated risk values. That's found on pages 71 through 74.

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DR. DuTEAUX: So does the Panel have any

questions on those additional data or do you -- I guess a question from us. Have we covered all the bases - we hope we did - on everything that was requested in the January and March meetings?

I'm seeing Cort.

PANEL MEMBER BLANC: There was one small question about whether there was any estimation of dietary exposure from almond milk. And it may be that there was no data available.

DPR ASSISTANT DIRECTOR VERDER-CARLOS: Yes, Dr. Blanc. We -- unfortunately, we were not able to do that because that would require a longer period to ask our CDFA lab to come up with a method development to be able to analyze almond milk. And so in order to be able to do that, it would take longer, and we couldn't -- we wouldn't be able to, but we -- and so we were not able to get to that at this time.

PANEL MEMBER BLANC: But I also noticed that in that list of foods and exceedances of allowable residue concentrations, almonds were not included in that list. Is that because that's not -- leaving almond milk aside, since almond is a heavy use crop, as I understood it from your earlier presentations?

DR. DuTEAUX: Sure just to add what -- to what Dr. Verder-Carlos said, we have met with the CDFA

laboratory twice in the last four months talking specifically about method development. They are in the throes of hiring additional staff to be able to do al method development for pesticide -- pesticide evaluation. At this point, we don't have California specific data.

And to develop a method for the analytics in the laboratory, they're estimating about two years, and we didn't want to delay this process that long.

PANEL MEMBER BLANC: Well, I mean, I'd be willing to see what almond levels were like outside of California. Really was just a -- it was sort of a question as to you have this long list of foods, and litchi nuts and things. And I was just a little surprised that almond is a heavy use crop, not only here but elsewhere, wouldn't that have been something that someone would have looked at somewhere? I mean, like the Federal FDA.

DR. DuTEAUX: So we -- there was a table we were going to show you, we can bring up, as a supplemental data, if you'd like, later in the discussion about the dietary. Almond hulls is -- has one of the highest tolerances established by EPA at 12 parts per million. Almond hulls tend to go into cattle and sheep feed. So it might increase the burden of what shows up in meat products and by-products.

But my understanding, and we can talk about this

a little bit more when we get into the dietary assessment, is that they're very limited consumption data for almond milk as a commodity to base any of our information on.

So therefore developing a method that's actually targeted towards that commodity and also California's specific would help us gather those data, but we don't feel as a department we want to delay this process of TAC evaluation and determination for an additional two years.

PANEL MEMBER GLANTZ: Well, could a reasonable way to deal with this issue be to just basically put this information in the report to say that, you know, this -- that almonds are -- have a user of chlorpyrifos, and -- but -- and, you know, would -- you know, could reasonably be expected to be one mode of dietary exposure, but there's no data available or laboratory methods. That way at least it's in the report and acknowledged, but it wouldn't holdup finishing the document. Does that seem okay?

DR. DuTEAUX: We can absolutely do that or we can.

PANEL MEMBER GLANTZ: Is that okay with you, Paul? Do you see that as a reasonable.

PANEL MEMBER BLANC: Yeah, it's always important to be transparent about what you've been thinking about.

PANEL MEMBER GLANTZ: Okay.

DR. DuTEAUX: Sure. We'll note that in the final report.

Any other questions before I go into the actual evaluation of chlorpyrifos?

PANEL MEMBER BLANC: Well, I'll make one other comment just as a reader. I'm sensitive to your comments about the potential massive bulk of the report. But as one reads it, because when -- specifically in terms of the neurodevelopmental issues, and for both the animal experimentation, which is more relevant, and then the supportive epidemiologic data. So you've reviewed in detail all of the newer studies that were not included in the previous draft or were dealt with briefly. But as I understand it reading it, there are other neurodevelopmental studies that were sufficiently summarized in the previous draft that they don't reappear here. Is that -- did I understand that --

DR. DuTEAUX: That's correct. The addendum is only new data or deeper analysis of existing data.

PANEL MEMBER BLANC: Right. So it does make it difficult. This is a challenge to be aware of. It makes it rather difficult to assess the assessment of the body of the literature that then leads to the endpoint determination of the effect and your model points of departure and all of that.

So I'm just putting it out there that because the data are in two separate places, I'm assuming that anything that you use to derive -- any studies that you used to derive your final risk assessments are dealt with in what is currently called the -- the -- this -- this what is called an addendum. Because you do get into a problem where the tail is wagging the dog.

DR. DuTEAUX: So to answer your question -- and I know that you've been traveling and so you might not have had a chance to read the document, but the actual studies that we base the point of departure for chlorpyrifos using a developmental neurotoxicity endpoint are in the addendum.

PANEL MEMBER BLANC: Right. I just wanted to make sure that -- but the studies that you're trying to use for your secondary thing are at the previous study, right?

DR. DuTEAUX: So for cholinesterase --

PANEL MEMBER BLANC: Yeah.

DR. DuTEAUX: -- inhibition, everything remains in the previous draft.

PANEL MEMBER BLANC: Right. So I'm just pointing out.

DR. DuTEAUX: Right, and so -- so this addendum is specifically focused on developmental neurotoxicity

endpoints in animals.

PANEL MEMBER BLANC: Right. Right. What will -- what will then flow out of that and will be important as our discussion continues so to make clear what, in fact, the actual risk assessment is based on?

PANEL MEMBER GLANTZ: Well, in fact, I mean, I've had a little bit of a concern about that same thing. I understand why you didn't want to produce a 600-page document. But the way I -- the way I -- I actually now think of the addendum as the primary document. And the original draft is really an addendum to that document. And I think -- I think there is -- for people who haven't been obsessing about this, this could be a point of confusion.

So my suggestion for dealing with the issue that Paul raised is I think the addendum should become the primary document, because we're now saying that the developmental neurotoxicity is the primary endpoint, and then have the other report as -- it's just changing the cover page -- present that as an addendum to this document. Because, you know, I mean, I've had a couple discussions with these guys about the executive summary and the conclusions that we'll get to.

And I think those are the key, you know, for people who only read the executive summary and the

conclusions, which is 99 percent of the world, those to me are the important things. And I think the way to deal with that, without making a lot of additional work and dragging this process on, would be to just take the document we're taking about today as the primary document. But we don't want to throw out all that other work. I mean, all the other stuff is important too.

DPR ASSISTANT DIRECTOR VERDER-CARLOS: Thank you, Dr. Glantz. What I was just thinking was to make the other document an appendix at the -- for the final one, so refer to it as a draft for 2017 and put it in the appendix, so the whole document will be --

PANEL MEMBER GLANTZ: Yeah, I think that would be fine too. I

DPR ASSISTANT DIRECTOR VERDER-CARLOS: Yeah, so then the whole document will be long, but it will at least have the -- both documents will be in one place.

PANEL MEMBER GLANTZ: I mean, I think -- I think you need material in the other document to tell the whole story, but I think we want to really keep the focus on what's in the -- in the document we're talking about today. But I think that would be a fine solution, and that would require just a very minimal amount of editing in the other document. And none of the editing would be substantive, yeah. That would be fine with me.

PANEL MEMBER ARAUJO: So what -- I appreciate the entire new section that you devoted on the additional effects on -- or additional human effects. And you certainly include some of the studies on obesity. You title that section chlorpyrifos effects on obesity. However, you're mentioning several other studies that are more in relation to effects on lipoproteins, and metabolic effects, and diabetes.

So I wonder if -- if in -- it could be better titled "Chlorpyrifos Effects on Metabolism", or "On Metabolism and Obesity", if you still want obesity in the title.

All the studies that are mentioned here are all human. There is also animal work in there that supports staff. And you previously made up very exhaustive presentation of all the human studies and animal studies, and that support the neurotoxicity outcomes. And it makes sense, because those are the main outcomes that we know. But for comprehensiveness, maybe you could add just like one paragraph where it mentions also there are additional -- there are also animal studies that support these additional effects.

And if you do that, so you could title like the whole section instead of, "Additional Human Effects", I don't know, you could say, "Additional Health Effects of

Chlorpyrifos", and that way so you -- you may include in the same section both human as well as the animal studies.

DR. DuTEAUX: May I -- may I respond to that request --

PANEL MEMBER ARAUJO: Sure.

DR. DuTEAUX: -- just briefly?

So it was just our understanding from going through the transcripts of the January and March meeting that the request was specifically on human effects, but we've developed an entire, oh, my gosh, treatise on animal effects of obesity, metabolic changes, and the like, which was probably 30 to 40 pages long. I want to say 30 to 40 pages long. It was an extensive overview of the animal date, and we can add that in as the section. We just went back through the transcript as our guiding philosophy for what to add to the addendum, and we'd understood it was human data that you wanted, but we can add in all the animal data.

PANEL MEMBER ARAUJO: Yeah. Well, I don't know if -- I -- yeah, I think that both would have value --

DR. DuTEAUX: Okay

PANEL MEMBER ARAUJO: -- of being included. I don't know if there was any specific interest on just including the human data, but I think that both the human

and the animal data would be --

DR. DuTEAUX: Right. We can either add it as an appendix or we can add it to the body of the document.

PANEL MEMBER ARAUJO: Sure.

PANEL MEMBER GLANTZ: Yeah, I think -- I mean, I'm -- we're really -- in the interest of getting the thing done though --

DR. DuTEAUX: Well, it's already written. It's already written.

PANEL MEMBER GLANTZ: Okay.

DR. DuTEAUX: We just didn't put it in, because it -- we thought --

PANEL MEMBER GLANTZ: Okay. But it's not going to change the substance of any of the risk numbers or anything?

DR. DuTEAUX: No. No, absolutely not.

