MEETING

STATE OF CALIFORNIA

OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT

ENVIRONMENTAL CONTAMINANT BIOMONITORING PROGRAM

SCIENTIFIC GUIDANCE PANEL

ELIHU M. HARRIS STATE OFFICE BUILDING

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ROOM 2

OAKLAND, CALIFORNIA

MONDAY, MAY 24, 2010

10:06 A.M.

JAMES F. PETERS, CSR, RPR
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APPEARANCES

PANEL MEMBERS

Dr. Ulrike Luderer, Acting Chairperson

Dr. Asa Bradman

Dr. Dwight Culver

Dr. Marion Kavanaugh-Lynch

Dr. Julia Quint

Dr. Gina Solomon

Dr. Michael P. Wilson

OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT

Dr. Joan Denton, Director

Mr. Allan Hirsch, Chief Deputy Director

Ms. Carol Monahan-Cummings, Chief Counsel

Ms. Amy Dunn, Safer Alternative Assessment and Biomonitoring Section

Ms. Sara Hoover, Chief, Safer Alternative Assessment and Biomonitoring Section

Dr. Farla Kaufman, Research Scientist, Reproductive Toxicology and Epidemiology

Dr. Gail Krowech, Staff Toxicologist, Safer Alternatives Assessment and Biomonitoring Section

Dr. Lauren Zeise, Chief, Reproductive and Cancer Hazard Assessment Branch

APPEARANCES CONTINUED

DEPARTMENT OF PUBLIC HEALTH

Dr. Rupali Das, Chief, Exposure Assessment Section, Environmental Health Investigations Branch

Ms. Diana Lee, Research Scientist

Dr. Sandy McNeel, Research Scientist

Dr. Robert Ramage, Research Scientist

Dr. Jianwen She, Chief, Biochemistry Section

DEPARTMENT OF TOXIC SUBSTANCES CONTROL

Dr. Myrto Petreas, Chief, Environmental Chemistry Branch

ALSO PRESENT

Dr. Felix Ayala-Fierro, Henkel

Mr. Davis Baltz, Commonweal

Dr. Kenneth Bogen, Exponent, Inc.

Ms. Luanne Jeram, LANXESS

Mr. Carl D'Ruiz, Henkel

Mr. David Steinberg, Steinberg & Associates(via Email)

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PROCEEDINGS

OEHHA DIRECTOR DENTON: Good morning. My name is Joan Denton. I'm the Director of OEHHA. And this is the Science Guidance Panel Meeting that we're just starting. I have a few words to say, and then I'll turn it over to our Acting Chair, Dr. Ulrike Luderer.

First of all, I'd like to welcome the members of the Panel, and also the people that are joining us here at the Elihu Harris building, as well as those that are on webcast. We appreciate you taking the time to join us at the meeting today.

Just a few notes on the logistics, the restrooms, if you exit the room pretty much the way you came in, just exit the room, they're on the hallway on the left and they're right there on the right.

And also the location of the emergency exit, the exit here to my right, and also the exit back -- the door back there, and then you just take the stairways that are marked with the green exit signs.

As we heard at the very beginning, this meeting is being webcast, and it's also being transcribed. So the transcription of the meeting will be posted on our website several weeks -- in several weeks.

At our last Science Guidance Panel meeting, which was on February 9th, 2009 -- 2010.

(Laughter.)

DWR DIRECTOR DENTON: Okay, 2010. The focus of the meeting was to get the Panel's advice and input on potential designated and priority chemicals, a proposed change in the format for the designated and priority chemicals' list, and the questionnaire and participant materials for the MIEEP, which is the Maternal Infant Environmental Exposure Project. It's also known as Chemicals in Our Bodies Project. Dr. Luderer will be going over today's agenda in just a minute.

My last comment is at the end of this meeting, we will -- I will be facilitating the selection by the Panel members of our permanent chair. With Dr. Moreno's departure at the last meeting, Dr. Ulrike Luderer has graciously agreed to facilitate this meeting. But then at the end of today, then we'll need for you to select the permanent chair.

So with that, I will turn it over to our Acting Chair, Dr. Luderer.

ACTING CHAIRPERSON LUDERER: Good morning. I would also like to thank everyone for coming and welcome you all, members of the public who are joining us by webcast as well as here, the Scientific Guidance Panel members and the Program staff.

I also just wanted to briefly summarize our goals

for the meeting today. We'll first be receiving updates from the program and laboratory staff. And the Scientific Guidance Panel members and members of the public will have the opportunity to provide input on those.

We will receive a briefing on the Firefighter Occupational Exposure Project. And again, there will be opportunities for public and Panel discussion and input.

We'll discuss an overview of the Draft Public Integration Plan and comment on the process for developing this draft plan. And there will be -- the Panel will make recommendations on one potential designated chemical and four potential priority chemicals.

And there will also be an opportunity to provide input and recommendations on the new format for the Designated and Priority Chemicals as well as other issues related to the Priority and Designated Chemical Lists.

I wanted to also mention now that each presentation will be followed by an opportunity for Panel members to ask questions. Then there will be a public comment period. As well as, after that time, for further Panel discussion and recommendations.

The way that we'll be handling the public comments is that if a member of the public would like to make a comment, please fill out a comment card, which can be obtained at the staff table, and then turn the cards in

please to Amy Dunn. Amy, if you could wave your hand.

Okay, great.

And then anyone who's listening on the webcast and would like to submit comments can do so by Email to the Biomonitoring Email address, which is biomonitoring one word OEHHA, O-E-H-H-A dot C-A dot G-O-V during the meeting.

MR. LLOYD: And we've got it on the screen as well.

ACTING CHAIRPERSON LUDERER: Okay, great.

And then Program staff will provide all the comments to me, so that I can read them allowed during the meeting, the comments that were sent in by Email. We have 10 minutes for each comment period. So depending on how much people wish to comment, that will determine the length of time that will be provided for each of the commenters. And Amy will be our timekeeper for that as well.

We also please ask that the commenters focus on the agenda topics that are being presented for their comments. I also wanted to remind the Panel members and the commenters to speak directly into the microphones and to please introduce yourselves before speaking. And this is for the benefit of people who are listening to the webcast as well as for the benefit of our transcriber.

Finally, the meetings for -- the materials for the meeting were provided in the meeting folder for the Scientific Guidance Panel members and are also available as handouts and via the website. There's also one folder for viewing at the staff table, which I believe is located in the back corner of the room there.

There will be three breaks: One this morning, one for lunch at around 12:30, and one in the afternoon. And we have a list of restaurants in the surrounding area available at the welcome table as well.

So we're just about ready to start with the first agenda item now, which is an update on the California Environmental Contaminant Biomonitoring Program activities. And Dr. Rupali Das who is Chief of the Exposure Assessment Section, California Department of Public Health and the lead of the California Environmental Contaminant Biomonitoring Program will be making that presentation.

Dr. Das.

(Thereupon an overhead presentation was Presented as follows.)

DR. DAS: Thank you, Dr. Luderer.

Good morning, Panel members and members of the audience. Just a minute before I get this up.

This morning I'm going to be giving you an update

on the activities since our last meeting.

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DR. DAS: Just as an overview of my presentation, I'll be going over the public name once again, introducing new staff, going over our program goals, giving you an update on the funding status and progress towards meeting our CDC cooperative agreement objectives.

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DR. DAS: Just to you remind you, that the official name of this program is the California Environmental Contaminant Biomonitoring Program, but we've adopted a more public friendly name Biomonitoring California. So throughout this presentation and in documents, you'll see the name Biomonitoring California.

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DR. DAS: Since the last meeting we have hired some new staff, two of the staff are hired under the labs. And Dr. Jianwen She will be introducing them in his presentation. We still have one staff member to be hired, the Laboratory Information Management Systems Specialist.

On the State side, we have a new staff member, a research scientist who replaced Robbie Welling. Berna Watson is our new Research Scientist. I'll just introduce her to you.

Dr. Watson was trained as a physician in Turkey

and did her Masters in Public Health here in the U.S. She has a background in maternal child health, and came to us from the Tobacco Control Branch of the Department of Public Health.

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DR. DAS: To remind you of the goals of the Biomonitoring California Program, there are three goals. First, to determine the levels of environmental chemicals in a representative sample of Californians. Secondly, to establish the trends in the levels of chemicals over time. And finally, to assess the effectiveness of public health efforts and regulatory programs to reduce Californian's exposure to chemicals.

In addition to these three goals, the Program is committed to providing opportunities for public participation, through both activities and materials.

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DR. DAS: Our state funding is summarized in this slide. The base level of funding for the Program remains stable at 1.9 million a year, divided by between the three departments, Department of Public Health, Department of Toxic Substances Control, and OEHHA.

The source of funding is the Toxic Substances Control Account, TSCA. And the funding has been maintained for 2009-2010. And we anticipate that it will

remain stable for the coming year.

This funding supports 13 FTEs, not full-time positions, but FTEs. And there is significant in-kind contribution from staff. In addition, we continue to be fortunate to have fellows from the Association of Public Health Labs, the Council of State and Territorial Epidemiologists and CDC Public Health Prevention Specialists as well.

As you know, we have mandatory furloughs for the State, and we've had to make some workload adjustments because of that. The mandatory furloughs are due to end at the end of June.

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DR. DAS: In addition to State funding, our CDC cooperative agreement provides us funding as well. Just to remind you of that, it's the five-year cooperative agreement that began in September of 2009. We received 2.6 million for the first year. There were three states funded. And the total amount was five million divided between the three states. The other states being New York and Washington.

We submitted our continuing application to CDC for the second year on Friday.

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DR. DAS: Let me just go over briefly the five

objectives that we specified in the CDC cooperative agreement: First, to expand laboratory capability and capacity; Secondly, to demonstrate the success of laboratory quality management systems; Third, to apply biomonitoring methods to assess and track exposure trends; Fourth, to assess exposures in a representative group of Californians; and finally, to collaborate with stakeholders and communities. And I'll be going over these objectives.

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DR. DAS: Objectives 1 and 2 really apply to the labs. And Dr. She and Dr. Petreas will be going over these objectives in their presentations.

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DR. DAS: Objective 3 is to apply biomonitoring methods to assess and track exposure trends. And under these objectives there are some updates to the projects that you've heard about before.

Our first collaboration under this is with the Environmental Health Tracking Program, as required under the terms of the cooperative agreement. We're collaborating with Tracking on two projects that you've already heard about.

In Tulare, we focused on participants of -- well, the Tracking Program focused on participants living near

orange groves where chlorpyrifos was sprayed. There were approximately 30 individuals. And the labs analyzed for chlorpyrifos metabolites. The results are not yet available, and we anticipate the results will be returned to the participants later this year.

In Imperial county, the Tracking Program identified 31 residents. This was a convenient sample. These were adult residents consuming local produce. And analyzed urine for several chemicals thiocyanate, perchlorate, nitrate, and iodine.

These were analyzed by the CDC labs and aren't considered results of the Biomonitoring Program. Split samples were retained by our labs and will be analyzed for QA/QC.

And other State labs analyzed perchlorate in food and water samples. The results are to be returned to the participants by the Tracking Program. In the coming year, we hope to explore more collaborations with Tracking.

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DR. DAS: The second collaboration under this objective is with Kaiser. The CYGNET project has been described to you already. But to remind you, this is a study looking at the role of environment, genetic, and other factors following a cohort of 400 girls between the ages of six to eight years of age who receive care at the

Kaiser Permanente clinics in Oakland, San Francisco, and San Rafael.

Baseline blood and urine was collected in 2006. And about 350 whole blood and urine samples are available and will be analyzed for metals and possibly other chemicals in collaboration with the other centers that are part of this study.

Our MOU with Kaiser is complete.

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DR. DAS: At the last meeting, we described to you in detail the Maternal and Infant Exposure -- Maternal and Infant Environmental Exposure Project, or MIEEP, also known as the Chemicals in Our Bodies Project.

Just to remind you again, the purpose of this project is to look at -- to measure and compare levels of chemicals in pregnant women and newborn infants. We will be recruiting at San Francisco General Hospital. Our collaborators are UC Berkeley and UCSF. We'll collect biological samples from between 50 to 75 pregnant women, as well as newborn umbilical blood cord samples.

And the chemicals will be analyzed in our Biomonitoring California labs. And the results will be returned to participants.

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DR. DAS: This is a slide that you saw last time.

It describes the different phases of the project. We will first meet the women in their third trimester at 28 to 34 weeks gestation. We will then see them again a few weeks later, when they come in for a routine exam and collect a maternal urine sample. The third encounter will be at delivery, when we'll collect maternal blood and umbilical cord samples. And then finally, they will receive results in two phases, because of the way the results are being analyzed, about a year after they first come to us, and then about two years after, depending on which results we're returning.

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DR. DAS: Progress made since the last meeting is shown here. We have gained IRB approval from both UCSF and the Department of Public Health IRBs. And that was the last step we were waiting for before beginning field testing of the sample -- of the project instruments. Field testing is slated to begin in the next couple of weeks. And we will have a dry run testing the sample collection protocol shipping and all the different procedures in June.

And we hope to start collecting specimens and to recruit participants in July -- actually to recruit participants in July and then start collecting specimens when the women deliver. And that we anticipate will

continue through December.

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DR. DAS: The Firefighter Occupational Exposure Project is a new project. Last time you did hear about some attempts we had made to collaborate with fire -- with the fire department in Contra Costa County. Actually, at the last meeting, I had just heard that that collaboration was not going to be successful, but Dr. Luderer, at that meeting, suggested that we might want to collaborate with some colleagues at UC Irvine.

We initiated those collaborations. And actually that's been very successful and very heartening collaboration. And I'll be describing this project to you in a little bit more detail this afternoon.

Just to briefly tell you about that, it's a collaboration with UC Irvine and the Orange County Fire Authority. Like the Maternal Infant study, we'll be collecting blood and urine from these firefighters.

In addition, we have an environmental sampling component to this one. And we have -- the other components that are common to both the maternal study and this one are data analysis, report back, and project evaluation.

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DR. DAS: Objective 4 is to assess exposures in a

representative group of Californians. And to do this, we're exploring various different options to look at the utility of biospecimen retrieval for chemical analysis. And we're always mindful of the cost to obtain and analyze these samples. And we're looking at appropriate sampling strategies.

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DR. DAS: Some of the collaborations under this objective are with the Kaiser Research Program on Genes, Environment, and Health, or RPGEH. You heard from Dr. Stephen Van Den Eeden at a previous Scientific Guidance Panel meeting. We have had some additional meetings with Dr. Van Den Eeden. And during year two of the cooperative agreement, we hope to move forward on this collaboration.

We will be writing a subcontract with Kaiser in September of this year. And our work with them will be -- will be two-fold. First, working with our biobank repository, which is a repository of banked samples for Kaiser members over a number of years, as well as a pregnancy cohort, something they're starting this year, collecting samples from pregnant women in northern California.

In addition, we've started discussions with the Genetics Disease Screening Program. You heard about this at the last meeting. Our primary efforts in this

collaboration will be to look at methodology to analyze infant blood spots. And then following that, we'll be looking at specimen retrieval from the genetic disease screening program.

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DR. DAS: Objective 5 is to collaborate with stakeholders and communities. And to fulfill this objective, we're doing a number different things with Health Research for Action, which is within the UC Berkeley School of Public Health.

HRA looked at the Biomonitoring website, which is actually hosted by OEHHA, and provided a number of recommendations to change the website to make it more public friendly, and more negotiable. The review was provided this month, and will be part of the improvement. Actually, the improvement of it will be part of year two, partly funded by the CDC cooperative agreement.

In addition, we have a biomonitoring brochure, which HRA is also working on. And that we hope to have available later this year for public dissemination. This is a brochure that describes in lay language what biomonitoring is and can be given to a variety of different members of the public.

It will eventually be translated into Spanish and Chinese as will much of our other material.

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DR. DAS: So to summarize, we have taken a number of different efforts to increase the capacity and capability to analyze chemicals in urine and blood, through collaborations through obtaining samples from researchers who have already collected them, as well as collaborations with researchers who are collecting them now, such as Environmental Health Tracking Program, CYGNET, at Kaiser, the maternal-infant study, the firefighter study, which you'll hear about today. And our plan collaborations include Kaiser, and genetic disease screening program.

In addition, we have a number of different efforts targeted at results communication and outreach, which will spread the information about this program to a nonscientific audience.

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DR. DAS: I wanted to acknowledge our staff. We have -- just do the next two slides show you the number of different staff that are working on this project. But I do want to let you know that most of these staff are either grant funded through CDC or providing in-kind support.

Very few of these are actually funded through the State Biomonitoring Program, but I wanted to give you a

sense of the number of different people that are working. On this slide, you see staff from California Department of Public Health, Environmental Health Investigations Branch and the Environmental Health Labs. And here are staff from OEHHA and Department of Toxic Substances Control.

And I want to thank all the staff that have provided so much work on this -- moving this program forward, as well as submitting the CDC cooperative agreement renewal and all the other efforts that go into making this program a success.

And I'd be happy to take any questions from the Panel.

ACTING CHAIRPERSON LUDERER: Thank you very much, Dr. Das. Do any of the Panel members have clarifying questions regarding Dr. Das's proposal?

I have one question. You mentioned at the beginning for the Environmental Health Tracking Program collaboration, that the participants would be receiving their results soon during the coming year. I was wondering will those results also be available to the public and what the timeframe for that might be?

DR. DAS: The first step in returning -- in making results public is for participants, in any project, to receive them.

Since this is primarily a Tracking Program

project, we will be following their lead. So they will return results to the public -- I mean, I'm sorry to the participants individually. Once they have made them more publicly available, either in the form of a publication or a report, at that point, we will be then considering them part of the biomonitoring program and making them public as is required under the program but. We will be taking the lead from the Tracking Program researchers.

ACTING CHAIRPERSON LUDERER: Do any other Panel members have questions?

Dr. Wilson.

PANEL MEMBER WILSON: I guess it's a follow-up question, around the -- similarly with the maternal-infant project and the firefighter project to what extent that information will become publicly available?

DR. DAS: Yeah. These are both great questions.

All the results of the biomonitoring -- the analyses that will be done under the Biomonitoring Program will eventually be made public. That is a requirement of the legislation.

Again, similar to the Tracking Program, the results will first be returned to individuals. And then we will be eventually making them public, but, you know, the steps involved before making them public are yet to be negotiated. But, in general, the first individuals will

get the results, then we'll be packaging them in a format that deidentifies them and will be made presentable to the public in some format, either through publication, presentation, or a report. So eventually they will be made public.

PANEL MEMBER QUINT: This is Julia Quint. I want to congratulate the Program, I think you've done -- there's a lot of activity. You obviously are moving forward with a lot of interesting projects.

I guess I have two questions, maybe three. One was the status -- I think there was a legislative report that was due, I suspect that's been submitted. And I'm wondering if there has been any discussion of where we are, in terms of these smaller projects and the representative sample, because the legislation clearly -- you know, the mandate is to do a representative sample. And we all know that there are -- we're resource limited, and so we are doing these other very wonderful smaller projects.

But I'm wondering if there is any discussion of the relationship between these projects and what they will or will not be able to tell us about a representative sample or, you know, what progress we're making toward, you know, educating people about this, still the need to do the representative sample.

That's one question.

And then the other question is, as we return results to people, to subjects that have been biomonitored, I think question of what the results mean definitely will come up. And I know there is ongoing now interpretation of biomonitoring results. It was mentioned in one of the papers in our binder. And I'm wondering, whether or not, we've been able to make any progress, in terms of, you know, some of the scientific discussion about what the results mean -- how you interpret these results? Because other scientists are busy interpreting the results. So I'll just leave it at those two questions.

DR. DAS: Okay. Thank you, Dr. Quint

To answer your first question, the legislation does require the assessing of a representative sample of Californians, but also allows for targeted subpopulations. So what we're doing is definitely within the scope of the legislation.

And we are -- as you mentioned, we're starting out with these smaller projects, but we're also making efforts to obtain a representative sample of Californians through our collaborations with Kaiser, for example, that would be one way. And I guess that's the main one and through other methods that we'll be exploring.

And so while the funding allows us to do the small projects in a shorter timeframe, we are exploring the attempt to obtain a representative sample, and hopefully during year two, and subsequently -- year two of the cooperative funding, and subsequently we will make some progress towards attaining the representative sample.

In terms of results return and the interpretation of the results, yes, we are planning to incorporate that into our results return and report back. For the maternal-infant study we're working with UC Berkeley Dr. Rachel Morello-Frosch, who you heard from in an earlier meeting. We'll be working with her to help interpret the results. And so we're not just giving numbers back, but actually interpreting them and expressing their results in a format that's understandable to the participants.

And so there will be usability testing of the format of the return material, as well as doing some field testing, in terms of how the results are returned.

And that will be starting soon. Part of the field testing we'll look at how results are returned, the format of the results that are returned, and make sure that we're actually packaging materials in a format that's understandable to participants. And so that is built into the different phases of the project, starting off with the maternal-infant study.

And Tracking has done that to a certain extent as well, in their results return. They're testing the understandability of the results as they're returned to package the materials in a way that makes sense to the participants and isn't just purely scientific.

Does that answer your question?

PANEL MEMBER QUINT: Thank you. That does answer it in part. But in terms of the interpretation of the results, I was actually thinking more of the scientific. I understand the lay interpretation, and I, you know, trust that Dr. Morello-Frosch and the group at UC Berkeley will do an excellent job of assisting us with that. But there is an ongoing sort of effort to interpret -- a scientific interpretation of what biomonitoring results mean or don't mean, and so that is what I'm really concerned about also, as well.

DR. DAS: Yes, so --

PANEL MEMBER QUINT: So my question was really directed toward that particular aspect.

MS. HOOVER: Yes. Rupa, do you want me to make a comment?

DR. DAS: Sure.

MS. HOOVER: So. Yeah, we're working on that project ongoing. And we're hoping -- we're just starting off with sort of surveying what's out there, and what

information is already available and how people have been interpreting the results.

So we're in progress on that right now. And what we're hoping to do is have a more substantive discussion with the Panel at the fall meeting.

PANEL MEMBER QUINT: Thank you. That's wonderful.

DR. McNEEL: Identify.

MS. HOOVER: Sara Hoover, Chief of the Safer Alternatives Assessment and Biomonitoring Section of OEHHA. Sorry about that

MS. LEE: Hi. This is Diana Lee with the California Department of Public Health. And I just want to add that much of the work that we're doing with the pilot projects and so on help to establish procedures and protocols that we ultimately hope to be using in more representative samples.

So much of the data collection instruments, so much of the protocols with respect to the field collection of specimens, the transference to the labs et cetera, will all apply ultimately to a larger representative sample as well. So we see them as kind of setting the ground work for much of the representative samples.

ACTING CHAIRPERSON LUDERER: Are there any other questions from Panel members at this time?

Then why don't we, at this point, move on to the public comments.

Do we have any?

MS. DUNN: We have one public comment.

ACTING CHAIRPERSON LUDERER: We have one public comment.

MR. BALTZ: Davis Baltz with Commonweal, and nice to be with you again. We've tracked your work since the Program's inception, and just wanted to acknowledge the continuing progress that the Program has made under Dr. Das's leadership, in a, as Dr. Quint said, a resource-limited environment, to say the least. The Program has been entrepreneurial in finding new funding, and hiring new staff and starting to plan for projects that will actually collect data that will be useful to Californians.

I'm particularly interested that you have chosen to explore cohorts with pregnant women and their babies, and this new project with the firefighters. I'm interested to hear about it this afternoon. And as these opportunities continue to present themselves, the occupational cohorts I think would certainly be of interest to the public interest community, because of the potential harmful exposures to people who work with chemicals.

So congratulations to the Program for the continuing work that you're doing. And I'll look forward to hearing more over the course of the day.

Thank you.

ACTING CHAIRPERSON LUDERER: All right. Thank you very much. Are there no additional public comments?

Great.

So then we now will move on to additional Panel discussions and Panel recommendations. Do any Panel members have comments or questions?

Dr. Bradman?

PANEL MEMBER BRADMAN: No.

ACTING CHAIRPERSON LUDERER: Dr. Quint?

There are no questions or comments from the Panel members?

Shall we move on to the presentations from the laboratories then?

(Thereupon an overhead presentation was Presented as follows.)

DR. DAS: I'd like to -- this is Dr. Das from the Department of Public Health. I'd like to introduce our two speakers that will be coming up here next. Dr. Jianwen She is Chief of the Biomonitoring Section of the Environmental Health Laboratory Branch in the Department of Public Health. And he'll be followed by Dr. Myrto

Petreas from the Environmental Chemistry Lab in the Department of Toxic Substances Control.

So, Dr. She.

DR. SHE: Thank you, Dr. Das, for the introduction.

Good morning, Panel members and everyone. I'm glad to have this opportunity to update you on what EHLB has done since our last meeting.

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DR. SHE: My update will include the new staff, laboratory set up and instrument, new method development, method performance, and year two activities.