PANEL MEMBER GLANTZ: Okay. Well, that's fine then. Then adding it in is fine.

PANEL MEMBER ARAUJO: It's more like for comprehensive -- comprehensiveness. So these other effects and -- are at least mentioned. And who knows if in the future they end up being even more important than the --

PANEL MEMBER GLANTZ: Yeah. No, I'm not objecting to putting it in. I'm just trying to finish.

DR. DuTEAUX: Right. Understood.

PANEL MEMBER GLANTZ: And if you guys are Happy to put it in and it's going to materially effect, the hazard identification of the risk --

DR. DuTEAUX: We were quite prolific from the last two and a half months.

PANEL MEMBER GLANTZ: Okay.

(Laughter.)

DR. DuTEAUX: My staff is laughing. They were quite prolific.

PANEL MEMBER GLANTZ: Yes, I agree with that, by the way. I think that the amount of work reflected in this new document for the time it took was quite impressive, I think.

DR. DuTEAUX: Thank you.

Any other questions about the additional data before we move on and do a deeper dive?

Okay.

--o0o--

DR. DuTEAUX: Hearing none. Let's move on to the evaluation of chlorpyrifos as a toxic air contaminant, and the data that we're evaluated in this addendum. So this addendum, which will then be renamed, presents a comprehensive analysis of all the currently available data to establish a point of departure directly on

developmental neurotoxicity. We also added new data and reanalysis as requested. And we've also updated appendix three to provide the revised acetylcholinesterase inhibition, margins of exposures, because we had some changes in the model outputs, as well as adding the additional 3X uncertainty factor. So all of that is in addendum -- appendix number three.

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DR. DuTEAUX: But moving on to how we went through the animal data to come up with the point of departure and the margins of exposure. We want to start first with a description of the hazard identification.

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DR. DuTEAUX: And for this, we thought it would be helpful again to go over the definition of a point of departure. So using a modified definition from IRIS, a point of departure is the dose response point that marks the beginning of a low dose extrapolation. It can be a lower bound on a dose for an estimated incidence or a change in response level from a dose response model, such as a BMD, benchmark dose, or a no observed effect level or low observe -- lowest observed effect level for an observed incidence, or a change in level of response. So it basically is that point or that dose at which these changes start to occur.

The critical point of departure established from in vivo animal data reporting developmental neurotoxicity, or DNT - you'll see that acronym throughout the slide slow - DNT effects at dose levels lower than those that inhibit acetylcholinesterase. So those were the data we focused on.

The in vivo animal data that report DNT effects at dose levels lower than those that inhibit acetylcholinesterase. The acronym we use is AChE.

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DR. DuTEAUX: So a brief overview of the studies that we used specifically to derive this point of departure. There are five recently published studies reporting developmental toxicity in rodents. Four studies were conducted in rats and one in mice. All of them used oral exposure. This is important when we get to the exposure analysis. Three were by gavage, meaning that the animals were fed by a tube and the chlorpyrifos in a solution or pure was directly administered into the stomach. Two of the studies used chlorpyrifos-infused diet food or rat chow.

The studies were not available -- there were no studies available to establish either dermal or inhalation points of departure, meaning that there were no data that we could unearth that showed any animal studies using skin

exposure or inhalation exposure only, and that showed developmental neurotoxicity effects.

Two of these animal studies employed both gestation and lactational exposure, meaning that the pregnant dams were exposed during gestation, and that their exposure was continued through lactation, so the pups were exposed both in utero and through milk.

Two of the studies employed direct pup exposure, either for one or seven days starting at postnatal day, or PND, 10 meaning that the mothers were not exposed, but the pups were exposed to chlorpyrifos starting at postnatal day 10. And they were either exposed for one day or a series of seven days.

And the neurodevelopmental responses in offspring were tested in either young pups at postnatal day 21 to 25, or in adults at age 60 to 90 days. So just by this simple slide, you can tell that even though we're only looking at five studies, the approach in each one was different.

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DR. DuTEAUX: Three of the studies reported increased motor or total activity. Two of the studies showed altered anxiety levels, one showing an increase and one showing a decrease. And one study detected impaired spatial learning. So not only are the study methodologies

on the first slide different, but the measurement of developmental neurotoxicity in the studies were also different from each other. So it was impossible to do study-to-study comparison.

In four of the studies, the lowest observed effect level was the lowest tested dose, meaning that at the lowest dose either 0.1 or 0.5 mg per kg per day of chlorpyrifos, they still saw effects.

And when we have studies like that, we apply an uncertainty factor of 10 to those lowest observed effect levels, which results in an estimated no effect level, or ENEL, for developmental neurotoxicity of the range of 0.1 to 0.5 milligrams per kilogram per day. So because we had in four studies just a LOEL, to get a NOEL, we divide that dose by a factor of 10.

In one of the studies of five, they actually did note a no observed effect level, a NOEL, based on increased anxiety and motor activity in rats that were exposed in utero for six days. And that study is Silva et al., in 2017.

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DR. DuTEAUX: One -- only one study concurrently measured acetylcholinesterase activity, and that -- for particular study which was Carr et al., 2017, the LOEL for brain acetylcholinesterase inhibition was one milligram

per kilogram per day, which again underscores the fact that we're looking at developmental neurotoxicity effects that occur below acetylcholinesterase inhibition.

So in response to one of our sister scientific agencies, we went back and looked at the registrant-submitted FIFRA guideline study, which is Hoberman 1998. In that study, the rodents were exposed gestationally and lactationally. The red blood cell acetylcholinesterase was the most sensitive endpoint in this study with a BMDL 10 to BMDL -- sorry to BMD 10 ratio of 0.03 or 0.06 milligrams per kilogram per day.

So human health assessment branch set the developmental null of this study at one milligram per kilogram per day for brain morphometric changes, which was what we were asked to look at in postnatal day 66 to 71 day old females.

And this LOEL for the brain morphometric changes was 10-fold higher than the LOEL for developmental neurotoxicity effects reported in the published studies, again, underscoring the fact that the changes we were looking at for developmental neurotoxicity were occurring at lower levels.

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DR. DuTEAUX: This chart, although a little difficult to read, is also found in your document. It's

Table 11, if you'd like to look at it in your addendum. This is just the summary of those studies with the LOELs and NOELs for cholinesterase inhibition and the LOELs and NOELs, if measured, for developmental neurotoxicity. So again, this is just simply a summary of everything that I just went through with the dose -- the dosing type, the ages, or the period of time where the animals were dosed, the dosing ranges, which is all found on the left-hand column, the time that they were tested, and whether effects were measured and a description of those effects.

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DR. DuTEAUX: Through all of this in comparing those five studies to reach other, the NOEL of 0.01 milligrams per kilogram per day, based on Silva et al. in 2017 was set for increased anxiety and motor activity in the rat pups. This level of 0.01 milligrams per kilogram per day was supported by applying that 10-fold uncertainty factor to the LOEL values in the other four studies, as I mentioned earlier.

The exposure duration in the five studies varied from one day to 35 days. Therefore, the NOEL that we've chosen of 0.01 mg per kg per day could be applicable to both acute and repeated exposures.

Therefore, the acute oral point of departure of 0.01 milligrams per kilogram per day was used to evaluate

both acute dermal and inhalation exposures using route-to-route extrapolation, so that we could develop our margins of exposure, again because we had no dermal or inhalation data from any animal studies.

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DR. DuTEAUX: So now I'd like to move to an overview of our exposure assessment. And because --

PANEL MEMBER BLANC: Can I just ask a question --

DR. DuTEAUX: Sure.

PANEL MEMBER BLANC: -- a clarification on the table?

I think I understand. If -- it's not that if you used one of these other studies with the similar LOEL, the NOEL would come out to be also the same, it's just that you -- the ones that's in red are the ones that you used, as an example?

DR. DuTEAUX: The type in red is just to indicate it's a -- whether a NOEL was measured or not. That's the only indication. And in the -- in the slide handouts, we don't have the footnotes. But in Table 11 in the document, you'll see it noted that red type indicates whether or NOEL was measured or not -- whether it's -- sorry, whether the --

PANEL MEMBER BLANC: NOEL was calculated.

DR. DuTEAUX: -- dose level was measured.

PANEL MEMBER BLANC: So it's actually measured in Silva, it's not that it's divided by 10?

DR. DuTEAUX: Right. Right. So the actually -- the authors actually denoted 0.01 milligrams per kilogram per day as NOEL.

PANEL MEMBER BLANC: I've got you now. Right. But on the other -- so it's reinforcing, because if you simply used the LOELs that you have from the other studies, you come out with the same --

DR. DuTEAUX: Right. Divide it by 10, you come out to the same number.

PANEL MEMBER BLANC: Right. Okay. So it reinforces it.

DR. DuTEAUX: Right. Right.

PANEL MEMBER BLANC: Okay. Thanks. That's very helpful.

DR. DuTEAUX: Right. Did you have anything else?

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DR. DuTEAUX: Okay. Any other questions before we move on to the exposure assessment?

Okay. So to be clear, and this came up in some conversations with individual SRP members who wanted to make it very clear that the exposure assessment was comprised of two independent parts that were then combined together when we were looking at the margins of exposure.

The first was bystander exposure to spray drift from chlorpyrifos applications, either aerial, ground boom, or air blast. So that was one exposure assessment.

The second exposure assessment was dietary exposure to food and drinking water.

So we're going to go through the bystander exposure first and then the dietary exposure show, and then show how they're combined.

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DR. DuTEAUX: So for bystander drift exposure assessment, we were calculating exposure estimates from direct inhalation exposure from airborne chlorpyrifos resulting from pesticide applications. They were one-hour exposures and these were modeled air concentrations, not direct measurements. And I'll -- I'll explain a little bit more about that briefly.

The incidental oral exposure was also estimated. And incidental oral exposure includes all non-dietary ingestion of soil, or dirt, or other things from contaminated surfaces by hand-to-mouth, hand-to-object contact. So this is from chlorpyrifos that has been deposited from spray drift on areas close to treated field. As I said, contaminated surfaces or soil that somehow gets ingested.

And because we're of the age groups we were

looking for for the exposure assessment in the document as a whole, this is an important route of exposure.

We also looked at dermal exposures through skin contact with again contaminated soil and surfaces, estimating a 1.5 hour exposure. And then we combine all of those three, the direct inhalation from estimated air concentrations, incidental oral exposure, and dermal exposure to come up with the combined spray drift exposure.

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PANEL MEMBER GLANTZ: So I just have one questions. So you used the half a mile as your boundary for the bystanders. I don't know if you're --

DR. DuTEAUX: Actually, we modeled every distance from 25 feet in increments out to a quarter -- it's a quarter mile 2,608. Half a mile.

PANEL MEMBER GLANTZ: Yeah, half a mile.

DR. DuTEAUX: Right. So there -- there were increments.

PANEL MEMBER GLANTZ: Yeah. So you -- I was just curious, because you did still find exposures at a half a mile, why did you pick a half a mile since you were --

DR. DuTEAUX: That's the limit of air model.

PANEL MEMBER GLANTZ: Oh. Okay.

DR. DuTEAUX: Right. That's the -- that's the

limit of its ability to calculate these with the -- a better signal-to-noise ratio.

PANEL MEMBER GLANTZ: Okay. So I think just to clarity that, again I don't think this is something to hold the document up over. But I think just putting a statement in there of what you just told me that, you know, the reason you -- that it ended at a half a mile is that was the limit of your model, but that the -- the fact that you were still detecting substantial exposures at a half a mile, you know, indicates that the people beyond a half a mile are actually getting exposed, because -- you know, alternatively, if you'd gone out to a half a mile and come up with negligible levels, then that would have, you know, meant something different.

So I don't think you need to -- you know, this is not a fatal problem with the report. But I just think -- especially since I worried about that and I noticed it came up in one of the public comments, just clarifying that will just be useful. And again, I think that -- I don't think that changes the report, but I think it would just make it, you know -- it's a matter of transparency and making sure that subsequently someone doesn't misrepresent -- not you guys, but somebody else misrepresent the finding that you don't have to worry after a half mile.

DR. DuTEAUX: We will definitely add a statement to that effect. Any other comments before we move on to the next item?

CHAIRPERSON KLEINMAN: Just for clarification, the drift equations do not take into account evaporation and vapor phase exposures, right? I think that was dealt with in the original document.

DR. DuTEAUX: Right, in the original document. We do have a small section about the spray drift re-volatilization. And I can talk to that in a little bit. I think we have a table coming up about that.

But you're right, the bottom many, and we can talk about this later in the presentation, is that regardless of what additional things we add in going out further distances or adding re-volatilization in, chlorpyrifos still meets the definition of a toxic air contaminant, either with a developmental neurotoxicity endpoint or a acetylcholinesterase inhibition endpoint. So the definition is met.

Okay. So we modeled for -- again, this is strictly for bystander drift. We modeled distances of 25 feet to 600 -- 2,608 feet from the edge of a treated field. We used the most common and reasonable worst case scenarios for application rates and volumes. We used aerial application, either fixed wing or rotary, because

the -- they are the worst case scenarios.

But because chlorpyrifos is also used through air -- orchard air blast and ground boom, to be as conservative as we could, we modeled those applications as having the same air drift as the aerial application, which in reality they typically don't.

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DR. DuTEAUX: We assessed four age groups, infant children one to two years old, children 6 to 12 years old, and females of child bearing ages, 13 to 49.

We estimated absorbed doses for inhalation and dermal routes for our margin of exposure calculations. For inhalation, we assumed 100 percent external availability, meaning that in the spray drift cloud, the air concentration was 100 percent available. We also assumed 100 percent absorption at the target site, both of which are very conservative as you could estimate. A Hundred percent absorption means that we did not count any metabolism of chlorpyrifos as it -- or as it entered the body, meaning there was no detoxification that we allowed for in this model, 100 percent absorption at the target site.

For dermal, we assumed a 9.6 absorption. And this was developed in a memo approximately 1991 in DPR specifically for chlorpyrifos. And so we used that

number. That is up from the dermal absorption level that we used in for acetylcholinesterase inhibition, which was approximately three percent, is that right, Eric?

DR. KWOK: Yeah, the -- for our --

DR. DuTEAUX: In the model.

DR. KWOK: In the model, we don't need the dermal absorption, because the PBPK model already using the permeability coefficient to account for the dermal absorption. So but because now we are using the animal study, so then we need to have dermal absorption factor to -- for use in calculating the internal dose. And the 9.6 percent actually, as Dr. DuTeaux mentioned, it was a determination at DPR by a staff toxicologist when he reviewed all the available human study and come up with a number.

DR. DuTEAUX: Thank you.

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DR. DuTEAUX: Okay. So that was the est -- how we modeled the exposure assessment for spray drift.

Moving on to how we assess dietary exposure. Again, we looked at the same four age groups. For food, we were looking both at acute and steady state analyses. We looked at all foods with -- where chlorpyrifos is legally registered to be used on it. So all crop groups, all food types, and that includes 79 individual U.S. EPA

tolerances, and three crop group tolerances.

The residues were based on the USDA Pesticide Data Program monitoring database. And consumption was based on a 2003 through '08 NHANES data.

The drinking water was based on DPR measured residues in surface water in California. So not necessarily drinking water, but surface water.

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DR. DuTEAUX: So this is how we combined the exposure for one day. We take the spray drift exposure for dermal, non-dairy -- dietary oral and inhalation. We combine it with the dietary exposure from food and drinking water, and we come up with a spray drift and dietary combined exposure estimate.

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DR. DuTEAUX: These are the margins of exposure -- from exposure to chlorpyrifos for children one to two year old, as an example. The margin of exposure using a developmental neurotoxicity endpoint is 100. So if you look at the distances downwind from an application site, which is in the left-hand column, from 25 feet to 2,608 feet, you'll see specifically for spray drift what I talked about. Our exposure estimates -- sorry, the margins of exposure for dermal exposure, incidental oral, exposure, and inhalation, and then combined. Then you'll

see two columns showing the dietary exposure and MOEs, one for food, and one for drinking water. And then the combined spray drift and dietary margins of exposures at the far right.

Please note that the spray drift values for all exposure routes and combined routes vary from the distance downwind from an application, as you would expect, because it's based on deposition and air concentration.

However, dietary analysis of food in drinking water is completely independent of the distances, but we wanted to show those values in the same table. That dietary assessment is based on what people consume on an average one day basis.

As Dr. Glantz was pointing out, there are distances where the MO -- where the exposures are above the level of the MOE, indicating less of health risk. And those values for dermal, incidental, oral inhalation and combined for this particular age group, one to two year olds, is acceptable or above the margin of exposure of 100 at that half mile distance.

However, the important thing here is that no level of spray drift exposure combined with dietary exposure is above the margin of exposure. So all of the combined values, when you look at what people eat and drink, along with if they're potentially exposed to

inhalation or deposition, is below the MOE, and therefore, indicating a potential health concern.

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PANEL MEMBER ANASTASIO: Sorry, Shelley, can I interrupt for a second?

DR. DuTEAUX: Sure.

PANEL MEMBER ANASTASIO: So I don't remember this from the last version that food and drink were so important. Has that changed or am I mis-remembering here?

DR. DuTEAUX: You are spot on. It's because the endpoint of developmental neurotoxicity drives the margins of exposure. This was different for acetylcholinesterase endpoint. These are specific to using a developmental neurotoxicity endpoint.

PANEL MEMBER ANASTASIO: I see. And the water exposure, you say that's from surface water measurements. Is that specifically in agricultural areas where you expect a lot of chlorpyrifos application or is this more statewide average?

DR. DuTEAUX: It's where -- this is where -- this is a statewide average. So DPR measures surface water and it could vary from actual rivers that are drinking water sources to irrigation canals. And this is a combined value for chlorpyrifos for surface water in California.

If we looked at drinking water specifically, we

are actually in the process of developing a method to look at combined data sources and mapping that. We're not at that point yet, but we're going to be working on it for another -- another pesticide. So this is a very conservative estimate, because the ex- -- the concentrations can be high.

PANEL MEMBER ANASTASIO: And you use some kind of weighted average concentration or how do you come up with a --

DR. DuTEAUX: For the surface water monitoring program?

PANEL MEMBER ANASTASIO: For the water. Right, for the water concentration.

DR. DuTEAUX: Eric, do you happen to know that answer or should we get back with Ann.

DR. KOSHLUKOVA: So there were -- my recollection, there were over 2,000 residues that were measured within, I believe, five-year period. And there were detected residues. Some were very high. We could not verify that their -- those detections would become potable water, but we used them in a probabilistic analysis. And the exposure that was calculated was at the 99.9 percentile.

PANEL MEMBER ANASTASIO: I see. So this is kind of an upper limit of what you'd expect from water.

DR. DuTEAUX: Right, what you'd expect from surface water.

PANEL MEMBER ANASTASIO: Right.

DR. DuTEAUX: I'd have to say not completely all potable water.

PANEL MEMBER ANASTASIO: Right. Okay. Thank you.

DR. DuTEAUX: So again, a very conservative estimate, 99th percentile, and, you know, high concentrations.

PANEL MEMBER ANASTASIO: Right.