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DR. SHE: Scientists are the most important resource for the program. Since our last meeting, we recruited two more scientists to the Program. Let's welcome Dr. Xia and Dr. Wang.

(Applause.)

DR. SHE: Dr. Xia has a lot of experience in using advanced instrument. And in the short amount of time he has been with us, he has made an important contribution to the development of our PAH method.

Today is, in fact, Dr. Wang's first day with us.

(Laughter.)

DR. SHE: And he brings a lot of biomonitoring

experience with him from Duke University.

We also expect to add Laboratory Information Management Specialist by July.

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DR. SHE: We have a few functional lab already. In addition to the current lab space, we also expect to add two more rooms to our laboratory space. They are especially welcome since we are adding new instruments with CDC grant.

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DR. SHE: Here is a list of the new instruments we order or plan to order. We own two LC-MS/MS. We ordered one GC-MS/MS.

The two LC-MS/MS will be used for the OP specific metabolites and the pyrethroid metabolites. LC-MS/MS will be used for environmental phenols. And the GC-MS/MS we have for the common metabolite dialkyl phosphate.

The other two instruments we plan to order is IC-MS/MS for perchlorate, and also we try to order some equipment for the laboratory automation. The equipment ordered according to the priority chemicals the Panel recommended to us.

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DR. SHE: SGP established the priority chemicals for the lab to work to develop methods. Let's discuss

method development.

We have validated five methods. The first one is blood metals. The second one is chlorpyrifos metabolite, trichloropyridinols. And also the metabolite for pyrethroid, 3-PBA.

The third method we validated and finished is the phthalate method, MbP and MeP.

Number four method is for hydroxy-PAH. We work out 3-Phen. Also, we finished creating this method.

At the same time, three other methods are under progress in the development. Metals in urine, arsenic speciation and bisphenol-A. We did exploratory work on the DAPs and the perchlorate.

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DR. SHE: Let's see the method performance. The first slide I wanted to show here is our method precision. As you can see from the top charts, our relative standard deviation is less than five percent. Over 20 sets have run.

The bottom right bottom -- bottom chart is for high quality control samples for 3-Phen. Our relative standard deviation is also in the range of three percent -- three to four percent. Usually for the trace level analysis, we required less than 15 percent. So our method have a very good precision. In other words, our

repeatability is high.

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DR. SHE: Let's also look at the method accuracy. We compare to the CDC monitored. We call it LAMP, which means Lead And Multiple Metals Proficiency Test Program. To compare with the CDC, we have very good linearity. And so the method have a very small bias, you can see from the slopes.

For both mercury and the lead -- and the cadmium. I showed the performance for the lead in last presentations.

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DR. SHE: This leaves just two examples to show the method of performance.

In the year two, the laboratory plan to expand the method to cover more analytes, which are recommended by the SGP. For example, for PAH, right now we have only one analyte, but SGP gave us three in the priority chemical list.

And for phthalate, we only have two. Right now we work out the method, but SGP also give us more than two to work on it. OP's the same.

We also tried to finish the method that we are currently in progress. For example, metals in urine, arsenic speciation, bisphenol A. And bisphenol A and

triclosan is SGP-recommended chemicals. So we will work on bisphenol A and triclosan together.

At the same time, we plan to increase laboratory capacity to improve the throughput, which means we will work on laboratory procedure automation, and also we will participate in more PT program to make sure our quality of the data is high.

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DR. SHE: What you have seen and what we see are the works from this group of scientists. Personally, I want to thank them.

Thanks for your attention.

ACTING CHAIRPERSON LUDERER: And I think next on the schedule was Dr. Petreas, but we may have time for a few questions now from the Panel, if there are any, for Dr. She?

Dr. Culver.

PANEL MEMBER CULVER: My question.

MR. LLOYD: Sir, could you speak more directly into the mic.

PANEL MEMBER CULVER: Is that better?

MR. LLOYD: Yes.

PANEL MEMBER CULVER: My question grows out of need for my education perhaps. I have the impression that the equipment that you're buying or expect to be receiving

soon is rather substance specific or specific to certain families of compounds. Are you also trying to increase your capability to analyze more generically compounds that don't necessarily fit into those specific families?

DR. SHE: For example, more generically, means -- sorry about that. More generic chemicals --

PANEL MEMBER CULVER: Yes, more flexible analytical capability.

DR. SHE: Actually, I link each instrument to a specific group of chemicals. But on other hand, this instrument they are generic enough to be used for some other chemicals, maybe the SGP recommended in the future. For example, LC-MS/MS can work on a group of chemicals, have the life impact. Also, GC-MS can work on the less polar -- low polar compound. So these are two group of instruments that are supposed to cover a lot of chemicals.

ACTING CHAIRPERSON LUDERER: Dr. Solomon.

PANEL MEMBER SOLOMON: Thanks. That's great to see so much progress, even since the last meeting.

I notice that manganese was listed as one of the metals. And CDC isn't even doing manganese yet. I'm excited to see it there, but I was hoping to hear a little bit more about how that's going and what challenges you might have encountered, because that's a difficult one, I think, to measure?

DR. SHE: I wish Dr. Frank Barley be here and can be given more specific answer on that one. He's the one who's in charge of inorganic. So I didn't hear so much from him about what challenges he encountered during the process. But I will follow up with that to see what does he really go through and what difficulty he has.

PANEL MEMBER SOLOMON: One more. The GC-MS/MS for the OP DAP metabolites, is that instrument really just going to be focused on measuring those DAPs? Because I know that when we talked about this in the Panel, there was some concern about those not being specific enough to be as helpful as we might like. And I'm hoping that if we're buying a whole instrument that it will be useful for other things as well, because that seems like probably a big expense just for those specific metabolites.

DR. SHE: Actually, I think you get very good questions. That instrument, while we are talking here, CDC also suggests that we return or switch a different instrument, because used one is DAP, not specific enough. At the same time, CDC also change their methods. So a lot of the recommendation which machine we are buying, we talk with the program office in CDC. Recently, he recommended can you switch? Do not open the box. Switch back with the vendor. So I work with Agilent to work on that part. And so that machine may never be set up. And then we will

go to buy another LC-MS/MS.

So that's a very good question and good comment.

ACTING CHAIRPERSON LUDERER: Dr. Bradman.

PANEL MEMBER BRADMAN: Yeah. But also to reiterate Dr. She's point early that these instruments are flexible across many different kinds of compounds. So if it can do certain metabolites, there's also many other types of chemicals you can measure outside pesticide classes or otherwise.

DR. SHE: Yeah. If we keep it and if we have difficulty to return, for example, volatile chemicals in the future, if the Program tried to do it, that machine can be used.

ACTING CHAIRPERSON LUDERER: Dr. Wilson.

PANEL MEMBER WILSON: Yeah. Mike Wilson.

Thank you very much for your presentation, Dr. She. And I'm wondering if you could put the method precision slide back up. I just had a couple of questions about that.

So that is -- is that showing us the coefficient of variation, the standard deviation as a percentage of the mean? So are those -- for example, on the top graphic, are those 21 runs of the same standard, drawn from the same standard?

DR. SHE: (Nods head.)

PANEL MEMBER WILSON: Okay. And so you're basically seeing five percent.

DR. SHE: (Nods head.)

PANEL MEMBER WILSON: So that's instrumental variability essentially, is it?

DR. SHE: Actually, this top one we call the quality control low. We measure the CV, like you mentioned. And then actually this is a standard added to the solvent. And this solvent we go through the sample preparation procedure each day, because we cannot measure them directly. The hydroxy-PAH cannot be measured in the GC directly, involved the derivatization deconjugations of the steps. So this is the measurement of the precision of the laboratory procedure, plus incident of instrument precisions.

PANEL MEMBER WILSON: I see, so it's your whole process --

DR. SHE: Whole process, yes.

PANEL MEMBER WILSON: -- from start to finish?

DR. SHE: Yes.

PANEL MEMBER WILSON: And so over -- to run 21 days -- or, I'm sorry, 21 runs takes -- how long does that take?

DR. SHE: Bob, are you here? Can you comment on that.

DR. RAMAGE: Yes. My name is Bob Ramage from EHLB.

It took over a month. I mean -- and we were running every day. And a few days we ran twice, but separate sample preps and separate sets of reagents.

PANEL MEMBER WILSON: Right, okay. Thank you.

And so it's really plus or minus two and a half percent, is that on either side of the mean is what we would -- is sort of -- on the top one there, or is it plus or minus five percent on either side, so a total of 10?

I'm sorry, if I'm -- I'm just --

DR. SHE: Let me see the math.

PANEL MEMBER WILSON: Yeah, I guess I'm --

DR. SHE: This is RSD standard deviation divided by the mean.

PANEL MEMBER WILSON: The mean, right, okay.

DR. SHE: I think that's plus or minus five percent is that about right?

DR. RAMAGE: Yes.

DR. SHE: Yea, plus minus each side.

PANEL MEMBER WILSON: Right. That's great.

And do we have a -- do we know how that, at this point, compares with what CDC is doing, in terms of their coefficient of variation of the method?

DR. SHE: For the method, it depends on which

one. If you have high levels, it's easier for lab to measure it. And then we expect to have lower values.

For the very low levels, the variation is big. So I think CDC accept 15 percent. Yeah, from extreme lows, sometimes people go to 20 percent.

PANEL MEMBER WILSON: And then on one -- on the next slide is your accuracy slide, that's measuring known standards?

DR. SHE: This is actually a PT Program result. So CDC administrated this program. They sent us the samples. We do not know the result. We measure it and then later on they evaluate it to compare what we have. So that's real blood samples that they already did the Round-Robin test. They load the values they provided us to, and then we test and then compare. So this regression curve compares our value with their values.

PANEL MEMBER WILSON: Right.

DR. SHE: It also goes through the procedure we are doing.

PANEL MEMBER WILSON: That's great. That's very impressive.

Thank you.

DR. SHE: Thank you.

ACTING CHAIRPERSON LUDERER: I have a follow-up question to that. So the accuracy and precision data that

you showed us for these particular chemicals are very impressive. These are looking really great. The other chemicals that you already have the methods developed for, are you getting equivalent precision and accuracies for those as well?

(Laughter.)

DR. SHE: Some of them are very good. For the ones we totally validated, they're all very good. So comparable.

But I think the 3-Phen is extremely well, is less than five percent. The other ones, I mean, are good, according to CDC's requirement below 15 percent. Two phthalate, for example, is not validated. We have bigger troubles right now, and we are still working on it..

The major reason we identified it is because the standard -- the vendor-provided standard is wrong. And we work with them, and then we cannot meet -- the standard is not stable enough. They put in different solvent. Right now we will ask them to try different solvent.

So short answer to your question, the one we called validated are very good. The one we do not have a good one, we even did not put it on the list. We are still working on it.

ACTING CHAIRPERSON LUDERER: Any other questions from Panel members at this time?

Okay. We can move on to the next presentation. Dr. Das, were you going to introduce Dr. Petreas?

(Thereupon an overhead presentation was Presented as follows.)

DR. DAS: Yes, I'd like to introduce Dr. Myrto Petreas from the Environmental Chemistry Lab in the Department of Toxic Substances Control. She will be talking to you about the DTSC laboratory update.

DR. PETREAS: Good morning. So as you know, we were not part of the CDC cooperative agreement in the first year. So I have no staff to introduce to you, and I have no Instruments to talk about.

(Laughter.)

DR. PETREAS: Hopefully, with part of the second year application, hopefully we'll hear good news or we'll know something later.

So with the existing staff, we have two staff funded originally and the existing equipment, that would be my update.

In addition, as you know, DTSC has other projects where other staff work on, but because of the overlap, this Program gets some benefits from these other activities.

And I want to address Dr. Culver's comment before and question, that in terms of what equipment we're going

to get eventually. We plan to have an instrument that will look at unknowns down the road. So once we get part of the CDC cooperative agreement, we will get the TOF instrument, Time of Flight, which is good for identifying unknowns, because between now and then who knows what will be the priority. So we have to be prepared for that. That's down there the road.

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DR. PETREAS: So with our current resources, we are charged to look at PBDEs, polybrominated diphenyl ethers, flame retardants, and perfluorinated chemicals, PFCs. And the progress so far is that both methods are operational. With PBDEs, we have completely transitioned into the CDC methodology. We adapted what we used to do to incorporate CDC's methods. And we use this technique to measure PBDEs in several blood samples from studies we conduct.

With the perfluorinated chemicals, the last time we met, we were in the middle of validation. And we had some glitches with some of the compounds. Since then, we collaborated with the staff from New York Department of Public Health and Minnesota Department of Public Health. And we have changed standards and samples. We found an error in our standard, took corrective action, and now we're fully validated. And our stand operating procedure

draft is in use and we are in review to finalize it.

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DR. PETREAS: Talking about perfluorinated chemicals, just to remind you, basically there are three main classes. The PFOS, which are the sulfonates, the acid, the second one, and the sulfonamide. And the O in this case means octa, referring to eight carbon molecules, but this could be anything from tetra to dodeca, so we have in -- we'll talk about those.

So these are the three subclasses that we are looking at. And we're driven again by the SGP recommendations and what NHANES does. And I realize the next slide was not printed. Hopefully -- yeah, it is shown here.

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DR. PETREAS: What I'm showing here is the PFCs that we will be looking at in human serum. The far right columns are the NHANES results showing the medians from two rounds of sampling in 1999 and 2000, and then '03-'04.

So just if you look at those, CDC added some compounds, but at the same time levels have dropped. So there's an overall decline in most of the PFOS -- PFCs that CDC has been monitoring. So that's the milieu for where we're coming in.

And the first column giving the full name of all

the compounds. There are 12 that we are looking at. The first segment are the PFOA type of -- the most common one is the PFOA, the second line. The second group is the sulfonates, so PFOS. The last one in this group is a major one. And then PFOSA the first one of the sulfonamides are the most prominent ones that people talk about. So these are the levels that CDC had measured.

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DR. PETREAS: Going here in our method validation, following what Dr. She presented, these are the in-house quality control samples. These again are samples that we -- in bovine serum that we prepare every time. It's our control. And we are -- these are 32 times -- 32 batches. And everyone takes -- through the whole procedure. It's not just a standard, but it gets extracted and all the steps, all the way to the instrument.

And the dashed line is the true value. And the little breakpoints are where we were every time we run it over these 32 batches, which is several months of work.

And so the dashed line here is the QC value. The dark one -- oh, good.

So we have two levels, what we call the medium level -- I will not point to anything.

(Laughter.)

DR. PETREAS: Anyway, the top point -- the top group is what we call the -- we have three levels. I'm showing only the low and the medium, because this is what applies to human serum. We have the high level for biota, but it's not applicable here. So in both cases, we're happy. That's the bottom line. I mean, we are -- we had some ups and downs, but especially the last few parts of the -- few months, we're on target. These is for PFOS. Another thing we did, and we have in-house controls for every analyte that we do out of the 12.

Of the 12 that we embarked to do, two of which we have -- with two we have problems. So with 10 we're happy. Here I'm showing you that when we did the comparison with the CDC, they sent us unknown blood, and we had to analyze that.

And here, you can see the box plot shows our spread of responses over time. And the dash next to it in the same color is the true value from CDC.

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DR. PETREAS: We have some problems with the fourth -- not the green one, if you can see. The fourth point. We know we're off. And I can't -- okay, the blue one here -- no. I'm sorry. I know there's a problem with one of them too. But nevertheless, both of these are not detected in NHANES. So it's not a high priority. We're

happy with the major ones, which are the PFOS, PFOSA, and PFOA.

So that's -- and everything is within the 15 percent that Dr. She described CDC allows, so we're content with that.

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DR. PETREAS: Now, using these methods, we ran some samples. We have 17 human samples that we collected as part of our pilot study to test our methods. And what I'm showing here is the individual results in blue bars of each of the 17 samples. And the top line around 30 is the NHANES 1999-2000 -- I think it's a geometric mean here. The blue line lower is the NHANES 2003-2004. So NHANES has dropped. And our values are -- now remember, our values reflect 19 -- '09. So they were sampled subsequently.

And given that there's a declining trend, had there been an NHANES '08-'09, maybe that line would be even lower, so more of our samples might have exceeded that, but we don't know. So we're in the ballpark. It's not in the PBDE territory here. We don't have anything unusual. So from the limited 17 samples, that's all we can say.

But basically, we can measure them. That's the important things. So we're happy we can measure -- this

is PFOS an very similar PFOA, the two major compounds were in the ballpark where NHANES is.

Now, as part of another study we do -- we have, we analyzed these chemicals in cats, cat serum. We're doing a study with veterinarians to study persistent organic chemicals in indoor environments. And cats are good sentinels to show what can be absorbed and would -- anyway, we're measuring also the house dust and trying to get some ideas for exposure assessments.

So the next slide is for cats. And I guess we measure them in cats. Now, we have to contrast with NHANES, which doesn't make much sense.

(Laughter.)

DR. PETREAS: But that's the only -- there's no NHANES for cats. But, you know, comparing to humans, cats are very similar to humans and that's my message here, both for PFOS and PFOA in cats.

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DR. PETREAS: And what I said in the next slide, here these are the two major PFOS in blue and PFOA in purple, PFCs in both the human serum and the cat serum, and it's very, very similar, which is very interesting.

But now remember, these are in nanograms per milliliter. We don't adjust for lipids here. And contrasting with the next slide, where I'm going to

project the same bars. And I will add the PBDEs in the same humans and cats, and you can see how different they are.

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DR. PETREAS: This is dwarfed down here, is what we had for PFOA and PFOS in human and cats, very similar levels. But when you look at the PBDEs, which is another target we want to do, humans are high for us, but much, much lower than cats.

So cats are extremely high, have extremely high PBDE levels. We knew that from results from a previous paper on cats alone that they have high levels. California, 20 cats, are more than double than the North Carolina cats. So again we're higher here. But I think it's very interesting to contrast, in terms of thinking about what exposure pathways there are.

Cats do something that humans don't do, so there's more contact with dust, or they lick themselves, or what's something they do and they get more PBDEs, but not PFCs. So PFCs may be in some more common exposure pathway, diet, and not so much the dust or the indoor environment.

So this is rather exciting information. As we speak today in Utah, is the American Society for Spectrometry conference. And these data are being

presented by Dr. Wang, one of our two funded staff.

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DR. PETREAS: So in summary, we have validated methods. And we analyzed 17 human serum samples collected in 2008-2009. And they fall within the expected NHANES ranges. We also analyzed cat serum, and we find very similar levels of PFCs in humans and cats, but very different levels of PBDEs in humans and cats. So that's what's happened.

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DR. PETREAS: Now, in the future, we hope to be part of the CDC cooperative agreement. And our plan is to get an LC-MS that would allow us to go into the brominated flame retardants, the alternative flame retardants, that need to be analyzed by LC-MS, for example HBCD and Tetrabromobisphenol A among others. So this is our target for the next six months or so.

And that concludes my presentation.

ACTING CHAIRPERSON LUDERER: Thank you, Dr. Petreas. Do any of the Panel members have questions?

Dr. Wilson.

PANEL MEMBER WILSON: Mike Wilson.

I've, you know, raised the issue about precision and accuracy. And, of course, the environmental variability inter-personal and intra-personal is often,

you know, orders of magnitude different from one to the next.

And so I'm not worried about one nanogram difference in the analytical methods. As you know, you showed your comparison with the CDC blanks. And it sounds like you're not worried about it either, when you looked at the -- it was the fourth one over. There was -- you were -- on your bar graph. Right, exactly.

You commented on that. And again, I mean, it doesn't -- that doesn't worry me. Does it worry you?

(Laughter.)

DR. PETREAS: No. Well, it's a combination. It's not only the unknown sample that you -- blind samples that we do, not only with CDC but with the other -- we have this agreement with, I guess, a collaboration with Dr. Cannon from New York who is the foremost authority on PFOS, other colleagues from Sweden and Minnesota departments. So we have exchanged samples, and we plan to continue doing that, just to be on -- but internally, I mean, it's important to have these, because this alerts you, there's a decline, there's a trend. So that's what -- every time, we run any sample, we run these controls. So that's something that keeps us to be consistent and on target.

PANEL MEMBER WILSON: Yeah, I mean this looks

really good to me.

DR. PETREAS: Yeah, we're happy. That's we can use them now and produce data.

PANEL MEMBER WILSON: Good. Excellent. Thank you.

ACTING CHAIRPERSON LUDERER: Dr. Solomon.

PANEL MEMBER SOLOMON: Right at the beginning of your presentation, you mentioned the instrument that you're hoping to get some day to look at unknowns. Can you tell us a little bit more about that? It sounds very interesting.

DR. PETREAS: When we put -- the first time the announcement -- the RFP came from the CDC was a five-year plan. And internally we thought what we need, in terms of being within budget and within target of what we need to be doing. And the TOF is An instrument that we thought that we would be getting later on.

I mean, this allows you -- it's mostly a research instrument to try to identify unknowns. It's not so much a production instrument. And there's a lot -- very, very rapid evolution of technology. So by waiting a year or two will be better to get the best instrument and use it more appropriately, because we anticipate there will be more classes coming and more things, which may not be exactly or optimally done with these instruments.

ACTING CHAIRPERSON LUDERER: Dr. Quint.

PANEL MEMBER QUINT: Thank you for that really nice update. This is Julia Quint.

I'm wondering if you're actually measuring any of the -- doing any measurements in the samples from some of the studies that, Rupa, some of the shorter studies that were described by Rupa.

DR. PETREAS: Yeah. We will be working with the maternal and infant --

PANEL MEMBER QUINT: The MIEEP.

DR. PETREAS: Yeah, so we'll be doing maternal blood and cord blood from that. And we'll be doing the firefighters.

PANEL MEMBER QUINT: The FOX study.

DR. PETREAS: The FOX study, yeah.

PANEL MEMBER QUINT: And what will you be measuring, PBDEs and --

DR. PETREAS: PBDEs, PCBs, pesticides in blood and also in dust from the firefighters. Perfluorinated, yes.

PANEL MEMBER QUINT: All right. Great, thanks.

ACTING CHAIRPERSON LUDERER: If there are no additional questions from the Panel at this time, we can move to having our public comments. Are there any public comments?

MS. DUNN: There are none.

ACTING CHAIRPERSON LUDERER: There are no public comments on these presentations. Do any of the Panel members have any additional questions or discussion?

All right.

At this time, we are running a bit ahead of schedule. Our next scheduled item is a break. Shall we just take that, at this time, a little bit early.

Before we leave for break, I'd like to ask Carol Monahan-Cummings to give us all a reminder about the Bagley-Keene Act.

OEHHA CHIEF COUNSEL MONAHAN-CUMMINGS: Good morning, Carol Monahan-Cummings, Chief Counsel for OEHHA, and counsel for this group, and I think you already did it.

You've just got to remember that this is a public entity and that discussion of items that are on the agenda should be done as a group in front of the public. And so if you can avoid discussions among yourselves or with other individuals when you're on breaks or lunch that's appreciated.

If for some reason you do have a discussion with someone, it would be useful to just disclose that when you come back, and say, you know, I talked to so in so about it, and here's the gist of our conversation, so the public

is aware of the discussion.

Any questions on that?

ACTING CHAIRPERSON LUDERER: Thank you.

Okay, we'll take a 15 minute break, so if we can reconvene at 11:30.

(Thereupon a recess was taken.)

ACTING CHAIRPERSON LUDERER: It looks like all our Panel members are here, so I'd like to get started again.

I'd like to welcome everyone back from the break, and thank all of our speakers from this morning for the excellent presentations and for updating us on all the progress that has been made by the labs and the Program.

The next item is going to be a discussion of a potential designated chemical, triclocarban. And the item is going to start with a brief update on chemical selection, which is going to be given by Sara Hoover, Chief of the Safer Alternatives Assessment and Biomonitoring Section of OEHHA.

(Thereupon an overhead presentation was Presented as follows.)

MS. HOOVER: Thank you, Dr. Luderer. Hi again. I'm back to just give you a very brief update to provide context for the couple of chemical selection items that we're going to be talking about today.

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MS. HOOVER: So first I just want to briefly remind the Panel and the audience about the kinds of things we're still working in chemical selection. We're still going through the top 100 pesticides from the California Pesticide Use Report, and some other pesticides of interest.

We're also considering classes that are not fully designated on the designated list. And what I mean by this, is there's some cases where chemicals have been put on the designated list based on CDC studies. And in that case, just the subset of chemicals monitored by CDC are placed on the list.

So we've talked with the Panel about considering some of these as classes, such as perfluorinated compounds, PAHs might be another example. We're also continuing to keep track of and work through other suggestions that have been made by the panel, as well as State staff and the public.

And we're also keeping an eye out for emerging chemicals as recommended by the Panel.

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MS. HOOVER: In terms of the two -- well, the one designated and the potential priority chemicals that we're looking at today, triclocarban was originally suggested to

us in the state scientist and public surveys. And I should mention that these two things I'm talking about, both of them had reports on them. And they're available on our website if you're interested in looking at those in detail.

The Breast Cancer Fund also prepared a summary of triclocarban and brought it to our attention again at the December 2008 SGP meeting.