PANEL MEMBER BLANC: So I have a comment on the word "driving", because I know you used it in your oral comments, and it appeared in the text as well that the dietary is driving the --

DR. DuTEAUX: The risk.

PANEL MEMBER BLANC: -- the risk.

DR. DuTEAUX: Right.

PANEL MEMBER BLANC: And I probably would avoid that term, because it suggests that if there were no dietary, and there were only spray drift, there wouldn't be any risk. But actually what your data show is that you'd have to get out to a half a mile to fall -- to go above 100, if you see what I mean.

So I would -- I understand -- having seen and

heard the presentation, I understand better what you mean by drive. But I probably wouldn't use that word, even though it may cause you to use a more complex sentence.

DR. DuTEAUX: Okay. We'll take that under suggestion. Thank you.

PANEL MEMBER BLANC: Because I actually objected to it when I read it in the document, because it puts a spin on it.

PANEL MEMBER GLANTZ: So what -- yeah, so what language would you --

PANEL MEMBER BLANC: Well, consistent with what some of your other comments. I think what you could say is that at half a mile or more, the data suggests that spray drift alone would not achieve -- would not reach the 100 threshold, but anything -- but certainly at closer than that, it would. And that as -- and in contrast, the dietary is independent of distance -- I mean, is not driven by distance as spray drift. And therefore, it meets the threshold on its own.

Because, you know, you could say it's spin or it's cup half empty or half full, but the implication that could be misread into the use of the term "drives" the risk could be easily misinterpreted. That's not your intention is that spray drift is not consequential.

DR. DuTEAUX: I see what you're saying. However,

everyone in California eats and drinks, so how do we get away from saying that dietary for developmental neurotoxicity endpoint is the most important thing?

PANEL MEMBER GLANTZ: I think that -- if you just say that, I think that would be --

DR. DuTEAUX: Well, we try to stay away from --

PANEL MEMBER BLANC: Editorializing.

DR. DuTEAUX: Exactly, editorializing. We try to --

PANEL MEMBER BLANC: But I -- and I'm just trying to say that "drives" is also editorializing. I would just say explicitly that --

PANEL MEMBER GLANTZ: Well, he's what I -- can I make a suggestion? Because, you know, why don't -- I understand the point that Paul is making. And, you know, I think in writing a document like this, you need to be really careful to make sure you don't use language that somebody could take out of context. But why don't we let -- I think -- I don't think there's controversy about the need to be precise here. So maybe why don't we go on and maybe you could think about it, and maybe when we take a break, work -- talk to them and come up with a slightly rewording that would avoid the problem.

I don't think people are -- I don't think we're having a substantive discussion here. But I do -- I do

understand the point Paul is trying to make. I think -- but I think writing a -- you know, editing by committee is always a drag. So maybe when we take a break, you can get together and come up with a little -- a slightly different wording.

CHAIRPERSON KLEINMAN: Also, we do need to keep our focus on the fact that we are trying to determine whether it's a toxic air contaminant, and that's what's next, so why don't we do that.

DR. DuTEAUX: Thank you. Thank you.

(Laughter.)

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DR. DuTEAUX: Okay. So the criteria for listing pesticides as toxic air contaminants is very specific in the California Code of Regulation, Title 3, section 6864, meaning that for non-cancer effects, the threshold level is ten times below the air concentration, which has been determined by our Director to be protected -- protective of human health.

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DR. DuTEAUX: So for chlorpyrifos, specifically evaluating as a toxic air contaminant with a TAC being defined as air concentrations modeled or monitored that exceed the reference concentration divided by 10. Chlorpyrifos will meet the criteria of listing as a TAC to

protect against developmental neurotoxicity through both endpoints, developmental neurotoxicity specifically and acetylcholinesterase inhibition.

If we look at specifically for the developmental neurotoxicity reference concentration for children one to two years old, the TAC it will -- chlorpyrifos will be a TAC if the air concentration is greater than or equal to 0.0005 milligrams per meter cubed, or 500 nanograms per meter cubed in concentration.

So the RfC for children was 0.05 -- 0.005, so you can see that we've divided that by 10 to come up to determine the -- to do the TAC determination. If, instead, we use acetylcholinesterase, which was in the other document, the air concentration is greater than 0.000 -- 0.00095 milligrams per meter cubed, or 950 nanograms per meter cubed. And that's using the reference concentration in the other document for children ages one to two year old of 0.0095 milligrams per meter cubed.

Actually, I correct myself, that number is not in the Previous document, because that is the additional uncertainty factor of 3 -- a total uncertainty factor of 300, which you'll find in appendix 3 of this document. So by either way, chlorpyrifos meets the criteria of being a toxic air contaminant.

CHAIRPERSON KLEINMAN: Shelley, this pre-supposes

that the concentration that we're talking about is in a place where children are logically concluded to be exposed, you know, because you could say, you know, go out over the ocean and you're not going to find any.

(Laughter.)

CHAIRPERSON KLEINMAN: So, you know, is it with -- what is the spatial parameter? Where is -- is monitored where or does that have to be specified?

DR. DuTEAUX: If we find it at all.

DPR ASSISTANT DIRECTOR VERDER-CARLOS: ARB -- Air Resources Board is actually -- monitors chlorpyrifos for DPR. And also, we have an air monitoring network, so we do have monitoring results for chlorpyrifos in 2011 for DPR, and for ARB since -- for a long time now. So ARB monitors chlorpyrifos as well.

So these levels will then be compared to what the air monitoring network would have results for.

CHAIRPERSON KLEINMAN: But the air monitoring networks are located --

DPR ASSISTANT DIRECTOR VERDER-CARLOS: In California.

CHAIRPERSON KLEINMAN: -- in California, but also --

DPR ASSISTANT DIRECTOR VERDER-CARLOS: In high use.

CHAIRPERSON KLEINMAN: -- in areas where you'd expect to see --

DPR ASSISTANT DIRECTOR VERDER-CARLOS: Yes.

CHAIRPERSON KLEINMAN: -- chlorpyrifos. So I guess it would be -- you know, some specification of where --

ASSISTANT DIRECTOR VERDER-CARLOS: Where to compare it to?

CHAIRPERSON KLEINMAN: You know, in other -- what's the comparison locations or something. It may be in the original report, where, you know --

DPR ASSISTANT DIRECTOR VERDER-CARLOS: The air monitoring net -- you mean, the air monitoring network results.

CHAIRPERSON KLEINMAN: But I think, you know, to just put in a blanket number that it can't be less than this anywhere ever is -- you know, is somewhat unrealistic. Whereas, if we have, you know, within, you know -- you know, some guidelines for where monitoring is. Now, maybe that's the risk management side of things, in which case, we might -- you know, as a Committee, we might want to, you know, put in a recommendation that monitoring is, you know, in locations where bystanders are likely to be exposed.

DPR ASSISTANT DIRECTOR VERDER-CARLOS: So are -- ARB monitors application site -- monitoring applications sites as well, but our air monitoring network is bystander monitors. So it is located in high-use areas, but strategically downwind or -- downwind from pesticide applications. So we have a whole air monitoring network that we've been doing since 2011, actually in -- last year, we expanded that network as well to eight monitoring. So we can put something in here saying that we have an air monitoring network, I believe, or just to --

CHAIRPERSON KLEINMAN: The reason I bring this up is I think in one of the public comments there was a question about the likelihood of anybody being exposed. And I would like to, you know, make sure that -- because they use some very specious probability analysis that, you know, came up to ridiculous numbers. And I think if we have something concrete, it could be helpful.

DPR ASSISTANT DIRECTOR VERDER-CARLOS: Okay.

PANEL MEMBER ANASTASIO: I'd like to say one thing, really just to reiterate what Shelley said is that these two approaches yield very similar numbers, right, within a factor of two. So I'm very encouraged by the fact that the DNT endpoint and the acetylcholinesterase inhibition endpoint with a slightly higher uncertainty

factor are really close.So I think that's a good vote of confidence in terms of where we are on what the inhalation concentration should be.

--o0o--

DR. DuTEAUX: So as I mentioned, a TAC determination -- meeting the TAC criteria can be done by either modeled or monitored data. In this addendum, we specifically modeled spray drift air concentrations. And the one-hour time-weighted average concentrations that we came up with, using the scenario of a child one to three -- one to two years old with application by a fixed wing aircraft with two gallons per acre spray volume and a two pound per application rate comes up with these various air concentrations starting from 25 feet downwind all the way out to 2,608 feet downwind.

It's important to note that our modeled air concentration using the developmental neurotoxicity endpoint are all above the TAC value of 0.0005 milligrams per meter cubed. So all of our modeled air concentrations exceed the reference con -- the TAC reference concentration.

--o0o--

DR. DuTEAUX: So we used that conservative approach of using the modeled air concentration. But just to compare -- and I apologize for the quality of this.

This came from a 2016 DPR memo -- these are the measured air concentrations from the air monitoring network. And this shows points from Salinas, Shafter, and Ripon. And these are shown in nanograms per meter cubed and the value -- the only value on this table that exceeded the TAC concentration was a maximum value collected in Shafter in 2013.

So if we used the modeled, if we used the monitored air concentrations, our evaluation for exposure risk would have been different. We were much more conservative with the modeled air concentrations. So I just wanted to show this in comparison.

So any questions on the exposure analysis before we move on to the risk characterization?

CHAIRPERSON KLEINMAN: Shelley, just to make the -- you know, make it easier for people to make the comparison, would it be possible to add another column to the modeled spray drift to put it in nanograms per cubic meter?

DR. DuTEAUX: Sure. We can do that. We can add the measured air concentrations as well.

CHAIRPERSON KLEINMAN: Yeah, because I think that really lights it up very nicely.

DR. DuTEAUX: Okay. And most of those data are found in table 18.

--o0o--

DR. DuTEAUX: Okay. Moving on to the risk characterization. So the way that we calculate risk is we define it as a threshold effects expressed as margin of exposure. And a margin of exposure roughly is the ration of the critical NOEL, or point of departure, ratio to the estimated human exposure level.

The target margin of exposure, as I mentioned earlier, for developmental neurotoxicity effects is 100. And that is comprised of a 10-fold factor for interspecies sensitivity, and a 100-fold factor for intraspecies variability. The critical NOEL, as I remind you from the studies we looked at is 0.01 milligrams per kilogram per day.

--o0o--

DR. DuTEAUX: Because we had no inhalation or dermal data, we had to do a route-to-route extrapolation of the internal dose from a 0.01 milligram per kilogram per day dose -- internal dose to figure out what that means, as -- we kind back calculate -- back out to what it would have been as an air concentration or a skin concentration.

It's performed to convert these internal doses to external doses. But we have to start by having an external oral dose, and then an internal estimated dose.

There are a lot of assumptions that go into a route-to-route extrapolation. And to do so, we -- it's a very complicated process. And we're often forced to do so for pesticides, because we rarely have inhalation data except for the fumigants. The -- so we derived acute inhalation and dermal PoDs from an oral NOEL.

--o0o--

DR. DuTEAUX: And this is the table -- this is actually a copy of table 23 in the addendum. And it shows the critical NOELs used for our risk assessment, our point of dart departure. And as I mentioned earlier divide the point of departure by 100 to come up with a reference dose, depending on if it's oral, or dermal, or a reference concentration for inhalation. And these are the values that we look at for the evaluation of chlorpyrifos as a TAC.

For inhalation, you'll note that the infants are the age group that is the most sensitive age group here. And the reference concentration for acute inhalation for infants is 0.004 milligrams per meter cubed. However, both the dermal exposure, which we could only model for one age group and the inhalation exposure, which we could again only model for one age group is lower.

So although we aren't going to perhaps use the word "drive", you can see that acute oral exposure to

chlorpyrifos has a much lower reference dose when compared to the reference concentration for inhalation. That does not mean it's not a TAC. It definitely meets the definition of TAC. Although, oral exposure is of higher concern, I'll say that.

--o0o--

CHAIRPERSON KLEINMAN: Shelley, just a point. You know, the reference dose is different than the reference concentration. So, you know, just conflating the two numbers is not going to work.

DR. DuTEAUX: Yeah. You can't compare, because we had to do this route-to-route extrapolation. This --

CHAIRPERSON KLEINMAN: They're two different things you have to --

DR. DuTEAUX: -- this dose re-calculation.

(Video cut out.)

DR. DuTEAUX: When we combine spray drift exposure estimates at 2,600 feet from the edge of a field for dermal exposure, incidental oral exposure, and inhalation routes combined with the 99.9th percentile exposures for dietary and drinking water for chlorpyrifos, we find that -- actually, sorry, that's -- that's how we did the Margin of exposure.

At 2,600 feet from a field, those combined spray drift MOEs for all four sensitive populations were at or

greater than the target of 100 at that -- only at that measurement. And as Dr. Blanc pointed out, all measurements closer to the field than that, the MOEs were -- the numbers were below the target MOE 100. And we can make a clear statement about that in the document for you.

PANEL MEMBER BLANC: Yeah, that would be helpful.

DR. DuTEAUX: Thank you.

However, when dietary and drinking water exposures were added, the aggregate margin of exposure for these combined routes and sources of exposure were below the target of 100, indicating a health concern.

--o0o--

DR. DuTEAUX: And this is a partial table from the document as well. I don't remember the table number. It could be 27. So this shows the population subgroups, dietary only, drinking water only, combined spray drift and combined spray drift with diet in drinking water. Those numbers shaded in red indicate they're below the MOE of 100 at 2,600 feet. Those in white indicate the only ones that were acceptable.

However, again, you can't just separate spray drift exposure from people eating and drinking, because they have to eat and drink every day. So combined spray drift exposure with diet in drinking water, all the values

are below 100.

PANEL MEMBER BLANC: Can I ask a technical question? Would it be a lot of work to say as opposed to half a mile, what the distance is based on your model? And I know it -- it's obvious that at a quarter of a mile, you are below 100.

DR. DuTEAUX: Um-hmm.

PANEL MEMBER BLANC: But is it very difficult from your model -- it gives you continuous estimates, right, continuous doses?

DR. DuTEAUX: No, it doesn't. We actually have to put in the actual feet.

PANEL MEMBER GLANTZ: Well, I think the way to deal with this is to say that, is --

PANEL MEMBER BLANC: Yeah, I just -- it sounds like it's more --

PANEL MEMBER GLANTZ: No, it's to -- just to say that the -- that a half -- at a quarter mile --

PANEL MEMBER BLANC: You would be --

PANEL MEMBER GLANTZ: -- your over, you know, period. I mean --

DR. DuTEAUX: Okay.

PANEL MEMBER BLANC: Yeah, that's fine.

DR. DuTEAUX: Okay.

PANEL MEMBER GLANTZ: There's a theme here of

trying to get this finished.

DR. DuTEAUX: Okay. You mean, an 1/8th of a mile, a 1/4 of a mile? We've done that for our -- when we do mitigation efforts, we talk more in colloquial language like 1/4 mile, 1/2 mile. I don't think we talk about 1/8th of a mile, but we do talk about that.

PANEL MEMBER GLANTZ: Well, a quarter mile it would be over, so --

DR. DuTEAUX: Sure. Easy enough to add.

PANEL MEMBER GLANTZ: Yeah.

CHAIRPERSON KLEINMAN: You do have some of that data in the appendix.

DR. DuTEAUX: Yes. Yeah, appendix 2, which I think is your favorite appendix.

CHAIRPERSON KLEINMAN: Right.

(Laughter.)

PANEL MEMBER GLANTZ: But again, this is all points of clarification.

DR. DuTEAUX: Yes.

PANEL MEMBER GLANTZ: And making it harder for people to misrepresent what the document says, rather than any substantive scientific criticisms.

DR. DuTEAUX: Thank you for that. Okay.

--o0o--

DR. DuTEAUX: So these are some of our moving on

to things that aren't here, but that have come out of conversations with individual SRP members. These are some of the proposed additions or edits for the final document that we would like to give to you in a matter of weeks.

--o0o--

DR. DuTEAUX: So for the exposure -- along with the notes that I've written down here, these are additional things. For the exposure and the TAC determination discussion specifically, we want to clearly state how chlorpyrifos can meet the TAC criteria. And we'll either add it in the risk characterization, risk appraisal, or conclusion sections. And there's an option that we can reserve the TAC designation for acetylcholinesterase and put it in an appendix, if you think it's going to confuse it. But basically, by either endpoint, chlorpyrifos can be designated as a TAC.

(Thereupon a discussion occurred off the record.)

PANEL MEMBER BLANC: Now, straying into what could be a major point of -- in need of clarification, because of how the -- what we were distributed before we arrived how it reads. So I think if the -- I would suggest that you take the option or reserving your discussion for what it would look like if the TAC were not based on neurodevelopmental, rather based on acetylcholinesterase inhibition that you do relegate that

mostly to an appendix. And that everywhere where it says the first option is acetylcholinesterase inhibition. The second option would be neurodevelopment.

I think the first and the primary option is neurodevelopmental. And you can say were we to, instead of that, use acetylcholinesterase inhibition, and bearing in mind that we're now using a -- an added factor of 3, we would be less than an order of magnitude different. Although, we would be not quite as conservative.

DR. DuTEAUX: Um-hmm.

PANEL MEMBER BLANC: So I think everywhere in the document -- in the document that I've seen that has, you know, reversed the order --

PANEL MEMBER GLANTZ: Well, we've had -- I've had a couple of discussions with the DPR people. And if you look at the revised -- they hand it out --

PANEL MEMBER BLANC: Yeah, but I only got it, you know, right before.

PANEL MEMBER GLANTZ: Well, I know. I know. And I kept saying send it to us earlier. And they kept saying, like, we're doing it as fast as we can.

PANEL MEMBER BLANC: And it was hard for me to tell from the --

PANEL MEMBER GLANTZ: But I think -- I think what I would suggest in the interests of -- I mean, I agree

with you. I think they -- they have tried to do that. I have a couple of other tweaks to suggest later. But I think it would be good to read what they gave us, maybe come back to -- this is a very important point. But I think -- I think --

PANEL MEMBER BLANC: Also, to --

PANEL MEMBER GLANTZ: -- to take the time to --

PANEL MEMBER BLANC: Stan, let me, just say also because I did look at what you handed out at the start of the meeting, because I was very concerned about that table that had been in the executive summary, which has now been deleted. But if -- since you didn't pass out a modified version of the rest of it, I was kind of assuming that that table, nonetheless, which appeared twice in the document, stayed at the end.

PANEL MEMBER GLANTZ: No, it's out of the end too.

PANEL MEMBER BLANC: So it's just not there at all. Well, where is it at?

PANEL MEMBER GLANTZ: It's been moved -- it's been moved to an appendix.

PANEL MEMBER BLANC: Well, doesn't there have to be a table that shows what you're -- what you're --

DR. DuTEAUX: Sure. So table 23, which is the margins of exposure for developmental neurotoxicity, will

become that table. It will become -- we'll mention that in the executive summary. I don't think --

PANEL MEMBER GLANTZ: Yeah, I mean, the table -- I would just use the table from your slide 32.