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MS. HOOVER: In terms of the parabens, those were also suggested in the State scientist and the public surveys. They were just recently designated based on a CDC study, and they're included in the Maternal and Infant Environmental Exposure Project.

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MS. HOOVER: So just as a prelude to Gail's talk, I'm going to remind the Panel about the criteria for designated and priority chemicals.

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MS. HOOVER: So again, designated chemicals represent those chemicals both that are being biomonitored by CDC, as well as chemicals that the Panel may recommend adding to the designated list. And the law that established the program, lays out some criteria for the panel recommending additional designated chemicals and

these are shown here:

Exposure or potential exposure to the public or specific subgroups; the known or suspected health effects based on peer-reviewed scientific studies; the need to assess the efficacy of public health actions to reduce exposure; the availability of a biomonitoring analytical method; the availability of adequate biospecimen samples; and the incremental analytical cost.

And just to remind the Panel, these criteria are not joined by ands.

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MS. HOOVER: And later today, we'll be talking about some potential priority chemicals. And this is just a reminder, which Gail will reiterate later, about the criteria for recommending priority chemicals.

So the Panel can consider the degree of potential exposure to the public or specific subgroups; the likelihood of a chemical being a carcinogen or a toxicant; the limits of laboratory detection for the chemical; and other criteria that the Panel may agree to.

And again these criteria are not joined by ands. And the Panel is not required to name additional criteria.

So that's just a very brief intro, to give you context for the chemical selection items today.

And now, I'd like to introduce Dr. Gail Krowech

who's a staff toxicologist with OEHHA. She'll be presenting on triclocarban.

(Thereupon an overhead presentation was Presented as follows.)

DR. KROWECH: Hi. This first slide shows the structure of triclocarban or TCC.

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DR. KROWECH: TCC is a widely used antibacterial agent, mostly in deodorant soap bars, but also can be used in liquid soaps and body washes. Production/import volume was reported as one to ten million pounds in the 2002. A 2005 report had listed less than 500,000 pounds. And no other recent information is available on that.

The primary human exposure is via personal care products. A study conducted a decade ago found that TCC was in 84 percent of deodorant bar soaps sold in the U.S.

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DR. KROWECH: There are an increasing number of studies which have shown incomplete removal of TCC by wastewater treatment processes. It's been found both in surface waters and in sewage sludge. A recent study looking at 25 wastewater treatment facilities across 18 states found that triclocarban was in 100 percent of influent and 100 percent of the effluent from these plants.

But as I said, most is sequestered in sewage sludge. There is some degradation, mostly under aerobic conditions. And the levels of TCC that are in the remaining biosolids are in the parts per million range. Some reports have, I've seen, are about 20 parts per million and can be somewhat higher depending on the type of degradation used.

About 50 percent of biosolids in California and nationwide are applied to land as crop fertilizer. So there's concern about possible uptake of TCC. And, to date, OEHHA has not found any published literature that has looked at this.

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DR. KROWECH: In terms of known or suspected health effects, there are very few toxicology studies on TCC. There are a few studies that are relevant to endocrine disruption. And these studies indicate that TCC amplifies the action of sex steroid hormones. And in vitro studies in recombinant cells TCC enhanced the actions of estrogen and testosterone, while not having -- or having little or no agonist activity itself.

In another study, in an in vivo study in rats, rats were given TCC in diet for 10 days. And they were first given testosterone in the diet, and then TCC. And then TCC plus testosterone. It was found that TCC

amplified the effects of testosterone. And so the effects were greater than with testosterone alone or TCC alone. A very recent study showed that TCC was estrogenic in -- had estrogenic effects in freshwater mudsnails, increasing embryo production.

There's also concern about the possible presence of chloroanilines, and p-chloroaniline and 3,4-dichloroaniline are used in the synthesis of TCC. It's also been reported that they can be formed during the manufacture of soap. And there was one study in the seventies that showed that during aerobic degradation, these two were actually formed during the degradation process of sludge.

p-Chloroaniline is a Proposition 65 carcinogen. And the similar compound 3,4-dichloroaniline has not been well studied.

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DR. KROWECH: This slide is a slide that's actually from the TCC document and it has the physical chemical properties.

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DR. KROWECH: In terms of the persistence and bioaccumulation, the half-life of TCC was measured between 87 and 231 days in soil, depending on the type of soil and whether it was amended by biosolids -- amended with

biosolids.

And in terms of the bioaccumulation, there are a few studies in aquatic organisms. A low bioconcentration factor was reported in catfish. But bioaccumulation was found in algae and fresh water snails that had been exposed to wastewater treatment effluent. And also bioaccumulation was found in sediment-dwelling worms that were exposed to sediment that was spiked with TCC.

No studies have been identified in the literature that have looked at bioaccumulation in terrestrial organisms.

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DR. KROWECH: In terms of pharmacokinetics and metabolism, there were a number of studies in the 1970s and 80s that looked at both pharmacokinetics and metabolism, and found that TCC is absorbed from the skin after showering. Once careful study found .39 percent of an applied dose was excreted in urine and feces. And another study found that a small amount -- after showering, a small amount of TCC remains on the skin and it's slowly absorbed over time.

Excretion and metabolism are basically the same after oral and dermal doses. The main urinary metabolites are the N and N'-glucuronide conjugates. And an early study found that approximately 25 percent of the dose was

excreted in the urine, with the remainder being excreted in the feces.

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DR. KROWECH: There are a couple of biomonitoring studies to look at. After showering with TCC soap, N and N'-glucuronides have been identified in the urine. One study from the 1980s, which was looking at analytical methods, did measure N-glucuronides in the urine at levels of approximately -- in the range of 30 micrograms per liter.

And that study didn't provide any details about the number of individuals or the amount of TCC in the soap. So I'm just putting it here as reference. There's current research ongoing at UC Davis. And in that study of six individuals, TCC was detected in all individuals. There was a wide range in terms of the levels that were recovered in urine.

The peak concentrations after showering were from -- ranged from 6 to 24 hours. And the concentrations of TCC at the peak ranged from 35 to 300 micrograms per liter. And these are the metabolite which was hydrolyzed, so just to make that clear.

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DR. KROWECH: TCC was included in a study looking at environmental contaminants in breast milk. It was not

detected. CDC has not included -- CDC has not included TCC in biomonitoring studies released to the public. They have conducted some pilot studies. And those results from those studies have not been released.

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DR. KROWECH: In terms of laboratory analysis, Biomonitoring California would need to develop its own analytical methods, methods for urine sample preparation are developed. Analysis could be bundled with triclosan and certain other environmental chemicals -- environmental phenols.

In terms of the need to assess the efficacy of public health actions, TCC is widely used, persistent in the environment, absorption from common products has been established. There are concerns for endocrine disruption. And biomonitoring would help assess the extent and level of exposure in California and evaluate the need for further action.

ACTING CHAIRPERSON LUDERER: Thank you very much, Dr. Krowech. Do any of the Panel members have any clarifying questions at this time?

I did have a question. You mentioned the concentrations that have been found in influent and effluent from sewage treatment plants. Have there been any studies that looked for triclocarban in drinking water

or in food products?

DR. KROWECH: Not that I know of.

ACTING CHAIRPERSON LUDERER: Any other questions from Panel members?

Dr. Quint.

PANEL MEMBER QUINT: This is Julia Quint. In the written summary, you mentioned a study, I mean, I guess results that had been submitted by industry in the HPB program, but that you had not analyzed the studies. And I'm wondering if EPA had evaluated the data that had been submitted?

I know the studies were negative for two reproductive -- two generation reproductive study and some other negative findings, but there were no details about, you know, the amount administered or anything like that. So I'm wondering if you had other details.

DR. KROWECH: That information is available.

PANEL MEMBER QUINT: Okay, but it hasn't been evaluated by EPA?

DR. KROWECH: It's been summarized and there are details in that summary.

PANEL MEMBER QUINT: Right, because often those summaries are not evaluated, they just are summaries, so I just was wondering.

Okay, thank you.

ACTING CHAIRPERSON LUDERER: Dr. Wilson.

PANEL MEMBER WILSON: Thank you very much for that presentation. And I guess, you know, my question is, if -- your sense from the -- in your first slide on use and exposure, if this is a, you know, a substance that's increasing in use or do we have enough information to know?

DR. KROWECH: I don't think we have enough information to know.

PANEL MEMBER WILSON: Yeah. Is it -- if I could follow that up.

Is the use of triclocarban, is that identified -- I assume it's not exactly identified on product labels.

Right, so at this point, we didn't -- we wouldn't --

DR. KROWECH: I'm not sure about that. I didn't look at that.

PANEL MEMBER WILSON: Yeah. Thank you.

ACTING CHAIRPERSON LUDERER: Did you want to quickly clarify that?

MS. LEE: I've actually seen triclocarban listed as an ingredients -- Oh, sorry, Diana Lee with the California Department of Public Health.

So both triclosan I've seen, as well as triclocarban.

ACTING CHAIRPERSON LUDERER: Dr. Bradman.

PANEL MEMBER BRADMAN: I have a series -- a few questions here, just for a little clarification.

When we see it's used as an antibacterial agent, I just want to clarify whether this is being used as a preservative for products or whether it's considered to have some public health function?

DR. KROWECH: I think it's active against gram-positive bacteria. There are studies that -- or one study that someone handed me once that showed a study of -- a hand-washing study with, you know, no washing, soap with antibacterial agent and regular soap. And there was no difference. So I don't -- I don't think that -- there was no difference in disease rate.

PANEL MEMBER BRADMAN: So this isn't like some of the stronger compounds that are used in hospital settings?

DR. KROWECH: If it is, it's also used in, you know, consumer products. And it's not -- it's not clear that there's a public health purpose.

PANEL MEMBER BRADMAN: Okay, next question. In the persistence and bioaccumulation, you said there was some evidence of bioaccumulation algae in freshwater snails. Do you have any like factors on -- you know, if there's a bioaccumulation factor, do you know what those factors are?

DR. KROWECH: I can look that up for you in the break, but I think that it might have been around 2,000. I'm not sure. You know, I'm not sure, and I'll look that up.

PANEL MEMBER BRADMAN: Next question. It looks like from the pharmacokinetic and metabolism data here in, and in this document from LANXESS Corporation, that the half-life is around three to four days, what I can guess from some of these numbers.

Has there been any work looking at that in children, and what are the metabolism differences in children. And I've also extended that also just to group some of my questions together about some of the potential toxicity studies. Has there been any attempt to look at differences between, for example, young animals or how the impact may be different on children versus adults.

DR. KROWECH: Well, I think the answer is no, or that I have seen. But I think there have been so few studies of this. So I would guess that I would have talked to someone who knew about it.

The studies in the seventies and eighties only looked at adults. And if there's some ongoing research, I mean, that's possible.

PANEL MEMBER BRADMAN: So just my last question or comment. You indicated that CDC has done some pilot

studies, but there's been no biomonitoring studies released to the public. Is it possible for the Biomonitoring Program to request that from CDC, and that perhaps might provide some additional information?

DR. KROWECH: I can follow through with that -- follow up on that.

PANEL MEMBER BRADMAN: Okay. Thanks.

ACTING CHAIRPERSON LUDERER: Dr. Solomon.

PANEL MEMBER SOLOMON: Yes. One comment and one question. The comment is just to follow up on the issue of whether triclocarban appears on labels. And my understanding is that since triclosan is often included as an antibacterial and therefore registered pesticide, it does have to be on the labels, but triclocarban frequently is used just as a deodorant, and it's not therefore a pesticidal use, and therefore it does not have to be on the label. So on these deodorant soaps, it often doesn't appear.

And the FDA has a monograph that's been in draft form for quite a long time on these sort of antimicrobial soaps and so forth. And exactly what Gail said is correct, that they've concluded that there's no benefit over using regular soap to these products. So that's just something that was just released, I think, just a month or so ago.

But my question actually was, there's a mention in the write-up about binding to the aryl hydrocarbon receptor. And so I was just curious if there's any additional information about that? Any dioxin-like properties that have been identified in any other studies, or whether that's just kind of an isolated finding?

DR. KROWECH: That was one study that I found. There were, in general, so few studies about, not only -- you know, the toxicity but just about triclocarban. So I felt like I couldn't put everything, you know, on this slide, but I didn't find out any more information than really that one study.

ACTING CHAIRPERSON LUDERER: Do any other Panel members have questions at this time?

Dr. Wilson.

PANEL MEMBER WILSON: Mike Wilson. Has EPA managed to gather any information on this substance through their HPV challenge program, in that it's a high production volume?

DR. KROWECH: Yes. And so that's where there's a summary of data in there, yes.

PANEL MEMBER WILSON: Okay. Thank you.

ACTING CHAIRPERSON LUDERER: Dr. Quint.

PANEL MEMBER QUINT: I guess what's most -- this is Julia Quint. What's most intriguing to me, in the

information you presented, is the in vivo findings from the group from Davis, and the effects in whole -- what are they snails?

DR. KROWECH: Yes.

PANEL MEMBER QUINT: -- that wouldn't have been picked up in the endocrine disruptor screening program by EPA. The fact that these don't have direct effects, and so the binding to the in vitro studies that EPA is using in the screening program would not have picked up this particular chemical, that you see the result. They have the same results, probably a different mechanism, but would not have been picked up.

So I think that that's intriguing and repeated both for the estrogen effects agonist effects, as well as testosterone. So those are quite compelling. And it seems to me that -- yeah, I guess two things, that it really makes it a much more, you know, compelling reason to biomonitor for something like this, and also whether or not there would be -- would it be appropriate to communicate to EPA from this program that this chemical has been under discussion, and we are aware that -- of this particular finding. It's in the literature. I mean, it's in the paper, that it would have been missed or will be missed in the screening program.

But I think it's really important when we find

things like this, and there is active discussion of these chemicals, that there be some sort of communication between California Biomonitoring and EPA, that, you know, this is something that they should pay attention to and it's something that came up in a discussion of one of our chemicals or something like that.

So it's not -- you know, it's just a comment. I think it's really important to have that sort of interaction around these findings, because they're potentially a significant public health -- they are of significance, in terms of public health protection.

ACTING CHAIRPERSON LUDERER: Any more questions from Panel members at this time?

Okay. We will then move on to public comments. I have received notice that there's one public comment, are there additional public comments?

MS. DUNN: There's two more

ACTING CHAIRPERSON LUDERER: So we have three all together.

Okay. We are, let's see, running about 10 minutes ahead of schedule, at this point, by my watch. So I think we probably have time for all three to give their full comments as long as we stay within about a 20-minute comment period okay.

Sara, did you have a comment?

MS. DUNN: You can just call the person who I gave to you.

ACTING CHAIRPERSON LUDERER: I'll call the first person. So our first public comment is from Mr. Carl D'Ruiz, from the Henkel Consumer Goods, Incorporated.

MR. D'RUIZ: I have a presentation. Thank you, OEHHA, and the Panel for allowing to us speak.

In the interest of product stewardship, we have gotten together with our supplier of the ingredient. And since we are a manufacturer of the consumer product have decided to present some data, which may be useful in your assessment of the exposure of this chemical within the products that's being sold, as well as -- I'm moving over.

(Thereupon an overhead presentation was Presented as follows.)

MR. D'RUIZ: Hello. So anyway, I thought it would be essential for us to, in the interests of transparency, in terms of involving all the stakeholders, provide you with information from the horse's mouth, in terms of what we know about the chemical, so that you can make better and more informed decisions.

My background is public health. I've been in the business 25 years. I've been a regulator at EPA. I've worked in the industry for 20 years with chemicals and pharmaceuticals and consumer products. This presentation

is a collaboration between myself and my colleagues, which are listed here and are available, if you need to speak to them.

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MR. D'RUIZ: Just some background on the regulatory status. Triclosan -- I'm sorry, TCC has been used for over 40 years. World wide it hasn't had any adverse effects to my knowledge.

In the United States, TCC is primarily regulated by FDA, under the Tentative Final Monograph or Topical Antiseptic OTC drug products. As such, the indication is to reduce bacteria on skin. It's an OTC product, therefore it must conform to having the ingredient manufactured on the good manufacturing practices, in accordance to United States Pharmacopeia standards of purity.

Extensive information has been made available and exists on health and environmental impacts -- effects of TCC. This, of course, was submitted to the EPA under the High Production Volume Program, and other agencies throughout the world.

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MR. D'RUIZ: TCC has been reviewed for safety globally through European Union Scientific Committee on Consumer Products, SCCP, concluded in 2005 that the use of

TCC for non-preservative purposes in cosmetic rinse-off hand and body care products up to a maximum of 1.5 percent, does not pose a direct risk to the health of the consumer.

Additionally, it's approved as a cosmetic preservative. And the EU at a .2 percent, and Switzerland also at .2 percent. And in the Japanese cosmetic standard, it's listed as a preservative at .3 percent for leave-on products with no specified upper limit for rinse-off products.

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MR. D'RUIZ: Some information on the use and exposure potential. In the U.S. it's used primarily as an ingredient in antibacterial bar soaps. It's use in deodorants is less than one percent. The ingredient labeling for cosmetics, which deodorant is, is regulated by FDA. And any product which does include TCC as an ingredient would be captured under the ingredient listing, under the INCI name, which is the International Nomenclature of Cosmetic Ingredients, name provided, which is triclocarban.

The product import volume 2005 to 2010, filling in the gap that you noticed before, is less than 500,000 pounds. This has been steadily declining since the onset of the HP -- the high production volume program at EPA,

which had a limit of one million pounds in the nineties. So we're looking at this as being steadily a decrease in use.

Primary human exposure data via personal care products indicates acceptable margins of safety. We have provided a paper looking at the exposures and the margins of exposures looking at worst case scenarios for bar soaps, and have provided that to the Panel, as something to look at, which presents a range of product use, and the margins of exposure that can be encountered given current use.

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MR. D'RUIZ: In terms of environmental occurrence, it is found in surface waters. It's sufficiently removed by wastewater treatment plants at a level of 88 to 97 percents. Low levels in effluent of one part or less. One part per billion. It's removed in sewage sludge, 76 is sorbed into sludge, TCC is biosolids-bound, that means not available.

Biosolids land application results in low parts per million levels. We calculate .21 milligrams per kilogram of soil. Those can be found, in terms of exposure estimates, that we use in our paper, which is in the pack, if you need to see it.

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MR. D'RUIZ: Known or suspected health effects. Reproductive effects at high doses in animals. Testing has been conducted. No effects at 1,000 milligrams per kg per day. No observable effects level is 25 milligrams per kg per day, which is sufficiently lower or much lower than can be anticipated, in terms of product use in bar soaps.

Endocrine disruption. Cell culture experiments are not considered representative of exposure levels. Possible presence of chloroanilines, low levels of chloroanilines in USP grade of TCC. I believe FDA in the monograph specifies a limit of 300 parts per million for chloroanilines, in order to be used as an ingredient for topical antibacterial soaps. And that's a level which has been incorporated by United States Pharmacopeia, which has monograph on TCC.

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MR. D'RUIZ: Persistence half-life, depends on the soil. Bioaccumulation, I think, for aquatic organisms, we're looking at BCF of 137 in fish. Terrestrial organisms we're looking at BCF of 5 to 20.

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MR. D'RUIZ: In terms of pharmacokinetics and metabolism. We have observed low dermal absorption from rinse-off products at the .1 to one percent max level, given some studies that have been conducted in the

industry.

It's metabolized to the glucuronide metabolites excretion, as we had noticed primarily in the urine.

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MR. D'RUIZ: Biomonitoring. TCC is eliminated through the urine, not retained in the body. TCC levels in blood anticipated at low part per billion levels. I believe in 1975, Scharpf conducted a study showing a level of 10 parts per billion in blood, given that the production has gone down at least half fold from that data, we can probably see a mirroring of that as well.

Not detected in breast milk to any of the public literature that is available. We were made aware of the UC -- University of California at Davis study just recently, when we saw the presentation. So we haven't had the ability to look at that in detail, so can't comment at this point.

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MR. D'RUIZ: Okay. So conclusions. It's been around for 40 years. Safely used around the world. Extensive data is available not only in the U.S. under the High Production Volume Program. Data has been submitted to FDA on the efficacy and safety under the rule-making for topical antiseptic antibacterial products. That rule making is still ongoing.

They are evaluating the efficacy. The last time they evaluated that was 2005 where they had an expert panel convene and look at the benefits. Data has been submitted by industry in 2008, which was not considered in their press release of about a month ago.

That information should come out in their next rendition of the monograph, which will be in the spring of 2011. So we hope that, at that point in time, that information will also be considered. And if any further information is required, the industry will respond as appropriate.

Several authoritative bodies throughout the world have looked at TCC and have concluded that the ingredient is safe up to a level of 1.5 percent. In soaps you will find it commonly used .6 percent, if it's going to be used. And that predominant use, we're looking at 99 percent of the use. If it's used as a cosmetic ingredient a preservative or deodorant effect, it usually is at a level of .3 percent or lower. And that, of course, will be disclosed in the ingredient listing per the regulations, under cosmetics for FDA.

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MR. D'RUIZ: Again, the use is not as widely as it may have commonly been thought. It's not used in liquid hand soaps. It's not used in any other than in bar

soaps at the moment. And that's the 99 percent probability. Eliminated from the body.

Endocrine disruption from in vitro systems are very difficult to extrapolate to humans. This is an emerging science. We are trying to put our hands around this, and look at this. But the toxicological endpoints, which are the reproductive and development studies, do not show any adverse effects.

So our conclusion, in terms of our perspective, is that TCC should be a low priority for biomonitoring, based on the low annual volumes, which are decreasing, low consumer exposure, and acceptable margins of exposure.

And we also note that FDA is in the progress of conducting a rule making on this, and they will be active within the next six months or so and presenting another rendition of the monograph, which will summarize our thoughts in terms of safety and efficacy.

So that being said, thank you so much for your time.

ACTING CHAIRPERSON LUDERER: Thank you very much Mr. D'Ruiz. We have two additional public commenters. Mr. Davis Baltz from Commonweal is present. So if you'd like to come up and give your comment now.

MR. BALTZ: Davis Baltz with Commonweal.

I would just like to make a couple of comments

and reaction to the industry presentation. You know, we know of many chemicals that have been used for decades, with claims of their safety that have subsequently proved to be problematic. And I'm not necessarily saying that TCC is going to be one of those when all is said and done.

But we do need to look at evidence and research over time. And I think the staff presentation earlier today did point out some endocrine disrupting properties of TCC that the industry representative Mr. D'Ruiz did not mention, specifically the in vivo studies in rats.

So I would just encourage the Panel to list TCC as a designated chemical. It clearly meets most, if not all, of the criteria that you're charged to consider when considering whether to designate a chemical. And I think it would be a valuable addition to the designate chemical list.

Certainly, it would be another step to prioritize it, but we don't want to lose something that might be problematic now by failing to designate it.

Thank you.

ACTING CHAIRPERSON LUDERER: Thank you very much, Mr. Baltz.

We have one final comment, which was submitted by Email. And the commenter is Mr. David C. Steinberg from Steinberg & Associates.

And his comment reads, "I am the author of the book Preservatives For Cosmetics. TCC is rarely if ever used as a preservative in cosmetics. It is an active ingredient in deodorant soaps, which are regulated as over-the-counter drugs. It is mandatory to label this in the active ingredient section of the Drug Facts pane. Finally, it's use is decreasing."

So that's -- and that's the end of the Email comments.

Are there any additional comments that have been received in the interim?

MS. DUNN: No.

ACTING CHAIRPERSON LUDERER: No.

Okay, then I'd like to open this up again for Panel discussion? Do Panel members have any comments or questions?

Dr. Culver.

PANEL MEMBER CULVER: What I was wondering -- oh, that works better.

(Laughter.)

PANEL MEMBER CULVER: I was wondering whether Mr. D'Ruiz would feel that the biomonitoring information about the product would be helpful for product stewardship or detrimental to product stewardship?

MR. D'RUIZ: Good question.

Every product has a benefit and a risk. If we look at the benefits of the product, it's up to the Government to determine whether or not the benefits are more -- outweigh the risk.

From a biomonitoring perspective, the data, at least as far as we see it, does not indicate it should be a priority chemical, given other chemicals, which may be more important to study from a health perspective.

We have no indication of over 40 years of use that this chemical has been problematic. The endpoint, in terms of reproductive and developmental data, clearly show that there are no toxicological adverse effects associated with the use.

So from that perspective, it does not seem to be a high priority chemical. And if you will consider it, perhaps it should be a low category for future consideration within the next year or so, given all the activity that's currently ongoing with the rule-making within the federal level.

ACTING CHAIRPERSON LUDERER: Dr. Solomon.

PANEL MEMBER SOLOMON: Yes, don't go away. I have another question.

(Laughter.)

PANEL MEMBER SOLOMON: I was very interested in the data suggesting that the use of triclocarban has been

declining over time. And so I was just curious what, if anything, is replacing it in bar soaps? What's sort of behind the decline in use in the market?

MR. D'RUIZ: Maybe the supplier knows a little bit more about that, since they deal with all the purchasers of the product.

To my knowledge, AB soaps comprise about 30 percent of all bar soaps. So there's been a steady decline in the use of AB bar soaps over a period of time. That might be contributing to it.

But Luanne -- this is my supplier from LANXESS, Luanne.

MS. JERAM: Hi. Luanne Jeram from LANXESS Corporation.

As Carl mentioned, I think overall the market as I understand it, is just the use of bar soaps, in general, are declining. And then, in this case again, only 30 percent of that would be the antibacterial bar soaps.

So more popular are liquid soaps, that sort of thing. So I think that's why we're seeing a decline in the use of TCC overall.

ACTING CHAIRPERSON LUDERER: Dr. Quint.

PANEL MEMBER QUINT: Hi. This is Julia Quint.

I guess a couple of questions. You mentioned a couple of times -- and I want to congratulate the industry

on, you know, developing data that's submitted to EPA under HPV. There were no details in your slides about the information submitted to the studies, particularly the two generation reproductive development study that was submitted.

About, you know, how much was administered, that sort of thing. Do you have any of those details? You don't have to give me a lot of detail, but I'm just wondering if you have any information about those -- that study since it was negative.

MR. D'RUIZ: We don't have them with us, but we'll be more than happy to provide those to you.

PANEL MEMBER QUINT: Yeah, that's fine.

MR. D'RUIZ: It's under the HPV program if you look at EPA.gov.

PANEL MEMBER QUINT: Right, and I could look that up. But I also was very interested in the fact that you had not yet reviewed the Davis study, which, you know, you said the in vitro studies, in terms of endocrine disruption were not relevant, in your opinion, to humans, but there is this in vivo study on snails by UC Davis, which I think your group has not --

MR. D'RUIZ: We've only become aware of that since the publication of the presentation on the website two days ago. So we haven't had the opportunity to look

at that.

PANEL MEMBER QUINT: Right. And I guess the one final question is we've heard. I mean, why is this chemical -- why is TCC being put into the bar soaps. It sounds like it could be left out and you could still have a great product.

MR. D'RUIZ: Well, the consumers want it.

PANEL MEMBER QUINT: Because what?

MR. D'RUIZ: Consumers want it.

PANEL MEMBER QUINT: Consumers want it.

MR. D'RUIZ: Antibacterial deodorant is the primary claim. It's also used to a lesser extent in health care facilities as far as that infection-type control.

But as I said before, bar soaps are on waning -- on the wane. People like liquid soaps. They're much more convenient, so they're shifting more towards liquid forms of dosages, rather than bar forms.

PANEL MEMBER QUINT: And the liquid soaps used for consumer products don't have antibacterials in them, is that the case?

MR. D'RUIZ: I don't know what the market is, but there are antibacterial liquid handsoaps, body washes, and there are non-antibacterial soaps as well. So there's a little bit more.

PANEL MEMBER QUINT: So we may be declining in use in the bar soaps, the AB bar soaps, but we could have -- this chemical could be in the liquids.

MR. D'RUIZ: No, because of the formulation properties, it's not soluble in liquids. So it's not the primary choice for formulating in liquid soaps, so it doesn't appear as though it's a good substitute for the other dosage form.

PANEL MEMBER QUINT: Okay.

ACTING CHAIRPERSON LUDERER: Dr. Wilson.

PANEL MEMBER WILSON: Well, in California, we're known for getting exercise Mr. D'Ruiz, so we're going to ask you to come back up.

(Laughter.)

PANEL MEMBER WILSON: We're doing some laps here.

Thank you very much for your presentation, and for answering all our questions. We really appreciate it.

You know, you can sort of get a sense from the Panel here, we're trying to get a handle on what's happening with the use of this product in the market.

And as I understand it, what you're saying is its use is declining in bar soaps, because the use of bar soaps is going down. So I guess more clearly, its use is declining in commerce, because the use of bar soaps is going down, and it's not used in liquid soaps.

MR. D'RUIZ: Correct.

PANEL MEMBER WILSON: And Dr. Solomon asked, you know, well, what is the anti -- if consumers are asking for this product, as you say, are they -- is there a substitute that's being used as an antimicrobial or antibacterial agent in the liquid soaps and is that market expanding?

MR. D'RUIZ: Well, as you know, the antibacterial soaps category is regulated by the Food and Drug Administration on the topical antiseptics monograph. In that monograph, you'll find a number of active ingredients, which can be used, either for bar or liquid use, in making the claim antibacterial. On that list you'll find alcohol, which is used in hand sanitizers. You'll find iodine povidone as well. You'll find TCC. You'll find triclosan. You'll find triclocarban. You'll find a number of other quats. That monograph has been around since 1978.

FDA is in the process of reviewing this safety for at least more than half my lifetime. We anticipate now in the next rendition that they'll split the monograph into two, one the consumer side, and the other side is the health care side.

So there will be two monographs which will come out in the spring, and we're anxious to see what they say.

And within that, we're going to see what happens with the ingredients. And, you know, they basically classify the ingredients based on category one, two or three. One is safe and effective. Category two is not safe, not effective, therefore it's banned and not available for use in OTC drug products. And the category three, which most of these ingredients are under, is not enough information to determine safety and efficacy.

And that's something to which industry has been providing data over the last couple of decades, in terms of support of both the safety and the efficacy in search of getting the category one listing for the ingredients on the monograph.

Some of those, like benzethonium chloride, are quats which may be more acceptable for use in the longer term. We don't know. That's up to FDA to determine. They're used in drug products. They're used in ophthalmology products. They're used in a variety of other antiviral products.

So it's really up to FDA to make the decision on the benefit versus the risk. And the risk and the benefit are being addressed by industry, in terms of coalition effort.

So I'm not sure if I answered your question.

PANEL MEMBER WILSON: If I could follow up that

question. Does the -- you're with Henkel. Does Henkel produce the soap or the TCC?

MR. D'RUIZ: We make the consumer bar soap. TCC is manufactured by LANXESS --

PANEL MEMBER WILSON: Right.

MR. D'RUIZ: -- who is Luanne, and also by -- it's become a commodity over the several years, and it's also manufactured by a number of Asian companies as well. So because it's regulated as a drug, it needs to comply with the United States Pharmacopeia standards for purity, in terms of consistency for drugs.

So any product that will be used for OTC antibacterial products will be USP grade, which must conform with the limits of chloroaniline and the specifications listed on the Pharmacopeia, prior to its being allowed to be used in the final drug product.

PANEL MEMBER WILSON: Right. So then as the manufacturer of the product, of liquid soaps --

MR. D'RUIZ: Bar soaps, in this case.

PANEL MEMBER WILSON: Okay, but you're also manufacturing liquid soaps as well, is that right?

MR. D'RUIZ: We make liquid and bar, yeah.

PANEL MEMBER WILSON: So where is your industry headed, I guess, is my question? Your market is expanding in liquid soaps. That seems to be, as I understand it,

the interest on the consumer side.

MR. D'RUIZ: We're interested in health, hygiene, and skin moisturization and the benefits of soap to skin, in terms of preventing disease, healthy lifestyle, and wellness. So that's our goal to which I'm helping drive the ship a little bit.

ACTING CHAIRPERSON LUDERER: Dr. Solomon.

PANEL MEMBER SOLOMON: Just one more question for you about the issue that came up earlier --

MR. D'RUIZ: Can I have a job here.

(Laughter.)

PANEL MEMBER SOLOMON: -- about potential for uptake in crops or -- you know, it does seem to be sort of an interesting outstanding question, if there is -- you know, in your presentation it indicated that there is binding in the sewage sludge, and therefore presumably the TCC would not be bioavailable. And I was just wondering what that was based on and whether you have data to back that up.

MR. D'RUIZ: Yeah. I think my colleague, Dr. Ayala, has actually performed that calculation. And Felix, would you like to -- this is Felix Ayala from Henkel. And he did the exposure assessment, which he can address that

DR. AYALA-FIERRO: Good morning. I think last

year there was the Micropol workshop in San Francisco, and we have scientists from the University of Florida, Dr. George O'Connor, who provided a presentation regarding the uptake to plants. What he did, he measured the percent leachability of how much it leaches from the soil. He presented that TCC is biosolids bound and only a .2 percent was available for leaching as free.

And when they measured the TCC in plants, he provided some bioaccumulation factors, which were very, very small, like .000 something. So based on that, he seems to ask that these are free TCC would be very small levels as free to be taken up by these plants.

So even if we assume that all TCC is taken up by the plants, somebody will have to eat -- a consumer will have to eat incredible -- huge amounts of something growing in the soil to ingest significant amounts of TCC. But in this presentation, again, the recommendation factor was small extremely small like .0002. And I think we provided some of these numbers in the document that we provided for review.

PANEL MEMBER SOLOMON: It would be actually wonderful to have that study, if it's possible to get a copy of it.

DR. AYALA-FIERRO: We will.

PANEL MEMBER SOLOMON: Thank you.

ACTING CHAIRPERSON LUDERER: Dr. Wilson.

PANEL MEMBER WILSON: Thank you. Yeah, Mike Wilson. Thank you, Dr. Ayala-Fierro.

I'm still struggling with this question of, you know, we're trying to prioritize our thinking around what to do about this question of antibacterial agents in soaps. And I don't think I quite understand yet -- as I understand it, if I could restate what I heard, the liquid soap market is expanding. There's an interest in the industry in using antibacterial agents in those products.

And so I'm curious what that agent is, if it's not TCC. So either -- if either of you could answer that question or one of the three, I would really appreciate it.

MR. D'RUIZ: Industry is bound by the list of ingredients on the monograph. So that's all we've got to play with.

In addition to the safety side, there's an efficacy performance standard, which FDA has been issuing in the monograph, okay.

So since '78 -- in '94, the monograph was amended. And in the '94 monograph, the FDA said, okay, if you want to show efficacy for the products, what you have to demonstrate is a one log reduction of bacteria after first wash, and a three log reduction after the 10th wash.

Those are the current performance standards for antibacterial soaps.

Therefore, if you want to formulate or make a product, you have to meet that criteria, in addition to everything else that you have to do, in terms of making sure the chemical is appropriate for your formulation, et cetera.

So that is basically the final test, in terms of whether the product has benefit or not. So really, what the industry has been trying to do within the limited list of ingredients, is to utilize that ingredient which provides the best efficacy with the best safety profile, at the lowest cost.

So from that perspective, that's where we're at. And we're bound by the list that is given to us by the monograph.

PANEL MEMBER WILSON: You're not able to tell the Panel what the substance of -- that's of increasing use or likely to be introduced into the market.

MR. D'RUIZ: All I can say is we're evaluating all the ingredients in different proportions, and the endpoint is the efficacy standard. If it doesn't make the efficacy, then we can't use it, so it's no good. In a lot of cases, they don't make the efficacy, so you can't use it. So the ones that are being use do make the efficacy,

and that's where we're kind of stuck right now.

On the other side, we do have regular -- plain soap and water as well. And those are currently available, and they're doing well as well. So as long as we're able to meet the criteria for performance, we'll have those products available.

Should they change, then we'll adjust accordingly.

PANEL MEMBER WILSON: Thank you.

ACTING CHAIRPERSON LUDERER: Dr. Quint.

PANEL MEMBER QUINT: I don't know if this is a -- this is Julia Quint. I'm not sure if it's a question for you or for the supplier. But in the paper by the Davis Group, there was a statement that I think -- let me make sure I get it right, that TCC is estimated to be detectible in 60 percent of U.S. streams. And they give the concentrations and there's a reference. And I think -- I'm just wondering if you could comment on that, if you're aware of this aquatic -- seems like pretty widespread aquatic contamination with TCC and --

MR. D'RUIZ: Yeah, Felix is the environmental toxicologist, the public health guy and regulatory guy.

PANEL MEMBER QUINT: Okay.

DR. AYALA-FIERRO: Yes, you're correct. TCC is detectible in the influents in concentration, worst case

scenario up to five parts per million micrograms per liter, but is removed by the wastewater treatment plant up to 98 percent. So based on that, the TCC concentration, in this case, would be effluent water. After they come out from the wastewater treatment plant, they will be in the parts per billion range.

Recent data, and there is one study here from California, they measured TCC in water reuse up to .22 parts per billion. These are very low levels of triclocarban. And what it shows is the concentration after you go through the wastewater treatment plant, it will be removed. It will be sorbed into the sludge, up to 76 percent, I think that's the data that is publicly available. So based on that, it would be in the sludge, but it would not be in high concentrations in the effluents.

PANEL MEMBER QUINT: Yeah, I guess we'll have to wait your -- you know, when you look at the Davis study, but I think the importance of the study, with the Davis study, was showing that at environmentally relevant concentrations, we were having these in vivo effects. So that is the primary concern here, that these are not really high concentrations. These effects on estrogen, in this case, are happening at environmentally relevant concentrations, that could be, you know -- that, you know,

so far, we're seeing those levels in streams, in a lot of streams.

DR. AYALA-FIERRO: Well, last year at the ACS meeting, the Chemical Society meeting in Washington, we presented a talk, and with it a risk assessment. And based on the SSD, which is the Stability Distribution, which takes into consideration all the different species, vertebrate, invertebrate. And we do a PNEC -- the PEC versus PNEC ratio which is an acceptable number for risk assessment the environmental concentration to the no effect concentration ratio.

And we found that there were significant -- based on those numbers, the potential for diverse events will be low. And this was again presented at the ACS meeting in Washington in August at the 238th meeting, and we can provide a copy of the presentation.

PANEL MEMBER QUINT: Thank you.

ACTING CHAIRPERSON LUDERER: Dr. Solomon.

PANEL MEMBER SOLOMON: Just one more question about the studies. I'm a little confused about who did which study, but there's the Chen et al. study published in 2008, which is a rodent assay. And it was a whole animal study looking at male sex accessory organ weights in rats exposed to testosterone and triclocarban separately and together.

And so that was a study that kind of interested me, because it's not just an in vitro assay. And I noticed in your presentation, Mr. D'Ruiz, that you said that, you know, in vitro assays aren't relevant. And, you know, I actually put some stock in in vitro assays, but when there's also an in vivo assay in rodents and an in vivo assay in snails, it begins to add to the overall data set. Just wondering if you have a response to that.

DR. AYALA-FIERRO: Yeah, I think that paper was from Chen at al. 2008. In here they have a combination of in vitro system and in vivo system. And in the in vivo system, he used the Hershberger assay on castrated rats.

And the data was very interesting. We previewed the data and we considered that we should continue working with our supplier and see if we can expand that study. One of the things that we found in this paper is that TCC by itself did not affect the body weight, but it did affect the weights of androgen sensitive tissues such as seminal vesicles, the Cowper glands, the levator ani-bulbocavernosus muscles.

So there were some effects. There were not effects on the body weight itself, but there was some potential effects. We wanted to see what could be -- how to explain those effects. And we wanted to work and see if we could expand that research to answer some questions

we have, and hopefully we can do that soon.

ACTING CHAIRPERSON LUDERER: Do any Panel members have additional questions?

PANEL MEMBER BRADMAN: I have one brief question for Mr. D'Ruiz.

Just briefly, back to an earlier question I had, are any of the bar soaps here marketed for use with young children? And have there been any studies looking at uptake in exposure in young children or any relevant information on that and differences in metabolism?

MR. D'RUIZ: To my knowledge, I'm not aware of any study of that nature. The OTC drug fact indication does clearly state keep out of reach of children. So the product should be supervised by an adult in application. So I'm not aware of any children's studies on that.

PANEL MEMBER BRADMAN: So a bar soap would say on the packaging keep out of reach of children and --

MR. D'RUIZ: Yes, it would -- as an OTC drug facts in the back panel, it will say keep out of reach of children.

PANEL MEMBER BRADMAN: So it shouldn't be used with children?

MR. D'RUIZ: Unless under adult supervision, right.

ACTING CHAIRPERSON LUDERER: Dr. Quint.

PANEL MEMBER QUINT: Julia Quint. I'm just -- that's fascinating to me that a commercial bar soap would be -- that's brought into the home, would be specified as not be used by children. So that's very interesting. I've never seen that labeling. I don't know if you meant to --

MR. D'RUIZ: If you look at all OTC products, they have the same labeling.

PANEL MEMBER QUINT: What's OTC?

PANEL MEMBER BRADMAN: Over-The-Counter drug.

PANEL MEMBER QUINT: Oh, so that's in the fine print somewhere?

MR. D'RUIZ: No. Over-the-counter drug products are what you get.

PANEL MEMBER QUINT: Oh this is -- oh so none of these soaps are sold as --

MR. D'RUIZ: Well, they're over-the-counter drug products, in that they don't require pre-market approval --

PANEL MEMBER QUINT: So if I went into a store, where would I find a soap with TCC.

MR. D'RUIZ: You'll find it in the soap bar section.

PANEL MEMBER QUINT: In the soap bar section with the other bar soaps?

MR. D'RUIZ: Yes, in the antibacterial section.

PANEL MEMBER QUINT: Okay.

PANEL MEMBER BRADMAN: I think what you're saying though as an OTC, like, for example, infant Tylenol would probably say keep out of reach of children, but you would use it with children.

MR. D'RUIZ: Right.

PANEL MEMBER BRADMAN: So it's not that it's not to be used for children, but that didn't quite answer my question though. Are any of the these bar soaps marketed for --

MR. D'RUIZ: No. No, we don't specifically target children.

PANEL MEMBER BRADMAN: Okay, but it could be used with children.

MR. D'RUIZ: We do a safety assessment indicate -- which is a toxicological assessment indicating it's good for family use. I think -- Felix, do we have any -- Felix, do we have any data on children?

DR. AYALA-FIERRO: In the product safety group, we do safety margins for the different populations. We will -- we use the intra and then the interspecies extrapolation. And we take different unknown factors like based on potential difference in drug exposure by kids versus the adults, differences in potential ADME,

metabolism absorption distribution in adult. And also the difference in size in adult. And when we do all this recalculation, we find that it is still -- all the margins of exposure are still acceptable.

But we've taken into consideration all the different -- all the differences in the different population groups, including not only children, but also in the elderly and other potential subpopulations.

ACTING CHAIRPERSON LUDERER: Dr. Quint.

PANEL MEMBER QUINT: This is Julia Quint. I really didn't finish. That was just an aside comment about the over-the-counter soaps.

I guess we haven't talked about the residual chloroaniline content of TCC, which I understand when the compound is degraded, you also get chloroanilines released from TCC. And, you know, it's a carcinogen. And I think that we -- while we have appropriately probably concentrated on the endocrine disrupting qualities of TCC, we should -- I don't know if you have any comments.

I know Sigma, one of the companies that in the materials safety data sheet lists it as a carcinogen and a mutagen, possibly because of chloroaniline content. Probably, it contains at least a tenth of a percent for them to put it on the materials safety data sheet.

So do you have any data, in terms of TCC

concentrations in bar soaps when that is degraded, whether or not -- what is the chloroaniline release from that use of the product -- or from that product use or category?

DR. AYALA-FIERRO: The answers provide data based on the specs for TCC. Based on that information, I think the levels are in the low parts per million -- parts per billion to low parts per million range. The level is specified in the U.S. EPA and the monograph, but we don't have any data for the finished product.

Regarding the MSDS, since it is considered a carcinogen, I think OSHA only requires up to .1 percent in the finished product to be listed. So under these conditions, it would not be listed, but it can be provided as additional information in Section 15 for regulatory information.

Also, it is listed by California Proposition 65. It would require industry to do a consumer safety assessment for that contaminant just to comply with the warning for consumer products for this special warning statement, like the presence of certain ingredients may cause cancer or developmental effects. But at that low concentration, I wouldn't expect it to be high enough to represent a risk.

But we don't have -- to answer your questions, we don't have the actual level for a finished product. We

use data for the active ingredient itself as the information for us to decide what else we need to do.

PANEL MEMBER QUINT: So the Sigma thing is just to comply with the Prop 65 warning and doesn't mean that it's present in at least a tenth of a percent of the product is what you're saying?

DR. AYALA-FIERRO: That's correct.

PANEL MEMBER QUINT: Thank you.

ACTING CHAIRPERSON LUDERER: Dr. Wilson.

PANEL MEMBER WILSON: Mike Wilson.

What is the price differential for these products versus those that don't contain the antimicrobial or antibacterial substance is my first question. And the second is, if following up on Dr. Quint's point, if we go to that section of the market and -- or of the store and pick up a liquid-based soap that is marketed as an antibacterial soap, what are we going to read on the label?

MR. D'RUIZ: I know a lot, but I'm not sure about the marketing pricing scheme for these products. I can't answer that first question.

The second part was, what do you expect on a label?

PANEL MEMBER WILSON: Well, my first question has to do with why it is that the product is on the market.

And if it has -- you raised the question of efficacy, we understand that there is no efficacy here. And, in fact, there's a problem potentially with the use with children.

MR. D'RUIZ: No.

PANEL MEMBER WILSON: And so I'm trying to get a handle on what's the motivation for this product to be on the market? That's the first question.

MR. D'RUIZ: The motivation is to reduce bacteria on skin to a more effective level than regular soap.

Okay, and we're looking at the FDA criteria of a two log reduction after the first wash and a three log after the 10th wash. So that is the monograph level for efficacy, in terms of the benefit, of reducing bacteria on your skin, which may cause disease.

On the other side, you have the in vitro data, which is a time kill data, which shows a log reduction of specific organisms, which have been known -- E. coli, salmonella, shigella, et cetera, which are known to transmit diseases to humans.

And you do have a percent log reduction, in our case 99.9 percent, or better under the test conditions in vitro for showing cidal activity. So if you can demonstrate that then from a public health perspective, you have a soap product, which is superior than that of plain soap, in that it can be demonstrated through in vivo

and in vitro testing that is more beneficial for reducing potential harmful bacteria on skin, which may lead to disease.

And that's the ultimate benefit of the product. It is used in health care settings. It has quelled nosocomial infections in hospital units. There's no doubt that it is effective and it is a remedy of choice for reducing infection in high-risk settings.

So your situational risk will come into play, in terms of when you are exposing yourself to potential organisms, which may cause disease. If you need to add an extra measure of safety caring for old -- elderly people, sorry, or pets, or changing diapers, you might want to take that extra level of defense and protect yourself from those potential bacteria on your hands. That's the ultimate benefit with these products from a public health perspective.

PANEL MEMBER WILSON: And then the second was with regard to the ingredient label for the liquid soap, what is it that we would read?

MR. D'RUIZ: It's the same labeling, antibacterial.

PANEL MEMBER WILSON: But in terms of the ingredient disclosure, what is it that we would read?

MR. D'RUIZ: The ingredient disclosure is the

antibacterial agent, right?

PANEL MEMBER WILSON: And?

MR. D'RUIZ: It can be triclocarban. It can be benzethonium chloride. It can be triclosan. It can be iodine. It can be alcohol. They can see benzalkonium chloride active ingredient. Purpose, antibacterial. To reduce bacteria on the skin is the indication. That's the monograph prescribed. So that's mandated by law.

PANEL MEMBER WILSON: Okay, thank you.

PANEL MEMBER SOLOMON: I just had a quick follow-up question. So are you saying that solid bar soaps containing triclocarban are used in hospitals to stop outbreaks of nosocomial infections?

MR. D'RUIZ: No, I was speaking about liquid hand soaps, in terms of the category.

PANEL MEMBER SOLOMON: So not triclocarban then.

MR. D'RUIZ: I'm not -- I don't know the data there as well as I do for other ingredients.

PANEL MEMBER SOLOMON: Okay, so -- because it was a little confusing, because you seemed to be implying that --

MR. D'RUIZ: Yeah, I'm sorry. It was the category as a whole.

PANEL MEMBER SOLOMON: -- triclocarban had successfully stopped nosocomial infections in hospitals.

MR. D'RUIZ: No, triclosan has, but not --

PANEL MEMBER SOLOMON: Okay. And -- all right. And then in terms of the demonstration of efficacy that you were describing, that's data that industry has provided to FDA, but FDA is still considering triclocarban to fall into the category of not demonstrated to be effective or safe.

MR. D'RUIZ: I think all the ingredients other than alcohol are category three at this moment.

PANEL MEMBER SOLOMON: Okay.

ACTING CHAIRPERSON LUDERER: We are behind schedule at this point by about 20 minutes. So I guess one question I have is whether the Program would like the Panel to come to a conclusion regarding our recommendation about designation on triclocarban at this time.

MS. HOOVER: Sara Hoover, OEHHA.

I mean, it's up to you. You can either make the decision. We don't have a lot of spare time in the agenda today, as you probably noticed. So, you know, if you want to request a motion, you can do that or if you want to postpone and bring it back, you can also do that. So it's really up to the Panel.

ACTING CHAIRPERSON LUDERER: Well, then I will turn to the Panel and ask whether any of Panel members, at this time, would like to make a motion?

And if not, we can put this -- the designation question off to a subsequent meeting.

Dr. Quint.

PANEL MEMBER QUINT: I would like to move that we add tri -- I can't even say the word now, TCC to the designated chemical list or added as a designated chemical for the Biomonitoring Program.