DR. DuTEAUX: And then -- right, that's the same. That's the same table, just simple --

PANEL MEMBER GLANTZ: So that -- I think that table should appear --

DR. DuTEAUX: Right.

PANEL MEMBER GLANTZ: I think that table should appear in the executive summary and in the -- and in the conclusion --

DR. DuTEAUX: Right.

PANEL MEMBER GLANTZ: -- which is just the first three columns of the thing --

DR. DuTEAUX: Right.

PANEL MEMBER GLANTZ: -- they deleted, but --

DR. DuTEAUX: So if I may, I -- we actually -- I actually have my fourth point on the next slide talks about the handouts.

PANEL MEMBER GLANTZ: Okay.

DR. DuTEAUX: So I'm just going to go through these other additions really quickly.

We also were requested to clearly state how the inhalation RfC, using the developmental neurotoxicity

endpoint, meets the TAC criteria. However, consumption of food and drinking water and we'll strike the word "drive" and come up with some other language. Really, it's food and water for developmental neurotoxicity.

PANEL MEMBER GLANTZ: Maybe, you could use "paddle".

(Laughter.)

DR. DuTEAUX: Okay. Hammers. I don't know. We could use any other kind of verb we find appropriate.

--o0o--

DR. DuTEAUX: And then for the discussion of the developmental neurotoxicity in the endpoint, what we're going to do is move any comparison of the point of departure and reference concentrations or doses of developmental neurotox versus acetylcholinesterase to the front matter of appendix 3 and remove all -- all of -- so that it avoids confusion. However, we have to have that somewhere in appendix 3, because the number is different from the December 2017 draft, and we have to make note of that.

PANEL MEMBER BLANC: Right. No, good. Yeah, I understand that.

DR. DuTEAUX: So we'll have that as front matter for appendix 3.

PANEL MEMBER BLANC: Good.

DR. DuTEAUX: And probably have that table in there as well, and maybe the -- as we had in the previous executive summary, an introduction that comparison of this method or this method, we'll move all of that to the front matter of appendix 3.

PANEL MEMBER BLANC: Right. If you do that though, I would take out the columns that don't have the factor of 3.

DR. DuTEAUX: Okay.

PANEL MEMBER BLANC: That was also confusing.

DR. DuTEAUX: Okay. So, yeah, because the factor of 100 was just in the December 2017 draft.

PANEL MEMBER BLANC: Right.

DPR ASSISTANT DIRECTOR VERDER-CARLOS: But I think the reason why we put the one without the factor of 3 is because it's different from the other draft. It's 23 something.

DR. DuTEAUX: To tie the two documents together.

PANEL MEMBER BLANC: No, I know. I know. But I think for the purpose of -- the way you're describing it, I would just not have it in there. You can mention it in the text, but it's --

DR. DuTEAUX: We can do it in the text. Okay.

PANEL MEMBER BLANC: It makes it sound like you're -- you know, you haven't let go of it yet, so

that's fine.

DR. DuTEAUX: We'll just mention it in the text. But as in some of our independent phone conversations, it was just a matter of tying this document back to the other document --

PANEL MEMBER BLANC: Right. Right.

DR. DuTEAUX: -- because they're in succession. And then revising the executive summary and the conclusion to focus on developmental neurotoxicity and to say that this is a comprehensive analysis of all currently available data to establish the POD directly on developmental neurotoxicity and make that point clear.

And to that end, I'm going to pause these slides for a second. And do you want to bring up -- do you want to see the document? Okay. They have the document.

DPR ASSISTANT DIRECTOR VERDER-CARLOS: So you have the hard copy. We published it also online this morning, the excerpts from the revisions on the executive summary and the conclusion. And so it's available to the public this morning. And then we also have a hard copy. I think you have it.

PANEL MEMBER GLANTZ: So could I suggest maybe, because it is hard to read this and think about it in the middle of the meeting.

DR. DuTEAUX: Sure.

PANEL MEMBER GLANTZ: Maybe -- it is noon. Maybe we should take a break and give people time to read this and think about it. And then we can come back to this. I mean, I think this is the one last thing, right?

DPR ASSISTANT DIRECTOR VERDER-CARLOS: Yes.

DR. DuTEAUX: That, and just the scientific -- what do we call that, the document sufficiency.

DPR ASSISTANT DIRECTOR VERDER-CARLOS: Right. The scientific sufficiency.

DR. DuTEAUX: The scientific sufficiency of the document.

PANEL MEMBER GLANTZ: Yeah. But I just think -- I mean, I had -- as I said in the -- I had -- in the conversations I had with these guys last week, I said it would really help to get this to people before the meeting, because it's just coming up. But they just did the best they could, I think. And I think the amount of work -- I just want to say for the record, the amount of major work done in a very short time reflected in this addendum is very impressive, and --

DPR ASSISTANT DIRECTOR VERDER-CARLOS: Thank you.

PANEL MEMBER GLANTZ: -- it does -- and I think that the Department has been very responsive to the Panel. You know, so the fact that we may tinker a tiny bit more with this language or that you -- it took you until today

to give it to us, I don't think is a problem, so...

DPR ASSISTANT DIRECTOR VERDER-CARLOS: Thank you.

PANEL MEMBER GLANTZ: You know, I think we -- they've come up with what, in my view, is quite an impressive document now. So -- but I do think we are going to want to care -- really carefully look at the wording here. And I think that's better done, if we're not in the middle of a meeting.

Is that okay with you -- with everybody to...

CHAIRPERSON KLEINMAN: I think that would be appropriate.

So why don't we adjourn for lunch and reconvene at what 1:00 o'clock? That will give us time to read and eat.

DPR ASSISTANT DIRECTOR VERDER-CARLOS: Thank you.

PANEL MEMBER GLANTZ: Okay.

(Thereupon a lunch break was taken.)

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

CHAIRPERSON KLEINMAN: Welcome back. I'd like to reconvene this meeting of the SRP. And we were at the point of looking at the additional changes that have been drafted and are now excerpted from the June 2018 TAC draft. So I believe the Panel has all had a -- has a hard copy of this as well. So do you want to walk us through this and we'll go from there?

DPR ASSISTANT DIRECTOR VERDER-CARLOS: Okay. So we'll -- as Dr. Glantz had said earlier, we had individual conversations with some of the Panel members. And so we wanted to incorporate some of the changes that were suggested and would like the whole Panel's input on the -- on the proposed changes here to the executive summary and the conclusion of the report.

So the -- I guess I can -- sorry.

So the first change would be the one on the screen, and you probably already have a hard copy. The last paragraph on the summary, which is this addendum reflects the Scientific Panel's -- Scientific Review Panel's recommendation that DPR thoroughly evaluate the developmental neurotox effects as a critical endpoint for the chlorpyrifos risk assessment.

So we wanted your -- I mean, maybe you can just give us comments on how you read those revisions, and let

us know if those are acceptable or would you like any other changes at this point?

PANEL MEMBER GLANTZ: So, obviously, that would be re-worded slightly, now that this is becoming the main document. But rather than a critical endpoint, I think it should say the critical endpoint.

DPR ASSISTANT DIRECTOR VERDER-CARLOS: Okay. So Shelley is editing as we --

PANEL MEMBER BLANC: I think to the point --

(Thereupon a discussion occurred off the record.)

DPR ASSISTANT DIRECTOR VERDER-CARLOS: Okay.

(Thereupon a discussion occurred off the record.)

DPR ASSISTANT DIRECTOR VERDER-CARLOS: Right. Right.

PANEL MEMBER GLANTZ: And as I said, the other one is where you say "a", it should say "the", the critical endpoint.

DR. DuTEAUX: Right, I put it in blue.

PANEL MEMBER GLANTZ: Oh. Okay. I need new glasses.

(Laughter.)

DR. DuTEAUX: For those who are color blind, I'm just adding onto the track changes your additional comments, so we can go back and wordsmith it.

DPR ASSISTANT DIRECTOR VERDER-CARLOS: And then

we deleted the last -- the last sentence in that second -- in the middle of the page. And then again for updates in this addendum in this revision is what we would say, right? As the critical -- actually, put it in that.

So do you have any questions on that section where it says updates to this revision or addendum at this point?

PANEL MEMBER BLANC: So where it says along with the --

(Thereupon a discussion occurred off the record.)

PANEL MEMBER BLANC: It's just not clear. You mean all the body of --

(Thereupon a discussion occurred off the record.)

DR. DuTEAUX: Right. So from the toxicological and risk assessment perspective, we couldn't use the epidemiology studies, because we can't find a quantitative dose assessment out of those studies. When we were using acetylcholinesterase, it -- the epi studies, along with the animal in vivo studies, upheld the -- there was weight of evidence, and then the numeric justification for the uncertainty factor.

For here though, it's not -- because we don't really -- we can't use the epi studies to establish a point of departure, we could say it adds weight of evidence, but we didn't actually technically go through

the epi studies to establish a weight of evidence. So it actually -- it might be better just to take that language out.

PANEL MEMBER BLANC: If you deleted the word "the" along with epidemiologic. It's just going --

(Thereupon a discussion occurred off the record.)

DPR ASSISTANT DIRECTOR VERDER-CARLOS: Oh. Okay.

DR. DuTEAUX: Okay. Got it.

DPR ASSISTANT DIRECTOR VERDER-CARLOS: Dr. Blanc, do you have your microphone on just in case the --

PANEL MEMBER BLANC: Sorry. I just -- I would delete the word "the", so it's just along with epidemiologic studies.

DPR ASSISTANT DIRECTOR VERDER-CARLOS: Okay.

PANEL MEMBER BLANC: It's a little vaguer, but it's a little less confusing.

CHAIRPERSON KLEINMAN: Now, on the wordsmithing, on the previous paragraph in -- where it says "some model insufficiencies", I would take out the word "some", and just say "model insufficiencies". I think --

DPR ASSISTANT DIRECTOR VERDER-CARLOS: Okay.

DR. DuTEAUX: Okay.

DPR ASSISTANT DIRECTOR VERDER-CARLOS: Okay. And then the -- what page is this now, the third page?

DR. DuTEAUX: Three or four.

DPR ASSISTANT DIRECTOR VERDER-CARLOS: Fourth page, I think.

DR. DuTEAUX: Four.

DPR ASSISTANT DIRECTOR VERDER-CARLOS: And then page four. So we -- we moved the developmental neurotox endpoint to the first approach and added the -- added that language up top, and then put the acetylcholinesterase language secondary.

PANEL MEMBER BLANC: So one thing you'll note that further down in that paragraph by increasing the total uncertainty factor to 300 as it has --

DPR ASSISTANT DIRECTOR VERDER-CARLOS: In this revision.

PANEL MEMBER BLANC: -- in this revision, and related appendix, because remember you're going to move a lot of it --

DPR ASSISTANT DIRECTOR VERDER-CARLOS: Right.

PANEL MEMBER BLANC: -- to the appendix --

DPR ASSISTANT DIRECTOR VERDER-CARLOS: Right. Okay.

PANEL MEMBER BLANC: -- where you actually show the number. So you want to be consistent.

DPR ASSISTANT DIRECTOR VERDER-CARLOS: Okay. Thank you.

PANEL MEMBER GLANTZ: And then -- and this is a

point I talked to the DPR about it before lunch, but in the middle of that paragraph, where it say, "doses up to 10-fold lower", I would just say, "doses 10-fold lower".

DPR ASSISTANT DIRECTOR VERDER-CARLOS: Okay.

PANEL MEMBER GLANTZ: And there's another place where that comes up later, too.

DR. DuTEAUX: So my question is for the -- I guess it's the paragraph, where is it, that says the driver? Oh, the main risk driver, that would be the -- our preferred language.

PANEL MEMBER BLANC: Yeah.

DR. DuTEAUX: Do you have any suggestions, Dr. Blanc?

PANEL MEMBER BLANC: I would probably -- I couldn't write it off the top of my head, but I would say -- I would use different language that couldn't be misinterpreted as if there weren't the dietary, the airborne wouldn't be a problem, because that's --

DPR ASSISTANT DIRECTOR VERDER-CARLOS: Uh-huh.

PANEL MEMBER BLANC: -- that's what you want to avoid.

DPR ASSISTANT DIRECTOR VERDER-CARLOS: Okay.

PANEL MEMBER BLANC: -- and that potential misinterpretation.

DPR ASSISTANT DIRECTOR VERDER-CARLOS: And it's

the same thing for the next -- the acetylcholinesterase, we have that word there too.

DR. DuTEAUX: I'll just highlight it there.

DPR ASSISTANT DIRECTOR VERDER-CARLOS: Yeah, just highlight it, and you can think of a replacement.

And then the next page.

PANEL MEMBER GLANTZ: Yeah, and at the end of this paragraph, there's another as much as 10, where I would just say 10.

DPR ASSISTANT DIRECTOR VERDER-CARLOS: Yeah.

PANEL MEMBER GLANTZ: And then the one other thing and then you'll -- is if you go down a little further, the table that you deleted, the next -- yeah, I would put back the first three columns.

DPR ASSISTANT DIRECTOR VERDER-CARLOS: Okay.

CHAIRPERSON KLEINMAN: So I think that would be the new table 23.

DPR ASSISTANT DIRECTOR VERDER-CARLOS: Right.

CHAIRPERSON KLEINMAN: Yeah.

PANEL MEMBER GLANTZ: Yeah, that would be also be the new table 23 at the end.

CHAIRPERSON KLEINMAN: And that would show up in both places.

PANEL MEMBER GLANTZ: Yeah.

(Thereupon a discussion occurred off the record.)

PANEL MEMBER BLANC: I think for me the big problem still remaining in this proposed revision are the last two paragraphs. The big problem for me are the last two paragraphs of the revised text, which is just a holdover from the previous, I believe. The very last -- go to the end where it says -- yeah. Yeah, maybe it is -- no, I have text here that says, "Developmental neurotoxicity can also be protected against by implying an uncertainty factor of 10x". It would be after the table, I think. What comes after this?

DPR ASSISTANT DIRECTOR VERDER-CARLOS: Oh, the one --

PANEL MEMBER BLANC: Yeah, it's in the conclusion section.

DPR ASSISTANT DIRECTOR VERDER-CARLOS: Oh. Okay. So we're only in the -- in the executive --

PANEL MEMBER BLANC: I know. I'm just saying --

DPR ASSISTANT DIRECTOR VERDER-CARLOS: Okay. Okay. So for the executive summary, this paragraph is okay, the developmental neurotox database, the added language, which removed actually from -- except for Dr. Glantz "as much as" deletion. And then adding the -- adding back the first three columns of that table.

(Thereupon a discussion occurred off the record.)

PANEL MEMBER GLANTZ: I'm sorry. You might want

to -- as the heading instead of animal DNT just say DNT, because the numbers that you have in the third column are the numbers you would use through people.

DPR ASSISTANT DIRECTOR VERDER-CARLOS: Oh, okay. You mean, the table itself is what you're referring to is the -- or this one? Yeah. Okay.

So the end of that executive summary is that table with the three columns and then revised the title of the animal DNT to just DNT. And the footnote will be different.

Yeah. So the footnotes will be similar to what is on page 75 on table 23, because it's really the same as table 23 at this point. So then the next one is the conclusion, which I think Dr. Blanc was having questions on.

Your microphone is not on.

PANEL MEMBER BLANC: The paragraph that --

DPR ASSISTANT DIRECTOR VERDER-CARLOS: The third paragraph.

PANEL MEMBER BLANC: What's the next paragraph?

DPR ASSISTANT DIRECTOR VERDER-CARLOS: That one.

PANEL MEMBER BLANC: Yeah, this paragraph. So if -- if the effect even with the application of the three factor uncertainty, it's still a half an order of magnitude difference. So I'm not sure if your intent here

is that you would still be listed as a toxic air contaminant either way, is that what you're trying to say? I don't think that's appropriate here, because it's not just being listed as a toxic air contaminant. Later on, the Air Resources Board will use field data to trigger actions. And it will be a different action depending on -- it would be different were a value that's five times higher to be used.

So this wording makes it sound like it's capricious to have used the neurodevelopmental value. I know that's not your intent, but that's how it could easily be interpreted, because the other way would be just as protective. It wouldn't be just as protective. Both might yield a toxic air contaminant designation, but that's not the same as both values being equivalent to each other. So I would actually delete this paragraph or -- all together probably.

And I also think that the next sentence -- the next paragraph which starts, "Regardless of which approach is taken...", where we're not recommending two different approaches. We're recommending one approach. So I think that wording has to go too.

So I would delete this paragraph, delete the first sentence. And one that would just say, "In conclusion...", you know, whatever your concluding

sentence is.

That's -- that's what I would recommend. I think it's quite problem ridden to suggest that both approaches are interchangeable. I think, as was stated by Jesús, in fact -- I think was Jesús quite reassuring -- no, it was Cort -- it's quite reassuring to see that if you use and alternative approach, you come out to something which is similar. And I think we've done that a lot over the years, in this -- in this panel, have pointed that out and taken that to be good evidence. But that's not that they're interchangeable.

PANEL MEMBER GLANTZ: Well, maybe the way to -- what to say would be to replace it with a paragraph saying something like, "Even if one use uses the less sensitive endpoint of red blood cell acetylcholinesterase, it still meets the definition of a toxic air contaminant". I mean, that's what you said a couple minutes ago.

So, I mean -- and my understanding is that's why you think it's -- that point is why you think it's important to say something here. So why not just say that. And by saying it's even using the less sensitive endpoint, then no one can, you know, claim that you're endorsing that as the endpoint. But it makes -- it -- let's you say what you need to say to justify the TAC to sort of double justify the TAC determination. Does that

seem okay? Would that work for you, Paul?

PANEL MEMBER BLANC: Sure.

PANEL MEMBER GLANTZ: Okay.

PANEL MEMBER BLANC: Don't misinterpret -- I don't think you wrote it that way in order that someone would use it -- misuse it, but I just want to protect against that.

And the document itself, aside from the executive summary, I don't think we have to dwell on it here, but in the latter part -- in the summary part of the main text, you should make sure that it mirrors what you do here, because there's -- there were similar -- there was similar language that was potentially problem ridden in that final -- in the main document, wherever -- it returned to this wording. You'll find it easily.

PANEL MEMBER GLANTZ: And then to that point, at the very end, I would just add, either a clarifying phrase or sentence, reiterating that -- you know, that where you talk about develop to protect the general public, I would just say, "...based on developmental neurotoxicity". Just again, so there can be no -- I know that's what you did. But again, we're just thinking about making it harder for people to misrepresent what the report says.

DPR ASSISTANT DIRECTOR VERDER-CARLOS: Okay. So we will make those changes. And then for those -- and

then make sure that the body of the document is consistent with these.

CHAIRPERSON KLEINMAN: Is there a better way that we can deal with -- you've got the sentence both in the text and the conclusion, the main risk driver for the DNT approach is consumption of food and drinking water. It sounds like the inhalation is unimportant, unless you put something in that -- I think, that -- you know, something to the effect that -- let me see. I scribbled something. The CPF contribution from food and drinking water exacerbates the DNT effects of exposure to airborne CPF.