ACTING CHAIRPERSON LUDERER: All right. So we have a motion from the Panel to recommend that triclocarban be added to the designated chemicals list for the California Biocontaminant Environmental Monitoring Program. I think I just said it wrong.

Do we have any seconds for that motion?

PANEL MEMBER SOLOMON: Sure, I will second that. This is Gina Solomon.

ACTING CHAIRPERSON LUDERER: Okay, we'll take a formal vote then at this time or do we --

PANEL MEMBER SOLOMON: Discuss it.

ACTING CHAIRPERSON LUDERER: Do we have any additional discussion from any Panel members regarding the motion.

Dr. Solomon.

PANEL MEMBER SOLOMON: Yeah, this is Gina Solomon.

You know, this is an interesting chemical. The

reason that I think that it's worth putting on the designated list, at this point, is that we do have pretty good information that it's in consumer products, that there is some skin absorption, that there is some, you know, environmental contamination. And we don't really have a good handle on the magnitude of any of those issues.

In fact, you know, in this discussion, it's really been clearly shown that there's quite a bit of dispute about how much is really getting into waterways, how much is really potentially bioavailable in, you know, through sewage sludge and food crops, how much is really getting, you know, absorbed from consumer use.

And yet those are all extremely important questions. And there are various ways to go about looking into those. Obviously, I would recommend that somebody go out there and test food crops, for example.

But within our purview is the possibility of including this in some, you know, biomonitoring efforts to get a better handle on human exposure which has, you know, as I understand it already been demonstrated, you know, in some very small studies.

And the presence of endocrine disrupting, the sort of interesting magnifying effect on both estrogens and androgens is to me very, very interesting finding and,

you know, suggestive of something that we would want to, you know, a chemical that we would want to look at, because it would seem not just in vitro, but also in several in vivo studies.

So there obviously needs to be more work looking at that -- you know, those endocrine effects per se in lab animals and so forth. But it's enough to put it into a category where I'm not sure. You know, I'm not sure if we're going to want to designate it as a high priority for the Program, but I think we should put it into a category where it's a designated chemical, which I consider to be almost like, you know, the watchlist. The ones that we will look at if we have opportunities or if it can be bundled with other phenols in a, you know, laboratory analysis.

ACTING CHAIRPERSON LUDERER: Are there any additional comments from Panel members, any discussion?

Dr. Bradman.

PANEL MEMBER BRADMAN: Well, just a question. It's really discussion and it's not really specific to biomonitoring. But, you know, one concern I have about antibacterials is that they may provide potentially, although we're not clear it's true for this compound that there's, a public health benefit, in terms of maybe reducing skin bacteria, but there's also these materials

may breed, you know, super bugs like MRSA. And when we think of the risks associated with them, we maybe need to think more broadly than just the immediate toxicological effects.

And since these things are used on a widespread basis, it's important to understand, you know, how large a portion of the population is using them, and what the exposures are, and then we also need to think more broadly about what the public health implications are.

ACTING CHAIRPERSON LUDERER: Any additional comments from Panel members?

Then I think -- Dr. Wilson.

PANEL MEMBER WILSON: I'm sorry. Yeah, Mike Wilson. You know, obviously from my line of questioning to the industry representatives, I was, you know, very interested in knowing what is the emerging antibacterial that's in these products, in the liquid products. But I think it makes sense again here to designate this substance for the Program, in that it's -- the population-wide exposure is likely in the millions, you know, in California alone. And there's enough information to be of concern here.

And I think we're going to -- hopefully, we're going to get more information on chemical ingredient and product ingredient disclosure in California, and on the

use and distribution of chemicals and chemical products in the State as the Green Chemistry Initiative rolls along and that process sort of comes into effect.

And so I think it makes sense to designate it at this point for that reason.

ACTING CHAIRPERSON LUDERER: Dr. Solomon.

PANEL MEMBER SOLOMON: Sorry, just one more addition. I think that the information from industry is very useful. And the additional information that we've requested today would also be helpful, in terms of figuring out if this is or isn't something that we would want to prioritize, because I think that there -- you know, there certainly is a question about that and some more information that we would need, if we were going to decide to really put, you know, a lot of resources behind making this a high priority for the program.

So I would say that that information would still be something that I would want to see. And so I'm hoping that we can gather that.

ACTING CHAIRPERSON LUDERER: All right, thank you.

Then if there's no further discussion from the Panel, we have a motion and a second that the Panel recommends designation of triclocarban. So we can, at this point, take a vote.

So I'd like to start with Dr. Quint?

PANEL MEMBER QUINT: Yes.

PANEL MEMBER SOLOMON: This is Gina Solomon. Yes.

PANEL MEMBER WILSON: Mike Wilson. Yes.

ACTING CHAIRPERSON LUDERER: Ulrike Luderer. Yes.

PANEL MEMBER KAVANAUGH-LYNCH: Mel Kavanaugh-Lynch. Yes.

PANEL MEMBER CULVER: Dwight Culver. Yes.

PANEL MEMBER BRADMAN: Asa Bradman. Yes.

ACTING CHAIRPERSON LUDERER: Okay. We have a unanimous vote from the Scientific Guidance Panel recommending designation of triclocarban.

At this point, we will now take our lunch break. We were scheduled for a one-hour lunch. Is that still -- we're about a half hour behind at this point.

MS. HOOVER: I think it would be great if we could maybe try to get back in 45 minutes instead. I know a half hour is always too short. Also, to let people know there's a cafeteria now on the second floor very close by. There's also a couple of lunch places directly behind where you can get sandwiches and salads.

So you can make it a quicker lunch break than we normally do. That would be great. So can we say 1:45

then to start back.

ACTING CHAIRPERSON LUDERER: All right, we'll reconvene at 1:45.

(Thereupon a lunch break was taken.)

AFTERNOON SESSION

ACTING CHAIRPERSON LUDERER: Yes. Now, we're ready. Okay, I'd like to welcome everyone back. I hope you all had a good lunch. I'll call the meeting back to order.

And the first presentation for the afternoon is going to be given by Amy Dunn, who is a research scientist with OEHHA. And she's going to present an overview of the Draft Public Integration Plan for the Program.

(Thereupon an overhead presentation was Presented as follows.)

MS. DUNN: Good afternoon. As Dr. Luderer said, I'm here today to provide an overview of the Program's plan for bringing the public into Biomonitoring California.

The draft plan I'll describe has been developed over a fairly long period of time, with staff from both OEHHA and the California Department of Public Health working on it. And although I'm making the presentation, CDPH staff are here and available to answer questions if you have some on portions that they worked on.

I just want mention that it might seem a little strange to be talking about a plan, when we're a few years into the program. But really what the plan does, is it makes explicit the kinds of activities we have been doing

and expect to be doing in the future, which gives an opportunity for the public to kind of engage with us and make sure we're on the right track.

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MS. DUNN: This is an outline of what I'm going to cover today. First, I'd like to provide some background on the direction from the legislation with regard to involving the public in the Program.

I'll also briefly describe some current and previous activities intended to involve the public in the program. Then I'll go through the structure of the draft plan and give some examples of the types of activities we'll be carrying out to achieve the goals that we've developed. Finally, I'll go through a timeline of the plan's development from today forward.

I want to emphasize that the purpose of providing the overview today is to begin a process of dialogue on the plan and that the plan is a draft. We welcome your suggestions and ideas on all aspects of the plan. I'd also like to just mention that the name of the plan, the Public Integration Plan, was developed a couple of years ago when we first started down this path. And our intention was to convey that the public would be brought into all aspects of the Program's activities. And it's already been called to my attention that the term might be

misunderstood by some people. And we really have complete openness to having the best possible name for the plan. So we welcome your comments on that.

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MS. DUNN: I'd like to start by providing some context for the plan's development. The enabling legislation, Senate Bill 1379, directs the Program to use the principles of CalEPA's Environmental Justice Strategy and Action Plan to guide our activities.

The legislation also directs us to provide opportunities for community capacity building and meaningful stakeholder input.

In carrying out all Program activities, we are directed to accord the highest respect and value to every individual and community, and to promote equity and afford fair treatment, accessibility and protection to all Californians, regardless of race, age, culture, income, or geographic location.

The sections of the legislation related to Environmental Justice and to involving the public in the Program are in Appendix 1 of the overview document, which is in your packets and is in the back of the room.

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MS. DUNN: The legislation mandates that the Program create a framework for integrating public

participation into the Program. As part of this, we're directed to develop a plan and strategy for bringing the public into the Program. The draft plan we're discussing is intended to address this mandate. We are to provide materials and carry out activities that are culturally appropriate. Our reports on the findings of our biomonitoring efforts are to be made in a manner understandable to the average person.

We're directed to provide individual results to participants if they request them.

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MS. DUNN: As the Panel is aware, from the beginning of the Program, we've made an effort to engage the public. For example, we have tried to encourage participation in Panel meetings by webcasting whenever possible, and providing the opportunity for remote viewers to comment during the meeting, as we're doing today. We've also made sure that there's time for public comment on each agenda item at each meeting.

Early on, we carried out a campaign to encourage public input on chemical selection for the Program and to build awareness.

This included three workshops -- this included workshops held in three locations around the State. Three teleconferences and an on-line survey. The survey was

focused on chemical selection issues.

We've also built a website and made efforts to encourage people to subscribe to our listserv. The listserv now has approximately 600 subscribers. As the Program has begun to carry out pilot projects, these have included efforts to engage local communities in the projects.

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MS. DUNN: Drawing from the directives of the legislation, Program staff developed four goals for our efforts to involve the public in the Program.

The first two goals relate to the public at large, as well as to specific groups, such as study participants. The first goal is to build awareness and understanding of the Program by making information available and accessible in a timely and understandable way.

The second goal is to provide opportunities for stakeholders to contribute to program design, implementation, and evaluation.

The third and fourth goals relate to biomonitoring projects, including the pilot efforts, as well as eventually our statewide sampling efforts. The third goal of involving the public in the program is to achieve high participation rates within the target

population to be biomonitored, that is, to successfully recruit participants. CDPH, with its extensive experience recruiting participants, has led development of this goal and related activities.

The fourth goal is to communicate individual results and resources related to understanding those results in a manner that is understandable, supportive, and responsive to Program participant's concerns.

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MS. DUNN: This diagram represents the elements of the plan. Here at the top is the direction from the legislation, as I've already described, that feeds into the four goals that we've developed. What's below the goals on the diagram are the activities that the Program is carrying out or will be carrying out to achieve these goals. Underlying all of these activities are core principles of public engagement.

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MS. DUNN: These core principles for public engagement were developed by the National Coalition for Dialogue and Deliberation in collaboration with the International Association of Public Participation and others. A more detailed version of these core principles are found in Appendix 2 of the overview document.

Briefly, these seven principles reflect common

beliefs and understanding of those working in the fields of public engagement, conflict resolution, and collaboration. The first principle is to use careful planning and preparation to ensure a process -- that the process serves a clearly defined purpose, and addresses the needs of stakeholders.

Inclusion and demographic diversity are the second principle.

The third principle relates to collaboration and shared purpose, working together to advance common goals.

The fourth principle is to have an approach of openness and learning.

The fifth principle is to be transparent and carry out activities in a way that engenders trust.

The sixth principle points to making sure each participatory effort has real potential to make a difference.

The seventh and final principle is to promote an approach that supports ongoing quality public involvement.

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MS. DUNN: Turning now to examples of the activities we envision carrying out under each of the draft goals of the plan.

For goal one, building public awareness and understanding. As an example of an activity, we hope to

develop an on-line survey to assess the needs of Program stakeholders. We intend to then develop materials in response to the results of the survey, such as the kinds of information that people need from the Program.

We're also planning to move forward with modifications of the website to improve access to information.

As Dr. Das mentioned earlier, we were fortunate to have Health Research for Action at UC Berkeley review our website and provide recommendations for how it can be improved. We are already beginning to implement those recommendations and plan to do more so in the future.

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MS. DUNN: For the second goal, providing opportunities for stakeholders to contribute to Program design and implementation, we will continue and expand our outreach to groups with potential interest in biomonitoring, inviting them to join the listserv and become involved in Program activities.

We also intend to continue holding meetings in venues such as this one that have good public transit, and then webcasting to the extent possible in any venue where we have public meetings.

We're hoping to add an on-line comment form to the website, to allow those who visit the site to give us

feedback on what they find there as well as what they'd like to see in the future.

This comment form would allow feedback in an ongoing way, not only on the website content, but also on all Program activities.

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MS. DUNN: As I mentioned earlier, goal three addresses activities related to recruiting participants for biomonitoring -- for biomonitoring. Activities carried out primarily by CDPH staff.

The goal is to achieve high participation rates within the target population. The type of activities this involves, includes partnering with individuals and groups, who are trusted by the community such as health care providers and clinics, to have their input on how to approach potential participants.

Involving potential or actual participants and other community members in field tests of materials, such as focus groups or interviews is another type of activity intended to achieve this goal.

In the presentation that follows this one, on the FOX Project, you'll see an example of this type of field testing.

Initially, these activities are being carried out as part of the pilot projects, with the lessons from these

efforts expected to inform future activities carried out on a larger scale.

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MS. DUNN: The fourth goal is to communicate individual results in a manner that is understandable, supportive, and responsive to Program participant's concerns. Current efforts include testing the effectiveness of specific approaches in the pilot studies. As was mentioned earlier, we're fortunate to have the assistance of Rachel Morello-Frosch in some of these activities. These efforts in the pilot projects will then be assessed to inform our future efforts.

We also anticipate interviewing staff of other biomonitoring efforts to learn from their approaches. We'll draw on what we learn from these interviews and pilot studies to develop guidance on best practices for the Program as it moves forward.

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MS. DUNN: Here's a diagram of the projected timeline of plan development. We're here today on the left-hand side of the screen in the green box to discuss an overview of the plan and initiate a dialogue, as I mentioned earlier.

From here we intend to release a draft plan later this summer, that takes into consideration feedback we get

today, and in the next few weeks on the concepts provided in the overview. The draft plan will be sent by Email to the Panel and to those on our Program listserv.

We'll also post the plan on our website. We also intend to carry out active methods of engaging with our stakeholders, such as public teleconferences or individual interviews. These methods have not yet been determined and we welcome your suggestions.

We'll then bring the draft plan together with the comments and suggestions we've gathered to that point to the Panel's fall meeting, shown in the purple box, where there will be an opportunity for additional discussion and comment on the draft. We then anticipate finalizing the plan and posting it on our website toward the end of this year.

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MS. DUNN: So finally, we're here -- I'm here today to hear your comments and suggestions on what's in the plan overview, including general input on the draft plan and its development, the name of the plan, as well as specific suggestions related to the questions listed on this slide.

These include comments on the aspects of our efforts to involve the public in the Program that should be priorities; thoughts on effective methods for

increasing the number and diversity of Program stakeholders, ideas about what actions may work best for achieving high participation rates in biomonitoring studies; as well as your suggestions of individuals or organizations to interview for insight into effective communication of biomonitoring results.

We welcome comments at the meeting. However, given the brief time available for today's discussion, I would also like to encourage those interested here in the room and listening on the web to send us your thoughts and suggestions after the meeting via our Email address.

So thank you very much for your attention. And now I'd like to try to answer any questions you have and hear your comments.

ACTING CHAIRPERSON LUDERER: Thank you very much for giving us that interesting overview of the draft plan.

Do the Panel members have any questions or comments at this time?

Dr. Quint.

PANEL MEMBER QUINT: Thanks, Amy. This is Julia Quint. That was very thorough and looks very promising.

I noticed that from the beginning when we had meetings to get public input, that there -- we had a -- the attendance -- we were much more diverse in terms of the people who attended the meetings. And there has

been a fall off of that, in terms of, you know, public attendees at the meetings. And I'm wondering if, two things, whether or not, in addition to the on-line survey to get feedback, whether or not we could tap into some of those early participants who represented, I think, some EJ groups and other groups, and find out more specifically from them -- maybe, you know, they're no longer interested, but maybe we could use that as some source of information to find out what we could be doing a bit differently to engage them or to find out, you know, why there's no longer participation.

It's just, to me, noticeable that we don't have attendance, at least at some of these local meetings, of some of the people who attended in the beginning.

And I think the other thing is that Amy Kyle's group over at UC Berkeley did a very great workshop on cumulative impacts. And it was -- it engaged a lot of people from Environmental Justice groups and things like that. And I think she would be a good person to talk to. Rachel Morello-Frosch was there. But the people who attended that meeting were very much leaders, in terms of their communities and struggling with some of these health issues.

So I think it would be good to reach out to people like that to find out other ways to get feedback.

MS. DUNN: Thank you.

ACTING CHAIRPERSON LUDERER: Dr. Culver.

PANEL MEMBER CULVER: I think you've done a wonderful job of putting together -- you have to remind about that.

(Laughter.)

PANEL MEMBER CULVER: I think you've done a wonderful job in putting together a plan. And plans of this sort can really be only a framework or they can represent a real major endeavor and accomplishment.

Part of the degree to which that's implemented will depend upon the resources you have to do so. Do you have enough resources to do what you want to do?

And then I have another question.

MS. DUNN: Well, you know, I think there's always more that you could do than -- I mean, all right, I guess speaking for myself, there's always more that I want to do than I can do. But I think, as someone mentioned earlier, I think we've been trying to be creative and resourceful with the resources that we do have.

And I think it might be possible if we modify the website to start getting a little more engagement with people. We're hoping that that's true, because the in-person workshops are very resource intensive. And so, you know, I think if we had more resources, we might be

able to do a little more in-person outreach than we have the resources for.

PANEL MEMBER CULVER: It's either a question or a comment. The fourth slide that you showed had, as one of its last points, something that kind of struck a note that concerned me. And I'm sure it wasn't intended that it would concern me, and that was provide results to individual participants, if they requested.

You know, that's like saying well, if you want the truth, I'll tell you.

(Laughter.)

PANEL MEMBER CULVER: I think every effort needs to be made to make every participant understand what's going on, and understand their need to ask for those results and to understand those results.

I don't know whether the wording could be made a little bit differently, so that it doesn't have quite the connotation that it does, but I suggest that that effort be made to do so.

MS. DUNN: Thank you. Yes, it's, I think, probably a result of trying to take what's in the legislation and crunch it down in just a few words to be on a side, but I understand your meaning.

PANEL MEMBER CULVER: No, I'm sure it's like that.

ACTING CHAIRPERSON LUDERER: Dr. Wilson.

Dr. Das.

DR. DAS: Dr. Das, Department of Public Health. I do want to just add something to what Amy said about the fourth bullet. The legislation does require us to return results to participants if they request them. And all of our projects do also go through the Institutional Review Boards. And that is the language that we have in the protocols that go to them that we certainly would like people to get their results. But understanding that these results may be concerning to individual, we give them the option of choosing to receive their results or not.

Other studies conducted by other researchers, such as Dr. Morello-Frosch, have shown that most people do want their results. And so I think we're anticipating that most people will elect to receive them, but I think the language here reflects both the legislation and our sensitivity to people who may choose not to get their results. But we certainly understand your intent in letting people know the results in full disclosure of the information.

ACTING CHAIRPERSON LUDERER: Dr. Wilson.

PANEL MEMBER WILSON: Mike Wilson.

You really, you know, describe this challenge of how do we get the word out to Californians, and involve

the public. And I guess, you know, as Dr. Quint is saying, in a way that represents the whole, you know, sort of spectrum of California residents. And one suggestion would be through the California labor movement, that, you know, represents about 20 percent of working Californians, that are certainly a cross section, economic racially, ethnically and so forth of the State.

And, you know, the labor movement has a whole set of challenges that it's facing, and it's hard to know where this would land, in terms of priorities. But our experience, both through the labor occupational health program on campus and working with the Labor Institute in New York, has been that this issue of chemical contaminants appearing in umbilical cord blood is a very live issue among -- in the workshops that we've run that were intended to be workshops on sort of how do we integrate the concepts of green chemistry and source reduction in an occupational setting as a way to protect worker health and safety.

And at the end of those workshops, we conduct survey -- you know, a survey. And it turns out that the issue, almost hands down, among the participants, including among, you know, refinery workers in West Contra Costa county and so forth, was that appearance of, you know, the Environmental Working Group's findings of

industrial chemicals in umbilical cord blood as a labor issue and an occupational exposure issue.

And so there are, you know, ways to engage the labor movement. But I think it makes sense if we're -- if that's what, you know, we're trying to achieve a cross-section of the population and a group that could benefit from this. And also just recently this year, the U. S. sort of national labor movement has made chemicals policy reform one of its other key sustainability initiatives alongside climate change and so forth. So there's a potential of some opening there for that to happen in California.

MS. DUNN: Great, thank you.

ACTING CHAIRPERSON LUDERER: Are there other questions or comments from Panel members?

Okay. Perhaps then we can move to public comments. It looks we have one public comment, and this is from someone who's here.

Mr. Baltz.

PANEL MEMBER WILSON: He's up there too on the slide.

(Laughter.)

MR. BALTZ: Davis Baltz with Commonweal.

I'd first like to thank Amy for the presentation. And I think throughout the Program's history staff have

been welcoming of the public and have really created a lot of opportunities for people to come and participate. And so I want to just express my appreciation of that.

At the same time, I think what Julia Quint mentioned about the numbers of people and the kinds of people who are coming to comment having dropped off, it's clear that that has happened also. But I think that there's an explanation for that, that doesn't reflect badly on the Program at all.

And that is that in the first years of this program, because of the funding shortfall, it's been necessary to focus on getting the laboratory equipment in hand with the initial funding that's been raised, so that the actual testing and biomonitoring can take place. And thanks to the efforts of the program and the CDC cooperative agreement, now we see some very significant equipment acquisitions.

And the Program is ramping up. And as we've seen in the staff presentation earlier, we now actually have some data that are coming down the pike with the MIEEP program, and the new firefighters project, which we'll learn more about in the next presentation.

So I think that there are a cadre of both organizations and individuals who, while they may not be coming to these meetings, they're actually very interested

in what is happening with the California Biomonitoring Program and they are ready to be activated at the appropriate moment.

And maybe with some of these data becoming available some time soon, I mean, I certainly feel that's an opportunity on my end to, you know, reach out and contact some of these groups again and get them to come and provide input.

I think it would behoove the Program obviously to have more public participation, if you have sort of residents of California who can serve as ambassadors for the value that the Program brings to California, then of course that can translate into political support in Sacramento, which can hopefully lead to increased funding, and we can sort of -- I don't think we can necessarily call it a snowball effect, but we can create some synergies to call more attention to the Program and its value.

And then maybe, at some point, when the State's finances improve, we can actually get some more base funding and not have to rely exclusively on the efforts of the Program staff to go outside of California to find the Program funding to keep things rolling.

We all recall that a couple of years ago there was actually an effort that didn't come to fruition to

biomonitor a number of Californians who represented different interest groups who'd be interested in biomonitoring. And for a number of reasons that didn't come to fruition, but you will recall that there were about a dozen people who eagerly signed up and were sort of thought leaders in their field. So this again is another example of how I think there are groups out there who are ready to support this Program and will step forward and start to participate in some of the public outreach activities when there are things that are actually relevant and timely for them.

I'd like to echo Mike Wilson's point about the labor movement, biomonitoring having relevance for them and the umbilical cord study blood, that the Environmental Working Group did, which is a few years old now, still generates a lot of interest. And the fact that the MIEEP program is going to biomonitor cord blood, I think is another real opportunity, not only to reach out to the labor movement, but anyone who's paying attention will see the value and the relevance of biomonitoring cord blood.

Of course, we have parent's groups, school groups, mom's groups, you know, all Californians will be concerned about this and interested in it. And I think that can be a real stepping stone to elevate the profile of the Program.

So, from my point of view, I look forward to seeing the plan that Amy has laid out, take some more concrete steps and am happy to be of service in any way that I can.

Thanks.

ACTING CHAIRPERSON LUDERER: Thank you very much for those comments

MS. DUNN: We have another public comment.

ACTING CHAIRPERSON LUDERER: We do? Okay, great.

DR. BOGEN: Hi. My name is Ken Bogen from Exponent, a company with an office right nearby, a few blocks away in Oakland. We represent various clients. One of mine currently is a manufacturer of pyrethroids. Another of mine is upstairs, the Department of Justice, who had a concern about phthalates in children's products. And so I've been involved in many different sides.

I had a question that I didn't see addressed, which is what governs access to the data by epidemiologists, in terms of how data on individual participants is -- will be used in the future to investigate potential correlations with health endpoints?

And in that context, what efforts are going to be made to address the issue that as more and more of such investigations are done on this particular data set that's accumulating, you would expect inevitably to find

statistically significant associations, simply by virtue of the number of those that are done, unless you adjust appropriately for the number of such investigations that are done, which can only be done if you monitor the total number of investigations using that single data set as it evolves, which is something that only the group amassing the data can really do, so they can provide to other investigators what the total number of investigations done so far now is, so they can appropriately adjust their analyses accordingly.

That was my question.

Thanks.

ACTING CHAIRPERSON LUDERER: Thank you. Would one of the Program -- Dr. Das would like to comment on that or respond to that.

DR. DAS: Yeah. This is Rupa Das from the California Department of Public Health.

Regarding the access to specimens, currently, the specimens are collected with the intent of analyzing for the chemicals that we present to you. With a clause in the consent form for those projects where we're actually actively collecting specimens, there's a clause in which participants can opt in asking them whether they consent to having their left-over specimens stored for subsequent -- for storage, if they consent to have it

stored for analyses in the future.

So the specimens that are collected now will only be used to look at the levels of chemicals that are specified and we present to you.

We are not currently planning to look at health effects. So the question could be interpreted very broadly to say are we -- down the road, if these participants have certain health effects, will they be -- will these results be analyzed together with those health effects. We, as a Program, are not planning to do that. Is it possible that researchers in the future would do that?

That is not our plan, at this point. Any specimens that are stored will be deidentified, and access to those specimens will -- our plan is to not have them associated with individual identifiers at this point.

As far as keeping track of the numbers of specimens and numbers of analytes and making sure that we don't have associations just based on statistical probability alone, those are probably factors we'll have to address in the future. But at this point, we're not looking at health effects. We're only looking at the analytes.

So perhaps I could clarify that further, if that doesn't address it.

ACTING CHAIRPERSON LUDERER: Was there another -- thank you very much. Diana, did you have a comment?

MS. LEE: Only in the context that a number of our current investigations that we're carrying on are being done in collaboration with other researchers. So to the extent that they choose to look at other data, that's certainly discussed. But right now we're not making it a priority as part of the Program to collect that routinely.

So we do -- we're certainly going to be doing, what we call our investigations are really exposure investigations. And we are trying to collect some data about potential sources of exposure and so on. We're not emphasizing the health output end of it at all.

And so if a collaborator chooses to do that, they are proposing to look at certain data that they have access to through say their own personal -- their medical records that they have access to, for instance, if we're working with a specific provider. And that data would not be necessarily collapsed with other data that we would be routinely collecting. So hopefully that clarifies it.

ACTING CHAIRPERSON LUDERER: Another comment?

Yes.

DR. KAUFMAN: This issue was raised early on when -- I sorry, Farla Kaufman, Office of Environmental Health Hazard Assessment.

So we had discussions about this early on, when the statewide survey was an option. And certainly there are -- there were lots of ideas about how to make the data available to collaborators, because it's going to be such a rich data set. So this is definitely intent of the Program. And we sort of step back from it, in this instance, when we are focused on getting community studies up and running. But that definitely is an idea of -- we want to make it available. We want the data analyzed as much as possible.

The issues that Dr. Das addressed, certainly the multiple comparisons and the prospective findings, significant findings just spuriously is a possibility. But the health -- that's usually an issue for health effects. I don't think NHANES has any provision when they make their data available to say, oh, well, there's like 80 different groups analyzing this data, what do we do for multiple comparisons. I don't think they do that, because most of the time, again, it's not health outcomes. It's more looking at correlations.

But we will address these in the future. These questions are very good. And there will be a plan put in place for how to facilitate collaborations on the data and having other researchers look at it.

ACTING CHAIRPERSON LUDERER: Thank you.

Do we have other questions, comments from Panel members?

Are there additional questions that Program staff would like us to answer as a Panel or things that we haven't addressed on this topic, before we move on?

MS. DUNN: I could put the questions back up.

ACTING CHAIRPERSON LUDERER: Yeah, that would be helpful, I think.

MS. DUNN: Oh, actually, I have them. So I guess the screen just needs to be switched. So I guess there maybe -- I don't know if you talked -- I'm not sure if the Panel has talked about the third and fourth items at all. That would be great if there are ideas on those.

ACTING CHAIRPERSON LUDERER: Do any Panel members have any specific suggestions for the third and fourth items, ideas about actions that may work best for achieving high participation rates and individuals or organizations to interview for insight into effective communication of biomonitoring results.

Dr. Quint.

PANEL MEMBER QUINT: I think part of the answer or part of what my suggestion was for getting more participation also applies to that question. I think, you know, Amy Kyle is a person who convened the cumulative impacts workshop, had a lot of people at that workshop who

are working with community groups who are very -- already have a high interest, in, you know, health outcome studies -- not health outcome, but contamination issues in communities and things like that. So I think that would also apply to this. I mean, it's difficult to engage people, in terms of participating in biomonitoring studies when we -- you know, you can overplay that, because we're not sure which studies we have the resources to do at this point, it seems to me.

I mean, you know, we have limited funding. The studies we are doing are really sort of piggybacking off of other group's studies or we've gone out and -- or somebody has gone out and gotten foundation funding or something like that for the study.

So I think one thing is you don't want to promise -- you know, hold a false promise to people that, you know, you can actually want -- you know, to get them interested in participating in a study that may not, you know, be implemented. So we -- it's hard for me to sort of weigh those two issues. I think participating, as Davis said, so that they know what is going on and what the potential for this Program can be, and being advocates for this or ambassadors for the Program is one thing.

But we have to be really careful, I think, at this point, because we're not able to do a lot of

individual studies. And a lot of people from the EJ community have always wanted studies, have always wanted biomonitoring studies. And I think they would be more than willing to participate in those studies, but I'm not sure that they would be focused on the analytes that we have prioritized or whether or not, you know, we have the resources to do them.

But I think actually involving community people who are involved in their communities in a leadership role like Margaret Gordon. And the Environmental Health Tracking Program has on their advisory committee a number of people who are active -- you know, they have -- community people who are active in their communities. I think that would be another source of individuals that you could talk to, in terms of these issues. But I think we just need to use some caution.

ACTING CHAIRPERSON LUDERER: Dr. Culver.

PANEL MEMBER CULVER: I got the switch on this time.

(Laughter.)

PANEL MEMBER CULVER: I heard the word "deidentification" someplace along the presentation of this Program. And I think one should be very concerned about throwing away the identity to the samples that you collect. I think one of the major goals in the Program is

to look at change in the population over time.

If you don't have the samples available to you in some kind of a biorepository, you're not going to be able to follow that, especially as new analytical methods come available.

So I hope that although we are not collecting health information, that we are retaining the identification of the samples for that time.

ACTING CHAIRPERSON LUDERER: Dr. Das.

DR. DAS: Rupa Das, California Department of Public Health. I should clarify my statement. The samples when they are stored in whatever form they're stored in will not have personally identifying information on the sample itself. There will be a number associated with the sample. A sample will be able to be identified by linking it to another database.

But in terms of -- I was addressing in terms of sharing it with other researchers, we would probably not share the identity of the samples, but that is something in the future. It's not something we've specifically spoken about. I was referring specifically to when the physical samples are stored, they are not stored with the actual -- personal identifying information of the individual from whom it was collected.

PANEL MEMBER CULVER: But you're going to code

them in some fashion, and you'll have a key, so that you can go back and identify where the samples came from and who they came from or at least what the attributes of that individual were --

DR. DAS: Yes, that's correct. We will be able to -- we'll have the key accessible to us.

PANEL MEMBER CULVER: Okay, good.

DR. BOGEN: Ken Bogen, Exponent. I was just asking, unless people opt out to modify the statement.

DR. DAS: So people can opt out of a number -- a couple of different components. They can opt out of having their extra samples stored. And they can opt out of having individual results returned to them.

If they don't have samples stored, then it would -- we will destroy the samples, so there will no need to then link it with identifying information.

ACTING CHAIRPERSON LUDERER: Dr. She.

DR. SHE: I want to follow Dr. Culver's and Dr. Das's question. Basically, sample information we'll log into the LIMS, and then LIMS have sample information, physical sample stored in our freezer farm. We intend to have the biorepository built up, so this -- all of the information in the LIMS with certain client information, demographic information. We will be linked with the relation database eventually, so people can still find out

what sample we have. So we do like to have the biorepository features built up.

ACTING CHAIRPERSON LUDERER: Dr. Wilson.

PANEL MEMBER WILSON: Well, I just wanted to weigh in with Dr. Culver's point. And I think I understand how it's working now. And my question was that, as long as they're not opting out, the default is that those samples will have identifiers and they will be stored. And that's -- and the human subjects protocol reflects that.

DR. DAS: Rupa Das, California Department of Public Health. It's an opt in. They have to opt in. The default is to not have the samples stored.

PANEL MEMBER WILSON: I see. And that's to opt in -- and then that's --

DR. DAS: Opt in to have the samples stored, the extra samples.

PANEL MEMBER WILSON: Okay. And that's in the consent process?

DR. DAS: That is in the consent form, yes.

PANEL MEMBER WILSON: Okay.

DR. DAS: And what I'm saying applies to those projects where we're actively collecting samples, not to -- a separate issue for collaborations with researchers who have already collected samples.

And I also want to add again to Dr. She's statement about the linking of the information, the number that's going to be on the physical sample and the personally identifying information. There will be a link, but only a few people will have access to that link. I mean, our goal is to really protect the identity of the individual. So there will be a way to link that information, but not everybody on the project will have the ability to do that.

PANEL MEMBER WILSON: Thank you.

ACTING CHAIRPERSON LUDERER: Dr. Bradman.

PANEL MEMBER BRADMAN: Just a comment and a challenge that we've experienced. I'm sure you will down the road too, about the issue of returning results, especially when you have banked samples that may be used significantly far into the future for other analyses.

And people who opt in or intend -- want their results back, but years down the read you may have new results, hopefully you'll be able to reach them. And if you can, you'll need a protocol to do that.

And then, of course, there's some people you may not be able to reach. And that's just one of the challenges. You know, in a cross-sectional analysis, it's easy to report results back. But as time passes, and those samples are still valuable, they may be used again,

it just raises some methodological issues that should be on your radar.

DR. DAS: Yeah, that's a very good point. And actually our CDPH Institutional Review Board brought up that point as well, when they were reviewing the maternal-infant study. And they urged us to return results, if they were -- if certain analyses down the road, after this initial phase, were found to be significant, in terms of health outcomes, they encouraged us to return results to individuals over a period of, say, up to 10 years as an estimate.

And recognizing that people do move and information changes, we have built that into the consent form as well, and will be setting up a toll free line for people to let us know of their change in contact information. So as far as possible, we'll be trying to maintain that information to return results, recognizing that we may lose some people or some people may not let us know when they do move.

ACTING CHAIRPERSON LUDERER: Okay. And any additional questions or comments from Panel members?

Okay, then I think it's probably time to move on to the next agenda item, which is going to be a discussion of the Firefighter Occupational Exposure Project. So I'd like to again introduce Dr. Rupali Das, Chief of the

Exposure Assessment Section of the Environmental Health Investigations Branch at the California Department of Public Health and lead of the California Biomonitoring Program.

Dr. Das.

(Thereupon an overhead presentation was Presented as follows.)

DR. DAS: Thank you, Dr. Luderer.

As I explained briefly this morning, the Firefighter Occupational Exposure Project is a new one that's being presented to this panel. One of our staff members, Robin Christensen, who's not here today, came up with this great acronym that the firefighters love, FOX.

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DR. DAS: Again, to reiterate that this came about because we were interested in conducting a project looking at exposures in a worker population, and we identified firefighters as one population of workers that's likely to have high exposures to chemicals and might be a good population to study. And at the last meeting, we were proposing to work with the Contra Costa County Department of Public Health. That did not occur. And at Dr. Luderer's suggestion we pursued a collaboration with UC Irvine.

My presentation today we'll tell you briefly

about the current project status; the project design; we'll describe briefly the questionnaires and other materials that we'll be using in this project; and go over the project timeline.

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DR. DAS: So our collaborators on this project are the University of California, Irvine Center for Occupational and Environmental Health, where Dr. Leslie Israel is the principal investigator. Dr. Israel is an occupational environmental physician and runs the clinic there that I'll be describing in one of the next slides.

In addition, we're collaborating with the Orange County Fire Authority, which is the employer, the fire department in Orange County. And specifically, we'll be working with the Wellness and Fitness or WEFIT Program. That is a part of the fire authority. The WEFIT Program actually is an effort of the International Association of Firefighters, but working specifically with Orange County.

The overall funding for the program is approximately -- for this project is approximately $75,000 split between two sources, the CDC cooperative agreement for year two, which will start September 1 of this year, as well as a State special fund.

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DR. DAS: So this slide briefly describes the

wellness and fitness or WEFIT Program. As I said, it's a component of the International Association of Firefighters, and it has several different elements. A wellness and fitness medical evaluation, which is performed at UC Irvine, Center for Occupational and Environmental Health. There are also peer fitness trainers, a rehabilitation program, and health and fitness education that's a part of this program.

At OCFA in Orange County, there's an oversight committee for WEFIT, called the WEFIT Oversight Committee. And that is a joint labor-management collaboration.

This particular oversight committee is very progressive and has been great and supportive and very easy to work with. And I'm told that their labor-management relationships are particularly harmonious. I guess this doesn't happen everywhere, but in Orange County they have a very good relationship. And I think that's been very helpful for us to get our project moving.

We have support from both the union as well as from the Fire Department. And we have a letter of support jointly signed by the union president and the president of the Fire Department.

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DR. DAS: We have a liaison with the WEFIT

Program, a fire fighter Marty Driscoll, his role is to act as a liaison between the oversight committee, WEFIT and the clinic. And he has been very helpful to us in getting this project moving forward.

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DR. DAS: The aims of this project are to assess the levels of approximately 40 chemicals in blood and urine. And we hope to collect samples from up to 100 firefighters in Orange County. And in addition, the unique aspect of this program is that we'll also measure a subset of these chemicals in dust, so there will be an environmental sampling component in three fire stations in Orange County. And the three was -- the number three was just chosen in terms of feasibility and resources.

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DR. DAS: Our project aims are also to develop and test protocols and procedures that might be applicable to a larger study, perhaps in firefighters. And parts of this might be applicable to other workers as well.

And the parts that we are hoping to test are the recruitment and enrollment procedures, the exposure assessment questionnaire, the process for collecting processing, and shipping biospecimens, conducting laboratory analyses, reporting results to participants, assessing their response to receiving their results and

their understanding of those results, and looking at which lessons might be applicable to other worker studies.

Some of these, as you will note, are common to the maternal-infant study. And some are maybe a little more applicable to worker populations.

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DR. DAS: The list of chemicals that we're going to analyze was a combination of what the labs can or will soon be able to analyze, as well as those exposures that we felt were of particular significance for firefighters through occupational exposure not through home exposure.

And these include the brominated flame retardants, as well as newer flame retardants, the perfluorinated chemicals, polychlorinated biphenyls, and the organochlorine pesticides Listed here.

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DR. DAS: I'm sorry, I should clarify that this list that I just read to you are the chemicals that will be analyzed by DTSC's lab. In addition, the chemicals that will be analyzed by the California Department of Public Health labs include the metals, the pesticide metabolites specific to organophosphates and pyrethroids, and poly aromatic hydrocarbons.

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DR. DAS: As I mentioned, the project will be

funded through two different methods. And on this slide, you see two different colors, green and the purple. The green parts of this project are funded through a special fund, not biomonitoring funds, and the purple is funded through the CDC cooperative agreement.

As part of this project, we'll be conducting focus groups -- as soon as we get our approval from both IRBs, we'll be conducting focus groups and individual interviews to evaluate the project materials. And this will be done with some firefighters in Orange County, who may or may not subsequently be participants in the biomonitoring part of the project.

We'll also test recruitment, informed consent, and enrollment procedures. And we'll test the exposure questionnaire in the focus groups as well as in the firefighters when we conduct the biomonitoring study.

And as noted previously, we'll be collecting blood and urine and testing the processing and shipping processes.

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DR. DAS: This slide shows both the environmental sampling as well as subsequent phases of the project. The walk-through of the fire stations with a checklist to look for sources of exposure to the chemicals of interest, and the fire station dust collection and analyses are funded

through our special fund. And the data analysis and report generation will be funded through in-kind support.

The results report-back -- the testing of the results report-back, that will primarily be done through the focus groups, as well as an on-line survey where we'll ask them what their understanding of the results is will be funded through the special fund.

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DR. DAS: This is a depiction of the project similar to the one you saw for the maternal-infant study. So moving from left to right, we'll be field testing the study materials, as soon as we get IRB approval for this project. Again, this will have to go through the two IRBs, the UC Irvine as well as Department of Public Health.

In addition, the field -- I'm sorry, the testing of the biosample collection and handling will be done early on. Actually, last week, a week ago tomorrow, we collected samples in three fire stations. And I think the collection process went fairly smoothly. No samples were shipped to our labs here in northern California, where they will be analyzed.

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DR. DAS: The data collection process will occur in a couple of different phases. The dust collection has

already occurred for this first phase. In addition, for each fire house from which we draw participants, we'll ask a firefighter to walk through that firehouse with a checklist looking for exposure sources.

At the UC Irvine Center for Occupational and Environmental Health Clinic, the firefighters will be enrolled, and they will give their blood and urine specimens, fill out the exposure questionnaire, an evaluation questionnaire that asks them about the process that they just went through, and we'll be abstracting medical records.

So just to give you a little bit more detail on that, we're going to be disseminating information about the project through the WEFIT newsletters. And we're going to post the study -- the flier in the firehouses. The participants will be enrolled at the time of their physical exam at the clinic. And that's where they'll fill out the questionnaire and they'll give the blood and urine samples.

As part of the WEFIT, they actually get blood drawn and give urine specimens. But sometimes that happens before they get to the clinic, so they might have to have an extra stake to get the blood collected. There are actually several different evaluation phases, as you might be able to tell from what I've said. We'll be

asking them to evaluate their experience in participating in this study right away at the clinic, as well as later on down the road on the extreme right of this slide.

The results, just like the maternal-infant study project, will occur -- will be returned in two different phases. They'll receive results on metals and the nonpersistent chemicals up to a year after they first encounter this project. And they'll receive the rest of the results, the persistent chemicals, up to two years after they initially participate in the project.

And then finally after they received all their results, we're going to ask them to fill out an on-line survey trying to assess what they understand about their results.

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DR. DAS: So I've gone over this a little bit, but just a little bit more detail. The focus groups and interviews will occur in firefighters from the same fire department, but they'll be drawn from a separate pool. They may or may not subsequently participate in biomonitoring. We're hoping to get that started in late June. And they'll provide input into the study materials, and the results report-back.

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DR. DAS: These are the inclusion criteria to

participate in the study. Firefighters should have been employed by the Fire Authority for more than a year, so it won't be new recruits.

They should be scheduled for this physical exam, either through -- from September through December. That's the period of the recruitment and enrollment and sample collection.

I already mentioned that we'll be recruiting through electronic reminders, as well as posting the hard copy of the flier.

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DR. DAS: The study participants will be given an informed consent and fully consented to participate in three different components. Participation in the project overall will involve filling out a questionnaire and donating blood and urine. They will opt to receive individual results, as we've already talked about today. And they will also have the option of donating unused blood and urine samples, along with the deidentified personal data as we've talked about today. They will receive compensation for each of these phases, monetary compensation.

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DR. DAS: The exposure questionnaire is in draft form. And just overall though, the questionnaire is

depicted here. The purpose is to identify occupational factors and work-related behaviors that might affect exposure to chemicals. And the questions have to do with how frequently they respond to what kinds of incidents; what kinds of activities they do as part of response to incidents. So by incidents, I mean, either fighting fires, responding to hazmat incidents, things like that, what kinds of fires they're respond to. What kinds of personal protective equipment they use, how they're maintained and how frequently they use them

And the chemicals targeted on the exposure questionnaire are flame retardants, perfluorinated chemicals, and the PAHs. But the chemicals we're going to measure are more broad than the list of these three. It's just that the questionnaire had to be short. We were told the firefighters won't fill out a questionnaire that's any longer than 15 minutes. And so it's a real challenge to get the information we want into the 15-minute questionnaire for them, because we want complete information.

And the checklist that I mentioned, the walk-through checklist, will hopefully get more information that they're able to answer in 15 minutes.

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DR. DAS: So we'll be collecting urine samples,

that will be analyzed for pyrethroid pesticides and organophosphate pesticides and metals; as well as PAHs in creatinine; and four tubes of blood for blood metals, PCBs, and flame retardants, the perfluorinated chemicals, and another two for splits in archiving.

All these samples will be stored initially at UC Irvine and then shipped to our labs in Richmond and Berkeley.

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DR. DAS: In terms of follow-up, the metals will be among the chemicals that will be analyzed first. And if there's a critical value detected, we'll be following up with the firefighters as soon as we detect those values. For lead, we've chosen a value of 10 micrograms per deciliter or higher. We'll receive immediate follow up. Mercury and other metals may also be followed up immediately.

The levels of concern are yet to be determined. We're doing that with -- in cooperation with our colleagues at OEHHA.

And in terms of follow up, the results will be reviewed both at the Department of Public Health, as well as UC Irvine. And the firefighters will be given contact information at both those centers, and can contact either Dr. Israel or myself and can choose to be seen by Dr.

Israel at the clinic there.

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DR. DAS: In terms of the dust collection, as I mentioned, we already collected dust from three fire stations last week. And we're doing this to assess for potential sources of persistent chemical exposure. We selected three fire stations using a number of different criteria, they were located in three different geographical areas of the county. They were also chosen on the basis of the number of firefighters at these houses, and the types of fires that -- or the types of incidents that the firefighters at each of these houses responded to.

An industry hygienist -- actually, two industrial hygienists conducted a walk-through of each of these firehouses and filled out a checklist, collected bags from vacuum cleaners and conducted some wipe sampling -- or micro-cassette sampling as well.

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DR. DAS: The vacuum cleaner bags will be analyzed at the DTSC labs for PBDEs, perfluorinated chemical, flame retardants, PCBs and organochlorine pesticides. And we'll also be conducting analyses for some metals.

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DR. DAS: The checklist that either firefighters will fill out or the industrial hygienists have already filled out will ask questions related to exposure. And these are just some of the exposures that we're asking about, the presence of non-stick cookware in the firehouses, electronic devices, fire -- the fire trucks or other vehicles that they use as part of work with ripped foam seats, furniture with foam padding, the use of foam pillows, because they sleep in the firehouses and some of them bring their own pillows in. If they use foam pillows, we'll be asking about that. We'll also be asking about areas that are carpeted to get at flame retardants as well as perfluorinated chemicals.

We'll also ask about pesticide application that's occurred at the firehouse in the past 30 days, and the heating source for the fire station.

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DR. DAS: So as with the material-infant study, those who choose to get their results will receive both the individual results, as well as the overall results for the whole project. And we anticipate that it will be at least nine months to a year before they receive the first set of results. And that will be blood in urine, metals in nonpersistent chemicals, and it could be 18 months to two years until they receive the second set of results,

and that will be the persistent organic chemicals. And they will be able to contact the researchers and PIs if they have questions.

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DR. DAS: The results interpretation survey is the on-line survey that I mentioned. They'll get this after they receive all their results. And by conducting this survey, we would like to learn what they think of the results, if they understood the meaning. Does it raise concerns for them? Are they going to make changes in their behavior and so on. And they'll receive a monetary incentive for conducting this part of the project as well.

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DR. DAS: As with the maternal-infant study, it will be primarily descriptive analyses assessing the presence of chemicals measured. And we'll compare the data with other adult studies, such as NHANES or other occupational studies when available, as well as firefighter-specific studies. For example, there is a study that looked at firefighters who responded to the World Trade Center disaster. Some of those chemicals are similar to the ones we're looking at.

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DR. DAS: This is the timeline for the project. We've both -- the institutions, UC Irvine as well as the

Department of Public Health have submitted to the IRBs. Our projects will be reviewed by the IRBs soon, and we hope to start testing the first part of the human subjects part of this, as focus groups and individual interviews. And we hope to start that towards the end of June.

And then begin recruitment and begin collecting data and biospecimens this fall. We hope to have that completed by the end of the year early next year, with the project results and report ending in about two years from the end of the -- the end of data collection, which is December of this year.

So we hope to have a report and to return the final results in December of 2012.

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DR. DAS: I wanted to just acknowledge all the project staff. In addition to the staff that I showed you this morning, there are additional staff. Some are providing in-kind support at the Department of Public Health. There's staff at UC Irvine. There are nurse practitioners, as well as a medical assistant and clinic manager whose name, I'm sorry, I didn't put on there. But there's a clinic manager who's helping out at UC Irvine as well. Orange County Fire Authority, and other staff who have conducted some walk-throughs for us.

Elaine Vaughan is a Professor Emeritus at UC

Irvine, who is a health educator and expert in returning results. And she will be helping us with focus group and individual interviews of the firefighters.

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DR. DAS: And this concludes my presentation for the FOX study. I welcome any of your questions.

ACTING CHAIRPERSON LUDERER: Thank you very much, Dr. Das, for that interesting presentation about the study. And it's really impressive all the progress that you've made since our last Scientific Guidance Panel meeting putting together really this whole study since then.

So do any of the Panel members have questions or comments, at this time?

Dr. Solomon.