Because even without the food and water for most of the groups, you do meet the definition for a TAC --

DPR ASSISTANT DIRECTOR VERDER-CARLOS: Right.

CHAIRPERSON KLEINMAN: -- even down to half a mile.

DPR ASSISTANT DIRECTOR VERDER-CARLOS: Right.

CHAIRPERSON KLEINMAN: So I just don't want to leave the impression that it's not an inhalable or not an inhaled issue, you know, in this respect.

DPR ASSISTANT DIRECTOR VERDER-CARLOS: Yeah. I think that was also Dr. Blanc's point. So that lang -- could you send us that language, Dr. Kleinman?

DR. DuTEAUX: I scribbled that down, yeah.

DPR ASSISTANT DIRECTOR VERDER-CARLOS: Okay.

PANEL MEMBER BLANC: So, you know, often when we're in this kind of penultimate wording, what we try to do to avoid delays is assign a couple of people from the Panel to review the final, final. And we have a tentative -- we have a motion to tentatively approve the document, presuming the changes that have been proposed will be made. And I'd feel comfortable with that if Dr. Kleinman would be willing to work with Dr. Glantz, since he wordsmithed much of these changes, I think, to do that.

PANEL MEMBER GLANTZ: Yeah. So I'd like to make a motion to that effect, to -- that the Panel tena -- you know, tentatively finds the report as not scientifically deficient, or whatever the legal language here.

CHAIRPERSON KLEINMAN: Not seriously deficient.

PANEL MEMBER GLANTZ: Not seriously deficient. And then delegate to Dr. Kleinman, as the Chair, the authority to review the final document.

PANEL MEMBER BLANC: I'd like -- no, it has to be you and he.

PANEL MEMBER GLANTZ: You me and -- okay. Well, I kind of feel uncomfortable making a motion about me, so I'll --

PANEL MEMBER BLANC: Well, I'll make the motion.

(Laughter.)

PANEL MEMBER GLANTZ: Although, I hereby move I

deserve the Nobel Prize --

(Laughter.)

PANEL MEMBER GLANTZ: All of them.

(Laughter.)

PANEL MEMBER GLANTZ: Okay. I'll withdraw what I was saying.

PANEL MEMBER BLANC: No, just modify it. You can move that you be the other person.

PANEL MEMBER GLANTZ: No, I was just -- just -- what I was moving that it -- that Dr. Kleinman review it in consultation with other members of the Panel.

PANEL MEMBER BLANC: No, I really want you to be involved. Sorry.

PANEL MEMBER GLANTZ: Okay. Well, thank I think you should make the motion, because -- I also move that I should get a raise and --

(Laughter.)

PANEL MEMBER BLANC: I'd like to move that the document be accepted as -- without scientific deficit presumptive that the changes that have been discussed will be made and pending joint review by Dr. Kleinman as Chair and Dr. Glantz as de facto lead.

PANEL MEMBER ANASTASIO: Second

CHAIRPERSON KLEINMAN: Okay. I'd like to amend that, or I'd like to ask for someone to amend it, to

include that the scientific basis, you know, to assign the toxic air contaminant category to chlorpyrifos was scientifically validated by the report, or, you know, that it was sufficient to declare CPF as a TAC. I think that's --

PANEL MEMBER BLANC: I mean that's implicit.

CHAIRPERSON KLEINMAN: That's implicit.

PANEL MEMBER BLANC: But if it makes you feel better, fine. I accept your amendment.

(Laughter.)

CHAIRPERSON KLEINMAN: I would like the Committee to, you know, be behind that.

PANEL MEMBER ANASTASIO: Yes. I second the amended motion.

(Laughter.)

CHAIRPERSON KLEINMAN: Wordcraft it later.

PANEL MEMBER BLANC: You want to call the question.

CHAIRPERSON KLEINMAN: Okay. All in favor?

(Hands raised.)

CHAIRPERSON KLEINMAN: Okay.

Any opposed?

(No hands raised.)

CHAIRPERSON KLEINMAN: Any abstentions?

(No hands raised.)

CHAIRPERSON KLEINMAN: Motion passes. We have been successful. We have cleared the docket of something. All right. So --

DPR ASSISTANT DIRECTOR VERDER-CARLOS: Thank you.

CHAIRPERSON KLEINMAN: -- you will amend the report. And what sort of time frame was -- I think 30 days?

DR. DuTEAUX: I think it's 30 days. So that puts us going back and forth with you on the final draft and making sure that we have it, so that if you approve it, I guess, at the -- at your July meeting.

PANEL MEMBER BLANC: Well, we don't -- we don't have to approve it actually.

DR. DuTEAUX: You don't have to approve it. Okay.

PANEL MEMBER BLANC: We just have to --

DR. DuTEAUX: Accept it.

PANEL MEMBER GLANTZ: Yeah. It would only come back to the Committee --

PANEL MEMBER BLANC: If there was a major --

PANEL MEMBER GLANTZ: -- In Dr. Kleinman or I thought there was some horrible problem, which don't think is.

DR. DuTEAUX: Okay. Then in statute it's 30 days.

CHAIRPERSON KLEINMAN: Okay.

DR. DuTEAUX: And I think 45 days for their findings, is that correct?

DPR ASSISTANT DIRECTOR VERDER-CARLOS: I think.

PANEL MEMBER GLANTZ: Well, I would hope we could have findings at the July 12th meeting, too, just to be done with it.

DR. DuTEAUX: This was an auspicious date to have this meeting too.

PANEL MEMBER GLANTZ: What?

DR. DuTEAUX: This date.

PANEL MEMBER GLANTZ: Why is that?

DR. DuTEAUX: June 12th, because there was some other meeting in a different continent between two world leaders that was very important today.

(Laughter.)

PANEL MEMBER GLANTZ: Yes. Hopefully, we're more stable than they are.

(Laughter.)

PANEL MEMBER BLANC: I'm. So is July 12th already fixed for our -- no. Okay.

PANEL MEMBER GLANTZ: But I think -- I think -- I think that the findings are going to be pretty straightforward.

CHAIRPERSON KLEINMAN: Yeah. If -- you know, the

key findings are that the report is not deficient.

PANEL MEMBER GLANTZ: Oh, I guess there is one other -- now, that the thing -- I talked to them about this. I think that same slimmed down table, the table 23, with just the first three columns should also be in the conclusions, but we had talked about that.

PANEL MEMBER BLANC: Just as you had before.

PANEL MEMBER GLANTZ: Yeah. Okay. Well, that was easy.

PANEL MEMBER BLANC: So I guess my question for DPR would be, as a model of how to handle a complicated and potentially contentious air contaminant, if we were to do this all over again with the next air contaminant pesticide, what should the Scientific Review Panel as a group do to make your life easier, or the process better, or should we just plod along just as we have?

PANEL MEMBER GLANTZ: We could approve it without change when they present the initial draft. That's easy.

(Laughter.)

DR. DuTEAUX: Is that a motion?

(Laughter.)

PANEL MEMBER GLANTZ: No.

DR. DuTEAUX: Second.

(Laughter.)

DPR ASSISTANT DIRECTOR VERDER-CARLOS: Well, I

think that we had a, you know, really good discussion in the last three meetings. And the new data that we received and were able to evaluate, actually I would just publicly want to commend the team for -- the whole branch was working on this document the last two months. And it was a really big document. So I just wanted to give kudos to the Human Health Assessment Branch for doing such a great job. So thank you for acknowledging that as well.

But I think just a conversation, and having -- you know, talking to Dr. Kleinman, and being open to having one-on-one conversations with the Panel as well helped a lot in making the document robust.

PANEL MEMBER BLANC: I mean, it's an interesting observation that I think the final document is -- the gap between your vision and OEHHA's vision has narrowed considerably in this final document. So I wonder if there's something there about how the interactions with OEHHA, you know, could make this kind of process, you know, more synergistic?

I don't know. That would be between the two groups. But it just, as an outside observer, seems like what I was hearing at the beginning has sort of come much closer together.

DPR ASSISTANT DIRECTOR VERDER-CARLOS: So -- and we also received the studies -- you know, the studies from

OEHHA as well. So when we -- when we got the December document to you, it didn't have much of the specifics on the developmental neurotox animal data, which then we were able to now analyze and do an assessment of. So, you know, having a collaborative, I think, conversation also with OEHHA, which we really welcome, is a good thing.

CHAIRPERSON KLEINMAN: Well, I'd like to commend, you know, DPR staff and management, you know, for accomplishing a tremendous amount of work, relatively short period of time, and in a very complete and rigorous way. And I think speaking for myself, I learned an awful lot about the process and how it works. And I thank you for that. I'm sure the Panel agrees.

Okay.

PANEL MEMBER BLANC: So I think I'd like -- were there any administrative matters, which is the last item of the agenda.

CHAIRPERSON KLEINMAN: Okay. The only administrative matter is, as I've already mentioned, we are going to be polling everybody to -- for a telephone conference for July. So respond to Jim's poll.

And if there are no other questions or matters to be brought up, I'd like to ask for a motion to adjourn.

PANEL MEMBER BUCKPITT: I'd like to make the motion to adjourn.

(Laughter.)

CHAIRPERSON KLEINMAN: All in favor?

PANEL MEMBER BLANC: It hasn't been seconded.

CHAIRPERSON KLEINMAN: Second?

PANEL MEMBER GLANTZ: Second.

CHAIRPERSON KLEINMAN: He seconded it.

All right. All in favor?

(Hands raised.)

We are adjourned.

(Thereupon the California Air Resources Board, Scientific Review Panel adjourned.)

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 transcribed from a digital recording provided by ARB, in shorthand by me, James F. Peters, a Certified Shorthand Reporter of the State of California;

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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 28th day of December, 2018.

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