PANEL MEMBER SOLOMON: Yeah, that's very impressive. Great study. And I had a few questions about the exposure assessment pieces. You mentioned asking about pesticide exposures in the last 30 days. So are you asking about -- I mean, I don't know if fire stations contract out their pest control services and they have people that come in and provide that service? And if so, are you trying to track down what's being used?

And also on the non-stick cookware question, it seemed almost maybe -- well, I just wondered whether

you're asking about microwave popcorn use and other kinds of non-stick or grease-proof packaging that might be used in the firehouse, because I'm guessing pizza boxes and Chinese food takeout containers and so forth, and microwave popcorn might be used.

And then I guess the other question -- I don't want to pile on too many, but I noticed the phthalates are not among the chemicals of interest, but -- and I'm not sure about this, but the SCBA apparatus, I think those masks may be PVC, and may contain phthalates. And so I just thought that there might be an interesting exposure pathway there.

DR. DAS: Yeah, thank you, Dr. Solomon. Those are all really interesting points. We work backwards in phthalates. That's an excellent suggestion and we'll include that in our list of chemicals to be analyzed.

Regarding the pesticide use and the application bye by pest control operators, yes, that may be an issue having to track that down. I will find out what -- I believe whatever process they use, it will be a county-wide process, and probably not a firehouse by firehouse, but that's something we'll have to look into and track down if the firefighters themselves aren't aware of that.

And regarding the food issue, it's been -- it's

difficult to separate -- you know, I guess occupational versus home use. Of course, the questions -- we have the questions from the maternal-infant study. And it's been -- we've been trying to focus on the firefighting activities. But, of course, staying in the firehouse for 24 hours at a time is certainly an occupational hazard. So those are issues we will take into consideration, and we'll have to tie that in somehow in one of the exposure assessment pieces, probably not the individual questionnaire, because we have to stick to 15 minutes for that. Did I get to all of your questions?

PANEL MEMBER SOLOMON: I think so.

ACTING CHAIRPERSON LUDERER: Dr. Quint.

PANEL MEMBER QUINT: Thank you, Rupa. That was very impressive.

I had a similar question about the exposure questions that you're asking. All of them could be home exposures as well. So you'll just by process of deduction -- in other words, you know, non-stick cookware could be home use. Just all of the questions, pesticide use, all of those could pertain to exposures at home and not in the firehouse.

So you won't ask them questions about home exposures, only firehouse exposures. So how do you -- I mean, I'm just wondering how you're handling that. You'll

just assume if -- well, how are you handling home exposures versus, you know, the time that they're not actually, you know, staying in the firehouse? Because all of them are very similar, you know, they could happen in either place

DR. DAS: Yes, that's a good point. And we're -- we are not asking about home use, because we are really constrained in terms of the time for the questionnaire. And we just want to get a complete questionnaire -- we want something that we're going to be guaranteed to get back.

Part of the reason we're analyzing these chemicals is that they are likely to be chemicals of interest while fighting fires, because so many of these chemicals are used in consumer products and could potentially be of -- the firefighters could be exposed to them, aside from their exposure in the firehouse, while fighting fires.

We, as you noted, will not be able to differentiate whether the exposures are a result of home exposure or work exposure through this pilot study, but this is a pilot study and we just want to assess our ability to get back the information and the levels of chemicals in the firefighters.

Whether -- we don't anticipate being able to say

that the exposures are solely as a result of occupational exposure, especially exposure in the firehouse versus exposure at home. But if we do conduct a subsequent larger study getting at home exposures and occupational exposures, it's potentially something we could study in the future.

We're look at this as a pilot study to look at an occupational cohort to test our ability get this information and to measure it, and to get measurements in an occupational group.

And the perfect study that we'd like to conduct and elements of which you've kind of touched upon here are some thing that we hope to do down the road.

ACTING CHAIRPERSON LUDERER: Dr. Culver.

PANEL MEMBER CULVER: I think part of the answers that you just gave are applicable to my question, which is that firefighters are notorious for having second jobs, and for having avocations. And certainly when you go beyond the pilot study at least, it would certainly be important to take both considerations into account.

The second question was, is UC Irvine going to keep samples? Will there be splitting of samples between UCI and the State? And if so, how do you plan to do that?

DR. DAS: Okay. Regarding your first question about the questionnaire and whether we ask about second

jobs, we really had to cut this down a lot. So Sandy McNeel is our questionnaire queen, and I will ask her to answer that.

(Laughter.)

PANEL MEMBER CULVER: Hi, Queen.

(Laughter.)

DR. McNEEL: Yes. Sandy McNeel, California Department of Public Health. We're very aware of the second job and additional kinds of activities that firefighters do. A couple of those questions did not make the final cut, but we do have a question that asks about exposure to certain kinds of things, like welding and certain kinds of chemical exposures from other activities. We don't specify whether it's a second job or how many hours they spend, but we do ask a fairly general question about whether some of the chemicals of interest are involved in other activities that our participants take place -- that they have actions that involve these other analytes.

DR. DAS: So the intent of that, not asking whether it was a second job, was they might be doing it as a hobby or a job. And for this questionnaire, we didn't make that distinction.

Regarding the split samples, UC Irvine will not be retaining any split samples. Any samples that are

stored as split samples and extra samples that the participants consent to will be done at the biomonitoring labs only, and not retained at UC Irvine. The only samples that will be analyzed at the labs through UC Irvine will be the clinically relevant tests, those that are done through the WEFIT questionnaire, not as part of the Biomonitoring Program.

ACTING CHAIRPERSON LUDERER: Dr. Bradman.

PANEL MEMBER BRADMAN: Just a few comments, kind of similar to the train we just had.

I'm wondering if it might be possible to have GPS coordinates or some address information for the specific station houses that they work at, and be able to look at, for example, nearby traffic density, truck traffic, things like that, other potential sources of PAHs.

And also, it seems like this would be a great opportunity if had one for a biomarker for diesel exposure.

(Laughter.)

PANEL MEMBER BRADMAN: And, you know, the samples may be useful for that endeavor in the future.

DR. DAS: Yes, we will have the addresses of the firehouses. And so we will be able to have GPS coordinates and look at traffic and other patterns. And regarding diesel, the union and the firefighters are very

interested and aware of that as an exposure. So I thank you for your comment about the importance of diesel for this population. We'll take that into consideration.

ACTING CHAIRPERSON LUDERER: Dr. Wilson.

PANEL MEMBER WILSON: Mike Wilson.

So, yeah, again, I want to echo the comments of the other panelists on how far this has come. It's really impressive, and moving a big organization like the Orange County Fire Authority and as quickly as you have is really encouraging.

And it looks like, if I understand it right, that the exposure piece of it is really focused on the fire house itself or did I -- there's no -- it's not anticipated to have questions that would be related to exposures that occur during fire responses or did I get that wrong?

DR. DAS: No, you understood correctly. For this phase of the project, the exposure assessment is restricted to the firehouse. Again, it's a resource and feasibility issue. The union has expressed interest in assessing exposures at the site of fire and through taking contaminants back to the firehouse on personal protective equipment and so on.

And I think those are questions we're aware of the need to look at that in the future. And we'll let you

know if we make any progress on that.

PANEL MEMBER WILSON: Yeah. I mean, I think it's obviously important. And they're -- I'm sure you've thought of looking -- you know, assessing sort of the call volume at the three stations that you're assessing and trying to, you know, identify those stations that have a high call volume for example, because I'm sure it's fairly broadly distributed in Orange County from the very slow stations to those that are very, very busy.

DR. DAS: Yes. And that will be part of the information that we collect as part of the checklist and other information we get on the firehouses.

PANEL MEMBER WILSON: Okay. I guess, you know, on this 15 minute thing.

(Laughter.)

PANEL MEMBER WILSON: I would -- I guess, I think, you know, from your description of the buy-in that you've had, both from the union side and the Department side, that if it's understood by, you know, the rank and file firefighters that this is an important study, and if it goes beyond 15 minutes, not -- actually, not to worry about that as -- in my experience, that as long as the union leadership is behind the study, and really encouraging the membership to do their very best at filling it out et cetera. And you need to get a little

more information beyond what you can in 15 minutes --

DR. DAS: Yeah, well, there are a couple of different factors, because we're doing the collection of the information on the questionnaire while they are getting their physical exam at UC Irvine. And that takes place over a morning. There's a certain number of firefighters that come through. They have to go through four different stations in a certain amount of time.

So they'll be filling out the questionnaire in between these different stations. And so we were told by a number of different people, Contra Costa County, as well as UC Irvine, that once they leave that clinic, then don't count on getting the questionnaire back. So we would like the questionnaire back before they actually leave. And we felt that the time they have between those different stations amounted to about 15 minutes.

But I see what you're saying about the union does think of this as a high priority for them. And that perhaps that would be enough of an initiative to, you know, let the firefighters do a longer questionnaire. I mean, that's something we could test in the focus groups and in the individual interviews and in some of the surveys, the feedback surveys, that we get, whether they'd be willing to do a longer questionnaire and under what circumstances.

PANEL MEMBER WILSON: Yeah, I would encourage that. I think it's worth doing -- at least worth exploring.

ACTING CHAIRPERSON LUDERER: Dr. Solomon.

PANEL MEMBER SOLOMON: Yeah. Just to clarify further about the question of whether you're focusing on exposures at the firehouse or at fires. Are you asking questions about how many fires people have actually fought within any period of time, and what actually they're doing on site or, you know -- because their job title and so forth would be helpful in that regard. But it would be good to know actually how many calls of what kind they've gone out on over the last month or so.

DR. DAS: We do have questions that get at that. I don't have the wording of the exact question with me, but we do ask about how many incidents they've responded to over a certain period of time. Sandy, do you have more specific information on that?

DR. McNEEL: Sandy McNeel. In the 15-minute questionnaire, we ask specifically what kinds of incidents and how much time they've spent in the last 24 hours, primarily because through our OCFA liaison, we identified that the firefighters who are scheduled for their WEFIT examinations are usually coming on duty that morning, so they have not been on active duty as a fire fighter within

the past couple of days to perhaps as long as a week.

Now, in addition to our 15-minute questionnaire, part of the routine WEFIT examination involves filling out another questionnaire that also asks about responses, different types of activities that the firefighters have been involved with, different kinds of incidents, I believe, it's over a week, the past week or past month. But it doesn't get into the number of hours. It's just simply the number of incidents.

So we tried to refine that a little bit for the, you know, for the firefighters who may have been on duty in previous 24 hours.

ACTING CHAIRPERSON LUDERER: Any additional questions from the Panel?

Do we have any public comments at this time?

MS. DUNN: None.

ACTING CHAIRPERSON LUDERER: No public comments.

I did have just a quick question about the specimen collection. When you were talking about the different blood samples, you know, you measured there were going to be different sample for certain analytes and then there would be split and archive. But for the urine, are those also going to be split? You just -- it was kind of a one specimen. And I assume that that's also going to be archived and there will be split samples?

DR. DAS: If they consent to their specimens being archived, then we would archive the left-over urine as well.

Dr. Quint.

PANEL MEMBER QUINT: Julia Quint. I do have a quick question. You mentioned, what is it, the emergency feedback information -- the trigger for getting back to people, in terms of the level of analyte. And you mentioned 10 micrograms per deciliter, I guess it is, for lead, and to be determined mercury, and I don't know what else.

How are you going to do that? I mean, this is sort of -- for lead, you know, it's well recognized the correlation between the biomonitoring results and the potential health information. But we're cutting kind of new territory here, aren't we, or are we, with mercury and the other metals that you were going to consult OEHHA about.

I'm just highlighting this as something that we might want to pay attention to, so that it might be useful for other, you know, biomonitoring studies or, you know, more curious about how you're going to determine what is the trigger for getting back to people.

MS. HOOVER: Sara Hoover, OEHHA.

And we've actually been looking at everything

that's available, in terms of action levels or levels that could be related back to biomonitoring information, so we're still in that process.

So we're going to be providing that information to DPH, but we'll be talking about it internally. And, you know, there's certain things that are clear action levels. Like you said, lead is clear. So we're going to figure out what is actually -- has been designated by authoritative body or, you know, what was well developed rationale for calling it an action level.

So at the moment, we're approaching it as kind of summarizing what's available, and then figuring out is there something that's usable as an action level for a particular project.

PANEL MEMBER QUINT: Yeah. And in that regard, I guess Rupa would be the best source of this information. But I'm wondering if occupational medicine physicians already have some sort of value -- some sort of guidelines that they use for just this purpose -- and, Dwight, of course, the preeminent person here who could answer that.

PANEL MEMBER CULVER: I was wondering whether you had looked at the biological BEI list that has probably the best list of biological indicators of occupational exposures that we have.

MS. HOOVER: Yeah, we're also looking at -- we're

look agent those exactly and any other occupational information we can find.

ACTING CHAIRPERSON LUDERER: Dr. Denton.

OEHHA DIRECTOR DENTON: Rupa, thinking back on Julia's question early on this morning, the Program being primarily focusing or designed originally for the statewide representative sample, and you mentioned that these studies will also inform the development of the statewide representative sampling issue, I'm just curious about how you think or what will be -- what will evolve or what will you determine from this study that will help answer that part of the purpose of the Program?

DR. DAS: Well, I see this as a prototype for a study looking at occupational cohorts. We're using firefighters as one of a potentially highly exposed worker cohort, but a representative sample of the general population may not have the same lessons or the same exposure patterns as a worker cohort and the means to outreach and get information from a worker cohort may be different.

So in addition the Panel has expressed support for looking at worker cohorts specifically. So I guess I would, in terms of informing a representative sample, this is a microcosm of a worker cohort that might inform a statewide sample of workers. Although, I think any kind

of statewide sample of workers would have to focus on a particular occupation. It would be difficult to get a statewide sample of workers without being more specific.

So I think for occupational cohorts, the generalizability is a little more specific, in terms of you're looking at the generalizability to workers. So I would say the lessons that are learned that are more broadly applicable would apply to worker populations.

ACTING CHAIRPERSON LUDERER: Were there any other questions or comments from Panel members?

DR. DAS: I just wanted to make one last comment that I thank you for your compliments on how far we've gotten. It's because of the hard work of all our staff. People have worked very hard.

And in addition, it's been a real joy to work with our colleagues at UC Irvine, as well as our WEFIT and OCFA colleagues. I think without everyone's interest and support and hard work, we wouldn't have come this far in such a short time. So I really would like to publicly acknowledge everyone's assistance.

ACTING CHAIRPERSON LUDERER: Thank you.

We actually are scheduled to have a break at this point. We've caught up a little bit since lunch time. But shall we take a 15-minute break, so that would be coming back at about 3:40.

(Thereupon a recess was taken.)

ACTING CHAIRPERSON LUDERER: Okay. I'd like to welcome everyone back and introduce the next item, which is going to be a discussion of parabens as potential priority chemicals. And so I'd like to introduce Dr. Gail Krowech, who is OEHHA's staff toxicologist, who's going to be talking about parabens.

(Thereupon an overhead presentation was Presented as follows.)

DR. KROWECH: So before I talk about the parabens, I wanted to just quickly go over the criteria that Sara mentioned earlier today for the criteria for recommending priority chemicals. And they are the degree of potential exposure to the public or specific subgroups, the likelihood of a chemical being a carcinogen or toxicant, the limits of laboratory detection and other criteria that the Panel may agree to.

And also to -- as a reminder, these criteria are not joined by "ands" and the Panel is not required to name additional criteria.

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DR. KROWECH: These are the four parabens that are designated chemicals: butylparaben, ethylparaben, methylparaben, and propylparaben. They're alkyl esters of p-hydroxybenzoic acid. And the paraben shown here as an

example is ethyl paraben.

Parabens are -- and these four in particular are antimicrobials preservatives. They're widely used in cosmetics, in lotions, shampoos, deodorants, in sunscreens, pharmaceuticals, and food and beverages. A number of studies have shown endocrine disrupting effects of parabens. And it's been shown that intact esters are absorbed.

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DR. KROWECH: This slide shows CDC's findings of the four designated parabens. And you can see by the table that methylparaben was detected in 99 percent of individuals propylparaben in 93 percent and butyl and ethylparaben in somewhat less than 50 percent. And there's also a wide range of levels.

In all of these cases, females were much greater -- had greater levels than males.

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DR. KROWECH: CDC looked in particular at methylparaben and propylparaben, because of the high levels, and again found that urinary levels in females were much greater than in males. And they looked also -- they used their categories for race and ethnicity. And looking at that found that non-Hispanic blacks had greater levels than Mexican-Americans, who had greater

levels than non-Hispanic whites.

And that for non-Hispanic black children and adolescents, the levels were greater than or equal to non-Hispanic black adults. And this can be seen better with this next slide on methylparaben.

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DR. KROWECH: The graph shows a concentration in urine for methylparaben in CDC's three race ethnicity categories by age group. And the blue one is Mexican-American. And you can see that the levels increase with age up until the last age group. The non-Hispanic blacks they're high in the children as well, and then taper down slightly.

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DR. KROWECH: And this table is very similar for propylparaben as well. We just happened to show this one.

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DR. KROWECH: And this last slide is the standard slide that we show about laboratory considerations. If it were to be a priority chemical, CDPH would be the lab that would be doing the analysis. And the methods are not developed, but methods for related chemicals are under development.

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DR. KROWECH: That's it. Any questions?

ACTING CHAIRPERSON LUDERER: Do any Panel members have any questions about the presentation?

Dr. Bradman.

PANEL MEMBER BRADMAN: Is there any reason to think that levels in Californians are higher, in other words, maybe sunscreen or other cosmetic uses?

DR. KROWECH: I don't know.

ACTING CHAIRPERSON LUDERER: Dr. Solomon.

PANEL MEMBER SOLOMON: I was just wondering if there are any hypotheses about the major racial and ethnic differences in paraben concentrations, because that's hugely striking, and I was just wondering if there were some products that have been identified as being potentially likely sources?

DR. KROWECH: This paper, Calafat et al., they suggested it could be hair products that are used from an early age. And they also suggested that age 60 is when the levels seem to even out. And that might have something to do with pharmaceuticals, that everybody is taking medication, and so that increases -- it increases certain groups and decreases others.

Should I put that slide back?

ACTING CHAIRPERSON LUDERER: Dr. Wilson.

PANEL MEMBER WILSON: Thanks. Mike Wilson. Just for clarification, we've designated parabens.

PANEL MEMBER SOLOMON: CDC did.

PANEL MEMBER WILSON: Yeah, and that was my question, yeah -- and CDC did as well, is that right?

DR. KROWECH: We designated only these four parabens, based on the fact that they were part of CDC's program. And so that -- when that publication came out, that actually meant that they were part of our program and designated.

PANEL MEMBER WILSON: Right.

ACTING CHAIRPERSON LUDERER: I do have a question. You mentioned that these could be bundled with other phenols, I guess you said, right, environmental phenols. Is that something that the labs are currently working?

DR. KROWECH: I didn't mention that, but that's my understanding that they are analyzed at CDC as phenols.

Maybe Jianwen wants to say something.

DR. SHE: Jianwen She, Environmental Laboratory.

Yes, CDC actually developed a method to look for bisphenol A, triclosan, triclocarban, and also parabens with one method. And we are supposed to able to do the same things. So we will look for the standard, if the recommendation is for us to do it.

ACTING CHAIRPERSON LUDERER: Currently, the one -- you're working on bisphenol A is the only one of

those that you're currently developing a method for, is that right? Am I remembering that correctly or --

DR. SHE: Actually, we also looked for triclosan, the two, because they're both priority chemicals already. So we purchased some paraben standards. We will start to look at them very soon. They can be bundled.

ACTING CHAIRPERSON LUDERER: Are there other questions from Panel members?

Dr. Solomon.

PANEL MEMBER SOLOMON: It's just kind of striking that the exposure ranges, you know, covers about four orders of magnitude. I'm not used to seeing that. My recollection is usually it's just, you know, maybe one or two orders of magnitude difference. It's usually, you know, sort of a log normal distribution, but this one is -- and so I just wondered if you had like other -- experience about other chemicals that had such wide exposure distributions in the population or if this is as unusual as I think it is.

DR. KROWECH: I can't really speak to that. But look at it, I'm wondering if there's a difference of absorption, because there's some issues about being metabolized by esterases. So that might have wide variation among the population. And I know that orally that was at least something that I've read, that a lot of

it was metabolized to the p-hydroxybenzoic acid, but there might be a wide range, in terms of metabolism that way and definitely on the skin.

ACTING CHAIRPERSON LUDERER: Dr. Quint.

PANEL MEMBER QUINT: I find the -- I guess it was the hypothesis in Calafat paper -- I mean, their hypothesis that the high levels in non-Hispanic blacks -- black children may be due to personal care products. I don't know if they -- did they say hair products in particular or I forget now?

DR. KROWECH: Yeah, me too.

PANEL MEMBER QUINT: But I know that in Region 9 they have done a project on ethnic hair products as a part of the work that they did with the Healthy Nail Salon Collaborative. And it would be interesting to find out whether or not, you know, any of the products contained parabens, because I don't find that to be very plausible with kids that age of the types of products that I'm familiar with as being used on children at that young age.

So, I mean, I think just that ethnic difference and especially the very, very high levels in the children from 6 to 11 for an endocrine disrupting chemical is of particular concern. And it's interesting, because I'm not sure if we did make this a priority chemical, it almost begs the question of being able to do some sort of

biomonitoring either as a smaller study or some sampling where you would make sure that you could pick up this, you know, population in California. And I'm not sure that extent to which we would be able to do that, because the other results don't seem to be significantly of concern, as much as the results in non-Hispanic blacks. So I think that's kind of an ethical issue or something.

MS. LEE: Yeah, that's something we could look into possibly doing -- sorry, this is Diana with the California Department of Public Health.

We might be able to explore using our collaboration with Kaiser's CYGNET study, which is pre-adolescent girls. And they have roughly 350 samples, urine samples, that we might be able to look at. But again, it's predicated on our labs developing their capability first. So that's something we could certainly bring up with our CYGNET collaborators.

ACTING CHAIRPERSON LUDERER: Yeah, I mean, I think the other striking thing is the huge gender difference with the much higher levels in women. And again, with exposure to endocrine disrupting chemicals and women of child-bearing age, that's obviously another big concern. Might even suggest that perhaps it could be added -- I don't know if things can be added to the MIEEP study, but in that kind of a population also might be a

very good population for looking at these chemicals.

MS. LEE: Yeah. I also just got reminded that a number of the collaborators in the Breast Cancer Environmental Research Center, BCERC, which NIH is funding, I think they are looking at some of this too. I think Sinai -- Mount Sinai is looking at that, so we might be able to get some data from them too.

DR. KROWECH: And parabens are apart of the MIEEP study.

MS. LEE: Proposed.

ACTING CHAIRPERSON LUDERER: Do we have any other comments from Panel members?

Do we have any comments from the public?

MS. DUNN: Yes.

ACTING CHAIRPERSON LUDERER: Mr. Davis Baltz.

MR. BALTZ: Well, that last comment just prompted a question. If parabens are in the MIEEP study, shouldn't that mean that they have been prioritized?

MS. HOOVER: So to clarify, it's proposed as part of the MIEEP. So Diana was -- so my slide actually said it's part of the MIEEP. It should have said it's proposed to be part of the MIEEP. It's partly predicated on the fact of whether the labs can analyze it or not.

But the other thing to remember is that the MIEEP is not only a Biomonitoring California Program project,

it's also a project that involves other collaborators and other collaborators may have interest that goes beyond the priorities chemicals in Biomonitoring California.

ACTING CHAIRPERSON LUDERER: So we do have one public comment.

MS. DUNN: Well, that was -- I do actually have someone that just Emailed me.

ACTING CHAIRPERSON LUDERER: That was it, okay.

Any other comments or questions from the Panel members?

Dr. Solomon.

PANEL MEMBER SOLOMON: Well, I guess if we're starting kind of our discussion about whether to prioritize this chemical, I think the question is, if we were to -- you know, if we were to prioritize it to basically kind of replicate the NHANES' results, that might be less useful, because the likelihood that there's a significant difference in the California population is probably pretty low, given the types of exposure pathways.

But if we were to prioritize it for purposes of incorporation into some of these more focused population studies, then I think that could be, you know, very useful and a huge addition to the, you know, literature out there.

And so, it sort of, to me, a little bit depends

on what we're thinking about, you know, when we make our decision about whether to prioritize this. I certainly would love to see studies done on, you know, sort of more of these kinds of focus studies, like the MIEEP study and others where we can target non-Hispanic blacks in California, et cetera.

So, for that reason, it seems potentially very useful.

ACTING CHAIRPERSON LUDERER: We did have one additional public comment. So I'll just read that now. It was by Email. And it was from David Steinberg of Steinberg & Associates.

And he wrote, "Parabens..." -- he wrote "...allow they are allowed...", I think he means "...although they allowed, are not used in any foods in the U.S." And that was the comment.

Any further discussion from Panel members about prioritizing parabens?

PANEL MEMBER BRADMAN: I just want to say I agree with what Gina said about the purpose of this. Certainly, there's a lot of interest in parabens, and concern about their endocrine-disrupting potential. And they certainly have not been studied from a health effects point of view very extensively. Although, that's not the focus of the Biomonitoring Program.

But given their potential to be endocrine disruptor, and given the disparities that we see in the national population, and given the diversity in California, biomonitoring information may be valuable in knowing who's most exposed. And if health issues become of concern, you know, where to target outreach or -- or just, in general, supporting policies to reduce exposures.

So given those issues over time, having some data on it might be very valuable, especially if we are able to show trends.

ACTING CHAIRPERSON LUDERER: Dr. Wilson.

PANEL MEMBER WILSON: I'm simply -- Mike Wilson -- concurring that both with Dr. Solomon and Dr. Bradman that this class of substances has a -- has sort of a unique application to California, given the data that we're seeing across race and ethnicity. And so I just -- I want to just weigh in and agree with those two comments.

ACTING CHAIRPERSON LUDERER: So I'm hearing from various members of the Panel support for prioritizing parabens. Would anyone in the Panel, at this time, like to make a motion or is there additional discussion?

PANEL MEMBER WILSON: I'll make a motion.

ACTING CHAIRPERSON LUDERER: Dr. Wilson.

PANEL MEMBER WILSON: Mike Wilson. I move that we prioritize parabens as a class.

PANEL MEMBER SOLOMON: No, it has to be the four designated --

OEHHA CHIEF COUNSEL MONAHAN-CUMMINGS: Excuse me, Dr. Wilson

PANEL MEMBER WILSON: Oh, the designated ones, yes. Thank you.

OEHHA CHIEF COUNSEL MONAHAN-CUMMINGS: And it might be best to just say that you would move to recommend prioritizing those four parabens that are already designated, just a suggestion.

(Laughter.)

PANEL MEMBER WILSON: Thank you, suggestion from counsel.

(Laughter.)

PANEL MEMBER WILSON: So I would move that we prioritize those parabens that are designated for purposes of biomonitoring in California.

ACTING CHAIRPERSON LUDERER: All right. So we have a motion to recommend that we prioritize the four designated parabens. Would anyone like to second the motion?

PANEL MEMBER QUINT: Julia Quint. I second the motion.

ACTING CHAIRPERSON LUDERER: All right. Should we have some further discussion about the motion. Are

there any additional comments or thoughts from Panel members?

Dr. Quint.

PANEL MEMBER QUINT: Julia Quint. I was just reading. I remembered that there was another source for at least methyl and propylparabens besides -- aside from personal care products, and they are in foods as well. So that's another source that could explain some of the differences that we're seeing. But anyway, that's just an add on, it's not -- it doesn't substantially change anything.

ACTING CHAIRPERSON LUDERER: Dr. Solomon.

PANEL MEMBER SOLOMON: Just that public comment was interesting, in that there's the idea that it's not actually used in food, even though it's allowed in food. And so it would be interesting to try to gather more information about the uses of these chemicals. I don't think that we -- that our decision today on whether or not to prioritize them is contingent on that information. But that get -- you know, I would certainly recommend that we try to gather more information on the use patterns and whether really they're used in food or really just in personal care products.

ACTING CHAIRPERSON LUDERER: Yeah, the comment did say they were not used in foods in the U. S., but

they may be in imported foods. Those kinds of things would be useful information to have.

All right. Are we ready to -- Dr. Quint, did you have another comment.

PANEL MEMBER QUINT: (Shakes head.)

ACTING CHAIRPERSON LUDERER: I guess we're ready to take a vote then on the motion to recommend that the four designated parabens be prioritized.

Dr. Bradman, would you like to start the vote.

PANEL MEMBER BRADMAN: Yes.

PANEL MEMBER CULVER: Dwight Culver. Yes.

PANEL MEMBER KAVANAUGH-LYNCH: Mel Kavanaugh-Lynch. Yes.

ACTING CHAIRPERSON LUDERER: Ulrike Luderer. Yes.

PANEL MEMBER WILSON: Mike Wilson. Yes.

PANEL MEMBER SOLOMON: Gina Solomon. Yes

PANEL MEMBER QUINT: Julia Quint. Yes.

ACTING CHAIRPERSON LUDERER: We have a unanimous vote in favor of prioritization of the four parabens.

All right. So the next item on the agenda is a discussion of the new format, and some other issues related to the designated and priority chemicals list.

So Sara Hoover, Chief of the Safer Alternatives Assessment and Biomonitoring Section of OEHHA is going to

present this item.

(Thereupon an overhead presentation was Presented as follows.)

MS. HOOVER: So this is the item that we're bringing back from the last meeting. So we had proposed this new format. We got Panel support. And then we said that as part of implementing the format, there may be some issues to revisit. So this item is covering some of those issues, but also another issue that came up during the course of preparing the new list format.

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MS. HOOVER: So the goals of this item are to discuss certain specific format issues that I'll highlight. We also want to propose an approach to you for including new parent compounds for metabolites that already appear on the priority list.

I'm going to discuss some proposed footnotes for both diesel exhaust, that would be a revised footnote for that one, and a new footnote for PAHs on the priority list, and to obtain SGP and public input on all of the above.

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MS. HOOVER: So as we talked about last time, just to remind you, the aim is for the list to be both readable and informative. In general, we're using the

format that was adopted in the CDC fourth report, with some variation -- program-specific variation. And one of the changes is that we would be including both the parent compounds and the metabolites on both the designated and priority lists.

And we also made some updates on the format, based both on Panel recommendations and some additional research, that we did in the -- since the last meeting.

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MS. HOOVER: So here's some of the specific format issues that I want to highlight. We have decided -- we're proposing -- so again, this is just a proposal, and the document you got is strictly a proposal, so any input is welcome. We're proposing that, in general, we're going to, on this list, group the stereoisomers.

So we would only explicitly list a particular isomer if it's informative, for example, lindane. And I'll show an example of what I mean on the next slide, or in one of the later slides.

We also talk about using full common names including them in parentheticals or common chemical names. For example, as I've shown here, triclosan appears on the list. Its full chemical name appears in the parenthetical. Dichloromethane appears on the list.

Methylene chloride appears in the parenthetical.

We're not entirely consistent in this item. We've tended to include things that we thought are widely recognizable names like methylene chloride or in the case of triclosan, we adopted an approach of giving the full chemical name when this does not represent a chemical name. But we haven't done that consistently, so I want to hear your input on that.

And the other idea that we had is to basically include just widely used abbreviations, such as MTBE and PBDEs, and not necessarily include every abbreviation that we showed before. And this is mainly again to make the list less cluttered and more readable.

Now, before I go on, I just want to let you know that as an aside to this, this list is more of a publicly accessible, readable list as opposed to a full technical list, like something like the Prop 65 list where you have CAS numbers, you tend more to have the full chemical name.

And so what we intend going forward is to actually create a full technical list where we would have the CAS number. We would have the full chemical name. We would have the abbreviations and any common names.

So that's our intention to do over time. It's actually quite a large undertaking to do that. But that's the backdrop for some of the clean up of the list right

now.

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MS. HOOVER: So this just shows a sample of the proposed format for the designated list. So you'll see, for example, in the top left the dioxins. Here, we've only shown TCDD as an abbreviation, because that's commonly recognized.

If you look down to the right, there's a couple examples, for example DBCP is shown, methylene chloride is shown, but we also have for 1,2-dichlorobenzene, we have o-dichlorobenzene. You know, is that really needed? So there's still some issues to work out like that.

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MS. HOOVER: Here's a sample of the priority list. And this shows on the brominated and chlorinated organic compounds used as flame retardants, we actually had created -- Gail and I had created this large document with a large list. And in that document, we've used some abbreviations for our own purposes, but they're not widely used. So those were removed from the list and only abbreviations that are actually used more widely were kept. And we're going to reevaluate that before we finalize this.

You'll see on cyclosiloxanes we put in the abbreviations D5, D6, D4 and so forth.

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MS. HOOVER: Now, here's the stereoisomer example I wanted to highlight. So currently -- and this partly is a legacy of how the list was developed. So over time, we've been developing the designated list based on CDC information. And the CDC information has involved both this CDC third report, as well as a list of chemicals included in their studies, some of which appear in the third report, some of which have now been added to the fourth report, and some of which are not reported on by them as yet.

So the Program early on had decided that it was useful to list parent compounds associated with metabolites. So this comes from some early efforts to link parent compounds with metabolites. So permethrin is a parent of 3-phenoxybenzoic acid. But we've explicitly split out cis-permethrin and trans-permethrin. CDC has taken this approach now of just calling it permethrin and listing the relevant metabolites. And we prefer this simpler approach.

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MS. HOOVER: So actually before I go on to -- the talk has very different topics involved. So I'm going to just stop here for a moment and see if you have any questions about what I've said so far.

ACTING CHAIRPERSON LUDERER: It looks like there are no questions.

MS. HOOVER: Okay, good.

So the other thing that we encountered in developing the format was that, as I mentioned, I think in an earlier talk as well, there's certain categories where we've identified groups of chemicals based on those chemicals that were designated by CDC. So the entire class was not moved to the priority list, for example, pyrethroids.

So the parent compounds were identified for specific metabolites in those groups, based on the information that we had available at the time. However, as time goes on, there may be additional parent compounds identified for particular metabolites. And I'm going to show you this example coming up.

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MS. HOOVER: So what we're proposing, and hopefully it will be clearer when I show you the exact example, but if you've moved a group -- so you moved, for example, all pyrethroid pesticides that were designated. Those were moved to the priority list. It wasn't an individual choice of compounds.

So the entire -- that entire class that was already designated, which was a specific set of chemicals

was moved over. That included certain metabolites associated with certain parent compounds.

So what we're proposing is if CDC identifies additional parent compounds for those same metabolites that have already been moved over, we would simply add those parent compounds rather than bringing them back to the Panel for approval.

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MS. HOOVER: So this is the example. This is why we're bringing this item to you, so that we don't have to keep asking you about this. So the example is 3-phenoxybenzoic acid. The parent compounds identified in the third report were cypermethrin, deltamethrin, permethrin and possibly other pyrethroid insecticides.

And in the fourth report, they actually list six parent compounds, and the additional three are cyhalothrin, fenpropathrin, and tralomethrin. So we would propose just adding those.

So before I move on to the next topic, any questions about that? Is it clear what I'm trying to get across?

Okay.

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MS. HOOVER: Okay. So sorry for the -- this is all related to the list, but they're very different

topics. So moving to another topic.

At the last meeting, I mentioned to you that there was some inconsistency, in terms of implementing the format. And what we had proposed to do is make the priority list look like the designated list, i.e., the parent compounds and the relevant metabolites or indicators would be listed on the priority list, instead of only the parent compounds.

However, when the SGP recommended PAHs for the priority list, there were three hydroxy-PAH's actually recommended to the priority list. And at the last meeting I had suggested that we would bring back to you the idea of adding the parent compounds to the priority list explicitly, and get the Panel's approval.

However, in doing research for this topic, it turns out that part -- well, if you look back at the transcript, the SGP picked those particular three hydroxy-PAHs, based on the understanding that there would soon be lab capability for those three compounds. And the SGP had interest in PAHs, in general. And those three were moved because of the idea that well these will be ready quickly.

It turns out that CDC -- so there's two separate pieces of information here. CDC is not going to analyze any longer for two of the three. And I can give you the

details of that. I don't want go into the details of that, but it's basically some detection issues, and they talk about some method issues as well in the fourth report. So they're dropping two of the three. And the one that is continuing on is the one that CDPH has a method for 3-hydroxyphenanthrene.

So DPH, like I just said, has a method for one of the three. They've not been able to get appropriate standards for the other two. And so they've been pursuing developing methods for other PAHs.

So what I'm proposing, instead of adding parent compounds that may not be pursued in the future, that we bring back to you priority PAHs as the topic. We actually look at the PAHs again, revisit the issue of priority PAHs, and in the interim just add a footnote. And I'm proposing this wording. Feel free to recommend something else. The wording would be "The SGP recommended the three hydroxy-PAHs listed as priority chemicals. The corresponding parent chemicals are benzo[a]pyrene, chrysene and phenanthrene, respectively."

So any questions on this?

So that's just an option as an interim placeholder.

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MS. HOOVER: Okay. The next topic. So diesel

exhaust. This is actually a separate issue that Dr. Culver raised. And we agreed with his opinion on this and wanted to bring it to the Panel.

So the current footnote on diesel exhaust says, "All components of diesel exhaust are designated chemicals." And really the purpose of that broad footnote was to allow flexibility, to choose an appropriate biomarker or component to biomonitor.

But it's really not the message of the panel that every single component of diesel exhaust is a concern and should be designated and prioritized. So when we went back and looked at the discussion of the topic, we came up with a proposed revision, shown here, "Diesel exhaust is a complex mixture that contains many components, one or more of which may be useful as an indicator for biomonitoring."

This doesn't necessarily capture all possible elements of how we might proceed, but it's a more accurate indication of what the Panel's intent was.

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MS. HOOVER: So the next steps on this item will be to finalize the format following Panel and public input. We're going to be posting updated lists by July 2010. And we would bring priority PAHs back to be addressed at a future meeting, as well as development of a fully technical list, as I mentioned.

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MS. HOOVER: So the discussion points are just reiterated here. And if anybody has any questions, I'm happy to answer them.

ACTING CHAIRPERSON LUDERER: Do we have any questions, comments?

Gina -- Dr. Solomon.

PANEL MEMBER SOLOMON: That was a great presentation. And I feel comfortable with all of the things that you've proposed. I certainly agree on further reflection with Dr. Culver's issue that he raised about diesel exhaust. And I think the new revised wording makes a lot of sense. And I think the proposed footnote and plan of action on PAHs as well as -- and the other specific issues that you raised also sound good to me.

I don't want to add too much to your workload, but when I was looking through the list again, the disinfection byproducts jumped out at me. And this isn't a matter of how they're listed. It's just a matter of that this, I think, has come up -- this hasn't come up recently, but in the efforts to solicit public comment and expert comment on chemicals to include in the program, I think that there -- it came up several times to look at -- look more broadly at disinfection byproducts, and in particular to look at some of the knew chloramination

byproducts. And so I just wanted to flag that again in case that's something that could be put in the queue for potentially coming before the Panel for designation.

MS. HOOVER: That's one of the ones we're tracking. Earlier, in my update, I didn't have time to go into a whole big long list, but that still is being tracked by the Program, so that's one of the things on there.

ACTING CHAIRPERSON LUDERER: Is there any other questions or comments from the Panel members?

Dr. Bradman.

PANEL MEMBER BRADMAN: I just have a brief comment. I don't know if it's worth highlighting in the list, but certainly any future analyses will need to reflect that sometimes different isomers may have different toxicity. I mean, permethrin is an example where cis and trans are different potentially. Certainly, things like, you know, arsenic where we're talking about different valence states. There are certainly differences in toxicity there, and that's probably more obvious.

I don't know if it's worth footnoting there or at least making sure that that's understood.

MS. HOOVER: Well, another option we considered -- we were trying to keep it simple, and then deal with something like that in a larger technical list.

But another possibility would be to do, you know, permethrin parentheses, including cis and trans. I mean, if you wanted to be explicit about certain chemicals. And that's what I was saying that we did make an exception. So we listed lindane in a parenthetical. So if there's certain ones that you would like to see explicitly listed, we're happy to do that as a parenthetical.

ACTING CHAIRPERSON LUDERER: It looks like there are no other comments from the Panel members or -- Dr. Wilson.

PANEL MEMBER WILSON: Yeah, Mike Wilson. Do you anticipate -- I may have missed this -- that the CAS numbers would be part of the public database?

MS. HOOVER: Yeah. Well -- okay, so I carefully didn't put this down in black and white, but it's my intention and desire to develop a full list with all the CAS numbers and that that could be made publicly available. But it's going to take time to develop that. It wouldn't go on this list, this style of list. We retain this as a more readable simpler kind of list but, we would develop a full list of the parents and the metabolites with all the CAS numbers, yeah.

PANEL MEMBER WILSON: Okay. Thank you.

ACTING CHAIRPERSON LUDERER: It looks like there seems to be broad consensus among the Panel members

agreeing with the proposed changes to the designated and priority chemicals list. Were there any other questions that you wanted us to address that we haven't yet on this topic?

MS. HOOVER: I guess I would just want to state explicitly then, the Panel is fine with me changing the diesel footnotes on both the designated and priority lists, as well as adding the PAH footnote that I proposed?

MS. HOOVER: And I also want to encourage you to take a look through it, if you have time. And just like Asa raised, if there's any other issues you notice, any other abbreviations you'd like to see -- you know, any other minor issue, if you have time to look at it and comment on it, please feel free to contact me with that.

ACTING CHAIRPERSON LUDERER: I guess I forgot to ask about public comments on this topic. Were there any public comments?

MS. DUNN: There were none.

ACTING CHAIRPERSON LUDERER: Okay, thank you. Sorry about that.

(Laughter.)

ACTING CHAIRPERSON LUDERER: So the next item on the agenda then -- actually, that was our last specific item for discussion, before the summary of the SGP recommendations by Dr. Lauren Zeise, who's the Chief of

Reproductive and Cancer Hazard Assessment of OEHHA and who's going to summarize the recommendations from today.

Dr. Zeise.

PANEL MEMBER SOLOMON: Can I make one comment?

ACTING CHAIRPERSON LUDERER: Dr. Solomon.

PANEL MEMBER SOLOMON: I'm sorry. I just meant to mention this, because it sort of came up during the break. In reference to the public integration section, I actually had asked one of the staff members in the restroom if the Program has a Facebook page. And I learned that it does not. And so I just would like to recommend that for public outreach to create a Facebook page for the Program and try to keep it active, because I think that is a good way of connecting with some people.

DR. ZEISE: So I'll add that to my list.

(Laughter.)

PANEL MEMBER SOLOMON: Yeah.

DR. ZEISE: It looks like everyone agrees.

So the day started with -- so what I'm going to do is I'll give some highlights. For some of the items, there was a lot of discussion. And we took that in. So I'll go through the highlights. There will be an extended discussion and summary on -- posted on the Biomonitoring website.

So we started the day with updates on the status

of biomonitoring studies, those that are underway and also in development, and on the progress in laboratory capacity. And I think all around, the Panel was supportive and complimentary in acknowledging the progress since the last meeting.

The Program -- the second point, the Program is going to have an initial discussion of biomonitoring reference levels at the fall meeting.

Triclocarban was added as a designated chemical by unanimous vote. And the Program will be following up to obtain more detailed toxicology and persistence and other exposure information to be included in any Panel discussion of triclocarban as a priority chemical.

The Panel made several suggestions regarding the public participation plan and engaging the public. And that included discussions with other people, like Dr. Kyle at UC Berkeley, and the California labor movement. And we also heard about modulating the intensity of the effort, depending on where we are with respect to results and our resources. So we'll be cautious.

And then regarding the update on the firefighter's study, the Panel congratulated the Program on the development of the study since the last meeting -- that's quite a bit of work done, that the Panel acknowledged -- and made some suggestions regarding

questionnaire questions, the length of the questionnaire, capturing diesel exposure in a variety of ways, including GIS coding, a hope for finding a good biomarker, action levels and various other suggestions.

There was unanimous vote to add the four parabens that are already designated. So methyl, ethyl, butyl, and propylparaben as priority chemicals.

The Panel agreed to the proposed changes to the simple list. And also, we heard that the Panel found that it was a good idea to have much more technical priority and designated chemical list that includes CAS numbers and so forth.

Oh, I forgot to mention that the Program, as part of public participation, did agree, I think, to include a Facebook page.

(Laughter.)

DR. ZEISE: And so the Panel is continuing to track broadly disinfection byproducts.

And with respect to the formatting of the list, there is flexibility. The Panel agreed with the idea that we would diverge from standardization in formatting with parentheticals for some of the stereoisomers as appropriate.

So thank you. And I guess I'll turn it back over to you.

ACTING CHAIRPERSON LUDERER: Thank you very much Dr. Zeise. And now I would like to turn things over again to Dr. Denton, the Director of the Office of Environmental Health Hazard Assessment.

OEHHA DIRECTOR DENTON: As I mentioned in my introduction, this is the time for the Panel to choose the Chair -- choose a permanent chair. Dr. Luderer has been very generous with her time to be Acting Chair for today but we do need a permanent Chair.

So I think the easiest way to do that would be, you know, to entertain nominations and then take a vote. So that sounds good.

Do we have any nominations?

Dr. Solomon.

PANEL MEMBER SOLOMON: Yes. This is Gina Solomon. I think Dr. Luderer did such a fantastic job today --

(Laughter.)

PANEL MEMBER SOLOMON: -- that I would like to nominate her to continue on as Chair and to become permanent Chair of the Panel.

PANEL MEMBER CULVER: Second.

OEHHA DIRECTOR DENTON: Okay. Well, be careful what you volunteer for.

(Laughter.)

OEHHA DIRECTOR DENTON: So let's just have just a voice vote. All of those in favor aye?

(Ayes.)

OEHHA DIRECTOR DENTON: All of those opposed?

With the exception of Dr. Luderer.

(Laughter.)

OEHHA DIRECTOR DENTON: No.

It's unanimous.

Okay, well, Dr. Ulrike Luderer then is our permanent Chair of the Science Guidance Panel. And before I turnover it to you, I'd like to voice my appreciation for all the work that the Panel has done today. And we really appreciate the guidance that you're giving this program. So I'll turn it back to you, Dr. Luderer.

CHAIRPERSON LUDERER: Thank you.

OEHHA DIRECTOR DENTON: Our permanent Chair.

CHAIRPERSON LUDERER: Thank you very much for the vote of confidence.

(Laughter.)

CHAIRPERSON LUDERER: I hope I can live up to it.

Finally, I would like to adjourn the meeting and let everyone know that the presentations -- yes. Is there any additional item?

MS. HOOVER: Yeah. Right before you adjourn, I just wanted to -- normally we announce when the next

meeting is of the meeting -- oh, you're going to do that. And I just wanted to give you an update that we're still actually trying to come to a date in the fall. And also that there were a few presentations that varied from the presentations that were posted. So we will be posting that in the next few days too.

CHAIRPERSON LUDERER: Right. So the presentations will be posted. As well as the transcript of the meeting will also be posted, and a summary of the Scientific Guidance Panel recommendations and then an Email will go out to the listserv, letting all the members of the listserv know when those things are available.

Then the next meeting is tentatively planned for October still or are we not sure about the month yet either?

MS. HOOVER: Everyone is really busy obviously, so we have -- this incredible Panel who is very busy. We have problems coordinating with people at OEHHA who are busy and DPH. So we're now looking into the first week of November actually. So you're going to be getting -- if you haven't already received that, you'll be getting a survey on your dates.

The other issue is that we -- you know, Dr. McKone couldn't be here today. And one of the dates we'd settled on, he couldn't be at that meeting either. So

we're to avoid, you know, having certain Panel members have multiple absences, because they -- you know, everyone contributes so -- is such a value contributor that we don't want to lose that contribution.

So we're trying to get maximum participation, so excuse the multiple Emails surveying dates.

CHAIRPERSON LUDERER: All right. So we'll have the meeting in the fall.

(Laughter.)

CHAIRPERSON LUDERER: Date to be announced.

Oh, I'm sorry. Dr. Wilson

PANEL MEMBER WILSON: I just wanted to make one final comment, that -- in appreciation for the technical staff today, video and audio, as these things can --

(Applause.)

PANEL MEMBER WILSON: -- they can make or break meetings, as we all know.

MR. LLOYD: Thank you so much.

PANEL MEMBER WILSON: And you were a really professional team. We all appreciate it.

MR. LLOYD: Thank you. Nate, Jason and I --

PANEL MEMBER WILSON: And the transcription of course, with -- yeah exactly. Thank you so much.

(Applause.)

MR. LLOYD: The fingers of smoke.

I do want to remind the Board and the public we archive this meeting up onto CalSpan, our CalSpan site. And we also put a KPI, or Key Point Indexing, so that you can go directly to items on the agenda, so you don't have to sit and watch the entire meeting download, you can go specifically right to the items. And we'll also link all the PowerPoints with that as well. So it will incorporate that as far as your website as well. And it was a pleasure doing business with you guys.

CHAIRPERSON LUDERER: Thank you.

If there are no additional items to discuss, then I'd like to adjourn the meeting.

Thank you all for coming.

(Thereupon the California Environmental Contaminant Biomonitoring Program, Scientific Guidance Panel meeting adjourned at 4:39 p.m.)

CERTIFICATE OF REPORTER

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

That I am a disinterested person herein; that the foregoing California Environmental Contamination Biomonitoring Program Scientific Guidance Panel meeting was reported in shorthand by me, James F. Peters, a Certified Shorthand Reporter of the State of California, and thereafter transcribed under my direction, by computer-assisted transcription.

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

IN WITNESS WHEREOF, I have hereunto set my hand this 7th day of June, 2010.

JAMES F. PETERS, CSR, RPR
Certified Shorthand Reporter
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